

Advances in Patient Safety: New Directions and Alternative Approaches

Volume 2. Culture and Redesign

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Preface

It has been nearly 10 years since the Institute of Medicine (IOM) published its 1999 landmark report, *To Err Is Human: Building a Safer Health System*. Although we have made improvements in the safety of the health care system since that time, there is much more work to be done.

In February 2005, the Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense (DoD)-Health Affairs collaborated to publish *Advances in Patient Safety: From Research to Implementation* to help the health care system by providing state-of-science information on preventing medical errors and the harm they can cause. The publication included work by AHRQ-funded patient safety researchers as well as the patient safety initiatives of other components of the Federal Government.

This new publication, *Advances in Patient Safety: New Directions and Alternative Approaches* builds on and expands the growing body of evidence for reducing medical errors and improving patient safety. It also provides a forum for the airing of new ideas and approaches that are likely to be successful in the future.

The 115 papers distributed across four volumes—Assessment, Culture and Redesign, Performance and Tools, and Technology and Medication Safety—cover a considerable breadth of content dealing with reporting systems, taxonomies and measurement, risk assessment, safety culture and organizational issues, process improvement, system redesign, patient involvement, teamwork, simulation, human factors, tools and practices, health information technology and medication safety.

Advances in Patient Safety: New Directions and Alternative Approaches presents contributions from a wide variety of disciplines and clinical settings—a very promising sign that the development and spread of patient safety initiatives continues to grow.

It is important to note that some of the same issues and areas of research interest as appeared in the 2005 *Advances of Patient Safety: From Research to Implementation* appear in this *Advances* as well. Although no one takes pleasure in recognizing that some threats to patient safety are quite resistant to change, these four volumes give testimony to the perseverance and technical skills of our best researchers. They continue to seek answers to the most challenging patient safety questions.

Excellent progress is being made, and many of the papers describe patient safety success stories in a variety of health care settings. Other papers focus on what we still need to accomplish. This is as it should be.

The bottom line is that improving patient safety and reducing medical errors must continue to be an important priority for the Nation and for our health care system. To achieve a safe, high quality health care system, we need dedication, leadership, and the best information available. AHRQ is very pleased to bring you *Advances in Patient Safety: New Directions and Alternative Approaches* for you to use as a vital tool in meeting that challenge.

Carolyn Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Acknowledgments

The present *Advances in Patient Safety: New Directions and Alternative Approaches*, like its predecessor, *Advances in Patient Safety: From Research to Implementation*, contains well over a hundred patient safety papers distributed across four volumes. In undertaking a project of this scope and completing it in a timely fashion, the editors depend upon the good will, collaborative efforts, and commitment of many people, both internal and external to the Agency for Healthcare Research and Quality (AHRQ). Foremost among this group are the patient safety researchers and their teams, whose work will be found in the pages that follow. We are indebted to them for their scholarship, research skills, and willingness to share with us their conceptual schemes, empirical findings, and lessons learned in addressing significant patient safety issues. Given the breadth of content, readers are sure to find much of interest to their own work. At the same time, a large number of peer reviewers willingly gave of their time in commenting constructively on the submitted manuscripts to ensure their quality and appropriateness. A list of the peer reviewers can be found in the back of each volume.

Also in evidence throughout the entire effort were the organizing skills of Ms. Alene Kennedy, Ms. Felicia Cerbone, and their colleagues at the National Opinion Research Center (NORC) at the University of Chicago. Their assistance in keeping track of submitted manuscripts, maintaining communication with authors and reviewers, and engaging the editing skills of Dr. Lane Lenard of BioMedical Communications, Inc., is very much appreciated.

We also would like to acknowledge the support and encouragement from AHRQ's Office of the Director, the Center for Quality Improvement and Patient Safety (CQuIPS), and the Office of Communications and Knowledge Transfer (OCKT). Within OCKT, a hearty thank you is extended to Ms. Randie Siegel and other helping hands in her Print and Electronic Publishing group. Of special note are the desktop design skills of Ms. Frances Eisel and Mr. Joel Boches. Editorial assistance was provided by Ms. Stephanie Grant of EEI Communications, Inc.

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Editors

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Prologue

Culture and Redesign for Improved Patient Safety

James B. Battles, PhD

The articles in this volume explore issues of culture and the redesign of organizations and clinical practices to improve patient safety. Within this broad theme are four categories of related articles addressing (1) safety and organizational issues, (2) clinical process improvement, (3) systems redesign, and (4) collaboratives and patient involvement.

Creating a culture of safety has been a major goal of the patient safety movement. Only recently have instruments become available for use by organizations to assess their patient safety culture. Several articles in the first section of this volume describe the use of standard cultural assessment instruments and discuss the results and lessons learned from such assessments. Many organizations are finding that an assessment of the safety climate of culture within both individual clinical units and the organization as a whole can serve as a starting point to bring about organizational change and improvement. There are differences between various components of a health care institution that will differ at the clinical micro system or unit level. Understanding the nature of systems operating at both the overall macro level and at the micro level within an organization are essential for any improvement activity to succeed. Several of the articles in this first section explore the characteristics of the organization relative to patient safety improvement activities. The lack of a complete understanding of the organization at both the macro and micro levels will limit the effectiveness of improvement efforts.

The second section of this volume comprises articles that focus on the implementation of specific clinical process improvements. The authors address their experiences in introducing various clinical improvements targeted at identified risk and hazards at the clinical micro system level. Targeting improvement efforts on specific clinical processes as a change strategy seems to be an effective way to have measurable impact and achieve buy-in from the health professionals who work in a particular micro system. While each of the clinical improvements described are different, readers will be able to discern patterns in the change processes involved in making the improvements. Many of the issues and concerns raised in these papers related to clinical process improvement are similar from one clinical process to another. It is in the commonality of implementation issues that major lessons can be learned about the nature of clinical process improvement.

While most of the articles in section two represent clinical process improvements at the micro system level, the articles in section three of this volume examine redesigning systems of care at the more macro level. It has often been stated that overall quality and safety improvement requires major system redesign. Others say that the health care system was never designed in the first place, so the issue is system design, not redesign. The articles in this section describe the process of design and redesign that have been used to make major improvements. The authors focus on design as a deliberate and planned activity. The emphasis on design and design methods is a new and growing area of interest in quality and safety improvement. This emphasis stems

from the realization that quality and safety improvements can be made by thoughtful design and/or redesign of our systems of care.

The fourth and last section of this volume features articles that discuss organizations working together to bring about change. Collective or shared improvement activities are a relatively new phenomenon that has been emerging in patient safety. Institutions working together to solve common problems have shown us a powerful way for reinforcing and sustaining patient safety and quality improvement efforts. Members of a collaborative can and do share success stories and improvement strategies—as well as stories about unsuccessful efforts—so that the overall rate of improvement is higher across the entire collaborative. These articles serve as a series of case studies on the use of this approach in patient safety. The involvement of patients in solving patient safety issues is emerging as another promising approach within the patient safety movement. Patients are an important source of information about risks and hazards and about how care can be made safer. The voice of the patient as a partner in patient safety improvement is one that will be growing over time.

The articles in this volume represent an important group of case studies focused on issues of organizational culture and system redesign. Together, they help to paint a picture of present day patient safety improvement activities. There are lessons to be learned from the rich experiences expressed in each of these case studies.

Safety Culture and Organizational Issues

The AHRQ Hospital Survey on Patient Safety Culture: A Tool to Plan and Evaluate Patient Safety Programs

Katherine J. Jones, PT, PhD; Anne Skinner, RHIA; Liyan Xu, MS; Junfeng Sun, PhD; Keith Mueller, PhD

Abstract

Objectives: We used results from our rural-adapted version of the Hospital Survey on Patient Safety Culture (HSOPSC) to plan, execute, and evaluate a 2-year patient safety program in 24 Critical Access Hospitals (CAHs). **Methods:** Use of sound survey methodology at baseline and reassessment produced valid results. We used a generalized estimating equations approach to account for the correlation of respondents within CAHs. **Results:** Implementing a systematic voluntary medication error reporting program supported by specific patient safety practices was associated with improved perceptions of safety culture. Safety culture varied by work area, position, and extent of participation in a patient safety program. **Conclusions:** The HSOPSC detected changes in safety culture over time when managers used a change strategy to execute specific practices that support the four components of an informed, safe culture. The execution and evaluation of organizational practices led to changes in respondents' beliefs about safety culture.

Introduction

Lack of safe, reliable systems of care is the problem that all health care providers face in crossing the chasm from the care we currently provide to the care we could provide.¹ Solving this problem requires changing the culture of health care 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.² A voluntary reporting system that emphasizes learning from errors and improving systems of care is the foundation of an informed, safe culture.³

In July 2005, the University of Nebraska Medical Center (UNMC) received a Partnerships in Implementing Patient Safety grant from the Agency for Healthcare Research and Quality (AHRQ) to fund the project, "Implementing a Program of Patient Safety in Small Rural Hospitals." The primary aim of this project was to develop the organizational infrastructure for voluntarily reporting and analyzing medication errors in small rural hospitals.

We used the AHRQ Hospital Survey on Patient Safety Culture (HSOPSC)⁴ to evaluate the effectiveness of our reporting and educational interventions on the culture of safety in 24 critical access hospitals (CAHs). CAHs 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; they are the Nation's smallest hospitals.⁵ CAHs are limited to 25 inpatient beds for acute care and an average inpatient length of stay of 96 hours. As of May 2007, there were

1,283 CAHs,⁶ representing approximately one-fourth of the community hospitals in the Nation.⁷ CAHs are characterized by limited resources and low patient volume.⁸

The primary objective of this paper is to demonstrate how the AHRQ HSOPSC can be used to plan and evaluate patient safety interventions across CAHs. A secondary aim is to demonstrate that safety culture varies by work area and position across this sample of the Nation's smallest hospitals.

Defining a Culture of Safety

The various definitions of safety culture^{9, 10} contain several common elements. Safety culture refers to the enduring and shared beliefs and practices of organization members regarding the organization's willingness to detect and learn from errors. The Institute of Medicine (IOM)¹¹ states that a culture of safety in health care requires three elements:

1. A belief that although health care processes are high risk, they can be designed to prevent failure.
2. A commitment at the organizational level to detect and learn from errors.
3. An environment that is perceived as just because managers discipline only when an employee knowingly increases risk to patients and peers.¹²

A culture of safety is present in high-reliability organizations, which are characterized by complex, risky processes but very low error rates. Such organizations achieve high reliability, because they are preoccupied with failure, sensitive to how each team member affects a process, allow those who are most knowledgeable about a process to make decisions, and resist the temptation to blame individuals for errors within complex processes.¹³

Components of Culture

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.⁹ Reason categorized a culture of safety into four components, which reflect his assertion that an informed culture is a safe culture.³ These components identify the beliefs and practices present in an organization that is informed about risks and hazards and takes action to become safe. Fundamentally, a safe organization depends on the willingness of front-line 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-taking¹²; 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 front-line 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 results in an informed, safe organization that is highly reliable. We recognized that the organizational beliefs and practices associated with these components of culture are assessed by the HSOPSC.

Assessing Safety Culture

Achieving an informed, safe culture depends on how leaders at all levels of an organization obtain, use, and disseminate information.^{14, 15} Consequently, to identify areas of culture in need of improvement, increase awareness of patient safety concepts, evaluate the effectiveness of patient safety interventions over time, and conduct internal and external benchmarking, organizations must assess safety culture at the unit/department level and at the organizational level.¹⁶ Internal comparisons require assessment using the unit/department and position as the unit of analysis to allow organizations to prioritize interventions by unit and department. External comparisons allow organizations to identify how their culture may differ from that of others and to prioritize organization-wide improvement efforts.¹⁷ AHRQ established the HSOPSC Comparative Database to enable hospitals that administer this survey to conduct valid external comparisons by using standardized data.¹⁸ The biggest challenge in assessing culture is to establish a link between safety culture and patient outcomes.^{16, 19, 20}

When assessing culture, organizations 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 health care organizations face challenges when independently administering a safety culture survey. Inappropriate sampling, bias in data collection procedures (e.g., administering the survey in a group setting), and respondent concerns about confidentiality can result in poor response rates and useless results.¹⁶ The limited resources in CAHs make it especially difficult for them to independently administer and analyze a safety culture survey and take action to improve systems.

Methods

Study Design and Population

In the fall of 2005, we conducted the HSOPSC in 24 CAHs to obtain a baseline assessment of their cultures of safety and to raise awareness about safety culture. We used the results to create benchmarks and plan educational activities to address components of culture in need of improvement. In the spring of 2007, 21 of these 24 CAHs chose to participate in a reassessment using the HSOPSC. In both years, we conducted a mailed, self-administered survey of all eligible personnel in the participating CAHs. Eligible personnel included 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 identify themselves as supervisors, managers, or administrators.⁴ This paper focuses on the HSOPSC results for the 21 CAHs that participated in the baseline assessment and reassessment. These CAHs serve 21 counties that had a median 2006 population of 5,317.²¹ They are all nonprofit, and 12 are county-owned.

Implementing Practices to Support a Reporting Culture

Since the primary aim of our project was to develop the organizational infrastructure for voluntarily reporting and analyzing medication errors, we trained personnel in the 24 CAHs to use MEDMARX[®], the Internet-based, anonymous medication error-reporting program operated by the United States Pharmacopeia.²² MEDMARX uses standardized classifications of the

severity, type, cause(s) of the error, and phase of the medication use system in which the error originated. CAH personnel used this standardized taxonomy and MEDMARX tools to analyze their medication errors from a systems perspective and to compare their data with data from hospitals of similar and larger sizes. Prior to implementing MEDMARX, these CAHs did not report and analyze near misses or categorize errors by phase of origination or cause. We chose MEDMARX to provide the infrastructure for reporting medication errors because it embodies the characteristics of successful voluntary error reporting systems.³ In addition, because MEDMARX is Internet-based, we were able to remotely monitor reporting for accuracy and provide assistance with data analysis to multiple CAHs.

Use of Baseline Assessment

Through monthly telephone conference calls, quarterly newsletters, and workshops, we engaged and educated CAH personnel about the components of an informed, safe culture in response to the results of the baseline survey. The 21 CAHs that participated in the baseline survey and reassessment used the MEDMARX reporting program. However, only 17 CAHs chose to participate in followup safety culture educational activities. We combined didactic presentations with team-based action planning and opportunities to perform desired practices, such as a mock root cause analysis (RCA). We partnered with the Nebraska Hospital Association and the national Quality Improvement Organization Support Center to disseminate lessons learned. We assisted six CAHs to conduct RCAs within their organizations to further model this practice that supports a learning culture. The key interventions we used to build on the MEDMARX reporting program and support the just, flexible, and learning components of an informed, safe culture are available on our Web site (www.unmc.edu/rural/patient-safety/) and are listed below.

Interventions to Support a Just Culture

- Education regarding the nature of human error and organizational accidents.³
- Education regarding the concept of just culture.¹²
- Education regarding the concept that the same individual who is responsible for employee discipline should not collect and analyze safety information.³
- Tool: algorithm for determining the blameworthiness of unsafe acts.³

Interventions to Support a Flexible Culture

- Education regarding teamwork knowledge, skills (e.g., leadership, communication, situation monitoring, and mutual support), and beliefs.²³
- Tools: team huddles, team briefs, team debriefs, Patient Safety Leadership WalkRounds™ and safety briefings.^{23, 24}

Interventions to Support a Learning Culture

- Education regarding individual RCA and aggregate RCA.²⁵
- 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.
- Tool: Mapping the medication use process.

Adapting the HSOPSC for CAHs

AHRQ funded the development of the HSOPSC to provide health care organizations with a valid tool to assess safety culture. The HSOPSC consists of 42 items that are categorized in 12 dimensions (Table 1). Seven dimensions measure safety culture at the unit/department level: supervisor/manager expectations and actions promoting patient safety, organizational learning, teamwork within departments, communication openness, feedback and communication about error, nonpunitive response to error, and staffing.

Three dimensions measure safety culture at the hospital level: hospital management support for patient safety, teamwork across hospital departments, and hospital handoffs and transitions. Two dimensions are outcome measures: overall perceptions of safety and frequency of events reported. Two additional items are outcome measures: patient safety grade and number of events reported. Pilot testing ensured that the survey had sound psychometric properties.⁴

We modified the demographic sections of the survey to fit the CAH environment and protect the anonymity of survey respondents in these small organizations. We modified the Customized Excel™ Data Tool²⁶ available for entering and analyzing the survey data to incorporate these demographic changes and to allow sorting by work area or position when there were five or more respondents per category, rather than 11 or more as required by the original tool. We posted these adaptations of the survey and data tool on our Web site and shared them with quality improvement organizations that used the HSOPSC in their work with rural hospitals.

Survey Administration and Data Preparation

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 personnel 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,²⁷ 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

Table 1. Average percent-positive scores for 21 critical access hospitals in 2005 and 2007

Dimension and item	2005				2007			
	Mean (%)	Min (%)	Max (%)	SD ^a (%)	Mean (%)	Min (%)	Max (%)	SD ^a (%)
Overall perceptions of safety	69	57	87	7	72	52	84	9
1. ^b Patient safety is never sacrificed to get more work done.	70	52	91	11	72	47	93	12
2. ^b Our procedures and systems are good at preventing errors from happening.	69	49	91	10	73	41	86	10
3. ^c It is just by chance that more serious mistakes don't happen around here.	69	55	81	7	71	47	84	11
4. ^c We have patient safety problems in this department.	68	50	90	9	72	51	85	9
Frequency of events reported	61	49	71	6	65	45	80	9
1. ^d When a mistake is made but is <i>caught and corrected before affecting the patient</i> , how often is this reported?	48	33	61	7	54	29	79	12
2. ^d When a mistake is made but has <i>no potential to harm the patient</i> , how often is this reported?	58	42	74	8	61	39	74	10
3. ^d When a mistake is made that <i>could harm the patient</i> but does not, how often is this reported?	76	61	88	7	79	65	90	8
Supervisor/manager expectations & actions promoting patient safety	72	60	84	6	75	63	87	7
1. ^b My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.	63	34	81	10	67	44	85	11
2. ^b My supervisor/manager seriously considers staff suggestions for improving patient safety.	73	58	86	8	75	51	92	11
3. ^c Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.	75	59	97	9	80	68	92	7
4. ^c My supervisor/manager overlooks patient safety problems that happen over and over.	76	64	85	6	78	63	90	7

Table 1. Average percent-positive scores for 21 critical access hospitals in 2005 and 2007 (continued)

Dimension and item	2005				2007			
	Mean (%)	Min (%)	Max (%)	SD ^a (%)	Mean (%)	Min (%)	Max (%)	SD ^a (%)
Organizational learning – continuous improvement	72	55	89	8	75	60	89	8
1. ^b We are actively doing things to improve patient safety.	83	65	96	8	85	69	96	8
2. ^b Mistakes have led to positive changes here.	65	52	84	8	68	53	84	9
3. ^b After we make changes to improve patient safety, we evaluate their effectiveness.	67	42	88	10	72	46	88	11
Teamwork within departments	80	64	91	7	81	69	88	6
1. ^b People support one another in this department.	86	64	97	7	86	76	97	6
2. ^b When a lot of work needs to be done quickly, we work together as a team to get the work done.	89	73	100	7	89	69	98	6
3. ^b In this department, people treat each other with respect.	77	60	91	9	77	61	90	8
4. ^b When one area in this department gets really busy, others help out.	67	41	87	10	70	55	89	9
Communication openness	58	38	72	9	62	47	77	8
1. ^b Staff will freely speak up if they see something that may negatively affect patient care.	72	42	89	10	74	53	87	9
2. ^b Staff feel free to question the decisions or actions of those with more authority.	41	13	59	10	46	29	61	8
3. ^c Staff are afraid to ask questions when something does not seem right.	61	42	78	11	66	50	89	9
Feedback and communication about error	59	44	73	7	62	45	83	10
1. ^b We are given feedback about changes put into place based on event reports.	45	36	58	7	47	21	68	13
2. ^b We are informed about errors that happen in this department.	63	39	82	9	67	51	90	10
3. ^b In this department, we discuss ways to prevent errors from happening again.	68	50	85	9	71	51	90	9
Nonpunitive response to error	50	35	64	8	52	33	64	9
1. ^c Staff feel like their mistakes are held against them.	59	44	84	9	59	39	79	9
2. ^c When an event is reported, it feels like the person is being written up, not the problem.	50	31	62	8	52	25	67	11
3. ^c Staff worry that mistakes they make are kept in their personnel file.	41	20	63	10	46	24	60	10

Table 1. Average percent-positive scores for 21 critical access hospitals in 2005 and 2007 (continued)

Dimension and item	2005				2007			
	Mean (%)	Min (%)	Max (%)	SD ^a (%)	Mean (%)	Min (%)	Max (%)	SD ^a (%)
Staffing	67	45	88	10	69	52	87	10
1. ^b We have enough staff to handle the workload.	68	49	95	12	70	42	98	15
2. ^c Staff in this department work longer hours than is best for patient care.	62	46	84	11	64	49	86	10
3. ^c We use more agency/temporary staff than is best for patient care.	75	37	97	14	77	46	91	11
4. ^c We work in “crisis mode,” trying to do too much, too quickly.	62	48	88	11	65	42	90	12
Hospital management support for patient safety	73	56	87	9	74	52	92	11
1. ^b Hospital management provides a work climate that promotes patient safety.	84	62	100	9	84	65	98	10
2. ^b The actions of hospital management show that patient safety is a top priority.	73	46	91	11	74	55	94	11
3. ^c Hospital management seems interested in patient safety only after an adverse event happens.	63	46	82	11	65	32	85	13
Teamwork across hospital departments	64	47	90	10	65	44	79	11
1. ^b There is good cooperation among hospital departments that need to work together.	66	45	94	12	66	36	90	13
2. ^b Hospital departments work well together to provide the best care for patients.	75	62	97	8	74	47	89	11
3. ^c Hospital departments do not coordinate well with each other.	51	28	81	12	54	28	71	13
4. ^c It is often unpleasant to work with staff from other hospital departments.	63	41	90	11	65	41	84	11
Hospital handoffs & transitions	57	38	85	10	58	28	76	12
1. ^c Things “fall between the cracks” when transferring patients from one department to another.	57	40	87	11	58	34	84	13
2. ^c Important patient care information is often lost during shift changes.	56	39	81	12	59	26	83	13
3. ^c Problems often occur in the exchange of information across hospital departments.	52	29	84	12	54	29	74	12
4. ^c Shift changes are problematic for patients in this hospital.	61	44	94	12	62	22	86	14

Table 1. Average percent-positive scores for 21 critical access hospitals in 2005 and 2007 (continued)

Dimension and item	2005				2007			
	Mean (%)	Min (%)	Max (%)	SD ^a (%)	Mean (%)	Min (%)	Max (%)	SD ^a (%)
Patient safety grade								
A – Excellent	22	8	38	8	25	11	41	8
B – Very Good	52	37	63	7	52	37	68	9
C – Acceptable	23	10	42	8	20	9	39	8
D – Poor	3	0	8	2	3	0	13	3
E – Failing	0	0	3	1	0	0	1	0
Number of events reported^e								
No event report	63	51	79	9	49	28	70	11
1 to 2 event reports	16	4	34	8	24	11	33	7
3 to 5 event reports	13	5	31	8	15	8	31	6
6 to 10 event reports	5	0	6	2	7	0	14	4
11 to 20 event reports	2	0	6	2	4	0	17	5
21 event reports or more	1	0	6	2	2	0	7	2

a Standard deviation.

b “Agree” and “Strongly Agree” are positive responses.

c “Strongly Disagree” and “Disagree” are positive responses.

d “Most of the time” and “Always” are positive responses.

e The “Number of events reported” item in 2005 asked respondents how many *medication safety reports* have you filled out and submitted. The same item in 2007 asked respondents how many *event reports* have you filled out and submitted.

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.

Statistical Analyses

We calculated the average percent-positive score and standard deviation for each dimension and item across the 21 CAHs that completed the HSOPSC baseline in 2005 and the reassessment in 2007. To limit the number of comparisons, we chose *a priori* five specific survey items (see Table 2) to evaluate the effectiveness of our interventions. We had three reasons for choosing these items:

1. Each item evaluated a specific respondent belief or organizational practice needed to support one of the four components of an informed, safe culture.
2. Each item represented a belief or practice that we emphasized in our reporting and educational interventions.
3. Four of the five items were the least positively perceived items in their dimension. For each of these five items, responses were converted to “positive” or “not positive.”

Table 2. Odds ratio of responding positively in 2007 compared to 2005 for five survey items

Survey item	Odds ratio (95% CI)	P-value
When a mistake is made but is caught and corrected before affecting the patient, how often is this reported? ^b (<i>Evidence of a reporting culture</i>)	1.30 (1.14, 1.47)	<0.0001 ^a
Staff worry that mistakes they make are kept in their personnel file. ^c (<i>Evidence of a just culture</i>)	1.24 (1.04, 1.46)	0.01 ^a
Staff feel free to question the decisions and actions of those with more authority. ^d (<i>Evidence of a flexible culture</i>)	1.23 (1.07, 1.41)	0.004 ^a
In this department, we discuss ways to prevent errors from happening again. ^d (<i>Evidence of a learning culture</i>)	1.08 (0.86, 1.36)	0.51
Mistakes have led to positive changes here. ^d (<i>Evidence of an informed culture</i>)	1.09 (0.90, 1.32)	0.36

a Significant at $P \leq 0.01$.

b "Most of the time" and "Always" are positive responses.

c "Strongly Disagree" and "Disagree" are positive responses.

d "Agree" and "Strongly Agree" are positive responses.

A logistic regression was used to model the odds ratio (OR) of a respondent reacting positively to an item in 2007 compared with 2005. We used a Bonferroni correction ($P = 0.05/5 = 0.01$) to control the Type 1 error rate due to the five comparisons. A generalized estimating equations (GEE)²⁸ approach was used to account for the correlation among the data. Specifically, we used alternating logistic regressions (ALR)²⁹ with 1-nested log ORs to account for the repeated measurement of respondents and the clustering of respondents within hospitals. We used the GENMOD procedure in SAS[®] version 9.1 (SAS Institute, Cary, NC) to fit the model. We used the same five items to compare responses among three work areas and three positions across the 21 CAHs using the 2007 survey data. We used a GEE with an exchangeable covariance structure to account for the correlation of respondents within the same hospitals. We used a Bonferroni correction ($P = 0.05/3 = 0.017$) to control the Type 1 error rate for the comparisons among the three work areas and three positions. We used a t-test to compare the average change in the percent-positive score for each dimension from 2005 to 2007, according to whether a hospital participated in our safety culture educational activities. We did not adjust for multiple testing in this comparison.

Coding of Open-Ended Comments

The final section of the HSOPSC invites respondents to write comments about patient safety, error, or event reporting in their hospital. We used an integrated approach to coding these comments by starting with a literature-based organizing framework and then identifying themes that emerged from the experiences of the respondents.³⁰ All comments were coded by consensus of two researchers (Jones and Skinner).

Results

Response and Demographics

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 percent. In the 2007 reassessment, there were 1,963 eligible employees, and we obtained an aggregate response rate of 70.0 percent. 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 from the 21 hospitals was 51 to 92 percent in 2005 and 58 to 95 percent in 2007.

Respondent demographics by position were consistent in 2005 and 2007: nurses, 35 and 37 percent, respectively; allied health personnel, 28 and 24 percent, respectively; support personnel, 12 and 12 percent, respectively; administrators/managers, 12 and 12 percent, respectively; providers, 7 and 6 percent, respectively; and other, 7 and 8 percent, respectively.

Respondent demographics by work area were also consistent in 2005 and 2007: acute/skilled care, 32 and 31 percent, respectively; dietary, 12 and 13 percent, respectively; no specific department, 8 and 12 percent, respectively; laboratory, 7 and 6 percent, respectively; surgery/OR, 5 and 5 percent, respectively; pharmacy, 2 and 2 percent, respectively; and other, 8 and 7 percent, respectively.

Approximately 87 percent of respondents reported having direct patient contact in both years. Six hospitals had attached long-term care units; 99 respondents (5 percent) in 2005 and 63 respondents (3 percent) in 2007 identified their primary department as long-term care. Since this paper focuses on hospital culture, we excluded long-term care respondents from these results.

Safety Culture Similarities and Variations Across Hospitals

The pattern of percent-positive responses by dimension and item across hospitals was similar in 2005 and 2007 (Table 1). The most positively perceived dimensions were teamwork within departments, 80 and 81 percent, respectively; hospital management support for patient safety, 73 and 74 percent, respectively; organizational learning, 72 and 75 percent, respectively; and supervisor/manager expectations and actions promoting patient safety, 72 and 75 percent, respectively. The least positively perceived dimensions were nonpunitive response to error, 50 and 52 percent, respectively; hospital handoffs and transitions, 57 and 58 percent, respectively; communication openness, 58 and 62 percent, respectively; and feedback and communication about error, 59 and 62 percent, respectively.

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 percent, respectively; and from the nonpunitive response to error dimension, “staff worry that mistakes they make are kept in their personnel file,” 41 and 46 percent, respectively. Hospital-level dimensions across the CAHs were less uniform (had greater standard deviations) than unit/department level dimensions.

Using the HSOPSC to Assess the Effectiveness of Interventions

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 an informed, safe culture were greater at reassessment in 2007 than at baseline in 2005 (Table 2). This difference was statistically significant for the three beliefs and practices that support a reporting culture, a just culture, and a flexible culture but not for the beliefs and practices 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.

As previously described, 4 of the 21 CAHs chose not to participate in the followup safety culture educational activities that we offered in response to the baseline survey. These four nonparticipating CAHs had baseline percent-positive scores on the 12 safety culture dimensions that were equal to or slightly higher than the baseline scores of the 17 CAHs that chose to participate in the followup activities (Figure 1). Among the 17 participating CAHs, the average percent-positive scores on the 12 dimensions increased from 2005 to 2007. Among the four nonparticipating CAHs, these scores decreased, except for frequency of events reported, which did not change. This difference in the change in the average percent-positive score according to whether a CAH participated in the followup safety culture activities was statistically significant for four of the unit/department level dimensions: nonpunitive response to error, communication openness, teamwork within departments, and organizational learning (Figure 1).

Safety Culture Variation by Work Area and Position in 2007

In 2007, 399 respondents among the 21 CAHs worked in the acute/skilled care area; 83 respondents among the 21 CAHs worked in the laboratory; and 62 respondents among 13 CAHs worked in surgery. The median number of respondents in a work area per CAH was as follows: acute/skilled care (19), laboratory (3), and surgery (2).

In 2007, respondents who worked in the laboratory and in surgery had a more positive perception of the culture of safety within their work area than did those who worked in the acute/skilled area (Figure 2). In 2007, 481 respondents among the 21 CAHs indicated that they were nurses; 161 indicated they were managers; and 80 respondents among 20 CAHs indicated they were providers (physician/NP/PA). The median number of respondents by position per CAH was as follows: nurses (20), managers (6), and providers (4). In 2007, those in management had a more positive perception of the culture of safety than did nurses or providers (Figure 2).

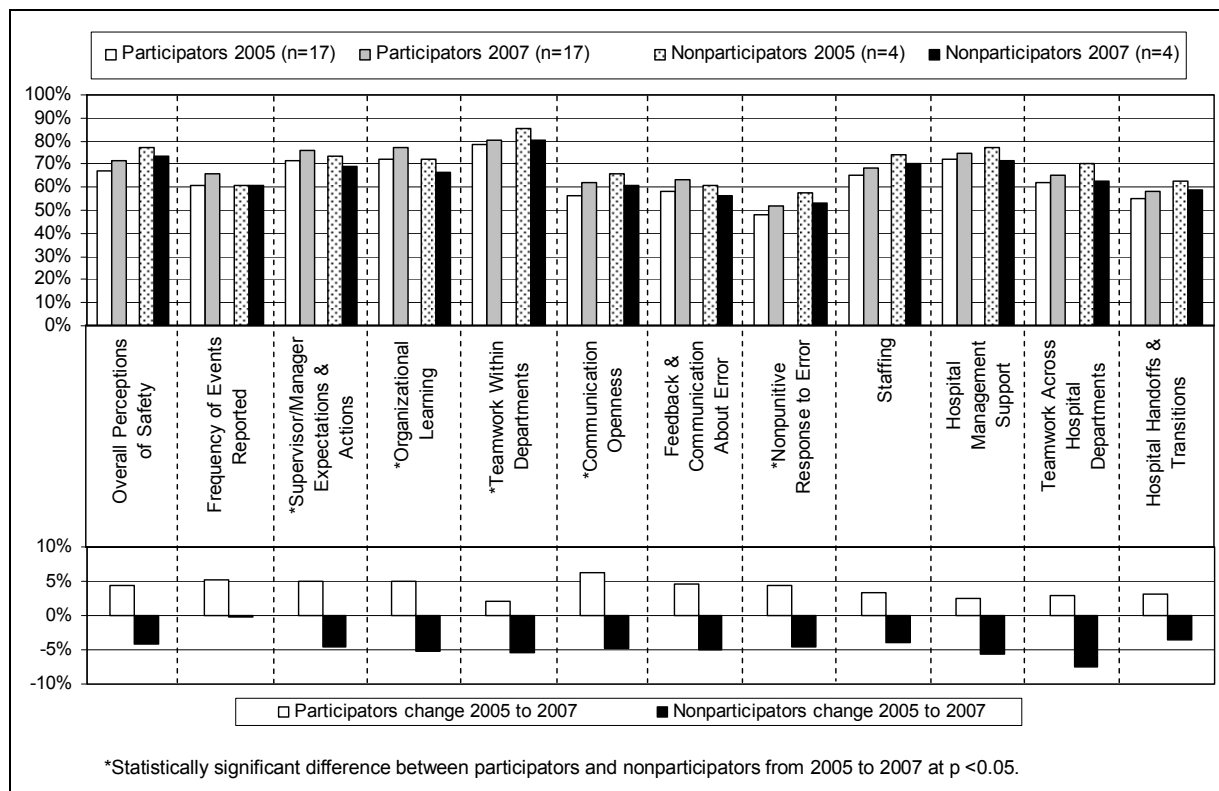


Figure 1. Comparison of change in average percent-positive scores by participation status on 12 safety culture dimensions from 2006 to 2007 for 21 critical access hospitals.

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 (Table 3). 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. When considering work area, we compared the laboratory and surgery departments to the reference group of acute/skilled care. When considering position, we compared management and providers to the reference group of nurses:

- The odds of a respondent working in the laboratory disagreeing that “they worry that mistakes they make are kept in their personnel” file were 1.96 times the odds of a respondent working in acute/skilled care responding similarly. The odds of a manager and a provider responding similarly to this statement were 2.33 and 0.41 times the odds of a nurse.

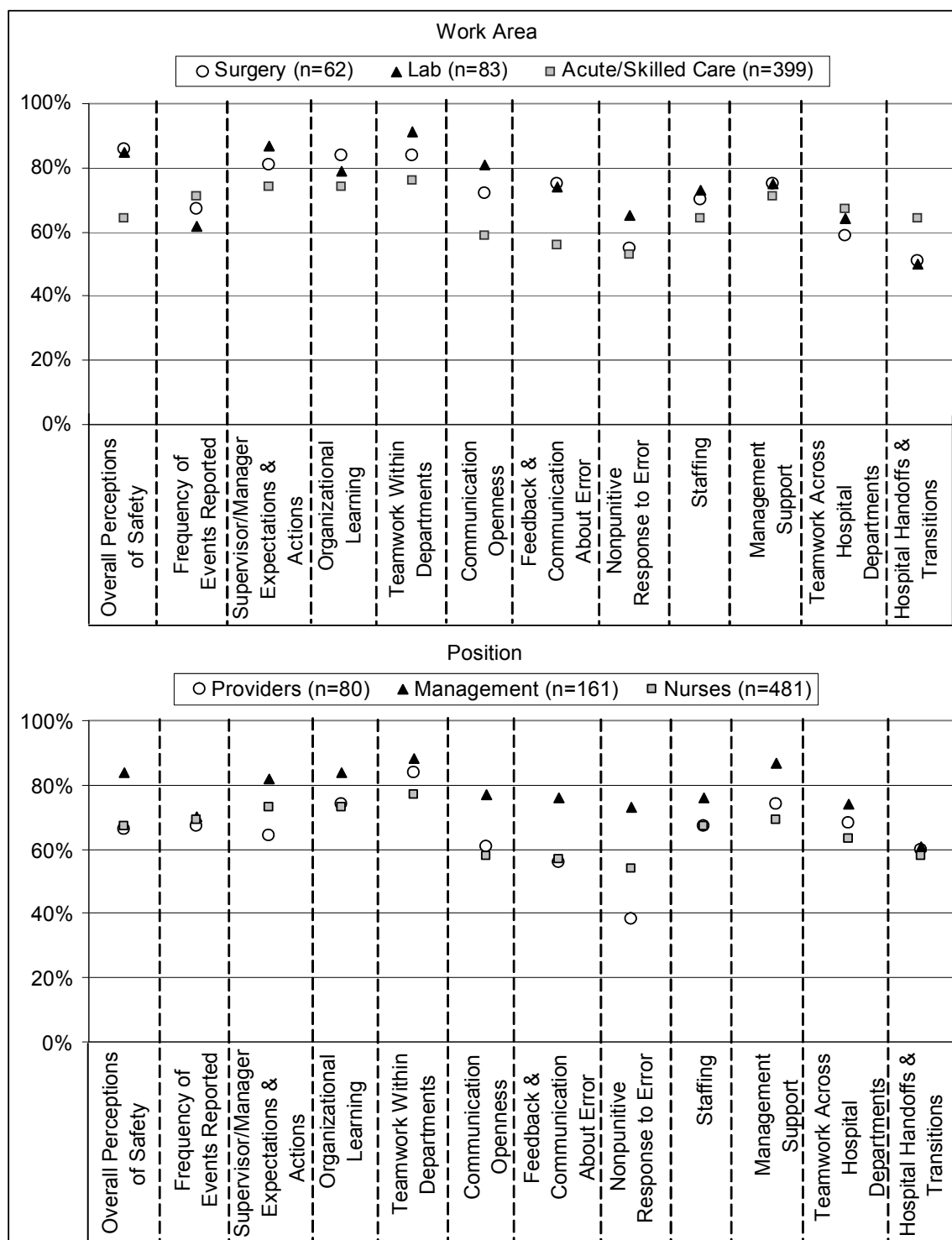


Figure 2. Comparison of percent-positive scores on 12 safety culture dimensions by work area and position, 2007.

Table 3. Odds ratios of responding positively in 2007: Comparisons between work areas and between positions for five survey items

Survey item	Odds Ratio (95% CI)	P-value
When a mistake is made but is caught and corrected before affecting the patient, how often is this reported?^b (<i>Evidence of a reporting culture</i>)		
Work Area (acute care, surgery, lab)		0.162
Surgery personnel compared to acute care personnel	0.77 (0.45, 1.33)	
Lab personnel compared to acute care personnel	0.64 (0.39, 1.04)	
Position (nurse, management, provider)		0.349
Management compared to nurses	1.31 (0.90, 1.90)	
Providers compared to nurses	1.16 (0.69, 1.95)	
Staff worry that mistakes they make are kept in their personnel file.^c (<i>Evidence of a just culture</i>)		
Work Area (acute care, surgery, lab)		0.025
Surgery personnel compared to acute care personnel	1.19 (0.69, 2.05)	0.533
Lab personnel compared to acute care personnel	1.96 (1.20, 3.19)	0.007 ^a
Position (nurse, management, provider)		<0.001
Management compared to nurses	2.33 (1.60, 3.40)	<0.001 ^a
Providers compared to nurses	0.41 (0.24, 0.70)	0.001 ^a
Staff feel free to question the decisions and actions of those with more authority.^d (<i>Evidence of a flexible culture</i>)		
Work Area (acute care, surgery, lab)		<0.001
Surgery personnel compared to acute care personnel	2.26 (1.30, 3.93)	0.004 ^a
Lab personnel compared to acute care personnel	2.89 (1.75, 4.74)	<0.001 ^a
Position (nurse, management, provider)		<0.001
Management compared to nurses	3.30 (2.25, 4.84)	<0.001 ^a
Providers compared to nurses	1.90 (1.16, 3.09)	<0.010 ^a
In this department we discuss ways to prevent errors from happening again.^d (<i>Evidence of a learning culture</i>)		
Work Area (acute care, surgery, lab)		<0.001
Surgery personnel compared to acute care personnel	3.12 (1.50, 6.53)	0.002 ^a
Lab personnel compared to acute care personnel	3.20 (1.68, 6.10)	<0.001 ^a
Position (nurse, management, provider)		<0.001
Management compared to nurses	3.34 (2.05, 5.44)	<0.001 ^a
Providers compared to nurses	0.89 (0.54, 1.47)	0.656

Table 3. Odds ratios of responding positively in 2007: Comparisons between work areas and between positions for five survey items (continued)

Survey item	Odds Ratio (95% CI)	P-value
Mistakes have led to positive changes here.^d (<i>Evidence of an informed culture</i>)		
Work Area (acute care, surgery, lab)		0.012
Surgery personnel compared to acute care personnel	1.64 (0.88, 3.04)	0.117
Lab personnel compared to acute care personnel	2.05 (1.15, 3.63)	0.014 ^a
Position (nurse, management, provider)		<0.001
Management compared to nurses	2.49 (1.60, 3.89)	<0.001 ^a
Providers compared to nurses	1.50 (0.88, 2.56)	0.138

a Significant at $P \leq 0.017$.

b "Most of the time" and "Always" are positive responses.

c "Strongly Disagree" and "Disagree" are positive responses.

d "Agree" and "Strongly Agree" are positive responses.

- The odds of respondents working in surgery and the laboratory agreeing that "they feel free to question the decisions or actions of those with more authority" were 2.26 and 2.89 times, respectively, the odds of a respondent working in acute/skilled care responding similarly. The odds of a manager and a provider responding similarly were 3.30 and 1.90 times the odds of a nurse, respectively.
- The odds of respondents working in surgery and the laboratory agreeing that "in this department, we discuss ways to prevent error from happening again" were 3.12 and 3.20 times, respectively, the odds of a respondent working in acute/skilled care responding similarly. The odds of a manager responding similarly were 3.34 times the odds of a nurse. Providers did not differ significantly from nurses regarding this belief that supports a learning culture.
- The odds of respondents working in the laboratory agreeing that "mistakes have led to positive changes here" were 2.05 times the odds of a respondent working in acute/skilled care responding similarly. The odds of a manager responding similarly were 2.49 times the odds of a nurse.

Respondent Comments

In 2007, 201 respondents (15 percent) provided written comments; the number of respondents providing a comment from each CAH ranged from 1 to 30. The most prevalent themes in these comments were "feedback about patient safety systems" (13 percent) or a "specific patient safety concern" (13 percent). The 17 CAHs that participated in the followup safety culture educational activities accounted for 83 percent of the coded comments. The representative themes in the comments varied according to participation status. Specifically, the three most prevalent themes in the comments from the 17 participating CAHs were "feedback about patient safety systems" (13 percent), "specific patient safety concern" (11 percent), and "evidence of a positive safety culture and organizational learning" (8 percent). In contrast, the three most prevalent themes in the comments from the four nonparticipating CAHs were "specific patient safety concern" (23

percent), “feedback about patient safety systems” (11 percent), and “lack of teamwork” (11 percent). In addition, 7 percent of comments from the participating CAHs described “progress in patient safety” since the 2005 baseline, but there were no comments coded as “progress in patient safety” from the nonparticipating CAHs.

Discussion

Key Findings

These results 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 the Nation’s smallest hospitals.

These results also demonstrate that 21 of the Nation’s smallest hospitals can make improvements in safety culture by implementing practices that support all components of an informed, safe culture. These practices must include a voluntary error reporting system that uses a standardized taxonomy to support a reporting culture; Reason’s algorithm³ for determining the blameworthiness of unsafe acts to support Marx’s concept of a just culture; teamwork training that emphasizes the knowledge, skills, and beliefs necessary to function as a team within and across departments to support a flexible culture; and multiple approaches to communicate about and learn from errors (e.g., 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.

The overall test of the effectiveness of our intervention (Table 2) demonstrates that the HSOPSC can detect improvements in safety culture related to specific patient safety interventions over time in real-world settings. This test also reveals two important concepts about patient safety. First, it demonstrates the impact of providing a structured reporting system as the foundation of an informed, safe culture. The odds of a respondent reacting positively to the survey item about reporting near-misses were significantly greater in 2007 than in 2005 for all 21 CAHs; none of these CAHs had reported near-misses prior to participating in our project. Use of a structured reporting system provides a common language that hospital personnel can use to understand errors in the context of the interdependent structures and processes that make up their systems.¹³ Despite not engaging in any of the other educational activities that we offered during the 2 years of the grant, the four nonparticipating CAHs used MEDMARX, which explains why frequency of events reported was the only dimension in which the percent-positive composite score did not decrease from 2005 to 2007 among these four CAHs (Figure 1). When financial support from the grant ended, all 21 CAHs continued their subscriptions to MEDMARX.

Second, we believe that the overall test of the effectiveness of our intervention (Table 2) illustrates Pronovost’s change model. This model summarizes four strategies for leading change within an organization.³¹ Those leading a change effort must engage and educate about the relevance and content of a proposed practice, execute change to implement the practice, and then evaluate whether the change made a difference. Reassessment with the HSOPSC in 2007 revealed that we were most effective at improving safety culture when we completed at least three of these four stages. Specifically, we engaged hospitals about the relevance of MEDMARX to improving medication safety; we educated hospitals to use MEDMARX; we ensured that each

hospital executed MEDMARX; and we evaluated and provided quarterly reports to each hospital about its use of MEDMARX to support a reporting culture.

We engaged and educated about Marx's concept of a just culture, and we facilitated execution of this concept by distributing our adaptation of Reason's algorithm³ for determining the blameworthiness of unsafe acts. We engaged and educated about the use of structured communication practices to give front-line personnel the tools to speak up about safety concerns to those with more authority. We facilitated execution of these practices by distributing a structured communication toolkit to the CAHs. Although we engaged and educated about numerous practices to support teamwork and a learning culture, executing these activities varied widely across project hospitals.

Throughout our project, we had a key contact in each CAH, who was responsible for quality improvement or was the director of nursing; in six CAHs, our key contact was responsible for both of these tasks. The fact that the average change in the percent-positive score for supervisor/manager expectations and actions promoting patient safety differed by participation status (Figure 1) reflects the effectiveness of our key contacts in the CAHs that participated in the safety culture education. Their effectiveness is further demonstrated by the fact that the average change in the percent-positive score for organizational learning also differed by participation status.

We conducted an outcomes survey and site visits at the end of the project to determine which specific patient safety practices the hospitals had implemented. We found that the nonparticipating CAHs were aware of few of the patient safety practices. This lack of awareness and progress in these nonparticipating CAHs was supported by the absence of open-ended comments coded as "progress in patient safety."

The fact that the percent-positive score decreased from 2005 to 2007 in every dimension except frequency of events reported among the four nonparticipating CAHs illustrates the ability of the HSOPSC to raise awareness of respondents about safety culture. Participating in the baseline survey educated respondents about the beliefs and practices associated with an informed, safe culture and raised expectations that leaders would act and change would occur. When change did not occur, respondents in nonparticipating hospitals held their organizations to a higher standard at reassessment than they had at baseline.

Relevance to Previous Research and Patient Safety Concepts

These results are consistent with previous research, which demonstrated that safety culture varies by position and work area.^{20, 32} Specifically, we found that nonclinician managers consistently perceived an organization's safety culture more positively than did those actively engaged in patient care. We believe this finding is related to the consistent perception of a punitive environment in health care; the percent-positive score for nonpunitive response to error was 43 percent in the HSOPSC 2007 comparative database of 382 hospitals.¹⁸ We believe this perception of a punitive environment persists despite well-structured reporting programs when reporting is not supported by the beliefs and practices of just, flexible, and learning cultures. Many of our key contacts explained, "MEDMARX gave us a new way of talking about error that helped us understand our system, but we continued to focus on retraining the individual."

(Despite an anonymous reporting system, the individual at the “sharp end” of the error is often readily identified in these small hospitals).

This focus on the individual is consistent with the anxiety-avoidance approach, in which managers engage in the “blame and retrain” cycle to seem as if they are doing something about an event.³ This behavior may explain why the percent-positive scores did not improve similarly for all items in the nonpunitive response to error dimension. Perceptions of a punitive environment will continue until managers consistently execute organizational learning practices in place of the individual “blame and retrain” cycle. As of June 2007, only one CAH was using aggregate root cause analysis to analyze multiple nonharmful events, and approximately half had implemented Leadership WalkRounds™ or safety briefings to discuss errors in the context of daily work.

Our key contacts helped us to understand why surgery and lab personnel may have a more positive perception of safety culture in the same organization than acute/skilled care personnel. The “Time Out” verification of the procedure, patient, and site is considered a universal surgical protocol. Work in surgery and the laboratory was described as “less chaotic and more controlled by professional standards.” In addition, errors in surgery and laboratory were described as events that were investigated by the group. In contrast, errors in nursing were described as “picking on individuals.” These perceptions are consistent with the fact that the odds of those working in surgery and laboratory agreeing with the statement, “in this department we discuss ways to prevent error from happening again,” were three times the odds of respondents working in acute/skilled care responding similarly. These results are consistent with the view that organizations contain microcultures that are influenced by the flow of information that is controlled by leaders.^{14, 15} However, these results also demonstrate the influence of differences in safety culture training within health care professions.

Strengths and Limitations

The strengths of this study include the fact that we grounded our activities in the theoretical work of Reason³ and Weick and Sutcliffe;¹³ and we used effective data collection procedures to avoid bias and the common sources of error associated with survey research.²⁷ Specifically, we surveyed all eligible employees; we obtained an excellent overall response rate of 70 percent at baseline and reassessment; and as a neutral third party, we ensured respondent confidentiality. An additional strength of our work is that our adaptations of the HSOPSC resulted in the ability to categorize over 93 percent of respondents by work area and position, which facilitates understanding of microcultures that are present, even in the Nation’s smallest hospitals.

There are limitations in this study. These CAHs were not a representative sample of all CAHs; they were self-selected to participate in an organized patient safety program. Also, our analysis of the effectiveness of our interventions by participation status in safety culture education was the result of a natural experiment, which resulted in only four CAHs classified as nonparticipants. This small group size limited the power of this analysis.

Conclusion

Our focus on CAHs reflects the IOM's belief that the health care environment should be safe for all patients.² 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 link to the practices required to achieve an informed, safe culture. Reason has asserted that an informed, safe culture must be socially engineered by executing these interacting practices.³ Hospital leaders influence beliefs about organizational culture by supporting front-line managers and workers as they execute these practices. Reporting practices provide a common language for describing error in terms of a system and provide the foundation for an informed, safe culture.

Using the taxonomies associated with the MEDMARX voluntary medication error-reporting program resulted in improvements in reporting culture across 21 CAHs. However, a reporting culture must interact with just, flexible, and learning cultures. Consequently only the 17 CAHs that participated in our safety culture educational interventions demonstrated improvements in all dimensions of the survey. Safety culture emerges gradually from sustained attention to engineering the interactions between the practices associated with the four components. In CAHs, directors of nursing and quality improvement must engineer these interactions while often continuing to provide care at the bedside. Consequently, they require support from their senior leaders and education and tools from network hospitals, quality improvement organizations, and other organizations that advocate for rural hospitals. This study exemplifies the type of field-based, mixed-methods research that is necessary to understand how patient safety interventions can change the beliefs and practices that define an organization's safety culture.¹⁷

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Hospital Administrative Staff vs. Nursing Staff Responses to the AHRQ Hospital Survey on Patient Safety Culture

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Abstract

The West Virginia Patient Safety Project is an Agency for Healthcare Research and Quality (AHRQ) funded, voluntary network of hospitals working to report, analyze, and learn from medical errors. As part of this project, we assessed the safety culture in 29 West Virginia rural hospitals using the AHRQ Hospital Survey on Patient Safety Culture in two measurement periods. We computed scores for each item and dimension on the survey for each hospital and generated reports to share with hospitals as a basis for interventions to improve their safety cultures. In general, nurses rated safety culture less positively than administrative staff in all hospitals, independent of duration of employment, hours worked, or work unit. Most differences were still evident after remeasurement, and in some cases they had increased. The continuing discrepancy in positive responses between administrative and nursing staff in several survey dimensions may be indicative of the need for more intensive interventions in certain areas of safety culture.

Introduction

Public and professional concern over patient safety, adverse health care events, and medical error has been increasing since before the beginning of the new millennium. Lucian Leape, Don Berwick, and others pioneered research on these topics in the 1990s.^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10} The landmark 1999 Institute of Medicine (IOM) report *To Err is Human* called for developing a “culture of safety” within health care organizations and defined many of the characteristics of such a culture.¹¹ Although creating a culture of safety in hospitals is the responsibility of all employees, to be successful it must be driven by senior management. Indeed, it has been said that “... leadership is the critical element in a successful patient safety program and is non-delegable.”¹² To understand where to focus efforts in building this environment, hospital senior management and administrators must be cognizant of the opinions and beliefs of the frontline staff regarding the safety culture of their facility.

Shortly after the release of the IOM report, the West Virginia Medical Institute (WVMI)—the Medicare Quality Improvement Organization for West Virginia, Delaware, and Pennsylvania—convened leaders of West Virginia’s hospitals and physicians to develop a statewide plan to address medical errors. Out of this grew the West Virginia Patient Safety Project, a voluntary network of hospitals working together to report, analyze, and learn from medical errors. This

project was greatly expanded in 2004 to include more hospitals and organizational partners, with the support of a cooperative agreement from the Agency for Healthcare Research and Quality (AHRQ; grant UC1 HS01 4920-02). As part of this project, we assessed the safety culture in West Virginia hospitals using a standard instrument. This report presents findings of the baseline and remeasurement surveys and describes systematic differences in attitude toward patient safety between nurses and administrative staff in West Virginia hospitals.

Methods

We originally recruited 29, mostly rural acute care hospitals (including 16 critical access hospitals) in West Virginia to participate in the voluntary patient safety event-reporting system component of the project. This represented a majority of the 34 acute care hospitals in the State. After recruitment, staff in each hospital received training on the system. In conjunction with the training, we administered the AHRQ Hospital Survey on Patient Safety Culture¹³ to participants. We also left extra copies of the survey at each hospital to be distributed to staff that could not attend the training. We attempted to reach as many staff as possible, but we could not control attendance at the training or enforce a response; therefore, the sampling methodology was not uniform across hospitals. We also had no way to determine denominators to establish response rates by facility. However, the hospitals involved estimated their staff participation rates as between 25 percent (for the smallest critical access hospitals) and 75 percent (for larger facilities). The baseline survey was administered between January and October 2005.

At approximately the midpoint of the 3-year AHRQ grant, we resurveyed participating hospitals to determine if attitudes and beliefs concerning the patient safety culture of each hospital had changed since baseline. Only 26 hospitals participated at remeasurement: one facility did not participate due to the timing of the survey; one merged with a larger hospital; and one used a different survey mechanism in the remeasurement period. Surveys were again administered on site in each facility. The remeasurement survey was administered between July and September 2006. Again, survey sampling methodology and response were determined by the individual facility and were not uniform across facilities.

The AHRQ Hospital Survey on Patient Safety Culture consists of 12 dimensions of safety culture. Each dimension comprises three or four items, for a total of 42 survey items. The survey used a 5-point Likert scale, where 1 = strongly disagree; 2 = disagree; 3 = neither; 4 = agree; and 5 = strongly agree. For questions assessing frequency of event reporting, 1 = never; 2 = rarely; 3 = sometimes; 4 = most of the time; and 5 = always.

Eighteen of the items are reverse-worded; that is, disagreement implies a more favorable patient safety culture. For example, item A10 (reverse-worded) states, “It is just by chance that more serious mistakes don’t happen around here.” This compares item A18 (non-reverse-worded), “Our procedures and systems are good at preventing errors from happening.” Scoring takes these differences into account.

In addition, the survey captures several demographic variables, such as hospital work area, number of events reported, length of time worked in the hospital, length of time in current work area, length of time in current specialty or profession, hours worked per week, staff position, and

whether or not the respondent has direct interaction with patients. Respondents are also asked to give their work area/unit a grade on patient safety.

Respondents completed the survey on an optically scanned form, which was converted to digital data using Teleform[®] software. Free-text comments were collected and manually entered into the dataset. For the 42 response items, 12 dimension scores were constructed as specified in the survey documentation.¹⁴ We computed scores for each item and dimension for every participating hospital and generated hospital-level reports at both baseline and remeasurement.

For all participating hospitals, we calculated scores as above and examined the relationship between scores and demographic variables using 2-way frequency tables, consolidating levels of multilevel variables when appropriate. (For example, for the demographic variable “staff position in the hospital,” we combined the positions for registered nurse, licensed vocational nurse, licensed practical nurse, physician assistant, and nurse practitioner into one category, “nursing.”) We compared scores with the AHRQ benchmark, a published set of national norms on the instrument representing 382 hospitals and over 108,000 respondents.¹⁴

In preliminary analyses of the baseline data, we discovered apparently consistent differences in response patterns by respondent position in the hospital. To investigate this further, we identified a subset of respondents with the most extreme answers and conducted additional analyses on this subset. In the subset, we computed relative risk of a positive response to each item by position, where a positive response was 4 or 5 for items worded normally and 1 or 2 for reverse-worded items. Where we found significant differences between job classes, we tested for confounding by other demographic characteristics.

These differences by respondent position in the hospital persisted in the remeasurement data and in some cases increased. Analyzing these differences is the focus of this study.

We used SAS[®] version 9.1 (SAS Institute, Cary NC) for statistical analysis. We considered a probability value of <0.05 to be statistically significant.

Results

Demographic characteristics were quite similar for both measurement periods. There were 1,967 respondents to the survey from 29 West Virginia hospitals at baseline and 1,717 responses from 26 hospitals at remeasurement. The median number of respondents per hospital was 52.5 at baseline (10th to 90th percentile range 15.8 - 96.6) and 47.0 at remeasurement (10th to 90th percentile range 22.5 - 149.0). We were unable to determine denominators, as we did not have information on staffing levels and thus were not able to establish response rates.

In the baseline survey, 661 (33.6 percent) of the respondents were nonphysician providers (including nurse practitioners and physician assistants, although the majority were registered nurses and licensed practical nurses), and 333 (16.9 percent) were administration/management. At remeasurement, 578 (33.7 percent) respondents were nursing staff, and 225 (13.1 percent) were administration/management. These two groups accounted for 50.5 percent of total responses at baseline and 46.8 percent at remeasurement. The remaining categories of employees

were ancillary health care, clerical, and others. Physicians (two respondents statewide at baseline and six at remeasurement) were remarkable for their low participation; they are counted in the “Other” group, as are the somewhat more numerous pharmacists (34 statewide at baseline and 21 at remeasurement) (Table 1).

Respondents generally were long-term employees in their hospitals, with 848 (43.3 percent) at baseline and 667 (39.4 percent) at remeasurement having worked in the same hospital longer than 10 years. Similarly, more than 25 percent of respondents at both baseline and remeasurement had been in the same profession more than 20 years. Nearly three-quarters of the respondents reported direct patient contact at baseline and remeasurement, 1,414 (71.9 percent) and 1,296 (75.5 percent), respectively.

Table 1. Respondent job classification State-wide West Virginia survey of hospital patient safety culture

Job classification	N (%)	
	Baseline	Remeasurement
Administration/management	333 (16.9)	225 (13.1)
Clerical	198 (10.1)	193 (11.2)
Nursing/physician assistant	661 (33.6)	578 (33.7)
Ancillary health care	386 (19.6)	413 (24.1)
Other and unknown ^a	389 (19.8)	308 (17.9)
Total	1,967	1,717

a Includes pharmacists, physicians, other, unknown, and no response.

Total respondents’ views on patient safety are illustrated in Figure 1, which presents scores for each of the 12 dimensions at both baseline and remeasurement, compared to AHRQ benchmarks. The scores represent the percent of respondents answering each item in the dimension positively. For most dimensions of patient safety culture, West Virginians rated their hospitals the same or better than AHRQ benchmark participants. Exceptions included “nonpunitive response to error” and “hospital handoffs and transitions,” where West Virginia hospitals scored below the nationwide AHRQ benchmarks. No significant differences were noted among overall scores at baseline and remeasurement in any of the patient safety dimensions (Table 2).

However, when we examined responses by job position, consistent patterns emerged. We found large and consistent differences between nurses and administrators in the global patient safety grade. This one item explains, on average, almost 10 percent of the variance in every other item in the survey. We also noted in the baseline analysis that nursing staff tended to rate safety culture lower and administrative staff higher, compared to the rest of the respondents, and that nurses’ and administrators’ responses to individual items often defined the extremes. This discrepancy persisted in remeasurement and in some cases even increased. Figure 2 illustrates this point, showing the patient safety dimension scores for nurses and administrators in West Virginia at both baseline and remeasurement.

For all dimensions but two (“Frequency of Events Reported” and “Handoffs & Transitions”), administrative staff rated safety conditions higher than nurses at baseline; in most cases

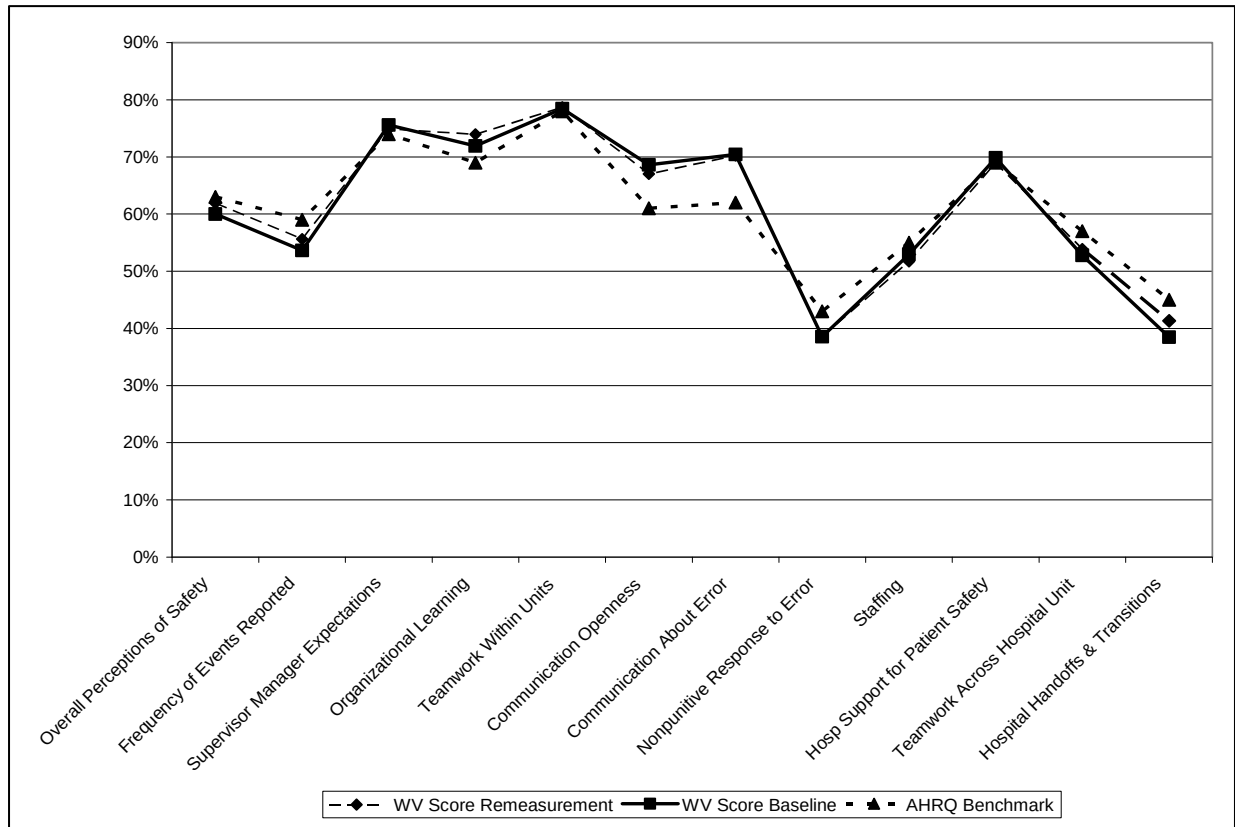


Figure 1. Responses to baseline and remeasurement hospital survey on patient safety culture by dimension West Virginia vs. AHRQ benchmark. Dimensions are groups of survey items testing similar themes. “Positive” responses are agreement or strong agreement to positively-worded items, and disagreement or strong disagreement with reverse-worded items. Note: Although the data do not represent a time series, this format was chosen for clarity.

significantly so (Table 3). At remeasurement, in only “Frequency of Events Reported” did nursing staff continue to score more positive responses than administrative staff.

Several of the dimensions of patient safety showed significant changes in positive response rate from baseline to remeasurement, both between administrative and nursing staff and among each of the types individually. Dimensions in which the gap between these positions increased included:

- Nonpunitive response to error.** This dimension, which denotes the extent to which staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file, showed a large and widening gap in positive responses between administrative and nursing staff. At baseline, administrative staff’s positive score exceeded nursing staff’s score by 12.7 percent; at remeasurement, the gap had increased to 17.6 percent. Almost the entire increase was due to administrative staff’s rise in positive score between baseline (48.8 percent) and remeasurement (55.2 percent); no similar increase occurred among nursing staff. Additionally, this dimension had the lowest overall score among nursing staff, at 36.1 percent.

Table 2. Positive responses to hospital survey of patient safety culture by dimension and job classification (administration vs. nursing), West Virginia baseline and remeasurement and AHRQ benchmark

Safety culture dimension	Baseline score		χ^2	Remeasurement score		χ^2	Change (%)	AHRQ benchmark (%)
	Admin (%)	Nursing (%)		Admin (%)	Nursing (%)			
Overall perceptions of patient safety	65.2	53.6	50.63 $P < 0.001$	72.2	58.6	50.24 $P < 0.001$	2.0	63.0
Frequency of events reported	54.0	56.3	1.37 $P = 0.24$	54.7	56.5	0.59 $P = 0.44$	0.5	59.0
Supervisor/manager expectations & actions promoting patient safety	79.0	74.5	10.90 $P < 0.001$	80.3	75.4	8.52 $P = 0.003$	0.4	74.0
Organizational learning – continuous improvement	82.7	70.4	46.10 $P < 0.001$	81.6	76.5	7.12 $P = 0.007$	-7.2	69.0
Teamwork within units	85.5	77.8	31.33 $P < 0.001$	87.2	79.5	25.53 $P < 0.001$	0.0	78.0
Communication openness	78.8	67.3	42.02 $P < 0.001$	80.6	66.5	45.55 $P < 0.001$	2.6	61.0
Feedback & communication about error	75.3	67.9	17.30 $P < 0.001$	77.4	69.8	13.32 $P < 0.001$	0.2	62.0
Nonpunitive response to error	48.8	36.1	41.85 $P < 0.001$	55.2	37.6	60.66 $P < 0.001$	4.9	43.0
Staffing	58.6	53.0	14.35 $P < 0.001$	61.2	52.8	18.04 $P < 0.001$	2.7	55.0
Management support for patient safety	83.4	60.6	156.80 $P < 0.001$	84.6	64.8	89.13 $P < 0.001$	-3.1	69.0
Teamwork across units	57.1	52.7	4.66 $P = 0.03$	63.2	53.6	23.76 $P < 0.001$	5.3	57.0
Handoffs & transitions	38.3	40.5	2.43 $P = 0.12$	49.2	44.5	5.56 $P = 0.018$	6.9	45.0

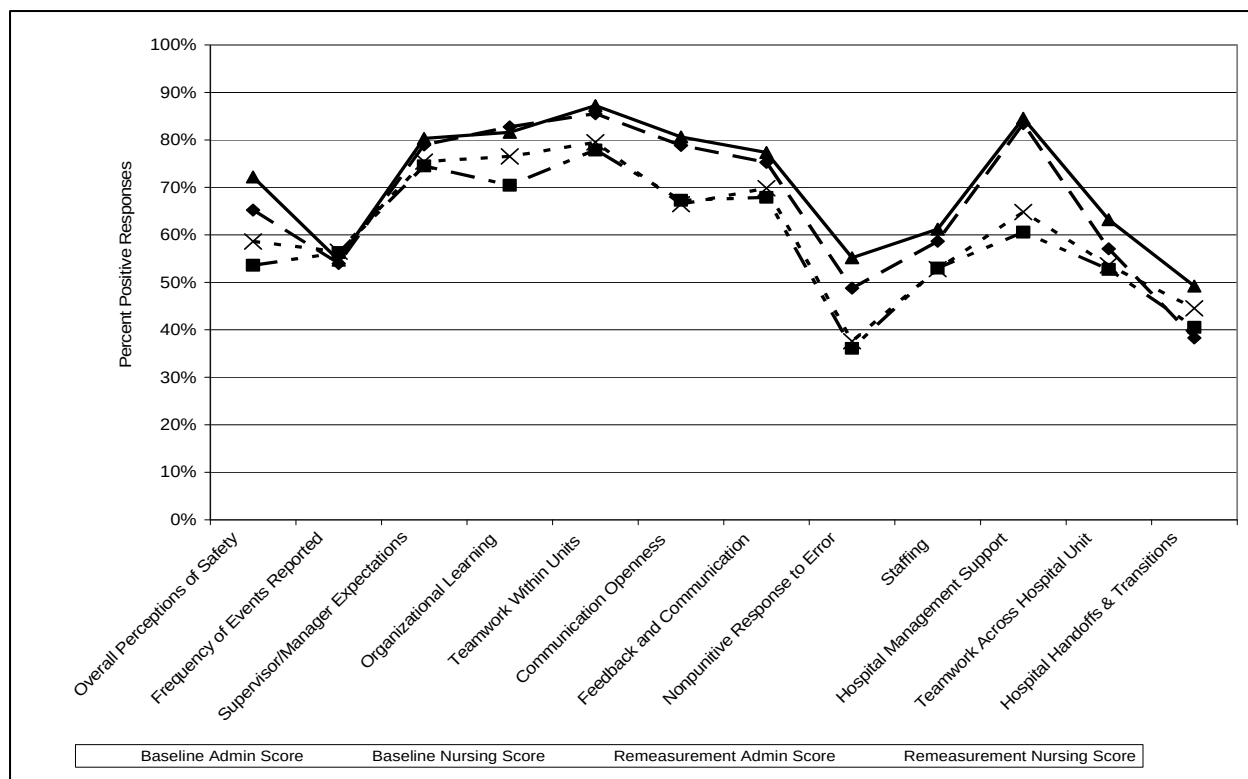


Figure 2. Responses to hospital survey on patient safety culture by dimension and job classification (administration vs. nursing) West Virginia baseline and remeasurement. Dimensions are groups of survey items testing similar themes. “Positive” responses are agreement or strong agreement to positively-worded items, and disagreement or strong disagreement with reverse-worded items. “Admin” denotes West Virginia hospital staff who are administrators or managers; “Nursing” denotes nurses, nurse practitioners, or physician assistants. Note: Although the data do not represent a time series, this format was chosen for clarity.

- **Communication openness.** This dimension indicates the extent to which staff freely speak up if they see something that may negatively affect a patient and feel free to question those with more authority. This dimension showed an increase in the gap between nursing and administrative staff’s positive response rates, from 11.5 percent (absolute) at baseline to 14.1 percent at remeasurement, but there was no significant increase in scores.
- **Teamwork across units.** This dimension is defined as the extent to which hospital units cooperate and coordinate with one another to provide the best care for patients. The positive scores for this dimension showed a fairly small gap between administrative and nursing staff at baseline (4.3 percent), which widened to 9.6 percent at remeasurement. This widening gap was due almost entirely to an increase in positive scores among administrative staff from 57.1 percent to 63.2 percent.
- **Staffing.** This dimension is defined as the extent to which there are enough staff to handle the workload, and work hours are appropriate to provide the best care for patients. The gap in positive responses between administrative and nursing staff increased slightly between baseline and remeasurement, from 5.7 percent to 8.4 percent. This was due to a slight increase in administrative staff’s positive score on this dimension, combined with a slight decrease in nursing staff’s positive score.

There were two dimensions in which the gap between nursing and administrative staff decreased, one significantly. These were:

- **Organizational learning – continuous improvement.** This dimension—which indicates the extent to which there is a learning culture in which mistakes lead to positive changes—showed the greatest narrowing of the gap between nursing and administrative staff of any dimension of patient safety culture. The difference in positive response rates between the two at baseline, 12.3 percent (absolute), had been narrowed to 5.1 percent at remeasurement.

However, this change was

due almost entirely to improvement in nursing staff’s positive response from 70.4 percent to 76.5 percent, which was the greatest increase among nurses in any dimension score.

Administrative staff’s positive score in this dimension actually decreased by 1.1 percent.

- **Management support for patient safety.** This dimension indicates the extent to which hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority. By far, this dimension had the greatest discrepancy in positive scores between nursing and administrative staff. At baseline this discrepancy was 22.9 percent, with administrative staff giving a positive score of 83.4 percent, and nursing staff giving a positive score of 60.6 percent. At remeasurement this gap had narrowed slightly, to 19.8 percent, but it still remained the largest discrepancy of any dimension.

Dimensions in which the gap between nursing and administrative staff remained relatively unchanged included:

- **Overall perceptions of patient safety.** Both administrative and nursing staff’s positive response rate to this global dimension increased significantly from baseline to remeasurement. However, the large gap between the two changed little and, in fact, increased slightly, from 11.6 percent (absolute) to 13.6 percent.

Table 3. West Virginia responses to baseline and remeasurement hospital survey on patient safety culture by dimension

Dimension	Score	
	Baseline (%)	Remeasurement (%)
Overall perceptions of safety	60.0	61.9
Frequency of events reported	53.6	55.6
Supervisor manager expectations	75.6	74.9
Organizational learning	71.9	73.9
Teamwork within units	78.4	78.7
Communication openness	68.6	67.0
Communication about error	70.4	70.3
Nonpunitive response to error	38.6	38.6
Staffing	52.9	51.7
Hospital support for patient safety	69.8	68.9
Teamwork across hospital unit	52.8	53.9
Hospital handoffs & transitions	38.5	41.3

- **Frequency of events reported.** Scores in this dimension remained relatively unchanged between baseline and remeasurement, with just over half of both nursing staff and administrative staff giving it a positive score during both measurement periods.
- **Teamwork within units.** Positive scores in this dimension remained relatively unchanged, with a 7.7 percent gap between nursing and administrative staff at both baseline and remeasurement. However, both groups rate this dimension relatively high, with administrative staff scores of 85.5 percent to 87.2 percent (baseline to remeasurement) and nursing staff scores of 77.8 percent to 79.5 percent (baseline to remeasurement).
- **Feedback & communication about error.** This dimension signifies the extent to which staff are informed about errors that happen, given feedback about changes implemented, and discuss ways to prevent errors. Scores for both groups remained relatively unchanged from baseline to remeasurement, and the gap in positive scores between administrative and nursing staff also did not change significantly, remaining at about 7.5 percent.
- **Handoffs & transitions.** This dimension signifies the extent to which important patient care information is transferred across hospital units and during shift changes. This dimension garnered the lowest positive score from administrative staff at both baseline and remeasurement, although it is the dimension that also showed the greatest increase among that group from baseline (38.3 percent) to remeasurement (49.2 percent). Nursing staff's positive responses also increased, although not as greatly as the administrative staff. This dimension was one of two in which nursing staff's positive responses were higher than those of the administrative staff at baseline (although not at remeasurement).

Discussion

We have presented summary data from acute care and critical access hospitals in West Virginia, showing significant and, in some cases, widening differences between nursing staff and administrative/management staff attitudes about patient safety in their hospitals.

While the perceptions of all staff are important, any large discrepancy between frontline staff (those with direct patient contact) and management/administrative staff is of particular concern. To understand where to focus efforts in building a safety culture environment, hospital senior management and administrators must be cognizant of the opinions and beliefs of the frontline staff regarding the safety culture of their facility.

Although not the focus of this report, one of the goals of the wider West Virginia Patient Safety Project was to help hospitals improve their patient safety culture. This was to be done in part by supplying them with the results of their Hospital Survey on Patient Safety Culture, with the expectation that facilities would use this information to drive interventions to improve their culture of safety. This report shows some encouraging signs of this occurring, although areas of concern remain.

Overall perceptions of safety have increased, although a significant difference remains between nursing and administrative staff. Organizational learning is an area in which great strides have been made in narrowing the gap between nursing and administrative staff, as might be expected

if facilities had undertaken interventions to increase their learning culture to make sure that mistakes lead to positive changes. Teamwork within units is perceived positively by both groups.

However, communication openness is an area with a large and increasing gap in the perceptions of nursing and management staff, as is nonpunitive response to error. The disparity in scores in these two areas indicates that management's perception of how it responds in these areas is not shared by frontline nursing staff. The wide and continuing discrepancy in positive scores in the dimension of management support for patient safety may also indicate a need for more intensive interventions in these areas.

There are several possible explanations for the uniform differences in views on patient safety culture between the two groups. One possibility is that the different experiences nursing and administrative staffs have in the hospital, and their tenure within that facility, affected their perceptions of patient safety culture consistently across all dimensions. One might expect, for example, that nurses might have greater knowledge of events that could have resulted in safety incidents or have greater anxiety about staffing shortages than administrators, but it is hard to imagine that these differences would be of nearly the same magnitude across all items of interest by chance.

The simplest explanation is that these nurses had a more pessimistic global view of safety culture in their institutions than administrative staff. That view is buttressed by the large and consistent differences in the global patient safety grade, and the observation that this one item explains, on average, almost 10 percent of the variance in every other item in the survey. Why nurses should have a more pessimistic view of safety culture than management is an area of some conjecture, and the literature for this line of inquiry is sparse. In a study in four Canadian university-affiliated intensive care units (ICUs), managers perceived a more positive safety climate than frontline staff. The authors speculated that this might be due to information about patient safety being more available to management, and also that management might also be more attuned to the identification and resolution of patient safety concerns. It was also noted that this discordance could provide opportunities for discussion of patient safety concerns.¹⁵

A study conducted in 15 California hospitals using a safety culture survey designed to discover "problematic responses" found a definite discrepancy between the attitudes and experiences of senior managers (particularly nonclinicians) and those of nonmanagers, and that nurses in particular gave more problematic responses than nonclinicians, regardless of management status.¹⁶ The researchers hypothesized that this could imply a tendency for frontline workers to gloss over patient care problems when briefing senior management, and that this in turn could make it difficult for nonclinician executives to understand the true state of their organization.

Comparisons of nurse vs. physician attitudes regarding safety issues are somewhat more prevalent. In an international cross-sectional study comparing error, stress, and teamwork in medicine and aviation, although 77 percent of intensive care doctors reported high levels of teamwork with nurses, only 40 percent of nurses reported high levels of teamwork with doctors.¹⁷ Similarly, in another study, operating room surgeons rated the quality of their collaboration and cooperation with other surgeons "high" or "very high" 85 percent of the time,

but nurses rated their collaboration with surgeons as “high” or “very high” only 48 percent of the time.¹⁸

On the contrary, nurses had higher scores than physicians for perceptions of safety at The Johns Hopkins Hospital, including fewer physicians (54 percent) than nurses (84 percent) who perceived encouragement from their supervisors to report safety concerns.¹⁹ The author concluded that senior leaders must become more visible to frontline staff in their efforts to improve patient safety. This apparent discrepancy may be a reflection of specific institutional efforts at Johns Hopkins, since the author states, “...most of the efforts to enhance reporting of medication errors have been led by nurses and pharmacists.”¹⁹

Limitations

Although the instrument itself has been validated, respondents to this survey represented a convenience sample and were nonrandomized and nonuniform across hospitals. Nonresponders, including most physicians, may have potentially biased the results. The survey was conducted at different times in different hospitals, both with respect to the community’s awareness of patient safety issues and to the hospital’s own patient safety efforts, of which the reporting system was but one component.

We were not involved in designing or implementing interventions to improve safety culture in the study hospitals, and so we did not collect data on the safety culture training or interventions provided to the staff. This limitation makes it difficult to evaluate how the training might have influenced the study findings.

We also did not collect any information regarding hospital characteristics or changes in hospital characteristics between measurement periods. We recognize that, during the period of time between the first measurement and the second measurement (3 years), substantial changes in hospital characteristics, such as organizational structure, could pose a threat to the validity of these findings.

Conclusion

Patterns of responses to the AHRQ Hospital Survey on Patient Safety Culture during two measurement periods from a convenience sample of respondents in mostly small, rural hospitals in West Virginia showed a marked and continuing discrepancy in positive responses between administrative/management staff and nursing staff in several dimensions of patient safety culture. In general, nurses rated safety culture less positively than administrative staff in all hospitals, independent of duration of employment, hours worked, or work unit. This discrepancy could indicate a need for more intensive interventions in certain areas of patient safety culture and is certainly an area for future research inquiry.

Additional analyses exploring the differences between administrative/management staff and nursing staff as these manifest in critical access hospitals vs. other rural and vs. urban facilities will be the topic for a future paper.

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Using the AHRQ Hospital Survey on Patient Safety Culture as an Intervention Tool for Regional Clinical Improvement Collaboratives

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Abstract

Objective: From 2005 to 2007, the Agency for Healthcare Research and Quality (AHRQ) *Hospital Survey on Patient Safety Culture* was used as an assessment and intervention tool for hospitals participating in regional improvement collaboratives led by the Delmarva Foundation and Maryland Patient Safety Center. The collaboratives focused on specific hospital microsystems [emergency departments (EDs), intensive care units (ICUs), and operating rooms (ORs)] and measurable clinical outcomes. **Methods:** The survey was administered to staff during the collaborative's pre-intervention period and end point. Teams implemented clinical interventions and selected culture goals. Collaborative support was provided through workshops, site visits, conference calls, and a virtual workspace. **Results:** 38 percent of ED teams, 57 percent of ICU teams, and 92 percent of OR teams improved in the *Overall Perception of Safety*. Teams improved in several culture dimensions, including *Teamwork Within Units* and *Communication Openness*. **Conclusion:** Improvements were most robust within each microsystem and less apparent between microsystems.

Introduction

Culture change and a positive safety culture are increasingly being identified as essential components of successful and sustainable transformative change. The Institute of Medicine (IOM) has identified safety as a property of a health care system rather than of an individual, noting that moving from a culture of blame to one of learning and improving is one of the major challenges in creating a safer health care system.¹

There are many definitions for safety culture, ranging from culture as an organizational attribute to a general descriptor of an organization.² Mearns and Flin have observed that safety culture is a “complex and enduring trait reflecting fundamental values, norms, assumptions, and expectations.”³ The Advisory Committee on the Safety of Nuclear Installations defines the culture of safety as the “product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and proficiency of, an organization's health and safety,”⁴ a definition that has also been identified as relevant to health care organizations.^{5,6}

A number of frameworks or models for culture change have been developed and applied to health care. In “Human Error: Models and Management,”⁷ James Reason describes the attributes

of high-reliability organizations and the application of these attributes to the health care setting. He discusses the debate between a person and system approach, noting that high-reliability organizations display approaches that focus on the system and system improvements are dynamic in response to an event, and see those events as opportunities for system improvement.

Another widely applied model is the “Just Culture” model by David Marx,^{8, 9} which balances individual responsibility with system values, addressing the need to find equilibrium between blame-free versus overly punitive approaches. As another example, the “Capability Maturity” model describes five steps or stages to sustainable high performance.¹⁰ These five steps have been adapted to the health care environment and suggest a developmental approach to culture change that builds a strong foundation for improvement.

Culture assessment was the foundation for three regional clinical improvement collaboratives hosted by the Delmarva Foundation from 2005 to 2007. These unit-based programs coupled safety culture approaches with clinically relevant topics and provided training on quality improvement techniques and culture measurement. By partnering culture change with clinically relevant interventions and implementing those changes at the unit level, we expected to create a workplace where employees would be engaged in identifying, measuring, and redesigning processes of care, with the goal of providing every patient with the best possible care. This approach has also been used in other regional and national collaborative improvement programs.

It was our hypothesis that a focus on safety culture as well as on clinical interventions would lead hospitals to implement improvements that change fundamental norms in the targeted microsystem. Efforts to address and improve the culture of patient safety required an instrument for assessing and measuring the patient safety culture. To this end, we employed the *Hospital Survey on Patient Safety Culture*, developed by the Agency for Healthcare Research and Quality (AHRQ),¹¹ as a tool for hospitals to assess their patient safety culture, track changes in patient safety over time, and to evaluate the impact of patient safety interventions.

Since its release in November 2004, the *Hospital Survey on Patient Safety Culture* has been used by more than 400 hospitals across the country. The survey, which measures hospital staff opinions about patient safety issues, medical errors, and event reporting, includes 42 items that measure 12 dimensions of patient safety culture:

1. Communication openness.
2. Feedback and communication about error.
3. Frequency of events reported.
4. Handoffs and transitions.
5. Management support for patient safety.
6. Nonpunitive response to error.
7. Organizational learning/continuous improvement.
8. Overall perceptions of patient safety.
9. Staffing.
10. Supervisor/manager expectations and actions promoting safety.
11. Teamwork across units.
12. Teamwork within units.

Incorporating the *Hospital Survey on Patient Safety Culture* into the collaborative model provided the hospitals with a measure of their safety culture and a benchmark for comparison, all at no cost to the hospital. This manuscript describes how the *Hospital Survey on Patient Safety Culture* was applied as an intervention and assessment tool in regional collaboratives that focused on clinical improvements in high-risk emergency department (ED), intensive care unit (ICU), and operating room (OR) settings. Trends in improvement measured by these tools are also described.

Project Descriptions

Delmarva Foundation is a nonprofit organization that offers regional clinical improvement programming to hospitals in the Mid-Atlantic region. The programs catalyze improved patient safety by focusing on enhancing improvement and teaming skills within clinical microsystems while at the same time, building durable networks of cooperation and innovation between health care facilities. Using an approach inspired by the Institute for Healthcare Improvement (IHI) Breakthrough Series Collaborative model, Delmarva Foundation worked with hospitals from Maryland, the District of Columbia, and Northern Virginia to implement evidence-based strategies to improve the process of care and clinical outcomes within three high-risk clinical settings: the ED, ICU, and OR.

For each collaborative, national and regional regulatory and accreditation patient safety goals and priorities were aligned with clinically relevant outcomes and local priorities. A mosaic of stakeholders, experts, and funders supported each program. Collaborative resources and activities were offered without charge to participating hospital teams. Enrollment in the collaboratives was voluntary but required hospital chief executive officer commitment of in-kind resources and senior leadership support.

The ED Collaborative was offered by the Maryland Patient Safety Center, in partnership with the Maryland Chapters of the American College of Emergency Physicians and the Emergency Nurses Association. ED teams from 28 hospitals focused their efforts on improving patient safety by delivering appropriate and time-sensitive care to ED patients before and after clinical diagnosis. Multidisciplinary teams from each facility tested a variety of “change ideas” from the *ED Collaborative Improvement Guide*.¹² These change ideas represented a mix of systems and behavioral changes. For example, prediversion alert systems, an intervention usually led by a hospital administrator to ease crowding in the ED, not only improved flow but also affected the survey dimension of “Hospital Management Support for Patient Safety.”

Outcomes measured by participants included delivery of time-sensitive care to patients with invasive infections (e.g., pneumonia, sepsis) or myocardial ischemia; reduction of catheter-associated bloodstream infections in central lines inserted in the ED; an overall decrease in ED length of stay; and improvement in a patient safety dimension measured by the AHRQ *Hospital Survey on Patient Safety Culture*.

The ICU and OR Collaboratives were offered to hospitals in the region through the *100,000 Lives and Beyond Collaborative* sponsored by CareFirst BlueCross BlueShield. The

collaborative was designed to provide hospitals with a vehicle for incorporating platforms from the national IHI *100,000 Lives Campaign* with existing local and national priorities.¹³ Of the 28 hospitals that participated in the *100,000 Lives and Beyond Collaborative*, 26 hospitals enrolled teams in the ICU Collaborative, and 20 enrolled in the OR Collaborative. Multidisciplinary teams implemented evidence-based clinical interventions using change ideas from the *100,000 Lives and Beyond ICU and OR Collaborative Improvement Guide*.¹⁴

Outcomes measured by participants in the ICU Collaborative included incidence of invasive health care-associated infections (e.g., catheter-associated bloodstream infection, ventilator-associated pneumonia) and improvement in a patient safety dimension measured by the *Hospital Survey on Patient Safety Culture*. Culture improvement was embedded into several clinical improvement approaches. These included rounding in the ICU to plan daily goals for patients and to check compliance with the ventilator bundle, thereby impacting “Communication Openness” and “Teamwork Within Units,” two of the survey dimensions.

Outcomes measured by participants in the OR Collaborative were focused on avoidable perioperative complications, including surgical site infections, venous thromboembolic events, and improvement in a patient safety dimension as measured by the *Hospital Survey on Patient Safety Culture*. Culture improvement was embedded into these efforts. For example, several OR teams added a line item on antibiotic timing to their “Time-Out” process, which is performed prior to surgery to verify the particulars of the procedure. This embedded the culture dimensions of “Communication Openness” and “Teamwork Within Units” into the antibiotic timing intervention and involved nurses, surgeons, and anesthesiologists.

All three collaboratives followed a framework adapted from the IHI Breakthrough Series model. Hospital teams participated in a series of three facilitated workshops that introduced evidence-based practices and implementation change ideas, as well as training in the application of rapid cycle improvement. Teams were encouraged to share successful strategies during the learning sessions and via facilitated calls held during interval action periods and through a community LISTSERV® and Web portal. Adaptations to the IHI model included executive sponsorship activities, skill training for team leads, on-site training visits, and inclusion of culture change goals.

Culture Improvement Resources and Interventions

The AHRQ *Hospital Survey on Patient Safety Culture* was used as both an intervention and a collaborative assessment tool. Measurement of patient safety culture at the start of each collaborative was used by the hospital teams to guide selection of a culture improvement goal. A *Culture Improvement Guide*¹⁵ toolkit provided participating hospitals with comprehensive resources for understanding culture in patient safety and planning and implementing culture interventions.

The toolkit incorporates the five processes identified by Weick and Sutcliffe,¹⁶ which high-reliability organizations apply to avoid and address unpredictable events. The Guide also includes a discussion and adaptation of the “Capability Maturity Model”¹⁰ to the health care

quality improvement environment. The Model, which defines five stages to sustainable high performance, views culture as a reflection of the infrastructure of the organization.

The *Culture Improvement Guide* provides a framework for planning culture interventions and includes a table of interventions and resources, tying multiple culture interventions to the different dimensions of the culture survey. In total, the Guide¹⁵ includes more than 50 ideas and approaches that can be applied to enhance communication, teamwork, and other aspects of organizational culture, with the goal that teams use their *Hospital Survey on Patient Safety Culture* results to guide them in selecting subsequent steps and approaches. Examples of interventions linked to the AHRQ patient safety culture dimensions appear in Table 1.

The first workshop for each collaborative included an overview of the purpose and application of the culture survey, along with a dedicated breakout session on culture change approaches. At that same workshop, facility- and collaborative-level results were distributed to each team. Using the reports, teams were able to compare the results for their facility with those of other teams and the average for the collaborative.

At the end of each collaborative program, which was November/December 2006 for the *100,000 Lives and Beyond Collaboratives* (OR and ICU) and March/April 2007 for the ED Collaborative, the survey administration process was repeated to provide an opportunity for remeasurement.

Table 1. Examples of interventions included in the culture improvement guide, by culture dimension

AHRQ culture dimension	Example of intervention
Overall perceptions of safety	Executive review of projects
Frequency of events reported	Unit-based error-reporting systems
Supervisor/manager expectations and actions promoting safety	Staff patient safety award
Organizational learning/continuous improvement	Root cause and failure mode and effects analyses
Teamwork within units	Implement SBAR technique
Communication openness	Safety briefings
Feedback and communication about error	Provide feedback about reported errors to staff
Nonpunitive response to error	Implement effective reporting systems
Staffing	Appoint a safety champion for every unit
Hospital management support for patient safety	Patient safety leadership walk rounds
Teamwork across units	Teamwork training
Hospital handoffs and transitions	Relay safety reports at shift change

Source: Culture Improvement Guide, Delmarva Foundation, 2006.

SBAR = Situation-Background-Assessment-Recommendation

ICU and OR hospitals participated in a postsurvey conference call to discuss the culture survey results.

Throughout the course of each collaborative, each participating hospital team communicated their project activities through monthly reports, site visits, events, phone calls, and other informal tracking mechanisms. These qualitative data allowed for tracking each team's progress in meeting the collaborative and team-selected goals. However, because each hospital team self-selected goals and multiple interventions, it is not possible to correlate their diverse culture initiatives with survey outcomes.

Methods

The following section describes the data collection and analysis methods used for this review.

Data Collection

The baseline AHRQ *Hospital Survey on Patient Safety Culture* was administered between October and November 2005 for all three collaborative groups. Improvement Leads, the collaborative team's operational lead, were responsible for the administration of the survey within their facility. Leads were given a packet of surveys to administer to all staff whose work affected patient care (e.g., clerks, doctors, nurses) in each respective unit. Some recommended approaches for administering the survey were to:

- Distribute the surveys at a department/staff meeting or educational session, providing pencils and return envelopes.
- Hand-deliver surveys to individual staff members/physicians with instructions on where and how to return the completed survey.

Improvement Leads maintained a copy of the completed surveys, tracked the number of surveys returned, and submitted the surveys and data to Delmarva via mail. Upon receipt, the surveys were entered into a database using a double-data entry process. Discrepancies were resolved by verifying the entry on the hard copy of the form.

Limitations in the survey distribution process included the inability to identify which distribution method was used for each hospital team; whether the same method was used for the baseline and followup surveys; and whether the same individuals participated in both surveys.

Analysis

Culture survey results were analyzed for each hospital that participated in the ED, ICU, and OR Collaboratives and completed a baseline and/or a followup survey. These data were analyzed separately for each collaborative group. Data from one hospital in the ICU Collaborative were removed because the hospital submitted only two surveys. Overall, 54 percent of hospitals had teams participating in more than one collaborative.

Characteristics of the facilities and respondents from hospitals participating in the three collaboratives were calculated using descriptive statistics. Hospital characteristics included bed size, urban/rural designation, and teaching affiliation. The characteristics of each hospital were obtained from the *American Hospital Directory*.¹⁷ Respondent characteristics included profession. The mean and median number of respondents per hospital were provided, as well as the average response rate and percentage of hospitals that provided response rates.

Calculating Dimension Scores

The AHRQ *Hospital Survey on Patient Safety Culture: 2007 Comparative Database Report*¹⁸ provided guidelines on calculating scores for the 12 patient safety dimensions measured by this tool. Dimension scores for each collaborative were generated following a four-step process:

1. “Strongly agree” and “Agree” responses were identified for each question and indicated a positive response. When questions were reversed, a positive response was indicated with an answer of “Disagree” or “Strongly disagree.”
2. For each hospital, the percentage of positive results for each question was calculated.
3. Dimension scores for each hospital were calculated as the average percentage of positive responses for each question within the dimension.
4. Collaborative dimension scores were then calculated by averaging the hospital dimension scores across each collaborative. Standard deviations were also calculated for each dimension score.

Comparisons

The baseline and followup dimension scores were compared for hospitals within each collaborative that completed both surveys. The relative change in each of the 12 dimension scores was calculated for each collaborative.

Improvement was defined as any increase in the average percentage of positive responses from baseline to followup. The percentage of hospitals improving in each dimension was based on this definition.

Within each collaborative, the dimension scores among hospitals completing both baseline and followup surveys were compared with those for hospitals completing only a baseline or followup survey. Tests were not performed for statistically significant differences in dimension scores over time or differences in dimension scores between collaboratives due to the exploratory nature of the study and the small sample size.

Results

Characteristics of Hospitals and Respondents

Use of the AHRQ *Hospital Survey on Patient Safety Culture* was high for all three collaboratives. During the collaborative intervention period, 26 hospitals in the ED Collaborative

(93 percent), 26 hospitals in the ICU Collaborative (100 percent), and 19 hospitals in the OR Collaborative (95 percent) completed at least one survey. However, although all hospitals in the ICU Collaborative participated in at least one survey opportunity, for purposes of the analysis one was removed due to a low number of surveys.

Facility characteristics for hospitals that completed both the baseline and followup surveys were compared with those for hospitals that completed only the baseline or followup survey. Facility characteristics studied included size (based on number of inpatient beds); hospital urban/rural designation; and hospital teaching affiliation. Facilities were defined as teaching hospitals or community hospitals based on their American Medical Association designation (Table 2).

In the ED Collaborative, 13 hospitals (50 percent) completed both surveys and 13 hospitals (50 percent) completed only the baseline survey. Hospitals from both groups were similar in size, urban/rural designation, and teaching affiliation. The distribution of respondents from hospitals completing both surveys was similar to that of hospitals completing only the baseline survey, with nurses being the most heavily represented group.

In the ICU Collaborative, 14 hospitals (56 percent) completed both surveys, 4 (16 percent) completed only the baseline survey, and 7 (28 percent) completed only the followup survey. Compared with hospitals completing both surveys, those completing the baseline survey only tended to be smaller, rural, and community nonteaching hospitals. Facilities completing only the followup survey were slightly smaller but more likely to be urban teaching hospitals. The distribution of respondents from hospitals completing both surveys was similar to that of hospitals completing only the baseline survey, with nurses being the most heavily represented group.

In the OR Collaborative, 12 hospitals (63 percent) completed both surveys, and 7 (37 percent) completed only the baseline survey. Hospitals completing only the baseline survey tended to be smaller, but were similar to hospitals completing both surveys in their urban/rural designation and teaching affiliation. The distribution of respondents from hospitals completing both surveys was similar to that of hospitals completing only the one survey, with nurses being the most heavily represented group.

Although all three collaboratives exhibited differences in the facility characteristics of hospitals completing both surveys compared with hospitals completing only a baseline or followup survey, there was no consistency in these trends across the collaboratives.

Among the subset of hospitals in each collaborative completing both the baseline and followup surveys, ED hospitals tended to be urban, community, nonteaching facilities with an average bed size of 208. ICU and OR hospitals were heavily skewed toward urban designations and more likely to be community nonteaching hospitals. The average bed size for the ICU and OR hospitals in this subset was 272 and 257 beds, respectively.

Although hospitals were asked to track survey response rates, submission of this information was inconsistent at baseline. Hospitals that completed only one round of the survey reported lower response rates than those that completed both the baseline and followup survey opportunities. At

the time of the followup survey, more hospitals submitted their response rates, which was likely due to improved tracking and followup on this data element.

Table 2 presents the response rate for each collaborative group. The overall cumulative response rate at baseline was 61 percent (with 46 percent of hospitals reporting), while at followup, the overall response rate was 65 percent (with 96 percent of hospitals reporting).

Qualitative data collected from collaborative tracking tools described in the Methods section indicate that reasons for failing to complete a followup survey were similar across all three collaboratives. The three most common reasons for not completing the followup survey were:

- Changes or vacancies among hospital personnel responsible for administering the survey.
- Hospital plans to conduct a hospital-wide survey in the near future.
- A perception that survey completion would be excessively burdensome for staff.

The seven hospitals in the ICU Collaborative that completed only followup surveys joined the collaborative after the baseline data collection had been completed.

Findings

As shown in Table 3, the AHRQ *Hospital Survey on Patient Safety Culture* dimension scores for all three collaboratives have been aggregated into a single overall score for each dimension. The overall dimension scores for hospitals completing both baseline and followup surveys are then compared with the overall baseline scores for hospitals completing only the baseline or followup survey.

The differences in overall dimension scores between hospitals completing both surveys and those completing only a baseline or followup survey ranged from 0 to 15 percent. Hospitals completing only a baseline survey had a lower safety score and scored lower in 11 of 12 (92 percent) of the patient safety dimension scores. Hospitals completing only a followup survey also had a lower safety score and scored lower in seven (58 percent) of the patient safety dimension scores. Standard deviation for the dimension scores of the baseline survey ranged from 9 percent to 22 percent. For the followup survey, they ranged from 7 percent to 21 percent.

Analysis of Patient Safety Dimension Scores Among Hospitals with Baseline and Followup Surveys

Overall and individual collaborative changes in patient safety dimension scores were analyzed for the subset of hospitals completing both baseline and followup surveys. These results are summarized in Table 4. Due to the small sample size in each collaborative group, it was not possible to determine statistical significance in the change from baseline to followup survey results. Therefore this discussion highlights the trends observed among the different collaborative groups and in the aggregate.

Table 2. Respondent characteristics, by collaborative

Characteristics	Hospitals completing baseline and followup surveys		Hospitals completing only one survey	
	Baseline	Followup	Baseline only	Followup only
ED collaborative				
Total number of hospitals participating in survey	13	13	13	0
Average number of inpatient beds	208	208	229	–
Location (%)				
Urban	77	77	85	–
Rural	23	23	15	–
Type of hospital (%)				
Teaching	31	31	39	–
Community	69	69	62	–
Total number of respondents	656	470	376	–
Number of respondents per hospital				
Mean	51	36	29	–
Median	40	34	23	–
Response rates (%)				
Average response rate	71	63	52	–
Hospitals reporting response rates	46	100	62	–
Profession of respondent (%)				
Physician	15	13	13	–
Nurse	51	59	50	–
Other	35	28	37	–
ICU collaborative				
Total participating hospitals	14	14	4	7
Average number of inpatient beds	272	272	155	201
Location (%)				
Urban	86	86	50	100
Rural	14	14	50	0
Type of hospital (%)				
Teaching	36	36	25	57
Community	64	64	75	43
Number of respondents total	429	429	90	237
Number of respondents per hospital				
Mean	31	29	22	31
Median	27	28	21	37

Table 2. Respondent characteristics, by collaborative (*continued*)

Characteristics	Hospitals completing baseline and followup surveys		Hospitals completing only one survey	
	Baseline	Followup	Baseline only	Followup only
Response rates (%)				
Average response rate	76	70		56
Hospitals reporting response rates	57	100	0	100
Profession of respondent (%)				
Physician	6	3	7	7
Nurse	64	64	62	66
Other	31	33	31	26
OR collaborative				
Total number of hospitals participating in survey	12	12	7	0
Average number of inpatient beds	257	257	217	—
Location (%)				
Urban	92	92	100	—
Rural	8	8	0	—
Type of hospital (%)				
Teaching	42	42	57	—
Community	58	58	43	—
Number of respondents total	524	536	175	—
Number of respondents per hospital				
Mean	44	45	25	—
Median	28	42	26	—
Response rates (%)				
Average response rate	52	67	59	—
Hospitals reporting response rates	42	83	29	—
Profession of respondent (%)				
Physician	13	6	8	—
Nurse	50	53	55	—
Other	38	41	37	—

Table 3. Percent ($\pm$ SD) positive responses of aggregate dimension scores for hospitals completing a baseline or followup survey vs. those completing both surveys

Culture dimension	Baseline survey results [% (SD)]			Followup survey results [% (SD)]		
	Completed baseline only (N = 24)	Completed baseline & followup (N = 39)	Compared ^a	Completed followup only (N = 7)	Completed baseline & followup (N = 39)	Compared ^a
Safety grade (A/B vs. other) ^b	57 (22)	63 (18)	↓	47 (11)	55 (21)	↓
Overall perception of safety	51 (15)	54 (13)	↓	49 (12)	54 (18)	↓
Frequency of events reported	51 (16)	51 (10)	↑	51 (7)	49 (12)	↑
Supervisor/manager expectations and actions promoting patient safety	69 (13)	74 (9)	↓	62 (12)	71 (12)	↓
Organizational learning/continuous improvement	64 (15)	71 (9)	↓	66 (7)	71 (13)	↓
Teamwork within units	69 (15)	76 (11)	↓	78 (8)	77 (11)	↑
Teamwork across units	35 (13)	47 (13)	↓	47 (5)	45 (14)	↑
Communication openness	57 (9)	60 (10)	↓	56 (5)	59 (12)	↓
Feedback and communication about error	50 (15)	58 (13)	↓	49 (9)	58 (12)	↓
Nonpunitive response to error	34 (14)	36 (10)	↓	33 (8)	34 (12)	↓
Staffing	41 (16)	47 (13)	↓	50 (16)	45 (15)	↑
Hospital management support for patient safety	57 (16)	66 (12)	↓	47 (18)	62 (14)	↓
Hospital handoffs and transitions	37 (13)	43 (12)	↓	45 (11)	41 (11)	↑
Internal transitions	43 (16)	49 (13)	↓	54 (14)	47 (13)	↑
External transitions	31 (12)	37 (13)	↓	35 (10)	36 (10)	↓

N = Number of hospitals

a Arrows denote whether the group completing one survey (either baseline or followup) scored lower (↓) or higher (↑) than the group that completed both surveys.

b Positive responses for the Safety Grade included grades of A and B.

Table 4. Percent ($\pm$ SD) positive responses of aggregate dimension scores and relative change, by aggregate and collaborative group

Culture dimension	Aggregate (N = 39)			ED collaborative (N = 13)			ICU collaborative (N = 14)			OR collaborative (N = 12)		
	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %
Safety grade (A/B vs. Other)	62.5 (18.4)	54.6 (20.6)	-12.6	49.5 (16.1)	39.8 (24.2)	-19.5	69.2 (14.7)	59.8 (13.6)	-13.6	68.9 (18.0)	64.7 (14.2)	-6.1
Overall perception of safety	54.2 (13.1)	54.4 (17.9)	0.3	44.7 (9.5)	40.9 (18.6)	-8.5	56.6 (13.0)	56.0 (10.8)	-1.1	61.6 (11.2)	67.0 (14.2)	8.8
Frequency of events reported	50.7 (10.3)	48.9 (11.7)	-3.6	44.2 (7.2)	41.1 (10.9)	-7.2	53.3 (12.1)	48.3 (8.7)	-9.4	54.7 (7.8)	58.1 (9.4)	6.2
Supervisor/manager expectations and actions promoting patient safety	74.2 (9.2)	71.4 (11.7)	-3.8	69.8 (8.9)	66.0 (12.5)	-5.4	78.9 (7.8)	74.7 (11.6)	-5.3	73.4 (9.3)	73.4 (9.7)	-0.1
Organizational learning/continuous improvement	71.4 (9.3)	71.2 (12.6)	-0.3	64.2 (6.2)	61.5 (13.1)	-4.2	77.2 (6.5)	77.4 (7.7)	0.3	72.6 (10.0)	74.5 (11.0)	2.6
Teamwork within units	76.3 (11.1)	76.8 (11.3)	0.6	73.5 (9.1)	70.4 (7.0)	-4.3	83.1 (10.9)	83.5 (11.0)	0.4	71.4 (10.0)	75.9 (11.6)	6.4
Teamwork across units	46.9 (13.0)	45.1 (13.5)	-3.8	38.2 (10.6)	33.7 (9.3)	-11.6	52.1 (11.8)	52.5 (13.7)	0.9	50.2 (12.8)	48.7 (8.9)	-3.0
Communication openness	59.6 (10.4)	59.3 (11.9)	-0.5	56.3 (10.8)	53.4 (12.0)	-5.2	64.0 (10.5)	63.8 (9.9)	-0.3	57.9 (8.6)	60.5 (12.1)	4.4
Feedback and communication about error	58.1 (12.8)	57.6 (12.5)	-1.0	49.2 (8.8)	49.9 (11.2)	1.4	63.2 (14.0)	62.4 (10.6)	-1.4	61.9 (10.1)	60.3 (12.7)	-2.5
Nonpunitive response to error	36.1 (10.4)	34.1 (12.5)	-10.4	31.8 (9.1)	29.5 (10.4)	-7.1	42.2 (6.9)	35.8 (12.1)	-15.3	33.7 (12.2)	37.3 (14.5)	10.7
Staffing	47.3 (13.3)	44.9 (14.8)	-5.0	40.7 (10.9)	36.8 (14.2)	-9.6	53.7 (12.9)	46.2 (12.3)	-14.0	46.9 (13.4)	52.3 (14.6)	11.4

Table 4. Percent ($\pm$ SD) positive responses of aggregate dimension scores and relative change, by aggregate and collaborative group (*continued*)

Culture dimension	Aggregate (N = 39)			ED collaborative (N = 13)			ICU collaborative (N = 14)			OR collaborative (N = 12)		
	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %	Baseline % ($\pm$ SD)	Followup % ($\pm$ SD)	Rel chg %
Hospital management support for patient safety	65.7 (12.4)	62.4 (14.5)	-5.0	57.6 (11.9)	51.4 (17.2)	-10.8	67.3 (11.4)	67.2 (7.8)	-0.1	72.6 (9.6)	68.8 (10.5)	-5.2
Hospital handoffs and transitions	43.2 (12.1)	41.1 (10.7)	-4.9	41.4 (7.7)	37.3 (10.7)	-9.8	49.8 (15.6)	47.9 (10.0)	-3.7	37.5 (7.5)	37.2 (7.9)	-0.9
Internal transitions	49.2 (12.8)	46.6 (13.3)	-5.2	46.7 (8.9)	42.6 (10.8)	-8.7	57.7 (14.8)	56.9 (13.2)	-1.5	41.9 (7.6)	39.1 (7.7)	-6.8
External transitions	37.2 (13.0)	35.5 (10.0)	-4.5	36.1 (8.4)	32.1 (11.7)	-11.2	41.8 (17.9)	39.0 (8.6)	-6.7	33.0 (8.9)	35.3 (9.0)	6.7

N = number of hospitals

Rel chg = relative change

Table 5. Percentage of hospitals improving per dimension, by collaborative group and aggregate

Culture Dimension	Hospitals Improving (%)			
	ED (N = 13)	ICU (N = 14)	OR (N = 12)	Aggregate (N = 39)
Overall perception of safety	38	57	92	62
Frequency of events reported	46	36	75	51
Supervisor/manager expectations and actions promoting patient safety	38	50	58	49
Organization learning/continuous improvement	38	57	67	54
Teamwork within units	38	50	75	54
Teamwork across units	38	43	42	41
Communication openness	38	64	58	54
Feedback and communication about error	62	57	58	59
Nonpunitive response to error	38	29	58	41
Staffing	31	21	58	36
Hospital management support for patient safety	38	64	33	46
Hospital handoffs and transitions	31	50	58	46

N = number of hospitals

The highest scoring dimensions in both the baseline and followup survey results were Teamwork Within Units, Supervisor/Manager Expectations and Actions Promoting Patient Safety, and Organizational Learning/Continuous Improvement. These trends were consistent in each of the three collaboratives and overall. The lowest scoring dimensions in the baseline and followup survey results were Teamwork Across Units, Hospital Handoffs and Transitions, and Nonpunitive Response to Error. These trends were also consistent in each of the three collaboratives and overall.

A comparison of the baseline and followup survey scores suggests that overall improvement in survey patient safety dimensions was greater among OR teams than among ICU or ED teams. OR teams achieved an increase in positive responses for seven patient safety dimensions (58 percent), compared with three (25 percent) for ICU teams, and one (8 percent) for ED teams.

Two dimensions measured global perceptions of safety. The Safety Grade asks respondents to rate the overall safety in the unit. The Overall Perception of Safety dimension combines four questions that relate to processes and safety at the unit level. The Safety Grade decreased by 12.6 percent among the three collaboratives overall and by 19.5 percent in ED, 13.6 percent in ICU, and 6.1 percent in OR. The Overall Perception of Safety dimension was unchanged (+0.3 percent) among the three collaboratives overall, but variation among the collaboratives was

considerable. Perception of Safety decreased by 8.5 percent and 1.1 percent in the ED and ICU, respectively, but increased by 8.8 percent among the hospitals in the OR Collaborative.

Teamwork Within Units scored substantially higher than Teamwork Across Units at Baseline and followup among hospitals participating in each of the three collaboratives and overall. The overall score for Teamwork Within Units remained unchanged (+0.6 percent), whereas the overall score for Teamwork Across Units decreased (-3.8 percent). Variation in the changes in these domains among the three collaboratives was considerable. For Teamwork Within Units, hospitals in the ED Collaborative reported a decrease of 4.3 percent, while ICU hospitals were unchanged (0.4 percent), and OR hospitals reported a 6.4 percent increase in positive responses. For Teamwork Across Units, hospitals in the ED Collaborative reported a decrease of 11.6 percent, while ICU hospitals were unchanged (0.9 percent), and OR hospitals reported a 3.0 percent decrease in positive responses.

Questions within the Handoffs and Transitions patient safety dimension were divided into two subsets, one reflecting Internal Transitions and the other External Transitions. Although the Handoffs and Transitions dimension was among the lowest-scoring patient safety dimensions, hospitals within each of the three collaboratives and in aggregate rated *Internal Transitions* higher than External Transitions.

Hospital Improvement

Changes in individual patient safety dimension scores for hospitals participating in each of the three collaboratives were analyzed to judge how accurately collaborative averages reflected the changes experienced at the hospital level. Table 5 shows the percentage of hospitals in each collaborative demonstrating an improvement in individual patient safety dimensions. All together, 62 percent of hospitals reported an improved Overall Perception of Safety, with 38 percent of ED hospitals, 57 percent of ICU hospitals, and 92 percent of OR hospitals showing improvements.

Changes in Teamwork Within Units paralleled those seen in the Perception of Safety dimension. Overall, 54 percent of hospitals reported an improvement in this dimension, with 38 percent of ED hospitals, 50 percent of ICU hospitals, and 75 percent of OR hospitals showing improvements. A larger proportion of hospitals in all three collaboratives reported improvements in Teamwork Within Units (54 percent) than in Teamwork Across Units (41 percent). Changes in Teamwork Across Units were similar for the ED, ICU, and OR hospitals, with 38 percent, 43 percent, and 42 percent reporting improvements, respectively.

Discussion

Overall, 3,922 culture surveys were administered within the ED, ICU, and OR collaboratives at 38 distinct hospitals participating in three patient safety collaboratives administered by Delmarva Foundation in Maryland, the District of Columbia, and Northern Virginia from 2005 to 2007. Some hospitals participated in more than one collaborative. A subset of hospitals in each collaborative setting completed both baseline and followup surveys.

Analysis of facility characteristics among hospitals completing both surveys compared to those completing only a baseline or followup survey was conducted but did not identify any consistent trends. Respondents appeared to be similar in their staffing distribution.

However, the response rates and scores of hospitals completing only baseline surveys differed consistently from those completing both surveys. In all but one patient safety dimension, the baseline-only group scored lower than peers from hospitals completing both surveys. Exposure to blinded comparative data from all collaborative participants might have been perceived as discouraging by these hospitals. Alternatively, a diminished capacity to succeed in an improvement intervention generally geared toward “early adopters” may be reflected in their lower baseline patient safety dimension scores.

Response rates were higher for hospitals that completed both survey opportunities (61 percent at baseline and 65 percent at followup) and within each collaborative group, with the exception of the OR baseline-only group. In that case, only 2 hospitals provided response rates. Cumulative response rates were consistent with those reported by AHRQ in the *2007 Comparative Database Report*,¹⁸ which published the results of 382 hospitals that applied the *Hospital Survey on Patient Safety Culture*. Among those facilities that used a paper-based survey, the overall average response rate was 62 percent.

The three collaborative programs included in this report targeted microsystem rather than hospital-wide culture and systems change. Our analysis of culture survey data at the ED, ICU, and OR microsystem levels suggests that participants were more likely to perceive a positive patient safety culture within their microsystem. Ratings of dimensions—such as Supervisor and Management Support, Overall Perception of Safety, and Teamwork Within Units—exceeded those of Teamwork Across Units, External Transitions, and Nonpunitive Response to Error. This appears to be consistent with the findings reported by AHRQ in the *2007 Comparative Database Report*.¹⁸ Among the 382 hospitals, Teamwork Within Units (78 percent positive response) was the strongest dimension, while Nonpunitive Response to Error (43 percent positive response) scored the lowest.

There were substantial and unexpected differences among the three collaboratives in the direction and degree of improvement among the patient safety dimensions that had the most direct relationship with the collaborative interventions. These dimensions included Teamwork Within Units and the internal components of the Handoffs and Transitions dimension. In the ICU, “team” includes more individuals from outside of the unit, such as pharmacy and respiratory therapy personnel. In the ED, “team” includes many staff members working in various locations – triage, main ED, urgent care, and others – indicating that the concept of teamwork within the ED may be much more dynamic.

External transition scores decreased from baseline to followup survey for the ED and ICU teams, while they increased for OR teams. ORs tend to conduct handoffs with a limited number of units. For ORs, handoffs are limited to postanesthesia care units or, in some cases, ICUs. The number of handoffs is larger for the ICU and even greater for the ED. Qualitative data indicate that the increase in positive perceptions of external handoffs in the OR is related to the limited number of units involved in handoffs, compared with those involved in handoffs in the ICU or ED.

All three collaboratives were similar in terms of design, recruiting and enrollment criteria, supporting materials, facilitator experience and expertise, and improvement methodologies. In some cases, there was even an overlap of team members. All three collaboratives demonstrated improvement in clinical and/or process measures, but it was not possible to correlate these to improvements in patient safety culture dimensions.^{19, 20}

In the aggregate, 50 percent or more of all hospitals participating in both the baseline and followup surveys improved in 7 of 12 patient safety dimensions. ORs demonstrated the most improvement overall in terms of the aggregate patient safety dimension scores, with more than half of the participating hospitals improving in 10 of 12 dimensions. ICUs exhibited moderate improvement in the overall dimension scores, with 50 percent or more of participating hospitals improving in eight dimensions. EDs demonstrated a general reduction in overall dimension scores, with one dimension in which 50 percent or more of the participating hospitals improved.

Given the timeline of the application of the culture survey, it is difficult to determine whether areas where teams exhibited a movement toward the negative indicate a worsening of culture, response to external factors, or an enhanced awareness of patient safety culture issues. A number of factors may have contributed to the trends in culture scores, and the time between baseline and followup surveys, as well as limited qualitative data, may have been insufficient for a full analysis of culture.

Conclusion

Perceptions of culture and change patterns following interventions measured by the AHRQ *Hospital Survey on Patient Safety Culture* among hospitals participating in three uniformly designed collaboratives are consistent with recent studies indicating that organizational culture may vary among hospital units, and that culture change efforts may best be tailored to the unit level.²¹ Mohr, et al.²² have noted that health care organizations exhibit variations at the microsystem levels, and that these different microsystems are important units to involve in improving patient safety. Creating a culture of safety within microsystems is identified as one of the key principles for safety within a clinical microsystem.²³

Within the three collaboratives, the voluntary administration of the *Hospital Survey on Patient Safety Culture* was high among participating facilities. Qualitative tracking suggests that application of the assessment tool was well received among participants. While patient safety dimensions more closely linked with collaborative interventions, such as Teamwork Within Units, were more robustly affected than other dimensions, the direction and factors influencing those changes are not easily identified. Further qualitative study would add granularity and internal confirmation of these trends. The component questions for the Handoffs and Transitions dimension were grouped as internal and external to the microsystem and indicate that perceptions of safety differ between the two groupings.

The scope of the survey's patient safety dimensions was broader than the areas naturally associated with the clinical outcomes targeted by each collaborative. Hospitals using low positive response rates for specific patient safety dimensions as a guide for selecting their collaborative culture intervention may have found themselves challenged by the lack of overlap

between the culture focus and clinical objectives. For example, collaborative teams often selected Nonpunitive Error Reporting, a frequently identified dimension with a low rate of positive responses at both baseline and followup, as a focus area because of the low perceptions at baseline. However, this patient safety deficiency was not well aligned with collaborative clinical objectives heavily weighted toward infection prevention, teamwork, and improved flow.

The highest value of the AHRQ *Hospital Survey on Patient Safety Culture* remained at the microsystem level and not as a tool for measuring overall collaborative performance. Averaging patient safety dimension scores at an aggregate level obscured highly variable improvement trends experienced by hospitals in the three different collaborative settings. Therefore, it is important to examine the hospital-level improvement by dimension as in Table 5.

It has been suggested that safety culture perceptions could be considered a complementary, or perhaps a proxy measure, for outcomes and processes related to patient safety.²⁴ Because positive responses related to culture varied by dimension and microsystem, there is a need for further research in this area. In addition, it will be helpful to see the report of the second year of the comparative database from hospitals using the *Hospital Survey on Patient Safety Culture* to see how hospitals shift over time in their patient safety culture scores and to better understand what rate of change in scores hospitals can expect to see over time.

Further analysis is required for examining differences in scores for academic vs. community settings, physicians vs. nurses, and rural vs. urban settings.

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Measuring Safety Climate in Primary Care Offices

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Abstract

The Safety Attitudes Questionnaire (SAQ) is a self-administered survey that measures six safety attitude constructs. The performance of the ambulatory version of the survey (SAQ-A) has not been evaluated in primary care offices. **Objectives:** The objectives of this project were to (1) test the internal consistency-reliability of the SAQ-A in primary care offices, and (2) develop a cybernetic model to help clarify the terms, culture, climate, and attitude. **Methods:** Internal consistency-reliability for each safety attitude construct was estimated using Cronbach's alpha. A literature review informed the development of the cybernetic model. **Results:** For all respondents combined, Cronbach's alphas for the six safety attitude constructs ranged from 0.58 to 0.77. The lowest alphas were for perceptions of management (especially for nursing staff) and working conditions (especially for administrative staff). **Conclusion:** The instrument appears to have good overall consistency-reliability in primary care offices, but it performed poorly with some subgroups. Further work is needed to evaluate and refine the SAQ-A for use in primary care settings.

Introduction

Of the various strategies available for improving patient safety, creation of a culture of safety is widely considered to be the most effective and sustainable.^{1, 2} This approach has been embraced by the National Quality Forum,³ and The Joint Commission has appropriately included an annual assessment of safety culture in its 2007 Patient Safety Goals.⁴

The term "safety culture" made its first appearance in the literature in 1987. In safety-critical industries, such as health care, safety culture is the prime facet of overall organizational culture. Definitions of organizational and safety culture abound in the literature.^{5, 6} These constructs aspire to help analytic reasoning and practical research. Taking a holistic view, we accept the United Kingdom Health and Safety Commission's 1993 definition of safety culture. The safety culture of an organization is ...

*"...the product of individual and group values, attitudes, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety programmes. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures."*⁷

The causes and effects of an organization's safety culture are intertwined. A highly reliable organization has a safety culture and is a safety culture, wherein the objective of cultivating this culture is to continuously enhance safety, advisedly, with self-empowered and motivated teams.⁸

Our functional implicit definition is adopted from Guldenmund.⁴ Accordingly, we define safety culture as, "those aspects of the practice's culture that have impact on attitudes and behaviors related to enhancing patient safety." It is also helpful to acknowledge and treat each ambulatory practice (organization) as a unique and complex adaptive microsystem.⁹ In the paradigm of complex adaptive systems, a culture of safety not only functions as a conceptual model but also as a central attractor, bringing order to disorder (i.e., reliability where there was risk).¹⁰ It creates stability and continuity, reducing anxiety and performance variation in its members.⁴

The term "safety culture" is often used interchangeably with "safety climate" and occasionally with "attitudes." We believe this is unfortunate and misleading; important and useful distinctions can be made between these concepts. In broad terms, climate can be seen as the observable/measurable part of culture. Safety attitudes, in turn, are a subset of safety climate; they are the part of the climate that resides in individuals and, therefore, can be most readily and conveniently measured via surveys.

Figure 1 depicts a framework that attempts to clarify the contributors to safety culture and the relationship of culture to climate and attitudes. The figure displays eight factors that, in our view, contribute to a safety culture.⁷ Although the relative importance of these contributors (and potentially others not identified in this framework) is not well understood at this time, it is important to note that each of these contributors interacts with and influences every other contributor (see narrow arrows); they work synergistically to create a culture of safety. This culture is complex and hyperdimensional and is the result of complex interactions between multiple players and their attitudes, beliefs, and behaviors over time.

Some aspects of safety culture are not observable or measurable because they are subconscious or rarely manifest themselves. The manifest, or observable, aspects of safety culture are referred to as the safety climate and are in a cybernetic loop with overall safety culture (via the wide arrows). Cybernetics can be defined in many different ways. A recent definition, attributed to Louis Kauffman, president of the American Society of Cybernetics, is "the study of systems and processes that interact with themselves and produce themselves from themselves." It refers to the complex interactions of goals, predictions, actions, feedback, and response within systems.¹¹ In this context, climate is seen as a primary manifestation of culture which, in turn, influences and nourishes culture.^{12, 13, 14, 15, 16}

However, even climate is difficult to measure because, like culture, it exists largely not in individuals but in the interactions among them. Anthropologists use complex and labor-intensive methods, such as participant observation, to try to characterize climate qualitatively. These methods, while informative, are not suitable for widescale adoption outside of the research context.

Self-administered questionnaires have been developed in a variety of industries as a practical and convenient means of measuring quantitatively some of the important aspects of safety climate. These surveys—whether referred to as safety attitude, safety culture, or safety climate

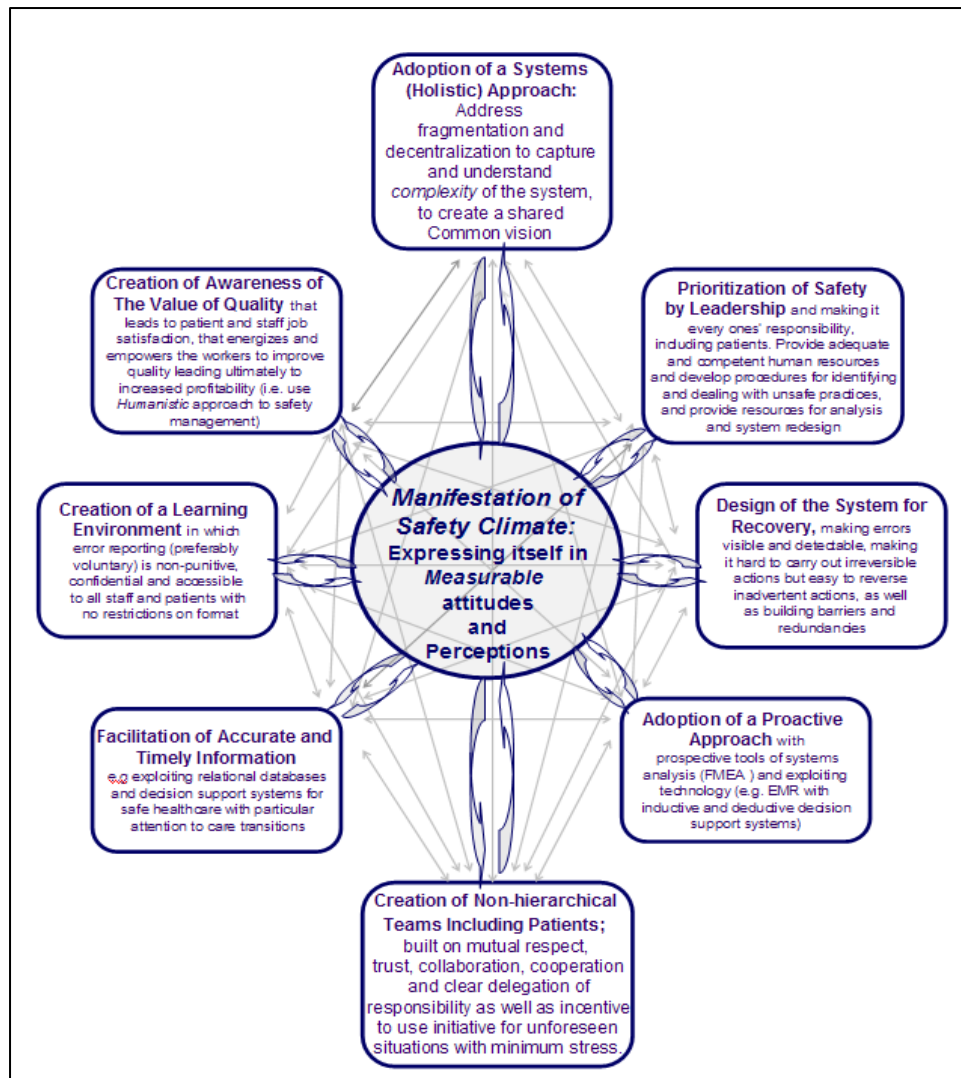


Figure 1. Framework of interactive contributors to the construct of culture of patient safety: Manifesting as safety climate, which expresses itself (partly) in measurable attitudes and perceptions with numerous cybernetic loops with the culture.

questionnaires—can examine only those aspects of climate that are quantifiable and expressible by individuals. In addition to perceptions about individual and group behaviors, these include individual attitudes and beliefs.

It is the apparent ability to quantify safety climate or culture, albeit in a limited way, that has driven the development of self-administered safety attitudes questionnaires over the last 30 or more years for the expressed purposes of measurement, description, diagnosis, and design of interventions for safety. These measures should be seen in light of the fact that the mere process of measurement influences the measured (i.e., there is a cybernetic loop here also).

In attempting to describe safety climate quantitatively, a large number of variables can be identified. A number of these measurable variables are interrelated and measure aspects of the same underlying dimension of safety climate. A number of these dimensions, in turn, capture different aspects of the same underlying (unobservable) latent factor,¹⁶ domain,¹⁷ or

group/category.¹⁸ It is, therefore, possible to reduce/transform, successively, these variables to manageable dimensions and factors. This transformation is usually done by using factor analyses.^{16, 17, 19, 20, 21, 22} Capturing the climate in terms of these factors helps provide a clearer view of climate changes within, and variations between, different health care settings.

The Safety Attitudes Questionnaire (SAQ)¹⁶ is a 60-item, self-administered survey tool that was derived from a questionnaire used in commercial aviation, namely, the Flight Management Attitudes Questionnaire.²³ In a 2005 study comparing published health care safety attitude/climate/culture surveys, the SAQ appeared to be the most robust psychometrically.²⁴ The SAQ has been successfully used in inpatient and ambulatory clinics.^{16, 25} It elicits attitudes through the following six scales (or factors): (1) teamwork climate, (2) safety climate, (3) job satisfaction, (4) perceptions of management, (5) working conditions, and (6) stress recognition. These scales (encompassing 30 of the 60 questions in the SAQ) were developed through multilevel factor analysis using data from 10,843 respondents from 203 clinical areas in three countries (United States, United Kingdom, and New Zealand). The 203 clinical areas included 179 intensive care units (ICUs), 11 inpatient settings, 11 ambulatory clinics, and 2 operating rooms.

A further study, using the ambulatory version of the SAQ (SAQ-A) in a single large multispecialty academic outpatient practice (282 respondents), demonstrated good internal consistency-reliability for the same six factors (Cronbach's alphas ranging from 0.68 to 0.86).¹⁵ Although the outpatient care environment is very different from the intensive care hospital settings where the factors were primarily developed, the same six factors appeared to be robust in this setting. This may be due, in part, to the fact that this study was conducted in a large academic practice that in some ways is organizationally similar to a hospital, with a centralized administrative infrastructure.

The typical primary care outpatient setting, where the majority of outpatient care is provided, is very different from this. For example, the organizational structure is typically flatter, roles are sometimes less clearly defined (with more cross-coverage), and relationships among staff are usually closer. These and other differences might have significant effects on the performance of the SAQ-A in this type of setting. A recent study that attempted to identify dimensions of safety culture, specifically in primary care settings, listed dimensions that overlap considerably with those shown in Figure 1 and with the SAQ-A.²⁶ The goal of the work presented here is to test the internal consistency-reliability of the SAQ-A in primary care offices.

Methods

Data Collection

The SAQ-A was administered voluntarily and anonymously to all eligible staff at eight primary care offices within the Upstate New York Practice-Based Research Network. To be eligible, staff had to have worked at the office (full- or part-time) for at least one month prior to survey administration. Table 1 shows the characteristics of the practices, which ranged from a rural solo practice to an urban academic residency practice site.

Table 1. Characteristics of the eight primary care study sites

Site characteristic	Site								Total
	1	2	3	4	5	6	7	8	
Ownership	Private	Hospital (satellite)	Hospital (onsite)	Private	Hospital (onsite)	Private	Private	Hospital (onsite)	
Geographic location	Urban	Urban	Urban	Urban	Urban	Rural	Urban	Urban	
Residency practice site?	N	Y	Y	Y	N	N	N	N	
Approximate visits per year	60,000	25,000	18,000	13,000	4,500	5,000	23,000	5,000	
Total staff	45	40	82	30	12	3	20	20	252
Returned SAQ-A surveys (%)	27 (60)	34 (85)	38 (46)	24 (80)	10 (83)	3 (100)	13 (65)	11 (55)	160 (63)

The main part of the survey consisted of a series of statements that respondents rated according to a 5-point Likert scale (1 = disagree strongly; 2 = disagree slightly; 3 = neutral; 4 = agree slightly; and 5 = agree strongly). Respondents also could indicate that an item was “not applicable.” The survey took approximately 10 to 15 minutes to complete. Most surveys were distributed in person at brief informational meetings accompanied by a concise explanation of the purpose of the survey, instructions for completion, and assurances of anonymity. For those employees unable to attend the informational session, materials were left with brief written instructions. To help maintain anonymity and confidentiality, participants were instructed to refrain from placing any identifying information on the survey; a secure drop-box was provided for completed questionnaires. Surveys returned within 2 weeks were included in the analysis.

Data Analysis

In keeping with the analytic technique of the originators of the SAQ, calculation of safety attitudes for each of the six safety factors (teamwork climate, safety climate, perception of management, job satisfaction, working conditions, and stress recognition) was performed by converting results from categorical to continuous variables as follows: strongly disagree = 0; disagree = 25; neutral = 50; agree = 75; and strongly agree = 100. Some items were reverse scored so that a higher score always represented a more positive attitude. For each respondent, a mean score of ≥ 75 for the items in a particular factor denoted a “positive safety attitude” for that factor. Internal consistency-reliability was estimated using Cronbach’s alpha. Survey data were analyzed using SPSS[®], version 14.0 (SPSS, Inc., Chicago, IL).

The study protocol was approved by the Social and Behavioral Sciences Institutional Review Board of the State University of New York at Buffalo.

Results

A total of 160 questionnaires were returned. Response rates for each site are shown in Table 1. The overall response rate was 63 percent. Table 2 summarizes the results for all eight practices, by factor. Analysis of variance (ANOVA) showed significant differences among sites ($P < 0.001$) on all subscales except stress recognition.

For example, Site 5, an urban hospital-based clinic with 12 staff, appeared to perform well overall; on four of the six scales, greater than three-quarters of staff had a positive attitude. Site 7 performed similarly well. In contrast, at Site 3 (another urban hospital-based clinic), less than one-third of staff had a positive attitude on five of the scales. Interestingly, this site is much larger than the others and is also a residency practice site—two factors that might contribute to the difference.

Table 3 shows the same data arranged by respondent type for all practices combined. ANOVA found no significant differences among respondent groups on any subscale, both overall and in *post hoc* comparisons of all pairs of groups.

Results of Cronbach analysis for each factor broken down by respondent type are shown in Table 4. For all respondents combined, alphas ranged from 0.58 to 0.77. Perceptions of management had the lowest alpha, while the other five factors all had alphas of ≥ 0.70 , generally taken to indicate good internal consistency-reliability. Among nursing staff, perceptions of management again had the lowest alpha (0.40). Safety climate and stress recognition scales performed better but still had alphas < 0.70 . Among administrative staff, working conditions and stress recognition had the lowest alphas. Physicians and physician extenders produced alphas that were consistently good except in the area of perceptions of management, which was slightly low at 0.63.

Discussion

The SAQ-A proved to be practical and convenient to administer in a variety of primary care office settings. As expected, attitude scores varied considerably among sites, helping to identify each site's strengths and weaknesses and highlighting the potential for this kind of instrument to be used as a means for driving climate/culture change in response to identified weaknesses.

Underlying reasons for the observed variations in safety attitudes are not well understood. Safety attitudes, as a reflection of culture, are intrinsically complex and unpredictable, resulting from the complex interactions among unique individuals and unique circumstances over time. However, there may be some measurable moderating factors, such as practice size and type, location, residency program affiliation, and others. Further study with a larger number of practices is suggested to continue to explore these potential relationships.

Table 2. SAQ-A scores by site for each factor: Percent with positive attitude, mean, and range of scores

Factor	Site								All Sites (N = 160)
	1 (N = 27) ^a	2 (N = 34) ^a	3 (N = 38) ^a	4 (N = 24) ^a	5 (N = 10) ^a	6 (N = 3) ^a	7 (N = 13) ^a	8 (N = 11) ^a	
Teamwork climate									
Positive attitude (%) ^b	56.5	58.1	31.4	73.7	80.0	100	100	44.4	58.5
Mean (SD) ^c	74.2 (19.6)	78.2 (14.5)	62.9 (19.9)	80.4 (16.1)	89.1 (14.1)	81.9 (2.4)	91.3 (6.5)	67.5 (10.7)	75.4 (18.4)
Range ^c	33.3 -100	50.0 -100	12.5 –100	41.6 -100	62.5 -100	79.1 - 83.3	83.3 -100	50.0 - 83.3	12.5 -100
Safety climate									
Positive attitude (%) ^b	60.0	46.9	29.4	60.0	77.8	66.7	100	22.2	51.1
Mean (SD) ^c	76.0 (16.3)	73.9 (14.9)	62.3 (17.9)	76.9 (13.2)	82.5 (17.1)	84.5 (11.4)	92.1 (7.8)	63.8 (13.6)	73.3 (17.2)
Range ^c	46.4 -100	46.4 -100	21.4 –100	39.2 - 100	50.0 - 100	71.4 - 92.8	75.0 - 100	39.2 - 85.7	21.4 - 100
Perception of management									
Positive attitude (%) ^b	66.7	31.3	24.2	63.6	55.6	0	50.0	0	41.0
Mean (SD) ^c	77.0 (18.9)	61.5 (17.2)	53.4 (22.6)	74.4 (17.1)	76.3 (17.8)	56.2 (8.8)	73.4 (16.2)	35.6 (17.4)	64.2 (22.0)
Range ^c	37.5 - 100	25.0 - 93.7	6.25 – 100	25.0 - 100	56.2 - 100	50.0 - 62.5	50.0 - 100	0 - 62.5	0 - 100
Job satisfaction									
Positive attitude (%) ^b	68.0	78.8	31.4	91.7	90.0	100	100	55.6	69.7
Mean (SD) ^c	76.8 (18.9)	80.0 (13.8)	63.8 (16.4)	85.8 (17.8)	89.5 (8.9)	90.0 (5.0)	95.7 (5.3)	72.2 (17.1)	78.3 (18.1)
Range ^c	30.0 - 100	40.0 - 100	30.0 – 100	20.0 - 100	70.0 - 100	85.0 - 95.0	85.0 - 100	45.0 - 95.0	20.0 - 100
Working conditions									
Positive attitude (%) ^b	37.5	53.3	33.3	72.2	85.7	(No data)	66.7	0	48.3
Mean (SD) ^c	62.5 (23.7)	69.7 (15.4)	63.3 (18.5)	79.5 (16.1)	85.7 (15.6)	(No data)	80.5 (11.4)	35.9 (18.2)	68.1 (20.6)
Range ^c	18.7 - 100	31.2 - 93.7	31.25 – 100	50.0 - 100	56.2 - 100	(No data)	62.5 - 93.7	0 - 62.5	0 - 100

Table 2. SAQ-A scores by site for each factor: Percent with positive attitude, mean, and range of scores (continued)

Factor	Site								All Sites (N = 160)
	1 (N = 27) ^a	2 (N = 34) ^a	3 (N = 38) ^a	4 (N = 24) ^a	5 (N = 10) ^a	6 (N = 3) ^a	7 (N = 13) ^a	8 (N = 11) ^a	
Stress recognition									
Positive attitude (%) ^b	31.6	39.3	53.6	25.0	25.0	0	11.1	62.5	37.2
Mean (SD) ^c	60.8 (21.1)	65.4 (25.3)	68.9 (23.1)	50.6 (27.8)	59.3 (26.3)	50.0 (0)	55.5 (16.0)	67.9 (15.8)	61.9 (23.8)
Range ^c	12.5 - 93.7	0 - 100	0 - 100	0 - 93.7	6.2 - 93.7	50.0 - 50.0	31.2 - 81.2	37.5 - 81.2	0 - 100

a The N shown for each site represents the total number of respondents. Respondents had to answer all questions in a particular factor in order to be included in the analysis for that factor. Therefore, in any given column, the true N (not shown) varies from row to row.

b A respondent has a positive attitude for a factor if their mean score for the items in that factor is 75 or above.

c Means and ranges are based on all responses in that site, not just those with positive attitudes.

Table 3. SAQ-A scores by job category for each factor: Percent with positive attitude, mean, and range of scores

Factor	Physician/Extenders (N = 69)^a	Nursing staff (N = 44)^a	Admin staff (N = 30)^a	Unknown position (N = 17)^a	All staff (N = 160)^a
Teamwork climate					
Positive attitude (%) ^b	59.1	55.8	60.9	60.0	58.5
Mean (SD) ^c	74.6 (17.1)	76.6 (19.1)	74.1 (23.1)	78.5 (13.3)	75.4 (18.4)
Range ^c	29.1 – 100	33.3 - 100	12.5 - 100	62.5 - 100	33.3 - 100
Safety climate					
Positive attitude (%) ^b	46.0	56.4	56.5	50.0	51.1
Mean (SD) ^c	69.3 (18.6)	76.0 (16.1)	77.7 (15.8)	76.4 (12.8)	73.3 (17.2)
Range ^c	21.4 – 100	42.8 - 100	50.0 - 100	57.1 - 96.4	21.4 - 100
Perceptions of management					
Positive attitude (%) ^b	44.4	33.3	44.4	40.0	41.0
Mean (SD) ^c	66.4 (21.4)	60.7 (20.4)	65.7 (26.9)	61.6 (18.7)	64.2 (22.0)
Range ^c	25.0 - 93.7	18.7 - 100	6.2 - 100	18.75 - 81.25	0-100
Job satisfaction					
Positive attitude (%) ^b	68.7	58.5	76.7	92.9	69.7
Mean (SD) ^c	76.5 (17.7)	75.2 (19.4)	84.1 (18.2)	83.9 (12.1)	78.3 (18.1)
Range ^c	20.0 – 100	30.0 - 100	30.0 - 100	55.0 - 100	20.0 - 100

Table 3. SAQ-A scores by job category for each factor: Percent with positive attitude, mean, and range of scores (continued)

Factor	Physician/Extenders (N = 69)^a	Nursing staff (N = 44)^a	Admin staff (N = 30)^a	Unknown position (N = 17)^a	All staff (N = 160)^a
Working conditions					
Positive attitude (%) ^b	50.9	50.0	37.5	46.2	48.3
Mean (SD) ^c	70.6 (20.1)	65.4 (23.8)	67.5 (26.9)	65.8 (16.6)	68.1 (20.6)
Range ^c	31.2 - 100	0 - 93.7	25.0 - 100	31.2 - 87.5	0 - 100
Stress recognition					
Positive attitude (%) ^b	44.8	42.9	5.9	27.3	37.2
Mean (SD) ^c	65.7 (24.5)	63.5 (22.9)	50.0 (22.2)	55.6 (21.5)	61.9 (23.8)
Range ^c	0 - 100	6.2 - 100	0 - 87.5	25.0 - 81.2	0 – 100

a The N shown for each site represents the total number of respondents. Respondents had to answer all questions in a particular factor in order to be included in the analysis for that factor. Therefore, in any given column, the true N (not shown) varies from row to row.

b A respondent has a positive attitude for a factor if their mean score for the items in that factor is 75 or above.

c Means and ranges are based on all responses in that site, not just those with positive attitudes.

Table 4. Cronbach's alpha (n) for office staff by position: All sites

Factor	Physician/Extenders	Nursing staff	Admin staff	All respondents ^a
Teamwork climate	0.76 (63)	0.74 (43)	0.89 (23)	0.77 (142)
Safety climate	0.79 (60)	0.65 (39)	0.74 (23)	0.74 (137)
Perceptions of management	0.63 (61)	0.40 (39)	0.74 (27)	0.58 (144)
Job satisfaction	0.78 (64)	0.73 (41)	0.90 (30)	0.77 (152)
Working conditions	0.76 (53)	0.76 (36)	0.53 (16)	0.70 (118)
Stress recognition	0.78 (57)	0.64 (35)	0.66 (17)	0.72 (121)

a All respondents includes those with unknown position.

The data presented in this article are part of a larger study in which the authors presented SAQ-A results to each office's staff (along with other data specifically related to medication safety) as a means of initiating discussions around change. Staff then worked together to design and implement change. Repeat measures of safety climate using the SAQ-A and correlations between safety attitudes and outcomes are underway and will be reported separately.

For SAQ-A results to be used meaningfully to drive change and monitor safety attitudes over time, the instrument must first demonstrate satisfactory psychometric properties. In prior studies, the SAQ has demonstrated good internal consistency-reliability for each of its six factors in multiple hospitals and in a large multispecialty ambulatory setting. In this study, in eight primary care offices, we found that overall; the six constructs were robust, with the possible exception of "perceptions of management." Other than with administrative staff, this scale performed suboptimally. Given the different and varied management structures found in most primary care offices compared to hospital-based facilities, this is, perhaps, not surprising. In most of the sites in our study and in most primary care offices, management generally consists of one or two people (perhaps a practice manager and a medical director, at most) who work closely on a day-to-day basis with the rest of the staff and are not perceived as a separate or distinct department.

This contrasts with the hospital settings in which this scale was developed, where management was often a separate and sometimes amorphous group of people who were less intimately involved in the practice team. More recently, the authors of the SAQ have developed a version that differentiates among levels of management. This distinction might also prove helpful in primary care settings. Further work is needed to identify the most suitable measures for this construct or perhaps even to identify a more relevant alternative construct to capture management issues in primary care settings.

Interestingly, in earlier studies of the SAQ in other settings, administrative staff, in general, had low response rates across multiple factors and so were excluded from the factor analysis. In our primary care settings, the administrative staff category included receptionists, schedulers, referral coordinators, medical records staff, practice managers, and (importantly) staff who performed a variety of these functions. In primary care settings, it is highly desirable to include these staff as part of a safety climate assessment because they are typically integrated very closely into practice teams (more so than in other settings).

It is encouraging to note that other than for working conditions and stress recognition, greater than 75 percent of administrative staff responded fully to the questions that made up the various factors. The two factors that had low response rates (i.e., “working conditions,” 53 percent; and “stress recognition,” 57 percent) also had low alphas, although these should be interpreted with caution since they were based on small numbers.

The four factors that had good response rates all demonstrated satisfactory internal consistency-reliability for administrative staff (Table 4), even though this class of respondents was not included in the original analyses that identified these factors. Therefore, our findings support the inclusion of administrative staff when administering the SAQ-A in primary care, with the caveat that the “working conditions” and “stress recognition” scales might not apply in their current forms, in light of their low response rates. The missing responses might indicate that some of those questions are less relevant to the primary care setting.

Among nursing staff, response rates to all scales were good. However, there were suboptimal alphas for “safety climate” and “stress recognition,” in addition to the “perceptions of management” scale discussed earlier. These and other differences (discussed earlier) in the internal consistency among different groups of respondents listed in Table 4 raise the question of whether a single questionnaire can reliably capture the safety attitudes of a diverse group of respondents, or whether tailored questionnaires are needed for each subgroup. Our experience suggests that common elements in surveys are helpful. For example, when we share practice-specific results with staff (showing scores on each scale for each group of respondents), we have observed that staff find it helpful to note similarities and differences of opinion between themselves and other staff groups. It helps them build a common vision (where there are similarities) and prompts them to explore the reasons for differences that are revealed. Further work is needed to explore these issues.

Note that, in the SAQ-A used to date, only 30 of the 60 items are included in the six climate scales evaluated in this and prior studies; the remaining items are retained only because individual organizations may find the responses useful. Shortening the questionnaire to include only the items that make up the six climate scales could help improve compliance and might also influence (probably favorably) the psychometric properties.

The theoretical framework described in the introduction (Figure 1) includes several contributors to safety culture. Some of these contributors can be mapped to measurable attitudes, many of which are covered by the SAQ and SAQ-A. For example, creation of a learning environment maps very closely to the SAQ’s safety climate scale; creation of nonhierarchical teams corresponds to teamwork climate, job satisfaction, and stress recognition in the SAQ; and prioritization of safety by leadership is an area that is well addressed via the perceptions of

management and working conditions scales. The framework reveals some areas that could be addressed further—such as design of the system for recovery and adoption of a proactive approach—that are not explicitly covered by the SAQ. These eight contributors manifest in complex multidimensional ways, some of which are either immeasurable or require methods of assessment other than self-administered surveys.

Conclusion

The SAQ-A holds promise as a convenient tool for assessing certain safety climate domains in primary care offices, with fairly good internal consistency-reliability across most of these domains. Weaknesses were found in the perceptions of management scale overall and in specific scales for nursing and administrative staff. Further study is warranted, preferably with a larger sample size, with the goal of developing a more robust instrument tailored to this setting.

It is hoped that the conceptual framework presented in Figure 1 can make a contribution to guiding further work in assessment of safety climate by various means, including qualitative and quantitative analyses.

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The PeaceHealth Ambulatory Medication Safety Culture Survey

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Abstract

Objective: The objective of this project was to construct a measure of medication safety culture in ambulatory settings. **Methods:** A 16-item survey was created to measure the degree to which a culture of medication safety exists within ambulatory clinics. The instrument was tested with two administrations separated by 12 months in three ambulatory clinics and evaluated with Mplus factor analysis, internal consistency reliability, and discrimination ability. **Results:** Of 105 staff, 62 (60 percent) returned surveys in the first administration and 80 (77 percent) in the second. The measure had good internal consistency reliability, with a Cronbach alpha of 0.94 and 0.90 for the two administrations and 0.90 to 0.96 across the three clinics. The measure demonstrated good sensitivity and discrimination between clinics. Five subdomains of medication safety culture were identified: (1) leadership, (2) learning culture, (3) quality improvement, (4) physician responsibility, and (5) safety as a priority. **Conclusion:** The measure is psychometrically strong and capable of assisting in the improvement of medication management safety.

Introduction

One of the biggest challenges in health care is providing safe, effective care, and one of the most significant areas of opportunity for improvement is medication safety. It is well known that many adverse drug events (ADEs) occur within the hospital setting. However, little is known about the incidence of ADEs in the ambulatory setting. This knowledge gap exists despite the fact that medication prescribing is the most frequently used therapeutic intervention, with nearly two-thirds of office visits concluding with a prescription for medication.¹ The risks for medication errors and subsequent ADEs in the outpatient setting can be a result of (or a combination of) physician/provider-related, health system/practice process-related, or patient-related factors. To best understand these factors, it is important to examine the processes involved in each of those three domains. In the health system/practice domain, a key measurable component is “safety culture,” which includes the management behaviors, safety system processes, and staff perceptions of safety that exist within the health care environment.²

The Institute of Medicine (IOM) has recommended that health care organizations improve patient safety culture.³ In their report, *Preventing Medication Errors*,⁴ the IOM notes that developing an organizational culture of medication safety in the health care setting is a key component to improving medication safety outcomes and preventing ADEs. A number of safety culture (or climate) surveys have been developed to assess the degree to which a safety culture exists within an organization. Most have measured safety attitudes and perceptions at the

individual level based on five common dimensions of the patient safety climate: (1) leadership, (2) policies and procedures, (3) staffing, (4) communication, and (5) reporting.⁵

Although many of these surveys were developed for general use, most have been utilized primarily within the hospital setting.^{6, 7, 8, 9, 10, 11, 12, 13, 14} Despite the known importance of patient safety in outpatient clinics, few surveys have been developed specifically for the ambulatory setting. Recently, the safety attitudes questionnaire was adapted to assess provider safety attitudes in the ambulatory setting.¹⁵ Others have attempted to better understand the theoretical framework of patient safety in primary care.^{16, 17} However, we are unaware of any survey that has been developed specifically to assess medication safety culture in the ambulatory clinic or hospital setting.

In order to improve medication safety in the ambulatory clinic setting, a better understanding of the safety culture or climate specifically related to medication management is needed before interventions to improve safety can be developed. Only through assessment and feedback to clinical work groups or office teams can safety culture and ultimately patient safety be transformed.

This report describes the development of an ambulatory medication safety culture survey, its psychometric properties, and findings from testing in three adult medicine primary care practices.

Methods

Study Design

An ambulatory clinic-focused survey measuring the degree to which a culture of medication safety is present in a clinical practice was developed using components of previously published patient safety culture surveys.^{6, 7, 8, 9, 10, 11, 12} Initially, an 18-item survey was constructed for testing. Baseline data were collected for three clinics (collected in June 2004 for two clinics; August 2004 for a third). All data were collected prior to an intervention to improve medication management in the participating clinics. A followup survey was sent out in June 2005 for all three clinics. Psychometric analysis of the instrument was performed using 142 completed surveys.

Participant Clinics

Three free-standing ambulatory primary care clinics were chosen to participate in the study based on their interest in improving medication safety and experience in quality improvement projects. The following clinic sites participated in the study: the Senior Health and Wellness Center (SHWC), Eugene, OR, with four geriatric providers and two nurse practitioners; the Center for Senior Health (CSH), Bellingham, WA, with seven adult medicine and geriatrician providers; and Health Associates Peace Harbor (HAPH), Florence, OR, with 13 adult care providers.

This survey was completed prior to an intervention to improve the medication reconciliation process in the clinics and introduction of a patient-centered electronic medication list. Total number of clinic staff completing the survey in the first administration was 62 (overall response rate, 60 percent; Clinic A: N = 20, response rate, 80 percent; Clinic B: N = 16, response rate, 55 percent; Clinic C: N = 26, response rate, 51 percent). In a second administration 12 months after the intervention, the staff completed a total of 80 surveys (overall response rate, 77 percent; Clinic A: N = 20, response rate, 80 percent; Clinic B: N = 28, response rate, 96 percent; Clinic C: N = 32, response rate, 63 percent).

Survey Instrument Construction

Initially, eighteen questions specifically addressing medication safety were constructed based on existing generic safety culture surveys. Two of the 18 items were not retained for the final analysis. It was found that inclusion of these items lowered internal consistency reliability. These two items were, “I often worry about whether I have all of the information I need to make sure that a medication is prescribed safely for a patient” and “The health care providers in this clinic frequently disregard rules or guidelines for medication safety.” Table 1 lists the remaining 16 items used in the final analysis.

Psychometric Analysis

Psychometric analysis was performed on data collected from participants who completed the 18-item survey at both time periods. Analysis consisted of internal consistency reliability (Cronbach’s alpha) to determine whether the 16 analyzed items could be used to construct a single culture-of-medication safety score. Exploratory factor analysis in Mplus¹⁸ with the items treated as ordered categorical variables was conducted to understand the different domains of medication culture within the 16 items. In the Mplus analysis, maximum likelihood estimation of missing values was employed. Finally, ability to discriminate differences among clinics and change over time was assessed by a general linear model analysis.

Results

Internal Consistency Reliability

The final 16-item instrument had good internal consistency reliability and alpha did not increase by deleting any item. For all three clinics combined, Cronbach alpha was 0.94 at the first administration and 0.90 at the second administration. The internal consistency reliability was maintained in all clinic sites (Clinic A = 0.96; Clinic B = 0.90; Clinic C = 0.94). The ceiling and floor effects of the 16 items were small (floor effect = 0.7 percent; ceiling effect = 2.1 percent).

Factor Structure

An Mplus factor analysis revealed that a one-factor solution was not satisfactory with a root mean square residual (RMSR) of 0.08. An unsatisfactory one-factor solution was due to item 1 (“The culture of this clinic makes it easy to learn from the medication mistakes of others”) having a loading of 0.03, while all other items loaded 0.5 or above on the single factor.

Exploratory factor analysis in Mplus found that the best solution was a five-factor solution (RMSR = 0.03) as shown in Table 2, where 7 of the 16 items can be seen to load high on the leadership factor; another four items load highly on the quality improvement factor. Because these two factors dominate the 16 items, the fact that item 1 loads 0.004 on leadership and -0.051 on quality improvement and is the only question addressing learning culture explains why item 1 fails in a one-factor solution. Therefore, although the 16 items all measure culture of medication safety, they address five separate domains of that construct: (1) leadership, (2) learning culture, (3) quality improvement, (4) physician responsibility, and (5) safety as a priority. An overall score is calculated by taking the mean response across the 16 items where the disagree-agree response options are scored “disagree strongly = 1” to “agree strongly = 4.” The higher the score, the more a culture of medication safety is present.

Discriminant Validity and Sensitivity

The discriminant validity of the 16-item measure was assessed by evaluating the ability of the measure to distinguish between clinics qualitatively known to differ on their likelihood of (a) having a culture of medication safety in place and (b) the degree to which such a culture could be increased. This qualitative classification of the clinics comes from our observation and experience working with the three clinics over a 3-year period, thereby gaining some insight into

Table 1. Culture of medication safety items

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1. The culture of this clinic makes it easy to learn from the medication mistakes of others.
 2. Medication errors are handled appropriately in this clinic.
 3. The management/leadership in our clinic listens to me and cares about my medication safety concerns.
 4. The physicians in our clinic listen to me and care about my medication safety concerns.
 5. Leadership in the PHOR region is facilitating us to be a medication safety-centered clinic.
 6. My suggestions about medication safety would be acted upon if I expressed them to clinic management.
 7. The management/leadership of this clinic does not knowingly compromise medication safety concerns for the sake of productivity.
 8. I am encouraged by my colleagues in this clinic to report any medication safety concerns I may have.
 9. I know the proper channels to direct questions regarding medication safety in this clinic.
 10. If a member of my immediate family were to be a patient in this clinic (not my patient) I would have no concern at all about possible medication errors.
 11. This clinic is doing more for medication safety now than it was 1 year ago.
 12. Medication safety in this clinic is approached as a process of care issue and not a personal blame issue.
 13. The health care providers in this clinic take responsibility for patient medication safety.
 14. In this clinic we have clearly defined rules and guidelines for medication safety.
 15. Medication safety is constantly reinforced as a priority in this clinic.
 16. In this clinic we have defined protocols about reporting and discussing medication mistakes that almost happened and could have harmed a patient but did not.
-

Table 2. Varimax rotated factor loadings of the five-factor solution

Item	Leadership	Learning culture	Quality improvement	Physician responsibility	Safety as a priority
2	.650	-.050	.286	.334	.295
4	.736	-.022	.323	.393	.196
5	.519	-.090	.406	.322	.320
6	.649	-.065	.111	.385	.303
7	.700	.007	.342	.529	.103
9	.842	-.020	.292	.142	.218
10	.901	.128	.256	.101	.198
1	.004	.977	-.051	-.023	.066
14	.175	.003	.643	.339	.304
3	.428	.083	.597	.406	.221
8	.429	-.113	.527	.337	.176
11	.362	-.075	.909	.163	.151
12	.440	.014	.292	.530	.182
13	.299	-.036	.327	.904	.114
15	.295	.131	.078	.153	.618
16	.185	-.036	.385	.058	.677

the cultural dynamics of the clinical practices. Based on this knowledge, we hypothesized that clinics A and C would have more of a culture of medication safety in place at the 2004 baseline. We further hypothesized that clinics A and B would have greater capacity for improvement over time than clinic C.

To evaluate differences among the three clinics and their change over time in the culture of medication safety, a univariate general linear model analysis was conducted on culture of medication safety scores. Clinic site and year (2004, 2005) were fixed factors with no covariates.

There was a significant between-subjects effect for clinic ($F = 9.65$, $P < 0.0001$) and year ($F = 17.5$, $P < 0.0001$) and a significant clinic x year interaction ($F = 14.28$, $P < 0.0001$). As shown in Figure 1, the nature of the interaction was that Clinic A and Clinic B significantly improved in culture of medication safety from 2004 to 2005, while there was no significant change in Clinic C (95 percent CI). At baseline in 2004, there were no significant differences among the three clinics. In 2005, both Clinics A and B had a significantly higher culture of medication safety score than Clinic C (95 percent CI). The measure does appear to discriminate among the clinics in the degree of medication safety culture present and is sensitive to detect change over time in culture of medication safety after an intervention.

Discussion

Medication management is known to be a critical component of patient safety across the care continuum, and a focus on the ambulatory setting provides an emerging opportunity to improve medication safety. Creating a culture of medication safety in ambulatory clinics that patients consider their “medical home” will be important to ensure that safe, reliable health care is adequately managed across that continuum.

The PeaceHealth Ambulatory Medication Safety Culture Survey, although in its early stages of development, appears to be a valid and valuable tool to assist ambulatory clinic staff in their pursuit of safer medication management. Although developing useful instruments to measure medication safety culture is important, the tool development process and the use of these tools will also assist in understanding the complex nature of the safety culture within an organization. Certainly, a simple unidimensional survey tool would have some benefits. However, it is clear from the evaluation of this instrument, as supported by previous work, that the culture of safety is more complex.

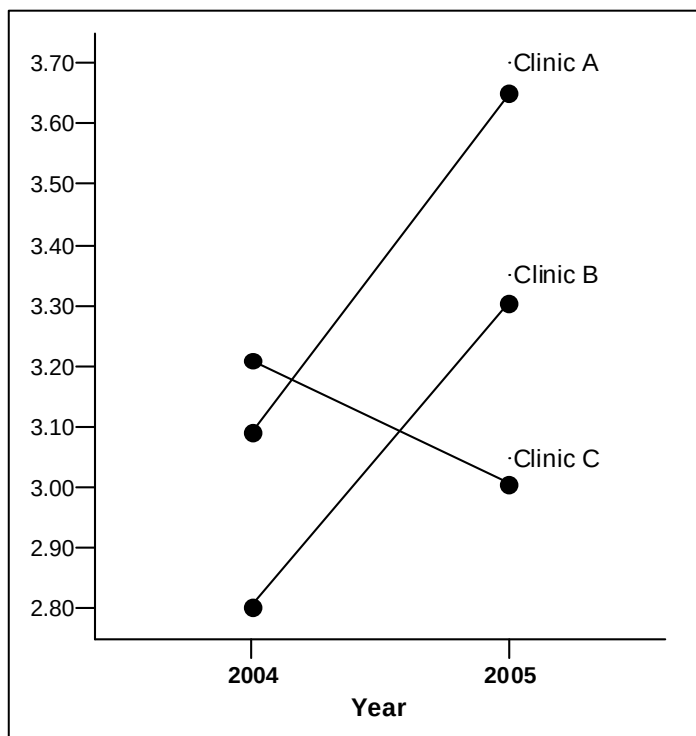


Figure 1. Mean culture of medication safety score by year by clinic.

In this study, the best Mplus factor analysis solution revealed five subdimensions: (1) leadership, (2) learning culture, (3) quality improvement, (4) physician responsibility, and (5) safety as a priority. This instrument contains seven items that appear to measure attributes of leadership within the clinical setting. These items suggest that leadership involves not only the actions of leaders, but also the processes/outcomes, or lack thereof, of leadership attributes.

The most heavily loaded item in the leadership dimension was, “If a member of my immediate family were to be a patient in this clinic (not my patient), I would have no concern at all about possible medication errors.” This item supports the staff perception that a criterion for a culture of medication safety is reflected by the degree with which it would be safe for one of their family members. Although this item does not specifically mention leadership, it does suggest the importance of leadership in creating an environment that staff feel is safe for those that are close to them.

The learning culture subdimension contains only one question, albeit an important attribute of a safety culture. More exploration through item development is needed to better understand what it means to be a learning organization in the context of clinic medication safety. The third

subdimension of “quality improvement” assesses the environment in which the processes are defined to ensure medication safety and whether staff perceptions of continuous improvement are an attribute of that dimension.

The centrality of the provider role in patient care and safety is suggested as a theme of the physician responsibility subdimension. A core activity of patient safety is the “physician responsibility” for creating a safe environment through the positive focus on processes rather than blame. This is reinforced by moderately high loading of item 12 (mistakes not approached as personal blame) on the leadership subdimension.

Finally, the subdimension of “safety as a priority” is necessary in order for conversations about defined safety protocols to occur. If safety is not perceived to be a high priority, conversations and actions that lead to safer care will not occur. It is clear that there is still much to learn about the components of a culture of medication safety in the ambulatory environment. Better understanding of subdimensions and attributes within a culture of medication safety will ensure more accurate measurement and thus improved feedback to clinical staff endeavoring to improve the safety of care provided to patients.

This survey tool appears to have the ability to discriminate the degree of medication safety culture differences among clinics, and it has the sensitivity to detect change in the culture of medication safety over time after an intervention. Two of the three clinic sites improved their culture of medication safety after an intervention to improve medication safety was implemented. As a component of the intervention, clinic staff discussions about clinic medication safety were part of the survey feedback and were believed to have been an effective intervention. Also, staff and provider involvement in the process improvement of medication management within the clinic most likely affected the safety culture results.

Based on qualitative observations, it appeared that team members, particularly providers, who were closer to changes in the medication management process at the point of service and participated actively in the study, produced better staff engagement. This explains why two of the clinics improved their culture scores while the third did not. At the site where medication safety culture did not change over time, direct provider and patient participation in the intervention was not as active. Thus, engagement of staff and providers was perceived to be lower. In this third clinic, the accuracy of medication lists improved through the process redesign, but the culture of medication safety did not. This raises the issue of whether improving care processes leads to improved safety culture. This clinic will require continued observation to evaluate whether the medication reconciliation workflow processes will remain reliable and sustainable, as we believe that the clinic culture will influence the sustainability of work processes.

While the current instrument appears to be of value, the measure could be enhanced with further development. The factor analysis clearly indicates that more items could be constructed in the subdimensions of “physician responsibility,” “safety as a priority,” and “learning culture.” Although the subdimensions of “leadership” and “quality improvement” have sufficient internal consistency reliability to be used for creation of subdimension scores ($\alpha = 0.85$ and 0.84 , respectively), the measure would be far more useful if it provided subdimension scores for all five subdimensions. Testing in ambulatory clinic settings other than adult primary care and larger

samples of providers and staff are needed for further evaluation of the generalizability of this instrument. Also, assessment of differences of responses among clinic staff disciplines would further enhance the usability of this tool for medication management quality improvement.

Conclusion

The PeaceHealth Ambulatory Medication Safety Culture Survey has strong psychometric properties. The survey was found to be an effective tool for providing feedback to clinic staff regarding the perception of medication safety in the work environment. Based on early testing, we believe the utility of this survey is strengthened by its strong psychometric properties and its development specific to the care environment and purpose of medication safety. Further development of the instrument is needed to better define survey subdimensions. Finally, caution is needed in inferring that improving medication safety culture will lead to better patient outcomes and, alternatively, that an improvement in medication safety outcomes translates into an improved culture of safety.

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Views of Emergency Medicine Trainees on Adverse Events and Negligence: Survey Results from an Emergency Medicine Training Program in a Regional Health Care System Following the National Standard of Care

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Abstract

Objective: Little is known about the awareness, understanding, and attitudes of emergency medicine (EM) trainees regarding the medicolegal aspects of adverse events statewide. Investigators evaluated EM trainees' perception of adverse events and medical negligence in Rhode Island. **Methods:** A cross-sectional questionnaire study was conducted during a randomly selected EM trainee conference. EM trainees rotated in a 966-bed health care system with annual adult and pediatric ED census of over 190,000 patients. **Results:** Of 28 EM trainees, 17 (61 percent sample; 35 percent target population) participated in the questionnaire assessment. Two-thirds of respondents indicated that health professionals not working together or not communicating as a team were very important causes of adverse events; 12 of 16 respondents properly defined negligence; 5 respondents were able to provide an appropriate example of an adverse event due to negligence. **Conclusion:** EM trainees are cognizant of adverse events and their causes and perceive medical negligence as a significant problem.

Introduction

Emergency medicine (EM) trainees in the United States strive to treat emergent and nonemergent events in the hospital emergency department (ED) in accordance with established medicolegal care standards.^{1, 2} Clinical reports^{3, 4} meticulously document trainees as legally being held to the same standard of care as their attending physicians. Quality of care standards are especially salient when a trainee is faced with a patient adverse event. Yet, in adverse event situations in which care standards do not exist, rules with which to proceed are absent, and a trainee may be at risk for providing negligent care.⁵ Such situation-specific adverse events, especially in a volatile ED environment where rates of utilization continue to rise,⁶ make conditions for EM trainees ever more challenging. Concerns over EM trainee expectations and ED conditions have pressured State and Federal policymakers to formulate streamlined care standards.^{7, 8}

To date, standards of care for physicians and for trainees are inconsistent across the United States. A 2007 commentary by Lewis and colleagues⁹ noted that 29 States and the District of Columbia are governed by the U.S. national standards, while 21 States are governed by a

standard of care based on locality rules. For the former, the United States as the national ruling jurisdiction suggests that general (e.g., internal medicine) and specialty (e.g., emergency medicine) physicians and trainees follow rules typically drafted by professional medical societies. For the latter, with a locality ruling jurisdiction, general and specialty physicians and trainees are held to a State locality rule, in which a statute or case law holds physicians and trainees to the standard of care practiced by those physicians in the “same or similar community” of that State.⁹ State-to-State variation in patient care standards adds to difficulties facing the medical community when addressing an adverse event due to negligence. In light of practice conditions unique to the specialty, this standard may severely compromise patient safety in EM.^{10, 11}

Little is known about an EM trainee’s awareness of and attitudes about adverse events, negligence, and their relationship to patient safety in the context of a statewide jurisdiction practicing the U.S. national standard of care. As the patient safety topics of adverse events and negligence become drafted into board certification exams,¹² surveying of EM trainees—those candidates anticipated to take such tests in the future—might provide general insights and suggest strategies to assess which areas need further attention by EM residency programs and for the betterment of patient safety.

In this study, we assessed views of EM trainees on adverse events with respect to negligence in the State of Rhode Island, where all practicing EM physicians and trainees are expected to follow the U.S. national standard of care, including clinical practice guidelines, position statements, and education resource guides as developed by the Society for Academic Emergency Medicine,¹³ the American Academy of Emergency Medicine,¹⁴ the American College of Emergency Physicians,¹⁵ and collaborative partner organizations.

Methods

Study Setting and Population

Forty-eight trainees (12 interns and 36 residents) in the EM residency program affiliated with the Alpert Medical School of Brown University were chosen as the study population. Study participants rotated in three separate EDs of a 966-bed health care system with annual adult and pediatric ED census of over 190,000 patients. Two of these EDs are Level 1 Trauma Centers.

The implementation strategy aimed to capture a representative sample of the study population from an EM residency teaching conference. One conference was randomly selected from those scheduled during 2006. Twenty-eight trainees (58 percent of the target population) were present at the selected meeting. Seventeen of 28 responded to the questionnaire (61 percent sample response rate; 35 percent target population response rate).

Approximately two-thirds of the study sample was male (11/17). A total of 6 interns and 11 residents completed the questionnaire; this represented half (6/12) of the interns and one-third (11/36) of the residents within the target population. Three residents were in their second training year, four residents in their third training year, and four residents in their fourth training year or more of EM. More than half of the respondents (9/17) were within the age range of 25 to 29

years. About one-third of the respondents (6/17) were between the ages of 30 and 34; one respondent was between the ages of 35 and 39. No trainee respondent in this study sample had been sued for malpractice.

Questionnaire Design

This study employed measurement tools from previous studies^{16, 17, 18, 19, 20} and those developed by the primary investigator (HS). The Institute of Medicine (IOM) definitions of medical error and adverse event were adapted for study use. A medical error was defined as “the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.” An adverse event was defined as “an injury caused by medical management error rather than the patient’s underlying disease or condition.”¹⁶ The latter definition was modified to strictly address medical practice in the United States and to control for training electives abroad.

Examples of adverse events came from a previous study¹⁷ addressing views of residents on medical error and adverse events causes: “pneumothorax, retained objects, hospital-acquired infections, decubitus ulcers, perioperative myocardial infarctions (MIs), line infections, and falls.” Finally, the American Board of Medical Specialties – Council of Medical Specialty Societies (ABMS-CMSS) semantic and literature review helped develop a uniform definition of negligence as: “Medical care that fell short of the expected standards; expected standards refer to widespread use by U.S. EM physicians, and/or national or local organization-based written guidelines in the contextual situation.”^{12, 18}

Twelve main questions, divided into four sections, were included in the questionnaire. Sections were developed and ordered based on a review of patient safety literature. Quantitative questions included: “General Issues of Adverse Events,” “Causes of Adverse Events,” “Strategies to Reduce Adverse Events,” and “Malpractice Issues.” The “General Issues of Adverse Events” section, with six questions [Q1– Q6] derived from a previous national study,¹⁹ was designed to introduce the terminology of adverse events and engage the respondent to think of adverse events. The standardized questionnaire was pretested on an internal medicine residency program at the same institution and modified for content validity. Full description and study results are in an unpublished report.²¹

The “Causes of Adverse Events” section, with one question [Q7], aimed to transition to the topic of adverse events by querying subjects on objectively identified causes of hospital-based adverse events. The “Strategies to Reduce Adverse Events” section, with one question [Q8], asked respondents to consider several national strategies proposed by physician experts to reduce adverse events. The “Malpractice Issues” section, with two open-ended questions [Q9-Q10] and two closed-ended questions [Q11-Q12], was designed to evaluate views on the medico-legal aspects of EM practice and personal experience, respectively. One question [Q11] of malpractice fear came from a previous report²⁰ using skilled opinion and factor analysis. (This main section was addressed last, as malpractice can be a sensitive topic and might be perceived as intrusive.²²) Finally, six questions [Q13 – Q18], asked for trainee demographic information.²³ The EM Trainee Patient Safety Questionnaire can be found in the Appendix.

Implementation Strategy

This study utilized a cross-sectional design and was conducted during an EM trainee conference. The purpose of the study and the importance of confidentiality were explained to the trainees. A typewritten questionnaire instrument and blank envelope were distributed to each trainee present at the conference. Trainees were asked to read the written consent form and instructions section, serving as the first page of the questionnaire instrument, and to complete it privately on a voluntary basis.²⁴ No honorarium was offered. Trainees placed their completed questionnaires in anonymous envelopes that were then collected in a separate container. The Institutional Review Board at the participating health care system approved the study.

Questionnaire Analysis

All categorical data from the questionnaire instruments were entered into Epi Info™ version 3.3.2, and free-text answers were transcribed verbatim. Data entry was rechecked for quality purposes. Categorical results were analyzed by cross-tabulation.

Open-ended responses were qualitatively assessed for thematic content;²⁵ answers that fell into a specific theme were tabulated. Those answers that did not fall into a theme were tabulated into a section entitled “other.” Response meanings of adverse events were analyzed by reviewing statements that addressed the theme of “care that fell short of the expected standard” or any variations of those words (e.g., providing substandard care); these were tabulated into two columns, either noted directly or indirectly. Statements addressing negligence as doing harm to a patient were added into a separate column. Response examples of adverse events due to negligence were qualitatively analyzed by separating each content description into three areas: context, standard of care, and injury. Each standard-of-care response was then considered in context and compared with written guideline policies¹⁵ (when available) in widespread use by EM physicians as the U.S. national standard of care. An EM physician analyzed the results for depth and validity. Full responses from the open-ended questions are detailed in the Results section. For the purpose of improved clarity, acronym and grammatical errors have been corrected without changing the phrase content or meaning.

Results

Closed-Ended Categorical Analysis

General issues of adverse events. All respondents (17/17) labeled adverse events as a problem that is at least “important.” More than half the respondents (10/17) marked adverse events as occurring at least “often.” Less than half the respondents (8/17) considered the patient partially responsible for adverse events made during their care. Three-fourths of the respondents (12/16) agreed on keeping hospital reports of adverse events confidential instead of releasing them to the public; one of the respondents did not appropriately check the item, so this was omitted from the analysis. All respondents except one (16/17) agreed that physicians should be required to inform patients about an adverse event that resulted in serious harm. All but two respondents (15/17) marked the most important cause of adverse events as mistakes made by physicians; the

remaining two marked two important causes (the question explicitly stated to choose only one answer): accordingly, their responses were omitted from the analysis.

Causes of adverse events. Among the four listed causes of adverse events, almost two-thirds of the respondents (11/17) marked health professionals not working together or not communicating as a team to be “very important” causes. Next, overwork, stress, or fatigue was marked as a “very important” cause of adverse events by less than half the respondents (7/17). Not having enough nurses and poor supervision of health care professionals were labeled as “somewhat important” causes of adverse events by two-thirds of the respondents (12/17 and 11/17, respectively).

Strategies for reducing adverse events. From four listed strategies for reducing adverse events, more than three-quarters of the respondents (13/17) marked the use of an online adverse event reporting system as at least “somewhat effective.” Providing a mechanism of coping support was marked by more than two-thirds of respondents (12/17) as at least “somewhat effective.” Having adverse events addressed in board certification exams was marked by more than half the respondents (10/17) as at least “somewhat effective.” However, one listed item was overwhelmingly perceived as a noneffective solution: three-quarters of the respondents (13/17) considered the development of a system to quickly and fairly compensate an injured patient as at least “not effective.”

Malpractice issues. Of the six listed items of malpractice concern, more than half the respondents (9/17) “strongly agreed” on the statement regarding the use of clinical judgment rather than technology to make decisions as a risky endeavor. The feeling of pressure from a day-to-day threat of malpractice litigation, as well as the ordering of tests/consultations to avoid the appearance of malpractice, were noted with “strong agreement” by more than half the respondents (9/17 and 9/17, respectively). Less than half the respondents (7/17) “strongly agreed” on asking for consultant opinions to reduce the risk of being sued. The concern of being involved in a malpractice case sometime in the next 10 years was “strongly agreed” upon by less than half the respondents (6/17) compared with the previous four items. Finally, the issue of having to make significant changes in practice patterns because of recent legal developments was decisively not “strongly agreed” upon by respondents (3/17). Results of all closed-ended responses are documented in Table 1.

Open-Ended Qualitative Analysis

Meaning of negligence. Responses to an open-ended query to assess how trainees defined negligence were qualitatively assessed for thematic content, based on the U.S. national standard of care definition. Three-quarters of the responses (12/16) directly or indirectly addressed the theme of substandard care. Select responses included: (a) “Failure to provide care equal to the standard of care in terms of thoroughness, timeliness”; (b) “Intentional lack of the appropriate attention to patient care or management, resulting in patient harm; not abiding by practice patterns considered to be the standard of care”; and (c) “Not providing the standard of care.” Some responses that addressed negligence other than substandard care included: (a) “Doing harm without consideration of alternative medical therapies or inattention to procedure/clinical management”; (b) “Willful action that causes damage”; and (c) “Not being aware of a medical problem or failing to search for it.” Table 2 contains all 16 responses.

Examples of adverse events due to negligence. Based on sample responses, three themes were developed: (1) a theme addressing both components of adverse events and negligence (5 examples); (2) a theme addressing negligence, but no adverse event injury (11 examples); and (3) a theme for responses with inadequate information or context for reliable assessment (12 examples). All 28 responses are provided in Table 3.

Statements addressing an adverse event due to negligence made up less than one-fifth of the responses (5/28). Some examples noted: (a) “Placing central line quickly without consideration for ultrasound guided peripheral line, and sustaining a complication”; (b) “Giving patient pneumothorax post-central venous access placement and not checking chest x-ray”; and (c) “Patient who dies after ruptured ectopic 2 days after coming to hospital with abdomen pain and sent/brought home without a urine pregnancy test.”

Statements addressing a negligence-based event made up less than half the responses (11/28). Some examples were: (a) “1-month old presents with fever, lethargy, no workup despite two presentations”; (b) “Intubating the esophagus and not recognizing it”; and (c) “Not giving antibiotics within 4 hours of a pneumonia presenting to the emergency room.”

Finally, statements addressing no clear theme made up 40 percent of the responses (12/28). Some examples included: (a) “Not calling cardiology for an ST-elevation myocardial infarction”; (b) “Failure to obtain a post-central line chest x-ray”; and (c) “Not ordering an appropriate test.”

Discussion

Overview

This statewide assessment found that EM trainees understood the importance of studying adverse events. The study also found that EM trainees were concerned with medical negligence. Previous ED work²⁶ has addressed EM trainee views on patient safety issues, but it did not clarify whether trainees practiced in a jurisdiction that followed the U.S. national standards of care or the locality rule. The jurisdiction in our study was defined to help create a more precise context for assessing patient safety issues associated with adverse events and negligence.

In our study, EM trainee respondents viewed adverse events as an important issue of clinical practice. This compares with another study¹⁷ assessing trainee views on adverse events in a different State. As frontline physicians, trainees are a target population that encounters many situation-specific events. Accordingly, the emotional and affective drive to improve patient care may be high within this population.

We found an overwhelming majority of the respondents (75 percent of 16 EM trainees) preferred that adverse event reporting be kept confidential and used only as a deterrent to future errors. This finding parallels the 2002 project, “U.S. Medical Error: Practicing Physicians and Public Views Study.”¹⁹ In that study, a representative sample of 831 U.S. physicians was assessed via mail and online survey; the majority (86 percent) of respondents chose the same option. Confidentiality of adverse event reports and their use as a feedback mechanism might be

Table 1. EM trainee closed-ended responses [Q1-8; Q11-17] & open-ended responses [Q18] (%)

Question	Not at all important	Not important	Somewhat important	Very important	Total N
1. <i>How important a problem do you think adverse events are in the United States today?</i> [N (%)]	0	0	7 (41)	10 (59)	17
2. <i>When people seek help from a health care professional, how often do you think adverse events are made in their care?</i> [N (%)]	Not often at all	Not often	Somewhat often	Very often	Total N
	0	7 (41)	9 (53)	1 (6)	17
3. <i>How often do you think patients are at least partially responsible for adverse events made in their care?</i> [N (%)]	Not often at all	Not often	Often	Very often	Total N
	2 (12)	7 (41)	7 (41)	1 (6)	17
4. <i>Should hospital reports of adverse events be confidential and only used to learn how to prevent future mistakes, OR should they also be released to the public?</i> [N (%)]	Confidential (used only to learn how to prevent future mistakes)		Also released to the public		Total N
	12 (75)		4 (25)		16
5. <i>Should physicians be required to tell patients if an adverse event resulting in serious harm is made in their care, OR not?</i> [N (%)]	Yes		No		
	16 (94)		1 (6)		17
6. <i>Which of the following do you think is the MOST important cause of adverse events? (Check one only.)</i> [N (%)]	Mistakes made by nurses	Mistake made by physicians	Mistakes made by other health care professionals		Total N
	0	15 (88)	0 (0)		15
7a. <i>Overwork, stress, or fatigue of health professionals</i> [N (%)]	Not at all important	Not important	Somewhat important	Very important	Total N
	0 (0)	0 (0)	10 (59)	7 (41)	17
7b. <i>Health professionals not working together or not communicating as a team</i> [N (%)]	0 (0)	0 (0)	6 (35)	11 (65)	17
7c. <i>Not enough nurses in hospitals</i> [N (%)]	0 (0)	2 (12)	12 (71)	3 (18)	17

Table 1. EM trainee closed-ended responses [Q1-8; Q11-17] & open-ended responses [Q18] (%) (continued)

Question	Not at all important	Not important	Somewhat important	Very important	Total N
<i>7d. Poor supervision of health care professionals [N (%)]</i>	0 (0)	4 (24)	11 (65)	2 (12)	17
<i>8a. Providing coping support, for the health care professional, when involved with an adverse event [N (%)]</i>	1 (6)	4 (24)	10 (59)	2 (12)	17
<i>8b. Developing a system that quickly and fairly compensates a patient injured by an adverse event [N (%)]</i>	6 (35)	7 (41)	3 (18)	1 (6)	17
<i>8c. Having adverse events be addressed in board certification examinations [N (%)]</i>	3 (18)	4 (24)	8 (47)	2 (12)	17
<i>8d. Using an online Adverse Event Report [N (%)]</i>	2 (12)	2 (12)	9 (53)	4 (24)	17
Questions 9, 10a, & 10b	On separate tables				
Question	Strongly Disagree	Disagree	Agree	Strongly agree	Total N
<i>11a. I have had to make significant changes in my practice patterns because of recent legal developments concerning medical care delivery [N (%)]</i>	3 (18)	3 (18)	8 (48)	3 (18)	17
<i>11b. I am concerned that I will be involved in a malpractice case sometime in the next 10 years [N (%)]</i>	0 (0)	0 (0)	11 (65)	6 (35)	17
<i>11c. I feel pressured in my day-to-day practice by the threat of malpractice litigation [N (%)]</i>	1 (6)	2 (12)	5 (29)	9 (53)	17
<i>11d. I order some tests or consultations simply to avoid the appearance of malpractice [N (%)]</i>	0 (0)	14 (24)	4 (24)	9 (53)	17

Table 1. EM trainee closed-ended responses [Q1-8; Q11-17] & open-ended responses [Q18] (%) (continued)

Question	Strongly Disagree	Disagree	Agree	Strongly agree	Total N	
11e. Sometimes I ask for consultant opinions primarily to reduce my risk of being sued [N (%)]	0 (0)	5 (29)	5 (29)	7 (41)	17	
11f. Relying on clinical judgments rather than on technology to make a decision is becoming riskier from a medico-legal perspective [N (%)]	0 (0)	1 (6)	7 (41)	9 (53)	17	
12. Have you ever been sued for malpractice? [N (%)]	Yes		No		Total N	
	0		100 % (17)		17	
13. Are you male or female? [N (%)]	Male		Female		Total N	
	11 (65)		6 (35)		17	
14. Which of the following describes your current training level? [N (%)]	Medical student	Intern	Resident	Attending	Other	Total N
	0 (0)	6 (35)	11 (65)	0 (0)	0 (0)	17
15. Which of the following describes your current training year? [N (%)]	1	2	3	4		Total N
	6 (35)	3 (18)	4 (24)	4 (24)		17
16. What is your current training hospital? [N (%)]	Rhode Island		Memorial ^a		Other	Total N
	17 (100)		0 (0)		0 (0)	17
17. How old are you? (years) [N (%)]	≤24	25 - 29	30 - 34	35 - 39	≥40	Total N
	0 (0)	9 (56)	6 (38)	1 (6)	0 (0)	16

Table 1. EM trainee closed-ended responses [Q1-8; Q11-17] & open-ended responses [Q18] (%) (continued)

	Open-ended responses	Total N
18. <i>If you were the researcher, what question would you like to ask providers about adverse events?</i>	1. 1) What do you think should be done to reduce adverse events? 2) Have you ever informed a patient of a mistake, accident, or poor outcome for which you felt responsible? Why or why not?	8
	2. Have a blank area for writing in suggestions in addition to just asking what we think about a preselected list of possible solutions.	
	3. How many mistakes with serious consequences have you made in the last 6 months and the last 2 years?	
	4. How many times have you <i>not</i> told a patient about an adverse event that affected them?	
	5. How to decrease them?	
	6. I would ask about other areas in which errors could be reduced than the ones in this survey.	
	7. N/A	
	8. What means of reducing adverse events have you undertaken in your practice?	

a Of note, the survey was erroneously printed with Memorial Hospital. Miriam Hospital was the intended category.

N = 17 respondents of 28 EM trainees: 61% sample response rate.

N = 28 respondents of 48 EM trainees in target population: 58% of target population present, and 35% target population response rate.

Table 2. EM trainee open-ended responses [Q9] to the meaning of negligence

Theme of substandard care (direct)	Theme of substandard care (indirect)	Theme of doing harm to a patient	Theme of other
"Establishment of physician-patient relationship, <i>failure to provide standard of care</i> resulting in poor outcome as a result of that failure."	"Failure to give medical care that is appropriate based on the patient's presentation, history, and physical exam that is available at that time."	"Doing harm without consideration of alternative medical therapies, or inattention to procedure/clinical management."	
" <i>Failure to provide care equal to the standard of care</i> in terms of thoroughness, timeliness."	"Lack of attention/action resulting in an adverse outcome."	"Doing something that harms a patient."	
" <i>Failure to provide the "standard of care"</i> for a given medical problem to a patient in a safe and timely manner."	"Making an obvious mistake, realizing there is a mistake, but taking no action or ignoring the mistake."		
"Intentional lack of the appropriate attention to patient care or management, resulting in patient harm: <i>not abiding by practice patterns considered standard of care.</i> "	"Not offering proper use of treatment when necessary due to absence, or failed application."		"Not being aware of a medical problem or failing to search for it."
" <i>Not holding the standard of care</i> knowingly."	"Overlooking important info (e.g., lab values, phys exam findings) or failing to seek that important info and proceeding with action that results in harm to patient."	"Willful action that causes damage."	
" <i>Not providing standard of care.</i> "	"Negligence is an action that results in an unwanted clinical result that occurs because of an error in judgment/ deviation from accepted protocols."		
Total N = 6	Total N = 6	Total N = 3	Total N = 1

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
<i>"Giving patient hematoma if placing central venous access by not checking coagulants."</i> Context: Placing central venous access in patient Standard of care: Checking coagulants Injury: Hematoma	<i>"1 month old presents with fever, lethargy, no workup despite two presentations"</i> Context: 1-month old infant patient presenting with fever, lethargy, and performing no workup Standard of care: Performing a workup	<i>"Continue to do a procedure knowing something is wrong"</i>
<i>"Placing central line quickly without consideration for ultrasound-guided peripheral line, and sustaining a complication."</i> Context: Placing a central line quickly in patient Standard of care: Ultrasound guided peripheral line Injury: Complication	<i>"Intubating the esophagus & not recognizing it"</i> Context: Esophageal intubation of patient Standard of care: Recognizing esophageal intubation	<i>"Failure to obtain a post-central line chest x-ray"</i>
<i>"Worsening subdural hematoma due to lack of Fresh frozen plasma and increased INR."</i> Context: Increased International Normalized Ratio of patient Standard of care: Administering fresh frozen plasma Injury: Worsening subdural hematoma	<i>"Not checking enzymes in a patient with multiple risk factors & complaining of chest pain."</i> Context: Patient with multiple risk factors and complaints of chest pain Standard of care: Checking cardiac enzymes	<i>"Not calling cardiology for an ST-elevation MI"</i>
<i>"Giving patient pneumothorax post central venous access placement and not checking chest x ray."</i> Context: Post Central venous access placement in patient Standard of care: Checking a chest x ray Injury: Undetected pneumothorax	<i>"Not giving antibiotics within 4 hours of a pneumonia presenting to the ER"</i> Context: Staff knowledge of patient diagnosis of pneumonia within 4 hours of ED presentation Standard of care: Timely antibiotic administration	<i>"Not ordering an appropriate test"</i>

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence (continued)

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
<i>"Patient who dies after ruptured ectopic 2 days after coming to hospital with abdomen pain & sent/brought to home without a urine pregnancy test."</i> Context: Female patient with abdominal pain Standard of care: Performing a urine pregnancy test Injury: Death from ruptured ectopic	<i>"Patient with wrist pain after a fall, no x-ray, wrist fracture ultimately decreased function."</i> Context: Patient has wrist pain after a fall Standard of care: Ordering an x-ray	<i>"Patient is not re-evaluated over extended period while changes go unnoticed"</i>
	<i>"Failing to check mark INRs of person who is bleeding and takes coumadin."</i> Context: Patient is bleeding and taking coumadin Standard of care: Checking of INR	<i>"The adverse events I've witnessed did not seem to be due to negligence"</i>
	<i>"Giving a known allergen to a patient"</i> Context: Knowledge of patient allergies Standard of care: Not administering an allergen	<i>"Failing to give antibiotics that are needed"</i> Context: Not known whether provider has knowledge or not of need to give antibiotics
	<i>"Ignoring a lab result that may potentially be life-threatening, because patient has already been discharged & it's late to forget about it."</i> Context: Obtaining a patient's lab data revealing potential life-threatening results Standard of care: Conducting follow-up	<i>"Not appropriately treating a medical condition by the standard of care"</i>
	<i>"Not giving steroids for severe asthma."</i> Context: Patient has severe asthma Standard of care: Provision of steroids	<i>"Not entertaining a possible treatment option"</i>

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence (continued)

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
	<i>"Not using a local anesthetic for a laceration repair."</i> Context: Provider conducting a laceration repair on a patient Standard of care: Provision of local anesthetics	<i>"Not sending coagulants on a head bleed on coumadin"</i>
	<i>"Failure to check medications delivered to patient."</i> Context: Delivery of medicine to a patient Standard of care: Checking medication is appropriate	<i>"Giving a patient a med they are allergic to"</i>
		<i>"Worst headache of life, diagnosis migraine, refusal for further followup"</i> Context: Patient with major headache, and diagnosis is migraine; not clear if patient or provider refuses further follow-up
Total N = 5	Total N = 11	Total N = 12

a Adverse event due to negligence is defined as an injury caused by medical management, rather than the patient's underlying disease, due to provider-based substandard care

b Negligence is defined as substandard care. Negligence may or may not produce patient injury; the former product is called an adverse event due to negligence, and the latter product is a near miss event

c Not known whether provider has or was given knowledge or not of patient's

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence (continued)

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
<i>"Giving patient hematoma if placing central venous access by not checking coagulants."</i> Context: Placing central venous access in patient Standard of care: Checking coagulants Injury: Hematoma	<i>"1 month old presents with fever, lethargy, no workup despite two presentations"</i> Context: 1-month old infant patient presenting with fever, lethargy, and performing no workup Standard of care: Performing a workup	<i>"Continue to do a procedure knowing something is wrong"</i>
<i>"Placing central line quickly without consideration for ultrasound-guided peripheral line, and sustaining a complication."</i> Context: Placing a central line quickly in patient Standard of care: Ultrasound guided peripheral line Injury: Complication	<i>"Intubating the esophagus & not recognizing it"</i> Context: Esophageal intubation of patient Standard of care: Recognizing esophageal intubation	<i>"Failure to obtain a post-central line chest x-ray"</i>
<i>"Worsening subdural hematoma due to lack of Fresh frozen plasma and increased INR."</i> Context: Increased International Normalized Ratio of patient Standard of care: Administering fresh frozen plasma Injury: Worsening subdural hematoma	<i>"Not checking enzymes in a patient with multiple risk factors & complaining of chest pain."</i> Context: Patient with multiple risk factors and complaints of chest pain Standard of care: Checking cardiac enzymes	<i>"Not calling cardiology for an ST-elevation MI"</i>
<i>"Giving patient pneumothorax post central venous access placement and not checking chest x ray."</i> Context: Post Central venous access placement in patient Standard of care: Checking a chest x ray Injury: Undetected pneumothorax	<i>"Not giving antibiotics within 4 hours of a pneumonia presenting to the ER"</i> Context: Staff knowledge of patient diagnosis of pneumonia within 4 hours of ED presentation Standard of care: Timely antibiotic administration	<i>"Not ordering an appropriate test"</i>

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence (continued)

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
<i>"Patient who dies after ruptured ectopic 2 days after coming to hospital with abdomen pain & sent/brought to home without a urine pregnancy test."</i> Context: Female patient presents with abdominal pain Standard of care: Performing a urine pregnancy test Injury: Death from ruptured ectopic	<i>"Patient with wrist pain after a fall, no x-ray, wrist fracture ultimately decreased function."</i> Context: Patient has wrist pain after a fall Standard of care: Ordering an x-ray	<i>"Patient is not re-evaluated over extended period while changes go unnoticed"</i>
	<i>"Failing to check mark INRs of person who is bleeding and takes coumadin."</i> Context: Patient is bleeding and taking coumadin Standard of care: Checking of INR	<i>"The adverse events I've witnessed did not seem to be due to negligence"</i>
	<i>"Giving a known allergen to a patient"</i> Context: Knowledge of patient allergies Standard of care: Not administering an allergen	<i>"Failing to give antibiotics that are needed"</i> Context: Not known whether provider has knowledge or not of need to give antibiotics
	<i>"Ignoring a lab result that may potentially be life-threatening, because patient has already been discharged & it's late to forget about it."</i> Context: Obtaining a patient's lab data revealing potential life-threatening results Standard of care: Conducting follow-up	<i>"Not appropriately treating a medical condition by the standard of care"</i>
	<i>"Not giving steroids for severe asthma."</i> Context: Patient has severe asthma Standard of care: Provision of steroids	<i>"Not entertaining a possible treatment option"</i>

Table 3. EM trainee open-ended responses [Q10a&b] to examples of adverse events due to negligence (continued)

Theme of adverse events due to negligence ^a	Theme of negligence only ^b (not sustaining an adverse event injury)	Examples with inadequate context/information ^c
	<i>"Not using a local anesthetic for a laceration repair."</i> Context: Provider conducting a laceration repair on a patient Standard of care: Provision of local anesthetics	<i>"Not sending coagulants on a head bleed on coumadin"</i>
	<i>"Failure to check medications delivered to patient."</i> Context: Delivery of medicine to a patient Standard of care: Checking medication is appropriate	<i>"Giving a patient a med they are allergic to"</i>
		<i>"Worst headache of life, diagnosis migraine, refusal for further followup"</i> Context: Patient with major headache, and diagnosis is migraine; not clear if patient or provider refuses further follow-up
Total N = 5	Total N = 11	Total N = 12

a Adverse event due to negligence is defined as an injury caused by medical management, rather than the patient's underlying disease, due to provider-based substandard care

b Negligence is defined as substandard care. Negligence may or may not produce patient injury; the former product is called an adverse event due to negligence, and the latter product is a near miss event

c Not known whether provider has or was given knowledge or not of patient's condition

"Standard of care" is based on: (1) widespread use by U.S. emergency physicians as the national care standard, and/or (2) professional medical society written guidelines (when available). Of note, (1) and (2) are NOT necessarily mutually exclusive.

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appropriate to improve EM trainee curricula on preventability vs. nonpreventability of adverse events. Incorporating confidential reporting systems may be suitable for EM residency trainee programs seeking to develop or enhance preexisting adverse event learning programs via improving dialogue about adverse events among trainees and other health care providers.²⁷

Emergency medicine trainee respondents also marked health professionals' overwork, stress, fatigue, and the inability to communicate as a team as important factors contributing to preventable adverse events that lead to serious patient harm. The "U.S. Medical Error Study"¹⁹ assessed this aspect and found that 50 percent of practicing physicians nationwide viewed these factors as barriers to improving patient safety. Our study specifically studied the term "adverse event." Accordingly, it may be that frontline EM trainees find stress and communication failures perpetuate preventable adverse events. Mechanisms that improve communication through teamwork approaches for the reduction of bedside errors and that reduce EM trainee stress need to be further investigated.

As an effective strategy to deter adverse events that result in serious harm, EM trainee respondents emphasized coping support for health professionals. Other medical specialties have used focus groups and surveys to assess trainee views on coping methods. A focus-group study²⁸ of the impact of stress on British surgery trainees found strategies to overcome stress-based adverse outcomes. These strategies included "stop and stand back," distancing technique, and self-talk. A survey study²⁹ of emotionally burnt-out U.S. internal medicine trainees found that, when they used discussion strategies to talk about trainee errors with clinical colleagues, family, and friends, it was beneficial. Coping strategies for EM trainees merit attention as demands of cognition and decisionmaking are substantial within the ED—i.e., a high degree of uncertainty, undifferentiated problems of varying acuity, and a need for expeditious intervention.^{30, 31}

EM trainee respondents overwhelmingly reported that the development of a system that quickly and fairly compensates a patient injured by an adverse event as noneffective. Methods to make restitution for patients who have experienced medical injury warrant further discussion. The lack of studies addressing litigation and EM practice is serious, as the number of claims filed against EM trainees, especially for diagnostic errors, is moderate to high.³² Future studies should investigate other avenues to address this issue in the ED arena.

Most EM trainee residents noted the following concerns as weighing against their work: the threat of malpractice litigation, the ordering of more tests to avoid the appearance of little testing (an assurance offensive tactic),³³ and the risk of clinical judgment. The risk of clinical judgment was a high concern in another study²⁰ that surveyed EM physicians, rather than EM trainees, in university-affiliated hospitals. In that study, EM physicians were grouped based on their risk-taking behaviors of lower, middle, and upper. Interestingly, all groups strongly agreed that relying on clinical judgment rather than on technology to make a diagnosis is becoming riskier. This similarity may stem from the nature of EM work in a volatile malpractice environment. That study, though, did not specify the target population's patient care standards; a comparison with incomplete context may lead to a conjecture. Specifying region- and State-based ruling jurisdictions may help future work improve the assessment of EM trainees and physicians concerns.

Rather than asking negligence-related questions based on vignettes, as has been done in previous empirical work,^{33, 34} in this study we asked open-ended questions to define negligence and provide examples of an adverse event due to negligence. Almost all of the EM trainee respondents were able to define negligence from a U.S. national standard of care viewpoint. However, respondents had difficulty providing examples of adverse events due to negligence. Most respondents provided examples of negligence but not negligence-based adverse events.

In those examples that correctly provided an adverse event due to negligence, the substandard component was incorrect diagnostic testing or inadequate assessment.

This result signaled that some EM trainees practicing under the U.S. national standard of care might be cognizant of missed diagnoses and inadequate assessments while making decisions. Missed and delayed diagnoses tend to be situation-specific events. Accordingly, when EM trainees are confronted with this in the absence of rules, they might be uncertain as to how to proceed. It is important, therefore, that the EM trainee remains under the supervision of an attending physician whenever such situations arise.³ Educational interventions and instructional exercises could further aid EM trainees in appropriate responses to adverse events due to negligence in situation-specific events.

Overall, the results from our study underscore practical ways to assess EM trainees' awareness of and attitudes about adverse events with respect to negligence in a State practicing the national standard of care. Published literature^{35, 36, 37} finds many pervasive barriers to adverse event research, especially due to the complexity of medicolegal rules across States and relative to the U.S. health care system. In the volatile ED setting, reporting may be further complicated by situation-specific events. Consequently, the EM specialty must consider this when planning interventions and board exams to improve patient safety.^{38, 39}

Limitations

Results from this study may not be generalizable to other States that might operate under a different standard of care. Additionally, we were unable to capture information on each trainee's ability to tolerate risk and uncertainty (e.g., risk-seeking vs. risk-avoiding personalities⁴⁰). The small sample size precluded an ability to conduct statistical significance analyses among the demographic variables and each of the four main theme-based questions. The questionnaire used examples of adverse event injuries, but it did not consider threshold levels. For instance, past large-scale epidemiologic work^{41, 42} has categorized adverse event outcomes into severity scale injury levels. Finally, the developed questionnaire was erroneously printed with a hospital (Memorial) where rotations did not occur. However, no respondents checked the "other" option to indicate rotation-based hospital work at area hospitals. Therefore, the error is presumed to have had a trivial effect on the validity of participants' responses.

Conclusion

This study assessed EM trainees' understanding and perceptions of adverse events and negligence in the State of Rhode Island, where practicing physicians and trainees abide by the

U.S. national standard of care. The physicians in training who were surveyed were cognizant of medical negligence and significantly concerned about its impact on clinical practice.

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Appendix: EM Trainee Patient Safety Questionnaire

PATIENT SAFETY QUESTIONNAIRE

DEFINITION OF ADVERSE EVENTS

Sometimes when people in the United States are ill and receive medical care, mistakes are made that result in complication or injury to a patient. When mistakes are made from medical management and NOT from the patient's underlying condition or disease, they are called adverse events. A few examples include pneumothorax, retained objects, hospital-acquired infections, decubitus ulcers, perioperative myocardial infarctions (MIs), line infections, and falls. The following questions are about adverse events.

1. How important a problem do you think adverse events are in the United States today?

- ☐ ₁ Not at all important
- ☐ ₂ Not important
- ☐ ₃ Somewhat important
- ☐ ₄ Very important

2. When people seek help from a health care professional, how often do you think such adverse events are made in their care?

- ☐ ₁ Not often at all
- ☐ ₂ Not often
- ☐ ₃ Somewhat often
- ☐ ₄ Very often

3. How often do you think patients are at least partially responsible for adverse events made in their care?

- ☐ ₁ Not often at all
- ☐ ₂ Not often
- ☐ ₃ Somewhat often
- ☐ ₄ Very often

4. Should hospital reports of adverse events be confidential and only used to learn how to prevent future mistakes OR should they also be released to the public?

- ☐ ₁ Confidential (only used to learn how to prevent future mistakes)
- ☐ ₂ Also released to the public

5. Should physicians be required to tell patients if a adverse event resulting in serious harm is made in their care, OR not?

- ☐ ₁ Yes
- ☐ ₂ No

Please continue to the next page

6. Which of the following do you think is the MOST important cause of adverse events? (Check one only.)

- ☐ ₁ Mistakes made by nurses
- ☐ ₂ Mistakes made by physicians
- ☐ ₃ Mistakes made by other health professionals

7. Following is a list of some things that could cause preventable adverse events that result in serious harm to the patient. For each one, please indicate how important you think it is as a cause of these preventable adverse events.

	Not at all important (1)	Not important (2)	Somewhat important (3)	Very important (4)
a) Overwork, stress, or fatigue of health professionals	☐	☐	☐	☐
b) Health professionals not working together or not communicating as a team	☐	☐	☐	☐
c) Not enough nurses in hospitals	☐	☐	☐	☐
d) Poor supervision of health professionals	☐	☐	☐	☐

8. Following is a list of some possible solutions that have been proposed for adverse events that result in serious harm. Please indicate how effective you think each one would be in reducing preventable adverse events.

	Not at all effective (1)	Not effective (2)	Somewhat effective (3)	Very effective (4)
a) Providing coping support, for the health professional, when involved with an adverse event	☐	☐	☐	☐
b) Developing a system that quickly and fairly compensates an injured patient by an adverse event	☐	☐	☐	☐
c) Having adverse events be addressed in board certification examinations	☐	☐	☐	☐
d) Using an online adverse event reporting system	☐	☐	☐	☐

Please continue to the next page

OTHER ASPECTS OF MEDICINE

9. What does negligence mean?

10. Based on your definition from Q9, please provide two examples of an adverse event due to negligence:

- a) _____
- b) _____

11. Following is a list of some legal aspects of medicine. Based on your clinical experience, please indicate your view regarding each statement.

	Strongly disagree (1)	Disagree (2)	Agree (3)	Strongly agree (4)
a) I have had to make significant changes in my practice pattern because of recent legal developments concerning medical delivery.	☐	☐	☐	☐
b) I am concerned that I will be involved in a malpractice case sometime in the next 10 years.	☐	☐	☐	☐
c) I feel pressured in my day-to-day practice by the threat of malpractice litigation.	☐	☐	☐	☐
d) I order some tests or consultations simply to avoid the appearance of malpractice.	☐	☐	☐	☐
e) Sometimes I ask for consultant opinions primarily to reduce my risk of being sued.	☐	☐	☐	☐
f) Relying on clinical judgment rather than on technology to make a diagnosis is becoming riskier from a medicolegal perspective.	☐	☐	☐	☐

12. Have you ever been sued for malpractice?

☐ ₁ Yes

☐ ₂ No

Please continue to the next page

DEMOGRAPHIC INFORMATION

13. Are you male or female?

- ☐ ₁ Male
☐ ₂ Female

14. Which of the following describes your current training level?

- ☐ ₁ Medical student
☐ ₂ Intern
☐ ₃ Resident
☐ ₄ Attending
☐ ₅ Other _____

15. Which of the following describes your current training year?

- ☐ ₁ 1
☐ ₂ 2
☐ ₃ 3
☐ ₄ ≥4

16. What is your current training hospital?

- ☐ ₁ Rhode Island
☐ ₂ Memorial
☐ ₃ Other _____

17. How old are you?

- ☐ ₁ 24 or less
☐ ₂ 25 to 29
☐ ₃ 30 to 34
☐ ₄ 35 to 39
☐ ₅ 40 or greater

18. If you were the researcher, what question would you like to ask to providers about adverse events?

Thank you very much for your time in participating in this study.

Please place this Questionnaire in the blank envelope provided. You may seal it.

Is There an Association Between Patient Safety Indicators and Hospital Teaching Status?

Peter E. Rivard, PhD; Cindy L. Christiansen, PhD; Shibe Zhao, MPH; Anne Elixhauser, PhD; Amy K. Rosen, PhD

Abstract

Objective: We compared discharges from teaching and nonteaching hospitals for relative rates and likelihood of potentially preventable adverse events. **Methods:** We applied Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) to adult male patient discharges from Veterans Health Administration (VA) and non-Federal hospitals, calculated risk-adjusted PSI rates, and compared the likelihood of incurring a PSI event, controlling for case-mix and hospital characteristics. **Results:** PSI rates were higher in major teaching hospitals than in nonteaching hospitals for iatrogenic pneumothorax and selected infections due to medical care in both VA and non-Federal hospitals and for postoperative pulmonary embolism or deep-vein thrombosis in non-Federal hospitals. In non-Federal hospitals, likelihood of a PSI event was higher in major teaching hospitals for decubitus ulcer and postoperative wound dehiscence in addition to those PSIs with higher stratified rates. **Conclusion:** Further research is needed on the relationship of residency programs to adverse events. Differences between VA and non-Federal hospitals suggest that if residency programs increase risk to patients, the causes may be actionable at the organizational level.

Introduction

Evidence suggests that quality of care is generally higher in teaching hospitals than in nonteaching hospitals.^{1, 2} However, the evidence is less clear on whether hospital teaching status affects patient safety—that is, studies of rates of potentially preventable adverse events report inconsistent findings in comparisons among teaching and nonteaching hospitals.^{3, 4, 5} In the study described here, the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) were used to compare rates of potentially preventable adverse events in teaching and nonteaching hospitals.

In an effort to isolate the effect of teaching hospital status on PSI rates, we conducted parallel analyses of discharge data from Federal (Veterans Health Administration, VA) and non-Federal (AHRQ Nationwide Inpatient Sample) hospitals; in both analyses, we controlled for other hospital characteristics and for patient-level risk factors.

The AHRQ PSIs are based on the Institute of Medicine (IOM) definition of an adverse event: “Injury resulting from a medical intervention ... not due to the underlying condition of the patient.”⁶ The PSIs have been developed with the goal of distinguishing injuries that often can be prevented from those that cannot, due to patient characteristics or condition and/or the riskiness

of the treatment. For example, older and sicker patients are often at higher risk for incurring adverse events.^{4, 7, 8} Consistent with Donabedian's model of patient care quality,⁹ preventable adverse events are often the result of process failures, which may in turn be related to structural characteristics, such as teaching status,^{3, 4, 6, 10} bed size,⁸ nurse staffing levels,^{11, 12} procedure volume,^{13, 14, 15} and other organizational characteristics of hospitals. Therefore, to examine the relationship between teaching status and PSI rates, it is important to account for both patient characteristics and structural characteristics that can affect processes and outcomes of care (Figure 1). Controlling for patient and facility characteristics other than teaching status, we used logistic regression analysis to estimate whether a hospitalization in a teaching hospital was more likely to incur a PSI event than a hospitalization in a nonteaching hospital.

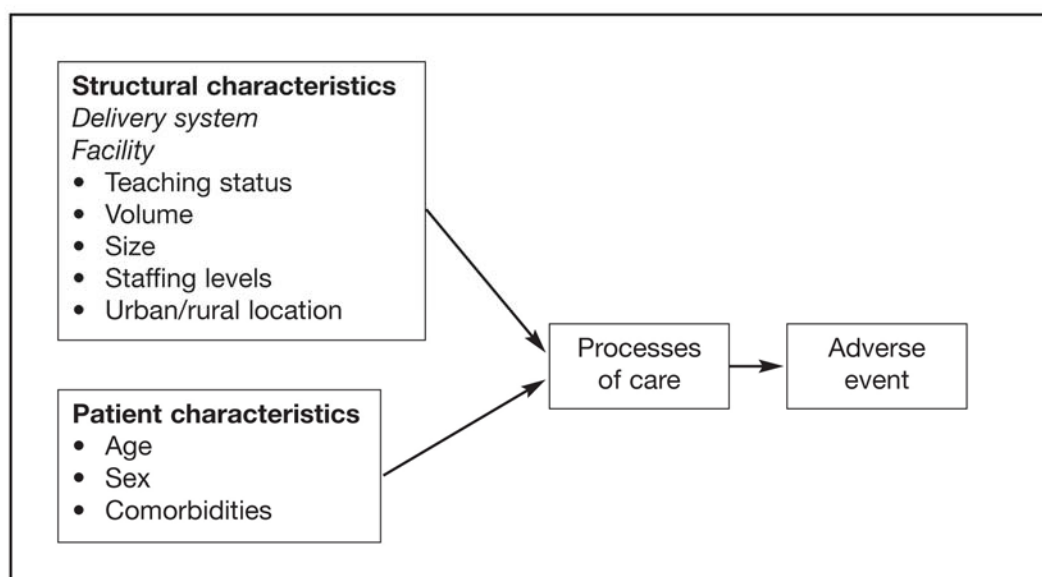


Figure 1. Conceptual framework: Predictors of adverse events.

Studies of quality of care, in contrast to those studies focused on safety only, suggest that quality is higher in teaching hospitals than in nonteaching hospitals.^{1, 2} This is true for both outcome measures, such as risk-adjusted mortality,^{16, 17, 18} and process measures.¹⁹ The pattern is not universal; for example, one study found higher 30-day risk-adjusted surgical morbidity and mortality in VA teaching hospitals;²⁰ another found higher rates of complications in non-Federal teaching hospitals, despite generally lower surgical mortality rates.²¹

Evidence on the relationship between hospital teaching status and risk of incurring a potentially preventable adverse event is much less consistent. The Harvard Medical Practice Study, using chart-abstracted data, found lower adverse event rates in teaching hospitals²² or no differences,²³ but subsequent studies, generally using administrative data, have found either no difference or higher rates in teaching hospitals. Defining “teaching hospital” as membership in the Association of American Medical Colleges (AAMC) Council of Teaching Hospitals (COTH), Iezzoni and colleagues found higher rates of complications overall in teaching hospitals. However, using accreditation by the Association of Colleges of Graduate Medical Education (ACGME) as the definition of teaching hospital, they found the opposite.⁸ Romano and colleagues⁴ found the highest risk-adjusted rates of most categories of potentially preventable adverse events but lower

rates of postoperative hip fracture at urban teaching hospitals. Other studies using the COTH-membership definition have found inconsistent relationships between teaching status and potentially preventable adverse events.^{3,5}

There is some correspondence of finding to method: when administrative data rather than chart-abstracted data are used, and when a narrower definition of teaching hospital (COTH membership) rather than a broader definition (ACGME accreditation or presence of residents) or a ratio of residents to beds is used, teaching hospitals appear to have higher adverse event rates. Therefore, the relationship between teaching status and patient safety bears further investigation, both because findings to date have not been consistent with research on the quality of care in teaching hospitals and because of the possibility of methodologic bias.

It is also important to learn whether teaching hospital characteristics—such as their relative size and volume, the complexity of care delivered in them, or more actionable aspects, such as coordination of care issues related to resident physicians—are at the root of apparent differences in adverse event rates. While the present study did not test all these specific potential explanations, it did control for size, it does include additional controls for patient demographics, and it does shed light on whether there seems to be a consistent trend across the two types of settings.

Two prior studies using administrative data found higher rates of selected infections due to medical care in teaching hospitals^{4,5}; one of those two studies and a third study found higher rates of postoperative pulmonary embolism or deep vein thrombosis (PE/DVT) in teaching hospitals.^{3,4} Based on these studies, we hypothesized that PSI events would be more likely to occur during hospitalizations at teaching facilities than at nonteaching facilities for these two PSIs. While a number of studies have also compared failure to rescue rates in teaching and nonteaching hospitals, the findings have been inconsistent across classes of patients^{21,24} and across studies,^{4,5} as have studies of rates of other PSIs in teaching and nonteaching facilities. Therefore, we hypothesized that PSI events would be neither more nor less likely in hospitalizations at teaching facilities than in those at nonteaching facilities for failure to rescue and for the remaining 11 PSIs in our study.

Our study first compared risk-adjusted PSI rates among major teaching, minor teaching, and nonteaching hospital strata, separately in the VA health care system and the private sector. We then tested our hypotheses concerning a patient's likelihood of experiencing a PSI event in major and minor teaching hospitals compared with nonteaching hospitals after controlling for patient-level and hospital-level characteristics, including nurse staffing levels and operating room procedure volume.

While previous studies have reported PSI rates in teaching and nonteaching hospitals, our study is distinctive in several ways. We tested the relationship between teaching status and 14 nonobstetric PSIs, and we performed multiple statistical analyses, whereas prior studies were limited to a few PSIs^{3,5} or did not present statistical analyses.⁴ Our study incorporated structural variables and compared the effects of teaching hospital status in VA and non-Federal hospitals under consistent and carefully controlled conditions. Given that VA and non-Federal patient populations differ considerably, both in demographics and health status,^{25,26} this afforded a new opportunity to see if any relationships between teaching status and PSIs were consistent across

differing groups of hospitals. While previous studies of teaching hospital effects on PSIs have relied on AHRQ Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS) data only, working with both VA and non-Federal discharge data afforded us an opportunity to increase the generalizability of our findings by applying comparable analytic methods to data from two very different health care delivery systems.

Methods

Data

The source of data for VA hospitalizations was the Patient Treatment File (PTF), an administrative database containing records of inpatient care delivered at VA facilities. Because each discharge record comprised four separate files and covered both acute and nonacute (e.g., skilled nursing) inpatient days, we built unified discharge records, with nonacute care excluded, for use with the AHRQ PSIs. The PTF and the methodology for creating acute-only records have been described elsewhere.^{27, 28} We included all VA acute inpatient care from hospitalizations with discharges in fiscal year 2004 (10/1/03 to 9/30/04), with certain exclusions described below. The source of data for non-Federal hospitalizations was the calendar year 2003 HCUP NIS, a stratified sample of all-payer acute inpatient care at non-Federal hospitals in 37 States.²⁹ The NIS sampling frame covered approximately 90 percent of all U.S. hospital discharges. We estimated PSI rates for the U.S. population by applying HCUP-supplied weights, based on the NIS sampling frame, to the NIS data.³⁰

The VA and non-VA patient populations differed in various ways, including age and sex composition (e.g., in the VA, no patients were under age 18, and 95 percent of patients were male)²⁵ and mental health status. Therefore, in order to make the VA and HCUP databases as comparable as possible, the discharges in this study were limited to adult male patients. The methodology for creating acute-only VA discharge records eliminated most pure psychiatric and substance abuse admissions from the VA data, which were assigned to Diagnosis Related Group (DRG) Major Diagnostic Categories (MDCs) 19 (mental disorders) and 20 (alcohol/drug use disorders). We, therefore, excluded all discharges in MDCs 19 and 20 from the NIS and VA datasets, except for DRG 424, a surgical DRG within the mental disorders MDC. We calculated the surgery volume for each facility based on counts of valid operating room procedures (as defined by DRG algorithms) in the VA and NIS discharge data.

We used secondary data sources to obtain information for both VA and NIS hospital structural characteristics. Data from the 2003 American Hospital Association (AHA) Annual Survey Database provided information on hospital teaching status, number of beds and nursing hours (estimated from Registered Nurse and Licensed Practical Nurse Full-Time Equivalents) per adjusted patient day.^{15, 31} COTH-member hospitals were categorized as major teaching hospitals; hospitals with ACGME accreditation only and without COTH membership were categorized as minor teaching hospitals; hospitals with neither major nor minor teaching status were categorized as nonteaching. Three bed-size strata were created: large (≥ 325 staffed beds), medium (200-324 beds) and small (< 200 beds). Because the VA sample was much smaller than the NIS, bed size stratum cut-points were driven by the need for an adequate count of VA facilities in each stratum. Information on Core-Based Statistical Areas (CBSA) from 2001 U.S. Census Bureau

data provided an indicator of metropolitan or nonmetropolitan location of hospitals.^{4, 32} Metropolitan areas were urban, with 50,000+ population; micropolitan areas had a concentrated population of 10,000 to 50,000; all others were non-CBSA. Because very few VA facilities were non-CBSA, we categorized VA and NIS facilities as metropolitan and nonmetropolitan. We linked facility-level AHA and CBSA data and surgical volume to the VA and NIS patient-level discharge records via facility identifiers.

Patient Safety Indicators

We used the AHRQ PSIs to estimate rates of potentially preventable adverse events in NIS and VA data. The PSIs, tools for assessing patient safety using administrative data, are evidence-based indicators of potentially preventable adverse events. As described elsewhere,^{4, 33, 34} the PSIs were developed by the UC-Davis-Stanford Evidence-based Practice Center under sponsorship from AHRQ. They were developed to maximize the likelihood that flagged events are preventable and to minimize false positives at the potential expense of some false negatives.^{4, 35} The PSIs have good face validity, and studies suggest that a number of the PSIs have good construct validity,^{4, 36, 37, 38} although recent analyses also suggest that several PSIs (decubitus ulcer, postoperative hip fracture, and postoperative PE /DVT) identified events that were present at the time of admission.^{17, 39, 40} For our analysis, we selected 14 of the 16 nonobstetric hospital-level AHRQ PSIs. We did not include complications of anesthesia or transfusion reaction because their low occurrence rates did not support meaningful comparison.

Data Adaptation

The VA data required modification in order to apply the AHRQ PSI software. The PSIs selected discharges based on data elements in the UB-92 (1992 Uniform Bill) hospital claim, some of which were absent in the VA discharge record. Therefore, we used algorithms, described in detail elsewhere,²⁸ to calculate variables, including principal procedure and admission type. For example, some PSI definitions excluded elective hospitalizations from the denominator and excluded cases based on length of stay. We used DRG and admission day to distinguish between elective and nonelective admissions. In addition, VA and NIS data were both modified to ensure that key data elements were as comparable as possible. For example, to minimize differences in methods for determining admission type or calculating length of stay that could affect PSI rates, we applied the VA algorithm for calculating admission type to both VA and NIS data, and we used the same length-of-stay definition for both NIS and VA hospitalizations (discharge date minus admit date, with a minimum of one.)

Analyses

All analyses were conducted separately on the VA and NIS database. First, risk-adjusted PSI rates were calculated by applying AHRQ's PSI software (Ver. 2.1, Rev. 3a)⁴¹ and the Statistical Analysis System (SAS[®]), Ver. 9.1, to the VA and NIS databases. Observed (raw) PSI rates (not reported here) were the number of hospitalizations flagged by the software with potential adverse events, divided by the number of hospitalizations at risk. The AHRQ software then computed risk-adjusted PSI rates using software-supplied parameter estimates from a logistic regression model that was developed by AHRQ on discharge data from all reporting hospitals in the 2002 HCUP State Inpatient Databases (SID) and included patient-level predictors of PSI events: age, sex, age-sex interactions, aggregated DRGs, and 27 comorbidities (modifications of the

Elixhauser comorbidity index).⁴² Thus, the risk-adjusted rates reflected the sampled hospitals' estimated PSI rates if they had the "average" case mix among all hospitals in the HCUP estimation sample. We generated overall risk-adjusted PSI rates for VA and NIS hospitals and then for VA and NIS hospitals stratified into major, minor, and nonteaching categories. We applied NIS sampling weights to the NIS data in calculating risk-adjusted rates, so that the rates would represent a national estimate. To determine whether rates differed across teaching hospital categories, we calculated 99 percent confidence intervals (CIs).

To compare the likelihood of a patient experiencing a PSI event in teaching and nonteaching hospitals, we created separate VA and NIS logistic regression models. The models were created at the discharge level of analysis, consistent with the conceptual framework shown in Figure 1. The models incorporated categorical variables for bed size and continuous variables for nurse staffing and operating room volume. The natural logarithm of operating room volume was used because the variable was positively skewed. We did not include geographic location in the model due to its high correlation with teaching status in the NIS sample and the small number of nonmetropolitan VA hospitals.

Each fixed-effects model also included a discharge-level (patient-specific) risk factor, calculated using all variables and weights from the AHRQ risk-adjustment software⁴¹ and used an offset. We used SAS Proc Survey Logistic to provide a more robust standard error and to account for NIS sampling weights and for hospital-level cluster effects in both NIS and VA data. Eleven NIS facilities (one major teaching, two minor teaching, eight nonteaching) were missing nurse staffing data; for these, we substituted the NIS mean value. One NIS small metropolitan nonteaching facility was excluded due to its high outlier nurse staffing value (2,934 nursing hours per patient day). We calculated the relative odds of experiencing a PSI, comparing major teaching to nonteaching and minor teaching to nonteaching hospitals. To determine whether the predictors of experiencing a PSI differed across teaching hospital categories, we calculated 99 percent confidence intervals for the estimated relative odds.

Results

VA and NIS facilities and discharges are described in Table 1. The VA data reported here are from 427,718 hospitalizations at 116 acute care VA hospitals in FY2004. This represents all but one of the 117 VA facilities providing acute inpatient care during fiscal year 2004; one hospital was excluded due to missing hospital-level data. The NIS data are from 2,381,353 unweighted hospitalizations at 992 non-Federal hospitals in 2003.

Teaching hospitals comprised a majority (75 percent) of the VA hospitals and a minority (17 percent) of the NIS hospitals; 52 percent of VA hospitals and only 5 percent of NIS hospitals were major teaching facilities. The majority of major and minor teaching hospitals were in metropolitan locations in both VA and NIS. However, while nonmetropolitan facilities comprised only 8 percent of VA nonteaching hospitals, they comprised 40 percent of NIS nonteaching hospitals. Compared with the VA, a greater proportion of NIS hospitals were small. However, in both VA and NIS, more of the major teaching hospitals were large in bedsize, rather than medium or small. In the VA, more of the minor teaching hospitals were small, but in the NIS, more of the minor teaching hospitals were large. Operating room volume and teaching

status were associated in both VA and NIS: major teaching hospitals had the highest volume and nonteaching hospitals the lowest.

The relationship of nurse staffing to teaching status differed between the VA and the NIS: nurse staffing was slightly higher in VA major and minor teaching hospitals than in VA nonteaching hospitals, whereas it was lower in major and minor NIS teaching hospitals than in NIS nonteaching hospitals. Nurse staffing was higher overall in the VA. Average length of stay (LOS) was longest in major teaching hospitals and shortest in nonteaching hospitals in both VA and NIS; in all but major teaching hospitals, LOS was slightly longer in VA facilities. Overall, VA patients were older than patients at NIS facilities. Mean patient age was lowest in major teaching hospitals in both VA and NIS. However, age differences across teaching hospital categories were very small in the VA and larger in the NIS.

Risk-adjusted PSI rates are shown in Table 2. In both the VA and the NIS, major teaching hospitals had higher risk-adjusted rates of iatrogenic pneumothorax and selected infections due to medical care than nonteaching hospitals. The greatest differences between major and nonteaching hospitals were for selected infections due to medical care: for VA and NIS, respectively, major teaching hospital rates were 2.6 and 3.8 per thousand and nonteaching were 1.0 and 1.7, respectively. NIS major teaching hospitals also had higher rates of postoperative PE/DVT than nonteaching hospitals. Differences in risk-adjusted rates between minor teaching hospitals and nonteaching hospitals were not significant in either the NIS or the VA.

Regression analysis results are shown in Table 3. There were statistically significant differences between major teaching and nonteaching hospitals for five PSIs in the NIS and for none in the VA; there were no significant differences for minor teaching hospitals in either the VA or the NIS. In the NIS, a PSI was significantly more likely in a major teaching hospital than in a nonteaching hospital for decubitus ulcer (42 percent), iatrogenic pneumothorax (45 percent), selected infections due to medical care (37 percent), postoperative PE/DVT (70 percent), and postoperative wound dehiscence (58 percent).

The results were consistent with our hypotheses that selected infections due to medical care and postoperative PE/DVT would be more likely, but for major teaching hospitals only. The results were inconsistent with our hypotheses that PSIs would be neither more nor less likely in teaching hospitals for decubitus ulcer, iatrogenic pneumothorax, and postoperative wound dehiscence.

Table 1. Characteristics of VA and NIS samples: Hospitals and discharges^a

Characteristics	Major teaching		Minor teaching		Nonteaching		Total	
	VA	NIS	VA	NIS	VA	NIS	VA ^b	NIS
Hospitals								
Number (%) of hospitals	60 (52)	54 (5)	27 (23)	120 (12)	29 (25)	818 (82)	116 (100)	992 (100)
By bed size category [N (%)]								
Large (≥325 beds)	27 (23)	39 (4)	7 (6)	51 (5)	6 (5)	57 (6)	40 (35)	147 (15)
Medium (200 - 324 beds)	17 (15)	8 (1)	7 (6)	39 (4)	3 (3)	90 (9)	27 (23)	137 (14)
Small (1-199 beds)	16 (14)	7 (1)	13 (11)	30 (3)	20 (17)	671 (68)	49 (42)	708 (71)
By geographic location [N (%)]								
Metropolitan	59 (51)	48 (5)	25 (22)	105 (11)	17 (17)	417 (42)	101 (87)	570 (57)
Nonmetropolitan	1 (1)	6 (1)	2 (1)	15 (2)	12 (8)	401 (40)	15 (13)	422 (43)
Mean RN + LPN hours per patient day	12.8	9.4	12.7	8.5	12.3	10.9	12.7	10.5
Mean OR procedures per year	1,919.6	6,202.4	863.5	2,766.2	227.6	775.9	1,284.4	1,350.0
Discharges^c								
Number	309,272	480,052	79,716	559,591	38,730	1,341,710	427,718	2,381,353
Mean patient age across discharges (years)	65.2	57.9	66.1	60.7	66.1	62.9	65.4	61.4
Mean length of stay (days)	6.0	6.0	5.8	5.3	5.2	4.9	5.8	5.0

a VA: Fiscal Year 2004 (10/1/03-9/30/04); NIS: Calendar Year 2003; NIS sampling weights are not applied to NIS data shown in this table.

b Of 117 VA hospitals, one is excluded due to missing AHA data.

c Includes male patients aged ≥18 years.

VA = Veterans Health Administration

NIS= Nationwide Inpatient Sample

Table 2. Risk-adjusted PSI rates (99% CI) by hospital teaching status: VA fiscal year 2004 and NIS calendar year 2003^{a, b}

PSI	Major teaching		Minor teaching		Nonteaching		Overall	
	VA	NIS	VA	NIS	VA	NIS	VA	NIS
Death in low mortality DRGs	2.6 (1.8 - 3.5)	1.2 (0.6 - 1.8)	1.1 (0.0 - 2.3)	1.4 (0.9 - 2.0)	3.7 (1.2 - 6.2)	2.1 (1.6 - 2.6)	2.5	1.8
Decubitus ulcer	20.74 (18.0 - 23.5)	29.61 (24.6-34.7)	20.2 (16.0 - 24.4)	25.2 (21.5 -28.9)	17.7 (11.2 - 24.1)	23.3 (21.1 - 25.5)	20.4	25.2
Failure to rescue	126.1 (114.6 - 137.7)	120.0 (110.2 – 129.8)	120.0 (102.4-137.5)	128.0 (116.9 -139.0)	126.9 (101.3 - 152.4)	118.8 (112.8 - 124.8)	125.1	121.4
Foreign body left in during procedure	0.1 (0.1 - 0.2)	0.1 (0.1 - 0.2)	0.2 (0.0 - 0.4)	0.1 (0.0 - 0.1)	0.1 (0.0 - 0.3)	0.1 (0.0 - 0.1)	0.1	0.1
Iatrogenic pneumothorax	1.4 ^c (1.1 - 1.7)	1.2 ^c (1.0 -1.4)	1.3 (0.8 -1.9)	0.8 (0.7 - 1.0)	0.7 (0.2 -1.1)	0.6 (0.6 - 0.7)	1.3	0.8
Infection due to medical care	2.6 ^c (2.0 - 3.2)	3.8 ^c (3.1 - 4.5)	2.3 (1.1 - 3.6)	2.1 (1.7 - 2.6)	1.0 (0.3 - 1.7)	1.7 (1.5 - 2.0)	2.4	2.2
Postoperative hip fracture	0.3 (0.2 - 0.5)	0.3 (0.2 - 0.4)	0.3 (0.0 - 0.8)	0.3 (0.2 - 0.5)	0.4 (0.0 -1.3)	0.3 (0.2 - 0.4)	0.3	0.3
Postoperative hemorrhage or hematoma	3.0 (2.2 - 3.9)	2.4 (2.0 - 2.8)	3.2 (2.0 - 4.4)	2.1 (1.7 - 2.5)	1.6 (0.2 - 2.9)	2.0 (1.8 - 2.3)	3.0	2.1
Postoperative physiologic/metabolic derangement	1.7 (1.0 - 2.3)	1.9 (0.8 - 3.0)	2.1 (0.0 - 4.2)	1.3 (0.7 - 1.9)	0.8 (0.0 - 2.0)	1.1 (0.8 - 1.4)	1.7	1.4
Postoperative respiratory failure	4.1 (2.5 - 5.6)	6.6 (2.1 - 11.0)	2.9 (0.0 - 6.0)	4.2 (2.6 - 5.7)	3.9 (0.0 – 9.0)	4.4 (3.6 - 5.2)	3.9	4.9
Postoperative PE/DVT	11.1 (9.0 - 13.3)	14.7 ^c (9.6 - 19.8)	9.3 (6.5 - 12.2)	8.6 (7.1 - 10.1)	7.3 (3.4 - 11.3)	7.5 (6.8 - 8.2)	10.7	9.6

Table 2. Risk-adjusted PSI rates (99% CI) by hospital teaching status: VA fiscal year 2004 and NIS calendar year 2003^{a, b} (continued)

PSI	Major teaching		Minor teaching		Nonteaching		Overall	
	VA	NIS	VA	NIS	VA	NIS	VA	NIS
Postoperative sepsis	9.9 (7.2 - 12.6)	15.1 (10.2 - 20.0)	7.3 (1.6 - 13.0)	11.9 (8.4 - 15.3)	8.8 (1.3 - 16.4)	11.9 (9.5 - 14.3)	9.4	12.6
Postoperative wound Dehiscence	4.5 (2.6 - 6.4)	1.9 (0.8 - 3.0)	4.3 (0.0 - 10.2)	1.9 (0.9 - 2.9)	9.7 (3.2 - 16.1)	1.2 (0.6 - 1.8)	4.8	1.6
Accidental puncture or laceration	3.9 (2.9 - 4.9)	4.1 (2.9 - 4.9)	4.4 (2.8 - 6.0)	3.5 (2.9 - 4.2)	3.2 (2.0 - 4.4)	2.9 (2.6 - 3.2)	3.9	3.3

a Rates are per 1,000 discharges at risk (99% CIs).

b Lowest rates among major-, minor-, and nonteaching hospitals are **highlighted in bold**, separately within VA and NIS.

c 99% CIs for teaching and nonteaching hospitals do not overlap.

VA = Veterans Health Administration

NIS = National Inpatient Sample

DRGs = Diagnosis-related groups

PE = Pulmonary embolism

DVT = Deep vein thrombosis

Table 3. Odds (99% CI)^a of incurring a PSI in major and minor teaching hospitals relative to nonteaching hospitals^{b, c}

PSI	Major teaching/Nonteaching		Minor teaching/Nonteaching	
	VA	NIS	VA	NIS
Death in low mortality DRGs	0.90 (0.40 - 2.01)	0.80 (0.54 - 1.19)	0.52 (0.23 - 1.17)	0.85 (0.64 - 1.13)
Decubitus ulcer	1.49 (0.86 - 2.60)	1.42 ^a (1.15 - 1.74)	1.43 (0.87 - 2.36)	1.10 (0.93 - 1.30)
Failure to rescue	1.12 (0.74 - 1.71)	0.99 (0.86 - 1.13)	0.96 (0.65 - 1.43)	1.07 (0.95 - 1.21)
Foreign body left in during procedure	0.57 (0.07 - 4.52)	1.56 (0.89 - 2.75)	0.95 (0.12 - 7.66)	1.20 (0.70 - 2.06)
Iatrogenic pneumothorax	1.63 (0.59 - 4.51)	1.45 ^a (1.13 - 1.85)	1.75 (0.65 - 4.70)	1.13 (0.92 - 1.39)
Infection due to medical care	1.22 (0.54 - 2.79)	1.37 (1.12 - 1.67)	1.40 (0.70 - 2.82)	1.00 (0.84 - 1.19)
Postoperative hip fracture	0.56 (0.04 - 6.96)	1.01 (0.54 - 1.92)	0.38 (0.02 - 5.96)	1.05 (0.63 - 1.77)
Postoperative hemorrhage/hematoma	1.26 (0.40 - 3.90)	1.23 (0.96 - 1.57)	1.43 (0.49 - 1.49)	1.06 (0.85 - 1.31)
Postoperative physiologic/metabolic derangements	1.65 0.10 – 28.17	1.38 (0.80 - 2.38)	2.18 (0.14 - 33.69)	1.10 (0.72 - 1.67)
Postoperative respiratory failure	2.17 (0.41 - 11.48)	1.23 (0.70 - 2.16)	1.46 (0.28 - 7.67)	0.88 (0.65 - 1.20)
Postoperative PE/DVT	1.81 (0.94 - 3.49)	1.70 ^a (1.15 - 2.51)	1.52 (0.80 - 2.89)	1.07 (0.89 - 1.28)
Postoperative sepsis	0.76 (0.25 - 2.25)	1.21 (0.83 - 1.75)	0.64 (0.19 - 2.19)	0.95 (0.70 – 1.29)
Postoperative wound dehiscence	0.53 (0.19 - 1.51)	1.58 (1.01 - 2.48)	0.55 (0.18 - 1.67)	1.40 (0.96 - 2.05)
Accidental puncture/laceration	0.61 (0.21 - 1.74)	1.18 (0.91 - 1.53)	1.06 (0.38 - 2.95)	1.19 (0.96 - 1.48)

a $P < 0.01$.

b VA Fiscal Year 2004 and NIS Calendar Year 2003; (99% CI).

c From logistic regression: controlling for hospital bed size, operating room volume, and nursing hours per adjusted patient day.

VA = Veterans Health Administration

NIS= Nationwide Inpatient Sample

DRGs = Diagnosis-related groups

PE = Pulmonary embolism

DVT = Deep vein thrombosis

Discussion

Comparison of teaching hospital and nonteaching hospital rates for 14 PSIs using data from two sets of hospitals with different structural characteristics and patient populations yielded moderately consistent results. Risk-adjusted PSI rates were either not different or higher in major teaching facilities compared to nonteaching facilities in both the VA and the NIS. Our findings of higher rates of selected infections due to medical care and postoperative PE/DVT in non-Federal major teaching hospitals are similar to prior studies.

Findings from our regression analyses suggest that, after accounting for other hospital characteristics and for patient risk factors, a hospitalization at a teaching facility may have similar or greater likelihood of a PSI event in comparison with hospitalization at a nonteaching facility. With a few exceptions, findings from regression analyses were consistent with the findings based on bivariate comparisons of risk-adjusted PSI rates. The inclusion in our models of variables representing hospital structural characteristics—bed size, operating room procedure volume, and nurse staffing—did not appear to have a substantial effect on the comparison between teaching and nonteaching facilities.

In a comparison of risk-adjusted rates and the regression analyses, the VA had two significant rate differences between major and nonteaching facilities and no significant differences in the regression. The NIS had three significant rate differences between major and nonteaching facilities and five significant differences (including the three PSIs with significant rates differences) in the regression.

PSI events were more likely in major teaching hospitals only in the NIS, for three medical-surgical PSIs (decubitus ulcer, iatrogenic pneumothorax, and selected infections due to medical care) and two postoperative PSIs (postoperative PE/DVT and postoperative wound dehiscence). We found no commonality among these five PSIs that suggests a single explanation. For example, some indicators, such as pneumothorax and wound dehiscence, are procedure-related and potentially more sensitive to residents' involvement in care. Others, such as decubitus ulcers, are likely more sensitive to nurse staffing and care. The five indicators cover a range from those more attributable to system weaknesses to those more attributable to individual technical error. Some indicators, such as decubitus ulcers and postoperative PE/DVT, are more sensitive to limitations of administrative data, such as lack of a "Present on Admission" data element, while others are less so.^{17, 39, 40}

While the stratified risk-adjusted rates showed no patterns across PSIs that distinguished VA from NIS on the apparent effects of teaching hospitals on PSI rates, in the logistic regression, which controls for other structural characteristics, major teaching hospital status increased the odds of incurring a PSI in the NIS for five PSIs but did not have a significant effect in the VA. Further research is needed to learn whether these differences between VA and non-Federal hospitals are associated with actionable differences, such as use of safety protocols that are tailored to the involvement of residents in patient care or in orientation, training, and supervision of residents.

Limitations

Despite the use of two large datasets for our study, the data and methods are characterized by certain limitations. For some PSIs, events are so infrequent on average in the VA that 1 year's data may not be adequate to detect "true" underlying event rates. The fact that the regression analysis yielded statistical significance for several PSIs in the NIS and for no PSIs in the VA may be indicative of limitations in statistical power. In general, factors such as limited clinical information and variation in coding limit the potential for adverse event detection using administrative data in comparison with chart-abstracted data.^{38, 43} Finally, our attempt to make the NIS and VA datasets more comparable by limiting our analysis to discharges of males aged 18 and older may limit the generalizability of our conclusions to the broader population.

Findings from our regression analyses in particular must be interpreted with caution. None of the hospital structural variables was a significant predictor of PSI events in our models for more than half of the PSIs in either the VA or the NIS, and the direction of a given variable's effect differed somewhat across PSIs and between VA and NIS models (results not shown). This was particularly surprising in the case of the nurse staffing variable, given evidence in the literature of a relationship between nurse staffing and both quality and safety. However, that evidence also suggests that the key nurse staffing predictor of patient safety may be RN-only staffing or nursing skill mix rather than total RN plus LPN staffing.^{11, 12, 15} There is also evidence that the AHA nurse staffing data used in our study may overstate staffing in small, rural and nonteaching hospitals.³¹ The hospital-level bed size and procedure volume variables we used may be too general to be valid predictors of adverse event rates: studies of the relationship between procedure volume and quality and safety suggest that the meaningful relationships are at the levels of specific providers and types of procedures.⁴⁴

Implications for Research

This study adds to the literature on the relationship between a hospital's teaching status and patient safety. We found significantly higher likelihood of a patient safety event occurring in major teaching hospitals relative to nonteaching hospitals for five PSIs in a nationwide sample of discharges from 992 non-Federal hospitals. Findings were not statistically significant in one year's discharges from 116 VA hospitals. Although it is possible that quality of care may be more homogeneous across VA facilities, the lack of significant differences between teaching and nonteaching facilities in the VA may be attributable to low statistical power, which would have constrained our ability to detect any differences.

It will be important to extend our exploration of whether higher PSI rates in teaching hospitals are the direct result of the presence of residency training programs, or if they are the result of an interaction between teaching status and other aspects of hospital structure. In addition, if higher risk-adjusted adverse event rates are, in fact, associated with the presence of residency training programs, then it would be important to discern whether differences in documentation and coding or differences in structures or processes of care account for the higher rates. Recent studies of the impact of changes in resident teaching hours^{45, 46, 47} are examples. The fact that the major teaching hospital effects on PSIs differed between the NIS and the VA suggests that if residency programs increase risk to patients, the causes may well be actionable at the organizational level. Finally, further research is needed to assess the adequacy of risk adjustment in the comparison between teaching and nonteaching hospitals.

The potential policy implications of findings such as ours also underscore the need for studies testing the criterion validity of the PSIs. In addition, given the potential limitations of administrative data in detecting adverse events, it is also important for future research to use other sources, such as chart-abstracted data, to address questions similar to those addressed here.

Conclusion

This study was among the first to compare teaching and nonteaching hospitals using a regression model that incorporates hospital structural characteristics as controls and to report comparable analyses on data from VA and non-Federal hospitals. Our conclusion that PSI events may be as likely or more likely in teaching hospitals compared with nonteaching hospitals has important implications both for the further study and development of the PSIs and other tools for assessing patient safety using administrative data and for the understanding of structural factors affecting patient safety.

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Organizational Behavior Management in Health Care: Applications for Large-Scale Improvements in Patient Safety

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Abstract

Medical errors continue to be a major public health issue. This paper attempts to bridge a possible disconnect between behavioral science and the management of medical care. Epidemiologic data on patient safety and a sampling of current efforts aimed at patient safety improvement are provided to inform relevant applications of organizational behavior management (OBM). The basic principles of OBM are presented, along with recent innovations in the field that are relevant to improving patient safety. Safety-related applications of behavior-based interventions from both the behavioral and medical literature are critically reviewed. Potential OBM targets in health care settings are integrated within a framework of those OBM techniques with the greatest possibility of improving patient safety on a large scale.

Introduction

Organizational behavior management (OBM) focuses on what people do, analyzes why they do it, and then applies an evidence-based intervention strategy to improve what people do. The relevance of OBM to improving health care is obvious. While poorly designed systems contribute to most medical errors, OBM provides a practical approach for addressing a critical component of every imperfect health care system—behavior. Behavior is influenced by the system in which it occurs, yet it can be treated as a unique contributor to many medical errors, and certain changes in behavior can prevent medical error. This paper reviews the principles and procedures of OBM as they relate to reducing medical error and improving health care.

First, we need to define medical error. This task is neither simple nor straightforward because the definition of a medical error varies markedly across different hospitals and health care systems. For example, the National Patient Safety Foundation¹ defines a “health care error” as: “[A]n unintended health care outcome caused by a defect in the delivery of care to a patient.” According to the Institute of Medicine (IOM), a health care error is “a problem in the *process* of care itself or failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”² Thus, while some refer to medical error as any *act*, or failure to act, which results in harm to a patient, others refer to medical error as any action within the process of care that may have the potential to cause harm. This latter prevention-focused definition best fits the application of OBM.

This distinction is relevant to interpreting the patient safety literature, since research results typically focus on frequencies of adverse events (outcomes) rather than process-level errors (or

behaviors) occurring during health care. However, a single error does not guarantee that a patient will experience a medical injury. An examination of case studies of errors presented in the *Annals of Internal Medicine* suggests as many as 17 separate individual errors may occur before a patient is actually harmed.³ Thus, process measures need to be addressed in designing patient safety programs.

Dimensions of Medical Errors

The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators⁴ (PSIs) are the most commonly used measures of patient safety performance. They include 16 classes of patient safety incidents (Table 1). Although this is a useful classification system, prevention requires a specification of actions leading to these types of patient safety incidents.

Leape⁵ has provided a brief and practical typology of medical errors that includes four main domains:

1. Diagnostic.
2. Treatment.
3. Preventive.
4. Other.

Within these domains is a more specific list of 14 types of errors that can be seen as a hierarchy of severity (Table 1). In comparing these two methods of classification, the difference between outcome and process measurement is salient. Although various patient safety incidents could be caused by a number of factors, Leape's taxonomy reflects specific problem behaviors.

The most common types of preventable errors resulting in adverse events have been identified as: technical errors (44 percent); errors in diagnosis (17 percent); failures of prevention (12 percent); and errors in the use of a drug (10 percent).⁵ In terms of overall numbers, preventable technical complications of surgery (10,891) and wound infections (9,659) were most common, indicating areas where hospitals should focus their intervention efforts.

A more recent report⁶ suggests that almost 60 percent of all patient safety incidents include: failure to rescue (delayed diagnosis and treatment); decubitus ulcer (bed sores); or postoperative sepsis (blood infection). This report also suggests the most lethal patient safety incidents—or those most closely associated with mortality—include failure to rescue and unexpected death during a low-risk hospitalization.

Between 1995 and 2000, an increasing trend of certain types of events suggested a need for special attention. These included postoperative medical- and nursing-related adverse events, such as respiratory failure (31 percent); infection due to medical care (14 percent); decubitus ulcer (19 percent); septicemia (41 percent); thromboembolism (42 percent); and accidental punctures and lacerations (7 percent).⁷

Certain signs of progress are also noteworthy. Specifically, anesthesia reactions and complications decreased by 18 percent, and foreign bodies left during procedures were reduced

Table 1. Two widely used taxonomies for patient-safety incidents and medical errors

AHRQ PSIs		Leape Typology of Errors	
		Domain	Error
1. Accidental puncture or laceration			
2. Complications of anesthesia			
3. Death in low-mortality Diagnostic Related Groupings (DRGs)			
4. Decubitus ulcer	Diagnostic		1. Error or delay in diagnosis
5. Failure to rescue			2. Failure to employ indicated tests
6. Foreign body left during procedure			3. Use of outmoded tests or therapy
7. Iatrogenic pneumothorax			4. Failure to act on the results of monitoring or testing
8. Selected infections due to medical care			
9. Postoperative hemorrhage or hematoma			5. Technical error in the performance of a procedure
10. Postoperative physiologic and metabolic derangement			6. Error in administering treatment
11. Postoperative pulmonary embolism or deep vein thrombosis	Treatment		7. Error in dose or method of use of a drug
12. Postoperative respiratory failure			8. Avoidable delay in treatment or in response to an abnormal test
13. Postoperative sepsis			9. Inappropriate care
14. Postoperative wound dehiscence			
15. Transfusion reaction			
16. Birth trauma and obstetric trauma (3 types related to delivery methods)			10. Failure to provide indicated prophylactic treatment
	Preventive		11. Inadequate treatment monitoring or followup
			12. Failure in communication
	Other		13. Equipment failure
			14. Other systems failure

by 7 percent. While small, these improvements are encouraging in terms of current proactive efforts to address patient safety.

Preventing Errors in Health Care

As depicted in Figure 1, patient safety outcomes are influenced by a number of factors, including several sources external to the hospital (e.g., relevant legislation, agency mandates, and special interest groups). Within-hospital sources include the health care culture, the institutional patient safety agenda, the specific environmental context in which the health care worker operates (which includes the patient), and the focus of this paper—the behavior of the caregiver. These multiple influences are, in turn, affected by patient safety outcomes in a reciprocal system most certainly affected by innumerable additional factors in varying degrees.

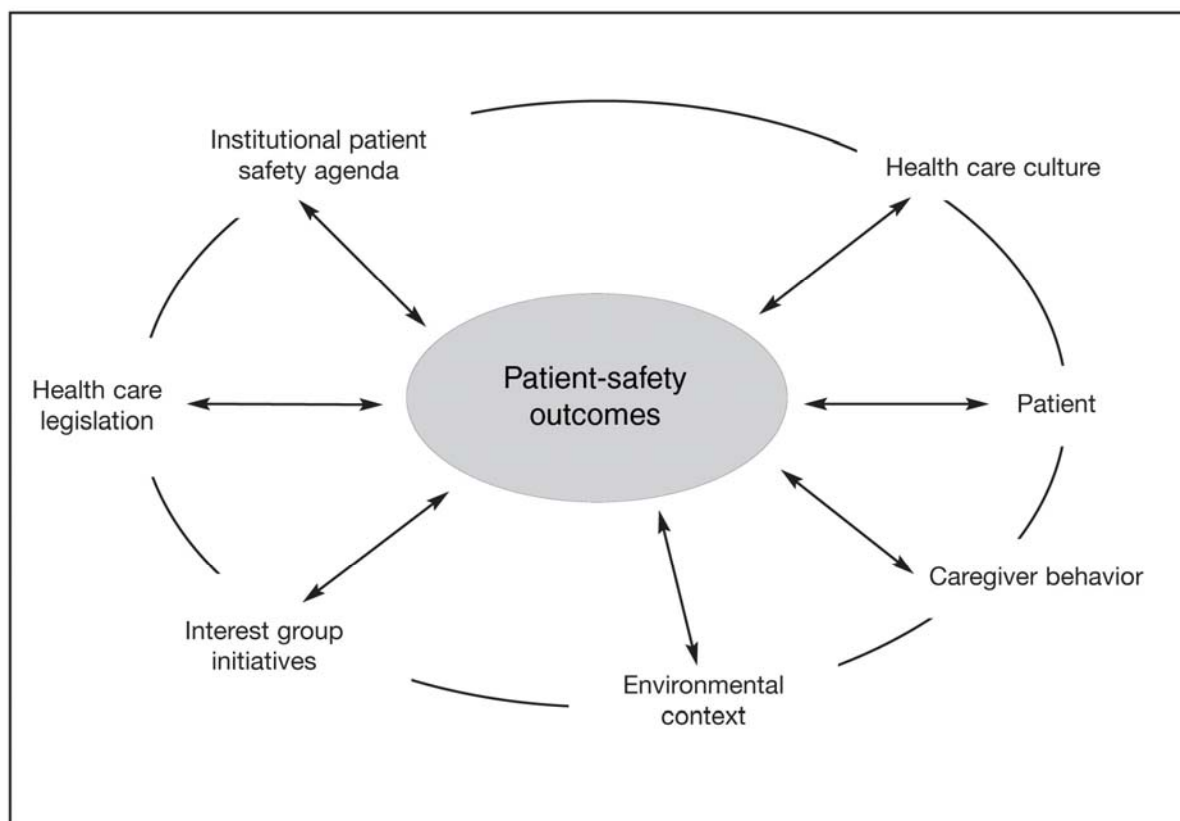


Figure 1. An overall model of patient safety. Domains of influence relevant to OBM are shown enlarged and in italics.

Errors Addressed by System Change

Medical mistakes caused by latent errors, such as similar sounding drug names or delays in treatment due to lack of staff, are best addressed by system change. For example, it would be reasonable to expect these errors to be reduced if drug names were altered and more personnel were hired. Yet, additional room for improvement often remains even after quality gains from system change are realized.

Advances in infection control often have been addressed by increasing hand hygiene among caregivers. One relevant system change has been the installation of antibacterial, alcohol-based rub dispensers in patient rooms and near sinks. This change should lead to improved infection control, because alcohol rubs reduce the volume of infection-related microorganisms by 88 percent, compared to hand washing with soap and water, which reduces the volume by only 49 percent.⁸

The use of information technology (IT) is a key component of system change for error reduction. For example, implementation of “computerized physician order entry” (CPOE) and clinical decision support systems are among specific IT practices recommended to help reduce errors.⁹ Early evaluations suggest that implementation of CPOE leads to significant improvements in patient safety.^{10, 11, 12, 13, 14, 15} Thus, a major contributor to medical errors (e.g., physicians’ poor handwriting) is removed from the process. However, despite these promising initial findings, adoption of CPOE has been slow.¹⁶

Unfortunately, system changes often are not readily embraced by all caregivers. This puts administrators in the uncomfortable position of choosing whether to make protocol improvement voluntary or mandated. Some may see this as a nonissue, saying simply, “Make them do it, or else....” However, this assumption fails to take into account the tendency of forced change to elicit reactance.¹⁷ Consistent with widespread calls for improving the health care culture, caregivers need to be supportive of autonomy¹⁸ and to feel empowered to change behaviors that could harm their patients. Patient safety can be engineered into a health care system, but peak performance also requires systematic attention to environmental hazards and at-risk behaviors related to patient safety.

This paper reviews practical solutions to motivating the adoption and sustained practice of patient safety behaviors that have produced large-scale community and organizational change. In the medical literature, this approach is alluded to simply as “behaviorism” or “behavior modification,” but the technical term should be “organizational behavior management” (OBM).

Organizational Behavior Management

OBM is defined as the application of behavior analysis to organizational settings.¹⁹ The three-term contingency, or “A-B-C model” (i.e., Antecedent-Behavior-Consequence) is the foundation upon which most behavior-based interventions used by OBM practitioners is developed.^{17, 20, 21, 22}

An antecedent (A) is a stimulus that precedes a behavior (B) and encourages performance of that behavior.²² These can take many forms, such as signs, reminder prompts, or even noises that direct behavior.¹⁷ One example of an antecedent strategy shown to be especially useful in improving organizational safety is goal setting (see Locke and Latham²³ for a review of the goal-setting literature).

A consequence (C) is an event that follows a given behavior and increases the probability the behavior will recur. Like antecedents, consequences can take many forms, such as behavioral feedback, monetary rewards, or a supervisor’s praise for a job well done. For this reason, it can be said that consequences *motivate* behavior,¹⁷ since we tend to act in response to the consequences we expect to receive.

Behavior-Based Feedback

One type of consequence used in numerous settings to affect behavior change is “feedback.” In general, a feedback intervention involves measuring a targeted behavior and then delivering information (e.g., frequency, rate, or percent correct) about this behavior to relevant individuals or groups. This approach has been shown to successfully increase safe behavior and decrease at-risk behavior in a variety of different nonmedical settings.^{24, 25, 26, 27, 28}

Behavioral Maintenance

Establishing desired behavior change during an intervention phase is not sufficient. The long-term objective of OBM is the institutionalization of contingencies needed to support the desired

behavior in the absence of intervention agents.^{29, 30} Ideally, the intervention techniques become part of the organization's day-to-day practices. Several factors are critical for behavioral maintenance, including: a) educating and training; b) involving indigenous personnel in customizing and delivering an intervention process; c) developing organizational structure to monitor the intervention process and outcome; d) providing ongoing social and organizational support; and e) generating "self-rules" that individuals can use to motivate their own intervention-relevant behavior.^{18, 29, 30}

Behavior is also maintained within an organization when influenced by natural (or intrinsic) contingencies. Thus, when a particular behavior's natural consequences are rewarding, external contingencies (e.g., feedback from another source) are not necessary for motivation. This occurs, notably, when physicians learn how to use CPOE and eventually find it more efficient and reliable than ordering prescriptions by hand. However, it often takes time to experience the intrinsic qualities that reinforce a behavior. People need to engage in a behavior fluently to experience its inherent, beneficial consequences. This means that external contingencies are often necessary to motivate the initiation of a target behavior.

Organizational Applications for Large-Scale Change

The OBM perspective has informed an innovative people-based patient safety approach to health care,³¹ which strategically integrates behaviorism and humanism in the design of interventions to benefit patient safety. This comprehensive approach to patient safety is based on the following evidence-based guidelines, which are derived from applied and experimental behavior analysis (see Geller¹⁷ for a comprehensive description and analysis of these guidelines):

- Target observable behavior.
- Focus on external factors to explain and improve behavior.
- Direct with antecedents and motivate with consequences.
- Focus on positive consequences to motivate behavior.
- Design interventions with consideration of internal feelings and attitudes.
- Apply the scientific method to improve intervention.
- Use theory to integrate information, not to limit possibilities.

Safety-Related OBM Research in Health Care Settings

Intervening to Improve the Safety of Health Care Workers

Several successful applications of OBM in health care settings, based on the seven guidelines listed above, provide the foundation for designing interventions to initiate and maintain behaviors relevant for patient safety.³¹ In one example, various feedback schedules were investigated to determine which best supported the acquisition and maintenance of three health-care routines: feeding, positioning, and transferring physically disabled patients.³² All feedback schedules were effective at increasing and maintaining the target behavior, but densely scheduled feedback produced more immediate behavior change.

In another study,³³ an intervention that combined goal setting with interpersonal reviews of behavior-based feedback increased nurses' use of behavioral feedback to promote infection control practices in a head injury treatment center. A different study of infection control found that applied performance feedback increased nurses' use of sterile gloves in potentially infectious situations in an emergency room.³⁴

OBM techniques—specifically, training, goal setting, and feedback—also helped increase nurse anesthetists' compliance with procedures (i.e., hand sanitizing) to reduce the probability of accidental exposure to blood-borne pathogens.³⁵ Hand sanitizing increased from 24 percent at baseline to 65 percent during the intervention and was maintained at 52 percent following withdrawal of the intervention. Additionally, nontargeted precautionary behaviors increased as a result of the intervention, including recapping needles with one hand (from 45 to 61 percent); removing gloves from the inside out (from 61 to 93 percent); and wearing gloves when discarding waste (from 31 to 52 percent). This impact on nontargeted behavior suggests a spread of OBM influence, a phenomenon known as “response generalization.”³⁶

This line of OBM research informed an intervention to decrease injuries from sharps among surgical team members during operations by increasing the use of a “hands-free” method for exchanging sharp instruments.³⁷ The intervention package, which included task clarification, pre-intervention feedback, goal setting, and weekly intervention feedback, led to dramatic increases in the use of this injury-reduction technique from 32 to 64 percent).

Whereas these examples of OBM research targeted the safe behavior of caregivers, each of these interventions indirectly advanced patient safety. Patient safety cannot be separated from caregiver safety.³⁸

An OBM Approach to System Change

A behavioral approach also can be useful in evaluating the impact of system change. For example, a systematic, behavior-based evaluation of a gradual, voluntary CPOE implementation found that CPOE medication orders were safer and more efficient compared to the standard paper-based ordering method.¹⁶ However, OBM may be needed to increase CPOE use.

For example, a number of strategies were evaluated to increase the use of CPOE among physicians. These included a) presenting evidence in support of CPOE use; b) rewarding CPOE use with small trinkets; c) providing individual access to computers; d) adding clinical decision support; e) instigating relevant peer pressure; and f) providing financial compensation for the extra time required to become proficient with the CPOE system. The financial compensation strategy was found to be most effective in the short term, increasing CPOE use from 35 to 57 percent. After financial compensation was discontinued, though, CPOE use declined to 42 percent after several months but did not fall to baseline levels.³⁹

The maintenance of CPOE use following the withdrawal of the financial incentive probably occurred because some physicians experienced intrinsic or natural reinforcement. However, the lack of peak maintenance raises the concern that external consequences of a financial incentive may over-control or over-justify the behaviors targeted for intervention, reducing self-persuasion or the influence of intrinsic consequences.

OBM for Patient Safety

In one study,⁴⁰ providing feedback to caregivers on their frequency of hand washing led to an increase in hand washing following patient contacts (from 63 percent at baseline to 92 percent post-intervention). The impact of this intervention was significantly greater than adding an emollient hand washing agent to the environment.

A number of other OBM intervention studies have demonstrated significant increases in hand washing among caregivers.^{41, 42, 43} The intervention programs varied substantially among these studies, but all included a behavior-based feedback component. Moreover, nonbehavioral attempts to increase hand washing among caregivers suggest that hand-hygiene interventions targeting attitude change, intentions, or self-reported practice are likely to fail at altering actual behavior.⁴⁴

Other examples of OBM interventions targeting patient safety include the following:

- A quota system (antecedent strategy) for emergency patients' admission to internal medicine departments resulted in reduced length of stay with no difference in outcomes.⁴⁵
- Education, discussion, and feedback on proper laboratory tests reduced the overall number of tests ordered without any decrement in patient outcomes.⁴⁶
- Standardizing the handoff communication procedure using antecedent reminders and feedback improved patient satisfaction, medication administration record-keeping, completion of cardiac enzyme regimens, and patient transportation without a cardiac monitor, thereby making an additional 67.5 hours of nursing time available each month.⁴⁷

This is not an exhaustive review, yet the OBM approach to patient safety certainly appears promising. However, additional field research in this domain is clearly needed.

A Disconnect Between OBM and Health Care Management

Methodological Distinctions

Health care has been noted as being resistant to importation of ideas from other disciplines.⁴⁸ This tendency has been referred to as the “not-invented-here” syndrome.⁴⁹ Generalizations about psychologists also may be a barrier to the acceptance of OBM techniques by health care professionals, since such consultants might be perceived as trying to fix the “mentally ill” caregiver. From a physician's or administrator's standpoint, one might even speculate that an OBM consultant might share potentially damaging data with the public.

The patient safety literature often contains rather illustrative case examples of how particular errors led to dramatically adverse events for patients.³ This emphasis on the case study outcome stands in contrast to the OBM paradigm, which focuses on objective behavioral data gained from several systematic observations of the process. In addition, standards of valid evidence differ between the fields of medicine and OBM. In medicine, the results of randomized, controlled trials from different institutions are considered to be evidence of the highest grade, whereas observational studies within the same institution are viewed as having less validity because they reportedly overestimate treatment effects.⁵⁰ Conversely, in OBM research, the multiple-baseline

design,⁵¹ employing nonequivalent controls, is the most frequently used evaluation methodology.

Health Care Organizational Structure

Within the vertical hierarchical structure that tends to be the norm in health care settings, differences in levels of authority contribute to many communication errors.⁵² In addition, the hierarchical structure that characterizes interprofessional communication among caregivers can limit valuable interpersonal feedback related to patient safety.⁵³ In fact, such occupational hierarchies have led to a low frequency of error reporting and corrective action. Practitioners are hesitant to report errors or incidents to senior colleagues because of “cultural taboos” associated with error reporting and the possible detriment to career advancement.⁵⁴ Junior practitioners do not want to seem incompetent or offend those in power.⁵² Expected and actual negative consequences from error-related communications serve to reduce such reporting and limit learning from mistakes.

The uncertainties of the health care profession have caused physicians to accept risk⁵⁵ and to view error as an unavoidable and necessary feature of their work.^{56, 57, 58} It has even been argued that errors and mistakes play a necessary role in the learning process of training programs.⁵⁹ In contrast, the OBM practitioner does not view an error as an unavoidable accident from which to learn, but rather as an instance of contingencies failing to influence appropriate behavior.

Medical Errors to Target with OBM

Errors Remaining After System Change

It is acknowledged that several types of errors are already being addressed by well-informed system-based changes, but a number of categories of errors persist. These include technical errors during care procedures, failures in communication among caregivers and between provider and patient, contamination errors due to ineffective employee and patient hygiene, and lapses in patient monitoring.

To be of maximum benefit to medical professionals and OBM practitioners, the categories of errors discussed here are based on already established classification methods and priority areas (e.g., Table 1; The 100,000 Lives Campaign⁶⁰). Also, given the aim of proactive measurement and intervention, they are process- rather than outcome-based and include:

- Diagnosis errors, such as using the wrong test, delays in diagnosis, and failing to act as indicated on test results.
- Treatment errors, such as ordering a wrong drug or dosage, accidental puncture or laceration, and incorrectly executing a procedure.
- Monitoring errors, such as bedsores, failure to rescue, and patient falls.
- Infection-control errors, such as failing to wash hands, lack of glove use, and compromising sterile-field maintenance.
- Communication errors, such as failing to inform other caregivers of acute risk, changes in care, and critical hand-off information, as well as ineffective communication with patients.

These intervention targets are not identified as independent of system influences, but rather as activators for specific kinds of OBM intervention. Behavior is a part of the health care system, which can be targeted for change within a supportive or unsupportive culture.

OBM Interventions to Address Medical Errors

Behavioral antecedents, including prompts, pledge cards, and communication strategies, as well as consequences, are the primary types of OBM intervention techniques (for a comprehensive description of available OBM techniques, see Geller et al⁶¹). The overarching theme of the intervention approach suggested here is to reduce the probability of error by increasing the frequency of safe standards of practice. Several behavioral targets might be relevant for a particular type of medical error, and one target behavior may be related to several categories of error.

Table 2 depicts a framework for classifying OBM interventions and specific behavioral targets for error prevention. As the IOM suggests in *Crossing the Quality Chasm*, “Attention to improving quality includes continuous monitoring, often based on small samples of events that can provide organizations with timely data at the front lines to manage the processes of concern.”⁶² This is precisely what OBM brings to the domain of patient safety.

System-Change Participation

Much of the patient safety literature calls for improved incident reporting systems that include less focus on finding fault and greater attention to the context in which the error occurred.^{2, 3, 63, 64, 65} Adding OBM to this directive could have an immediate positive impact. Winokur and Beauregard³⁸ offer a checklist for ensuring that investigations of caregiver errors are performed with a process focus, placing emphasis on specific task demands and contextual factors, rather than on the identification of individuals at fault. Anonymous error reporting and group feedback can influence individual behavior without assigning personal blame for poor performance.

Additionally, improved tracking systems include more uniform, reliable, and freely given close-call reporting. A close call is likely to have been previously paired with negative feelings, such as guilt, shame, or fear, thus leading to underreporting of close calls or “near misses.” Increasing the quantity and quality of close call reports is a critical behavioral target for OBM. The close call report should be portrayed as an event of success, whereby one or more holes in the system can be fixed and thereby prevent harm to a patient.

The best way to support close-call reporting is to visibly show knowledge gained from the report, which might be a change in the system that prevents similar errors from occurring.⁶⁴ In other words, the close call report should be treated as a trophy for patient safety. It offers the kind of feedback needed to develop a corrective action plan, and it suggests a possible target for an OBM intervention.

Table 2. Proposed framework of behaviors to target for error prevention

Patient safety outcome category	Potential behavior targets	Antecedent strategies	Consequence strategies	Relevant literature
Patient-HCW communication error	• Patient-centered communication	• Patient education for increased prompts/questions	• Patient rating feedback	Burroughs et al ⁶⁶ Larkin et al ⁶⁷
HCW-HCW communication error	• Communication of change in status of care	• Prompts on transcription order and patient transfer forms • Appreciative Inquiry training	• Praise • Communication-style feedback	Rotstein et al ⁴⁵ Shendell-Falik et al ⁴⁷ Wachter ³
Diagnosis error	• Complete diagnosis protocol compliance	• Written prompts, checklists, etc.	• Peer observational feedback	Geller ¹⁷
Infection-control error	• Hand washing • “Hands-free” exchanges of sharps • Glove use	• Goal-setting • Prompting • Task-clarification (modeling) • Incentive	• Feedback • Supervisor praise • Reward	Cunningham & Austin ³⁷ Babcock et al ³³ Devries et al ³⁴ Watson et al ⁶⁸ Stephens & Ludwig ³⁵ Mayer et al ⁴⁰ Sharek et al ⁴¹ Randle et al ⁴²
Decubitus ulcer monitoring error	• Increased checking of inpatients for decubitus ulcers	• Monitoring forms or behavioral checklists	• Decubitus ulcer incidence rate feedback • Supervisor praise	Geller & Johnson ³¹
Failure to rescue monitoring error	• Vigilance behaviors	• Prompts for patient checks	• Response time feedback	Geller & Johnson ³¹
Surgical treatment error	• Upward communication among team members	• CRM training	• Team perception survey feedback • Peer-to-peer coaching	Geller & Johnson ³¹ Gordon ⁶⁹ Salas et al ⁷⁰
Technical procedure treatment errors	• Recommended practice compliance	• Written policy statements • Reminders	• Peer-to-peer coaching	Geller ¹⁷
System-change errors	• Adoption of CPOE • Error reporting	• Software user training • Public reminders • Education on use of error reports • Anonymous reporting reminders	• SCF • Technology incentive • Recognition with corrective action • Rewards	Levick et al ³⁹ Cunningham et al ¹⁶ Boyce & Geller ²⁹ Force et al ⁷¹ Larkin et al ⁷²

HCW = Health care worker; CRM = Crew resource management; CPOE = Computerized physician order entry; SCF = Social-comparison feedback

Another key target behavior for patient safety is the adoption of emerging technologic innovations. Implementing CPOE is more easily accomplished with hospital-employed caregivers rather than with professionals operating under contract, because more immediate contingencies are available for these individuals. Increasingly intense levels of intervention are needed for individuals resistant to adopting system changes such as CPOE. Incentive and reward strategies have increased this target behavior, but other strategies such as promise card commitments may be more effective in the long term, since this approach tends to be perceived as imposing less external control and promoting self-persuasion.^{18, 65}

Social comparison feedback²⁹ (SCF) is another OBM option for intervening with groups and individuals resistant to adopting system changes. SCF involves providing caregivers with objective data comparing their own use of patient safety devices or methods with that of their peers. It should be most effective for groups with more individualistic and competitive tendencies.

Diagnosis Errors

Diagnosis errors are among the most difficult to address because despite system changes, they remain devastating in terms of their overall high frequency of occurrence and potential to harm patients. Furthermore, diagnosis is mainly the responsibility of physicians. One technique already being used in the training of symptom identification is a behavioral checklist. Following training, the trainer's checklist becomes a mental checklist to direct the behavior of a skilled caregiver.

A variation of the behavioral checklist for training is the behavior-based observation and feedback process, which has dramatically reduced injury rates in numerous industrial applications.^{17, 65} This OBM process involves workers in the development of a checklist of critical safety-related behaviors for a particular task. Subsequently, the checklist is used to conduct systematic peer-to-peer behavioral observations, followed by a review of the checklist data.

Both the observer and the person observed learn valuable error-reduction information throughout this peer-to-peer coaching process. Furthermore, the very act of observing another's behavior has been demonstrated to increase the observer's performance of desired behavior.⁷³ This is a paradigm shift from the "see one, do one, teach one" aphorism⁵ to continuous learning.

Treatment Errors

Some types of treatment errors may lend themselves to direct observation and feedback. Many complicated surgical procedures, which are problematic in terms of frequency and severity, provide a clear opportunity for peer-to-peer coaching. Often, observation is already sought for highly complicated cases among surgeons and for hands-on training of caregivers. However, there are no known reports of the regularity with which such strategies are used for more common types of health care procedures performed by experienced caregivers.

Peer-to-peer coaching can also ensure compliance with recommended practices and offer opportunities for corrective feedback. In the context of a patient safety culture looking for

success, this is a learning opportunity rather than an event to be dreaded and avoided. The observation and feedback process also fits with the burgeoning team approach to health care.^{66, 67}

Monitoring Errors

Failure-to-rescue errors seem to warrant a call for increased vigilance among all levels of caregivers. This is a highly desirable, yet difficult to attain objective without clear definitions of what behaviors make up “increased vigilance.” Geller and Johnson³¹ propose using a list of behavior-based expectations to specifically target behaviors linked to a patient safety objective, in this case increased vigilance on the medical unit floor. Once these behaviors are defined, they can be observed and recorded, and once a baseline level of performance is established, they can be targeted for OBM intervention. Continued data collection indicates whether the intervention is effective and should be continued.

Other types of monitoring errors may be addressed adequately by using process-based data for group feedback, which would also compliment a team-based approach. Group data allow for the diffusion of responsibility so individuals do not fear personal consequences from disclosing an error.

Infection Control Errors

Infection errors are best addressed by targeting behaviors, such as hand washing, glove use, sterile operating room entry, and other specific infection control practices (e.g., the Institute for Healthcare Improvement “Ventilator Bundle”⁷⁴). The pinpointed behavior of hand washing is widely linked to infection rates in hospitals. With reported levels of hand washing varying from one institution to another, and self-report being an inflated estimate of compliance with hygiene protocol, OBM is called for at both group and individual levels. While not directly referring to OBM practices, some research reported in medical journals suggests hospitals have been implementing OBM strategies to increase the occurrence of appropriate hygiene behaviors among caregivers.⁷⁵

Communication Errors

Regardless of advances in information technology, medical care will continue to involve direct communication between individuals.⁴ Handoff errors are a major type of communication error affected by multiple factors, including staffing shortages and caregiver fatigue. Providing all relevant patient care data to oncoming physicians and nursing staff is an obvious target for OBM. With signs in the locker room or other salient locations, oncoming caregivers might be prompted to ask end-of-shift coworkers about each patient.

Communication errors with the patient may also be addressed with a number of specific behavioral approaches. Patient education is one way to prevent medical errors.⁷³ When patients know the questions to ask and feel they can effectively communicate with caregivers, they are providing prompts to activate safe health care behaviors. Effective communication between the empowered patient and receptive caregiver not only helps alleviate patient concern about experiencing a negative outcome,⁷³ it also adds a patient-centered, customized set of cues to

prompt the occurrence of critical safety-related behaviors. Patient rating data gained from discharge surveys may also lead to pinpointing caregiver behaviors in need of OBM intervention.

Conclusion

Much of the patient safety improvement literature calls for moving away from a negative, punishment-governed culture of blame to a more empathic, interdependent, and positive context for discussing and preventing medical errors. However, for optimal patient safety improvement, the culture of health care needs to be modified so caregivers and their patients feel safe reporting and learning from medical mistakes observed or anticipated. OBM can increase and maintain desirable behavior, but it is necessary to define the behaviors that need to be avoided and those that need to be increased.

If medical errors are to be fully understood and adequately addressed, a health care culture of interpersonal trust, success seeking, and positive behavior change is needed. The effective and achievement-focused technology of OBM enables the development of this type of culture within the context of continuous learning and beneficial behavior change.

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Confidential Performance Feedback and Organizational Capacity Building to Improve Hospital Patient Safety: Results of a Randomized Trial

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Abstract

Objective: The objective of this study was to evaluate the effect of two intervention strategies, performance feedback reporting and organizational capacity building, both of which aim to improve patient safety in hospitals but for which there is a paucity of empirical data on effectiveness. **Methods:** We randomly assigned the 127 non-Federal, acute care hospitals in Wisconsin to one of three groups: (1) performance feedback reporting, (2) performance feedback reporting and organizational capacity building, and (3) control (no interventions). Reported medical injury rates were based on the Wisconsin Medical Injury Prevention Program (WMIPP) surveillance criteria. We compared adjusted pre- and postintervention injury rates overall, in four broad categories, and for five priority areas targeted in the organizational capacity building. **Results:** The groups of hospitals were similar with respect to location, structure, inpatient utilization, facilities, and services offered. Overall medical injury rates for drug-associated injuries increased significantly during the study period in all groups. No statistically significant differences among the intervention groups or between either of the intervention groups and the control group were detected for overall injury or any of the five major category injury rates. **Conclusion:** The inability to demonstrate a reduction in medical injury rates in relation to either confidential performance feedback reporting or organizational capacity building may be due to either methodologic limitations of the study or ineffectiveness of the interventions.

Introduction

The Institute of Medicine (IOM) report, *To Err is Human*¹ led to a recent increased interest in patient safety. That report emphasized the need to develop and evaluate alternative methods of patient safety reporting. Numerous groups have developed patient safety indices; a recent assessment by the RAND Corporation identified 14 different groups of patient safety indicators that had been prepared by various organizations.² While the IOM report emphasized systems that monitor the occurrence of medical errors, an approach that focuses on medical injuries or adverse events that occur from medical care may be more reliable, engender less defensiveness, and promote a greater emphasis on patient outcomes than approaches that focus on negligence.³

One approach to identifying medical injuries based on hospital discharge data, the Wisconsin Medical Injury Prevention Program (WMIPP) Screening Criteria, appears to have adequate

sensitivity and specificity for monitoring patterns and trends in medical injuries.⁴ The WMIPP criteria are based on the World Health Organization's International Classification of Diseases discharge diagnosis codes and thus are subject to the well-known limitations of administrative discharge data.⁵ Because diagnosis codes are universally collected on all patients discharged from hospitals in the United States, the WMIPP screening criteria avoid the limitations of voluntary reporting systems that require proactive reporting by health care providers and are likely to have very low sensitivity for patient safety problems.

One potential use of patient safety reporting systems is to provide performance feedback to institutions and health care providers to inform and target their efforts to improve patient safety. Numerous theoretical approaches to improving patient safety have been proposed by researchers from health services research, public health, clinical medicine, and ergonomics. Karsh and colleagues identified three paradigms for directing improvement efforts focused on reducing injuries, reducing errors, or improving evidence-based practice. They also proposed a fourth paradigm, a human factors engineering paradigm.⁶ While these paradigms have different theoretical foundations, they do share the perspective that comprehensive, systems approaches might be needed to improve patient safety. In some respects, these approaches can be viewed as complementary, rather than competitive.⁶

Implementing the systemic changes needed to increase patient safety poses daunting challenges to complex organizations like hospitals. Most patient safety research to date has emanated from academic medical centers, particularly tertiary care hospitals. General, acute care hospitals face many of the same challenges in improving patient safety but may lack the specialized resources and personnel that are available in academic tertiary care centers. To address these challenges, we developed a program of technical assistance to build necessary organizational capacity. The organizational capacity-building component included guidance on interpreting the medical injury data, provision of evidence-based information on effective interventions to address patient safety priorities, and consultations on organizational strategies to implement the necessary systemic changes.⁷

We conducted a statewide, randomized, controlled trial evaluating the impact of confidential performance feedback of patient safety experience and organizational capacity building on the occurrence of medical injuries in acute care hospitals in Wisconsin. We hypothesized that hospitals receiving regular, confidential, hospital-specific reports of medical injury rates would increase patient safety efforts and reduce medical injuries. However, hospitals receiving technical assistance in building organizational capacity in addition to the same patient safety reports would achieve a greater increase in patient safety efforts and a greater reduction in medical injuries.

Methods

To evaluate the impact of two different intervention strategies for improving patient safety, we randomly assigned all non-Federal, acute care, general hospitals in Wisconsin to one of three groups: (1) performance feedback reports only, (2) performance feedback reports plus organizational capacity building, and (3) control.

Random Allocation

To reduce the potential of residual confounding differences among the three groups of hospitals, we employed a multistep process analogous to prognostic stratification^{8, 9, 10} to obtain treatment groups from hospitals of comparable size and baseline injury rates based on data from 1999. Using the ability of cluster analysis to create natural groupings, hospitals were first grouped together based on a hierarchic clustering of number of discharges, overall medical injury rate, drug injury rate, biologic injury rate, device and implant injury rate, procedure injury rate, radiation injury rate, urban/rural location, and children's or tertiary care hospital. Some clusters were very similar and were combined; two hospitals were moved to clusters with similar averages, to create six clusters divisible by four and one cluster of six hospitals. Hospitals within each cluster were then assigned a random number and sorted according to that random number. The hospitals within each cluster were sequentially assigned to treatment groups 1, 1, 2, 3 in the larger clusters and 1, 2, 3 in the small cluster. The hospitals were allocated as follows:

- Performance feedback group: 64 hospitals.
- Performance feedback plus organizational capacity-building group: 30 hospitals.
- Control group: 33 hospitals in which we monitored the occurrence of medical injuries throughout the demonstration project, but to which we provided no feedback or intervention.

Medical Injury Surveillance Criteria

The methods we used for identifying medical injuries using hospital discharge data have been described in detail elsewhere.⁴ Here, we briefly summarize the patient safety surveillance methods directly relevant to this study. To develop comprehensive surveillance or screening criteria for medical injuries, we reviewed the ICD-9-CM codes to identify *N*-codes or *E*-codes indicative of a medical injury. Medical injuries were classified into four broad categories: (1) drugs; (2) procedures; (3) devices, implants, or grafts; and (4) radiation. These categories were further divided into 40 subcategories to more precisely indicate the cause of injury. These surveillance criteria were validated by comparison to results obtained from a blinded review of medical records.⁴

Case Definition

In this study, a discharge was considered to fulfill the criteria for medical injury if any of the nine diagnosis fields or the special *E*-code field contained any one of the codes listed in the surveillance criteria. A given patient discharge could be associated with more than one type of medical injury.

Study Population

The study population included all patients discharged from acute care, non-Federal hospitals in Wisconsin, with the exception of newborn delivery discharges. Also excluded were alcohol and other drug abuse (AODA) hospitals and psychiatric hospitals. This study used Form UB-92

hospital discharge data collected by the Bureau of Health Information and Policy through September 30, 2003, and thereafter by the Wisconsin Hospital Association Information Center.

Interventions

Performance feedback. For each general, acute care, non-Federal hospital in Wisconsin, a report was developed containing the following elements:

- Number of occurrences, risk-adjusted injury rates per 1000 discharges, percentile ranking among Wisconsin hospitals, and statewide increase in length of stay for all medical injuries and for four broad categories of medical injuries related to drug, device, procedure, or radiation.
- Similar details for the 40 more specific subcategories of medical injuries.
- Unadjusted rates for the 10 most frequent medical injuries at the particular institution with the greatest increase in length of stay.
- Unadjusted rates of 16 subcategories of medical injury relevant to surgery, using only surgical discharges in the calculation of rates (see Appendix).

Risk adjustment factors included patient age, sex, severity of illness, risk of mortality, primary payer, hospital ownership, presence of a residency program, percentage of board-certified staff, trauma center level, provision of oncology services, percentage of facility discharges that were surgical operations, provision of transplant services, number of medical record personnel per 1,000 discharges, average number of diagnostic codes across all hospital discharges, proportion of diagnostic codes that were nonspecific, and proportion of diagnostic codes that were unspecified. The severity of illness and risk of mortality scores were based on the APR-DRG (All Patient Refined-Diagnosis Related Groups) indices calculated by the APR-DRG medical information system.¹¹ Because these indices were intended to adjust for patients' underlying illnesses, they were calculated after excluding all medical injury-related diagnostic codes.⁴

Reports utilized the most recent 6 months of available hospital discharge data; they were sent semi-annually to each performance feedback hospital and each performance feedback + organizational capacity-building hospital. At each hospital, reports were sent confidentially to the CEO, head of quality assurance, head of nursing, and head of the medical staff. The first baseline report was sent in February 2002 and covered the period from October 1, 2000 through March 31, 2001. The sixth and final report, which was sent in October 2004, included a table showing trends in injury rates related to the five intervention manuals (described below) for the performance feedback + organizational capacity-building hospitals.

Organizational capacity building. In addition to the semi-annual reports, hospitals in this group received additional support and materials. An intervention specialist with considerable education and experience in clinical nursing, nursing administration, and organizational management visited hospitals assigned to the organizational capacity-building group for the purpose of answering questions on the reports; assuring the hospitals that all hospital-specific injury information in the reports was confidential; identifying obstacles to disseminating or using the reports; gathering information on mechanisms currently in place to address patient safety issues;

and conducting a needs assessment to identify which specific medical injuries should be the focus of intervention efforts.

Using extensive literature review and examples of hospital best practices, WMIPP physician experts developed a set of five condition-specific manuals that summarized research evidence and suggested practical strategies to prevent medical injuries within a quality improvement framework. The selection of targets for intervention were based on AHRQ's "Priority Areas for National Action,"¹² the frequency and severity of medical injury occurrences based on WMIPP surveillance reports, input from organizational capacity-building hospitals, and expert panel assessments of the relative feasibility of potential interventions. (See Appendix for intervention targets and priority indicators.)

These hospitals also received followup newsletters designed to reinforce the educational manuals and provide additional practical, evidence-based resources for patient safety interventions. The key elements and contents of manuals and newsletters are described elsewhere.⁷ The timeline of performance feedback reports and capacity building are shown in Table 1.

Table 1. Timeline of performance feedback reports and capacity building

Performance feedback reports	Performance feedback reports					
	#1	#2	#3	#4	#5	#6
Patient discharge dates	10-1-00 to 3-31-01	4-1-01 to 9-30-01	10-1-01 to 3-31-02	4-1-02 to 9-30-02	10-1-02 to 3-31-03	4-1-03 to 9-30-03
Reports sent ^a	2-15-02	11-24-02	8-16-03	5-28-04	10-30-04	10-30-04
Capacity building						
Manuals	Surgical site infections	Perioperative cardiac events	Central venous catheter complications	Anticoagulant complications	Catheter-related UTIs	
Date sent ^a	5-29-03	6-20-03	8-20-03	10-10-03	10-30-03	
Newsletters (date sent ^a)	11-27-03	2-6-04	4-7-04	6-7-04	9-18-04	

a Dates are approximate (within 1 week). There was a variable lag period between the discharge dates and the availability of data for analysis.

Impact on Medical Injury Rates

Statistical analysis. A discharge was considered to involve a medical injury if any of the nine diagnosis fields or the special *E*-code field contained one of the WMIPP criteria. A given patient discharge could be associated with more than one type of medical injury. Rates of medical injuries were calculated as the number of discharges with the particular type of medical injury divided by the total number of discharges. All statistical analyses were performed using SAS[®] and Stata[®] software. The effect of the interventions on medical injury after accounting for differences in relevant covariates was assessed using linear mixed-model analysis. However, due to lack of normality in residuals, nonparametric tests, such as the Kruskal-Wallis and Friedman's

tests, were conducted. All analyses were repeated after excluding patients under 18 years of age and women admitted for childbirth, with similar results (data not reported).

As was the case in the performance feedback reports, to adjust for possible differences in patient mix among hospitals, we adjusted for severity of illness and risk of mortality levels, based on the All Patient Refined-Diagnosis Related Groups, Ver. 15, software system for inpatient care.¹¹ Severity of underlying illness was a potential confounder because it varies among hospitals and is independently associated with the likelihood of injury.¹³ The assignment of a patient discharge to an illness severity or risk of mortality class considers not only the individual diagnoses but also the interaction among diagnoses and age and the presence of certain operating room and non-operating room procedures.

Results

Hospital characteristics within the three study groups are summarized in Table 2. The hospitals in the three groups did not significantly differ in their location, structure, inpatient utilization, facilities, and services offered. There was a significant difference in the number of medical record personnel per 1,000 discharges ($P = 0.01$). Characteristics of patients in the hospitals in each of the study groups are shown in Table 3. There were no significant differences in any of the patient characteristics measured among the three groups.

Overall injury rates per 1,000 discharges for all hospitals are shown in Figure 1 across the study years 2001-2005 via box plots at the different time points. Overall medical injury rates in the three study groups ranged from 10.0 to 10.4 per 1,000 discharges in the pre-intervention period and 11.0 to 12.0 per

1,000 discharges in the post-intervention period (Table 4). The randomized treatment design with longitudinal measurements called for analysis using a mixed normal linear model to detect possible treatment effect. This analysis showed a time trend but not a significant treatment effect nor a time-by-treatment interaction. Moreover, residual analysis indicated lack of normality, even after applying the logit and arc-sine transformations

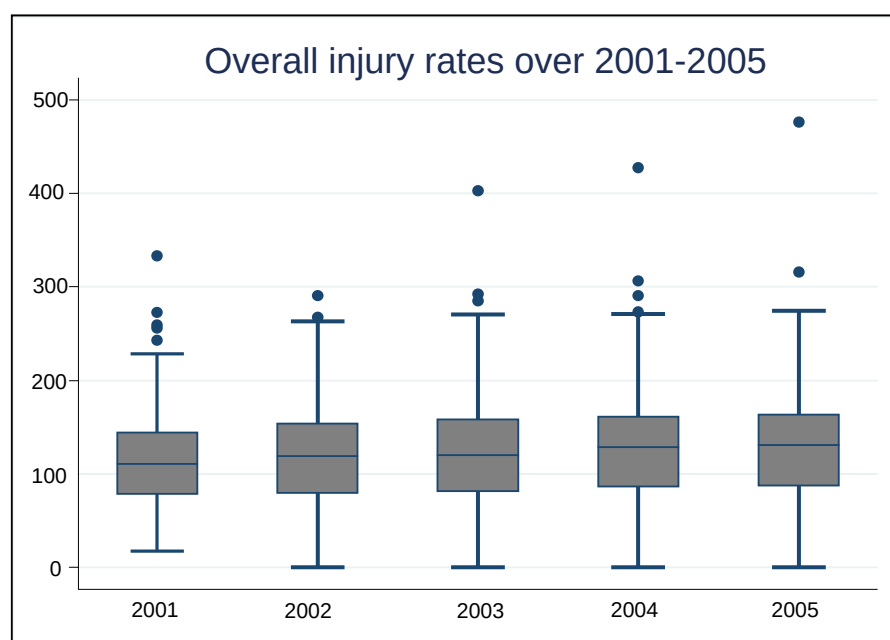


Figure 1. Overall medical injury rates in Wisconsin hospitals, 2001-2005.

to the injury rates. Therefore, we report here the results of subsequently used nonparametric analytic methods.

Table 2. Baseline hospital characteristics by study group

Hospital characteristics	Feedback	Capacity-building	Control	Total
Hospitals	64	30	33	127
Location				
Urban [N (%)]	24 (38)	12 (40)	8 (24)	44 (35)
Rural [N (%)]	40 (62)	18 (60)	25 (76)	83 (65)
Organizational structure				
Government [N (%)]	2 (3)	0 (0)	0 (0)	2 (2)
Not-for-profit [N (%)]	60 (94)	30 (100)	31 (94)	121 (95)
For-profit [N (%)]	2 (3)	0 (0)	2 (6)	4 (3)
Residency program present [N (%)]	18 (28)	7 (23)	5 (15)	30 (24)
Percentage board-certified staff	86.7	86.1	86.9	86.6
Trauma center level				
Regional [N (%)]	2 (3)	1 (3)	1(3)	4 (3)
Community [N (%)]	19 (30)	7 (23)	8 (24)	34 (27)
Rural [N (%)]	11 (17)	4(13)	5(15)	20 (16)
Inpatient utilization				
Average number of beds/hospital	130	112	81	14,353
Average admissions/hospital/year	5,755	5,160	3,207	628,970
Average inpatient days/hospital/year	35,137	28,212	22,450	3,835,988
Average length of stay (days)	5.4	4.9	7.1	5.7
% Inpatient surgeries/hospital/year	24.6	20.9	24.5	23.7
Births/hospital/year	671	637	346	73,501
Facilities and services provided				
Oncology service [N (%)]	44 (69)	19 (63)	21 (64)	84 (66)
Transplant service [N (%)]	4 (6)	1 (3)	1 (3)	6 (5)
Cardiac service [N (%)]	61 (95)	29 (97)	28 (85)	118 (93)
Mean % surgical discharges	23.1	22.9	21.1	22.6
Number medical records personnel per 1000 discharges ^a	5.1	3.2	4.7	4.5
Nonspecific codes (%)	12	12	11	12

a P = 0.01

Table 3. Characteristics of patients in hospitals in each study group^a

Patient Characteristics	Feedback	Capacity building	Control	Total
Median age (years)	61.5	60.3	62.6	61.5
% Women	60	60	59	60
% Private insurance	38	39	33	37
Severity of illness score (APR-DRG) (%)				
1, Minor	33.6	34.8	32.2	33.5
2, Moderate	46.2	46.8	46.1	46.3
3, Major	17.3	16.3	18.7	17.4
4, Extreme	3.0	2.0	2.8	2.7
Risk of mortality score (APR-DRG) (%)				
1, Minor	59	63	57	60
2, Moderate	23	22	24	23
3, Major	15	13	16	15
4, Extreme	3	2	3	3
Number of procedures (median)	0.6	0.6	0.4	0.5

a No significant differences by Kruskal-Wallis test.

Table 4. Pre- and post-intervention injury rates

	Feedback		Capacity-building		Control		P-value ^a
	Pre	Post	Pre	Post	Pre	Post	
Patient records with at least one medical injury code (%)	10.4	11.5	10.0	11.0	10.3	12.0	0.68
All injuries, 2001 vs. 2005							
Drugs	4.9	5.8	4.8	6.1	4.5	6.2	0.69
Devices	1.9	2.1	1.7	1.7	1.8	2.3	0.5
Procedures	4.4	4.4	4.1	3.8	4.6	4.6	0.88
Radiation	0.19	0.22	0.21	0.24	0.15	0.23	0.36
Any priority injuries, 2002 vs. 2005 (%)							
Post-op infections/nonhealing wounds	1.97	1.51	1.28	1.35	2.42	2.07	0.42
Cardiac events during surgery	2.27	1.72	1.47	1.27	1.66	1.43	0.66
Central venous catheter complications	4.57	3.20	4.00	6.08	3.65	3.17	0.006 ^b
Anticoagulation complications	0.39	0.45	0.26	0.44	0.38	1.50	0.63
Foley-catheter complications	0.21	0.29	0.23	0.24	0.34	0.35	0.36

a Kruskal-Wallis test of rate changes (pre- vs. post-) for three treatment groups

b The corresponding P = 0.02 in a Poisson regression model including a year and a treatment interaction effect.

Time trends were tested by Friedman's test for dependent (here, longitudinal) observations. Overall and drug-injury rates showed statistically significant increases over time ($P < 0.0005$). None of the other four major categories, nor any of the 40 subcategories, demonstrated monotonically changing injury rates over time.

To evaluate the possible effect of treatment, the change in rate from 2001 to 2005 was computed for each hospital. The Kruskal-Wallis test (nonparametric ANOVA) was then applied to these data. No statistically significant differences among the intervention groups or between either of the intervention groups and the control group were detected for overall injury or for any of the five major category injury rates.

The same nonparametric test was used to compare differences in rates of the five priority indicators from 2002 (latest baseline year prior to distribution of the manuals) to 2005. The central venous catheter complications injury indicator showed a significant difference between groups ($P = 0.02$), with the performance feedback group having the greatest decrease followed by the control group in a Poisson regression model. The performance feedback + organizational capacity-building group actually showed an increase in reported central venous catheter complications during the study period. No significant differences in rate change were seen for the other priority indicators.

Discussion

We found no evidence of a reduction in identified medical injuries—either overall or in specific categories—associated with confidential performance feedback to hospital administration or with confidential performance feedback coupled with organizational capacity building. Acute care hospitals in Wisconsin were randomly assigned to one of the intervention groups or to the control group, and there were no major baseline differences in hospital or patient characteristics among the three study groups that might have limited our ability to detect an impact of the interventions.

The framework for patient safety reporting and organizational capacity building efforts in this study⁷ was based on factors shown to influence line managers' perceptions of hospital performance data.¹⁴ The key medical injury topics selected for intervention were based on the Agency for Healthcare Research and Quality's (AHRQ) Priority Areas for National Action,¹² which in turn, were based in part on the evidence of effective interventions being available for implementation.

The inability to detect a measurable impact on medical injury occurrence of confidential performance feedback to hospital administration, with or without organizational capacity building, could reflect several possibilities. Unfortunately, a detailed process evaluation originally proposed as part of this study could not be undertaken because of funding limitations. Hospitals in this study, unlike in most patient safety research, included all non-Federal, general, acute care hospitals in Wisconsin and were not restricted to hospitals with a particular interest in, or commitment to, patient safety. By analogy with the transtheoretical model of personal behavioral change,¹⁵ such hospitals may have been in a pre-contemplation stage with respect to the changes necessary to improve patient safety.

Another possible reason for our inability to detect an impact of our interventions might involve limitations of hospital discharge data collected for administrative purposes.⁵ In this study, it is possible that the interventions could have increased attention to patient safety throughout the hospital, including in medical records, which might have resulted in more complete coding of medical injuries and may have obscured any potential reduction in their actual occurrence. This might, for example, have accounted for the increase in reported central venous catheter complications in the performance feedback + organizational capacity-building group.

In light of the complexity, culture, and incentives of hospitals, it is also possible that the confidential performance feedback and organizational capacity-building interventions used in this study were insufficient to produce an appreciable or sustained increase in patient safety activity in hospitals. Despite the emphasis on patient safety reporting,¹ there was no clear evidence of the effectiveness of different approaches to reporting on injury or error occurrence. A rigorous comparison of the impact of public vs. confidential patient safety reporting is clearly timely.

The model for organizational capacity building may need to expand to include focused instruction on how to respond to feedback provided at the individual and organizational levels. The recent decision by Medicare to no longer pay for the extra costs of care attributable to preventable errors¹⁶ could heighten receptivity to feedback and other interventions designed to reduce medical injuries.

Although this rigorously conducted, randomized trial of confidential performance feedback and organizational capacity building to improve hospital patient safety did not find a statistically significant impact, it might ultimately help in the search for effective patient safety interventions. While progress can be made by identifying what does work, it is also important to know what is insufficient. This study suggests opportunities for improvement in intensity and targeting of our capacity-building intervention and the need for comprehensive patient safety indicators that could be used to measure accurately the effect of patient safety interventions in future studies.

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APPENDIX: Definitions of intervention targets and priority indicators by ICD-9 codes

Priority indicator (applicable ICD-9 codes)	Denominator
1. Surgical site infections: • Dehiscence (998.3) or • Persistent post-operative fistula (998.6) or • Non-healing surgical wound (998.83) or • Infected post-operative seroma (998.51) or • Other post-operative infection (998.59)	All patients with a surgical procedure
2. Perioperative cardiac events: • Cardiac event during a procedure (997.1) or • Myocardial infarction (410.00-411.89) or • Cardiac arrest (427.5)	All patients with a noncardiac surgical procedure
3. Central venous catheter (CVC) complications: • Infection/inflammation due to vascular device, implant, or graft (996.62) or • Iatrogenic pneumothorax (512.1) or • Emphysema resulting from a procedure (998.81) or • Complication due to other vascular device, implant, graft (996.74), or • Mechanical complication of other vascular device, implant, graft (996.1)	All patients with a code for placement or replacement of a CVC
4. Anticoagulation complications: • Poisoning by anticoagulants (964.2) or, • Accidental poisoning agents affecting blood (E858.2) or • Adverse effect of correct drug anticoagulants (E934.2)	All discharges – excluding under age 18 or OB DRG (due to low prevalence of anticoagulant use)
5. Catheter-related urinary tract infections (UTI): • Infection/inflammation reaction to indwelling urinary catheter (996.64) or, • As a cause of later complication (E8 79.6), plus any one of the following: • Urinary tract infection, site not specified (599.0) or • Acute cystitis (595.0) or • Subacute and chronic cystitis NOS (595.2) or • Cystitis unspecified (595.9) or • Infections of kidney (590.0-590.9) AND • Foley placement or replacement (procedure 57.94 or 57.95)	All discharges

Clinical Process Improvement

Resident Sign-Out: A Precarious Exchange of Critical Information in a Fast-Paced World

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Abstract

Background: Sign-out is a mechanism of transferring information, responsibility, and authority from one set of caregivers to another. In teaching hospitals, sign-out between resident physicians has a long tradition. Because of the need to reduce the number of hours residents spend in the hospital, the number of sign-outs has increased, while continuity of care during hospital stays has decreased. As a result, when caring for hospitalized patients, residents have become increasingly dependent upon exchange of information during sign-out. Despite its critical importance, little research has examined the content, process, and effectiveness of resident sign-out. Even less is known about how sign-out should be conducted or how interventions might improve the quality of sign-out. **Methods:** Between October 2005 and February 2006, and again between October 2006 and February 2007, residents completed a post-call survey immediately after a call shift; we also audio-recorded sign-out sessions. **Results:** At baseline, an unexpected event arose during one-third of call shifts that should have been anticipated and discussed during sign-out. Recordings demonstrated sign-out was informal and unstructured with very wide variation in the type and extent of information exchanged. Based on these results, we explicitly defined the goals of sign-out; characterized information needed for concise, complete, and consistent sign-out; outlined a structured process to enhance the quality and efficiency of information exchange; developed a computerized tool to facilitate the process; and developed a curriculum to train residents how to sign-out more effectively. After implementing the new process and computer tool, the percentage of call nights when an unexpected event arose that should have been anticipated and discussed during sign-out was nearly identical to that at baseline. **Conclusion:** Although resident physicians frequently sign-out to one another, there are many times when important information is not transmitted. Future studies should be directed at identifying the information physicians need while on-call and clearly describing the goals and characteristics of a concise and complete sign-out. Additional studies are also needed to identify how to best teach and evaluate a physician's ability to sign-out and how technology can be employed most effectively and appropriately.

Introduction

Sign-out is a mechanism of transferring information, responsibility, and authority from one set of caregivers to another set of caregivers.^{1, 2, 3, 4} The primary objective of sign-out is the accurate transfer of information about a patient's state and plan of care from one set of health care providers to another.⁵ At the conclusion of an effective sign-out, caregivers should have a clear mental picture of the patients for whom they are assuming care, know the current status and plan of care for those patients, and have a sense of what problems and issues may arise during the next shift.

Effective and accurate sign-out is important for patient safety and successful patient care.⁶ Incomplete information transfer and incomplete and/or unclear communication of the plan of care to covering physicians can adversely affect the quality of care.^{6, 7, 8, 9} The risks of failing to be told, forgetting, or misunderstanding information that has been communicated during any patient care hand-off can be substantial.^{7, 8, 9, 10} Communication problems are the most common cause of in-hospital disability and death.¹¹

More than 60 percent of root causes of sentinel events reported to the Joint Commission are due to failures of communication between health care personnel.¹² Resident physicians believe communication difficulties play a major role in the vast majority of medical mishaps they experience.¹³ The discontinuity of care that results from frequent sign-outs and handoffs is associated with longer hospital stays, an increase in the number of laboratory tests ordered and performed, and an increase in the number of self-reported preventable adverse events.^{4, 6, 14}

In teaching hospitals, sign-out between resident physicians has a long tradition. In July 2003, duty-hour restrictions were instituted for all residency programs in the United States. Residents are limited to 30 continuous hours and 80 total hours per week in the hospital, accompanied by 10-hour rest periods away from patient care. Because of the need to reduce the number of hours resident physicians spend in the hospital, the number of sign-outs between resident physicians has increased, while physician continuity of care during hospital stays has decreased.^{15, 16, 17} As a result, when they are caring for hospitalized patients, resident physicians have become increasingly dependent upon the exchange of information during sign-out.^{1, 10, 18}

Despite its critical importance, little research has examined the content, process, and effectiveness of resident sign-out, and even less is known about how sign-out should be conducted or how interventions might improve the quality of sign-out.^{1, 3}

With the set of studies discussed herein, we characterized and ascertained the effectiveness of the sign-out process on two acute care wards at the University of Virginia Children's Hospital. After reviewing these findings, as well as the available literature, house staff, faculty physicians, and systems engineers explicitly defined sign-out, identified the content of an ideal sign-out, delineated an ideal sign-out process, and developed specifications for a computerized tool to facilitate the new sign-out process.

This idealized sign-out process and the new computer-based tool were implemented, and the impact of these changes were then assessed. Our primary outcome measure was the number of call nights when something unanticipated occurred that the residents judged could have been anticipated and should have been discussed during sign-out.

Methods

Scope and Study Population

The Institutional Review Board of the University of Virginia approved this study, and all participants gave informed consent. The study was conducted on two contiguous general pediatric wards at the University of Virginia Children's Hospital. The general pediatrics service

comprises three first-year pediatric and/or family medicine residents, two third-year pediatric residents, and a pediatric attending physician. Each patient is assigned to a first-year and a third-year resident. The first-year resident serves as the child's primary care provider, and the third-year resident functions as a supervisor.

The entire team rounds together every morning. Night coverage is shared by eight residents—the three first-year residents, two third-year residents on the general pediatric ward rotation, two second year pediatric residents, and one first-year pediatric resident—who are on other rotations and “cross-cover” at night. Residents are on call every fourth night. During each night shift, one first-year resident and one second- or third-year resident are on call and care for all of the patients on the two units. The organizational structure of the ward team is depicted in Figure 1.

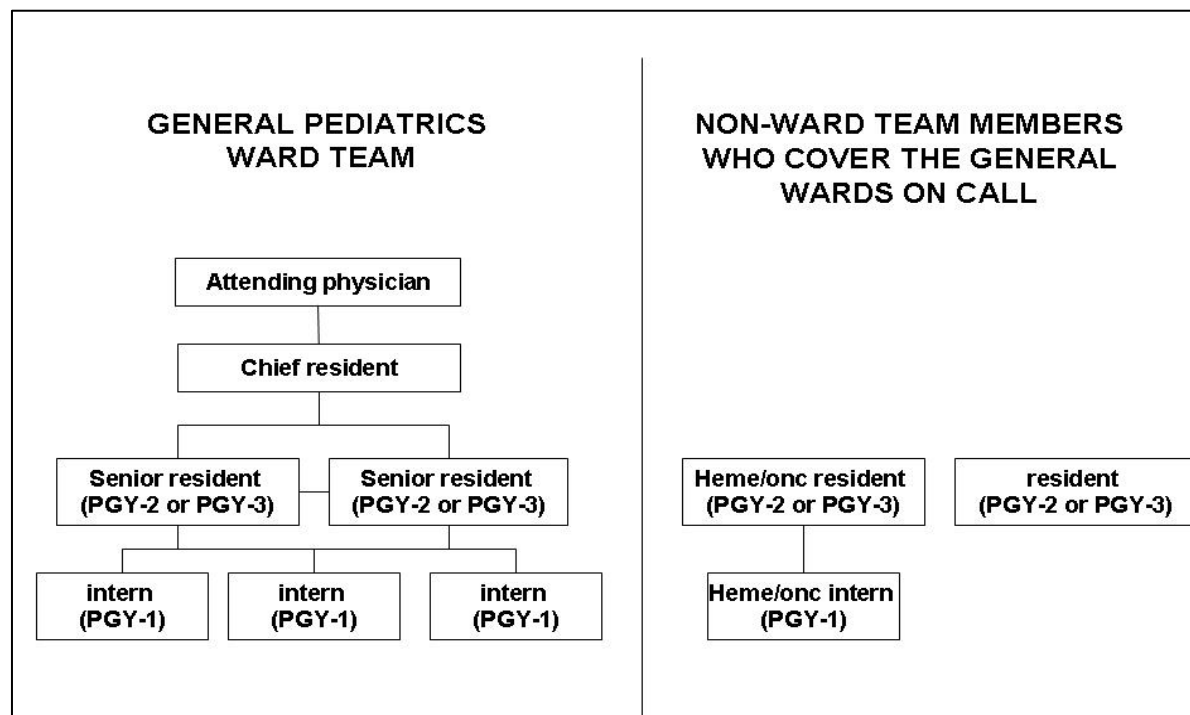


Figure 1. The organizational structure of the ward teams

Sign-out for these wards takes place in the pediatric library, which is located on one of the units. On weekdays, at 7:00 am, residents who had been caring for all of the patients on the wards during the night shift meet with other members of the team to review what happened overnight and to hand-off care back to the primary team. At 4:00 pm, team members meet with the two residents who will be on-call that night and who will care for the patients overnight. This is the longest, most comprehensive, and perhaps the most important sign-out session because members of the general ward team are handing off care of all the patients on the wards to two physicians who might or might not be members of the primary team.

On weekends, there is a single sign-out at noon each day, at which time the pair of residents who have cared for the patients over the previous 24 hours and are ending their shift hand-off care to a pair of residents who will assume care of the patients for the following 24 hours. During this study, we focused on the 4:00 pm weekday sign-out and weekend sign-outs because these often

involved physicians unfamiliar with the patients and were typically the most comprehensive sign-outs. The residents identified the 4:00 pm sign-out as the most important daily sign-out session.

Assessment of the Effectiveness of Sign-Out by Post-Call Surveys

Over 98 days, spanning a 4-month period during the winter of 2005-2006 (baseline), and during the same 4 months during the winter of 2006-2007 (post-intervention), after night post-call residents were on call on the two pediatric acute care wards, they received a text page reminding them to complete a confidential printed two-page survey (Appendix 1).

The survey characterized their night on call. They were asked to assess the adequacy of the sign-out they had received; whether any unexpected/unanticipated problems had arisen while they were on call; whether those problems could have and should have been anticipated and discussed during sign-out; and finally, where they went to get information they did not receive during sign-out.

The survey was created by the authors based upon a conceptual model of hand-offs of care developed through an institutional quality improvement project and preliminary data obtained by a systems engineer who attended and recorded 15 sign-out sessions. Concurrent with the audio-taped sign-outs, the engineer followed first-year physicians through their call period to ascertain what types of questions the residents were asked while on call and how they tried to answer those questions. There were repeated measures on individual nights of call and by individual residents on different call nights.

Our principal means of data collection was through post-call surveys, during which we asked resident physicians whether problems could have and should have been anticipated and discussed during sign-out. These types of assessments can introduce significant hindsight bias.

Baseline Characterization of Sign-out Sessions

Sign-out sessions were audio-recorded using two microphones placed at either end of the conference table where sign-out took place. In addition, an analyst silently observed the sign-out session and entered data about each sign-out using a software tool developed for this purpose.¹⁹ The tool supported real-time characterization of the type of patient information conveyed, in addition to recording the time and duration of patient discussions, events, and interruptions (such as pages and telephone calls). The tool also provided the ability to modify entered data and to review data at later times. All characterizations made using the software tool were stored in a Microsoft Access database for subsequent analysis.

Characterization of an Ideal Sign-Out

Results of a literature review, the sign-out survey described above, and the direct observation of sign-out described above were shared with the entire pediatric house staff and selected faculty physicians. There was a clear consensus that sign-out was a point of vulnerability and that opportunities to improve it were substantial. During two 1-hour facilitated sessions, the pediatric house staff, faculty physicians, and systems engineers explicitly defined the goals of sign-out and identified barriers and opportunities for improving ward sign-out.

During eight 1-hour facilitated sessions, a smaller working group of house staff, faculty, and systems engineers:

- Explicitly defined the purpose and goals of sign-out.
- Identified and characterized the information needed for a concise, complete, and consistent sign-out.
- Characterized a structured sign-out process meant to enhance the quality and efficiency of information exchange (including the logistics of who, what, where, and how).
- Developed specifications for a computerized tool to facilitate a new sign-out process.
- Developed a curriculum to train house staff on how to sign-out more effectively.
- Developed a process to evaluate a house officer's ability to sign-out effectively and provide them with constructive feedback.

The recommendations of this working group were brought to the entire house staff for approval, after which an implementation plan was developed.

Implementation of a New Sign-Out Process and Computerized Sign-Out Tool

During late June and early July 2006, we conducted two 1-hour teaching sessions about ward sign-out with the entire pediatric house staff. During the first session, we briefly reviewed the existing literature and shared our baseline data with them. We characterized the process we had gone through to define an ideal sign-out. We then shared the definition, goals, and characteristics of an effective and efficient sign-out and clearly outlined what information should and should not be included. Finally, we explicitly characterized a new and more structured sign-out process.

During the second teaching session, we conducted individual and group role-play exercises, during which we performed and critiqued simulated sign-outs. The information requirements for effective sign-out were operationalized in a prototype database application to support the sign-out process. During a 5-month period, resident physicians used the application and provided additional data entry and reporting requirements, which were iteratively incorporated into the application.

Residents initially characterized 6 general and 27 specific information requirements for the tool. Both data entry and reporting requirements were refined, and the application was modified as residents used the system. With respect to data entry, residents identified specific needs for adding, deleting, or modifying individual patient records, as well as sorting patients by acuity, service, and location.

With respect to reporting, customized reports were requested based upon time of day, acuity of patients, clinical service, or location. The report format was modified to maximize the amount of information on each page, while enhancing readability and highlighting critical data elements. By the end of the trial period, residents reported significant improvement in the efficiency of their sign-out process, and the database had become an integral part of their workflow.

Results

Data Analysis

Continuous variables were compared using unpaired two-tailed t-tests. Dichotomous variables were compared using Fisher's exact test. Differences were considered statistically different if the *P* value was <0.05. Unless otherwise stated, all results are presented as mean $\pm$ standard deviation.

Characterization of Baseline Sign-Out Sessions

Between July 2005 and February 2006, 15 different sign-outs, involving 209 patients, were observed and recorded. Sign-out sessions lasted 34.3 ± 15.5 minutes, with a range of 11.1 to 70.3 minutes, during which time resident physicians discussed 14.0 ± 3.6 patients, with a range of 8 to 20 patients. These 15 sign-out sessions were interrupted a total of 60 times. Pagers went off an average of 3.06 ± 2.12 times per sign-out (range, 0 - 7). Direct interruptions by members of the hospital staff, who were not involved in sign-out (e.g., nurses and physicians from other services), were common (0.87 ± 0.99 per sign-out session [range, 0 - 3]). Of the 15 sign-out sessions, 4 were interrupted by telephone calls. Significant background noise, such as from other conversations, was common during the recorded sign-out sessions, occurring 2.7 percent of the time (± 11.3 percent, range, 0 - 37.8 percent).

Matters not directly related to patient care ("off-task") accounted for 23.2 percent of sign-out session time. Of the time spent "on-task," 87.2 percent was spent on one-way information transfer from the resident going off call to the resident coming on call. Background information prior to the current hospitalization accounted for 32.2 percent of the information transferred. A mean of 12.1 percent of the time was spent discussing what actions, both planned and contingency, should occur overnight. Of the nine categories of patient information, no single category of information was discussed for every patient. Residents described the patient's current condition for 35.4 percent of patients, reviewed current medications for 62.7 percent of patients, and outlined contingency plans for possible scenarios for 17.7 percent of patients.

Characterization of an Ideal Sign-Out

Based on the process described above, ward sign-out was defined as a concise, face-to-face, written and verbal communication of pertinent patient information that was necessary for optimal patient care until the next shift. Sign-out should focus on identifying anticipated problems and the appropriate plan of care for each, and it should provide a process check of actions completed and those needed before the next hand-off of care, as well as an opportunity to ask questions and obtain clarification. In summary, recommendations for the ideal sign-out included the following:

- Sign-out should take place face-to-face to facilitate questioning, clarification, and collaborative cross-checking.
- Start/finish times should be defined
- Sign-out should take place in a quiet/secure location, such as a small private conference room, rather than the pediatric library to minimize interruptions/distractions.
- The roles and responsibilities of all participants should be clear.

- The focus should be on patient safety and effective communication, with an emphasis on abstraction, synthesis, and summation of information.
- The sickest patients should be discussed first, and information should be discussed in a consistent order.
- Ward sign-out should start at 4:00 pm. and last no longer than 30 minutes.
- All participants should be physically present the entire time.
- Uncompleted tasks should be completed after sign-out has been finished.
- Nursing staff and faculty should be instructed to not page ward house staff between 4:00 and 4:30 pm, except for emergencies.
- In general, interns should “give” sign-out with senior residents listening and/or clarifying.
- Medical students should attend but should primarily listen.
- Off-task activities, such as writing notes and putting in orders, should be minimized to promote efficiency, and only the essential information should be exchanged verbally. Other information can be written on the sign-out sheet and/or found elsewhere.
- Selected demographics, problems, medications, and treatments should be characterized.
- Only those things that are crucial to the child’s care should be discussed (e.g., if managing dehydration, the most recent set of electrolytes could be mentioned). Additional information can be included on the written sheet.
- It should not be necessary to replicate large amounts of information either verbally or on paper that are already in the patient’s medical record.
- Every sign-out should include a specific to-do list and contingency plans.
- The focus should be on trying to anticipate issues that might arise over the next shift, and what actions might be taken.

Assessment of the Effectiveness of Sign-Out Through Post-Call Surveys

During the baseline assessment, 158 of a total potential 196 surveys (81 percent) were completed, whereas during the post-intervention assessment, 168 of a potential 196 surveys (86 percent) were completed ($P = 0.71$). At baseline, 60 percent of the surveys were completed by members of the general pediatric ward team, and 40 percent were completed by residents who were “cross-covering” on the wards at night or during a weekend. By contrast, during the post-intervention assessment, 59 percent of the surveys were completed by members of the general pediatric ward team, and 41 percent of the surveys were completed by residents who were “cross-covering” on the wards at night or during a weekend ($P = 0.99$). For both time periods, this is very similar to the percentage of night calls covered by residents on the general ward team (62 percent) and residents who were cross-covering (38 percent).

Whereas the number of patients for whom residents were caring at the beginning of a call shift was significantly greater during the 4 months after the intervention than at baseline (20.24 ± 4.42 vs. 14.69 ± 4.39 , respectively, $P = 0.001$), the mean number of patients they admitted during a call shift was not significantly different after the intervention than at baseline (4.96 ± 2.67 vs. 4.86 ± 2.97 , respectively $P = 0.76$). Based on a 5-point Likert scale (1 = “slow” to 5 = “busy”),

the residents did not rate their call nights any busier after the intervention than at baseline (3.30 ± 1.11 vs. 3.02 ± 1.08 , respectively, $P = 0.25$), nor did they rate the quality of the sign-out they received any different using a 5-point Likert scale (1 = “inadequate to answer call questions” to 5 = “adequate to answer call questions”) (4.00 ± 0.77 vs. 4.08 ± 1.19 , respectively, $P = 0.47$).

Resident physicians indicated that something happened while they were on call for which they were not adequately prepared on 49 of 158 surveys (31 percent) at baseline assessment and on 62 of 168 surveys (37 percent) after the intervention ($P = 0.44$). During the baseline assessment, the residents indicated that in 40 of the 49 (82 percent) instances that something happened while they were on call for which they were not adequately prepared, there was information they did not receive during sign-out that would have helped them care for a patient overnight. At post-intervention assessment, the residents indicated that in 43 of the 62 (69 percent) instances that something happened while they were on call for which they were not adequately prepared, there was information they did not receive during sign-out that would have helped them care for a patient overnight ($P = 0.19$ as compared to baseline). These results are summarized in Figure 2.

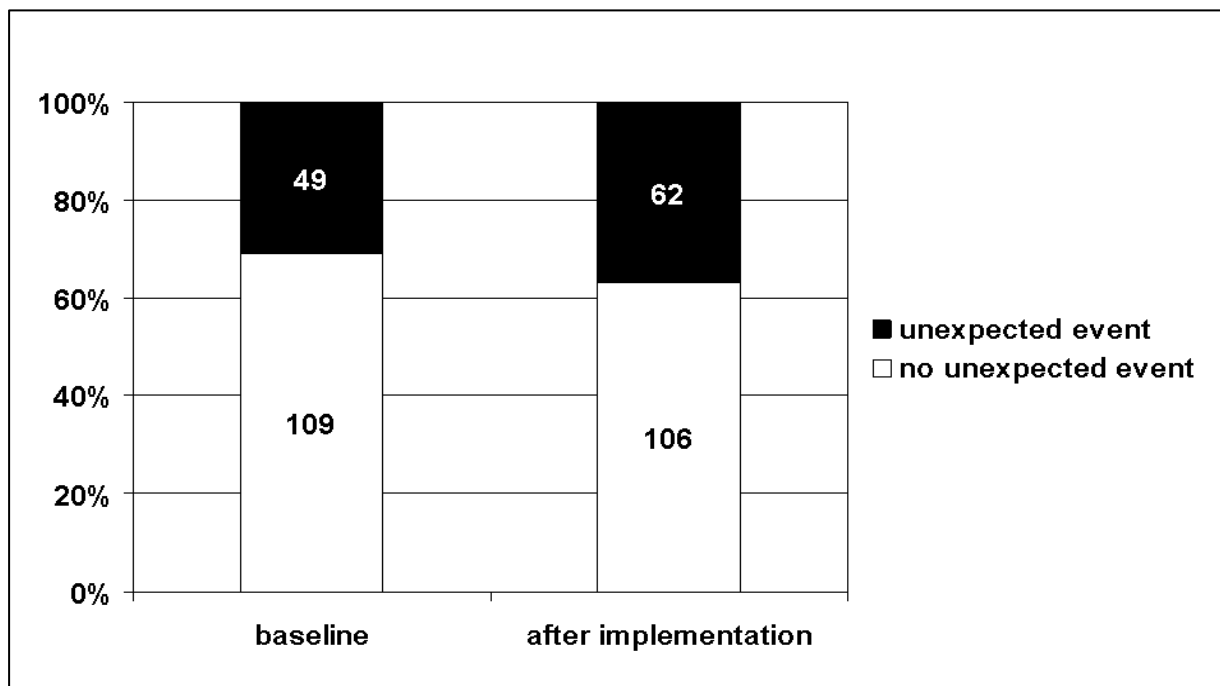


Figure 2. Percentage of call shifts with an unexpected event

During the baseline assessment, in 33 of the 40 instances (82.5 percent) in which they needed additional information, residents indicated the situation should have been anticipated and discussed during sign-out. During the post-intervention assessment, they indicated the situation should have been anticipated and discussed during sign-out in 33 of the 43 instances (77 percent) ($P = 0.59$ as compared to baseline). The number of call shifts when unexpected events occurred that the residents felt could have been anticipated and should have been discussed during sign-out was 33/158 (21 percent) at baseline and 33/168 (19.6 percent) after our intervention ($P = 0.79$). These results are summarized in Figure 3.

Residents assessed the quality of the sign-out they received using a 5-point Likert scale (1 = “inadequate to answer call questions” to 5 = “adequate to answer call questions”). During the baseline assessment and after the intervention, sign-outs for nights when something happened

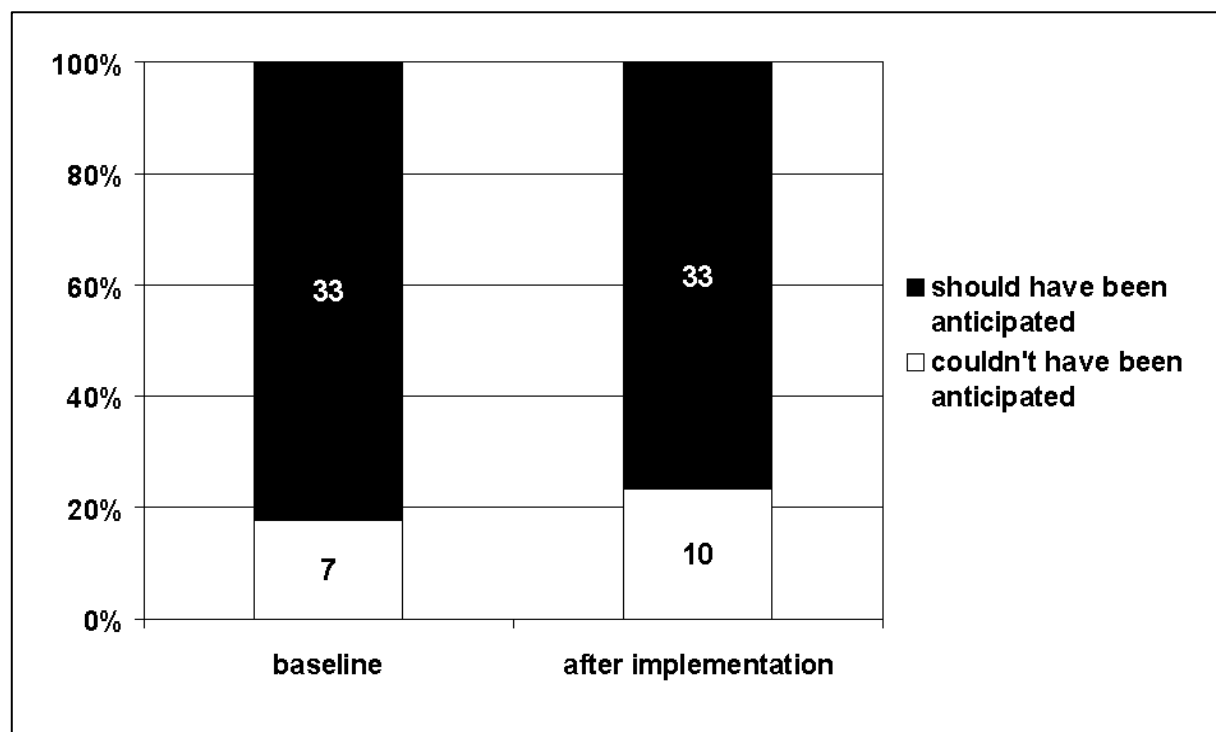


Figure 3. Percentage of unexpected events that should have been anticipated and discussed during sign-out

for which the residents were not adequately prepared were rated significantly lower than nights that nothing unexpected happened (3.58 ± 0.92 vs. 4.48 ± 0.70 , respectively, $P = 0.001$ at baseline, 3.74 ± 0.80 vs. 4.15 ± 0.71 , respectively, $P = 0.001$ after intervention).

At baseline, the likelihood of a resident experiencing an unexpected event during a call night did not appear to correspond to the number of patients the resident admitted during his call shift (4.86 ± 2.86 vs. 4.86 ± 3.21 , respectively, $P = 0.99$). However, after the intervention, residents experiencing an unexpected event during a call night tended to admit more patients during their call shifts than did residents who had no unexpected events during their call shifts (4.38 ± 2.21 vs. 5.27 ± 2.86 , respectively, $P = 0.03$).

The likelihood that a resident would experience vs. not experience an unexpected event during a call night did not seem to correspond to (1) how busy the night was (as assessed by a 5-point Likert scale (1 = “slow” to 5 = “busy”), baseline: 2.93 ± 1.07 vs. 3.25 ± 1.06 , respectively, $P = 0.08$; compared with after the intervention: 3.32 ± 1.10 vs. 3.29 ± 1.12 , respectively, $P = 0.86$, respectively; or (2) the number of patients the resident was caring for at the beginning of the call shift at baseline: 14.85 ± 4.33 vs. 14.33 ± 4.56 , respectively, $P = 0.49$; and after intervention: 20.5 ± 4.23 vs. 20.09 ± 4.54 , respectively, $P = 0.56$. These results are summarized in Table 1.

Table 1. Characterization of call nights before and after intervention

	Baseline (mean $\pm$ SD)		After intervention (mean $\pm$ SD)	
	No unexpected event	Unexpected event	No unexpected event	Unexpected event
How busy were you? ^a	2.93 $\pm$ 1.07	3.25 $\pm$ 1.06	3.29 $\pm$ 1.12	3.32 $\pm$ 1.10
How many patients were you caring for at the beginning of your call shift?	14.85 $\pm$ 4.33	14.33 $\pm$ 4.56	20.09 $\pm$ 4.54	20.50 $\pm$ 4.23
How many patients did you admit during your call shift?	4.86 $\pm$ 2.86	4.86 $\pm$ 3.21	5.27 $\pm$ 2.86	4.38 $\pm$ 2.21
Quality of the sign-out you received at the beginning of your call shift ^b	4.48 $\pm$ 0.70	3.58 $\pm$ 0.92	4.15 $\pm$ 0.71	3.74 $\pm$ 0.80

a 1 slow – 5 busy

b 1 inadequate – 5 adequate

Both during the baseline and post-intervention assessments, residents were no more likely to report events they were unprepared for when they were “cross-covering” at night than when they were members of the general pediatric ward team at baseline: 34.9 percent vs. 29.0 percent, respectively, $P = 0.60$; or after the intervention: 30.9 percent vs. 41 percent, $P = 0.20$. Similarly, both at baseline and after the intervention, when resident physicians reported an event for which they were unprepared, they were just as likely to have cared for that child previously as not: 50 percent vs. 50 percent, respectively, $P = 0.99$, at baseline; 51 percent vs. 49 percent, $P = 0.99$, after intervention.

On surveys in which residents ($N = 40$) indicated they did not receive information during sign-out that would have been helpful to them in caring for a patient overnight, they indicated where they went to get information that they did not receive during sign-out. At baseline, 14 residents (35 percent) went to the daily progress note in the chart, whereas after the intervention, only 6 (14 percent) went to the daily progress note in the chart ($P = 0.04$). At baseline, 8 residents (20 percent) reviewed the attending physician’s note, 4 (10 percent) reviewed a consultant’s note, and 10 (25 percent) reviewed nursing notes.

After the intervention, these numbers were 5 (12 percent), 4 (9 percent) and 10 (23 percent), respectively, $P > 0.3$, in every instance comparing baseline with post-intervention. At baseline 9 of the residents (22.5 percent) phoned an attending physician, 10 (25 percent) phoned a fellow, and 5 (12.5 percent) phoned a consultant. After the intervention, though, 10 of 43 residents (23 percent) phoned an attending physician, 6 (14 percent) phoned a fellow, and 1 (2.3 percent) phoned a consultant, $P > 0.1$, in every instance comparing baseline with after intervention. At baseline, in 13 of 40 instances (32.5 percent) and after the intervention, in 16 of 43 instances (37 percent), residents were unable to clearly find an answer to their question, and they used their best clinical judgment to resolve the issue ($P = 0.89$).

Discussion

The primary objective of any patient sign-out is the accurate transfer of information about the patient's current state and his or her plan of care.⁸ This transfer of information is crucial for patient safety and successful care.⁹ The risks of failing to be told, forgetting, or misunderstanding information that has been communicated during any patient care handoff are substantial.^{7, 8, 10} Incomplete information transfer and incomplete and/or unclear communication of the plan of care to covering physicians can adversely affect the quality of care.^{6, 7, 8, 9} Communication problems are judged to be the most common cause of preventable in-hospital disability or death,¹¹ and more than 60 percent of root causes of sentinel events reported to the Joint Commission have been judged to be due to failures of communication between health care personnel.¹² Resident physicians believe communication difficulties play a major role in the vast majority of medical mishaps they experience.¹³

Despite the increasing frequency and importance of sign-outs in medical practice, in most settings, sign-out remains an informal unstructured process with great variation and very little standardization, not only in the type and extent of information exchanged between care providers,^{9, 20} but also in the way and the order in which the information is conveyed.²¹ Even in the same “microenvironment,” hand-offs of care can vary tremendously.²²

This variability increases the potential for omissions of information and miscommunication.^{21, 23} It may also make it difficult to anticipate which information will be received in a hand-off, leading to wasted effort invested in looking for information in other places, even if that information has been covered. Moreover, it may make hand-offs less efficient because the “rules” would have to be negotiated for each hand-off.

This study further demonstrates that resident sign-out may be a point of vulnerability. Prior to and after our interventions, on nearly one-third of the nights they were on call, resident physicians indicated that something happened for which they were not adequately prepared. In the majority of these cases, they believed the situation could have been anticipated and should have been discussed during sign-out.

Surprisingly, resident physicians were no more likely to report an event they were unprepared for if they were “cross-covering” than if they were a member of the primary team. Similarly, residents were as likely to report an event for which they were not prepared whether they had cared for the child previously or not. When we reviewed answers to open-ended questions on our survey, three themes emerged about the deficiencies of sign out:

- Sign-out is not useful if the data provided during sign-out are not up to date.
- It is important to include a rationale for the plan of care so that if changes are needed during a call shift, there is a clear context for how to best make those changes.
- Residents should try to anticipate problems that might occur during a call shift and provide contingency plans for those potential problems.

The results of this and other studies indicate that sign-out between resident physicians is often inadequate and incomplete. While no studies have examined the sign-out process between

faculty physicians or between physicians in practice, it is likely these sign-outs suffer similar shortcomings. This should not be surprising, as few training programs formally teach resident physicians how to sign-out, and even fewer programs assess a resident physician's ability to sign-out to his or her colleagues.^{4, 12, 23, 24}

Presently, sign-out is almost always learned informally "on the job." Interns and junior residents learn how to sign-out by observing more senior residents give sign-out.^{1, 4, 23, 24} A number of authors have suggested that residents should be trained to communicate effectively at the time of hand-offs of care,^{1, 5, 14, 23, 24} however, there is little evidence to guide the development of such educational programs and even less evidence on the effectiveness of any training interventions.^{12, 24} While different authors have emphasized different components and strategies to improve sign-out,^{1, 5, 14, 23} the goals and characteristics of concise and complete sign-out must be defined before any specific curriculum can be created.

Some authors have proposed computer-based sign-out systems as a means of improving the efficiency and quality of resident-sign-out.^{1, 25, 26} In the few cases where computer-based sign-out systems have been characterized and evaluated, these systems have been developed as a means of automating existing sign-out processes to make them more efficient for the providers involved.^{20, 21}

Implementation of these systems has not been accompanied by any educational intervention(s), any systematic evaluation of pre-existing sign-out processes, or by any long-term systematic assessment of the systems' effect(s) on communication and patient safety. It is possible that, while these systems may increase resident efficiency and satisfaction with the sign-out process, they may increase rather than decrease miscommunications. Whereas technologic solutions can facilitate well-designed sign-out processes, they cannot substitute for successful communication.²⁷ Effective verbal communication will almost certainly remain crucial to ensure proper transmission of essential clinical information and facilitate collaborative cross-checking.^{12, 28}

With this group of studies, as part of our intervention, we characterized the goals and characteristics of concise and complete sign-out and created a curriculum to formally teach resident physicians how to sign-out to one another. We also characterized and developed a computer-based sign-out system built to the specifications outlined by the resident physicians as a means of improving the efficiency and quality of their sign-out process.

Informally, the residents felt that these interventions had substantially improved the quality and efficiency of their sign-out; however, we did not significantly influence our primary outcome measure. The number of call nights in which unexpected events occurred that the residents felt could have been anticipated and should have been discussed during sign-out was nearly identical before and after our intervention. Moreover, the residents themselves indicated that in the majority of cases, the unexpected event could have been anticipated and should have been discussed during sign-out.

There are many potential explanations for the apparent lack of effectiveness of our interventions. First, did the residents do what they had agreed to do? Despite plans to the contrary, sign-out

continues to take place in the Pediatric Library and remains rife with interruptions. Ward sign-out often does not start promptly at 4:00 pm and often runs longer than 30 minutes. As a result, nursing staff, faculty, and other house staff continue to frequently interrupt sign-out.

Despite incorporating an acuity index on the sign-out database and enabling residents to sort patients in the database a variety of ways, the residents continue to sign-out patients in an order based upon room numbers rather than by acuity. Although we have not yet completely analyzed our sign-out recordings after our interventions, our initial impression is that during their sign-outs, many residents do not emphasize abstraction, synthesis, and summation of information, nor does every sign-out include a specific to-do list and contingency plans.

Although we developed a brief curriculum and conducted several didactic talks and role-play sessions about sign-out, this may not have been an effective means of teaching residents how to sign out more effectively and more efficiently. This process helped the residents understand the general purpose(s) of sign-out and enabled them to characterize a structured sign-out process that may facilitate sign-out. However, it did not acknowledge that the objectives of sign-out likely change with the level of the learner and his/her clinical and interpretive skills. We developed a teaching curriculum and went through several simulation exercises, but we did not conduct any formal assessment of the curriculum, nor did we perform any formal assessment of the effectiveness of our teaching interventions.

To make it easier to assimilate, organize, and transfer information at sign-out, we also provided the residents with a computerized database tool built to their own specifications. The house staff readily accepted the tool, and it rapidly became an indispensable part of their workflow. In fact, they have adapted this computerized tool for use in a variety of other settings throughout the hospital. It is conceivable that the iterative process of developing and refining the tool may have been more useful than the tool itself, in that it may have helped force some standardization of process and content.

Perhaps some of our underlying premises were incorrect. After our interventions, the residents felt ward sign-out had become more efficient and more effective, and yet, we saw no decrease in the number of unexpected events during call shifts that should have been anticipated and discussed. Perhaps the information the residents told us they needed to conduct safe, effective, and efficient sign-outs is not the information they really need to best care for their patients during call shifts.

A number of authors have suggested what an ideal sign-out should entail, and guidelines have been proposed for a standardized approach to hand-offs of care.^{29, 30, 31} However, these recommendations are not based on any hard evidence but rather on some level of consensus. We, too, used consensus building as the means of characterizing the content and process of an ideal sign-out on our pediatric wards.

While many of the questions that arise during a call shift pertain to the plan of care and its rationale,³² most of the time spent during sign-out is devoted to one-way information delivery from the residents going off call to those coming on call. Much of the information that is

conveyed is background information that is, or should be, readily available from other sources, particularly the medical record.

One unanticipated outcome of our intervention was that, following our interventions, residents faced with an unexpected event were even less likely to go to the daily progress note in the medical record. The fact that at baseline residents rarely went to the daily progress note in the medical record to try to address issues that arose while they were on call suggests that they did not expect to find the information they needed in the medical record. The medical record has increasingly been marginalized as a source of communication between clinicians. Third parties have increasingly imposed additional demands on the clinical record; courts regard patient charts as evidence in legal proceedings; and payers use the quantity and quality of documentation in medical records to justify the level of reimbursement for services.²⁷ In many settings, residents and attending physicians view the generation of documentation for the medical record as a billing and administrative function, rather than as a means of communicating important clinical information to one another.¹⁰ As a result, important clinical information may be exchanged verbally and/or through sign-out and never be entered in the medical record.^{7, 8, 10} Perhaps we further compounded this tendency by providing the residents with a “mini-medical record” in their computerized sign-out tool.

This study has a number of limitations. While the study was performed prospectively, our principal means of data collection was through post-call surveys, during which we asked resident physicians to assess the quality of the sign-out they had received when they began their call shift, and whether problems could and should have been anticipated and discussed during sign-out. These types of assessments can introduce significant hindsight bias. Moreover, many factors may influence a house officer’s assessment of the quality of the sign-out they received prior to their call shift, including the level of interpersonal trust they share with the person giving them sign-out.³³

Another potential limitation of our study is that it was performed at a single institution on a single ward service. This may limit our results’ generalizability, as there may be unique aspects to this particular acute general pediatric ward service; e.g., it is geographically located on a single floor and by its very nature involves pediatric patients who often cannot talk. Thus, there may be an increased importance of caregivers and larger variation in medication doses.

Conversely, some aspects of the study may make our results applicable to a wide variety of settings. For example, there is a relatively rapid turnover of patients, as is typical of many pediatric and medical acute ward services in university hospitals. Moreover, the study included pediatric and family medicine residents at multiple levels of training.

Conclusion

The results of this study indicate that sign-out between resident physicians is often inadequate and incomplete. Our data suggest these deficiencies are not related to the specific role of the resident physicians giving or receiving sign-out, how busy those residents are while they are on-call, or how ill the patients being cared for by the on-call residents are.

Perhaps these deficiencies are due to exchange of the incorrect information during the sign-out process. A number of residents commented on the importance of including contingency plans, as well as the rationale for the plan of care, during sign-out, so that if changes are needed during an on-call shift, there will be a clear context for how to best make those changes. This type of information often is not included during sign-out, and increasingly, it is difficult to find in the medical record. This is evidenced by the fact that nearly one-third of the time, residents were unable to find answers to questions that arose while they were on call and had to rely on their best clinical judgment.

Future studies should be directed at identifying the information physicians need while on-call and clearly describing the goals and characteristics of concise and complete sign-out. Additional studies are also needed to identify how to best teach and evaluate a physician's ability to sign-out and how technology can be employed most effectively and appropriately.

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Appendix 1: Post-Call Survey

Name _____

Today's Date _____

Post-Call Survey: We are conducting a short survey to better understand our current sign-out process. Please answer the following questions based on your most recent call night.

ALL individual results will remain strictly confidential and, when entered into the database, they will be anonymous.

1. How would you rate your most recent call night? Please circle the correlating number.

1-----2-----3-----4-----5
Slow Medium Busy

How many patients were you responsible for caring for when you started call? _____

How many patients did you admit while you were on call? _____

How many patients did you transfer to the PICU while you were on call? _____

2. Did anything happen while you were on call that you were not adequately prepared for after sign-out?

No _____

Yes _____

If you answered yes to this question, please elaborate in one or two sentences:

If you answered yes to this question please pick the most important incident that happened during your call night to answer questions 3 thru 8. If you answered NO, skip to question #9.

3. Was there information that would have been useful that you DID NOT receive during sign-out?

No _____ If you answered no to this question, please skip to question #7.

Yes _____ If you answered yes, please continue with questions 4 thru 10.

4. Where did you go to get information that you did not receive during sign-out? (check all that apply)

The chart:

Made a phone call to:

_____ resident progress note

_____ an attending physician

_____ attending physician note

_____ a fellow

_____ consultant note

_____ the chief resident

_____ the bedside chart

_____ a consultant

_____ other

_____ somebody else

The computer:

_____ MIS

_____ CareCast

_____ other

_____ Made it up as it as best I could using my clinical judgment

- _____ Asked patient and/or patient's family
- _____ I couldn't get it
- _____ Other source not listed here, please describe
-

5. Which information sources were most useful in getting the information you required?

The chart:

A phone call to:

- _____ resident progress note
- _____ an attending physician
- _____ attending physician note
- _____ a fellow
- _____ consultant note
- _____ the chief resident
- _____ the bedside chart
- _____ a consultant
- _____ other
- _____ somebody else

The computer:

- _____ MIS
- _____ CareCast
- _____ other

- _____ Making it up as best I could using my clinical judgment
- _____ Asking the patient and/or patient's family
- _____ I couldn't get it
- _____ Other source not listed here, please describe
-

6. Should this situation have been anticipated and discussed during sign-out?

No _____

Yes _____

7. Had you previously cared for this patient (either during a previous call night or a previous day shift)

Yes _____

No _____

8. Did you write a cross-cover note (not a daily progress note) about this situation in the chart?

Yes _____

No _____

9. Overall, how would you rate the sign-out you received at the beginning of your call night?

1-----2-----3-----4-----5

Inadequate to answer
call questions

Adequate to answer
call questions

10. Do you have any other comments or suggestions about sign-out that you would like to share at this time?

*MIS = Medical Information System, which is a hospital wide computerized physician order entry system

**CareCast = computerized results and document repository

Documentation of Mandated Discharge Summary Components in Transitions from Acute to Subacute Care

Amy J.H. Kind, MD; Maureen A. Smith, MD, MPH, PhD

Abstract

Objectives: The Joint Commission mandates that six components be present in all U.S. hospital discharge summaries. Despite the critical importance of discharge summaries in care transitions and patient safety, no studies have examined how well discharge summaries adhere to Joint Commission standards. **Methods:** Joint Commission-mandated discharge summary components were specifically defined and abstracted from discharge summaries for all hip fracture, stroke, and cancer patients discharged directly to subacute care facilities from a large Midwestern academic hospital between 2003 and 2005 (N = 599). **Results:** Preliminary results show that most (88-100 percent) discharge summaries included five of the six Joint Commission components. The remaining component, “patient’s discharge condition,” was included the least often (79-90 percent). **Conclusions:** Overall, discharge summaries adhere well to Joint Commission discharge summary component standards. However, given the discharge summary’s pivotal communication role in care transitions, even a small frequency of omitted patient discharge condition information is a concern and may affect patient safety.

Introduction

Hospital discharge summaries serve as the primary documents communicating a patient’s care plan to the post-hospital care team.^{1, 2} Often, the discharge summary is the only form of communication that accompanies the patient to the next setting of care.¹ High-quality discharge summaries are generally thought to be essential for promoting patient safety during transitions between care settings, particularly during the initial post-hospital period.^{1, 3, 4, 5}

The Joint Commission has established standards (Standard IM.6.10, EP 7) outlining the components that each hospital discharge summary should contain.⁶ These components are:

1. Reason for hospitalization.
2. Significant findings.
3. Procedures and treatment provided.
4. Patient’s discharge condition.
5. Patient and family instructions (as appropriate).
6. Attending physician’s signature.

However, no clear and specific definition exists in the published literature for these components. Additionally, it is not clear to what extent these standards are met in hospital discharge summaries.

We are conducting a study designed to examine the completeness of discharge summary documentation in a large Midwestern academic hospital for patients discharged to subacute care facilities. In this paper, we provide an overview of the study methods, including definitions for the Joint Commission-mandated discharge summary components, and preliminary results regarding the prevalence of the Joint Commission-mandated components within study discharge summaries.

Methods

Study Sample

We identified all patients older than 18 years of age who were discharged from a single large Midwestern academic hospital (N = 612) to subacute care facilities (i.e., nursing homes or rehabilitation centers) with primary diagnoses of lung/colorectal/breast/prostate cancer, stroke, or pelvis/hip/femur fracture during the years 2003, 2004, and 2005. We focused on the subacute care patient population because they represent a vulnerable group of patients who are often unable to advocate for themselves and who are at high risk for adverse outcomes.⁷

Major cancers, stroke, and hip fracture were chosen because they represent some of the most common and complex diagnoses for geriatric patients in subacute care.^{7, 8} Eligible subjects with discharges to subacute care facilities during 2003, 2004, and 2005 were identified by use of administrative data compiled on a mandatory basis by hospital case managers for all patients in the study hospital prior to discharge. Internal testing of this system by the study hospital found approximately 99 percent reliability of this field.

Primary diagnoses were established using the International Classification of Diseases, 9th edition (ICD-9) diagnosis code in the first position on the acute hospitalization discharge diagnosis list in the study hospital billing records. ICD-9 diagnosis codes of 153, 153.0-153.9, 154, 154.1 (colon and rectal), 162, 162.0-162.9 (lung), 174, 174.0-174.9 (breast), 185, 185.0-185.9 (prostate) were used to identify cancer diagnoses;^{9, 10} 431, 432, 434, 436 codes were used to identify stroke;^{10, 11, 12} and 805.6, 805.7, 806.6, 806.7, 808, 820 codes were used to identify hip fracture.^{13, 14, 15}

A small number of subjects experienced more than one hospitalization meeting eligibility criteria during the 2003 to 2005 timeframe. Each of these hospitalizations was treated as a separate event (17 subjects contributed 2 discharge summaries to the study). During the abstraction process, patients were excluded if they did not have a discharge summary (N = 5) or if the abstractor deemed that it was clear from the discharge summary that the patient did not go to a subacute care facility (N = 5); did not have primary diagnoses of cancer, stroke, or hip fracture (N = 2); or if the patient had been discharged on hospice (N = 1). One cancer patient, eight stroke patients, and four hip fracture patients were excluded.

Discharge summaries were obtained from the study hospital's electronic medical record system and formatted so that they were identical in line/page length to the discharge summaries sent to patients' care providers after acute hospitalization. The Institutional Review Board at the University of Wisconsin approved this study.

This paper presents the preliminary results after 44 percent (266/599) of the total sample of eligible discharge summaries had been reviewed, abstracted and analyzed.

Variables

The Joint Commission-mandated discharge summary components do not have specific, operationalized definitions published for abstraction purposes. Therefore, to increase abstraction reliability for this project, specific definitions for each component were arrived at via consensus among two physicians and one geriatric nurse practitioner. Each component definition was then included within an abstraction instruction manual, which abstractors had available to them during the abstraction process and from which they were trained. The presence or absence of all Joint Commission-mandated components was abstracted from each discharge summary. The total page number was also counted for each summary.

Abstraction Process

To optimize abstraction reliability, a standardized protocol was used to train medical record abstractors and to abstract clinical data from medical records.¹⁶ Discharge summaries were abstracted onto paper abstraction forms by two medical abstractors (one geriatric nurse practitioner and one geriatric physician). An abstraction manual was created and included sample eligibility criteria and specific definitions for each discharge summary component to be abstracted (as defined via the process described above). Additionally, detailed instructions for each item in the abstraction form were included in the manual.

Prior to the initiation of formal abstraction, two half-day training sessions were conducted, during which each abstractor received a study overview, reviewed the manual, and abstracted 20 nonstudy ("training") discharge summaries onto the study abstraction form. The abstraction results for each training discharge summary were compared. For items with discrepancies, the abstractors discussed the reasons for their particular answers until a consensus was reached, and a uniform approach for abstraction was adopted. For each of these items, the manual was updated to reflect the consensus uniform approach.

During the formal study, after every 100 study discharge summaries had been completed, 10 percent of each abstractor's discharge summaries were re-abstracted by a second abstractor to measure reliability. The abstractors convened at least monthly to discuss difficult abstraction items and those items with low reliability (i.e., low percentage agreement and kappa <0.8) so that a consensus approach could be reached. After each of these discussions, the manual was updated to reflect the adopted approach.

After each update, new copies of the manual were given to the abstractors for their reference. As the abstraction forms were completed, data were transferred by trained data entry technicians

from the paper forms into a standardized Microsoft Excel® 2002 template and were then cleaned. Possible errors flagged during data cleaning were returned to the abstractors for correction or notation as to why the original information was correct.

Analysis

Analyses were performed using SAS® version 9.1 and Stata® version 9.0. All confidence intervals (CI) and significance tests were significant at $P < 0.05$. The kappa statistic and percent agreements were calculated to measure abstraction reliability.^{17, 18}

Results

Discharge Summary Characteristics and Joint Commission Component Definitions

A total of 599 eligible subjects were identified; 44 percent of discharge summaries were abstracted by the time of this report, with 20 cancer, 112 stroke, and 121 hip fracture patient discharge summaries included in this analysis. Discharge summaries averaged 3.6 pages (SD = 1.0) in length. Stroke patients had the longest [3.6 (1.2)] and cancer patients had the shortest [3.2 (0.5)] discharge summary lengths (Table 1).

Table 1. Discharge summary sample characteristics (N = 253)

Characteristics	Stroke	Hip Fracture	Cancer
Number of discharge summaries	112	121	20
Page length [mean (SD)]	3.6 (1.2)	3.6 (0.8)	3.2 (0.5)
Page number range	2 - 9	2 - 6	2 - 4

All Joint Commission-mandated discharge summary components were defined using the consensus process noted in the methods section. Definitions were created using common terms found in medical documentation (Table 2):

1. “Reason for hospitalization” was defined as chief complaint and/or history of present illness.
2. “Significant findings” was defined as primary diagnoses.
3. “Procedures and treatment provided” was defined as hospital course and/or hospital consults and/or hospital procedures.
4. “Patient’s discharge condition” was defined as any documentation that gives a sense for how the patient is doing at discharge or the patient’s health status on discharge.
5. “Patient and family instructions (as appropriate)” was defined as discharge medications and/or activity orders and/or therapy orders and/or dietary instructions and/or plans for medical followup.
6. “Attending physician’s signature” was defined as an electronic or physical signature of the attending physician on the discharge summary.

Table 2. Joint Commission-mandated component definitions

Joint Commission-mandated components	Consensus definition
Reason for hospitalization	Chief complaint (any description of the patient's primary presenting condition); AND/OR
	History of present illness (a description of a patient's initial presentation to the hospital admission including a description of the initial diagnostic evaluation)
Significant findings	Primary diagnoses (admission/discharge diagnoses noted in the discharge summary)
Procedures and treatment provided	Hospital course (a description of the events occurring to a patient during his/her hospital stay); AND/OR
	Hospital consults (a description of surgical, medical, other specialty or allied health consults a patient experienced as an inpatient or a specific statement that "no consults" occurred); AND/OR
	Hospital procedures (a description of surgical, invasive, non-invasive, diagnostic or technical procedures a patient experienced as an inpatient or a specific statement that "no procedures" occurred)
Patient's discharge condition	Any documentation that gives a sense for how the patient is doing at discharge or the patient's health status on discharge
Patient/family Instructions (as appropriate)	Discharge medications (a listing of all discharge medications OR a statement noting that admission medications are unchanged AND a listing of admission medications OR a statement noting that admission medications are unchanged except for a specific number of medications AND a listing of the altered medications AND a listing of admission medications); AND/OR
	Activity orders (orders for a patient's activity level upon hospital discharge); AND/OR
	Therapy orders (orders for physical or occupational therapy are present within the discharge summary or a reason is documented as to why such orders are not present); AND/OR
	Dietary instructions (a listing of a patient's recommended dietary intake); AND/OR
	Plans for medical followup (designation of a specific professional, professional type, or clinic for medical followup AND/OR a specific listing of appointment dates and times for medical followup AND/OR a specific timeframe for medical followup)
Attending physician's signature	An electronic or physical signature of the attending physician on the discharge summary

Prevalence of Joint Commission-Mandated Discharge Summary Components

In general, Joint Commission-mandated components were commonly included in study discharge summaries (Table 3). Four of the six Joint Commission-mandated components were included in virtually all discharge summaries (99 to 100 percent). These included “reason for hospitalization,” “significant findings,” “procedures and treatment provided,” and “patient/family instructions (as appropriate).” The “attending physician’s signature” component was included in 88 to 95 percent of discharge summaries, with hip fracture discharge summaries exhibiting the lowest and cancer discharge summaries exhibiting the highest inclusion rates. The remaining component, “patient’s discharge condition,” was included in 79 to 90 percent of discharge summaries, depending on disease type. “Patient’s discharge condition” was the component included the least often in stroke, hip fracture, and cancer patient discharge summaries.

Table 3. Prevalence of Joint Commission-mandated components in study discharge summaries (N = 253)

Joint Commission-mandated components	Frequency of inclusion (%)		
	Stroke (N = 112)	Hip fracture (N = 121)	Cancer (N = 20)
1. Reason for hospitalization	99	99	100
2. Significant findings	99	99	100
3. Procedures and treatment provided	100	100	100
4. Patient's discharge condition	79	83	90
5. Patient/family instructions (as appropriate)	99	100	100
6. Attending physician's signature	91	88	95

Discussion

Despite the critical role that discharge summaries play in care transitions^{1, 4} and the existence of Joint Commission standards mandating certain discharge summary components,⁶ ours is the first study to specifically define and document the prevalence of Joint Commission components in U.S. discharge summaries. Overall, preliminary results demonstrate that the discharge summaries within our sample adhere well to most of the Joint Commission standards. However, given the discharge summary’s pivotal communication role in care transitions, even a small frequency of omitted patient discharge condition information is a concern and may influence patient safety.

In this study, we offer reliable, specific, consensus-based definitions of each Joint Commission component. Remarkably, we are the first study group to do so. These definitions can be utilized to reliably and specifically abstract discharge summaries to document compliance with Joint

Commission standards. Reliable and specific definitions such as these will be helpful in ensuring adequate, reproducible assessments of discharge summary completeness in the future.

The high rate of adherence to five of the six Joint Commission component standards for discharge summaries within our sample is likely due to two major factors. First, the Joint Commission-mandated components are extremely broad/general. With minimal documentation, it is simple for a practitioner to meet the Joint Commission component standards. A recent systematic review noted that studies that have examined recommended discharge summary components more specific than those mandated by the Joint Commission have found relatively high rates of omission.^{1, 2, 19} However, the vast majority of studies referenced in this review were conducted within British and Canadian health care systems. Additional research is needed to verify if similar omission patterns exist in U.S. discharge summaries. Secondly, the Joint Commission standards themselves affect practice patterns substantially. It is likely that discharge summary creation may be carried out in a manner specifically designed to meet the Joint Commission criteria. This theory would suggest that a modification of the Joint Commission discharge summary component standards might be instrumental in changing U.S. discharge summary documentation practices.

The relatively high omission rate of the “patient’s discharge condition” Joint Commission standard we observed could have important implications for subacute care patients’ care plans and health outcomes. Ideally, such information allows the subacute care team to understand the patient’s health and functional status at the time of hospital discharge, enabling the team to better identify worrisome early changes in a vulnerable patient they otherwise do not know well. Within the subacute care population, such information is especially important because these patients are often unable to advocate for or provide medical information about themselves. They are an extremely medically complicated and vulnerable population, highly reliant upon the health care system to transmit information regarding their condition and care plan. Multiple experts have recommended that detailed information concerning the patient’s discharge condition be included in all hospital discharge summaries.^{1, 5, 20} Nevertheless, no evidence has been published to document the actual impact an omission of this nature has on patient health and safety outcomes.

From our data, it is clear that adherence to the discharge condition standard varies considerably across primary disease types, with cancer and stroke patients having the highest and lowest adherence rates, respectively. Cancer, hip fracture, and stroke patients are often cared for by physicians of different specialty types (i.e., internists, orthopedists, and neurologists). As physicians author the majority of discharge summaries—even though they usually receive little or no training in the creation of discharge summaries during medical school—it is possible that differences in formal or informal discharge summary training during residency account for the variation observed here. Alternatively, differences in the resources provided to a particular type of provider during discharge summary creation, such as dedicated time, medical record availability, and multidisciplinary team support, may also play a role. Additional research in this area would be helpful to guide the design of a targeted intervention to improve discharge summary communication.

The lower rate of adherence to the “patient’s discharge condition” Joint Commission standard noted in this study does not seem to have been reflected as a common deficiency in the Joint Commission accreditation process. Although the Joint Commission has a renewed focus on within-institution (i.e., intra-institutional) transitions and documents the quality of these transitions using the patient tracer methodology, less attention has been paid to between-institution (i.e., inter-institutional) transitions.²¹ Therefore, enforcement of the Joint Commission standards likely echoes this pattern of focus and may affect the enforcement of discharge summary standards.

Given the general nature of the Joint Commission discharge summary component standards, it remains unclear whether such standards are sufficient to maximize patient safety during care transitions. Many experts advocate for inclusion of more specific components in discharge summaries.^{1, 2, 3, 5, 19, 20, 22, 23} Omission of information regarding pending tests and plan of care at discharge, in particular, has been shown to have an impact on post-hospital patient care plans and physician practice behavior but has not been linked directly to post-hospital patient safety and health outcomes.^{24, 25} Future research needs to address the impact specific discharge summary components—such as discharge medications, plan of care, pending tests, and medical followup—have on post-hospital patient safety and health outcomes.

The primary limitations of this study relate to its preliminary nature and overall generalizability. Given that these results are based on a subset of our total sample, including only a very small number of primary cancer patients, our results regarding the discharge summary component frequencies may change slightly as the full sample abstraction is completed. However, thus far in our abstraction process, the inclusion rates of Joint Commission components have been largely stable. Since this work was completed using discharge summaries at a single large Midwestern academic institution, it is unclear whether these results are representative of other academic or community health care facilities in the United States. Additional research to examine the discharge summaries generated at other U.S. health care institutions is necessary to know whether the results presented here can be replicated. Our component definitions were based on input from a consensus panel of physicians and one geriatric nurse practitioner. Inclusion of additional multidisciplinary viewpoints may result in some alteration of the definitions reached.

Conclusion

In conclusion, it is possible to reliably and specifically abstract Joint Commission-mandated components from discharge summaries. Most discharge summaries in our sample adequately meet most of the Joint Commission standards. The Joint Commission-mandated component of “patient’s discharge condition” is most often omitted, and the impact such omissions have on patient safety during transitions of care is unclear. Additionally, whether the Joint Commission standards are sufficient to maximize patient safety during the highly vulnerable period of a care transition remains unknown.

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Challenges to Real-Time Decision Support in Health Care

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Abstract

This article describes challenges in the design and development of a decision support system for trauma patient resuscitation that is used to encourage consistency and reduce error rates. The Trauma Reception and Resuscitation Project links real-time, computer-generated prompts from best practice algorithms via visual and auditory displays. Its functionality is now being tested. Evaluation of this decision support approach can employ patient chart review or observation, but we describe an approach that measures the process of care by video audit. Key process problems in trauma management (e.g., errors of omission, commission, and misprioritization) are identified. The video record provides a framework for learning and feedback. Future testing and development of this system will include a randomized clinical trial and technology enhancement.

Introduction

The development, testing, and validation of a real-time decision support system for use during trauma patient reception and resuscitation present many challenges. The decision support system described in this article is part of the Trauma Reception and Resuscitation (TR & R) Project at The Alfred Hospital and Swinburne University of Technology in Melbourne, Australia. The hypothesis that inconsistency and medical errors can be reduced by use of a decision support tool is currently being tested in a randomized clinical trial. The TR & R Project concentrates on the first 30 minutes of trauma patients' hospital reception and resuscitation.¹ The types and causes of errors that occur in the complex dynamic medical domain of a trauma center and the need for decision support are described. An interdisciplinary approach to decision support development is outlined. Future output, testing, and development of the TR & R Project are described

Safety and Errors in Emergency Medical Care

Cognitive errors during emergency care are a significant contributor to patient harm. Approximately half the litigation brought against emergency physicians arises from delayed or missed diagnoses.² Traditionally, cognitive errors are classified into those of omission and commission. Omission errors are, in hindsight, events that occur through the natural progression of a disease, and they are noted as a tendency toward inaction. In a total error of omission, nothing has been done to achieve a goal; in a partial omission, some action has been taken. Errors of omission are more difficult to detect than those that can be attributed directly to the action of a physician.² In contrast, errors of commission result in harm to the patient that, in hindsight, could have been prevented by different or no interventions. Such errors are more

likely to be committed by overconfident physicians. They include premature, irrelevant, redundant, unmotivated, and prohibited actions. Commission errors are less common than omission errors.³

The problems associated with medical errors of commission and omission become most apparent in complex clinical settings where decisionmaking is carried out under stress and time pressure, as in trauma patient resuscitation. Human limitations in performing reliably and consistently in challenging situations have been documented in high-hazard industries, such as shipping, electric power production, chemical manufacturing, and the military.⁴ Efforts to improve patient safety and outcomes rely on strategies to ameliorate or eliminate the impact of human limitations.⁵ A “culture of reliability” is needed to encourage uniform responses and conformity to standard operating procedures. Health care providers might reject such an approach because they fear loss of autonomy.

Human variables that confound standardized environments and thereby lead to avoidable errors have been delineated by the airline industry.^{5, 6} To reduce critical error rates in that industry, computerized prompts have been built into flight control systems, providing immediate feedback and thus enhancing error avoidance.⁵ In the TR & R Project, uniform and appropriate responses for the trauma team are guided by decision support software and the structured data generated by computer prompts.

Decision support algorithms for trauma resuscitation in emergency departments have been developed over the past 2 decades,^{7, 8} in part, in an attempt to bring uniformity into complex environments that are often characterized by high staff turnover. Frequent changes in personnel result in a need for coordination of activities among team members who are trained in a variety of treatment approaches and have variable amounts of experience in a particular resuscitation workspace. Studies have demonstrated that formal trauma patient algorithms encourage consistency, reduce error rates, prevent cognitive overload, and significantly reduce resuscitation time.⁹

In the complex environment of receiving areas for patients with major trauma, communication remains problematic. Even when experienced clinicians are involved, communication of significant clinical decisions fails 50 percent of the time.¹⁰ An important reason for preventable adverse events in clinical care was found to be cognitive overload of physicians. Evidence-based clinical guidelines can reduce variability in practice and improve patient outcomes.⁸ However, clinical teams working in real time and providing emergency care do not have access to sufficient computer-based information to support their practice in this demanding environment. This is due to gaps in published clinical practice guidelines and also because trauma centers have been slow to adopt decision support systems.

Most errors that arise during the emergency department/trauma center phase of care relate to resuscitation.¹¹ Failure to intervene and reverse life-threatening conditions during this phase of care are related to inexperience, disorganized activity, an inability to organize priorities, fixation error, and failure to realize the complexities of the problem(s). The coordination of multiple activities¹² may be just as critical for patient survival as making the correct diagnoses or performing the most appropriate procedures. Errors in trauma resuscitation may have little immediate effect, yet they may eventually compromise patient outcome. Nonstandard and

nonuniform approaches confound the interpretation of error rates and hamper the retrospective, subjective judgment of error.¹³

Implementation Issues

Algorithms

A new approach is required, using point-of-care, integrated resuscitation treatment algorithms and real-time, computer-generated prompts. Algorithms act as decision support systems that define the standard of care for trauma reception and resuscitation. The most rigorous application of algorithms in clinical decisionmaking involves rule-based computer systems. Bedside (point of care) computerized protocols that standardize clinical decisions for the mechanical ventilation of patients with adult respiratory distress syndrome have been used since 1992.¹⁴ Clinical algorithms using a branched-tree logic approach have been used since the early 1980s to guide fluid resuscitation.⁷ These algorithms have improved the outcomes of hypotensive patients in the emergency department,¹⁵ encouraged consistency, and reduced resuscitation time and errors.⁸

Need for Decision Support Systems

During trauma patient resuscitation, errors occur due to uncertainty, time pressure, and communication failures among the members of ad hoc teams that often are brought together for a single patient encounter. Because of multitasking and inadequate information in this dynamic and complex environment, decisionmaking occurs under nonoptimal circumstances and could benefit from algorithm-based assistance.

During the initial resuscitation phase of trauma patient management, resources are in short supply, time is constrained, and shortcuts are being sought.² Decision support should facilitate what Reason called “flesh and blood” decisionmaking.¹⁶ Diagnostic errors are associated with proportionately more morbidity than are other types of medical errors. Decisionmaking during trauma patient resuscitation is limited by poor access to information and limited time to process it in a milieu well known for error production,² where heuristics dominate. In an analysis of emergency department closed claims, Morey found that improved teamwork behaviors would have prevented an adverse event and indemnity payments in 43 percent of cases.¹⁷ There is evidence that a standardized algorithmic approach reduces error, that real-time prompts increase compliance, and that video analysis improves accuracy and compliance.¹³ Clinical algorithms linked to real-time decisionmaking, with an awareness of team coordination needs, can deliver patient-specific advice, thus integrating decision support into the clinical workflow (“process alignment”).¹

Challenges in Emergency Trauma Care

The challenge of decisionmaking during emergency trauma care is that there is no consistent pattern of patient injury. The site and extent of injuries are unknown during the initial minutes after the patient is admitted to the trauma center. Team management for resuscitation is variable, with newer concepts (e.g., hypotensive resuscitation¹⁸) contradicting conventional [e.g., Advanced Trauma Life Support (ATLS)] training. There is a need for a variety of personnel with different training backgrounds, experience, and clinical disciplines (e.g., physicians, nurses, technicians, therapists) to work together in close physical proximity around the trauma patient.

Research findings have repeatedly demonstrated the difficulty of measuring the impact of a single intervention in a complex, nonstandardized environment with multiple variables.¹³ The major variables in resuscitation include human factors, especially staff experience and expertise, and associated variability in resuscitation practices. Access to specific expertise may not be readily available. The typical clinician is affected by these stressors. Although clinicians make the right decisions most of the time, many of the interventions undertaken in these first few critical minutes may not be done at the right time, in the right amount, or in the right order.⁷

Considering these challenges in combination with the fact that 50 percent of emergency department communications fail, it is surprising that patient outcomes are as good as they are. The stimulus for the TR & R Project in Victoria was the finding by the Consultative Committee on Road Traffic Fatalities that 25 percent of trauma deaths in the state were preventable.¹¹ The committee reported that the emergency department phase of care was responsible for the greatest number of errors—a mean of 7.52 per patient.¹¹

The human challenges to the study include the technology and psychomotor workload, preservation of confidentiality of video-recorded data, and obtaining consent and Institutional Review Board approval. Video recording can be a fruitful tool for the prospective evaluation of a decision support system.^{19, 20, 21} However, challenges in deploying video recording technology are numerous.²²

Long-running video recording programs, such as the one instituted at the University of Maryland, have utilized a number of techniques,²³ including transparency and communication with staff, technology solutions, and analytic approaches.²⁴ The main cost associated with audit is related to the personnel time involved. Video audit is a time-consuming task that requires dedicated support and funding. Linking computer-generated prompts via visual and auditory displays in the resuscitation bay may enhance clinicians' interactions and reduce errors of omission and miscommunication. The TR & R Project measures compliance with the prompts—rather than prelearned algorithms—using video audit. Such an approach may allow an objective and streamlined means of audit, reducing the time-consuming process associated with peer review.¹³

Products and Their Evaluation

TR & R Software Function

The treatment decision tools were developed after review of several hundred published algorithms—available for many resuscitation tasks and decisions—that were published in emergency medical, radiologic, anesthesiology, surgical, and nursing texts. The draft algorithms then underwent several levels of compliance testing of interfaces, screen displays, and content of the prompts. During this time, the clinical staff from The Alfred Trauma Centre went to the Swinburne University of Technology Laboratories to iteratively test the TR & R system and provide their feedback to the software developers. The final algorithms written into the TR & R software were agreed upon by consensus among emergency medical, radiologic imaging, surgical, anesthesiology, and nursing staff at The Alfred Trauma Centre. The TR & R software system is scalable and exportable, with computer-prompted algorithm displays for real time use

on patients with major trauma.^{1, 13} These algorithms define the standard of care for trauma patient resuscitation.

To facilitate maintenance and ensure robustness, the TR & R software architecture is modular and component-based. The modular design (Figure 1), developed by software engineers at Swinburne University of Technology, allows individual components to be replaced as existing hardware is upgraded (e.g., vital signs monitors, audiovisual equipment) and portions to be reused when the system is expanded as new capabilities are introduced. The algorithm designer is a separate custom built tool that allows the graphic representation of algorithms and customization of reference data (Figure 2) by medical staff themselves without intervention by the software developers. Software is written in an intuitive, easy language, in which the algorithms can be modified or new ones generated by the end users themselves. The data used by the algorithm engine are at the core of the trauma reception and resuscitation software (Figure 3). A video data acquisition system overlays patient monitoring data onto the video recording.²⁵ The audit tool utilizes the data outputs (Figure 4) for increased efficiency.

Measuring Errors and Algorithm Compliance

The traditional quality management approaches for improvement in future outcomes include mortality and morbidity (M&M) conferences,²⁶ completion of incident reports associated with each unexpected or preventable death, and corrective action, including clinician education and removal of causes of error. This approach takes a long time. The review of preventable deaths is usually done long after the event, and the lessons to be learned are diluted by the loss of immediate feedback.

The TR & R algorithm-driven treatment standard provides an objective video audit tool that is used to measure compliance with real-time prompts, overcoming the subjective nature, human variation, and flawed reliability of expert opinion, which have been critical weaknesses in preventable mortality studies to date. The audit, to monitor compliance with the algorithmic prompts, is accomplished by reviewing video recordings of resuscitation. The video record has the patient's physiologic signs overlaid.

In the ongoing randomized clinical trial of the TR & R system, two of the four resuscitation bays at The Alfred Trauma Center have displays of the prompts; the other two bays are control bays with video audit of resuscitation but no decision support. In addition, a historical control group performing trauma patient resuscitations was recorded before the decision support software became available. Subject matter experts reviewed the video images made in all four resuscitation bays to establish management differences with and without the prompts.

Using the framework of the algorithms, a standardized method for procedures and decisionmaking was agreed upon by the investigators involved in the TR & R Project. Start and end times for procedures were defined, and appropriate timing of decisions was identified, so that there was no ambiguity or subjectivity in reviewing the video records. Inter-rater reliability analysis confirmed the validity of the video audit parameters. Video recording minimizes the occurrence of hindsight bias, as occurs in reviewing a case at an M & M²⁶ conference, when knowledge of the outcome may influence the perception of past events.

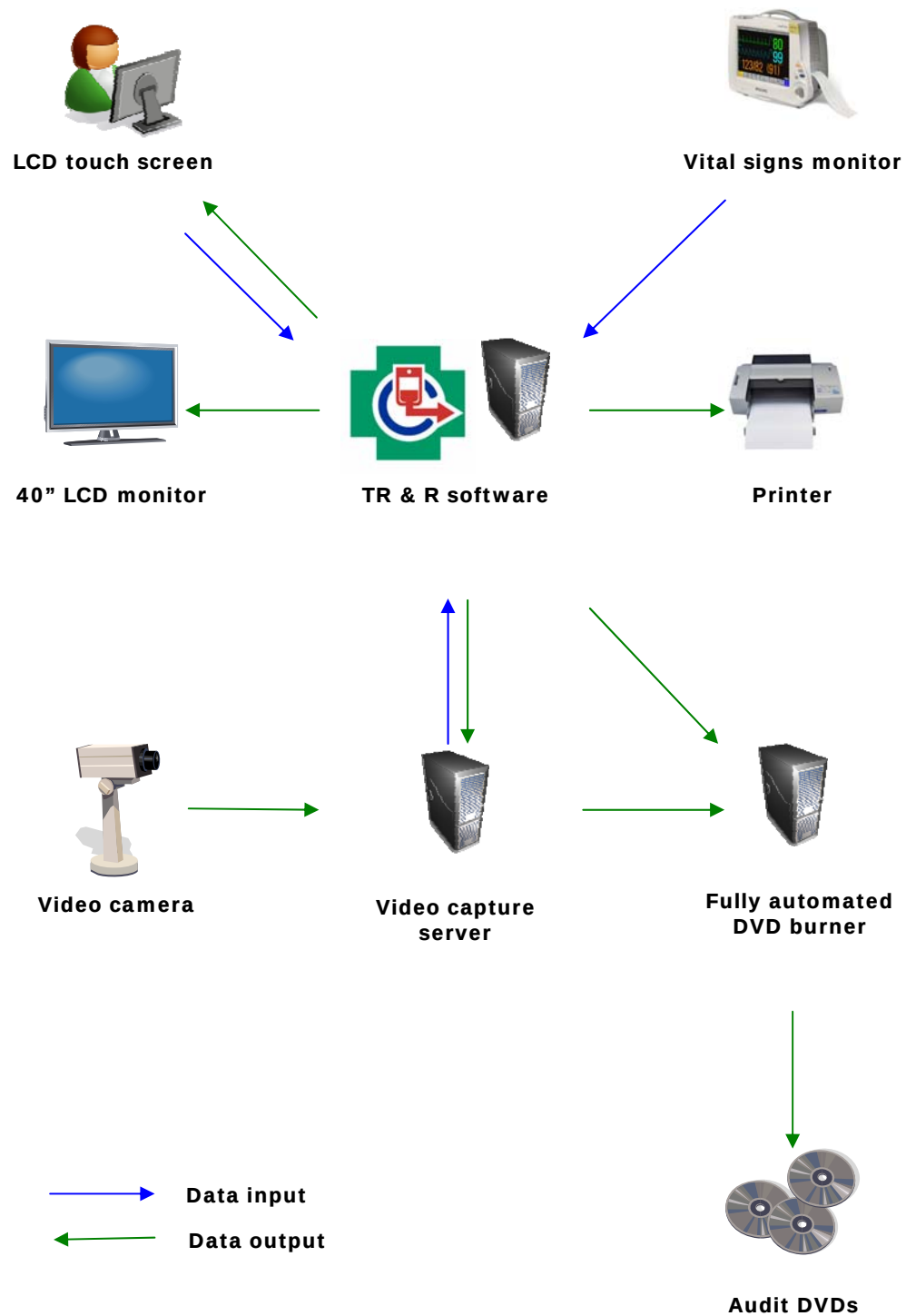


Figure 1. TR & R hardware.

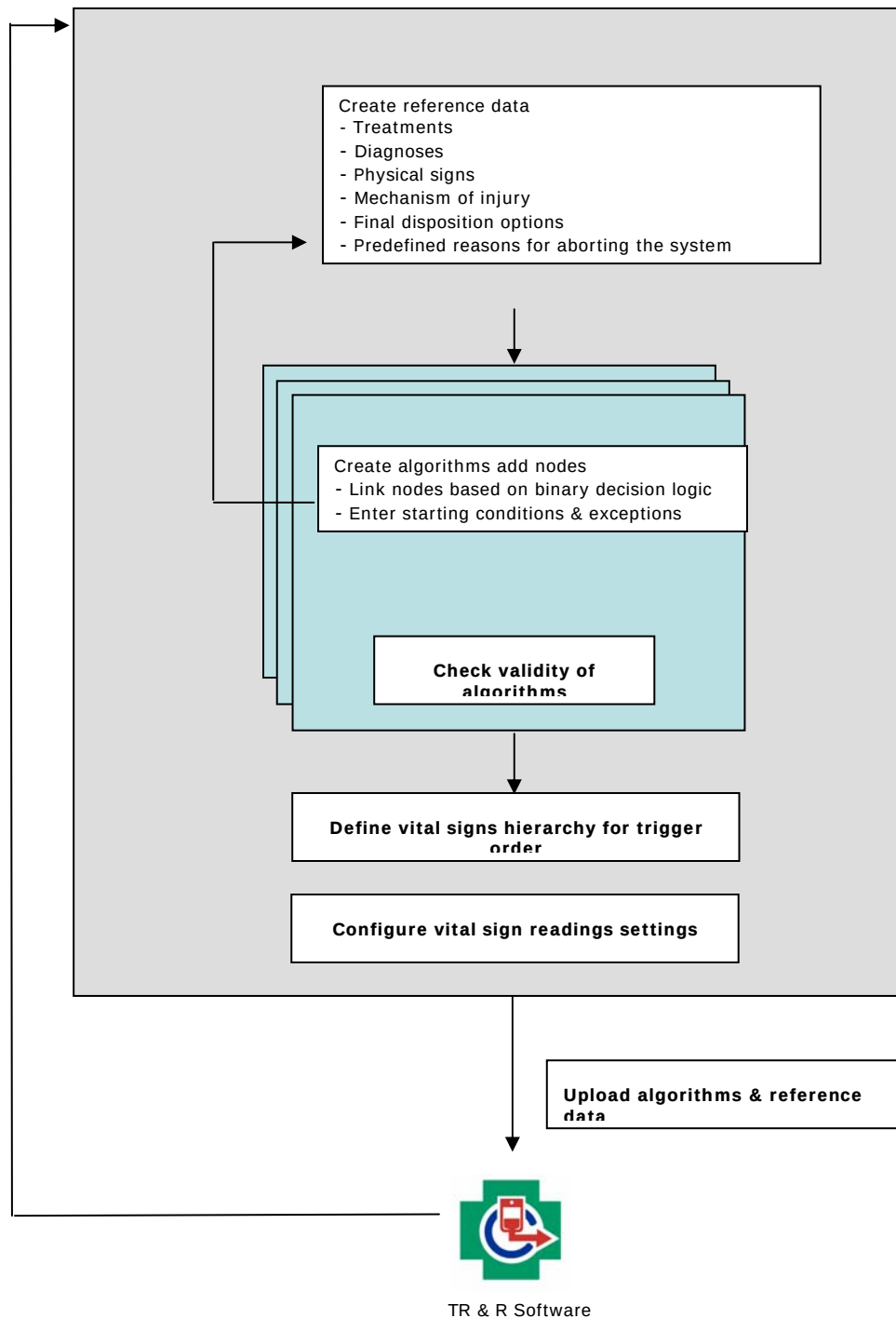


Figure 2. TR & R algorithm design process.

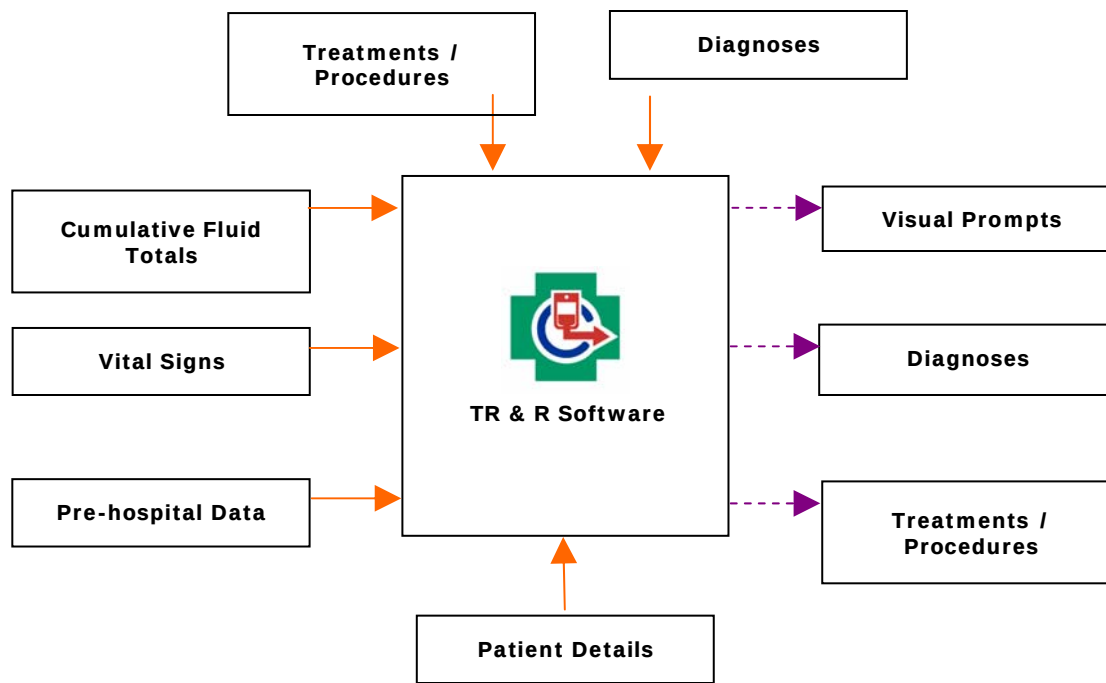


Figure 3. Algorithm engine data input/outputs.

Review of all cases of trauma patient reception and resuscitation is necessary to identify the relationship between process and outcome. A preliminary cohort of video records of trauma reception and resuscitation was made during the 3 months before the TR & R decision support software was installed. Analysis facilitated the development of performance measures, which included documentation of prehospital data and primary and secondary survey resuscitation landmarks. Note is made of the administration of adequate fluids, blood, and components; adequate bleeding assessment and control; warming; monitoring; and requests for appropriate tests and investigations.

Impact of the TR & R Project on Advancing Decision Support

Current methods of reporting errors made during the care of trauma patients usually rely on adherence to ATLS[®] protocols, missed diagnoses, improved outcomes (typically using historical controls), and preventable deaths using cohort comparison.^{27, 28, 29} Previously described medical decision support systems are rigid, not well integrated with the medical record, and lack capabilities for robust evaluation. The compliance of medical staff with prelearned guidelines remains problematic. Although reviews demonstrate improvements, compliance with algorithms is rarely measured in real time. Recognition of preventable error is usually retrospective rather than current.



TR & R Software

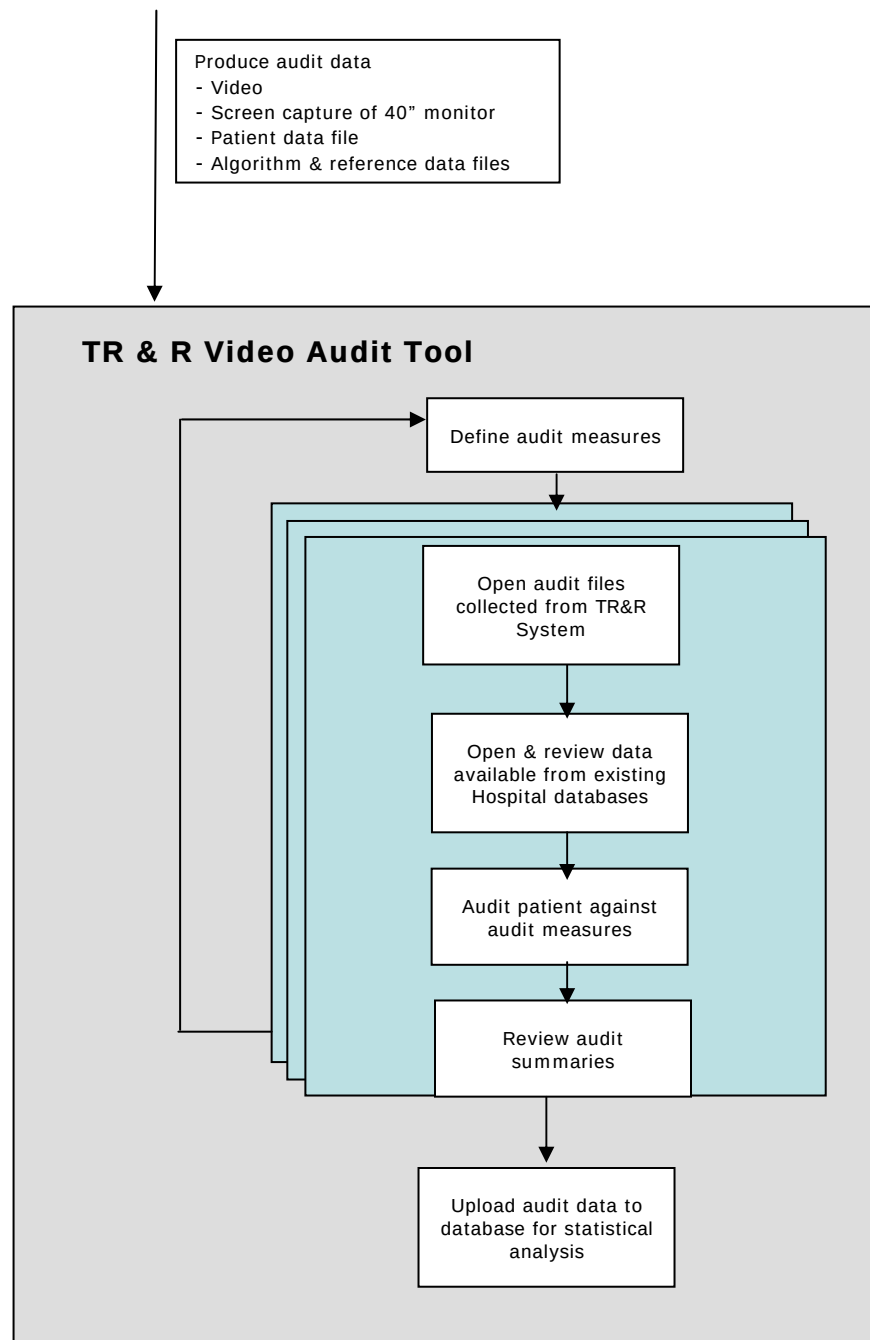


Figure 4. TR & R video audit process.

In comparison, the TR & R Project software advances decision support by collecting data in real time (for later review by video audit in the randomized clinical trial) and allowing detection of response to decision support prompts. Such an approach allows iterative validation of the decision support system's performance and identification of details about clinician performance not found in other quality improvement processes.¹³

Future Implementation

Possible Improvements

Most decision support systems have incomplete automation of data entry that activates the treatment algorithms, even though the need for complete data entry automation is widely acknowledged.³⁰ Usually a nurse or other experienced expert needs to be employed to enter clinical interventions and decisions that drive the decision support software. In the TR & R software, a scribe enters data manually at a terminal during resuscitation. These data then determine which algorithms, interventions, and decisions are displayed on a large LCD screen in the resuscitation bay. The branches of algorithmic decision trees (many can be active simultaneously) are displayed in real time.

Automation of data entry by voice recognition software (using a limited vocabulary to maximize accuracy) and other simple tools used by the resuscitation team leader would be a huge improvement in the utility of such a system. The plan would be to determine the limited vocabulary needed for accurate voice recognition by extraction of communications from existing audio-video records of reception and resuscitation. The software would need to be validated and bench-tested for accuracy and waveform data collection. After such an automated system is validated, it could be used to test the hypotheses that (1) automated data entry provides decision prompts equally effectively as scribe-entered data, and (2) the introduction of real-time, computer-prompted algorithms will measurably reduce management errors and protocol recruitment failures associated with reception and resuscitation.

Because so many errors occur during the time-critical and dynamic first 30 minutes of trauma patient resuscitation, it is possible that this effort might not be totally successful. A further refinement of the system might include minimizing the impact of an error by identifying redundancies, which would make the clinician reconsider a decision not carried out after being promoted by the algorithm. When time stressors are excessive, the decision support system could suggest task-shedding strategies to achieve lifesaving interventions expeditiously and allow less essential processes to be held back. When time allows, the clinician could be reminded with a prompt stating that the procedure still needs to be completed after patient stabilization.

The trauma reception and resuscitation software provides multiple simultaneous algorithmic decision supports in real time, continuously collects waveforms of vital signs, and provides a basis for activating research protocol recruitment and a definitive record by video audit of the vital first 30 minutes of resuscitation. A summary document is produced and can be entered into the patient chart as the official record of resuscitation care (Figure 5).

TRAUMA RECEPTION & RESUSCITATION SUMMARY (UP TO 30 MINUTES)

PATIENT DETAILS

Arrival Time: 17:17 06-Aug-2007
Age: 32
Weight: 70kg
Gender: Male
Incident Location: Williamstown
Triage Category: 1
Trapped: No
Trapped Duration:
Mechanism of Injury: Motor vehicle driver, No Seat Belt, car vs tree 60km/hr ejected

OBSERVATIONS

Time	Pulse	BP	RR	GCS	E	V	M	Temp	SpO2	EtCC
17:23	110	95/-	28	14	4	4	6	-	95	-
17:19	132	80/62	32	12	3	4	5	34	90	-
-	128	85/52	28	14	4	4	6	-	92	-

CONFIRMED DIAGNOSES

Closed Pneumothorax Right
Cardiac tamponade
Hypothermia
Pupils equal and reacting.r3/3

UNCONFIRMED DIAGNOSES

R Rib fractures ?
Shock
Closed head injury/cerebral concussion
R Compound Fractured Femur
Lacerations Forehead

FLUID AND DRUG TOTALS

Crystalloid IV infusion 500ml
Maxolon 10mg
Morphine 20mg

TREATMENTS

Time	Treatment
-	Needle decompression Right
-	L 18 G Peripheral IV insertion
-	Maxolon 10mg
-	Crystalloid IV infusion 500ml
-	Splint cervical spine
-	L Traction (Donway) splint lower limb
-	Dressing Forehead
-	Morphine 20mg
17:17	12 l/min via mask O2
17:19	FAST
17:20	12 l/min via mask O2
17:20	12 l/min via mask O2
17:20	Order O -ve blood 5 Units PRBC
17:20	ECG monitor
17:20	SpO2 monitor
17:20	Non invasive BP Blood Pressure monitoring
17:21	actively Rewarm patient

DISPOSITION AFTER INITIAL TRAUMA RESUSCITATION (up to 30 minutes)

Transfer to CT

COMMENTS

Signature

Print name & designation

Please staple to Trauma Resuscitation Record MR B-82
06/08/2007 17:27:25

Figure 5. Trauma reception and resuscitation summary (up to 30 minutes)

A future improvement could include the integration of laboratory results and radiographs into the LCD screen display and multisite or even mobile wireless “heads up” displays rather than a single screen. The video and other records associated with trauma patient resuscitation could become part of that patient’s electronic health record. In the future, remote direction of trauma reception and resuscitation via telecommunication links would be a natural advance of the decision support system, such that a single expert could direct patient management in multiple remote locations simultaneously.^{30, 31}

Future Testing and Goals

The TR & R software system is in daily use at The Alfred Trauma Center for the prospective, controlled, randomized trial that is evaluating its effectiveness. The video audit is used to verify compliance, error rates, and subsequent patient outcomes. Outcome measurements include compliance with prompts, error rate per patient, missed diagnoses, and time to major interventions. The goal is to reduce error through standardized decisionmaking, leading to a reduction in both preventable mortality and morbidity among patients with major trauma. Among the important functions of the TR & R Project are the standardization of resuscitation documentation, interventions, and diagnoses. The algorithms will be published, and there will be a critical evaluation of the cost-benefit of video audit to measure compliance with algorithms in real time.

Web technology (e.g., ProtoVIEW™ from Infragistics, Inc., Cranbury, NJ, USA) could be used to build a fast and easy flexible protocol information system. A wide range of diagnostic and therapeutic protocols can be retrieved and viewed with ProtoVIEW. It contains a radiograph viewer and provides a great deal of interactivity, such as validation of electronic patient data forms. An additional function of ProtoVIEW is the context-sensitive protocol support that could lead to improved protocol adherence.³⁰ A Web-based TR & R decision support system for trauma care would be a future goal, allowing remote access from multiple locations in the field and in hospitals during resuscitation and during the intensive care management of trauma patients.

Conclusion

The need for improvements in real-time medical decision support is recognized in both the civilian and military care of trauma patients.³¹ The TR & R Project is an ongoing research effort that is actively testing a decision support system through a prospective randomized clinical trial. The video audit of errors of commission and omission and the documentation of clinicians’ interaction with the system will determine whether such a system can reduce errors and improve trauma patient outcome.

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Risk Reduction and Systematic Error Management: Standardization of the Pediatric Chemotherapy Process

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Abstract

There is an urgent need to make the administration of chemotherapy to hospitalized children a less intricate, lower risk process. Children have a distinct physiology and an immature ability to metabolize drugs. Combined with complex chemotherapeutic regimens and narrow therapeutic indices, the probability and severity of adverse drug events in a vulnerable population like children are high. Given this need, near-miss chemotherapy ordering errors, and research that identifies the prescribing/ordering step as a significant source of pediatric chemotherapy errors, Memorial Healthcare System (MHS) has been working to integrate and decrease variability in the pediatric chemotherapy process. This paper describes MHS's ongoing program of standardization and integration of pediatric chemotherapy process components using information technology to promote a culture of safe practices and continued automation implementation in a complex health care delivery system.

Introduction

Chemotherapy administration to hospitalized children is an intricate, high-risk process that is prone to error at multiple points. Children, especially small infants, have a unique physiology and an immature ability to metabolize drugs. In addition, children with cancer receive diagnosis-specific chemotherapeutic agents that have narrow therapeutic indices and require complex protocol administration regimens.^{1, 2} Furthermore, weight-based dosing and toxicities inherent in the investigational drugs that are sometimes used present further challenges to the safe administration of chemotherapy to hospitalized children.^{3, 4, 5}

There is a consensus that most general medication errors, and pediatric chemotherapy errors in particular, occur at the prescribing/ordering step.^{6, 7, 8, 9} However, overall, studies demonstrate that medication process errors can occur during ordering, dispensing, and/or administration stages. Prescribing errors occur far upstream in the medication management process and are more likely to be mitigated if intercepted early. If prescribing/ordering errors are not interrupted early, their effects may be propagated and often exacerbated at subsequent steps.^{1, 7} These risks, combined with potential protocol disruption (secondary to the labile physiologic state of the patients and their disease processes), generate a relatively high probability of significant error. The potential exists for results that represent far worse patient outcomes in an already vulnerable population.^{4, 5}

There are few tools to safely integrate the distinct and complex variables of the pediatric oncology process into inpatient and ambulatory clinical workflows. Many leading pediatric oncology centers are struggling to minimize variability in the multiple stages of the chemotherapy process.^{3, 4, 5, 9, 10} More precisely, protocol-specific care plans, standardized order sets, medication administration records, and pharmacy medication profiles that consistently and clearly articulate the patient's treatment criteria are sporadically instituted. As a result, complex elements of pediatric chemotherapy protocols are double-checked by multiple clinicians at distinct points in the prescribing, dispensing, and administration processes. Nevertheless, a deficiency of tools for standardizing and connecting the multifaceted elements of pediatric chemotherapy into a clinician's workflow can result in a significant propensity for error.

Opportunity for error reduction at strategic process points, combined with a number of identified near-miss pediatric chemotherapy ordering errors, motivated the Memorial Healthcare System (MHS), including Joe DiMaggio Children's Hospital (JDCH), Hollywood, FL, into action. The innovative components of the MHS efforts have involved:

- Linked/integrated Children's Oncology Group (COG) protocol-specific, standardized order sets. (COG is the world's largest childhood cancer research organization¹¹ and is a pioneer in new treatments and cures for pediatric oncology patients.)
- Associated multiday medication administration records (MARs).
- Pharmacy profiles that clearly articulate the entire plan of care to all care providers, decrease the possibility of transcription errors, and reduce processing time from order to administration.

The protocol-driven order sets, associated multiday MARs, and pharmacy profiles developed by JDCH are unique in that they provide clinicians with standardized, integrated tools to follow complex COG protocols more efficiently and more safely. Since COG protocols are standardized across the cooperative research group, the innovative JDCH-developed tools could potentially have widespread implementation potential and thus enhance the patient safety arsenal of pediatric oncology centers nationwide.

Improvement Development: The Context

Prior to the development of the MHS error-reduction system, it had been noted that JDCH oncology nurses were spending an inordinate amount of time verifying physician's handwritten orders against complex COG protocols and roadmaps. In addition, the computer-generated MARs provided by the pharmacy system were failing to group patients' treatment criteria in a chronologic format, making the MAR/original order reconciliation process extremely difficult and labor intensive and, consequently, increasing the risk of error. Despite adhering to strict double-check policies, near-miss errors were often being caught during the order and MAR reconciliation process (Figure 1).

Oncology nurse-clinician verification of the discrepancies provided baseline measures of variability in the accuracy of the JDCH pediatric chemotherapy prescribing process. It was noted that from January through November 2005, 79 percent of chemotherapy orders were written correctly, but 58 problematic individual patient order sessions had chemotherapy errors. Flawed

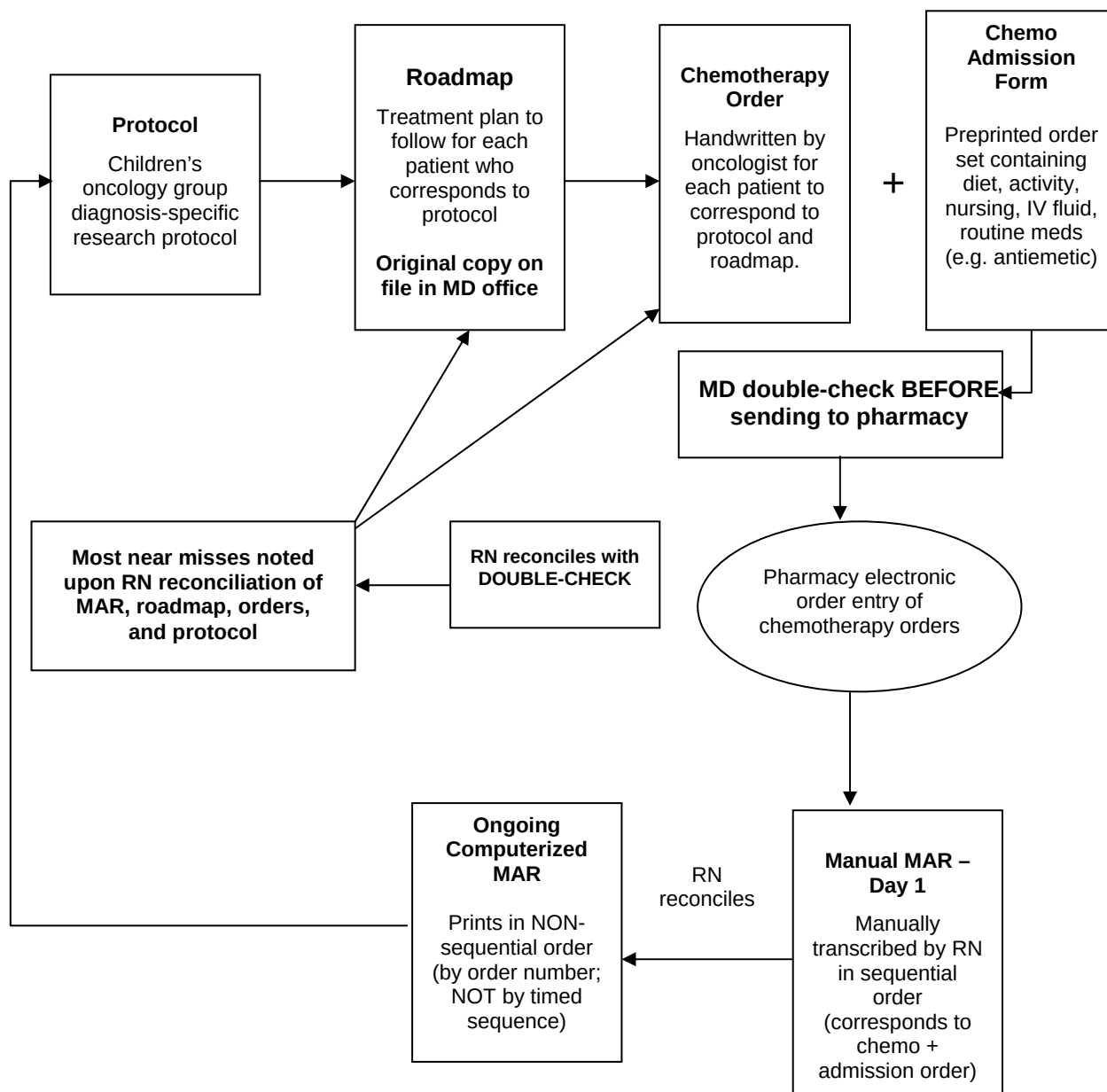


Figure 1. Joe DiMaggio Children's Hospital chemotherapy order process

chemotherapy orders included incorrect protocols, faulty calculations, inaccurate scheduling and weight/body surface area calculations, and missing dates, as well as legibility issues. For a vulnerable population of patients, such near-miss prescribing errors had the potential to cause serious harm had they not been caught and remedied.

With the growth of the pediatric oncology practice at JDCH, protocols increased in complexity. Recognizing the safety issues involved, JDCH nurses and oncology clinicians saw the need to improve the efficiency and safety of this process. Networking with peers at other pediatric oncology centers revealed that many centers were struggling with similar issues and that no

automated solution existed. Having identified the problem, MHS leadership empowered JDCH nurses to find a solution.

Standardization of the Pediatric Chemotherapy Process

With an awareness that nationwide centers were concerned about pediatric chemotherapy safety,^{3, 4, 8, 9, 10} that the pediatric chemotherapy system was excessively prone to errors, and that a systemwide initiative was needed to improve patient safety, a multidisciplinary team was formed to improve pediatric oncology patients' outcomes. The team consisted of two pediatric oncology physicians (employed by MHS), a nursing director of pediatrics, the JDCH chief nursing officer, three JDCH oncology clinicians, a JDCH oncology pharmacist, and three clinical informatics pharmacists. Team members were chosen for their particular clinical or process expertise, their willingness to work toward a solution, and their ability to make and enforce administrative decisions.

The team's intent was to streamline the pediatric chemotherapy process and implement standardized order sets and medication administration templates that would correlate with COG pediatric chemotherapy treatment protocols. The group's hypotheses were that: one, use of COG protocol-specific standard order sets and multiday MARs would decrease the number of chemotherapy order errors; and two, decreasing the number of individual patient order sessions with problematic chemotherapy orders would improve patient safety.

Although significant obstacles were not encountered in designing the new system, the team struggled with a number of decisions, including creating an effective and efficient forms-review process; facilitating ongoing forms maintenance; and implementing an alternative process for access to forms (to ensure that clinicians always had the most current version). The forms access issue was resolved by the group's decision to post the forms on the MHS physician portal site, which is accessible to any authorized MHS employee or medical staff member, either in-house or remotely.

The forms review/approval process was established as follows:

1. A protocol specialist develops order forms and MARs for an arm of the protocol.
2. Once the draft of these order forms is completed, a subset of the team members reviews that protocol arm.
3. The review process for each arm is assigned to a rotating group that includes two individuals from each discipline (i.e., physician, nurse, and pharmacist).
4. These individuals have 2 weeks to assess the protocol for accuracy and appropriateness, after which they share any feedback and/or necessary changes with the rest of the team at one of the scheduled monthly meetings. The approval process is usually completed within 2 weeks.
5. After changes are made, the team members perform their final review and then sign off using a sheet maintained by the protocol specialist.
6. Once finalized, the forms are converted to PDF format and attached to the intranet menu, where they can be accessed and printed as needed by pediatric oncology physicians or their designees.

The process for pharmacy orders was also changed. Previously, one pharmacy satellite entered orders for a patient's non-chemotherapeutic medications, while another entered only chemotherapeutic agents. However, with the new protocol standardization and implementation, a single pharmacist would enter all protocol medications, regardless of whether they were considered chemotherapeutic or non-chemotherapeutic agents. Lastly, a decision was made to adopt the standardized order forms and MARs, whether the patient was being treated as an inpatient, in an outpatient clinic, or in a physician's office.

Standardization of the Chemotherapy Process: Prescribing

Handwritten order sets are associated with significantly greater risk, compared with standardized, preprinted order sets.^{3, 12, 13} Incorrect, incomplete, or illegible chemotherapy orders require nurses and/or pharmacists to make assumptions that may be erroneous, thus putting the patient's health at risk.¹ In contrast, standardized, complete order sets are an inexpensive and readily available method that substantially reduces the need for clarification and the number of changes required during order verification and processing.^{14, 15}

MHS made a commitment to create standardized preprinted order sets for all oncology protocols. Since more than 90 percent of pediatric oncology patients are treated based on open or closed protocols,¹⁶ the team agreed to begin with open protocol order-set creation for the most common pediatric malignancies. Figure 2 shows the AALL0331 protocol, the first such standardized order set we developed, for acute lymphoblastic leukemia (ALL), the most common malignancy of children.¹⁷

The AALL0331 protocol consists of 13 treatment arms (induction, consolidation, maintenance), for which 67 order sets/multiday MARs were drafted and validated by the multidisciplinary design group through the articulated iterative process. Once the first group of documents was completed for ALL, the group conducted a "parallel go-live" by using the forms in parallel with the existing process. The feedback from the clinicians for the new protocol was so favorable that the forms were immediately implemented. Two additional protocols were developed to study patients with pre-B type of leukemia. Pre-B type pediatric oncology patients may be either on the "low risk" (AALL0331) or "high risk" (AALL0232) protocol.

Once feedback from the first diagnosis-specific protocol was completed, the task force presented their findings to MHS executives and leaders for review. This resulted in the hiring within a year of a full-time protocol specialist to design, create, maintain, and manage the approval and ongoing education process for full implementation of all COG-specific order sets and MARs. To date, 238 order sets/MARs for four pediatric COG diagnoses have been implemented at JDCH. There are 10 new and eight existing patients on the AALL0331 and AALL0232 protocols, respectively, and two on the AREN0532 protocol. A fifth order set/MAR for Wilm's tumor is in the final stages of approval. Our goal is an order set/MAR for 100 percent of all COG protocols.

Redundant, manual, multidisciplinary checks of chemotherapy orders are a proactive approach to error management.¹⁶ Thus, as an additional safety measure, two-physician verification and cosignature of all chemotherapy orders was implemented in December 2005. Oncology nurse-clinician assessment of both handwritten and template order sessions for chemotherapy order

CHEMOTHERAPY ORDER: PRE-B ALL STANDARD INDUCTION

PROTOCOL No. <u>AALL0331 (STANDARD INDUCTION)</u>		DAY: _____	
Protocol Starting Criteria: NONE			
Diagnosis: <u>ACUTE LYMPHOBLASTIC LEUKEMIA</u>		On Study (circle one): YES / NO	
Allergies: _____			
Height: _____ (cm)	Weight: _____ (kg)	BSA: _____ (m ²)	DOB: _____ Age: _____
Medication Dose Calculation:			
Med 1	Cytarabine IT	(age-based dosing refer to chart below)	
Med 2	Vincristine IV	1.5 mg/m ² /dose X _____ m ² X _____ % = _____ mg/dose	
Med 3	Dexamethasone PO	6 mg/m ² /day X _____ m ² X _____ % = _____ mg/day (divided BID)	
Med 4	PEG Asparaginase IM	2,500 units/m ² /dose X _____ m ² X _____ % = _____ units/dose	
Med 5	Methotrexate IT	(age-based dosing refer to chart below)	
* For Down Syndrome patients please see Physician regarding Leucovorin *			
Reason for dose adjustment, if applicable: _____			
DAY/DATE CHEMOTHERAPY MEDICATION ORDERS			
1 _____ 8 _____ 15 _____ 22 _____ Intrathecal Cytarabine (note age-based dosing) Dose by Age 1 - 1.99 yrs = 30mg 2 - 2.99 yrs = 50mg 3 yrs & above = 70mg = _____ mg in _____ mL of STERILE PRESERVATIVE FREE NS ONETIME. INTRATHECAL			
Vincristine (VCR) 1.5mg/m ² /dose (maximum 2mg) = _____ mg IV PUSH ONETIME.			
Dexamethasone (DEX) 6mg/m ² /day = _____ mg daily divided BID = _____ mg PO BID for 28 days (DO NOT TAPER)			
PEG Asparaginase (PEG) 2,500 units/m ² /dose = _____ units IM ONETIME on day 4 or 5 or 6 (circle day)			
on days 8, 29 *(CNS3 also days 15 & 22) CNS Status: _____			
8 _____ *15 _____ *22 _____ 29 _____ Intrathecal Methotrexate (note age-based dosing) Dose by Age 1 - 1.99 yrs = 8mg 2 - 2.99 yrs = 10mg 3 - 8.99 yrs = 12mg 9 yrs & above = 15mg = _____ mg in _____ mL of STERILE PRESERVATIVE FREE NS ONETIME. INTRATHECAL			
NOTE: Down Syndrome patients require Leucovorin rescue. Please check with Physician.			
Please communicate with physician prior to initiation of chemotherapy (with exception of dexamethasone)			
1 ST PHYSICIAN'S SIGNATURE/ID #		DATE/TIME	
2 ND PHYSICIAN'S SIGNATURE/ID # (Required PRIOR to transmission to Pharmacy)		DATE/TIME	
1 ST NURSE'S SIGNATURE/ID #		DATE/TIME	
2 ND NURSE'S SIGNATURE/ID #		DATE/TIME	
		Patient Label	

Figure 2. Standardized Pre-B ALL Standard Induction order form

errors continues. These efforts appear to be paying off, as evidenced by a decline in chemotherapy order errors from 58 in January to November 2005 (prior to standardization and integration of the pediatric chemotherapy process components) to 6 such errors for the same time period in 2007. No chemotherapy order errors have so far occurred using the four standardized chemotherapy order sets/MARs. The significant decrease in chemotherapy order errors in handwritten order sessions is believed to be a function of increasing physician familiarity and utilization of the standardized order method and incorporation of the standardized structure and content into the handwritten order session process.

To promote ease of access and consistency of use, MHS placed the current standardized leukemia chemotherapy order sets on the MHS intranet page (Figure 3), making them accessible to any authorized MHS employee or medical staff member, either in-house or remotely. Clicking on the link opens the actual order document in PDF format, so that it can be printed, completed, verified, cosigned, and used to initiate chemotherapy administration. This MAR is then reconciled with another nurse against the protocol-driven roadmap and individual patient chemotherapy order.

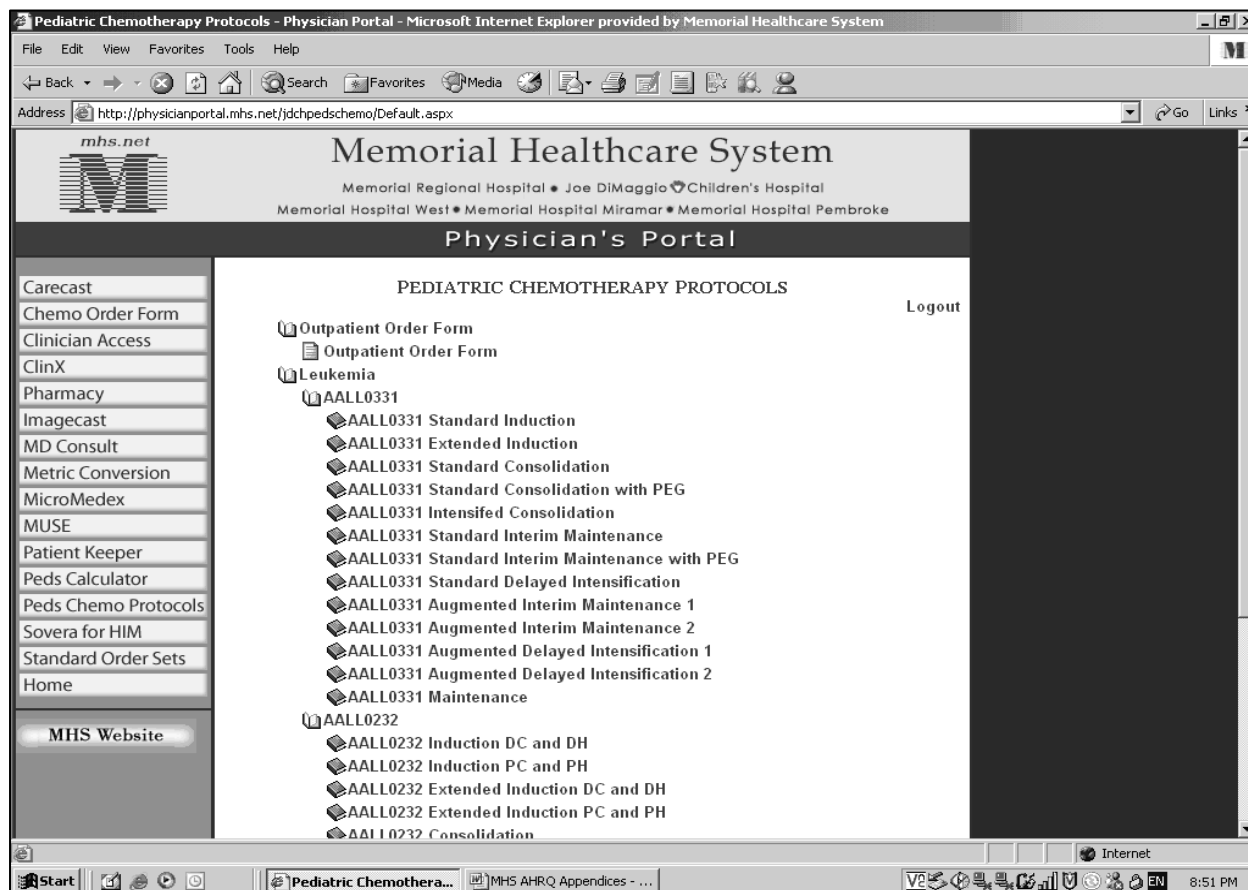


Figure 3. Online standardized pediatric chemotherapy order sets

Once the standardized chemotherapy form is completed, verified, and cosigned by two physicians, it is sent to the chemotherapy-dedicated pharmacy, where a pharmacy triple-check process is initiated (Figure 4). MHS's pharmacy triple-check process was instituted to mitigate modeled probability dispensing error rates of 2 to 3 percent.¹⁸ (Note: Probability dispensing error rates are a quantifiable statistical relationship between a measure of workload [e.g., number of prescriptions dispensed by individual pharmacy staff during a single workday] and the risk of committing at least one dispensing error during that same workday period.)

Figure 4. Pharmacy pediatric chemotherapy order triple check

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modes and effects analysis (FMEA) for safe order interpretation, compounding, and dispensing of chemotherapy medications to hospitalized children.³

Standardization of the Chemotherapy Process: Administration

Chemotherapy administration is the chemotherapy subprocess with one of the highest risks for errors.³ Every step in the standardized process—from prescribing to dispensing with redundant checks by physicians, pharmacists, and nurses against the protocol, roadmap, and individual order—could be performed, but if the nurse administers the wrong medication to the wrong patient, the entire process is a failure with potentially devastating consequences.

When caring for pediatric patients, health care organizations must have effective processes to ensure that their staff is competent in the use of devices, equipment, and drug administration.^{19, 20, 21} MHS's culture of safety is proactively focused on safety promotion vs. reactive error management. All personnel who administer chemotherapy must have completed the Oncology Nursing Society's chemotherapy provider course "Get Certified"²² and be able to demonstrate clinical competency with the clinical nurse specialist. All staff members are required to be competent in terms of drug therapy knowledge, ability to function safely in the medication administration system by adhering to policies and procedures, ability to foster communication and teamwork, and use of decision-support tools.

Upon receipt of the chemotherapy from the pharmacy, two certified chemotherapy provider nurses review the original chemotherapy order, the patient's protocol-based roadmap for appropriate dosage, and the administration schedule with the dispensed, labeled chemotherapy bag. The patient's absolute neutrophil count (ANC) is calculated from the most recent CBC, and relevant lab results, and specific tests are reviewed, verified, and documented. Inappropriate lab and test results are reported to the physician in a timely manner.

Immediately prior to chemotherapy administration, two certified chemotherapy provider nurses perform a critical check at the point of delivery. A critical check includes verification of the patient's name and medical record number and of the chemotherapy agent, dose, route, volume, and infusion time. The critical check is documented on the patient's MAR. To ensure safe administration of chemotherapy to hospitalized children, FMEA recommendations include redundant, two-RN verification of the chemotherapy order, the patient's individualized protocol-based roadmap, and administration dose, times, and bedside patient identification.³

Technologic Advances

The Institute of Medicine's (IOM) groundbreaking report, "To Err is Human," documented as many as 98,000 deaths per year from avoidable medical errors. It also identified information technology as an important tool for decreasing adverse medical outcomes.²³ In the aftermath of the IOM report, hospitals have prioritized patient safety and investigated new methods for improving the delivery of health care. Motivated by an awareness that current health care delivery practices are not as efficient or effective as they need to be, MHS has embraced technology to assist physicians and staff in providing more efficient, effective, and safe patient care.

Standardization of pediatric chemotherapy order sets and a more efficient order verification process are foundational process improvement steps toward implementation of computerized physician order entry (CPOE) and bar code medication administration (BCMA) in this complex setting. CPOE is one technologic process of medical management that provides a well-organized, electronic strategy to enhance efficiency, improve the quality of patient care, and decrease adverse medical outcomes.²⁴

MHS has developed and is testing the CPOE order set for Protocol AALL0331-Standard Induction Arm (Figure 5). MHS is already in the initial stages of CPOE. The pediatric and adult emergency departments (EDs) at three of the six facilities are “live on CPOE” with plans for two additional ED facilities to “go-live” in 2008. In addition, nursing computer-based clinical documentation and BCMA have been implemented at several facilities. These initiatives offer exciting opportunities to fuse quality and best practices at the point of care.

TEST-PATIENT-3, TEST-PATIENT-3 MRN: *CCCCCCC Facility: DOB - Age: 5-Feb2006-19m Nursing Station: Room-Bed: Adm LOS:

Select Patient Patient i

Enter Order Set ORDERSET NAME: AALL0331 PROTOCOL UPDATED 5/07 View Order Set Ref

Ordered By: Signed By: PAPERCHART, U P963 Order Mode: Orders: 36

Select	Detail	Order Description	Freq	PRN	Max	Start Date/Time	End Date/Time
☐	☐	CYTARABINE IT 30MG/SPFNS(1-1.99 YRS OLD)	ONETIME			9-Sep 15:11	
☐	☐	CYTARABINE IT 50MG/SPFNS(2-2.99 YRS OLD)	ONETIME			9-Sep 15:11	
☐	☐	CYTARABINE IT 70MG/SPFNS(3 YRS & ABOVE)	ONETIME			9-Sep 15:11	
☐	☐	VINCRISTINE ____ MG (1.5MG/M2)IV PUSH	ONETIME			9-Sep 15:11	
☐	☐	DEXAMETHASONE 1MG/ML PO LIQ	BID			9-Sep 15:11	
☐	☐	DEXAMETHASONE 2 MG TABLET	BID			9-Sep 15:11	
☐	☐	DEXAMETHASONE 4 MG TABLET	BID			9-Sep 15:11	
☐	☐	PEG ASPARGINASE ____ UNITS IM	ONETIME			9-Sep 15:11	
☐	☐	PEG ASPARGINASE ____ UNITS IM	ONETIME			9-Sep 15:11	
☐	☐	METHOTREXATE IT 8MG/SPFNS(1-1.99 YRS OLD)	ONETIME			9-Sep 15:11	
☐	☐	METHOTREXATE IT 10MG/SPFNS(2-2.99YRS OLD)	ONETIME			9-Sep 15:11	
☐	☐	METHOTREXATE IT 12MG/SPFNS(3-8.99YRS OLD)	ONETIME			9-Sep 15:11	
☐	☐	METHOTREXATE IT 15MG/SPFNS(9YRS & ABOVE)	ONETIME			9-Sep 15:11	

Select All Deselect All Reset Sel Save Cancel

User: Baldwin, Hilary System: PML1 Carecast Pathway LCJStatus: - | - OCSETS - | - 9-Sep07 - | - 3:11pm - | - TIC1094 - | - 0.5 - | - MRH - | - Applet LCJ started

Figure 5. CPOE test order set – Protocol AALL0331 Standard Induction Arm

Conclusion

Medicine is a knowledge- and information-intensive domain, where timely patient care decisionmaking must be effective, efficient, and accurate. Development of protocol-specific standardized order sets and medication administration templates—with a complex system of double-checks for physicians, pharmacists, and nurses—promotes dialogue among disciplines,

minimizing the possibility of serious error in ordering, dispensing, and administering chemotherapy in this high-risk area. Anticipated outcomes of this process include:

- Improved efficacy and accuracy in writing, checking, interpreting, and entering chemotherapy orders.
- Decreased pharmacy chemotherapy preparation turnaround times.
- Increased nursing chemotherapy administration efficiency.
- Shortened length of stay/throughput times for pediatric patients and their families.

Online access to protocol-specific order sets and medication administration templates, as well as future CPOE implementation, will integrate numerous safety processes into the culture of medication management. MHS is proud to be a part of the imperative for change, adapting technology for the delivery of safe, effective, quality health care.

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Analysis of Patient Safety: Converting Complex Pediatric Chemotherapy Ordering Processes from Paper to Electronic Systems

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Abstract

Objective: The objective of this project was to evaluate the risks associated with converting a paper-based pediatric chemotherapy ordering process to a fully electronic system. **Methods:** Formal process redesign and systems analysis, primarily through Failure Mode and Effects Analysis (FMEA), was used to evaluate the current, paper-based chemotherapy medications process. A commercial software system designed to accomplish computerized provider order entry (CPOE), safety checks, pharmacy dispensing, and medication administration documentation were examined to determine whether these integrated applications are as safe as a paper process with multiple redundant checks. **Results:** Formal process redesign and system analysis methods uncovered important potential failure points within the integration points of the electronic system. **Conclusion:** Prospective, institution-specific process redesign and system analysis is a valuable tool for determining the safety and feasibility of converting complex medication ordering processes from paper to electronic systems. Commercially available CPOE systems may not be immediately capable of safely executing complex chemotherapy regimens.

Introduction

Various technologies exist to increase patient safety associated with medication use. The entry of medical orders by clinicians directly into computerized electronic medical record systems (computerized provider order entry, CPOE) has been touted as a key method to reduce medication errors and adverse drug events. Influential entities, such as The Leapfrog Group, have encouraged the adoption of CPOE as a means of reducing errors.¹ Furthermore, in its 2007 report “Preventing Medication Errors,” the Institute of Medicine (IOM) recommended that all prescriptions be written electronically by 2010.² Most health care professionals concur that CPOE eliminates errors caused by illegible handwriting, and the technology is capable of substantially improving the medication use process through clinical decision support. However, implementing CPOE is challenging, particularly for high-risk processes, such as chemotherapy administration.

^{*} Deceased

Many hospitals are working to implement electronic ordering systems, but few (approximately 5 percent) have broadly implemented true CPOE, and only a very small percentage employ CPOE for complex chemotherapy regimens.^{3, 4, 5} Two recent systematic reviews revealed a dearth of high quality studies substantiating enhanced patient safety through CPOE. In particular, these reviews noted that most of the studies demonstrating benefits of CPOE were conducted at four health care systems that developed their own “homegrown” order entry applications and customized these applications over time to meet the specific needs of their institutions.^{6, 7}

Recently, the unintended consequences of CPOE, including descriptions of new errors brought about by CPOE, have been characterized.^{8, 9, 10} These negative studies have generated substantial concern, particularly in pediatric settings. Walsh and colleagues demonstrated that CPOE does introduce new kinds of errors in pediatric patients, but they suggested that serious computer-related errors are rare.¹¹ Nonetheless, harm from CPOE could exist in complex pediatric patient care areas. The introduction of CPOE in a pediatric intensive care unit was associated with an increase in mortality.¹² However, the shortcomings of CPOE identified in this publication were not intrinsic to CPOE, but rather, they were consequences of the process-redesign and implementation tactics.¹³ This observation demonstrates that the implementation process is crucial to realizing the safety benefits associated with CPOE.

It is incumbent on clinical and administrative leaders of health care organizations to be certain that all aspects of CPOE and other electronic health records systems are at least as safe, if not more safe, than current practices, especially in high-risk areas of patient care, such as chemotherapy administration. For over 45 years, our institution has focused on maximizing the safety of the paper-based ordering system for chemotherapy medications in children. Therefore, we are particularly concerned about the comparative safety of the electronic ordering system for this critical process. To prospectively assure the safety of CPOE with regard to chemotherapy ordering and administration, a formal process redesign and systems analysis was conducted.

Methods

Formal process redesign methodology was utilized to define and evaluate the current paper-based processes and subprocesses associated with chemotherapy ordering practices at St. Jude Children’s Research Hospital. Process flow maps outlined each step in the process, what role or resource accomplished each step, where each process ended and another began, and links between processes. Failure modes and effects analysis (FMEA) was used to assess how individual components of the chemotherapy ordering process could fail, how likely failure was, and the consequences of failure.¹⁴

A team consisting of individuals directly involved in chemotherapy administration processes was assembled: pediatric oncology physicians, nurse practitioners (NPs) and physician assistants (PAs), who generate chemotherapy orders; pharmacists and technicians, who receive, check, and transcribe orders and prepare and deliver chemotherapy; nurses, who receive, check, and carry out these orders, including administration of chemotherapy to patients; re-engineering analysts; quality improvement specialists; and informatics specialists, including a pharmacist/informatics specialist who led the team. To provide a mixture of experience levels, the team was composed

of staff members with several years of experience with the process as well as relatively new staff members.

Initial meetings with the entire team introduced the purpose of the project and provided education and training on the analytic method to be used, in addition to background information regarding previous efforts to analyze the chemotherapy process at St. Jude. The major components of the overall chemotherapy ordering process were identified and flow-charted.

Consensus was reached among team members that the overall process included three major subprocesses: (1) the clinician process of ordering the chemotherapy; (2) the pharmacy process of reviewing, processing, and dispensing the ordered medication; and (3) the nursing process of reviewing and carrying out the orders. Teams were then formed for each of the three major subprocesses. At minimum, subprocess teams included clinical practitioners directly involved in these processes on a daily basis, a re-engineering analyst, a quality improvement specialist, and an informatics specialist. Weekly 2-hour meetings were conducted to develop specific work-flow maps of the current state for each subprocess.

After flow-charting the three major process components, the full team reassembled to review and discuss the individual detailed processes and make any necessary modifications to the overall process-flow map. Upon reaching consensus on the overall process-flow map and individual detailed process-flow maps, each subprocess team reconvened to conduct the FMEA.

Each process step was evaluated for potential failure points, identifying the potential cause(s) and effect(s), and the detection method of the potential failure points. Potential failure points were scored by team members for severity (i.e., effect on the patient should failure occur); occurrence (i.e., an estimate of how often this potential failure might occur); and the likelihood of detecting a failure prior to completion of the process. A 10-point scale (0 = best, 10 = worst) was used to score severity, occurrence, and likelihood of detection. Each component score was then multiplied together to create a risk priority number (RPN). An RPN value >150 was used as a cutoff for further review and analysis.

To determine overall acceptability within the context of complex chemotherapy orders, available functions of the institution's electronic ordering application (Millennium PowerOrders[®], Cerner Corporation, Kansas City, MO) were presented to team members. Two available strategies for generating electronic orders and one strategy under development by the software vendor were presented to clinicians who generate complex chemotherapy orders and nursing staff members who execute these orders. The two available strategies included (1) individually initiating each order for chemotherapy and associated medications, and (2) using an electronic care set that presents orders as a logical group to the ordering clinician but does not maintain the grouping after electronic signature. The future strategy planned by the software vendor presents orders together in logical groupings that are retained after signature and execution, and it provides the ability to develop time dependencies between orders.

Paper-Based Chemotherapy Medications Process Flow

The paper-based chemotherapy medications process flow was delineated by current state process flow meetings. After St. Jude's Central Protocol and Data Monitoring Office confirms clinical trial or single patient treatment plan enrollment, an oncologist must request a set of preprinted

order sheets developed specifically for that clinical trial or treatment plan and approved by the principal investigator of the trial or author of the plan. This preprinted order set is then placed into the patient's chart for current or future use. Before initiating any chemotherapy order regimen, the clinician is expected to review the protocol and the patient's medical record for all pertinent information. The clinician then executes the preprinted order set for the appropriate day or week of treatment, calculating and filling in each medication dosage and the expected date and time of treatment.

If a nonphysician or physician who lacks chemotherapy prescribing privileges generates these orders, the orders are available within the medical record for cosignature by a physician with chemotherapy prescribing privileges granted within the organization. The orders are reviewed by a nurse in the clinical area where the orders are generated to determine protocol compliance and to double-check all calculations. Orders might then remain in a holding state until close to the date/time for which treatment is scheduled. Before further action, to comply with the protocol, the patient's clinical status and any protocol-required laboratory tests or procedures must be confirmed by a chemotherapy-certified oncologist. Once it is assured that these key clinical requirements have been met, the oncologist generates an order within 24 hours of the scheduled chemotherapy administration time, indicating that it is now "OK to give" (i.e., acceptable to administer the planned chemotherapy regimen at the scheduled time).

After the nurse has performed the necessary safety checks, orders are faxed or delivered to receiving departments, primarily the pharmacy and infusion center within the hospital. Parallel processes then take place within these areas. These include further safety-related checks to assure protocol enrollment, protocol compliance of the planned treatment, correct timing of therapy, and correct dosage calculations. Both the pharmacy and the infusion center require independent checks by at least two licensed professionals (pharmacists for pharmacy, and nurses for the infusion center). The pharmacy process includes transcription of the orders into the pharmacy information system (Cerner Inpatient PharmNet[®]), which provides automated allergy and drug interaction warnings, prints labels to be affixed to the final dosage formulations, and facilitates medication preparation. Release of the medications by the pharmacy and delivery to the patient care area are accomplished only after confirming the receipt of the "OK to give" order.

The nursing process in the ambulatory infusion center includes (1) an initial review of the faxed or written orders, which often occurs prior to patient arrival and receipt of the patient's medical record; (2) receipt of the drug(s) from the pharmacy; (3) planning the intended treatment regimen; and (4) performing the dual safety checks referred to above. Drugs received from the pharmacy are compared against the orders and electronic medication administration record entries for drug name, dosage, diluent type and volume, and infusion duration. Before chemotherapy administration, a dual, independent verification of the patient's identity, using at least two methods (typically name and medical record number), is completed, and appropriate venous access is verified. Nurses administer the ordered chemotherapy and related medications, complete all necessary documentation within the electronic health record (PowerChart[®], Cerner Corporation, Kansas City, MO), observe the patient, provide all necessary care during treatment, and finally, discharge the patient with appropriate education.

In summary, in the current paper-based system, the clinician ordering the chemotherapy regimen is expected to carefully compare the treatment regimen to be ordered with a reference document

and to scrupulously complete the order document, which comprises preprinted order sheets meticulously developed for consistency and safety reasons. Ordering is followed by redundant checks of the same information by at least three groups of health care professionals (a minimum of five individuals). Subprocesses include at least one redundant check to make certain that no individual completes his/her portion of the process without review.

Results

Proactive Evaluation of Proposed Process for Chemotherapy CPOE

Few steps of the current paper-based processes, which do not include CPOE, had RPN scores that reached a level requiring additional analysis (i.e., 150). The processes identified as requiring additional analysis are listed in Table 1.

Prior to conducting an FMEA of the proposed electronic ordering process, a proactive evaluation of the proposed process revealed important deficiencies in the integrated software applications in use at St. Jude. These deficiencies precluded immediate implementation of electronic prescribing for chemotherapy:

- Entry of individual orders one-by-one by clinicians was summarily dismissed as too time consuming and error-prone, compared with paper-based, preprinted orders currently in use.
- Electronic order sets were deemed unacceptable due to a system constraint within each order that required a specified date and time be established and completed by the end user.
- Complex chemotherapy regimens often have 10 to 20 individual component orders, some of which may need to be achieved in a critically timed sequence or time relationship with a single key component. Therefore, ordering clinicians determined that the risk of an error in dating and timing each order individually in the regimen sequence was too high, compared with the current paper-based process.
- An additional problem with electronic order sets was that upon electronic signature by the clinician, each order associated with the order set was distributed either to that order item's logical application (i.e., pharmacy, lab, radiology) or listed in the electronic health record under its category listing. In contrast to preprinted orders, this immediate distribution eliminated the context of the order set associated with the chemotherapy regimen, making pharmacists aware only of pharmacy orders, medical technologists aware only of lab orders, and clinicians and nurses unable to visualize the regimen (order set) again as it existed prior to clinician electronic signature.

Advanced ordering function, recently added to the vendor's software package (PowerPlans[®]), eliminated the deficiencies listed for individual order entry and electronic order sets. It also included features enabling predefined time-sequence relationships between orders commonly found in oncology (e.g., time 0, 1 hour after time 0, etc.). This functionality was evaluated

Table 1. Risk priority number (RPN) scores for components of the paper-based system for ordering, dispensing, and administering chemotherapy that exceeded 150^a

Process	Component that warranted additional concern	RPN score
Ordering	Generating an “OK to give” order by a chemotherapy-certified physician, who did not obtain and review all required information. This requires a nononcologist provider to hold the order until the last piece of pertinent clinical data is available before transmitting the order to receiving departments (i.e., a conditional “OK to give” order).	360
	Not recognizing that orders were transmitted with the incorrect patient name	420
Dispensing	A problem with legibility associated with either handwriting or fax transmission	280
	An incorrect volume of diluent being used for reconstitution of a medication product	200
	A medication being injected into the incorrect admixture bag, if multiple products were being prepared at the same time	224
Administration	Infusion center nursing staff not recognizing premedications that were indicated but not ordered based upon previous adverse drug reactions	210
	The second infusion center nurse failing to check multiple patient identifiers	210
	The second infusion center nurse performing the required checks without recognizing an error	210
	The second infusion center nurse administering a medication by an incorrect route of administration	200
	The second infusion center nurse failing to provide patient followup	210

a A predetermined level deemed to warrant additional analysis.

further by attempting to recreate existing chemotherapy regimens electronically from preprinted order sheets currently in use. As described below, although team members considered these functionalities to be key advances, they also recognized important deficiencies in the software applications or in the integration points between them that again precluded the immediate implementation of electronic prescribing of chemotherapy.

Limitations that Prevented Implementation of CPOE for Chemotherapy

As summarized in Table 2, several important limitations did not allow further implementation of CPOE for chemotherapy. The clinician ordering application supports two types of electronic orders: (1) orders for single medications and (2) orders for intravenous (IV) fluids that are to be administered continuously at a prescribed rate. An evaluation of this software with actual oncology orders uncovered several issues. First, functionality to allow ordering of IV fluids that

Table 2. Summary of important limitations of current enhanced software for ordering chemotherapy and implications for patient safety

Limitation	Representative implication for safe provision of chemotherapy
Clinician ordering: System does not allow clinician to order some types of orders important to the safe delivery of chemotherapy (e.g., corresponding intravenous fluids).	Appropriate hydration is essential for the safe delivery of many complex chemotherapy regimens.
Integration: Types of orders in the clinician order entry and pharmacy sections of the system do not match.	Falls short of seamless integration of clinician ordering and pharmacy functions, which limits the pharmacist's ability to review and check chemotherapy.
Medication frequencies: The system does not support interval frequencies, such as Q3H x 3 doses/day.	Common frequencies used in chemotherapy regimens. If alternate frequencies were used, confusion and error would result.

are to be administered intermittently at a specified rate over a specified period and repeated at a specified interval was not available (e.g., 500 mL of D₅W prehydration for chemotherapy to be infused over a 4-hour period at a rate of 125 mL/hr and repeated daily for 5 days). Second, orders that are generated within chemotherapy regimens that consist of more than one medication to be administered together in one intravenous admixture bag also were not supported by the software design.

The pharmacy dispensing application is automatically populated by orders generated within the clinician ordering application, or it can be the initial electronic point of entry if orders are generated outside the system (i.e., written on paper). The pharmacy application supports three types of orders: (1) continuous IV fluids, (2) single medications, and (3) intermittent IV infusion orders (unlike the clinician ordering application). These intermittent orders (IV fluids, multiple IV drugs admixed in the same admixture bag, or single IV drugs) include an infusion rate, an amount of time over which to infuse each dose, and the frequency at which the infusion should be repeated.

This discrepancy between the clinician ordering application (two order types) and pharmacy application (three order types) results in deficiencies associated with integration points between the two applications. For example, an order for a chemotherapeutic agent could be created using the CPOE application's medication functionality with a defined time over which to infuse each dose and a defined interval to repeat dosing. This order automatically populated the pharmacy application, allowed the pharmacist to assign an appropriate medication product to meet the dispensing needs of the order, but it did not populate the "infuse over" field within the list of defined order details for each intermittent medication order. Instead, the "infuse over" field was either left blank or was populated with a value defaulted for that product from pharmacy reference values.

In addition, a shared feature of CPOE and pharmacy applications, the "frequency of administration" field, had a design deficiency that caused problems during testing.

The frequency application was designed to use interval frequencies (e.g., repeat dosing every x hours, days, or weeks) and defined the number of doses per day at specified time-of-day frequencies (e.g., BID, TID, QID). However, the system did not support interval frequencies, such as Q3H x 3 doses/day, where the first dose should begin at a specified date and time but limited the number of doses due within a 24-hour period to something less than the interval would equate to over 24 hours.

Discussion

Formal process redesign and system analysis has proved valuable to the implementation of CPOE at our institution. Our initial intent was to perform comparative FMEA of both the paper-based and proposed electronic chemotherapy ordering processes. However, our proactive approach identified significant shortcomings in the software enabling the ordering, dispensing, and administration of chemotherapy prescribed as part of complex regimens, which is a high-risk and high-volume process at our hospital. These shortcomings undermined our plans to perform an FMEA of the electronic ordering process and prompted us to collaborate with the vendor to improve the software system and eliminate identified deficiencies before further considering transition. If CPOE implementation for chemotherapy had continued without recognizing these issues, serious patient harm could have resulted. Our efforts have allowed us to act to correct potential difficulties before implementation, thereby mitigating harm to patients. We plan to conduct a comparative FMEA of the electronic ordering process as soon as a fully functional ordering application is developed.

Safe Use of Chemotherapy

Chemotherapy medications are, by design, highly toxic agents that typically have very narrow therapeutic windows. The difference between a dose that causes the desired effect (i.e., killing cancer cells) and a dose that causes undesired or toxic effects is often small. As the benefits of combination chemotherapy regimens have been realized, regimens used in a variety of malignancies have become more complex; increased complexity results in a higher risk of error and potential harm.

These complexities are somewhat amplified in pediatric oncology, where doses of chemotherapy drugs might change from week to week or month to month, based on changes in the child's body size. Risks associated with individual chemotherapy regimens can vary widely. Some regimens are relatively simple (e.g., single, low-dose methotrexate in acute lymphocytic leukemia regimens), but others are incredibly complex (e.g., multidrug, multiday regimens with corollary and supportive care).

Because of St. Jude's commitment to research, the vast majority of patients treated for pediatric cancers are enrolled in clinical trials. This helps make treatment regimens consistent across patients with specific diseases, reducing variability of care, and providing a reference for treatment to all health care providers. However, research regimens are often more complex than conventionally accepted "best practices," which further adds to the increased risk of harm and errors.

Like other major cancer and academic centers, St. Jude Children's Research Hospital devotes a tremendous amount of effort and resources to ensure that systems and processes associated with delivering chemotherapy regimens are safely designed and executed.¹⁵ These systems and processes, listed in Table 3, have been refined and adjusted over the past 45 years to a point where serious errors rarely occur.

In 1997, St. Jude committed to convert patient medical records from the traditional pen-and-paper-based records to an integrated electronic health record, based on discrete data to the extent feasible. To achieve maximal integration, the institution elected to purchase applications from a single vendor that supported a wide range of clinical applications. A phased-in approach to installation of this suite of applications began in 1999 with implementation of an Oracle relational database and an application (PowerChart[®]) to view the laboratory information stored in this core database.

Table 3. Systems and processes associated with ordering, dispensing, and administration of chemotherapy

1.	Effective training and credentialing of staff to prescribe, dispense, and/or administer chemotherapy according to the staff member's role in patient care.
2.	The availability and use of clearly defined treatment plans (e.g., clinical trial document) within each patient's medical record.
3.	Clearly constructed, consistent, and carefully reviewed preprinted order sheets that are specific to the clinical trial or treatment plan.
4.	Elimination of the use of acronyms, brand names, or abbreviations of chemotherapy drugs.
5.	"Tall-man" lettering in both printed orders and electronic health record displays.
6.	Checks of prescriber's orders by nurses in the patient care area, where the orders originate, utilizing the treatment plan document as the reference prior to transmission to pharmacy and medication administration areas.
7.	Review of electronic order entry and dosage preparation by at least two pharmacists.
8.	Distinct labeling and packaging of chemotherapy drugs.
9.	A separate and distinct order by a physician with chemotherapy prescribing privileges to authorize the administration of chemotherapy regimens as ordered ("OK to give chemotherapy as ordered") before chemotherapy medications are delivered to the patient care area for administration.
10.	Checks of the prescriber's orders by at least two nurses in the patient care area where medication administration is to occur, with comparisons to the medications dispensed by the pharmacy.
11.	Separate and distinct patient care areas for administration of intrathecal antineoplastic medications, compared to medications to be administered by other routes.
12.	Independent positive patient identification by two nurses using at least two patient identifiers (e.g., medical record number and name, name and date of birth) prior to medication administration.
13.	Medication administration.
14.	Documentation of medication administration.
15.	Evaluation and documentation of patient response.

Since then, full implementation has been achieved with:

- Patient registration.
- Health information management.
- Patient scheduling integrated with CPOE.
- Research protocol management and enrollment.
- Inpatient pharmacy.
- Radiology with CPOE.
- Picture archiving and communication system (PACS).
- Human leukocyte antigen (HLA) and anatomic pathology.
- Management reporting.
- Transcription.
- Electronic prescription generation integrated with outpatient pharmacy.

CPOE for medications to be administered on site and documentation of care have been partially implemented. This type of integrated approach is a prerequisite for a fully electronic health record capable of enabling advanced clinical decision support, and taken together, these applications make up the system that serves as the electronic health record for the institution.

Context and Application

Our experience in attempting to achieve CPOE integrated with pharmacy, medication administration records, and clinical trial systems differs sharply from other published experiences of the use of CPOE for chemotherapy, including chemotherapy for pediatric patients. Kim, et al., used FMEA to guide implementation of CPOE for pediatric chemotherapy at a major academic medical center.¹⁶ These authors demonstrated that errors for pediatric chemotherapy ordering, including dosing calculations and incomplete nursing checklists, were reduced after CPOE implementation for chemotherapy. However, the likelihood of incorrect doses on treatment plans did not change, and the likelihood of inappropriate matching of orders to treatment plans increased after CPOE, possibly because the system evaluated did not automatically link drugs and protocols. A reduction in chemotherapy-related errors after CPOE implementation was also reported by a Swiss hospital.¹⁷

There might be several reasons why our results were different from the experiences cited above. First, our CPOE implementation effort for pediatric chemotherapy was within the context of an integrated electronic health record, where preparation was being made for all aspects of the process to become electronic and fully integrated (e.g., nursing, pharmacy processes). This contrasts with other published efforts, which have focused on limited electronic ordering efforts. For example, the first study cited above modified a commercial pharmacy order-entry system (RxTFC[®], BDM) for use as a CPOE application¹⁶; the second study appears to have been a rudimentary CPOE system, since a relational database product designed for personal computers was used (FileMaker Pro[®]).¹⁷

Beyond technical differences, the hospital setting and patient population might also have resulted in different chemotherapy CPOE implementation experiences. As a research hospital, where all patients are treated on protocols, chemotherapy regimens at our hospital often may be more

complex than those at other hospitals. In addition, specific chemotherapeutic agents might be dosed and administered differently in our research hospital, since pharmacokinetic studies are incorporated into most chemotherapy regimens. Moreover, we are comparing our CPOE system against a highly developed paper-based system that incorporated many of the features —e.g., limited formularies and preprinted order sets—that Kim, et al., first introduced electronically.¹⁶

Our experience illustrates the value for improving patient safety of formal process redesign specific to the exact technology and the environment in which it will be implemented. It is imperative to appreciate that new technologies to improve patient safety associated with medication use can also result in unintended consequences and error.¹⁸ As a general principle, implementation of new electronic processes is associated with a “window of increased risk” as a consequence of errors of unfamiliarity by end users and undiscovered deficiencies of new processes (Figure 1). To achieve a future state of reduced error, it might be difficult to avoid this window of increased risk, but risks can be mitigated using the methods listed in Figure 1. We have found this figure useful to help our medical staff, administrators, and board members appreciate the rationale for increased vigilance in the initial implementation phase of technologies that are intrinsically believed to increase patient safety.

The gains we achieved by applying formal process redesign and work-system analysis to the implementation of chemotherapy orders should likewise be applicable to other new technologies, such as barcoding for point-of-care medication administration and “smart” infusion pumps.¹⁹ Organizations accredited by the Joint Commission are required to complete one proactive risk assessment per year, and our data suggest that new technologies should be among an organization’s top priorities for FMEA, particularly for high-risk and high-volume processes.²⁰

Reengineering efforts not only answer “who,” “what,” and “when” questions associated with process changes, they also allow time for those affected by these changes to embrace the new technology by overcoming fears and anxieties associated with how change will affect them.

Making changes without first allowing this period of adjustment and acceptance can lead to failure by revolt.^{21, 22} In our experience, reengineering also provides a wealth of information for training staff. Training strategies and materials can be created to match process flows agreed upon at the end of the process-redesign sessions. Optimally, organizations that are investing substantial resources in CPOE and other new patient safety technologies should also

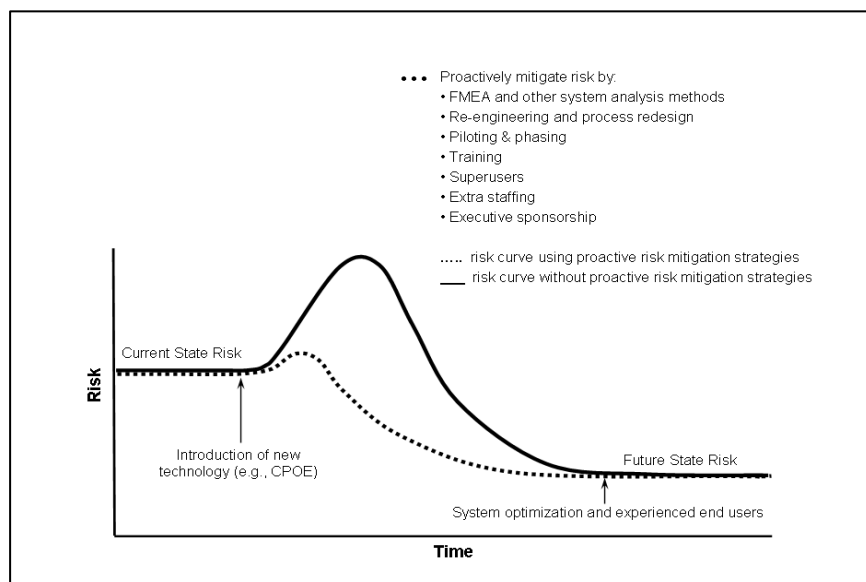


Figure 1. Implementation of new technologies often involves a window of increased risk before overall risk is reduced.

invest in dedicated reengineering staff who can consistently facilitate process redesign and workflow analysis in preparation for successful implementation.

Conclusion

Formal process redesign has proved crucial for safe and successful implementation of CPOE at our institution. We used this method to evaluate the use of CPOE to order chemotherapy for pediatric patients, and the analysis indicated that a commercial CPOE system was unable to exceed or even match the safety features of the current paper-based ordering process, pending further enhancements. Based on our experience, formal process redesign should be an essential element of the CPOE implementation process, particularly for areas of high-risk and high-volume care. Furthermore, these results suggest that process redesign should be employed for other technology implementations, such as barcoding and “smart” infusion pumps.

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Promoting Best Practice and Safety Through Preprinted Physician Orders

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Abstract

Defining how preprinted physician orders are developed within a hospital has the potential to positively affect care, services, reimbursement, safety, and patient outcome. When they are well designed, preprinted physician orders have the potential to improve interdisciplinary integration in care, promote accurate communication, and reduce variation by combining pertinent reminders, safety alerts, and “best practice” into a just-in-time process. Whether in electronic or paper format, preprinted physician orders can transform evidence-based knowledge into practice.

Introduction

Because physicians’ orders for hospitalized patients have the unique characteristic of affecting and bringing together multiple diverse disciplines and processes, designing orders is both an art and a science from which all medical disciplines and patients can benefit. Although physicians may rightfully feel they are responsible for the content of orders, clear, accurate, and concise communication requires a coordinated, team approach. Through multidisciplinary involvement, preprinted physician orders (both paper and electronic) provide an opportunity to involve a broad range of perspectives in decisions about the care of a single patient.

In addition to being available for immediate use for commonly performed interventions, other advantages of well designed, preprinted orders include:

- Continued, coordinated, and integrated care by communicating “best practice” through multiple disciplines, levels of care, and services.
- Modified practice through educated staff and physicians regarding evidence-based care.
- Reduced variation and unintentional oversight through standardized formatting and consistent style in a legible and clear presentation.
- Enhanced time-saving work flow with pertinent instructions that are easily understood, intuitively organized, and suitable for direct application to current information-management systems.
- Reduced potential for medication errors through integrated safety alerts and reminders.
- Increased utilization of continued outpatient services post-discharge via appropriate reminders.
- Convenient access to relevant references and other information.
- Simplified data abstraction via indicators for Joint Commission Core Measures and National Patient Safety Goals.¹

- Improved documentation for utilization and reimbursement purposes.
- Comprehensive orders that clearly communicate directions and reduce unnecessary calls to physicians for clarifications and questions.

Whether they are printed on paper or available for electronic access, development and implementation of well designed, preprinted physician orders requires engineering, education, and enforcement. Because physician orders exist at the intersection where multiple disciplines and services (e.g., case and risk management) converge, they are the ideal medium by which to address concerns pertaining to reimbursement, utilization, patient safety, and quality measures. Orders are the initial means that enable physicians to communicate with a variety of interdisciplinary hospital caregivers, and they represent the starting point for action and care. In the health care environment, nothing goes forward without calling on the assistance of and providing direction through physician orders.

Although research supports the effects of electronic reminders and computerized physician (or provider) order entry (CPOE) on patient care,² the present article describes our efforts (some of them through trial and error, some supported by research) to define and refine preprinted physician orders (including paper-based models) that improve interdisciplinary integration and accurate communication, while reducing unnecessary variation. We offer ideas about applying elements and concepts of computerized clinical decision-support systems to paper-based models and considering application of paper-based order structures and criteria to the electronic physician order format.

Advances in technology allow preprinted physician orders to have flexibility and the ability to rapidly adjust and adapt to changes in individual hospital processes, patients, and available services. Preprinted orders offer a low cost and simple-to-implement opportunity to affect the functional organization of the health care process, quality of care, and ultimately, patient outcome.

The Essence of Preprinted Physician Orders

Creating any well designed physician order requires considerations that can be broadly broken down into the headings of engineering, education, and enforcement.

Engineering

Engineering refers to the most mechanical aspects of developing orders, including items such as content, format, and medication safety.

- **Content** ensures that orders are comprehensive, correct, and coordinated. Content may include information beyond what the physician might initially consider, such as venous thromboembolism prophylaxis and influenza vaccination screening.
- **Format** defines type and layout considerations that can make orders easier to read and comprehend. Elements of format include font, point size, white space, use of symbols, capitalization, and adequate space for handwritten entries. Format consistency is improved through attention to standardizing usage, punctuation, arrangement, design, and other factors.

- **Medication safety recommendations** call for presenting medication information or instructions in a clear and consistent manner, which is very important for all aspects of physician orders. Advice from the Institute for Safe Medication Practices, the United States Food and Drug Administration, and others as it pertains to writing medication orders is presented later in this paper.

Education

Preprinted physician orders offer an excellent opportunity to provide and implement timely instructions to physicians, staff, and patients regarding “best practice” and general patient safety. This information might involve attaching pertinent printed patient education material to the orders for easy and timely distribution by the nurse to the patient. It might also involve printing appropriate reference information on the reverse side of paper orders (or offering an appropriate Internet link to this information in CPOE). This information might include a listing of applicable formulary medications and dosages, indications of appropriate antibiotic use, evidence-based algorithms to guide care and decisionmaking, and a list of reportable core measures for a particular diagnosis. Education regarding safety, “best practice,” infection control, and outpatient referrals might also be performed through well placed reminders and alerts within the orders.

Enforcement

Managing changes in orders, keeping them current to reflect “best practice,” and ensuring that only the most current versions are available and in use offer a different, but related, set of challenges. Without some control of the mechanics of and access to order changing, the potential increases for miscommunication, unacceptable variations, and error. Methods for guiding process standardization are discussed later in this paper.

Engineering: Content

Generally, orders begin with content. In other words, the physician writes or creates orders for a specific procedure, diagnosis, care, or admission. Examples of content criteria are shown in Table 1.

Table 1. Examples of content criteria

Criteria	Examples or clarification
1. Do the orders reflect current "best practice"?	Is there evidence to support the orders? Such evidence may come from recently published literature, research, association guidelines, or recommended practices.
2. Are orders comprehensive and do they consider other disciplines?	Do orders include all likely needs, e.g., other services, other disciplines, and discharge planning as appropriate? For example, some physicians might <i>not</i> consider the following when admitting a patient for a diagnosis of <i>dehydration</i>: ☒ Screen patient for smoking history. RT to provide smoking cessation counseling if patient has smoked within 12 months. (<i>Performance measure</i>)
	Sometimes it may be necessary to obtain the patient's weight before the pharmacy can determine proper drug dosing. If hospital process requires scanning paper orders to the pharmacy, it would be helpful to including the following information (for the nurse to complete) within the paper/scanned order. An order might read as follows: ☒ Obtain patient weight. Patient weight: _____ ☐ pounds ☐ KILOgrams ☐ actual ☐ estimated
3. Are automatic orders prechecked to reduce the possibility of their being overlooked?	Do orders include the following statement? "Strike through entire line to cancel a prechecked order."
4. Are performance measures indicated, e.g., Joint Commission Core and National Hospital Quality measures? ¹	☒ Screen patient for pneumococcal vaccination history and candidacy. Administer Pneumovax® 0.5 mL IM into deltoid as appropriate prior to discharge. (<i>Performance measure</i>).
5. Is the inclusion of National Patient Safety Goals (NPSG) considered? ³	☒ Verify (through read back) critical lab values and notify physician immediately. (<i>Safety measure</i>) Provide vital sign parameters re: when to notify the physician and when to initiate a rapid-response team call for immediate patient assessment. (<i>Safety measure</i>)
6. Is consideration given to infection control measures?	☒ Prep and clip hair of right groin area. <i>Do not shave</i>. ☒ Start IV antibiotic of cefazolin (Ancef®) 1 g no more than 60 min prior to incision time. (<i>Performance measure</i>) ☒ Cefazolin (Ancef®) 1 g IV q8h for up to 24 h after surgery end time. Start upon arrival at PACU. Surgery end time _____ (required for pharmacy to schedule doses). (<i>Performance measure</i>)

Table 1. Examples of content criteria (continued)

Criteria	Examples or clarification
7. Are listed medications and equipment available at your facility?	Check medications against the formulary. Make sure materials management or bioengineering is able to support equipment items.
8. Are considerations given to coding and reimbursement documentation requirements?	Clearly indicating <i>inpatient</i> , <i>outpatient</i> , or <i>observation</i> status can affect reimbursement. When feasible, include orders such as: • Admit as inpatient to _____ floor. • In some cases, it maybe preferable to provide a forced option for the physician to complete, such as: • Patient status: ☐ Inpatient ☐ Outpatient ☐ Observation status. • Likewise, the following statement may be very helpful in ED orders: "May use nursing documentation for coding."

Engineering: Format

As the population of health care providers ages, it becomes ever more important to make the printed words they rely on to care for their patients as easy to read as possible. Table 2 summarizes several ways to accomplish this.

Table 2. Improving legibility of printed documents

Criteria	Examples or clarification
1. Is the print simple to read?	A nonserif font (e.g., Arial 12-point) is recommended, especially for paper orders that may be faxed. Errors are more likely to occur when faxed copies are not as clean or legible as they could be. ⁴
2. Are instructions complete, unambiguous, and clear?	☒ Nothing by mouth after midnight. ... <i>But no diet was ordered before midnight.</i> ☒ Elevate head of bed as <i>appropriate</i> . <i>No indication why, when, or how high.</i> ☒ Advance diet as tolerated. <i>Inadequate guidance for the nurse to determine the proper action.</i> Likewise, write out "Left" and "Right." <i>The letters L and R may be interpreted as "Lower" or "Liter" and "Raise," respectively.</i>

Table 2. Improving legibility of printed documents (continued)

Criteria	Examples or clarification				
3. Is the use of symbols kept to a minimum? Be wary of letters and numbers that may be easily confused or misinterpreted.	- Do not use the symbols “<” and “>”. Instead, write out “less than” and “more than.” - Slashes (/) can be easily misread as the number one. If a slash must be used, provide a space before and after the slash; e.g., “20 mg / 500 mL”; or write “per” in place of the slash, e.g., 20 mg per 500 mL. - The letter “O” can be misread as the number zero. Writing out “one” and “zero” can sometimes reduce confusion. - Lower case L (l) can be misread as the number one or the capital letter I; e.g., Iodine (iodine) can easily be confused with Iodine, or Lodine® (etodolac). - To reduce confusion between certain look-alike letters, consideration may be given to using lower case “i” and upper case “L”. This may create issues with “tall-man lettering”; e.g., “miLLiLiTERS” and certain drug names in all capital letters: “iNSULiN”.				
4. Are attempts made to remove or reduce look-alike or sound-alike items?	For example, “BNP” vs. “BMP”. Instead, write out “ <i>brain natriuretic peptide</i> ” (or “ <i>BN peptide</i> ”) and “ <i>basic metabolic panel</i> ”.				
5. Is “tall-man lettering” used for all look-alike names and words?	“Tall-man lettering” can also apply to words like “eAr” and “eYe”. ⁵				
6. Do the orders include a space for physician ID# next to the signature line?	Including an identification number on the signature line helps identify the physician: <table><tr><td>Physician signature</td><td>ID#</td><td>Date</td><td>Time</td></tr></table>	Physician signature	ID#	Date	Time
Physician signature	ID#	Date	Time		
7. Are upper case letters used appropriately?	When lower case letters are used, “PRN” can be easily misread as “pm”. The best option is to write out “as needed” or place “PRN” in all capital letters. Likewise, while not entirely chemically proper, “KCL” has been read as “KCI” when all caps are not used, as is technically correct. “STAT” may be placed in all capital letters for emphasis.				
8. Are paper orders written on one side of the sheet only?	Orders written on the reverse side of sheets are often overlooked. The reverse sides of orders are best used only for references, additional information, etc.				

Further consideration should be given to the way orders look and feel. This involves standardizing the sequence in which information is presented on the order sheet or screen. This method can also be utilized on paper orders to help prepare staff for the transition to an upcoming CPOE implementation. For example, orders may be consistently grouped under headers, as appropriate, in the order shown in Table 3.

Table 3. Optimal presentation of orders

Order group	Examples
Admission status	<i>Inpatient, outpatient, observation status.</i> (These options may be adjusted, depending upon the type of order.) Other aspects of admission status include <i>full code, no code, comfort care, isolation status, diagnosis, and the procedure to be performed.</i>
Nursing orders	Wound care, Foley catheter, activity orders, vital signs.
Dietary	Diet orders, tube feedings, nothing by mouth.
IV fluid	Type, rate, amount.
Medications	By mouth, IV, IM, topical, scheduled, PRN, etc. Medication options, when listed on the orders, are generally listed, first by the most commonly used drug and dose, and then by dose size (smallest to largest) and dosing frequency (lowest to highest).
Cardiopulmonary	Echocardiograms, respiratory treatment.
Laboratory	Blood work orders.
Radiology / Imaging	CT, MRI, chest x-ray, and a prompt to include the reason for each test.
Therapy	Physical therapy, speech therapy, social worker.
Consults	Other physicians, case management, wound care nurse, nutritional evaluation, chaplain, et al.
Patient education	Stroke or CHF education booklets, diet education, diabetes care, ostomy training.
Venous thromboembolism prophylaxis	Sequential compression devices for bilateral lower extremities; anticoagulation therapy.
Vaccination status	Screening and orders to vaccinate as appropriate.

Formatting also involves consistency in expressing weights and measures. When abbreviations are used, they should follow the U.S. Pharmacopeia (USP) standard abbreviations for dosage units. The most common abbreviations are shown in Table 4.⁶

In addition, formatting should consider wording to assist unit secretaries in putting orders into hospital-specific information systems. For example, an order to request smoking cessation education for a patient might read as follows:

☒ RT for smoke cessation if patient has smoked within the past 12 months. (*Performance measure*).

All preprinted orders should use the same template, which includes specified areas for:

- Date.
- Orders.
- Name of orders.
- Date of latest review.

- Facility name.
- Allergies or adverse reactions.
- Pharmacy code (if used).
- Patient identification information.
- Page number (e.g., page 1 of 3).
- Appropriate barcode if applicable.

Depending on the information system used within a hospital, the pharmacy may be able to code orders for quick and accurate entry into their system. Placing this code under the name of the orders (e.g., “POLUM” printed under the name of post-op lumbar surgery orders 0707) saves order entry time in the pharmacy.

Additionally, to avoid potential inconsistencies, if patient allergies or adverse reactions are handwritten entries on paper order tools, they would be listed only on page 1 of multipage paper orders. Ample space should be provided to describe these reactions.

Table 4. USP standard abbreviations for dosing units

m	Meters
kg	KILOgram
g	Gram
mg	MILLIgram
mcg	MICROgram
L	Liter
mL	milliLITER (<i>do not use cc</i>)
mEq	Milliequivalent
mmol	MilliMOLE

Engineering: Medication Safety

Perhaps nowhere is safety more important than in orders pertaining to medications. Table 5 lists some common concerns regarding safety and medication orders.

Table 5. Common concerns regarding safety and medication orders

Criteria	Examples or clarification
1. Do the orders limit abbreviations to a minimum and never use unapproved abbreviations (e.g., QD or U)?	• Abbreviations are time-saving measures when handwriting orders. But, since preprinted orders can be readily reproduced by electronic or printed means, abbreviations are no longer a shortcut. They should be used rarely. Abbreviated medication names should be avoided.⁷ • The risk of dosing errors can also be reduced by avoiding the use of leading zeros before a decimal point and the use of trailing zeros after a decimal point.⁸
2. Are medication orders numbered?	This is not a recommended practice because the order number may be confused with the medication dose.

Table 5. Common concerns regarding safety and medication orders (continued)

Criteria	Examples or clarification
3. Are all medications listed together under the title, "Medications"?	- This makes it easier to take these orders off and lessens the possibility of overlooking a medication order. - It also helps the pharmacy in completing the medication administration record. (Remember to include "Saline flush every 8 hours and as needed to maintain patency" under "Medications" when a nursing order calls for a saline lock.)
4. Are blanket or multiple-range orders used? (e.g., 1-2 tablets every 3-4 hours)	Blanket orders can be confusing or imprecise and are not permitted, for example: "Continue previous medications" is never allowed. - A multiple-range order should read "□ morphine 1-2 mg IV every 3-4 hours as needed for moderate pain."
5. Do orders always list <i>indications</i> for PRN medications?	Listing the indication helps verify that the medication and dosing are correct. ⁶
6. Is "tall-man lettering" used for look-alike medication names?	- A listing of look-alike medication names can be found at: www.fda.gov/cder/drug/MedErrors/nameDiff.htm.^{6, 9, 10} "Tall-man lettering" can also be useful when spelling out words like "TEAspoon" and "KILOgram."
7. If salts are used as part of medication names, do they <i>follow</i> the drug name?	- Write "warfarin Na," NOT "Na warfarin," which may be read as "No warfarin." - Better yet, do not use the salt as part of the medication name unless necessary; or spell out the name of the salt, e.g., "warfarin sodium."⁶
8. Do orders use the word "thousand" and "million" for large doses?	Write "1 <i>million</i> units" or "150 <i>thousand</i> units" rather than 1,000,000 or 150,000 units
9. Do orders use commas for dosage numbers expressed in thousands?	Write "5,000," NOT "5000". ⁶
10. Is there a space between the name of the medication and the dosage or unit of measure?	Write "propranolol 20 mg," NOT "propranolol20mg," which may be misread as 120 mg. ⁶
11. Do orders contain a total dose warning for appropriate medications?	For example, many medications contain acetaminophen. The warning, "Maximum total dose of acetaminophen not to exceed 4,000 mg per 24 hours" (for adults)" should be included in all orders with any medication(s) containing acetaminophen.

Table 5. Common concerns regarding safety and medication orders (continued)

Criteria	Examples or clarification
12. Do paper orders contain a medication warning above the physician signature line as appropriate? e.g., “ Adverse Reaction / Allergy Alert! These orders contain [aspirin, NSAIDS, antibiotic, narcotic, sulfonamides or MAO] medications?”	This warning serves as a reminder for physicians to check adverse reactions or allergies prior to signing preprinted orders.
13. Do medication orders include drug name, strength, dose, route, and frequency?	☒ Furosemide (Lasix [®]) 40 mg. Take one tablet by mouth one time daily. ¹¹
14. Are generic and trade names, if applicable, used?	• Just as patients are identified in two ways, so should medications. List the <i>generic name</i> first followed by <i>trade name</i> in parentheses; e.g., bumetanide (Bumex[®]). • Some literature recommends placing the trade name in ALL CAPS. • Consider including the drug’s purpose for high-risk, easily confused, or problematic drugs.⁶
15. Do medication orders contain criteria for determining the route of administration to be used, if multiple routes are possible?	Give IV until patient is able to tolerate liquids by mouth.
16. Are medication doses written in MILLIgram (mg) when possible and not just in tablets or millilITER (mL) doses?	☒ Acetaminophen (Tylenol) 500 mg. Take one tablet by mouth every 6 hours as needed for mild pain.
17. Is a timeframe included for IV bolus and IV push medications?	☒ Diazepam (Valium) 5 mg / mL. Give 5 mg IV push, over at least 1 minute, every 4 hours, as needed for muscle spasm.
18. Do the orders refer to all medications (from different specialists, OTC, etc.) as appropriate?	☒ Refer to Medication Reconciliation Sheet for further medication orders. (<i>Safety measure</i>) • As appropriate, reconciliation of medications is a National Patient Safety Goal.
19. Do the scheduled times for medication administration promote patient safety?	• The schedule (and stacking) of medications can contribute to falls in the elderly. • Something as simple as changing scheduled medication times for every-12-hour diuretic medications from 9 am and 9 pm to 9 am and 5 pm can decrease nighttime falls in patients trying to get to the restroom.

Table 5. Common concerns regarding safety and medication orders (continued)

Criteria	Examples or clarification
20. Do orders consider potential errors within the local cultural setting?	- Consider look-alike and sound-alike words within your cultural population. - Perhaps most prevalent in the outpatient setting, a patient received a massive medication overdose when a Spanish-speaking caregiver interpreted “<i>once a day</i>” as “<i>eleven a day</i>.” (The Spanish translation of “eleven” is “<i>once</i>.”)¹²

Medication safety also includes alerts and reminders as appropriate to the patient’s condition or to the medications or treatments being ordered. Studies have concluded that electronic alerts favorably influence physician practice and patient outcomes.^{13, 14, 15, 16, 17}

Reminder systems can easily apply to paper orders and may involve separate checked (☒) or unchecked (☐) orders; or they may be part of an order. Examples include the following:

- ☒ Hold HEPARIN and enoxaparin (Lovenox[®]) while the epidural catheter is in place.
- ☒ Do not give narcotics by mouth, IV, IM, or by transdermal patch until epidural is discontinued.
- ☐ Enoxaparin (Lovenox[®]) 1 mg / kg subcutaneously every 12 hours x _____ doses. (Pharmacy to monitor and adjust dose if patient weight is equal to or greater than 180 kg and / or creatinine clearance less than 30 mL / minute. Hold if patient is going to surgery within 24 hours.)
- ☐ Clopidogrel (Plavix[®]) _____mg by mouth x 1 dose. (Hold if going to Cath Lab or CABG within 5 days).”
- Do NOT mix glargine (Lantus[®]) with other INSULINs.
- Administer pneumococcal and influenza vaccines in separate arms.
- Inform surgeon if the patient has taken warfarin (Coumadin), clopidogrel (Plavix[®]), or over-the-counter supplements of feverfew, garlic, ginger, ginkgo, vitamin E, kava kava, St. John’s wort, or valerian within the past 5 days. (Pre-op testing order.)

Two particularly high-risk, commonly used drugs deserve special attention. There have been several publicized errors involving the accidental switching of HEPARIN and INSULIN.¹⁸ As a result of this risk (and also because these two medications have no secondary names) and to bring more attention to the names, it is recommended that ALL CAPS be used when writing out these medications.

Education

All physician orders provide an excellent opportunity to educate others regarding “best practice” and safety through alerts, reminders, references, attached information, and indicators. Examples to consider as appropriate include the following:

Patient Safety

Integrating reminders into the process increases effectiveness;^{15, 17, 19} for example:

- This drug may increase risk of falls.
 - Do not use a zero AFTER a decimal; always use a zero BEFORE a decimal.
 - Do not use the following abbreviations: U; OD; QN; SS; ug; QD; QOD; MS; MS04; MGS04. INSTEAD, WRITE OUT INTENDED MEANING.
 - Provide an indication for each PRN order. (*Place this at the top of each order sheet or screen for quick reference.*)
- ☐ Ketorolac (Toradol[®]) 30 mg IV every 6 hours. (If patient is 65 years or older, reduce dose to 15 mg IV every 6 hours.) Notify physician if creatinine is greater than 1.8 mg / dL before giving this drug.
- ☐ Telephone Order Read-Back. (*Safety measure*) *Place this under the nursing signature line.*

“Best Practice”

Indicators are used to provide notice and awareness of *core measures and “best practice”*; for example:

Either an ACEI or ARB is prescribed at discharge unless there is a contraindication or reason for not prescribing EACH. (*Performance measure*)

If vancomycin is ordered, please indicate reason:

- ☐ Beta-lactam allergy
- ☐ Known colonization with MRSA
- ☐ Nursing home-stay within past year
- ☐ Chronic wound care or dialysis
- ☐ Other _____ (*Performance measure*)
- ☒ Give the patient / family “Living with Heart Failure” education booklet; instruct on diet, activity, medications, weight monitoring, followup, signs and symptoms (and what to do if they return), smoking cessation / avoidance, and hand washing. (*Performance measure*)

- ☒ Beta-blocker for left ventricular systolic dysfunction _____

Contraindications:

- ☐ Allergic
- ☐ Bradycardia (less than 60 bpm)
- ☐ 2nd or 3rd degree heart block
- ☐ Systolic blood pressure less than 90 mm Hg
- ☐ Other _____ (*Performance measure*)

Referrals to Outpatient Services

Preprinted orders also provide the opportunity to educate and remind health care providers of the continuation of optional services provided outside of the hospital. For example:

- ☐ Outpatient diabetes education postdischarge. Unless the patient has another preference, fax this order sheet to Memorial System Diabetes Center at 555-1234 today for followup.
- ☐ Cardiac wellness / rehab postdischarge. Unless the patient has another preference, fax this order sheet to Memorial System Cardiac Wellness Center at 555-4321 today for followup.

Infection Control

Health care providers should be aware that determining if infections are present on admission (as opposed to whether they were hospital-acquired) is becoming increasingly important for reimbursement and infection surveillance. For example, consider ruling out a urinary tract infection when a Foley catheter is first inserted, as follows:

- ☐ Insert Foley catheter. Collect and submit specimen for urinalysis with culture and sensitivity, if indicated.

Reference Information

References can be placed on the reverse side of paper orders, or a link to pertinent information may be inserted into electronic orders. Examples of reference information include:

- A list of formulary medications: e.g., ACEI, ARB, beta-blockers. (*CHF and AMI orders*)
- A list of pertinent core measures and “best practice.”
- Antibiotic usage recommendations for pneumonia, orthopedic surgery patients, et al.
- Recommended treatment algorithms for sepsis, stroke, chest pain, et al.

Attachments to Orders

Attachments provide additional printed information or forms that are specific to the orders. In the electronic environment, there may be a link to educational materials and information within the information system.²⁰ Examples of attachments include specific consent forms and patient education sheets for the nurse to provide to the patient. Attaching these types of documents to orders helps save storage space on the nursing units, and the information may be updated in tandem with the orders.

Other Tools

In an electronic environment, physician orders can offer automated support through links to research, literature, regulatory standards, and treatment algorithms. Advances in information systems can also compare orders against dosing standards, check for allergies or adverse drug reactions, perform drug-laboratory value and drug-drug interaction checks, and warn about potential errors of omission (e.g., failure to request a partial thromboplastin time [PTT] after ordering HEPARIN) in real time.

“Alert Fatigue”

Alerts, reminders, references, and attachments are helpful and timely job tools that assist with proper care, but they should not become intrusive or hamper the work process. Although they can be quite beneficial, care must be taken to ensure that reminders and alerts are not overused. “Alert fatigue” can occur in both the paper and computer environments, when caregivers start ignoring bothersome and inappropriate aids.²¹

Enforcement

Gaining control over preprinted paper orders within a hospital setting can be a challenge. Quite often, physicians create paper orders on their home computers. Frequently, old orders are hoarded, copied, and distributed from nursing units. These unreviewed orders show up suddenly on patient charts with confusing directions, outdated medications, unapproved abbreviations, conflicting instructions, poor legibility, and even letterhead paper from other hospitals. CPOE eliminates many of these issues.

Managing preprinted physician orders on paper includes limiting the number of copies that can be requested from the print shop at any one time (e.g., 25 copies or a 2-week supply). This helps to ensure that old orders are not still in use for months after changes have been made (e.g., waiting until current floor stock of previous form is depleted). Placing blank physician orders on copying machines should be prohibited. (Copying machines are unable to adequately copy barcodes, which disrupts scanning into an electronic record.) Nursing departments can print copies directly from the print shop intranet site until requested print shop copies are delivered.

Our clinical “best practice” (CBP) committee meets for 1 hour monthly to determine and develop order criteria and review existing and new physician orders. The ability and authority to modify orders has been limited to this committee only. The CBP committee also reviews current

literature and research as it pertains to, and can be integrated into, physician orders. Depending on the orders being reviewed, attendance or input at these meetings may be requested by any clinical area of the hospital—e.g., pharmacy, case management, various physicians, emergency medicine, Joint Commission coordinator, patient safety officer, nursing, dietary, admissions, birth care, unit secretary, radiology, laboratory, stroke coordinator, rehabilitation.

Each reviewed order (along with CBP recommendations for changes) is forwarded to the authoring physician for final approval. A brief list of the order criteria created by CBP is also provided to the physician for reference (see Appendix). Final approval by the physician is required before any modified order can be implemented.

The CBP committee names or titles each order in a standardized manner to simplify locating specific orders from the files or print shop. For example, an order from a particular physician might be named: “Dr. Black Post-op Pacemaker Orders 0907.” This title indicates the name of the physician; the type of order (e.g., pre-op, post-op, admission, discharge); the procedure or diagnosis; and the date last approved. Orders used by a specific group of physicians may be named with the group name first (e.g., “Riverside Vascular Post-op AAA Surgery Orders 0807”). Orders used by a diverse group of practitioners may be named, “Pneumonia ICU Admission Orders 0807.”

The CBP also reviews orders (and any associated references, information, alerts, or attachments) on a routine basis to ensure that they reflect current “best practice” and process.

Conclusion

Whether in paper or electronic format, well developed physician orders have the ability to affect and help with a multitude of concerns within health care today. Furthermore, preprinted physician orders have the potential to benefit all patients and disciplines. These orders do not require new technology (although they might use it), and once defined, they are low in cost and simple to use. However, maintaining orders in accordance with “best practice” does require a fair amount of vigilance and routine reviews. Perhaps the best advantages of preprinted physician orders lie in their ability to modify physician practice, guide care decisions, provide a comprehensive perspective, and readily adjust to changes.

CPOE may decrease errors and improve quality, but concerns regarding their high implementation cost, operational disruption, and return on investment have proven a major barrier to immediate and widespread adoption throughout the health care industry.^{22, 23} Fortunately, during this transitional phase of information management, we have an opportunity to share many of the beneficial aspects of paper and electronic formats of physician orders.

Writing good preprinted physician orders is both an art and a science that requires a team approach. When well designed, these orders integrate pertinent reminders, safety measures, and “best practice” into a just-in-time process. Whether in an electronic or paper format, preprinted physician orders can transform evidence-based knowledge into practice. As such, they have the potential to influence good practice and promote patient safety through clearly written communications.

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Appendix

Creating Preprinted Physician Orders for Clinical “best practice” Review

Criteria for consideration when creating or revising preprinted physician orders

Content and Format		Yes
1	Orders reflect current “best practice”	
2	Orders are created in Arial 10- or 12-point font	
3	Orders do not contain unapproved abbreviations	
4	Orders do not contain confusing symbols (e.g., < and >)	
5	Blanket orders are not used. (i.e., Resume home meds).	
7	Order contains space for physician signature, physician ID #, and date	
8	Admission orders include “Admit as inpatient,” “Outpatient,” or “Observation Status,” as appropriate	
9	Orders are single-sided (Reverse side of sheet should contain additional information or references only)	
Medication Safety		Yes
10	Abbreviations, when used, are kept to a minimum	
11	Medication orders are not numbered	
12	Medication orders contain drug name, dose, route, and frequency	
13	If multiple routes are listed, order contains criteria to determine which route to use	
14	When possible, order contains dose written as mg , and not as tablets or mL	
15	Order does not contain multiple ranges	
16	Order contains indication for PRN medications	
17	Time frame is written for IV bolus / IV push orders	
18	Generic and trade names (if applicable) of medication are used	
Actions by the Clinical “Best Practice” Committee (CBP) may include:		
	Arranging presentation of orders according to standardized format	
	Adding indications of regulatory / Performance measures, etc.	
	Adding DVT prophylaxis, vaccination status, smoking counseling, patient education, etc	
	Adding safety alerts and reminders as appropriate	
	Adding maximum daily dosage alerts on medications, as appropriate	
	Including computer software-specific language for order entry	
	Naming the orders according to standardized process to simplify order search / identification	
	Review of orders for clarity of intent	

CBP may contact the physician before modifying an order and will request final approval by the authoring physician before implementing or distributing orders. 1207

The Impact of Standardized Order Sets on Quality and Financial Outcomes

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Abstract

Objective: The objective of this project was to valuate impact of a standardized order set on quality and financial performance. **Methods:** We conducted an observational study to examine order set use by hospital, discharge month, severity of illness and risk of mortality for pneumonia patients between March 2006 and September 2007. We also assessed impact on in-hospital mortality and 30-day readmission rates using four measures: (1) Cox proportional hazards regression, (2) Joint Commission Core Measures compliance using logistic regression, (3) length of stay, and (4) financial indicators using robust regression methods for highly skewed data. **Results:** A total of 3,301 patients met the inclusion criteria. Over 19 months, order set use increased by 55 percent. Order set use significantly improved in-hospital mortality [hazard ratio (95 percent confidence interval (CI): 0.66 (0.45; 0.97) or 0.67 (0.46; 0.98); and Core Measures compliance (relative risk, 95 percent CI: 1.24 (1.04; 1.48) or 1.22 (1.02; 1.45)] following covariate or propensity score risk adjustment. **Conclusion:** Evidence-based pneumonia order sets can reduce inpatient mortality and increase delivery of important care processes.

Introduction

Baylor Health Care System (BHCS), an integrated health care delivery system located in North Texas, is engaged in a multiyear process and organizational redesign project that includes the implementation of an electronic health record (EHR) system supporting computerized physician order entry (CPOE) and point-of-care decision support. This process is intended to increase the overall standardization, quality, and efficiency of care. As an intermediate step—partly to achieve some of the quality of care benefits associated with the standardization and streamlining of care offered by CPOE, and partly to familiarize physicians with the use of standardized orders—BHCS is developing system-wide standardized order sets to be made available through the physician intranet portal at all BHCS locations. Ultimately, these order sets will serve as the core library of order sets supporting the CPOE system.

Since its introduction in 2001, the intranet physician portal has provided secure access to patient health information from any location via the BHCS Network. Using the portal to disseminate order sets simplifies the process of applying updates universally in a timely manner and eliminates the need to provide printed copies at all physical locations. Additionally, this system introduces an intermediate level of computer use, which is intended to ease the transition from

handwritten orders to CPOE. The Medical University of South Carolina pursued a similar strategy and reported success, both in attaining some CPOE-related benefits before implementing a full CPOE application and in achieving some of the cultural changes necessary for the successful implementation of CPOE.¹

Previous research suggests that implementation of standardized order sets, templates, or protocols can improve compliance with recommended processes of care—such as early administration of aspirin, prescription of angiotensin converting enzyme inhibitors, and use of β -blockers for acute myocardial patients,^{2, 3, 4, 5, 6}—and improve patient outcomes.³ The impact of such tools on resource use appears more variable, depending in part on the clinical area or type of care targeted. For instance, introduction of standardized order sets, care protocols, or critical pathways has been found to reduce overall length of stay, postoperative length of stay, and total charges for multiple surgical procedures, including total knee arthroplasty,⁷ appendectomy,⁸ total laryngectomy,⁹ cholecystectomy,¹⁰ carotid endarterectomy,¹¹ gastrectomy,¹² inguinal hernia repair,¹³ and colon surgery.¹⁴ In contrast, interventions to standardize treatment of conditions requiring inpatient medical rather than surgical management—such as pneumonia,^{15, 16, 17} congestive heart failure,¹³ and conservative management of acute appendicitis⁸—have had variable effects on length of stay and costs.

BHCS is in the process of developing and implementing more than 50 standardized order sets in a variety of clinical areas. The first of these—the adult pneumonia order set—was made available system-wide through the physician intranet portal in 2006. We investigated the effect of this order set on in-hospital mortality, compliance with evidence-based recommendations for pneumonia care, length of stay, cost of care, and fiscal operating margin.

Methods

Study Setting

BHCS is a not-for-profit, multihospital system in Dallas-Fort Worth, TX, that incorporates 20 owned, leased, affiliated, and short-stay hospitals with an annual total of more than 103,000 admissions. Only the eight acute care hospitals, where most patients with community-acquired pneumonia are treated, were included in this study.

BHCS is engaged in a multiyear process and organizational redesign project that is supported by the implementation of health information technology. The long-term goals for this project include:

- Creating a culture that fosters interdisciplinary collaboration.
- Eliminating unnecessary variability in patient care.
- Developing and deploying the best evidence-based operational and clinical models.
- Providing clinical decision support at the point of care.
- Providing caregivers with the opportunity to spend more time with patients.
- Significantly improving quality and reducing errors.

The first phase of this redesign project has been paper-based for the most part, predominantly involving the establishment of monitoring and feedback systems to track performance on quality indicators that facilitate the design and implementation of targeted quality improvement initiatives. These indicators include clinical preventive services delivery in the ambulatory care setting and Joint Commission Core Measures in the hospital setting. Introduced in 2004, the “Accelerating Best Care at Baylor” (ABC Baylor) class was designed to teach physicians, hospital administrators, nurse managers, and others the skills needed to actively lead quality improvement efforts and to facilitate process redesign.

The second phase of this multiyear project, currently ongoing, involves the standardization of care and the practice of evidence-based medicine through the development and implementation of standardized order sets and protocols. Although these tools are essentially paper-based, increasing technologic support (e.g., order set deployment via the intranet physician portal) is being introduced.

The third phase will involve the implementation of EHRs and CPOE, which will integrate the process redesign and order sets introduced during earlier phases.

Development of Order Sets

The identification of the most necessary order sets has been based on Diagnosis Related Group (DRG) data (particularly patient volumes), the Institute of Medicine’s 20 Priority Areas,¹⁸ BHCS performance on the Joint Commission Core Measures,¹⁹ and information from individual service lines (e.g., vascular, oncology, and radiology) about areas in which they feel the use of standardized order sets would have the greatest potential to improve quality of care.

The available evidence is reviewed, and a “straw model” is developed once a condition or procedure is identified as a target for a standardized order set. Appropriate leaders, physician champions (i.e., clinicians with dedicated BHCS-funded time for promoting quality improvement initiatives within BHCS), and other care providers and staff are identified and recruited for the development team. Sources used to identify the available evidence have included the National Library of Medicine, the Baylor Health Science Library, the Cochrane Database of Systematic Reviews, EMBASE, the University of Toronto Center for Evidence-Based Medicine, the Agency for Healthcare Research and Quality (AHRQ) Evidence-Based Practice Center program, the AHRQ National Guideline Clearinghouse™ (NGC), UpToDate®, and Zynx™.

Additionally, through physician town hall meetings, departmental meetings, and direct contacts, all BHCS physicians have the opportunity to contribute to the content and format of the order set. Based on the information thus gathered and on their knowledge of local practices, a subspecialty team develops a working draft of the order set and pilots it within their own practices/departments. At minimum, this team includes a representative from each BHCS hospital, a pharmacist, a nursing representative, and a relevant BHCS physician champion. Following revisions to address any issues identified through the pilot testing, the order set is reviewed by the BHCS Pharmacy and Therapeutics Committee and the Patient Safety Committee. Following their approval, it is reviewed by the Physician Design Team, which includes physician champions, a BHCS pharmacist liaison, the BHCS Partnership Council

leader, the Physician Team leader, and ad hoc physician leaders as needed. The Physician Design Team has final control over all order set content.

Finally, each order set is reviewed by the Quality and Fiscal Impact Committee and then sent to the Best Care Committee, a system-wide entity made up largely of hospital presidents, chief nursing officers, health care improvement directors, and physicians with specific quality improvement leadership roles. The order set is then deployed via the portal. Education on using the order sets has been provided to relevant care providers through “academic detailing”²⁰ by physician champions.

Each order set is reviewed and updated annually by subspecialty teams, physician champions, and the Physician Design Team. Changes are reviewed by the BHCS Pharmacy and Therapeutics and Patient Safety Committees. In addition, new evidence from research and local experience is monitored, facilitating ad hoc review and revision of the order set. This ensures that the standardized order sets are consistent with the practice of high quality, evidence-based medicine.

Development and Deployment of the Adult Pneumonia Order Set

Beginning in early 2005, the BHCS Adult Pneumonia Order Set was developed by a system-wide multidisciplinary team including pharmacists, nurses, respiratory therapists, care coordinators, health information management staff, and physicians specializing in infectious diseases, pulmonology, internal medicine, and family practice. Since this was the first effort at system-wide standardization of care processes, the development of the Adult Pneumonia Order Set highlighted the need for much of the supporting structure for such efforts, including a good internal communications process and system-level groups in which stakeholders are brought together with their counterparts from other hospitals (e.g., the Pharmacy and Therapeutics Committee, which was formed in response to this need). It has been intertwined with substantial organizational learning and development of the necessary infrastructure, especially the creation and tasking of teams and committees that play key roles in the order set development process.

From November 2005 to February 2006, the Adult Pneumonia Order Set was piloted by the providers involved in its development at several of the BHCS acute care hospitals. Although no widespread effort was made to inform other care providers about the order set or to encourage its use during the pilot stage, the order set was available to all providers through the BHCS intranet.

Subsequent order sets have not been made generally accessible during the pilot stage because the appearance of the pneumonia order set on the intranet with no preceding education or information about its use created some confusion. Based on pilot experience, minor changes were made to the Adult Pneumonia Order Set prior to its system-wide deployment in order to increase its effectiveness and user-friendliness. These included the addition of passive decision support reminders related to the use of the analgesic Darvocet,[®] the addition of a default care coordination consult, and a formatting change to eliminate confusion involving the separation of antibiotic groupings.

In March 2006, the Adult Pneumonia Order Set was deployed system-wide via the physician portal. At this time, “order set use” was made a required field in the integrated outcomes, resource, and case management system used for pneumonia patients at all BHCS hospitals

(MIDAS+™), facilitating the tracking of order set use. Strategies to increase awareness and encourage use of the order set included:

1. A high-profile awareness campaign, which was presented to the Best Care Committee and made available to frontline care providers through the BHCS intranet.
2. Just-in-time training provided to nursing units at some BHCS acute care hospitals.
3. Incorporation of the order set into the Baylor University Medical Center order entry system.
4. Academic detailing by physician champions.

Anecdotally, this last strategy was perceived as the most effective in raising awareness of and knowledge about the order set.

The Adult Pneumonia Order Set was the first standardized tool BHCS made a concerted effort to implement system-wide. For this reason, there was no preexisting method or infrastructure for widespread deployment. To increase standardization and improve quality of care, such tools and strategies are under development for the deployment of future order sets and other system-wide initiatives.

Patients for Evaluation of Pneumonia Order Set

All adults (>18 years) discharged from one of the eight BHCS acute care hospitals between March 1, 2006 and September 30, 2007, who had been admitted with a working diagnosis of pneumonia and who met the Joint Commission definition of pneumonia²¹ (based on ICD-9-CM diagnosis codes) were eligible for this study. Patients were excluded if “for comfort measures only” was recorded in their admitting physician orders or note, consultation notes, emergency department record, history and physical, physician orders, or progress notes.

Outcome Measures

The primary outcome measure was a difference in performance for clinical quality and financial indicators between pneumonia patients who were treated with or without the BHCS standardized Adult Pneumonia Order Set. Clinical quality indicators included inpatient mortality, readmission within 30 days, and compliance with the Joint Commission Core Measures for pneumonia, as indicated by the pneumonia composite compliance index. The core compliance index was based on eight of the national quality measures for pneumonia:

1. PN-1 oxygenation assessment.
2. PN-2 pneumococcal vaccination.
3. PN-3b blood culture before first antibiotic.
4. PN-4 adult smoking cessation advice/counseling.
5. PN-5b initial antibiotic received within 4 hours of hospital arrival.
6. PN-6a initial antibiotic selection for community acquired pneumonia (CAP) in immunocompetent ICU patients.
7. PN-6b initial antibiotic selection for CAP in immunocompetent non-ICU patients.
8. PN-7 influenza vaccination.

The core compliance index was calculated as the proportion of pneumonia patients eligible for the above measures who receive all the measures for which they are eligible.²¹ Financial indicators included length of stay, direct cost of care, expected payment (based on payer type), and contribution margin (calculated as expected payment less direct cost of care).

Data Collection

Data on order set use (“BHCS order set,” “personal order set,” or “no order set”), age, sex, race/ethnicity, admitting BHCS hospital, All Patient Refined Diagnosis Group (APR DRG) Severity of Illness (SOI) and Risk of Mortality (ROM), and delivery of the Joint Commission Core Measures for Pneumonia were collected from MIDAS for each patient. “Personal order sets” were those developed by individual physicians, physician groups, or hospitals that had not undergone the full development and review process described above for the BHCS order sets. Length of stay, inpatient mortality (including time from admission to death), readmission within 30 days (including time from discharge to readmission), direct cost of care, expected payment, contribution margin, and diagnosis codes used to calculate Greenfield comorbidity scores were determined from administrative data.

Statistical Analysis

To ensure the statistical assumption of independent observations was met, the analysis considered only first hospital admission for pneumonia for patients with multiple admissions during the study period. Due to the continuous decline seen in personal order set use over the study period, the analysis focused on comparing BHCS order set use vs. no order set use.

Univariate analyses were conducted to examine the association between order set use and patient characteristics/outcomes of interest. Chi-square tests and Fisher’s exact tests were used to assess the association of order set use with categorical characteristics/outcomes (sex, race, facility, mortality, core measure compliance, and readmission within 30 days). For ordinally scaled measurements (APR DRG risk of mortality, severity of illness, Greenfield comorbidity score, and month of discharge), trend tests were also performed. Two-sample t-tests were used for mean comparisons of continuous outcomes or characteristics that did not violate the assumption of normality. Robust estimation and regression approaches were used for continuous outcomes that were highly skewed.^{22, 23}

Multicollinearity of all covariates to be included in the adjusted analysis was assessed prior to performing multivariable analysis. No evidence of multicollinearity was observed, and the adjusted analysis was conducted following two approaches: covariate adjusted and propensity score adjusted. In the covariate-adjusted analysis, all covariates of interest (age, sex, race, physician specialty [hospitalist vs. other], Greenfield comorbidity score, APR DRG risk of mortality/severity, payer type, admission source, hospital, and discharge month) were included in the regression model, and the adjusted effect of order set use was estimated.

The propensity score approach involved the creation of propensity scores to determine the conditional probability of a patient being treated with an order set given the set of the patient’s characteristics (age, sex, race, physician specialty [hospitalist vs. other], Greenfield comorbidity score, APR DRG risk of mortality/severity, payer type, admission source, hospital, and discharge

month). Regression analysis with order set use and propensity score as covariates was then performed to determine the adjusted effect of the order set. APR DRG Risk of Mortality was used in the models for safety and effectiveness indicators, while APR DRG Severity of Illness was used for efficiency and fiscal indicators.

The effects of order set use on in-hospital mortality and on readmission within 30 days were assessed using Cox proportional hazard regression. Time to death during the hospital stay was considered for the in-hospital mortality model, while time to readmission from discharge date was considered for 30-day readmission. The adjusted effect of order set use on core measure compliance was modeled using logistic regression. However, since the outcome measure of interest (core measure compliance) was frequent in the study population (>70 percent), the resulting odds ratio overestimates the risk ratio.²⁴ We therefore applied a simple approximation²⁴ to obtain a better estimate of the true adjusted relative risk. Length of stay and cost data were modeled using robust regression methods. Analyses were conducted using SAS[®] 9.1 (SAS Institute, Cary NC) and S-Plus[®] 7.0 (Insightful Corp, Seattle, WA).

Results

Between March 1, 2006 and September 30, 2007, 4,032 adult patients admitted with a working diagnosis of pneumonia who met the Joint Commission definition of pneumonia and were not admitted for comfort care were discharged from the eight BHCS acute care hospitals (Figure 1). Average age among the patients meeting study inclusion criteria was 67 ± 17 years. About half (55 percent) were female, 75 percent white, 18 percent black, and 6 percent other.

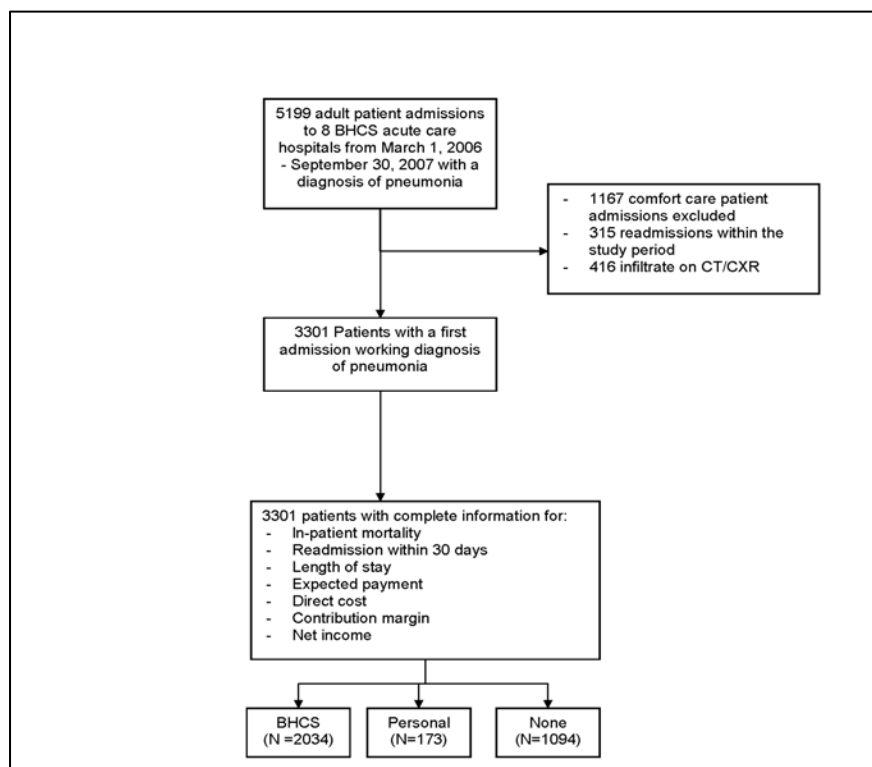


Figure 1. Identification and exclusion of patients included in the evaluation of the Baylor Health Care System Adult Pneumonia Order Set

Significant variation in order set use was observed by age ($P = 0.01$) but not by sex or race. When variation in order set use by APR DRG classes and Greenfield Comorbidity Score was examined using mean score statistics that take into account the ordinal nature of these categorizations, there was a significant association between order set use and APR DRG severity of illness ($P < 0.01$) and APR DRG risk of mortality ($P < 0.01$). Sicker patients were less likely to receive the order set. No significant difference was seen using the Greenfield comorbidity score ($P = 0.42$).

Order set use by month is shown in Table 1. For first pneumonia admissions, BHCS order set use increased from 27 percent in March 2006 to 82 percent in September 2007 ($P < 0.01$); no order set and personal order set use declined (from 51 percent to 18 percent, and from 22 percent to 0 percent, respectively). Despite system-wide promotion of the Adult Pneumonia Order Set, dramatic variation in use was seen among hospitals ($P < 0.01$), with use ranging from 43 percent of first admission pneumonia patients at one hospital to 91 percent at another.

Table 1. Order set use by month for first pneumonia admissions of adult patients to Baylor Health Care System acute care hospitals: March 1, 2006 - September 30, 2007

Discharge Month	Total (N)	BHCS Order Set N (%)	No Order Set N (%)	Personal Order Set N (%)
March 2006	219	59 (27)	112 (51)	48 (22)
April 2006	159	48 (30)	73 (46)	38 (24)
May 2006	153	63 (41)	73 (48)	17 (11)
June 2006	107	51 (48)	47 (44)	9 (8)
July 2006	126	50 (40)	65 (52)	11 (9)
August 2006	110	51 (46)	57 (52)	2 (2)
September 2006	115	59 (51)	49 (43)	7 (6)
October 2006	160	82 (51)	68 (43)	10 (6)
November 2006	176	97 (55)	74 (42)	5 (3)
December 2006	228	135 (59)	84 (37)	9 (4)
January 2007	252	146 (58)	100 (40)	6 (2)
February 2007	233	174 (75)	55 (24)	4 (2)
March 2007	261	212 (81)	46 (18)	3 (1)
April 2007	209	159 (76)	49 (23)	1 (0)
May 2007	196	159 (81)	35 (18)	2 (1)
June 2007	158	133 (84)	24 (15)	1 (1)
July 2007	172	141 (82)	31 (18)	0 (0)
August 2007	143	113 (79)	30 (21)	0 (0)
September 2007	124	102 (82)	22 (18)	0 (0)
Total	3301	2034 (62)	1094 (33)	173 (5)

Table 2 shows the unadjusted results for the effect of order set use on quality of care and fiscal indicators. In-hospital mortality was significantly lower among patients for whom the order set was used ($P < 0.01$), as were expected payment ($P < 0.01$) and contribution to margin ($P = 0.02$). Compliance with pneumonia core measures with order set use was significantly higher

($P < 0.01$). Decrease in readmissions within 30 days ($P = 0.24$) and length of stay ($P = 0.11$) were not significant, but direct cost ($P = 0.06$) was significantly lower for patients who received the order set.

Table 2. Unadjusted results comparing quality of care and financial indicators for first pneumonia admissions to Baylor Health Care System acute care hospitals that used vs. did not use the order set: March 1, 2006 - September 30, 2007

	Order set			<i>P</i> -value
	All (N = 3128) N (%)	BHCS (N = 2034) N (%)	None (N = 1094) N (%)	
Safety and effectiveness indicators				
In-hospital mortality	138(4.4)	67 (3.3)	71 (6.5)	$<0.01^a$
Pneumonia core measure compliance	2376 (76.0)	1585 (77.9)	791 (72.3)	$<0.01^a$
Readmission within 30 days	349 (11.2)	217 (10.7)	132 (12.1)	0.24^a
Efficiency and fiscal indicators	Mean ($\pm$SD)^c	Mean ($\pm$SD)^c	Mean ($\pm$SD)^c	
Length of stay (days)	5.3 (3.7)	5.2 (3.6)	5.8 (4.4)	0.11^b
Direct cost (\$)	5418 (4488)	5092 (3918)	6022 (5432)	0.06^b
Expected payment (\$)	7131 (4483)	6642 (3794)	8105 (6004)	0.01^b
Contribution to margin (\$)	1797 (3879)	1592 (3616)	2229 (4453)	0.02^b

a Based on Chi-square test
b Based on robust ANOVA test
c Robust mean $\pm$ standard deviation

Table 3 shows the effect of order set use on quality of care and fiscal indicators following adjustment. The reduction in inpatient mortality with use of the BHCS order set, compared to no order set use, remained statistically significant. The magnitude of this reduction was approximately 34 percent under both covariate- and propensity score-based adjustments. The increase in core measures compliance also remained significant following adjustment, with patients for whom the order set was used being 22 to 24 percent more likely than patients for whom the order set was not used to receive all pneumonia core measures for which they were eligible [relative risk, RR (95 percent CI) = 1.24 (1.04; 1.48) using covariate adjustment and 1.22 (1.02; 1.45) using propensity score adjustment]. Following adjustment, no significant effects of order set use were observed on readmission within 30 days, direct cost, expected payment, or contribution margin.

Table 3. Adjusted effect of order set use vs. no order set used on quality and financial performance measures for first pneumonia admissions discharged from acute care hospitals: March 1, 2006-September 30, 2007

Outcome	Covariate adjusted ^a	Propensity score adjusted ^b
Safety and effectiveness indicators		
In-hospital mortality [HR (95% CI)] ^c	0.66 (0.45; 0.97)	0.67 (0.46; 0.98)
Pneumonia core measure compliance [RR (95% CI)] ^d	1.24 (1.04; 1.48)	1.22 (1.02; 1.45)
Readmission within 30 days [HR (95% CI)] ^c	0.86 (0.67; 1.10)	0.85 (0.67; 1.09)
Efficiency and fiscal indicators [Reg est (95% CI)]^e		
Length of stay (days)	0.02 (-0.21; 0.25)	0.06 (-0.20; 0.33)
Direct cost (\$)	-68 (-273; 137)	-25 (-277; 226)
Expected payment (\$)	-87 (-197; 23)	-5 (-192; 181)
Contribution to margin (\$)	-57 (-300; 185)	-64 (-358; 231)

a Adjusted for age, sex, race, type of physician (hospitalist), Greenfield comorbidity, APR DRG (risk of mortality or severity), payer type, admission source, hospital and discharge month.

b Propensity scores based on patient's age, sex, race, type of physician (hospitalist), Greenfield comorbidity, APR DRG (risk of mortality or severity), payer type, admission source, hospital, and discharge month.

c HR (95% CI) = Hazard ratio (95% confidence interval).

d RR (95% CI) = Odds ratio (95% confidence interval).

e Reg est (95% CI) = Robust regression estimate (95% confidence interval).

Discussion

This study examined the impact of development and system-wide deployment of a standardized order set for adult pneumonia on quality of care and financial performance over a 19-month study period in the multihospital Baylor Health Care System.

Use of the BHCS Adult Pneumonia Order Set varied significantly and widely, by hospital and by month, with use for first admission pneumonia patients increasing from 27 percent in March 2006 to 82 percent in September 2007. The wide variation in use by hospital likely reflects variability in local physician leadership and their buy-in to implementation and use of standardized order sets (potentially influencing such factors as the degree to which local frontline providers were exposed to the order set awareness campaign) and differences from one hospital to another in the training provided to nursing units. Patients in higher APR DRG Severity of Illness and Risk of Mortality classes were significantly less likely to receive the order set.

Prior to adjustment, order set use showed a significant reduction in in-hospital mortality, expected payment, and contribution margin, as well as a significant increase in core measures compliance. Following adjustment for patient and provider characteristics, severity of illness, discharge month and hospital, the reduction in in-hospital mortality and the increase in core

measures compliance retained significance. The mortality effect was very large, with a 33 to 34 percent reduction in in-hospital mortality, depending on the risk-adjustment method employed. This mortality reduction translates into 32 patients that need to be treated with the order set to save one additional life, which is similar to the result reported for a pneumonia clinical pathway.²⁵ The increase in core measures compliance was also significant, with patients for whom the order set was used being 22 to 24 percent more likely than patients for whom it was not used to receive all the pneumonia core measures for which they were eligible, depending on the adjustment technique. No significant effects were seen on the efficiency and fiscal indicators examined following risk adjustment.

While we observed substantial and statistically significant mortality and core measures compliance benefits with order set use, no correspondingly large benefit with respect to length of stay or any financial indicator was evident. In a separate examination of APR DRG Risk of Mortality classes 1 to 3 and 4, the mortality benefit of the order set was sustained and even strengthened among patients with the highest mortality risk: for classes 1 to 3, in-hospital mortality was 1.4 percent with the BHCS order set vs. 2.0 percent with no order set [adjusted hazard ratio, HR (95 percent CI) = 0.87 (0.43-1.74)]; for class 4, in-hospital mortality was 19.0 percent with the order set and 31.4 percent with no order set [adjusted HR (95 percent CI) = 0.65 (0.42-1.02)].

An intranet portal had been shown in earlier research to be an accepted and effective means of disseminating a standardized order set throughout a multi-hospital health care system.¹ This intermediate level between fully paper-based order sets and CPOE avoids many of the identified problems with paper-based order sets²⁶ and is quicker and less expensive to implement than CPOE. The increased use of the Adult Pneumonia Order Set over time seen within BHCS is similar to the increasing “hits” the Medical University of South Carolina observed in tracking use of their order set intranet portal following its implementation in March 2002.¹

The 82 percent order set utilization rate demonstrated for first pneumonia admissions 19 months after implementation was substantially higher than adoption rates previously reported for pneumonia order sets/clinical pathways, which have been < 30 percent.^{25, 27, 28} Our observation that use of the order set decreased in-hospital mortality was consistent with previous studies examining the impact of order set use on mortality, both for pneumonia²⁹ and for other conditions,³⁰ as was the finding of increased pneumonia core measures compliance following implementation of tools to increase the standardization of care, such as order sets and protocols.^{2, 4, 5, 30, 31, 32}

Order set use may have effected larger improvements in delivery of certain indicators within the pneumonia core measures set than were observed for the composite score. It has been noted previously that tools—such as standardized orders, treatment guidelines, and critical pathways—are most effective in improving processes of care that are directly under physicians’ control. They are less effective with respect to those that depend on a more complex series of interactions between individuals and components of the health care system.¹⁵

With regard to the impact of an order set on efficiency and fiscal indicators, previous research investigating the effects on resource use and costs of tools to standardize care for conditions

requiring medical rather than surgical management has shown variable results.^{8, 13, 15, 16, 17} Looking specifically at pneumonia, one previous study of the implementation of a treatment guideline that included a standardized admitting order sheet demonstrated no change in length of stay.²⁹ On the other hand, other studies have shown a decrease in length of stay following implementation of a critical pathway or standardized order set plus intensive case management for pneumonia.^{16, 17}

To obtain definitive answers regarding the effects of such tools on efficiency and fiscal indicators, studies specifically targeting and powered for these measures may be needed. A more complete financial analysis would include the cost of administering the pneumonia order set at the patient level, examining fixed costs (e.g., Zynx™ order set evidence-based information, physician champion meetings, staff training, and implementation at the hospital) and variable costs (e.g., costs of specific aspects of the order set at the patient level). However, without specific cost data (fixed and variable) at the patient level, computing the necessary cost-effectiveness ratios is problematic.

Since this was an observational study as opposed to a randomized trial, it is possible that order set use was influenced by patients' characteristics, potentially masking or exaggerating the impact of the order set. To account for the differences among the patients that did or did not receive the order set, we conducted adjusted analyses using both covariate and propensity score approaches. These analyses also accounted for the variation in order set use by facility and time observed in this study. Standard covariate risk adjustment is limited in that it does not ensure a balanced distribution of covariates among the study subjects,³³ an issue which becomes increasingly important as the number of covariates that need to be considered rises.³⁴ Propensity score-based risk adjustment ensures that measures of patient characteristics are properly balanced across the study groups by estimating the probability that a patient will receive the order set, given his/her covariate values.^{35, 36, 37}

An additional aspect of this study design that cannot be discounted in interpreting results is the potential for contamination between study groups. Physicians and other clinicians may have been influenced by exposure to the order set in their care decisions, even for patients to whom the order set was not applied. Such contamination would attenuate differences between the study groups, underestimating the impact of the order set.

Another factor that must be considered and explored through future research is the inclusion of passive decision support and default care coordination consult in the BHCS Adult Pneumonia Order Set. Because the impact of individual components of the order set was not investigated in this study, the role of the passive decision support and the default care coordination consult in producing the observed improvements in outcomes is not known. Order sets that do not include analogous components may not have the same impact on care as was demonstrated here.

Our results show that important improvements in patient outcomes can be achieved through the implementation of a standardized order set throughout a health care system. This validation of improved patient outcomes is important, since order sets, like clinical performance measures, go beyond the relatively passive recommendations for care incorporated in clinical guidelines and work to actively ensure that patients receive certain processes of care. This is especially

important for patients (e.g., the elderly) who are likely to have been underrepresented in the randomized controlled trials that provided the bulk of the evidence on which evidence-based guidelines, order sets, and performance measures are based.³⁸

The development and deployment of standardized order sets has been undertaken by BHCS in part to prepare for the implementation of CPOE; future research will investigate whether further reductions in mortality and/or improvements in other outcome measures are achieved following the introduction of CPOE. The substantial increase in use of the order set over the 19-month study period suggests that health care organizations considering similar initiatives to improve quality of care may need to anticipate a period of several months before use of the order sets is sufficiently integrated into clinical practice to achieve detectable changes.

Finally, our finding that the Adult Pneumonia Order Set was less likely to be used for sicker patients, for whom it was associated with a 35 percent adjusted relative reduction in mortality and a 12 percent unadjusted absolute reduction in mortality, underscores the importance of increasing order set use among the patients who are most likely to benefit from this care improvement tool.

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Clinical Impact of an Anticoagulation Screening Service at a Pediatric Tertiary Care Facility

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Abstract

Background: As thromboembolic events increase in pediatrics, so does the need for formal anticoagulation practice and management. In 2003, Children's Hospital Boston implemented an inpatient anticoagulation screening service. **Objective:** The objective for this project was to describe the impact of the anticoagulation screening service at a tertiary care pediatric center. **Design/Methods:** We screened 1,340 inpatient records for recommended dose of anticoagulant, indication, monitoring, and clinician responsible for followup care. Ninety-four percent were screened in real-time; 6 percent were evaluated by retrospective review. A survey of staff knowledge was performed. **Results:** Interventions declined from 7 percent of cases (24/338) screened in FY 2004 to 3 percent (12/399) in FY 2006 ($P = 0.01$). The percentage of patients discharged on anticoagulation therapy increased from 46 percent (154/338) in FY 2004 to 62 percent (248/399) in FY 2006 ($P < 0.001$). A discharge plan was present for an average 96 percent of patients. **Conclusion:** An inpatient anticoagulation screening service optimizes compliance with recommendations for safe anticoagulation practice across many services in a large pediatric hospital.

Introduction

Anticoagulation practice in the setting of pediatrics is predominantly extrapolated from the adult literature,^{1, 2, 3, 4} yet anticoagulation therapy continues to increase in this population. This rise is attributed to longer survival rates of acute and chronically ill children, due in part to advances in medical technology.^{2, 5} Despite the upsurge in pediatric thromboembolic events, they are still 100 times less frequent in the pediatric setting compared to the adult setting, which contributes to a lack of evidence-based guidelines in the literature for pediatric prophylaxis.⁶ Most available information is focused on the treatment of thrombosis rather than prevention.⁷ Despite the fact that the safety and effectiveness of anticoagulant medications, such as enoxaparin, have not yet been fully established in pediatrics, they are widely used. As the prevalence of pediatric thromboembolic events increases along with the use of anticoagulants, the need to augment formal anticoagulation practice and management intensifies.

Background

Although only a few pediatric anticoagulation services exist in the United States and Canada,⁸ Children's Hospital Boston (CHB) recognized that anticoagulation practice is a high-risk area, and this triggered a review of practice to ensure safe patient care. In 2002, an interdisciplinary

team of nurses, hematologists, and pharmacists was established to examine the roles and care processes for patients receiving anticoagulation therapy at CHB.

This team devised a protocol to assess the need for enoxaparin dosing guidelines at CHB. A pilot study was completed as the first step for development of the guideline and to (1) determine whether an anticoagulation service would help to identify pediatric patients at high risk for bleeding, (2) analyze anti-Xa levels, and (3) evaluate the potential impact of the modified guidelines for patients at risk of complications. The retrospective review included a review of medical records of patients aged 18 years or younger that had been identified by pharmacy as receiving enoxaparin for treatment of a venous thrombotic event (VTE) between January 2000 and September 2002. Adverse events identified during the pilot study included: hemangioma, oropharyngeal bleed, bleeding at the central venous line, hematoma bruising, epistaxis, stroke, GI bleed, and a new cranial bleed into a tumor. Analysis of enoxaparin levels (as anti-Xa levels) suggested that draft conservative guidelines would have indicated a change from following the American College of Chest Physicians nomogram in nine unique admissions.¹ This retrospective cohort review also revealed variability in monitoring practices for patients receiving anticoagulation treatment for VTEs.⁹

Based on the pilot study results, the team concluded that a work-force redesign was necessary. An inpatient anticoagulation screening service was established and comprised a hematology attending, a dedicated pediatric nurse practitioner (PNP), and a consulting pharmacist. The screening service was designed to promote the safe management of anticoagulation therapy, with the goals of intercepting potential errors by ensuring correct indication, dosing, and monitoring and support of patients discharged on anticoagulation therapy with education, discharge planning, and followup.

A PNP was hired, and the anticoagulation service began in August of 2003. All inpatients ordered for an anticoagulant (warfarin, enoxaparin, and subcutaneous heparin) were included as part of the screening service, excluding cardiac patients receiving warfarin. Patients on the cardiology and cardiothoracic surgery services at our center who receive warfarin are followed by the cardiovascular program but not routinely by the anticoagulation service. Therefore, they were excluded from this screening program and subsequent analysis, unless their cardiologist had asked for hematology/anticoagulation consultation.

The purpose of this analysis was to examine the impact of the mandatory screening service on anticoagulation practice within a pediatric tertiary setting and to describe the influence of the service on improving the consistency of anticoagulation management. An evaluation of selected dimensions of prescribing and monitoring practices was conducted.

Methods

Anticoagulation Screening Service Practice

This report covers the period between October 2003 and May 2007. Since the screening of patients was implemented as a quality improvement measure for CHB, Institutional Review Board approval was not indicated. Patients and their records were screened Monday through

Friday by the anticoagulation service PNP. Screening on weekends and holidays occurred on the following business day. The CHB departments of pharmacy and information services developed a “clot buster report,” a comprehensive listing of all inpatients receiving anticoagulation, to facilitate identification of patients requiring screening. Medical records were reviewed to assess compliance with three major aspects of care: (1) recommended indication for anticoagulation, (2) recommended dose, and (3) recommended monitoring of levels. Results of the screening were documented in each patient’s medical record using a templated form. Concerns identified during the screening process triggered notification of the primary service, and all issues were addressed by the anticoagulation service PNP or the hematology attending. Additional information was gathered (e.g., unit, service, education needed, adverse event), coded, and entered into a Microsoft Excel[®] database. Data were analyzed quarterly, with results reported as a part of the routine process for departmental reporting of quality indicators.

The results shown below are reported on a per-patient-screened basis. If the patient was not discharged between orders, a new order did not generate a new screening episode. A small number of patients (< 1 percent of total) had length of stay > 30 days on anticoagulation and generated a new screen on a monthly basis.

Reduced Variation in Prescribing Practices

In 2004, the Pharmacy and Therapeutics Committee embarked on the implementation of an enoxaparin order template. This order template included recommendations for age-appropriate dosing, with considerations related to renal status and ordering per actual body weight vs. ideal body weight. Our actual practice in morbid obesity was to start with the mean of the ideal and measured body weight for initial dosing. The template also included appropriate monitoring measures and frequency. The screening service encouraged the use of this template and provided education to prescribers.

Enhanced Staff Education

In October 2003, following the introduction of the screening service, the PNP developed a survey to assess the education needs of registered nurses throughout the hospital. Surveys were distributed on the inpatient medical service and orthopedic inpatient nursing unit (day + evening shift nursing census averaged 98); 64 surveys (65 percent) were completed. The results were used to develop a training program. Initially offered to registered nurses on the inpatient units, this education is now offered on an ongoing basis to all clinical staff. Training methods consist of individualized consultations, lecture, and hands on demonstration. The training focuses on the following topics: warfarin/enoxaparin education (e.g., precautions, consistent vitamin K intake, subcutaneous injections), appropriate lab monitoring and techniques, and education on subcutaneous catheter devices.

To evaluate the effectiveness of training, an identical survey was redistributed in 2007 to the same areas, with a 57 percent response rate among a staff of 98. The results of this second survey revealed increased knowledge with regard to the management of patients receiving enoxaparin.

Patient Education, Discharge Planning, and Outpatient Followup

Based on our initial work on the service, adherence to recommended treatment was identified as a problem for patients discharged on anticoagulants. These findings led to the development of an outpatient followup program by the PNP to provide ongoing education and to closely monitor adherence. Participation in monitoring after discharge is at the discretion of the treating team. Referrals to the outpatient monitoring program are usually made by the primary inpatient service treating the patient. The PNP and RN for the service coordinate patient education, identify appropriate facilities for lab monitoring, and develop an outpatient anticoagulation discharge plan that is documented and forwarded to the primary care provider.

Outpatient lab monitoring and dose adjustments are completed in accordance with CHB hematology guidelines. Since October 2003, 30 to 50 patients per month have participated in this outpatient lab monitoring program. These patients could include, but are not limited to, patients who require deep vein thrombosis prophylaxis, prosthetic valve protection (only when specifically referred by their cardiologist, not as a routine), and patients with a history of thromboembolic events.

Results

Between October 2003 and May 2007, 1,428 patients were identified as having an order for an anticoagulant. Of those, 1,340 patients (94 percent) were screened during their admission by the anticoagulation service. Predominant anticoagulants used were enoxaparin, warfarin, and subcutaneous heparin. Dosing interventions (i.e., modifications of dosing inconsistent with recommendations and failure to comply with recommendations to hold anticoagulation) have steadily and significantly declined from 7 percent of cases screened in fiscal year 2004 (24/338) to 3 percent of cases screened in fiscal year 2006 (12/399) ($P = 0.01$). During the first 8 months of fiscal year 2007, 1.7 percent of cases screened (4/234) required dosing interventions ($P = 0.003$ vs. fiscal year 2004). Results are highlighted in Figure 1.

The percentage of patients discharged home on anticoagulation therapy has continued to increase from

46 percent (154/338) in fiscal year 2004 to 62 percent (248/399) in fiscal year 2006 ($P < 0.001$). During the first 8 months of fiscal year 2007, 145 patients (55 percent, $P = 0.02$ vs. fiscal year 2004) were discharged on anticoagulation therapy. The presence of a discharge plan for these patients averaged 96 percent (range, 91 to 99 percent). Anticoagulation discharges are highlighted in Figure 2.

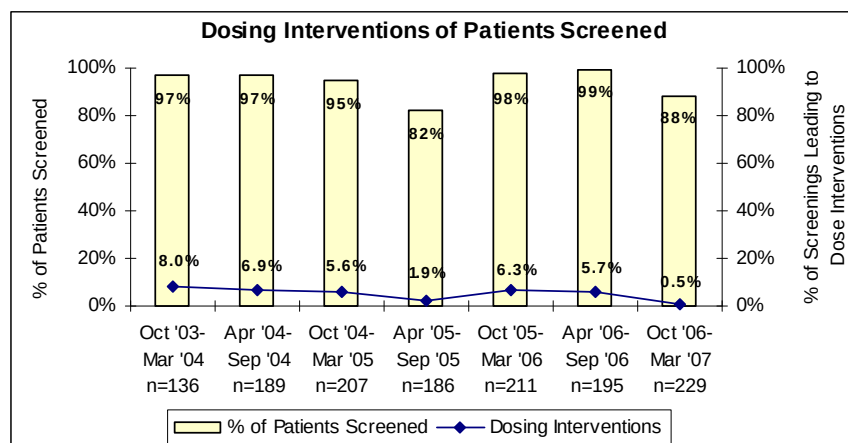


Figure 1. Dosing interventions of patients screened.

Data collection regarding readmission of patients within 3 months of the original diagnosis for bleeding, recurrent thrombosis, or extension of thrombus was initiated in the second year of the program. Readmission rates apply to those patients readmitted to CHB only.

At present, there is no evidence to suggest that any patients that were on

anticoagulation treatment were admitted to an outside hospital during the period listed. Because the anticoagulation team follows the majority of these patients, it would be unusual for them to be unaware of a hospital admission. Since October 2004, 0.98 percent of patients (7/716) were readmitted. Of these, two were readmitted for bleeding, one related to trauma, and one attributed to the patient's underlying diagnosis. Five patients were readmitted for recurrent thrombosis or extension of thrombus. On review of data obtained from the CHB Safety Events Reporting System, adverse event rates in FY 2005 and FY 2006 have been low, with a total of eight cases (four per year) and two for the first 8 months of FY 2007.

When the enoxaparin order template (a paper form available on the hospital intranet) was implemented during the fourth quarter of FY 2004, 28 percent (21/74) of initial orders were written using this template. Although the use of the enoxaparin template was encouraged by our service, it was not mandatory. In 2007, a hospital-wide automated medical record was introduced, and the template is now required for prescribing enoxaparin. Results of the knowledge survey are summarized in Table 1.

Discussion

As anticoagulation therapy has evolved, decisions about patient management have increased.¹⁰ CHB is a teaching hospital, and many clinicians in training rotate into the pediatric setting. The results of this quality improvement project should help in the further refinement of dosing and anticoagulation practice within the hospital.

The anticoagulation screening service has enhanced compliance with recommendations, education, and appropriate followup. In addition, patients who experience a thromboembolic event are routinely seen by the inpatient hematology team after a request for consultation by the patients' attending physician and are followed by the screening service. All patients with a thromboembolic event who are followed as part of the outpatient lab monitoring program are seen by the PNP 1 to 2 weeks following discharge and then at 3-month intervals. Monitoring of coagulation studies after discharge is based on the specific anticoagulant, as follows:

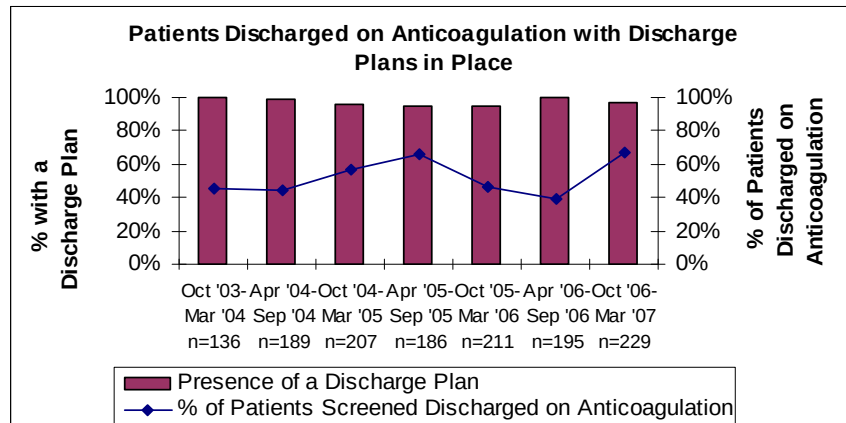


Figure 2. Patients discharged on anticoagulation with discharge plans in place.

- Warfarin is monitored with INR/PT (international normalized ratio/prothrombin time) by our initial dosing protocol; once consistently therapeutic, from week to week, the intensity of monitoring is tapered to monthly.
- Anti-Xa levels are monitored 7 to 10 days after discharge and then on a monthly basis. The responsibility for outpatient followup is shared with the hematologist. Each patient is followed until anticoagulation therapy is discontinued. Patients who complete therapy but continue to have morbidity issues related to their diagnosis and/or continue to have thrombotic risk factors are followed long term.
- One patient population monitored closely is the pediatric patient transitioning to adolescence. Continued followup of patients in this particular age group is needed due to the increase in thrombotic risk factors that occur during this period.^{11, 12}

There is no available literature describing the rate of readmissions for pediatric patients with an adverse event due to anticoagulation therapy. The screening service began collecting readmission data for CHB during the second year of the program; readmissions were defined as patients readmitted within 3 months of the original diagnosis for bleeding or recurrent thrombosis or extension of thrombus.

A review of all readmissions since October 2004 that occurred within 3 months of original diagnosis was completed by the anticoagulation service in collaboration with the primary teams. They found 7 readmissions out of a total of 716 admissions. The review revealed that due to the complexity of six of these cases, clinical outcomes could not be linked to monitoring practices, and it was unlikely that anything further could have been done to prevent the bleeding and reoccurrence/extension of the thrombus. In one case, anticoagulation dosing by the primary

Table 1. RN needs assessment survey^a

Questions answered correctly	Num/Denom ^b (%)		% Change
	2003	2007	
Total number of respondents	64	56	-12.5
What is enoxaparin?	51/64 (80)	55/56 (98)	22.5
Identify two indications?	49/128 (38)	65/112 (58)	52.6
Dosing appropriate for treatment based on recommendations?	1/64 (1.6)	35/56 (63)	3800
Identify side effects	38/64 (59)	51/56 (91)	54.2
Identify appropriate time to draw anti-XA level	29/64 (45)	55/56 (98)	117.8
Identify recommended level	7/64 (11)	33/56 (59)	436.4
Identify correct name of lab test	32/64 (50)	47/56 (84)	68

a The survey was made available to 98 registered nurses each time.

b Numerator represents total number of correct indications identified; denominator represents total number of potential indications.

service was not consistent with that routinely recommended by the anticoagulation service, suggesting that readmission might have been preventable. The PNP provided education regarding the benefits of twice-daily dosing to the primary service that prescribed the anticoagulant.

While few successful pharmacist-run inpatient anticoagulation programs have been documented,¹⁰ there are no reported inpatient PNP-led pediatric programs. The CHB anticoagulation screening service is the first of its kind that we are aware of in the pediatric setting. It has proven to be a valuable resource for patients, families, and clinicians. Although the need for interventions has steadily declined since the introduction of the anticoagulation screening service, this team continues to be a critical means of optimizing compliance with recommendations and standardizing practice for a low-volume, high-risk therapy. In addition to individualized consultation and education, the team has introduced updated guidelines, policies, and templates to guide practice. The screening service continues to be a vehicle for ongoing assessment of anticoagulation practices to identify potential opportunities for improvement and to determine whether education and/or broader interventions are necessary for system-wide improvement.

Conclusion

The findings of this review suggest that an inpatient anticoagulation screening service can increase compliance with recommendations for management of anticoagulation across many services in a large academic pediatric hospital. The screening service at CHB has continued to evolve and has overcome the natural challenges associated with launching a service designed to evaluate practice variation and to continuously assess “best practice.” This program is recognized as a clinical and educational resource for patients and staff. Given the emerging emphasis on anticoagulation practices by external regulatory agencies, the success of the anticoagulation screening service at CHB may serve as a model for other centers.

Limitations

This descriptive paper cannot provide definitive evidence for improved safety; that will require explicit evaluation of outcomes (clots and complications). Readmission rates are for our hospital only, so that if patients with clots or bleeding were admitted solely to another facility, we would not have counted them.

Further evaluation is needed to confirm the long-term effectiveness of interventions introduced by the service to standardize practice and improve patient safety. The relative costs and benefits associated with improved compliance with team recommendations for anticoagulation management will require future analyses. Future goals for this program will focus on broadening the base of evidence to guide management practices for the treatment of pediatric thrombosis and thrombophilia.

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Creating Safety in the Testing Process in Primary Care Offices

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Abstract

Background: The testing process in primary care is complex, and it varies from one office to another. We sought to understand how family medicine offices create safety in this process.

Methods: Using observations, interviews, and surveys, we collected data at four family medicine offices. We searched the interview and observation notes for stories of safety, error prevention, and recovery and coded them to a model of resilient engineering properties, work system components, and testing process steps. **Results:** We found only six examples of practices that were systematically creating safety in the testing process via organizational resilience. The most common resilience properties were top-level commitment and a learning culture applied to work system components of people and their tasks. Offices predominantly depended on individuals to double-check, remember, and work around ongoing problems.

Conclusions: While family medicine offices overwhelmingly depend on individuals to work around testing process problems, important properties of office-wide safety practices included a top-level commitment and a learning culture.

Introduction

The doctor-patient relationship has long been considered the center of primary medical care. However, this relationship does not occur in a vacuum. Each office visit is supported by systems of individuals, procedures, technologies, regulations, and organizational structure. This larger system has a significant impact on patient care. Researchers have recently begun to take a more global perspective on primary care and to evaluate the impact of the larger system on the quality of patient care.^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10}

One of the most common and important processes in primary care is testing. Tests ordered in primary care include laboratory, imaging, and special tests (e.g., cardiac stress tests, electromyograms). The testing process can be defined as all the steps that occur from the time a physician decides to order a test until the appropriate followup action is discussed with the patient and follow-through has occurred.

Some low complexity tests are performed in physicians' offices, but most tests are sent to outside facilities. Previous work^{11, 12, 13, 14, 15, 16, 17, 18, 19} has led to an understanding of the steps that make up the testing process in primary care and delineated the steps in which physicians and their staff members perceive the most errors occurring.^{11, 12, 14, 16, 17} Although some authors have

broken these actions down into “pre-analytical, analytical and post-analytical” phases,^{15, 20} we have expanded the pre- and post-analytical office-based actions into a series of steps, which taken together define the testing process (Figure 1):

- **Ordering:** A physician makes a decision to obtain a test and communicates that decision to the appropriate personnel.
- **Implementation:** The order is transmitted to those performing the test and/or obtaining the specimen(s); the patient is prepared for the test and/or the specimen(s) are obtained.
- **Tracking:** The test order is monitored internally (within the primary care practice) until the results are returned.
- **Return of results:** The results are sent back to the office (and to the physician) from testing facilities or locations.
- **Response:** The physician makes a decision as to the meaning of the results and creates an action plan.
- **Documentation:** Physician and/or staff note in the medical record that the result has been reviewed; that the physician has responded to the result; and that the patient has been notified.
- **Notification:** The patient is informed of his/her test result and the physician’s recommendations for action.
- **Followup:** The process whereby abnormal results and/or results requiring action are monitored until such action is taken or the patient refuses the action.

In a field as complex as medicine, there are multiple potential sources of ambiguity (e.g., patients with similar names) and small mistakes (e.g., incorrect filing of a test result) that can cascade into consequences disproportionate to their sources (e.g., allowing a critical condition to go untreated). Testing represents a common arena for these types of errors. Recent estimates show that the average family physician and general internist order laboratory tests in 29 percent and 38 percent of patient visits, respectively, and imaging studies in 10 percent and 12 percent,

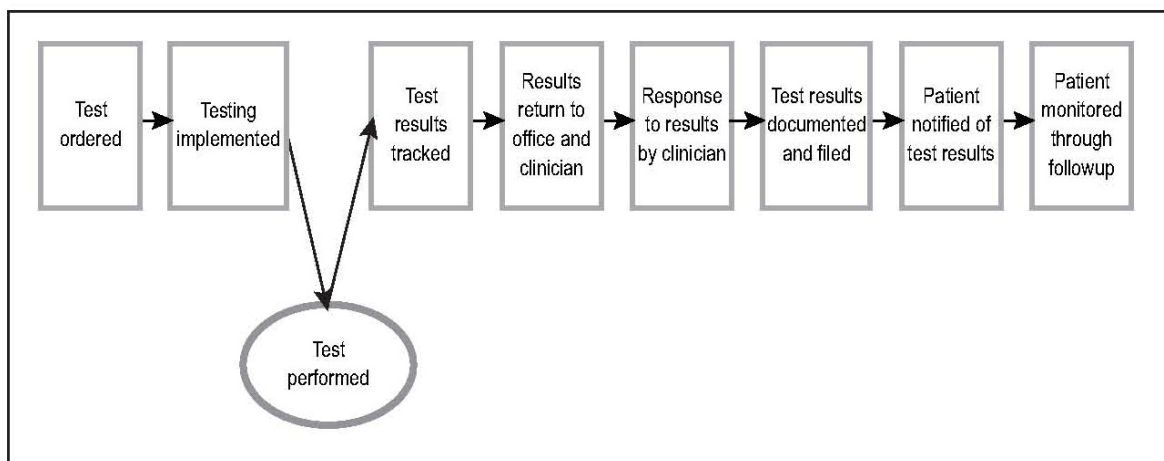


Figure 1. Steps in the testing process in primary care.

Source: Adapted from Hickner JM, Fernald DH, Harris DM, et al. Issues and initiatives in the testing process in primary care physician offices. *Jt Comm J Qual Patient Safety* 2005; 31: 81-89.

respectively.¹³ Therefore, it is not surprising that errors associated with these events are common; 15 to 54 percent of primary care medical errors reported by physicians and their staffs are related to the testing process.^{12, 13, 21, 22, 23, 24}

Errors have been reported in all office-based testing process steps, but those that occur in association with the implementation and return of results are the most frequently reported.^{12, 15, 21} Although these errors have rarely been associated with significant physical harm to patients, adverse consequences, including emotional distress, financial loss, and delay of diagnosis and treatment are common.¹²

The road to improved systems begins with an understanding of the testing process within the larger practice system.²⁵ The testing process can be described as a distributed cognitive system or a work system, where multiple people, tasks, technologies, and environmental and organizational factors interact to determine the outcome.^{2, 26, 27}

In order to move the focus from what is wrong with the testing process to what works well, we have framed our research in the context of resilient systems engineering.²⁸ In this context, a resilient testing process is viewed as a system process capable of adaptively learning to correct errors and to take advantage of new opportunities (e.g., information technology) to improve quality.^{28, 29, 30} Safety and resilience are not static properties of an organization but reflect a dynamic struggle to create safety. The properties necessary for resilient organizations have been described as follows:³⁰

- **Top-level commitment:** Top management recognizes performance concerns and addresses them with continuous and extensive follow-through.
- **Just culture:** Reporting of issues, problems, events, and errors throughout the organization is supported, but culpable behaviors are not tolerated.
- **Learning culture:** Issues, problems, events, and errors are handled with an eye toward repair and true reform, not denial.
- **Opacity:** Management is aware of how close they are to having serious problems and events due to weak safety defenses.
- **Awareness:** Management collects ongoing data to gather insight into quality of performance, problems, and the state of safety defenses.
- **Preparedness:** Management actively anticipates problems and prepares for them.
- **Flexibility:** New or complex problems are handled in a way that maximizes the ability to solve the problem without disrupting overall work.

To best understand how to increase safety in the testing process, we believe a model must describe both the complexities of the work place system and the existence of resilience properties in that practice (Figure 2). Resilience properties, such as those listed above, are exhibited through the work system: that is, the people, tasks, tools and technologies, environment, and organizational structure of the practice.

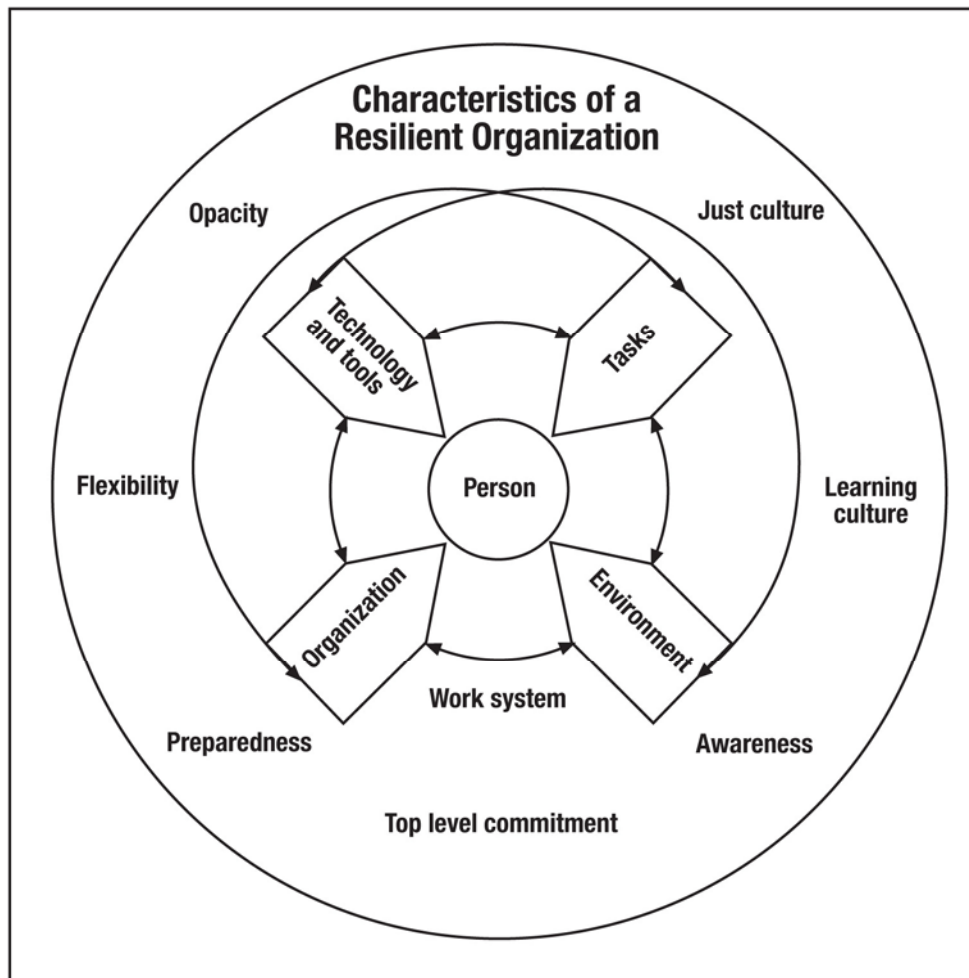


Figure 2. Creating safety: A model of possible components of officewide safety practices in family medicine offices.

Note: For an organization to create safety, it must develop officewide safety practices that incorporate one or more properties of resilience. These properties are used within one or more work system components that center on the person.

Source: Adapted from components noted by Carayon, Schoofs Hundt, Karsh, et al., 2006; and Wreathall, 2006.

In the current study, we applied this model to describe how family medicine offices enhance safety. As part of a larger multimethod study of actual testing process performance in primary care, we analyzed observations and interviews in family medicine offices in order to describe how these offices are working to improve quality and decrease errors in the testing process. Specifically, we asked these general questions:

1. How do offices safely manage the multiple steps of the testing process?
2. What work system components and resilience properties do offices use to enhance safety in the testing process?

Methods

To better understand the testing process in primary care, we elected to intensively study four family medicine offices. Each office was visited for 2 to 4 days, with other data obtained before and after these visits by phone, e-mail, postal mail, and personal visits. The study was conducted between December 2006 and June 2007.

We used data collection methods that allowed us to gather the maximal amount of information while causing minimal interference to patient care and productivity. As data were collected at each site, we also conducted ongoing discussion and analyses. This approach allowed each day's visit to build on the previously collected data.

This study received approval from the University of Cincinnati and Wright State University Institutional Review Boards.

Participant Selection

Financial constraints limited our participants to southwest Ohio. However, within that region, we purposefully selected offices that offered a variation of demographic and geographic factors that might influence how practice systems operate. For example, we specifically sought variation in:

- Geographic location (rural, suburban, urban).
- Physician diversity (sex, race, ethnicity).
- Practice size.
- Patient socioeconomic status (percentage of private, Medicaid, Medicare, or self-pay payer source).
- Technology level (electronic health record, no EHR).
- Residency program (program, no program).

Practices were identified by personal knowledge of the principal investigator (a family physician in Cincinnati); from recommendations of other physicians and nurses in the community; and via e-mails, letters, and phone calls to practice groups in the region that fit some of the above criteria. After participation, each practice received a detailed report outlining their specific testing process safety threats and strengths, including recommendations for improvements. Each practice also received a \$400.00 honorarium to be used for educational or support purposes within the practice.

Data Collection and Analysis

Multiple methods of data collection were employed in the larger study, including:

- Paper questionnaires that were filled in by office staff. These included a survey adapted from the American Academy of Family Physicians National Research Network^{11, 12} and surveys on office demographics and social networking.
- Direct observations, which occasionally were supplemented by talk-aloud protocols.
- Chart audits of test orders, results, and patient notification.
- Work analysis interviews of key informants.
- Patient surveys of their experiences with having a test performed and then receiving results.
- Collection of written documents and forms from the office. Most of these data were collected during the 2- to 4-day visit at each office by two members of the research team: a family physician researcher and a human factors psychology graduate student. Some forms, surveys, and interviews were also completed before and after the visit.

While all of the data collected served as background for the researchers, this research on creating safety in the testing process analyzed the observation notes and the key informant interview notes and transcripts. All notes and transcripts were “de-identified” prior to analysis. The observation notes, made daily by both researchers, were iteratively discussed and reviewed, and at the conclusion of the site visit, a summary set of notes was made, highlighting the findings at each step in the testing process.

The interviews, which focused on individual patients’ experiences with the testing process—including stories of problems, mistakes, and errors—were audiotaped, and extensive notes were taken for each interview. Selected portions of the tapes were also transcribed. All notes and transcripts were entered into the qualitative software program NVivo 2.0. Each document was searched for stories and examples of safety strengths. When applicable, each such finding was also coded to the step (or steps) in the testing process where it occurred, the components of the work system involved, and the properties of resilience it represented. Two members of the research team developed the coding strategy by reviewing and coding the interview documents together. The interview documents were then re-read, and all of the observation notes were coded using the final coding strategy. All researchers reviewed and discussed the findings after coding was completed.

Results

Testing Process Complexity

Prior to describing how these offices created safety, we will briefly describe the offices and the complexity of their testing processes. While the four medical offices we studied ranged in size, location, and patient characteristics (Table 1), they all performed a complicated series of tasks to move from a physician test order through patient notification and followup.

All of the offices performed some of their own low-complexity laboratory testing, but they sent the majority of their laboratory work to hospital or reference laboratories. Only one site had its own radiology suite and staff for plain films; all the others used nearby hospitals and free standing radiology centers for imaging and special tests.

Table 1. Characteristics of participating family medicine offices

Characteristic	Office 1 (Suburban)	Office 2 (Urban)	Office 3 (Rural)	Office 4 (Suburban)
Physicians/providers (N)				
Full time	7	2	4	1
Part time	6	2	0	3
Resident	0	0	12	0
Female physicians/providers (N)	7	3	8	2
African American physicians/ providers (N)	0	1	1	0
Staff (N)				
Full time	23	9	16	1*
Part time	2	0	4	0
Patient payer mix				
Insured (%)	50	24	35	47
Medicare (%)	45	41	30	47
Medicaid (%)	0	17	25	1
Self-pay (%)	5	18	10	1
Residency practice	No	No	Yes	No
Electronic health record	No	No	No	Yes
Outside laboratories used (N)	1	1	2	2
Outside radiology centers used (N)	>6	2	3	3

* Contracts with outside phlebotomy, receptionist, and health system billing office

We found variation both between practices and within practices. For all practices, the type of test ordered (laboratory, imaging, or special test) and the site where it was conducted (office, reference laboratory, or hospital) affected the specific tasks performed. For example, at one office, the procedure was as follows: a physician ordered an imaging test at a local hospital via a written prescription, received the results by fax days later, and then waited for the patient to return for a followup office visit for patient notification. At this same office, physicians' laboratory test orders were handwritten on the billing sheet; test samples were obtained by a medical assistant (MA) who entered the orders into an onsite laboratory computer terminal; results were returned via a dedicated printer the next day; and patients were notified of their results by mail.

Within offices, the procedure for ordering tests and managing results occasionally varied among individual providers and staff for identical tests performed at the same location. While each practice had preferred reference laboratories and radiology centers, a patient's insurance status occasionally necessitated using different testing sites (often requiring different tasks.)

No single individual at any of the offices, including the office manager or medical director, could describe all the tasks involved in any of the testing processes. However, these administrators were more aware of the general process flow than were the MAs, physicians, or clerical staff, who rarely knew what happened to an order, sample, or result before it came to them or after it left them.

None of the offices had written protocols for all of their testing processes; two offices had no written protocols at all; and the other two offices had protocols for some, but not all of the testing process steps and tasks. There were physicians and staff at every office who, when asked to tell us “what happens next with this...” described tasks and processes that were totally incorrect. For example, at one office, a physician, when asked what happened to test results that came back when he was absent from the office, noted that the MA reviewed them all and sent all abnormal results to a partner for review and action. However, the MA remarked that this was not one of her duties, and that she had never performed those actions.

Creating Safety

As mentioned earlier, safety is not a static property of any system. There is no such thing as an inherently safe process or device. Anything may become dangerous in the wrong situation. For instance, sending test results to a physician’s inbox to be reviewed seems like it ought to be a safe practice, and it usually is, unless the physician is out of town. Safety is an emergent property of a system that is created through the interactions of the people, tasks, technologies, environment, and organization within the context of what is appropriate for the given situation. In searching for the ways that offices safely manage the steps of the testing process, we found few examples of systematic officewide organizational practices for testing process safety. Instead, most efforts to assure quality in the testing process reflected localized responses of individual staff members and patients to double check, remember, work around, mitigate, and recover from potential and actual problems. We found only six examples of systematic officewide adaptations to improve resilience.

Localized Safety

The vast majority of testing process safety procedures were created by individuals who performed their separate tasks by working around dysfunctional systems, depending on their memory or memory aides (e.g., sticky notes, holding onto charts, copies of notes or orders), and performing multiple double-checks. Although these individuals employed the resilience factors of preparedness and awareness, they did so as individuals and not as part of an organization. For example, an MA at one office, aware that test results might not be filed and would need to be found, would check each scheduled patient’s chart for test results at the beginning of each day. Knowing that orders often get lost, a clerical staff member at another office said that she always copied each order that crossed her desk, preparing for those that would eventually get lost when sent to the hospital. But these are isolated actions performed by a few individuals, and they were not always done on a consistent basis.

Physicians and staff tended to work around system problems rather than try to solve them. When employees developed workable systems to order, track, or respond to results, they did not share

their systems with others. Others would cling to a clumsy or untenable practice because "...it works for me." In both large and small offices, we frequently heard, "I don't know how others do it, but this is what I do." For example, a physician stated, "If there's a patient I'm really concerned about, I will write their name down and put it in my inbox. That way, every time I look into my box, I see the patient's name." An MA said, "I feel that my memory is my greatest asset. I can remember nearly all the charts that are waiting in a doctor's office for results."

Organizational Safety

As noted above, we observed six instances that we felt fit within the "creating safety model" of officewide safety practices (Figure 2). One office had four safety practices; one had two; one had one; and one had none. The only demographic characteristic of the offices that separated them was the presence of a residency program at the office with four safety practices. These safety practices are described in Table 2, along with the major work system components and resilience properties involved.

All of these safety practices involved the support and involvement of the entire office organization. How people performed their tasks was influenced by these organizational decisions. In three of the safety practices, specific tools were also used (e.g., computer printouts, date and signature stamps, and standardized patient correspondence forms). Although one safety practice influenced the overall safety culture of the office, the other practices all dealt with steps in the testing process: tracking and return of results (one safety practice) and response to results, documentation, patient notification and followup (four safety practices). We did not find any examples of officewide safety practices involving the ordering or implementation of tests.

The main resilience property found in these safety practices was the use of a learning culture. In almost all the cases described, the successful safety practice grew out of experiences with error, failure, or adverse events. The office organization then responded to the events with the development and implementation of the described safety practices. It was (and continues to be) a top-level commitment to these safety practices that is largely responsible for the success of these safety practices. In the two offices with one or no examples of organizational resilience, a top-level commitment to safety was noticeably absent.

Two other resilience properties were each found in one safety practice. There was awareness in the safety practice of abnormal Pap smear review. Data gathered about the management of abnormal Pap smears gave the clinic administration insight into what was going on regarding the quality of Pap smear care. We also found flexibility in those practices that used patient communication tools both to document physician response to a test result and to notify patients. When standardized throughout the office, these tools solved the problem of notifying patients about results without increasing work for the physician. We found no examples of opacity, preparedness, or a just culture within any of these organizational safety practices.

Table 2. Creating safety in the testing process: Organizational safety practices identified in family medicine offices and their associated testing process steps, work system components, and resilience properties

Description of safety practice	Steps in testing process	Work system components	Resilience properties
Only one group of staff members (file clerks) is allowed to file results into charts and to file charts in medical records. This group is trained by management on what is required on results (e.g., signature) prior to filing.	• Response to results • Documentation	• Person • Tasks • Organization	• Top level commitment • Learning Culture
Staff and management write policies and procedures together for testing process protocols.	• Safety culture	• Person • Tasks • Organization	• Top level commitment • Learning culture
Pap smear quality review requires that copies of all abnormal Pap smears be reviewed by a nurse for followup according to a physician-developed protocol. This review is given to management monthly.	• Response to results • Followup	• Person • Tasks • Organization	• Top level commitment • Learning culture • Awareness
Development and use of a stamp on all test results, with spaces for dates, signatures, and notes by physician and nurses.	• Response to results • Documentation	• Person • Tasks • Organization • Technology and tools	• Top level commitment • Learning culture
A printout of all laboratory orders to the main reference laboratory is maintained: daily, an assigned MA marks the results returned; weekly, every MA reviews the printout for his/her doctors' patients' results; monthly, an assigned MA double-checks it for any results not yet returned.	• Tracking • Return of results	• Person • Tasks • Organization • Technology and tools	• Top level commitment • Learning culture
Standardized use of correspondence to the patient (e.g., letter, copy of handwritten note on actual result, check-box card) serves as documentation of the physician's response to the results and patient notification of results. (Found at two office sites)	• Response to results • Documentation • Patient notification	• Person • Tasks • Organization • Technology and tools	• Top level commitment • Learning culture • Flexibility

MA = medical assistant

Management = office manager, head nurse, and/or medical director

Staff = medical assistants, nurses, clerical staff

Discussion

Physicians order tests on their patients to screen for and diagnose disease, monitor treatment, and prevent complications. It is such a routine part of practice in primary care that physicians tend to give little thought to all the people, steps, and tasks that allow them to order a test today and receive a result tomorrow. But when an abnormal Pap smear is filed without physician review, or when a chest x-ray reveals a suspicious nodule but is never followed up, then physicians (and patients) ask, “What went wrong?”

In recent years, testing process research, especially in practice-based research networks, has focused on answering the “What went wrong?” question.^{11, 12, 13, 17, 18, 23, 24} However, it is equally important to answer the “What works well?” question.^{16, 31} “Creating safety” is one way to think about “What works well.” We found that creating safety was only rarely done via officewide safety practices. Instead, it depended on individual conscientiousness. Within our model of creating safety, we found that most officewide safety practices were characterized by a top-level commitment and a learning culture, and that these practices focused primarily on people and their tasks. Office practices without these organizational resilience properties depend almost exclusively on individuals working around dysfunctional systems to create safety.

Only a few officewide testing process safety practices were identified at these offices, but by examining these in the context of resilient systems, it is possible to better identify what family medicine offices need to do to create safety. The consistent resilience properties we found were a top-level commitment and a learning culture. Office improvement programs, such as the TransforMEDSM program of the American Academy of Family Physicians (AAFP)³² and the Clinical Microsystems initiatives,^{33, 34} note the importance of these factors in successfully implementing quality initiatives. While all of Wreathall’s organizational resilience properties³⁰ are important to the development of the highest quality office practices, using a learning culture to identify and remedy the immediate areas at risk, backed by a top-level commitment to address them with continuous and extensive follow-through, are natural starting places.

The organizational testing process safety practices also focused on the most elemental of work system components: the person and their tasks. While this is the logical and most appropriate starting place for safety practices, ultimately, incorporating technology, tools, and even environmental changes for safety will also be necessary.²

Since this was an exploratory study of only four primary care practice offices, we cannot determine whether demographic factors about the office were associated with the use of resilience factors. Although the residency office did have more safety practices, future research will be necessary to tell if that is true of training programs in general or just this specific office. In order to achieve an expansive view of testing process safety, we chose to study offices with a variety of demographic and geographic factors. Future research will also be necessary to study how incorporating safety practices will actually affect outcomes of patient care, including quality indicators, adverse events, harm, and patient satisfaction.

In offices without organizational resilience, safety is maintained almost exclusively by the diligence and conscientiousness of individual employees (and patients). While this diligence is important in even the most resilient organizations,^{28, 35} when it is applied mainly to working

around dysfunctional systems rather than searching for, finding, ameliorating, and reporting the few errors that slip through, then the status quo persists, and little progress is made toward safety and quality.³⁶

In the participating offices, we found many examples of individuals who had developed their own way of implementing orders, notifying patients, or keeping track of results and followup actions, either because no officewide system existed or because they found the existing system ineffective or cumbersome. There was little if any discussion of these methods among office physicians and staff. Unfortunately, when these individuals were absent or found themselves working with others or in different locations in the office, their “work-arounds” tended to fall apart, and problems ensued. While allowing daily work to proceed, the overall quality of the office suffers when safety depends on individual diligence.

It is interesting to note that at the four offices we studied, no one could fully describe the testing processes that existed in their offices, and there were many misconceptions about what took place in their work setting. This is in no small part due to how complex these processes are. The role of complexity in health care, and in ambulatory care, is becoming more important, especially as a factor in safety and quality.^{37, 38, 39}

The fact that workers do not know what tasks their coworkers perform is consistent with our finding that individuals at these medical offices often perform their tasks in relative isolation. Yet, teamwork is one of the strongest components of safe and successful health care units.^{40, 41}; Instruments that measure safety culture include major sections on teamwork.⁴²

Teamwork is a necessary component to move beyond the attitude that maintains, “I don’t know how others do it, but this is what I do.” Some such processes may be excellent, but when performed in isolation, without organizational system support, and surrounded by several other methods for performing the same tasks and steps, inconsistency, confusion, and error are likely outcomes. This is why standardization is a common and well-accepted tenet of effective safety practices.^{43, 44}

Moving beyond the stage of individuals working independently is important in creating a safer system because it allows individuals to better coordinate their efforts. Through better coordination, the system will change from an open-loop process to a process that includes feedback, allowing for a system that can change in response to the ever-changing circumstances that face those working in ambulatory care.

Conclusion

The testing process, a common and important function in primary care offices, can be studied using numerous methods from human factors, cognitive systems engineering, and resilience engineering. There are dozens of tasks to be performed by multiple people to complete the testing process, from an initial order through patient notification and followup. The family medicine offices we studied depended on individuals to be diligent with their memory and to do double-checks and work arounds in order to provide safe testing care. We did identify a handful of officewide testing process safety practices. These offices incorporated a learning culture to

identify and remedy areas at risk, backed by a top-level commitment to continuous and extensive follow-through. Further work is needed to study additional primary care offices to see if these findings are consistent and to find and implement best practices to assist offices in moving toward increased organizational resilience.

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Role of the External Coach in Advancing Research Translation in Hospital-Based Performance Improvement

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Abstract

The California Nursing Outcomes Coalition (CalNOC) Partners for Quality (PFQ) to Reduce Patient Falls Project aimed to reduce the incidence of patient falls and the severity of fall-related injury in 33 California acute care hospitals. The project used an innovative telephone-based coaching intervention to link project coaches with hospital “team leaders,” who confronted challenges of changing falls-related practice. CalNOC’s prior experience affirmed reports that education alone catalyzes interest and perhaps fosters awareness of new practices, but it does not ultimately change behavior. The coaching intervention—multifaceted and involving local leaders—included specific consensus-building, interactive sessions, and guided practice. Coaches initiated and sustained contact with hospitals for nearly 3 years. In this paper, we describe the operationalization and challenges of the coaching intervention, from pre-engagement through closure phases. We also discuss strategies for extracting themes from the coaching process, feedback from participating hospitals, and results from self-assessments of participating hospitals describing the impact of the intervention on fall-related policies and clinician practices.

Introduction

The primary aim of the California Nursing Outcomes Coalition Partners for Quality to Reduce Patient Falls Project (CalNOC PFQ) was to reduce the incidence of patient falls and the severity of fall-related injuries through expediting evidence-based performance improvement. The study involved a convenience sample of 77 medical-surgical units drawn from 33 CalNOC member acute care hospitals. CalNOC’s experience prior to this project supported the findings of a systematic review suggesting that education alone catalyzes interest and perhaps fosters awareness of and knowledge about new practices, but it does not typically change practice with sufficient strength to affect outcomes.¹

Scholars in various disciplines have documented the complexity of effecting organizational change.^{2, 3, 4, 5, 6} The change process is further complicated when individuals within the organization—the very people charged with making the change happen—are professionals whose practice is informed by research knowledge and practice-based or clinical knowledge.

Innovative ideas, groundbreaking practices, and new policies are implemented at the local level by clinicians, who must evaluate, adapt, and implement recommendations. As we looked at this process of translating research into practice through the lens of reducing patient falls, we found great variation in the degree to which practicing nurses adopted and implemented evidence-based practices that had been found to prevent or reduce patient falls.

The CalNOC PFQ coaching intervention was grounded in the premise that effective interventions—those that promote actual change in clinical behavior and codified practices (i.e., policies, procedures and protocols)—are multifaceted, involve local leadership, require consensus building, and benefit from interactive sessions with new knowledge, resources, and guided practice.^{7, 8, 9, 10} The principal elements of the coaching intervention used by the CalNOC PFQ team have been successfully used in catalyzing organizational and practitioner change in the field of education.¹¹

The CalNOC PFQ Project was informed by health services research and shaped by hospital-specific data related to falls and a detailed self-assessment. The project used an innovative telephone-based coaching intervention, sustained for nearly 3 years, to link project coaches with hospital “team leaders” who were confronting the challenge of changing falls-related practice or policy at the organizational level and implementing/setting specific new clinician practices. An important component of the intervention was having a coach facilitator serving as a coach to the project coaching team, a role found to be lacking in some educational coaching interventions.¹²

In this paper, we describe the operationalization of the coaching intervention, challenges to the delivery of this intervention, strategies for extracting themes and patterns from the coaching process, and an approach to documenting and tracing the content of coaching contacts. Formative and summative feedback from participating hospitals is discussed, along with the impact of the intervention on fall policies, practices, and outcomes.

Background on Coaching

The CalNOC PFQ Project began its coaching intervention by approaching each hospital in a systematic, somewhat standardized, yet highly individualized way. From the outset we acknowledged and recognized the following:

“Whatever strategies or practices may be used, they must be implemented, and implementation requires adaptation of a strategy or practice within the local context of a school [hospital]. Contexts vary greatly from one [setting] to another; they also change within the same [setting] over time. Furthermore, implementation follows a nonlinear path—a path that does not lend itself to be sufficiently captured in any one “model” for improvement. Therein lays the challenge. Implementation is a nonlinear process that is highly context-specific; therefore, it requires the authentic participation of those who know the context best.”¹¹

In preparation for launching the coaching intervention, the investigative team confronted key questions at the heart of the coaching role effectiveness, which included:

- How is authentic participation best supported and guided?
- How can implementation of new practices be supported?
- What are the key obstacles to successful adaptation and implementation?
- How can these obstacles be avoided or effectively addressed?
- Finally, and perhaps most importantly to the project's aims, in the midst of such a nonlinear process of improvement, how can an organization make steady and even accelerated progress and improve outcomes?

In the field of education, scholars and school-change experts have found that practitioners tend to engage in deep, sustained, technical, and normative change when they are in a relationship with a knowledgeable guide or coach. We began our coaching intervention in anticipation that the experience gleaned from education would be relevant to our efforts in health care. Furthermore, we posited that the explicit role of the coach working in collaboration with a designated hospital staff person, literally linking clinicians in that setting with the project team, was consistent with and operationalizing Havelock's Linkage Model, our conceptual perspective.¹³

What Is the Role of a Coach in the Context of Change?

In the field of education, coaching is effective, not only for facilitating changes in practice, but also for building individual and organizational capacity for continuous improvement. The commitment and capacity (i.e., knowledge, skills, habits) required to change practice are effectively supported by a coach. Likewise, the commitment and capacity (i.e., processes, systems, norms) required for an organization (e.g., team, unit, floor, hospital) to change are greatly enhanced through coaching support. What, then, is the role of the coach in the context of change?

In both education and nursing, coaches can help organizations navigate effectively through the complex process of change by addressing key elements of the change process, including, but not limited to:

- Obtaining buy-in for change efforts, including data collection and analysis that help identify goals and priorities.
- Ensuring systematic and detailed planning.
- Accessing support and ongoing professional development.
- Adapting new practices in the local context.
- Evaluating goals and the implementation process to inform next steps, paying particular attention to indicators of positive fall prevention efforts.
- Cycling back continuously to each element, maintaining thoughtful focus on each discrete element and the interconnectedness among the various elements.¹¹

This is not a sequential list of steps that the coach facilitates; rather, they are touchpoints that coaches can address as they build the capacity of the organization to engage in continuous learning and improvement. With the expertise and objectivity of an “outside” consultant—but with an understanding of the site's culture, history, and vision characteristic of an “inside” leader and advocate—coaches are well-positioned as “insider/outside” to help the organization

address tensions that, in many change processes, can erode or derail the change process. For example, coaches help sites (1) maintain focus and be adaptable and responsive, (2) achieve clarity and tolerate confusion, (3) understand reality and imagine other possibilities, and (4) think systemically and act specifically.¹¹

While coaches may at times provide instruction or training (e.g., in data analysis, goal setting, evaluation/measurement), they do not direct or instruct their sites as consultants might. Instead, coaches bring more of a mentoring, or guiding, presence by:^{11, 14, 15}

- Asking questions, e.g., “How might you...?” “What evidence do you have that...?”
- Brokering resources and relationships, e.g., “I know of a site that worked with that evaluation software last year. Let me put you in touch with them directly to see if they could guide you in implementing it at your site.”
- Developing the commitment and capacity of a core leadership team within the site, e.g., linkers and linker teams.
- Observing, listening, inquiring, and reflecting upon local processes in the context of larger efforts aimed specifically at improving the overall quality of patient care and reducing patient falls.
- Optimally, posing thought-provoking comments and questions that bring out the positive qualities in site personnel and organizations and ultimately deepening or accelerating the change process.

Project Conceptual Approach and Design

Conceptual Perspectives Guiding Project Methods

As noted above, the CalNOC PFQ Project coaching intervention was grounded in Havelock’s principles of reciprocal communication¹³ and guided by Rogers’ concepts of organizational, work unit, and individual innovation adoption and diffusion processes.¹⁶

Havelock’s Linkage Model posits reciprocal and interdependent relationships between the knowledge generation subsystem and the knowledge user subsystem, with human “linkers” playing a key role in transmitting new knowledge and in enabling feedback.¹³ The model assumes that knowledge diffusion and utilization are fundamentally acts of communication between resource systems producing new knowledge and systems that apply and use knowledge to attain societal goals (e.g., health care). Human “linkers” literally connect the resource and user systems, facilitating communication and feedback, thus making collaboration to accomplish the transfer and use of research possible. Our project highlighted communication by envisioning the project team as a “source of knowledge,” with individual coaches as representatives, by identifying “linkers” for each hospital site and by providing hospital “users” with assistance in accessing/synthesizing research-based evidence to support specific fall-reduction efforts.

Although Havelock’s linkage concept is invaluable in explaining reciprocal relationships between knowledge producers and knowledge users in health care practice, Rogers’ theorizing

relates to how practice change (i.e., innovation) diffuses or spreads. Rogers¹⁶ posits stages in the processes that make up individual and organizational adoption of innovations.

At the organizational level, the organizational innovation process comprises five stages:¹⁶ (1) agenda setting, (2) matching, (3) redefining/restructuring, (4) clarifying, and (5) routing. Affirming the organization's commitment to change emerges from agenda setting efforts and launches the next steps to refine the match between the organization's need and the target innovation. At the heart of innovation adoption is a concurrent process of sequential decisionmaking that culminates in a commitment to implementation of the change.

This five-stage process is the "Innovation-Decision Process"¹⁶ and includes the following phases: (1) knowledge acquisition, (2) persuasion, (3) decision, (4) implementation, and (5) confirmation. The challenge of interventions geared toward translating research into practice arises from the tough reality of moving through the phases of innovation decisionmaking within and between organizational, work unit, and individual levels.

Guided by Rogers' conceptualizations of these processes that culminate in successful diffusion of innovations, we aligned our coaches' approach with phases of the innovation decision processes. The content and tactics of coaching intervention were intentionally contingent on the needs of the organization and the medical-surgical patient care units working through the processes of fall-related innovation implementation unique to each setting.

Design and Implementation of the Coaching Intervention

In our project, the coaching intervention was designed principally as a telephone-based contact between one coach and the linker(s) assigned to the project, about 30 to 60 minutes in length at 3 to 6 week intervals, with the option for one or more site visits or multi-site conference calls. Coaches' actions included:

- **Monitoring:** Activity focused on tracking the status of target milestones; includes listening, assessing progress, eliciting feedback, and guiding discussion to clarify.
- **Providing information:** Knowledge is exchanged.
- **Providing support:** Mutual sharing; includes active listening, being a sounding board, and validating and highlighting common experiences across sites; also, anticipatory guidance.
- **Identifying action/prescription:** Identification of activities to be done; includes planning assistance; clarifying next steps; identifying stakeholders; interpreting/reframing organizational responses, challenges, and barriers; and articulating mutually agreed upon tasks.
- **Providing referral:** The process of connecting linkers/hospitals, who have needs with someone or something with the knowledge; includes connecting people to people and people to information (e.g., publications, Web sites).
- **Identifying resources:** Assistance in the form of individuals, information, and energy; identification of resources needed for "next steps" in advancing the improvement plan.

Recruiting Coaches – Characteristics of the Coaching Team

Prior to initiating coaching contact with linkers in hospital sites, the project team developed a role description for a project coach that clarified availability (hours/month; number of site visits/month), explicated principles of honesty and boundary setting, highlighted the importance of being able to deal with ambiguity, and outlined some of the content and skill areas that were desirable. The coaching team included six registered nurses with specialized knowledge and skills related to research utilization, evidence-based practice, nursing services administration, and fall prevention strategies. Three coaches were doctorally prepared, and three were masters prepared, including a gerontology clinical nurse specialist. Coaches brought a wealth of insight, expertise, and a strong commitment to their role, which was considered key to the authenticity of their relationship with hospital linkers. Eligible hospitals (N = 33) were distributed among coaches to address site mix (small, large, community, academic) and to cluster sites geographically. The coaching team remained stable throughout the project, with the exception of one coach, a doctoral student, who ended his role with the project after completing his doctorate. His three hospitals were reassigned to other members of the coaching team.

Coaching Role Clarification

At the beginning of the intervention phase of the project, coaches met several times with the seasoned coach facilitator—an educator—to discuss the coaching role. In order to differentiate the coaching role from more familiar consulting and mentoring roles, the following key points were stressed:

- The length of a coach's relationship is usually longer than that of a consultant.
- The scope of a coach's work is customized to a specific hospital culture and focuses on specific targeted areas of priority work. The coach always moves between the specific and the systemic, keeping the big picture in mind. In contrast, consultants tend to focus on the big picture or targeted areas of work, without the back-and-forth thinking.
- Coaches leverage site expertise to actualize improvement, whereas consulting often presumes that the consultant has the expertise to achieve the desired improvements.
- Coaches are interested in building site capacity to: (1) accelerate change/improvement (e.g., sites should reduce falls more significantly and more quickly than if the coach had not been involved) and (2) sustain improvements that continue after the coach is gone (i.e., coaches should try to work themselves out of a job). Building capacity may include the "brokering" of services, such as connecting sites with resources (e.g., people, literature, data). Compared with coaches, consultants may focus more on (1) than on (2).
- Coaches understand that context mediates the change/improvement process. In light of this, coaches do not come with a predetermined approach to the work. Rather, they bring project goals and objectives along with a repertoire of process skills, content knowledge, and relationships from which to draw to support, challenge, and guide the site's efforts to reduce falls. In comparison, consultants might bring a more specific "model" that might not take into account the unique context of the hospital.
- Mentors usually reside within the same organization as the person being mentored. On the other hand, coaches more often than not are external to the organization. However, there can

be internal coaches. The approach each coach takes differs in relation to the person being coached. Individuals engaged in coaching or mentoring relationships understand the unique support and assistance that each provides.

The coach facilitator was engaged as a “coach” to the coaching team throughout the project, regularly participating in team conference calls.

The Linker Role

Linkers for each hospital were designated by the hospital’s chief nurse officer (CNO). The nurse executives were asked to select nurses with specific characteristics when designating linkers. Preferred qualifications included an advanced practice role with at least a baccalaureate degree and multiple years of clinical experience. Additional linker characteristics suggested to CNOs included:

- Interest in fall prevention and reducing fall-related injuries.
- “Systems savvy,” i.e., experience and knowledge with making things happen within a nursing service organization.
- Credibility with staff and leadership.
- Support on immediate unit or work area.
- Ability to champion a cause and motivate others in championing a cause.
- Experience with making changes that lead to improvements, with evidence-based practice, or with implementing research-based changes.
- Familiarity with stakeholders for a fall prevention program.
- Ability to develop relationships among multidisciplinary stakeholders.
- Ability to develop, modify, and implement a plan among different stakeholders.

While our project team was able to guide hospitals in selecting certain types of linkers, we ultimately did not determine their selection. All but one linker were nurses. While most hospitals selected a single linker, about one-third of the hospitals chose to use a linker team with two or more staff.

Phases of the Coaching Intervention

Phase 1: Pre-Engagement – 60 Days

The target objectives were refined by the coaching team. Prerequisite “enabling aims” were made for each target outcome objective, providing direction for coach actions. To provide a common language to describe coaching actions, a worksheet served as a documentation/communication tool that captured the “content” of each coaching interaction. The content was framed in the target objectives, highlighting coach actions.

Phase 2: Site Entry and Planning – 120 Days

During the orientation period, coaches focused on building rapport with linkers and establishing a plan for ongoing telephone-based collaboration. In each contact, coaches informally assessed site capacity for evidence-based practice and fall prevention/assessment experience and practice. Coaches also established preliminary agreement with linkers related to their ongoing relationships, clarifying the relevance and appropriateness of target outcomes and the way this project fit into the site's strategic priorities. Based on self-assessment and review of detailed CalNOC falls data from each hospital, site-specific plans for improvement were developed by linkers and their teams with the support of the coach.

Phase 3: Doing the Work of Performance Improvement and Change – 24 Months

For most of the project, coaches worked with hospital sites to achieve site-specific performance improvement objectives. Guided by the focused plan for falls-related change, preliminary communication planning was refined and expanded to focus on the following:

- How the linker communicated with unit staff.
- How the linker, coach, and staff communicated with site leadership.
- How coaches and CalNOC leadership communicated with CNOs for participating hospitals.

All communications aimed at optimizing the work of the CalNOC Partners for Quality Project. The number of telephone calls and visits varied according to different coach assignments (e.g., one coach carried half of the sites), site needs, and linker availability. No interactions involved actual observation of practice.

As sites developed and implemented their plans for change and performance improvement, coaches worked with linkers to clarify outcome measures with the site and to identify resources necessary to attain goals and address emerging barriers to progress.

An ongoing focus for coaches and linkers was to develop site-team capacity to fully use site-specific CalNOC data as a source of evidence for identifying priorities for change and for evaluating progress. Throughout this phase, coaches sought to understand site priorities (goals/strategic plans) and pressures (external/internal) to help align this project within the context of overall organizational priorities. Ultimately, this maximized the strategic value of the work.

At the same time, coaches were doing some of their own role-development work with CalNOC. This included the following activities:

- Advocating for site resource needs (e.g., various query reports using CalNOC data).
- Experiencing professional development: “Coaching the coach.”
- Receiving feedback from CalNOC's evaluation of and reflections on coaching.
- Developing and using consistent documentation methods for site experience.

Phase 4: Phasing Out – 6 to 9 Months

During the final phase of the coaching intervention, coaches initiated anticipatory plans for ending the coaching contacts and assessing the impact of the project. During this phase, coaches and linkers considered the site's capacity to maintain data collection and analysis (i.e., making sense of the data and using it to inform practice). This involved activities such as tying reduced falls to job evaluations (accountability tied to outcomes) or linking data collection and analysis to dissemination and use with nurses on site, which in turn was tied to a reduction in patient falls. Coaches worked with sites to complete self-assessment surveys and to plan subsequent steps in sustaining the work and the changes achieved. Linkers and their CNOs were formally thanked for their commitment and contributions to the project. Preliminary outcomes were shared in formal and informal conferences/meetings.

The Reciprocal Roles of the Coach and Linker: Conceptual Foci and Deliverables

Table 1 presents an overview of the phases of the coaching interventions that link the activities of the coach with the conceptual approach, highlighting the reciprocal activities of linkers and hospitals sites and related mutual deliverables. As previously noted, the systematic approach to coaching reveals a high degree of site-specific customization and individualized strategic self-direction.

Outcomes of the Coaching Intervention

Upon completion of the coaching intervention, the overall project goal was that each hospital would reduce the incidence of patient falls and fall-related injuries on target medical and surgical units by improving its capacity to:

- Use data for performance improvement.
- Use reliable and valid risk screening and assessment.
- Implement individualized interventions to prevent falls/reduce injury.
- Effectively document and communicate, engaging staff, patient, and family members in preventing falls and fall-related injuries.
- Engage the hospital organization in a systematic improvement effort related to falls.

Tracing the Content and Activities of Coaches in Action

Throughout the coaching intervention, the content of site contacts—principally telephone contacts—was captured using Coaching Intervention Documentation Worksheets. Selected site visits did not differ substantively from telephone contacts and typically were used to “kick off” work or inspire teams by engaging them in face-to-face contact with the coach. Notes from the Documentation Worksheets enabled coaches to record content foci and key actions (described elsewhere in this paper) emerging from contacts with sites. In addition, “field notes” of conversations related to fall prevention efforts, issues, challenges, and concerns were recorded. These recordings helped coaches anticipate the foci and plan for next contacts.

Table 1. Key elements of the CalNOC coaching intervention to reduce patient falls

Phase 1:			
Conceptual foci	Coaching intervention	Reciprocal site activities	Deliverables
Catalyzed awareness of potential for improvement and establish preliminary organizational commitment	Engage sites in strategic vision of improvement potential related to falls/fall prevention	Affirm preliminary interest	Site confirmation(s) of commitment
Identify designated site “linker(s)”	Develop linker network	Designate key clinical opinion leader as “linker”	Linker roster and active network – conference calls
Focus organizational self-assessment; determine capacity for change	Collaborate with linkers and CNOs to conduct organizational self-assessment	Conduct organizational self-assessment	Analysis and validation of organizational self-assessment findings
Linker role development	Engage linkers in systematic education and coaching, self-directed study, supportive coaching	Linkers actively participate in ongoing role development	Linker role development with observable evidence of role implementation
Organization-specific self-query re: falls data integrity, practice consistency, and implications for improvement vis-à-vis literature and litigation	Identify elements of database self-query and coach linkers in data capture, descriptive analysis, and implications	Conduct, analyze and synthesize self-query as basis for mounting systematic improvement effort	Self-query initiated
Organizational capacity development	Provide expert assistance and referrals to build organizational capacity for data-driven improvement project to reduce falls	Site-specific activities are reported that reflect capacity development efforts based on self-assessment findings	Capacity development tactics are reported and shared across sites
Linkers engage a site specific team in falls-improvement effort	Coach linkers within context of their setting quality improvement model, stakeholders, and infrastructure; coach evolving project management	Site-specific teams mobilized with organizational buy-in; confirm project management roles and resources	Site-specific teams identified and activated

Table 1. Key elements of the CalNOC coaching intervention to reduce patient falls (continued)

Phases 2 – 4			
Conceptual foci	Coaching intervention	Reciprocal site activities	Deliverables
Knowledge synthesis	Provide linkers with general literature/references re: falls risk assessment and interventions; key indicators for falls quality monitoring and benchmarks.	Site teams review, translate, and adapt literature; critique current practices and integrate potential innovations into a “pilot” evaluation; build consensus	Knowledge synthesis products for Web-based delivery; knowledge access tactics observed.
Strategic planning for practice change	Coach linkers in developing systematic strategic plans for implementing and evaluating selected practice changes	Linkers and teams develop systematic strategic plans	Strategic plans documented and strategies shared among sites
Knowledge transfer	Coach linkers in process of research use, translation, and local adaptation	Linkers and teams engage in research; use processes and local adaptation; preliminary adoption of selected practice changes.	Research use tactics documented and shared among sites
Practice change implementation and evaluation	Coach linkers in implementing and evaluating preliminary practice changes	Linkers and teams implement and evaluate preliminary practice changes; refine plans as needed	Changes are documented and preliminary evaluation data analyzed and reported
Analyze results of preliminary change; refine plan or decide abandon strategy	Monitor/review results of work-in-progress; celebrate successes; and coach in revising plans, interpreting results and options for next steps; provide technical assistance as needed	Sustain implementation and evaluation; maintain gains; refine strategies; celebrate; provide qualitative data to aid in formative evaluation of project processes, tactics, and effectiveness.	Measurable results
Sustain validated improvements	Monitor organizational change over time; analyze falls risk assessment, incidence, and injury trends per unit per site using CalNOC data; feedback with reports, project conferences	Ongoing CalNOC data collection; sustained change; check inter-clinician reliability in adopting practice change(s)	Evidence of improved falls prevention; conferences reach target audiences, provide preliminary reports to sites and stakeholders

Descriptive analysis of the Coaching Documentation Worksheets for year 1 reveals that all topics were discussed across multiple contacts. Listed below are the topics and percent of times each was documented:

- Use of falls data 79-85 percent
- Risk assessment validity/reliability 63-81 percent
- Fall prevention interventions 5-71 percent
- Engagement of staff, patient/family in change 44-69 percent
- Engagement of organization in performance improvement 8-63 percent

Challenges Faced by Coaches

Coaches faced a number of challenges to the effectiveness and impact of the intervention. First, challenges arising from the linker role included turnover, inability to focus on falls due to competing demands, perceived lack of support from organizations, lack of time, and difficulty sustaining contact with coaches. These challenges across sites and coaches resulted in difficulty establishing and sustaining “traction” in advancing project outcomes.

Another challenge was related to the capacity of the hospital and project linkers to access and use their CalNOC fall-related data. In particular, linkers had trouble extracting from these data setting-specific implications for strategic performance improvement. Although assigned to spearhead the work in their setting, many linkers were initially unable to read and interpret these data because they lacked experience with spreadsheets and dashboards.

Organizational capacity for transformational change varied widely but was also a theme across sites as CNOs faced shifting priorities. Turnover of executive leadership influenced the pace and intensity of change as priorities became realigned with expectations of new leaders.

An interesting challenge arose when the coaching team explored linkers’ knowledge related to new literature on the impact of medication-focused interventions on falls reduction. The vast majority of linkers were unaware of this literature. To address this problem, the CalNOC coaching team developed a fact sheet that synthesized relevant findings and provided linkers with a tool (including references) to launch discussions within sites.

Impact of the Coaching Intervention on Policies, Procedures, Practices, and Outcomes

The coaching intervention lasted for just under 3 years. A short formative survey was sent to CNOs midway through the project to be completed by CNOs with linker input. Responses to three open-ended questions were received from 28 organizations (85 percent response rate). The findings suggested work in progress that may have ultimately led to many of the actual practice changes that were documented a year later on the final self-assessment evaluation.

Heightened awareness of falls as a universal problem in hospitals was reported as a common consequence of the coaching intervention. Participants reported a high degree of satisfaction with the coaching process, attributing the highest value to the interpersonal contacts.

Hospital pre- and post-intervention self-assessments suggested minor and major changes in policies and practices across sites. The percentage of hospitals that evaluated fall prevention equipment increased from 55 percent to 89 percent. An increase (from 29 percent to 79 percent) was also reported in the percentage of hospitals that used systematic post-fall analysis as part of the fall incident followup. There were also increases in the number of hospitals that reported fall rates monthly or more often

(from 3 percent to 39 percent) or quarterly (from 18 percent to 57 percent). While almost all hospitals had a fall prevention protocol in place at the beginning of the project (94 percent), elements of fall prevention policies or protocols changed over the time of the intervention (Table 2) to reveal more evidence-based strategies.

Similarly, hospital responses to a fall incident became more systematic, incorporating more elements that would truly assist in fall prevention efforts (Table 3). At the final assessment, linkers were asked to evaluate several elements of the project (Table 4).

In general, evaluations were positive about the coaching intervention and its impact on fall-related performance improvement efforts (Table 5). The lowest ratings were for elements without a personal component (e.g., CalNOC data). Analysis of pre- to post-intervention fall incidence and injuries did not reveal significant differences, despite reported process and practice changes.

Table 2. Impact of the coaching intervention on fall prevention protocols

Fall prevention protocol characteristics	Pre-coaching (%) (N = 33)	Post-coaching (%) (N = 29)
Interdisciplinary in nature	72	93
Literature-based	67	82
Based upon expert opinion	45	32
Offering an algorithm, or practice options based upon FRA	58	86
Consistently implemented	19	64
A guide to reevaluation of fall risk	55	57
Inclusive of sitters/safety attendants	70	75
Inclusive of a clear definition of falls	79	89
Included evaluation of medications administered and interventions related to polypharmacy ^a		71
Included use of universal fall precautions ^a		71

a Only asked of post-coaching intervention

FRA = fall risk assessment

Discussion and Conclusions

Findings from the CalNOC PFQ project self-assessment surveys suggested that the intervention package, which focused heavily on the coaching intervention described here, favorably affected organizational policies, protocols, and reported clinical practices. Although a detailed presentation and discussion of the quantitative results, measuring pre- to post-intervention fall incidence and injuries, are beyond the scope of this paper, it is noteworthy that these results did not reveal significant differences that could be attributed to the CalNOC PFQ Project. We posit that this study was ultimately underpowered and confounded by a number of factors that affected its pre-post comparisons.

Table 3. Impact of the coaching intervention on hospital response to a fall incident

Data collected for a fall	Pre-coaching (%) (N = 33)	Post-coaching (%) (N = 29)
Shift during which fall occurred	49	86
Time of day	49	86
Location of fall	70	96
Patient-level variables	52	96
Medications patient was on at time of fall	27	75
Equipment in use	46	82
Patient activity at time of fall	48	22
Prevention efforts in place	61	93
Restraints in use	64	93
Staffing levels at time of fall	27	54
Type of patient/diagnosis	21	75
Fall risk	61	82
Interval of fall risk reassessment	30	54
Type of fall (anticipated/physiologic/nonphysiologic)	58	89

Likewise, had we found significant differences, given the myriad forces influencing hospitals' efforts to reduce falls that emerged during this project, it would have been difficult to claim a benefit attributable to coaching alone. However, it might be suggested that the findings described here reveal that the coaching intervention, despite not making a significant difference in aggregate fall rates, did catalyze changes in hospital fall-related evidence-based process/practice improvements. Self-assessment reports from participating hospitals revealed effects from the coaching intervention that were congruent with its aims, foci, documented content, and observed results.

Changes may be explained by the "pressure" of the intervention (continuous reminders; ongoing scheduled contacts about fall prevention efforts over nearly 3 years) and the support and dissemination of evidence-based knowledge resources from coaches to linkers within trusted relationships. As such, it could be cautiously concluded that the CalNOC PFQ coaching

intervention advanced organizational change by addressing the complex interdependence of values, priorities, assumptions, and practices and by building capacity around data-based reflection and the transfer of evidence-based knowledge into practice.

Clearly, this preliminary observation merits further study.

Table 4. Linker-rated usefulness of CalNOC PFQ interventions at final self-evaluation

Usefulness of intervention resources ^a	Mean (±SD)
Coaching contacts	4.40 (0.13)
Coach site visits (not all coaches made site visits)	3.55 (0.24)
eReserve (CalNOC Web site)	2.92 (0.23)
CalNOC data	2.54 (0.23)
CalNOC bulletin board	2.56 (0.24)
Project all-site conference calls (not all sites took part)	3.86 (0.19)
CalNOC conference 2005 (focus on falls) (not all sites able to attend)	3.57 (0.43)
^a Scale, 1-5	

Table 5. Impact of the PFQ project on fall prevention efforts

PFQ project on fall prevention effort	Pre-coaching (%) ^a (N = 33)	Post-coaching (%) ^a (N = 29)
Fall risk assessment (FRA) on admission (%)	94	100
Intervals of fall risk assessment defined as:		
Q shift on all patients	40	64
Q shift on at-risk patients	36	4
Other	24	32
Fall risk assessment tool		
Internally developed with reliability and validity	6	7
Internally developed with no reliability and validity	24	11
Externally developed with reliability and validity	55	79
Externally developed with no reliability and validity	0	4

Table 5. Impact of the PFQ project on fall prevention efforts (continued)

PFQ project on fall prevention effort	Pre-coaching (%)^a (N = 33)	Post-coaching (%)^a (N = 29)
Policy for fall risk assessment		
For communication between units	45	71
For communication between departments	45	75
FRA policy matches actual practice		
Between units	31	62
Between departments	24	65
Policy for reporting falls		
Actual falls	33	50
Actual falls and near misses	39	50
Frequency of reporting of whether physical environment contributes to falls		
Monthly or less	0	39
Semi-annually	24	11
Sporadically	33	8
Actions taken based upon physical environment contribution to falls last 12 months	47	57
Plans for actions based upon physical environment contribution to falls next 12 months	57	36
Use of fall prevention equipment	91	93
Evaluation of fall prevention equipment in last 12 months	55	89
Actions taken based upon evaluation of equipment last 12 months	48	79
Plans for actions based upon evaluation of equipment next 12 months	37	54
Post-fall analysis as part of analysis of fall prevention efforts	29	79
New hires (RNs) oriented to fall prevention efforts	91	96
Annual competency evaluation of fall prevention knowledge/skills (RNs)	36	73
Timing of data reporting of fall rates		
Monthly or less	3	39
Quarterly	18	57
Semi-annually	61	4

Table 5. Impact of the PFQ project on fall prevention efforts (continued)

PFQ project on fall prevention effort	Pre-coaching (%)^a (N = 33)	Post-coaching (%)^a (N = 29)
Use of an administrative database that includes falls data	79	93
Fall reporting data gathering using		
Incident reports	91	96
Staff interviews	55	75
Patient interviews	33	57
Chart review	46	71
Fall reporting data sharing		
Reports to units	24	93
Dashboards	0	82
Fall data is now reported to:		
Director of nursing		91
Hospital quality committee		88
Medical staff committee		55
Board of directors		52
Staff meetings		49
Fall rates now compared to:		
CalNOC data	94	96
Other hospitals within corporate entity	49	50
Literature rates	27	29
Own hospital over time	85	93
Other data	12	32

a Percentages may not add to 100% due to missing data

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Strategies for Improving Patient Safety in Small Rural Hospitals

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Abstract

The Tennessee Rural Hospital Patient Safety Demonstration Project sought to improve patient safety in small rural facilities by strengthening their capacity to implement priority patient safety interventions. The project focused on interventions relevant to the core services and capacities of rural hospitals and was sensitive to their structure and processes. A process for assessing the status of hospital patient safety programs and providing technical assistance tools, and resources was developed. Organizational and clinical changes designed to prevent errors and improve safety were initiated. Eight participating hospitals completed a self-assessment tool to identify and prioritize rural hospital patient safety interventions. These hospitals implemented three interventions: assessment of patient safety culture and implementation of a safety culture plan, development and implementation of emergency department protocols, and use of personal digital assistant devices (PDAs) by clinicians at the point of care to decrease medication errors.

Introduction

Health care quality and safety improvement are critical to the viability of rural hospitals. National hospital patient safety initiatives promoted by purchasers and others do not always consider the unique characteristics of small rural hospitals. Current patient safety standards are based largely on research conducted in large urban settings. These institutions have resources with which to address patient safety challenges and a volume of incidents to examine and act upon. The results of these initiatives undertaken in larger hospitals may not be generalized to small rural hospitals due to differences in organization, staffing, financing, and other characteristics.^{1, 2} As a result, rural hospitals historically have been exempt from patient safety expectations in areas such as computerized physician order entry (CPOE), evidenced-based hospital referrals, intensive care physician staffing standards, and other National Quality Forum-endorsed safe practices. However, exemption from current patient safety standards may inappropriately encourage the perception that rural health professionals deliver less safe care.

In 2005, the Tennessee Hospital Association (THA) received funding from the BlueCross BlueShield of Tennessee Health Foundation to demonstrate the feasibility and impact of implementing priority safety interventions in a group of eight rural hospitals. The goal was to improve patient safety in these small rural facilities by strengthening their capacity to implement patient safety interventions. This article describes the design and implementation of the demonstration and its impact on these facilities.

Background: The Tennessee Rural Hospital Patient Safety Demonstration

The Tennessee Rural Hospital Patient Safety Demonstration (the Demonstration) grew out of a desire by the THA and BlueCross BlueShield of Tennessee (BCBS), the State's largest insurer, to expand the capacity of small rural hospitals to undertake significant and visible safety and quality initiatives. Beyond providing critical financial and logistical support for the development and implementation of these initiatives, the Demonstration was seen as a vehicle to ensure strong continuing support for these facilities among the health plan's subscribers.

The Demonstration was conceived and undertaken in the context of a growing recognition of how the differences between urban and small rural hospitals affect what should be done to improve safety in these smaller facilities.^{1, 3} Small rural hospitals differ from larger hospitals in several ways that are relevant to the patient safety discussion.

First, the smaller size and lower census in rural hospitals means that they do not experience a sufficient volume of events (e.g., unexpected deaths) necessary for using many quality improvement indicators and measures. Insufficient volume complicates reliable measurement of safety in many areas of the hospital.

Second, most rural hospitals provide only a subset of the services available at larger, urban facilities. For instance, rural hospitals rarely provide intensive surgical services, such as cardiovascular, neurologic, or pediatric surgeries that lend themselves to patient safety system interventions.

Third, smaller hospitals often do not have the information technology infrastructure and/or resources necessary to implement suggested patient safety practices, such as bar-coded systems for medications and patient identification and intensive medical record review.

Finally, the cultural communication norms at rural hospitals are different from larger hospitals. The communication structure in smaller organizations, where each individual serves in many roles, affects the openness of expected discussions. More open communication should improve the ability of an institution to address patient safety in a non-blame environment.¹

In 2004, recognizing the need for "rural-relevant" patient safety interventions and measures, a consortium of university-based rural health research centers identified a set of evidence-based patient safety interventions that the majority of small rural hospitals could readily implement and that rural hospitals, purchasers, consumers, and others would find relevant and useful.³ The study was designed to help rural hospitals prioritize their patient safety efforts to address safety problems related to medication errors, infections, and other core patient safety areas. The study identified a set of 26 priority interventions based on a comprehensive review of the literature, analysis of secondary data, and deliberations of a national expert panel, as well as a survey of rural hospital administrators and clinical quality improvement staff in 29 hospitals.⁴

In 2005, the THA identified the priority interventions in this study as a potential vehicle for mounting a rural hospital patient safety initiative. Specifically, the Association's Assistant Vice President for Rural Health Services and Workforce Initiatives saw the opportunity to design an initiative that would respond to the needs and circumstances of each hospital and, at the same time, promote collaboration and learning among the participating hospitals. He approached the authors of this study to enlist their assistance in the development of the Demonstration.

The Tennessee Rural Hospital Patient Safety Demonstration was officially launched in January 2005 with funding support from the BlueCross BlueShield of Tennessee Health Foundation. In addition to the eight participating hospitals, the Demonstration included technical support for design and implementation from the THA, the University of Southern Maine's (USM) Muskie School of Public Service, and Q-Source, the Quality Improvement Organization in Tennessee. Rural health researchers from the University of Minnesota and the University of North Dakota evaluated the short-term impact of implementation on the organizational and clinical systems of the participating facilities to inform future rural patient safety initiatives.

Implementation of the Demonstration required that hospitals be solicited and selected to participate, the patient safety interventions be selected, and plans for implementation be designed. These components of the Demonstration are described below.

The Demonstration

Hospital Selection and Structure of the Demonstration

The THA and the rural health research team discussed and used a set of criteria for identifying and selecting hospitals to participate in the Demonstration. Although many potential criteria were discussed, the key factors considered included the support of senior leadership and administration for the Demonstration, the ability of key staff (e.g., director of nursing and/or quality improvement director) to actively participate in the project, and successful participation in previous quality improvement initiatives.

Each hospital was represented in the collaborative by one or more administrators. In all cases, one of the representatives was the individual at their institution most involved in patient safety activities. However, many hospitals also had their CEOs directly involved in the Demonstration. Each hospital agreed to commit to a 2-year demonstration and was provided a modest stipend to cover travel, meeting, and other expenses.

Prior to the Demonstration, the THA had organized and supported a network of the Critical Access Hospitals (CAHs) to identify and work on priority initiatives within the State's Rural Hospital Flexibility Grant Program. Although some of the hospitals in this Demonstration were not CAHs, the Association sought to create a similar network arrangement. The THA and the research team opted for an informal structure involving:

- Regular face-to-face networking and technical assistance.
- One-on-one technical assistance to the participating hospitals.
- Peer-to-peer collaboration and technical assistance among the hospitals.

The THA and the research team developed a 2-year work plan based on several individual and group conference calls and written communications with the hospital participants. This work plan included a schedule of monthly project conference calls and quarterly face-to-face, 1-day meetings at the THA offices in Nashville, TN.

Choosing the Interventions

Identifying the current status of each hospital's patient safety program relative to the 26 patient safety interventions was a key step in the development of the Demonstration. To accomplish this task, the research team from the USM developed a needs assessment process and self-assessment tool that gave each hospital the opportunity to describe which of the 26 interventions they had undertaken and to assess the extent to which they felt they were fully or partially implemented. Administrative teams at each of the hospitals were guided through the self-assessment process in which they ranked rural-relevant patient safety interventions in terms of status of implementation, internal value, external value, and feasibility. These individual self-assessments were then aggregated (Table 1) and discussed at a network meeting.

At this meeting, Demonstration participants agreed on a set of three interventions that each hospital felt would be important to them and that would represent initiatives that they had not fully implemented:

1. Assessment of patient safety culture and implementation of a safety culture plan.
2. Development and implementation of emergency department protocols.
3. Use of PDAs by clinicians at the point of care to decrease medication errors.

A decision was also made on the sequence and timelines for implementing these interventions.

Technical Assistance, Support, and Evaluation

Technical assistance played a key role in supporting each of the hospitals in the implementation of these interventions and in facilitating the collaborative work of the Demonstration participants. A variety of organizations provided support to the Demonstration, including the THA, the universities' rural health research centers, and the Tennessee Quality Improvement Organization – Q-Source. The THA was principally responsible for managing the Demonstration, including communications with each of the hospitals and with external constituencies. THA staff also coordinated the distribution and training associated with the PDA intervention. Overall coordination of the project activities was achieved through significant and cooperative efforts of the THA vice president and a single project director from the research team (USM).

Staff from the USM Rural Health Research Center were responsible for coordinating and providing technical assistance resources to the hospitals. For example, all the hospitals received a binder of pertinent patient safety resources at the start of the Demonstration, as well as intervention-related resources throughout the project period. USM staff also designed and oversaw the survey of patient safety culture, including data entry and analysis,

Table 1. Patient safety intervention self-assessment results

Patient safety interventions		Participating hospital							
		1	2	3	4	5	6	7	8
1	Patient identifiers								x
2	24-hour pharmacist				x		x	x	x
3	Personal digital assistant (PDA)	x	x	x	x	x	x	x	x
4	Pharmacist-managed IV				x		x	x	x
5	Prescription software	x			x	x	x	x	x
6	“Read back” orders								
7	Drug abbreviations/dose standards	x					x		x
8	Look-alike/sound-alike drugs								
9	Admission medication list			x			x		
10	Transfer medication list						x		
11	Patient informed consent	x			x				
12	Hand hygiene								
13	Antimicrobial prophylaxis	x		x					x
14	Infection control program							x	
15	Specialized transport team								
16	Patient data communication	x	x		x		x		
17	Emergency Department protocols	x	x		x	x	x		
18	Emergency Department advanced training		x		x		x		x
19	Transfer protocols	x	x						x
20	Clinical information reporting	x							
21	Risk for falls								x
22	Patient safety program				x				

X = Not fully implemented at participating hospital

production of reports, and coaching around the dissemination of results. USM conducted and analyzed a survey of the PDA users and identified and coordinated additional outside sources of

support for the interventions, particularly the PDA intervention. Q-Source participated in all of the Demonstration meetings and was principally responsible for managing the collection and distribution of the ER protocols and working with the hospitals to assess and modify their protocols. The funder, BCBS of Tennessee, remained an active and interested partner in group meetings. Members of the research team from the Upper Midwest Rural Health Research Center were responsible for designing and carrying out the evaluation of the Demonstration.

Implementation

Patient Safety Culture Intervention

Each of the participating hospitals recognized the importance of safety culture as part of a comprehensive patient safety initiative and agreed to participate in the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Culture Survey.⁵ Measuring and benchmarking culture over time and communicating the results to the hospital board and others represents a core strategy for identifying target areas for building safety culture. In 2005, AHRQ developed this tool to measure patient safety culture. It can be used to assess the safety culture of a hospital, as well as to track changes in patient safety over time and evaluate the impact of patient safety interventions. National benchmarks for the AHRQ survey were published at the time of the start, as well as the end of the Demonstration.^{6, 7} This intervention was selected as a “kick-off” initiative to establish a baseline for the Demonstration and to guide the identification of appropriate hospital-specific improvement activities. The survey activity provided an opportunity for the group to share a common language and experience and to benchmark blinded individual hospital data.

Participating hospitals completed three rounds of the AHRQ Patient Safety Culture Survey over the 2-year project period. The survey helps each hospital assess the extent to which it emphasizes the importance of patient safety, facilitates open discussion of error, encourages error reporting, and creates an atmosphere of continuous learning and improvement. Each participating hospital learned to use the tool, database, and results to identify targets for culture improvement and to measure the impact of safety culture improvement activities. The research team coached the hospitals in the survey process and suggested methods to optimize survey response rates. All hospitals actively solicited staff participation including nondirect patient care staff in an effort to provide a more comprehensive view of hospital patient safety culture. Aggregate survey response rates were remarkable and averaged 74 percent over the three surveys.

After each round of surveys, the results were shared at both the individual hospital and the aggregate project level and compared to the AHRQ benchmarks. At quarterly participant meetings, the USM research staff modeled the results presentation using presentation tools (the survey report feedback template) available from AHRQ.⁵ In addition, each hospital received a packet containing both electronic and hard copies of their individual hospital level results, presentation materials, aggregate results, and benchmarks. Each hospital then shared these results with its board, staff, and community. Hospital staff reported back to the research team and project peers regarding this dissemination process.

The hospitals then developed action plans based on the areas of weakness identified in the survey. For example, one hospital initiated system changes for error-reporting by soliciting employee suggestions to create a new culture of nonpunitive communication. Another hospital emphasized organizational learning by sharing survey results and action plans at their employee fair and through a frank discussion of patient safety in the local newspaper. At monthly conference calls (2 hours) and quarterly face-to-face, day-long meetings, Demonstration participants shared both activities and resources as they worked on various improvement activities related to patient safety culture and the two other interventions. The meeting format provided structure, a reporting mechanism, peer communication, support and engagement, and an opportunity for technical assistance by the hospital association, quality improvement organization, and research team.

The impact of this component of the Demonstration appears to have been significant. Over the three surveys, there were significant improvements in the aggregate scores from baseline in 9 of the 12 dimensions of patient safety culture identified in the AHRQ survey (Table 2). The improvement in the Demonstration hospitals compared favorably with published AHRQ benchmarks in which improvement is noted in 5 of the 12 dimensions over a 3-year period.

Table 2. Comparison of Tennessee hospital composite scores for 12 AHRQ culture survey dimensions

Dimension	March 2005 (%)	Dec 2006 (%)	AHRQ benchmark 2004^b (%)	AHRQ benchmark 2007^c (%)
Overall perceptions of safety	56	69 ^a	56	63
Frequency of events reported	51	69 ^a	52	59
Supervisor/manager expectations & actions promoting patient safety	72	80 ^a	71	74
Organizational learning, continuous improvement	76	77	71	69
Teamwork within areas	68	83 ^a	74	78
Communication openness	50	67 ^a	61	61
Feedback & communication about error	53	68 ^a	52	62
Nonpunitive response to error	35	50 ^a	43	43
Staffing	46	52 ^a	50	55
Hospital management support for patient safety	72	78 ^a	60	69
Teamwork across hospital areas	60	64	53	57
Hospital handoffs and transitions	48	49	48	45

a Significantly different from March 2005 survey.

b Sorra J, Nieva V. Hospital survey on patient safety culture. AHRQ Publication No. 04-0041. Prepared by Westat under Contract No. 290-96-0004. Rockville, MD: Agency for Health Care Research and Quality; September 2004.

c Sorra J, Nieva V, Famolaro T, et al. Hospital survey on patient safety culture: 2007 comparative database report. AHRQ Publication No. 07-0025. Prepared by Westat under Contract No. 233-02-0087. Rockville, MD: Agency for Health Care Research and Quality; 2007.

Benchmarking the results after each survey and sharing blinded individual hospital results provided motivation for improvement activities. Movement in the scores over time reinforced the work of the improvement activities or facilitated focus on areas for improvement. The hospitals concentrated on improvement activities, such as increasing error/event reporting, nonpunitive response to error, and open communication. The hospitals embarked on new quality and safety improvement techniques, such as leadership walk-arounds, medication management tools, hand-off reviews, patient safety staff training, and orientation sessions, as well as new strategies to increase event reporting and feedback.

PDA Intervention: Information Technology at the Point of Care

The safe management of medications in a hospital involves careful attention to the use of the right amount of the right medication at the right time. As the volume and complexity of medication prescribing have grown, health care providers have increasingly sought technical support to manage medication prescribing and administration. Most patient safety standards recognize that essential drug information should be readily available in useful form and considered when ordering, dispensing, and administering medications. Yet, many rural hospitals are challenged by medication safety and lack access to computerized drug information systems, which include current protocols, guidelines, dosing scales, checklists for high-alert drugs, and information about herbal and alternative medicines.⁸

In this intervention, participating hospitals identified appropriate clinical staff to receive a PDA device and requisite training. Project funds covered the cost of the 190 PDAs, software, training, and technical assistance. These devices were preloaded with a drug database software program (Epocrates®) that enables the user to quickly check drug information, such as dosing, drug-drug interactions, adverse reactions, and formulary and pricing information. In addition, the software provides many clinical tools, including diagnostics, such as lab reference values, clinical tables and guidelines, symptom assessment, disease and condition compendium, medical calculators, and tools.

A team comprising staff from the THA, medical librarians from East Tennessee University, and research staff from USM trained the PDA users. Each participating rural hospital sent several staff to a train-the-trainer session. A local physician “champion” at each hospital was available to assist clinicians in their own training and rollout. Ongoing technical assistance was provided, including site visits and conference calls. Support from THA staff and the medical librarians was a key factor in the success of the intervention at the local level and contributed strongly to physician adoption of the technology.

The USM staff surveyed the new PDA users to measure the impact of the intervention using a slightly modified version of a tool from previous research on the use of PDAs in a clinical setting.^{9, 10} The survey served as quantitative measurement of behavior change, in addition to reinforcing the intervention training. A 96 percent survey response rate was achieved. The majority (71 percent) of the clinicians reported not using a PDA prior to the project period. The results indicated an increase in practice efficiency and provider knowledge, improved drug-related decisionmaking, and prevention of adverse drug events.¹¹ Immediate access to necessary

drug information was reported as a key benefit of the hand-held device. More than 80 percent of PDA users reported that it took them less than one minute to find the medication information they were seeking. Nearly all (95 percent) reduced their use of prior sources of drug information (often potentially out-of-date text references) through use of the drug database software.

For many physicians, this was their first experience with clinical support software, and for some, it represented a “gateway” use of technology. Following the success of the initial training, project funds were tapped to equip and train a second round of PDA users, primarily nursing staff. The hospitals reported significant interest in point-of-care technology via handhelds at nursing stations, hospital pharmacies, emergency departments, off-site clinics, and at the bedside.

Emergency Department Protocols Intervention

The research team and the THA recognized that this intervention might involve a stretch into areas of tension. By reviewing and modifying emergency department (ED) protocols, hospitals were asked to examine clinical processes that come with “baggage,” including organizational history, individual physician preferences, long-held clinical turf issues, and relationships with parent health systems or other tertiary care centers. For some hospitals, resistance to protocol development and adoption is a significant barrier. A common barrier in protocol development and implementation is a resistance to change by ED staff, including physicians, nurses, and administrators. This intervention required the hospital quality officer to recruit physician “champions” to achieve engagement in the process and eventual acceptance of the new protocol(s).

Participating hospitals completed an inventory of current ED protocols in their own facilities, while Q-Source compiled the inventory on a disk for all participants to share. Q-Source provided technical assistance for this intervention by sharing of best practices and coaching to develop intervention plans and activities. All eight facilities worked within their own teams to decide which protocols to adopt, adapt, approve, or implement. A number of the hospitals indicated some resistance to change from nurses and physicians but found buy-in through the review process and ED staff champions. The review process was “jump-started” by the shared protocols, and each hospital review team was able to update, add to, or tweak the protocol to fit local needs and preferences. These protocols were adapted first by the smaller group of ED leadership and then vetted through various hospital committees prior to implementation. Six hospitals have implemented or are in the process of implementing a total of 24 protocols.

Participants reported substantial benefit of the protocols to standardize treatment across shifts in order to reduce staff variances and improve patient flow, hand-offs, and transfers. Protocols become even more necessary at small facilities with low frequency of certain clinical events, but the protocols continue to be viewed as double-edged swords. While participants agree that protocols are valuable—particularly for small-volume facilities in optimum management of infrequent clinical events—there remains a resistance to “cookie-cutter” protocols.

In addition, the small hospitals in this Demonstration described the complications involved in coordinating protocols with a hospital system or with transfer hospitals. While this coordination prolongs the process time to implementation, it may increase the likelihood of successful

implementation in the long run. Many of the project hospitals intend to address this important next step. ED protocols are a long-term investment in patient safety and improvement and the collaborative process among hospital systems, emergency medical services, and transfer hospitals.

Conclusion

During the 2 years of this Demonstration, the hospitals assessed and identified needs for patient safety improvement. Three significant efforts were undertaken with the assistance of the THA, Q-Source, and the research team. The network of hospitals provided a forum for collaborative activity, information sharing, and collective learning. During the final months of the project, it became clear that process structure, clear action steps, and attention to a timeline were key factors in the successful results.

Beginning the formal improvement activities with hospital self-assessments afforded crucial hospital-level engagement. Consensus in the choice of interventions also promoted a sense of collaboration. The “kick-off” activity of the Patient Safety Culture Survey turned out to be a helpful and natural starting point for working together. Not only did the joint activity allow for a shared experience, common language, and group learning, but the results of the survey process were very useful at the local level and provided a link between collaborative goals and individual hospital needs. Substantial assistance with survey administration at the start of the project pushed all the hospitals forward in the same direction and provided a strong baseline for future work.

Quantitative measures collected in two of the three interventions suggest that organizational change and improvement in culture and processes are key elements to patient safety. Although the impact of the third intervention (ED protocols) was not quantitatively measured, reports from the hospitals indicate progress in protocol development and adoption.

The financial support provided by the funder and the hospital association enabled significant technical assistance, evaluation activities, and modest stipends for participating hospitals. The size of the working group was large enough to gain economy of scale, yet small enough for individual engagement and productive activity. After evaluating the results of the three interventions, it became clear that small rural hospitals can produce change in short periods of time.¹¹ Hospital participants recognized this phenomenon as they assessed the relative ease with which they were able to implement administrative and clinical changes.

This Demonstration shows that the implementation of patient safety initiatives is feasible and effective in rural hospitals and that rural hospitals are interested in and willing to invest in patient safety initiatives. The study provides a model of collaboration between providers, a payer, a hospital association, a quality improvement organization, and academic institutions to efficiently and effectively support patient safety activities in rural hospitals.

It is not known whether the individual hospitals are sustaining the improvement without the benefit of the collaborative. Sustainability should be enhanced by a new Patient Safety Center, which the THA has established with funding from BCBS of Tennessee, due in part to the success of this Demonstration.

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Systems Redesign

Systems-Based Practice: Improving the Safety and Quality of Patient Care by Recognizing and Improving the Systems in Which We Work

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Abstract

As the complexity of health care delivery has increased, it has become essential for physicians to understand how individual practices relate to the larger system of care.¹ It is within this context that the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) identified systems-based practice (SBP) as one of the six core competencies in which physicians must be proficient to deliver patient care that is safe and high in quality. SBP is challenging to define, incorporate into training and practice, and evaluate. Competency in SBP requires that physicians understand how patient care relates to the health care system as a whole and how to use the system to improve the quality and safety of patient care. Systems thinking is the cornerstone of SBP. Fostering the ability to recognize the contribution of the system is important for medical students, residents, and practicing physicians. However, current efforts in medical education focus on mastering knowledge of disease, diagnostic skills, and treatment at the level of the physician-patient interaction. As a result, there is a preoccupation with system components, while the system as a whole and its effect on the quality and safety of care remain invisible. To clarify the definition of SBP and to develop effective strategies for teaching and assessing SBP, it is necessary to provide a broad awareness of systems within a context of systems thinking. Patient safety is a good entry point into SBP because the concepts of safety, errors, and harm all place the individual, whether patient or provider, within the framework of a system.

Background and Rationale

The Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) identified six core competencies required of residents and physicians to deliver high quality medical care—patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice. Of these six, systems-based practice is one of the most challenging to define, incorporate into training and practice, and evaluate.

Systems-based practice can be thought of as an analytic tool, as well as a way of viewing the world, both of which can make caregiving and change efforts more successful. The focus is on understanding the interdependencies of a system or series of systems and the changes identified

to improve care that can be made and measured in the system. The metaphors “a village” and “a mirror” have been used to illustrate and differentiate the concepts of systems-based practice (SBP) and practice-based learning and improvement (PBLI). “SBP is like a village. A physician must work with a community of providers to deliver optimal patient care.”² This is contrasted with the core competency of PBLI, where the metaphor is “a mirror.” “PBLI is like holding up a mirror to ourselves to document, assess, and improve our practice.”²

In clinical settings, we can operationalize these concepts by asking two separate but related questions:

1. The PBLI question: “How can I improve the care for my patients?”
2. The SBP question: “How can I improve the system of care?”

Since the landmark Institute of Medicine (IOM) report focused national attention on patient safety, it has been generally agreed that the systems we work within are at the root of many of our patient safety problems.³ Safety is a property of systems. Many of our patient safety initiatives belong to the system. Furthermore, certain patient safety issues are especially relevant to system solutions. These include the World Health Organization’s list of “High 5” patient safety initiatives—managing concentrated injectable medicines, assuring medication accuracy at transitions in care, communicating during patient handovers, improving hand hygiene to prevent infections associated with health care, and performing correct procedures at correct body sites⁴—and The Joint Commission’s patient safety goals, which are updated yearly.⁵

Although an understanding of systems is essential to improve the quality and safety of patient care, training in SBP falls outside the scope of traditional training. As result, undergraduate medical institutions, residency programs, specialty boards, and societies may have difficulty effectively teaching and evaluating SBP. In addition, although SBP is required by the ACGME as one of the core competencies that residents must demonstrate, there is a lack of literature about how to integrate the theory of systems and systems thinking into medical education.

The common program requirements for SBP, as approved by the ACGME in February 2007,⁶ are outlined as follows: Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care. Residents are expected to:

- Work effectively in various health care delivery settings and systems relevant to their clinical specialty.
- Coordinate patient care within the health care system relevant to their clinical specialty.
- Incorporate considerations of cost awareness and risk-benefit analysis in patient and/or population-based care as appropriate.
- Advocate for quality patient care and optimal patient care systems.
- Work in interprofessional teams to enhance patient safety and improve patient care quality.
- Participate in identifying system errors and implementing potential systems solutions.

The aim of this paper is to further refine the definition of SBP by providing a broad awareness of systems within a context of systems thinking and to highlight the importance of teaching SBP as part of any program focused on improving the quality and safety of care.

Definition of a System

Implementing and evaluating SBP in a medical context requires a broader understanding of what constitutes a “system,” coupled with an understanding of systems thinking. Bertalanffy, the founder of the scientific, mathematical “Theory of Systems,” defined a system as a set of interacting, interrelated, or interdependent elements that work together in a particular environment to perform the functions that are required to achieve the system’s aim.⁷ The importance of understanding systems as interrelated parts of a whole cannot be overstated. Systems can be continually improved, but one must consider how its products are created, why they are created, and how they can be improved. Comprehending the assembly of the system as a whole can inform the work of those who are trying to create successful, interdependent systems.⁸ Learning to see interrelationships, rather than linear cause-and-effect chains, and grasping the phenomenon of change as a process, rather than as a snapshot, are essential for understanding systems.⁹

Systems have certain rules (or principles) that help us predict how they will behave:^{10, 11}

- The whole has one or more defining functions.
- Each part can affect the behavior or properties of the whole.
- Each part is necessary but alone is insufficient to carry out the defining function of the whole.
- Behavior and properties of one part of the system depend on the behavior and properties of at least one other part of the system.

Systems thinking is the cornerstone of how “learning organizations” think about their world.⁹ Learning organizations are those that measure outcomes and strive for improvement. Many fields outside health care—including education, telecommunications, and aviation—use systems theory to better serve their clients, understand applicable research, improve outcomes, and ensure quality and safety. Recognizing feedback from the system and using that feedback for design and redesign of services is an inherent element of systems thinking.

Competence in SBP necessitates that physicians understand how patient care and other practices relate to the health care system as a whole and how to use the system to improve patient outcomes, safety, and quality. SBP is care that is sensitive to the context in which it is delivered. Fostering the ability to recognize the contribution of the system is important for medical students, residents, and practicing physicians because care is never delivered in a vacuum—there is always a powerful context.

However, current efforts in medical education focus on mastering knowledge of disease, diagnostic skills, and treatment at the level of the physician-patient interaction, resulting in preoccupation with system elements, while the system as a whole and its effect on patients remains invisible. The context is what has been minimized as educators try to standardize the experience for trainees. Systems thinking and the application of systems thinking through SBP provide an opportunity to look at the context.

“The systems we work in often can be difficult to identify and define. Although we work in numerous systems all day, every day, it’s difficult to ‘see’ a system. It’s like asking fish to describe water—it’s easier to be aware of the system when the system fails” (P. Batalden, personal communication, 2005).

Health care is composed of a large set of systems—e.g., ambulatory care centers, physician office practices, inpatient hospital units, home health care, laboratories, and pharmacies—all interacting with one another. Each of these systems is connected via individuals and teams, regulations and rules, and technology.¹² Understanding how one functions within the system as a whole, and how one’s actions affect all other aspects of the system, is the key to unlocking an effective SBP strategy.

The concept of systems, in general, often brings up images of “well-oiled machines.” However, health care systems are often cumbersome, unwieldy, unfriendly, and opaque to their users—patients, physicians, nurses, and staff. Health care systems are best described as complex adaptive systems. As such, they are a collection of individuals who are free to act in ways that are not totally predictable. The organizational boundaries are “fuzzy” in that membership changes and providers can simultaneously be members of other systems. Furthermore, given the complexity of these systems, the actions of individuals are interconnected so that the actions of one changes the context for all the others.^{13, 14}

One organizational construct that operationalizes the concept of a complex adaptive system is the clinical microsystem, which can be defined as a group of clinicians and staff working together with a shared clinical purpose to provide health care for a population of patients.^{15, 16, 17} The clinical purpose and its setting define the essential components of the microsystem. These include the clinicians and support staff, information and technology, the specific care processes, and the behaviors required to provide care to its patients.

Microsystems evolve over time, responding to the needs of their patients, providers, and external pressures. They coexist with other microsystems within a larger (macro) organization. A health care organization is composed of multiple microsystems. Examples include a cardiovascular surgical care team, a community-based outpatient care center, and a neonatal intensive care unit. All of these have common core elements: a focused type of care, clinicians and staff with the skills and training needed to engage in the required care processes, a defined patient population, and a certain level of information and technology to support their work. What often differs across microsystems is the ability of individual caregivers to recognize their efforts as part of a microsystem, as well as the microsystem’s level of functioning.

The microsystem construct makes explicit the caregiving system, yet builds on systems theory by recognizing that “important systems” characteristics include the system-environment boundary, input, output, process, goal-directedness, and interaction of the elements of the system.”⁷ In its “Crossing the Quality Chasm” report, the IOM identified multiple layers of the health care system that influence the ability to improve care: the experience of patients; the functioning of the microsystem; the functioning of the organizations that house or otherwise support microsystems; and the environment (e.g., policy, payment, and regulation), which shapes the behavior, interests, and opportunities of the organizations.¹⁸ Efforts at each of the different levels

of the health care system and the interactions among them can influence the ability to achieve patient safety and quality of care objectives.

Systems and Outcomes

In addition to understanding what a system is, it is important to recognize how systems can contribute to or undermine outcomes, such as quality and safety of care. Patient safety is a good entry point into SBP because the concepts of safety, errors, and harm all place the individual, whether patient or provider, within a system. It is generally understood that patient safety is a systems issue and that interventions to improve patient safety should be made at the system level.³ High-risk industries—such as chemical manufacturing, nuclear power, aviation, and defense—have developed well-defined systems that have resulted in improved safety. Similarly, the health care industry is complex and high risk, and clinical outcomes can be profoundly affected by lapses in the system or misunderstanding of how the system operates, both within the sphere of practice and across the continuum of care.

For several years, the health care industry has had a growing recognition of the important relationship between safety and well-functioning health care systems. In 1999, the IOM's Committee on Quality of Health Care in America published the report, *To Err is Human: Building a Safer Health System*, which included several recommendations to health care providers regarding patient safety in health systems.³ The committee noted that the “most important barrier to improving patient safety is lack of awareness of the extent to which errors occur daily in all health care settings and organizations.” Individuals in an organization must feel empowered to report errors, while organization leaders must implement ways to discover errors and make process improvements to reduce error. Part of the solution is to ensure that providers have the tools to address system issues.

“Every process is a system. Simple systems are individual processes; complex systems may be hundreds, thousands of processes. Processes are inherently hierarchical – you can drill down into each process, into each step of each process. Finally you hit the level at which people make decisions. This drives where you link outcomes measurement and the data system. Outcomes, like processes, are hierarchical. Managers tend to go high up on the outcomes chain, but we need to drill down to the decision level. Goals need to be set around front line decision making – then roll them up to senior leaders and the Board.” – B. James, MD, Intermountain Health Care. (Personal communication, 2005).

Recognizing that one works within a system and understanding how that system functions are only the beginning. Physicians and other health care providers must be empowered to change aspects of the system they recognize as failed. Often, well-meaning providers are not sure how to effectively design and test cycles of change; they lack the authority or power, and they lack the time. As regulatory agencies continue to set goals [e.g., Health Plan Employer and Data Information Set (HEDIS[®]) measures for comprehensive diabetes care, the Joint Commission standards for accreditation] that affect the organization, there is a need to understand the underlying processes and systems at work at the local level, where patients and providers meet at the “sharp end” of health care.

Systems-Based Practice Across the Continuum of Medical Education

As educators begin to include SBP in their curricula, it is important that they have a common understanding of what SBP means, how it should be incorporated throughout the educational continuum, and how it can best be evaluated. Work is needed across the continuum of medical education—from medical school curricula for the student learner to opportunities for life-long learning for the practicing physician.

“In 1935, Lawrence Henderson wrote about the Henderson Hasselbach equation. He also wrote that patients and doctors are part of the same system. Students are required to learn the equation, but not about his observation about systems.” – P. Batalden, MD, Dartmouth Medical School.¹⁵

Systems-based practice is the deeply fundamental link as we seek to prepare physician learners for participating in and improving systems of care. SBP unlocks insight into the dynamics of the change that is necessary.

The ACGME states that competency in SBP is “manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system of health care and the ability to effectively call on system resources to provide care that is of optimal value.”¹⁹ Compared to medical schools, residency programs have been the most active in developing and assessing SBP curricula. However, similar to most undergraduate medical education programs, residency programs often lack a clear definition of SBP, as well as a consistent and reliable means of assessment. Progress is being made on this front, and the ACGME solicits current efforts through annual conferences, which are then disseminated via the Council’s Web site and through their publications.^{19, 20} Without a common understanding of SBP and consistent methods of evaluating competency in SBP, educators cannot hope to effectively incorporate SBP into the daily work of patient care.

Many programs train residents in SBP through brief seminars, courses, or field trips to managed care organizations. There does not seem to be a concentrated effort to integrate SBP into residents’ clinical training, although systems issues are prevalent in academic inpatient settings.

Residents work in the system everyday, but systems-based practice requires cross-disciplinary conversations that are often overlooked by today’s busy residents. Furthermore, residents don’t feel empowered to address the system symptoms because they lack the tools and required skills to change daily practice. This is manifested as a “workaround.” As residents are immersed in the system in which they are trainees, they become experts at finding ways to work around the most problematic system issues. A workaround, which is jargon taken from computer programming, is a temporary fix used to bypass or otherwise avoid a bug or “misfeature” in some system.

Workarounds, as a method for navigating system inefficiencies, are present at all levels of training and professional roles and across disciplines. Theoretically, workarounds are intended as quick fixes and are replaced by solutions that address the system problems. In practice, people often find themselves living with workarounds for long periods of time, with residents sharing detailed knowledge of workarounds with the next generation of residents. Adopting workarounds as part of one’s clinical practice suggests a failure to perform an appropriate analysis of the system’s failures or to truly understand systems failures that lead to the workarounds.

Often, even the most experienced individuals in the system do not recognize the destructive cycle of the workaround. It is only after a serious breakdown in the system occurs, (e.g., an adverse event), that an investigation might reveal the workaround. For faculty, a key opportunity is to learn to recognize the workarounds their residents adopt because they provide multiple opportunities to tease out and address the system issues.

Surfacing workarounds can be a Pandora's box—we need to assure that the organization can support the improvement work that would be required once the system issues have been identified.²¹ Some suggestions include:

- **Provide an easy avenue to report problems as they occur:** Give people an easy avenue to report and communicate issues.
- **Ensure that feedback is part of reporting:** Let providers and staff know they have been heard and that the issue will be addressed.
- **Identify appropriate institutional leaders who are willing to work with providers and staff to tackle system issues:** Identifying system problems is only the first part of any solution. It is critically important that institutional leaders be willing to tackle these issues with physicians and staff.
- **Provide feedback on what is being done to fix the problem:** Once system issues have been identified and reported, provide feedback about how the problem is being solved.

Overall, there is a need for generalizable methods and tools for teaching about the system and the effect of the system on the caregiving process.

Systems-Based Practice for the Board Certified Physician

In 2000, ABMS began to promote a replacement for recertification known as Maintenance of Certification™ (MOC), which when fully developed, will assess the continuing competencies of physicians. It is based on four components:

1. Professional standing, e.g., unrestricted license, hospital privileges, and peer and patient ratings.
2. Commitment to lifelong learning, e.g., self-assessment, CME, and simulations.
3. Cognitive expertise, e.g., secure exam.
4. Evaluation of performance and improvement in practice, e.g., an ability to demonstrate that care is safe, effective, patient-centered, timely, efficient, and equitable, and that one has incorporated quality improvement as a habit of practice.

The competency of SBP fits within both the second and the fourth components of MOC. A few medical specialty boards have indicated that they plan to include assessment of SBP in their certification and recertification exams in the near future. The Practice System Survey, which is part of the American Board of Internal Medicine's Web-based Practice Improvement Modules (PIMs), assesses SBP and could be a useful prototype for other specialty boards.²² The PIM is ABIM's prototype tool for evaluating the fourth component of its MOC program, physician practice performance. As SBP is incorporated into medical education at the undergraduate, graduate, and practicing physician levels, it will also become an integral part of the certification

and recertification process. However, the medical specialty boards can take a leadership role in providing guidance for understanding and evaluating SBP.

Medical specialty boards, in collaboration with specialty societies, can act as a catalyst to help define assessment modalities for SBP and, thus, promote appropriate and effective education and training for SBP. By requiring physicians to be proficient in SBP for certification and MOC, specialty boards are sending a clear message across the continuum of medical education about the importance of learning about SBP.

Discussion

Implementing and evaluating SBP in a medical context require an understanding of what constitutes a “system,” coupled with an understanding of systems thinking. Despite the best intentions of health care providers, misunderstanding about how the system in which one operates can break down or succeed can interfere with the delivery of health care. Undergraduate medical education, residency programs, and ABMS member boards are making progress toward training physicians in SBP. However, it is clear that current curricula and training have gaps. The major gaps in SBP curricula identified in this paper include:

1. No clear, common understanding of SBP.
2. Lack of assessment methods.
3. Lack of understanding of the relationship of SBP to patient outcomes and safety.
4. Lack of integration into daily practice.

Educators must develop clear, universally accepted definitions of SBP that are consistent with the medical profession’s understanding of it as a necessary competency. It might be helpful for each specialty to consider how daily aspects of their clinical practice relate to systems. Once a clear definition has been established, educators must train students, residents, and practicing physicians to recognize how they interact with systems, how systems affect their daily medical activities, and how they can change ineffective systems. Understanding the relationship between systems and outcomes of care will help increase the relevance for physicians as they master SBP.

Paul Miles, MD, vice president of the American Board of Pediatrics, delineates questions that every practicing physician, from recent graduates to the established physician, should be able to answer regarding SBP.²³

1. Can you define a system?
2. How do you describe the system you work in? (Can you draw a picture?)
3. How well does the system work?
4. How would you analyze and diagnose where the system can be improved?
5. How would you identify and prioritize change?
6. Do you participate in an interdisciplinary team?
7. What are the different systems your system interacts with, and how does your system interact with these systems?
8. How is your system financed?

9. How are new members of the team trained? (How does the system renew itself?)
10. If your system is involved in medical education, how is medical education done successfully?

SBP involves all aspects of a physician's practice of medicine. Opportunities for identifying system failures and successes, as well as how these failures and successes can affect patient outcomes and safety, should be integrated into clinical training. Faculty need effective tools for teaching and assessing SBP as part of daily practice.

Competency in SBP must be measured in a systematic way that assesses how knowledge of SBP contributes to improving quality and safety of care. Explicit strategies are needed for teaching SBP in clinical settings. By focusing on objective criteria and specific skills that relate to SBP, educators can design effective evaluation tools that truly measure physicians' knowledge and skills in SBP.

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Designing the Built Environment for A Culture and System of Patient Safety – A Conceptual, New Design Process

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Abstract

There is growing recognition that the risks and hazards of injury and harm associated with health care are a result of problems with the design of systems of care rather than of poor performance by individual providers. Furthermore, substantial evidence suggests that the design of hospital physical environments contributes to medical errors, increased rates of infection and injuries from falls, and to slow patient recovery and high nurse turnover. Growing research points to the need to change facility development and design methodologies used in the past to incorporate patient safety into the design. The design professions have been slow to comprehend the gravity and character of the problem. Designers appear to be taking “solution based” approaches rather than using intensive, focused research to develop environments that support caregiving processes. Key causes for these deficits relate to the way designers are trained, the way design knowledge is shared and propagated, and the history of architectural theory. In design, the notion persists that the same processes and tools used in the past will somehow result in the safe environments required for the present and future. The authors compare changes in medical education and architectural design training that illustrate the different approaches. Attention to systems thinking, evidence-based care, and the identification of a different design process that can be used to create health care facilities are needed.

Introduction

Hospitals occupy a unique place in our sensibilities. For some, they are safe havens; for others, they are the locus of dynamic civic and financial activity; and for still others, they have an image of being stressful places that provide only fragmented or even unsafe care. These mixed messages have created interest in obtaining a greater understanding of the relationship between quality of care and the physical environment.

One of the dangers in any emerging concept is that it will be taken over by forces that borrow the language but ignore the detail. Such appears to be the case in the area of “patient-safe” design for health care buildings. The need for a new approach to health care design is a byproduct of the national movement to reduce medical errors and prevent hospital-acquired infections. The current manifestation of the patient safety movement may date from the 1980s, when Lucien Leape¹ and others began investigating and writing about the problem. In this country, the issue was “brought in from out of the cold” by the Institute of Medicine’s (IOM) 1999 report, *To Err Is Human*.²

The Nature of Error and Its Relation to the Designed Environment

The IOM was careful to point out that medical errors are a product of systems of care rather than the fault of individuals. In other words, causation is related to the design of systems and to the culture of care, rather than to individual human failures. James Reason³ and Charles Perrow⁴ established the theoretical basis for this understanding through their work in the study of human error and accidents. Reason illustrated his concept using what he called “the Swiss cheese model,”³ which illustrates that there are many latent accident-causing conditions in the common environment, but that these are normally trapped by various layers of defense, such as training, supervision, and redundancy. However, each layer of defense is imperfect, and sometimes holes in each of the separate layers line up, allowing a causative event to result in patient harm. Perrow⁴ contributed the idea that accidents are built into systems, and that safety is an inherent property of a system.

Unfortunately, much of the research relating to safety in medical care has focused on characteristics of the clinical system other than the environment in which it is delivered. Donald Norman, who has described some basic characteristics of the design of objects, including buildings, provides tools for avoiding or reducing hazard-rich design solutions.⁵ However, his work does not discuss medical care environments. A literature search conducted by Ulrich and Zimring⁶ found a relatively small number of robust articles (out of approximately 600 articles reviewed) that related building design to patient safety. While the research base is small, a review of those studies and work published since demonstrates a link between quality of care and physical design.

This is not to say that evidence does not support current design conventions and techniques or that patient safety is being ignored in building design. A review of the history of health care design (conducted by the authors) clearly supports the contention that evidence has been highly respected in the past and that patient safety has been a key point in hospital development. The work of Filarte in Milan and the design of the British Army Field Hospital at Renkioi are just two of many examples.

Among the common themes in the history of hospital design is the need to have ever better methods for removing waste and the concept that adequate ventilation is essential for patient recovery. On a more current note, a review of the American Institute of Architects’ *Guidelines for Design and Construction of Hospitals and Healthcare Facilities* by James Gregory (*Personal communication*) (see www.aia.org/SiteObjects/files/CHD%20WHITE%20PAPERS.pdf) identified over 100 design requirements that relate to patient safety. In addition, a great number of requirements relate to fire and life safety, independent of patient safety considerations.

As a matter of note, the fire and life safety requirements were developed over a period of years in conjunction with organizations such as the National Fire Protection Association (NFPA). These provisions have been particularly successful in reducing the number of fire deaths in hospitals, which currently average less than 10 per year (*Personal communication*). Achieving this level of safety requires an extraordinary expenditure on building features that suppress, isolate, or eliminate fire threats. The unit cost per life saved is enormous.

How the Environment Contributes to Error

What symptoms of poor design in health care facilities could contribute to medical errors? Virtually any characteristic of the environment can have a supportive or detrimental effect on human performance and hence on patient safety. For example, consider lighting. A recent study correlated the relationship of medication errors to lighting levels. As lighting intensity approaches 1,500 lux,⁷ the incidence of medication errors dramatically decreases. Poor lighting and the lack of daylight are linked to depression, increased need for pain medication, medication errors, and order entry errors.⁸ Health care-acquired infections are related to air quality, ventilation rates, the presence of handwashing stations, the number of room occupants, and finishes.⁹ Research showing that noise is a significant stress-inducing element in open office landscape design has direct application to many health care environments. Noise is also known to reduce communication comprehension. The distance between two “related” departments affects service time, throughput, and transfer risk. The form of the pathway (straight, crooked, or convoluted) affects travel time and increases the risk of falls or transport accidents. Exposing nurses to nature vs. non nature views decreases their stress levels and enhances their awareness to errors.¹⁰

A Comparison with Building Life Safety

Education and training about the patient safety problem, reallocation of certain building resources, and fundamental changes to the building design process are required in order to create buildings that are “patient safe.” When comparing the characteristics of health care building life safety and patient safety, both involve cultural and organizational issues. Neither type of safety can be achieved solely by application of isolated, nonconnected protection features. Both types of safety have aspects of interdependence with the environments in which operations are conducted. In the case of fire and life safety, significant changes to design concepts and methods (in addition to operational concepts) were part of organization cultural changes. On the other hand, the design process for buildings that foster patient safety has not undergone such a transformation to date.

In this article, we make several comparisons between designing for building life safety and designing for building patient safety. For that reason, a few comments about the history of building fire safety are in order. Until the beginning of the 20th century, large loss fires were common in urbanized areas in the United States. The history of many cities—such as Chicago, Jacksonville, and San Francisco—is often retold from the time of “the big fire.”

The 20th century did not have an auspicious beginning. On December 30, 1903, 602 people perished in Chicago’s Iroquois Theater.¹¹ On June 15, 1904, barely a half-year later, 1,000 New Yorkers died when the steamship General Slocum burned to the water line.¹² Then, 7 years later in March 1911, 146 workers, mostly young women, perished in the Triangle Waist fire in New York City.¹³ In May 1929, 123 people lost their lives in a fire at the Cleveland Clinic (*Personal communication*). While no loss of life in major fires in any given year has come close to equaling the loss of life in residential buildings, the large loss fires in the early 20th century gradually led to the development and enactment of the effective life safety regulations we have today. These

tragedies captured the attention of the public and policymakers and changed the culture of fire safety. Today, residential fires cause an even greater proportion of fire deaths than do those in institutional and commercial buildings, yet the public has been very slow to accept changes, such as residential sprinklers, that would save lives.

The Scope of the Problem

Medical mistakes, or errors, in which the design of the physical environment is a contributing factor, have a substantial cost in lives and injury. To date, no study of this problem has been published. The following is a crude estimate, which we offer for the purpose of discussion. The IOM stated that between 44,000 and 98,000 people die every year in U.S. hospitals due to medical errors. Klevens, et al., calculated that approximately 99,000 deaths can be attributed to hospital-acquired infections every year.¹⁴ Accepting the smaller of the IOM numbers (which could also account for some overlap of the figures), total deaths each year would be 143,000. If we assume that the cause of death in these cases is proportionate to the ratio of capital expense to total operating expense, then 12 percent, or 17,160 deaths, would be related to the designed physical environment. For the purposes of conversation, this number is 1,700 times the number of deaths each year in U.S. hospitals due to fire.

Training for Design – A Tale of Deficits

How have architects and the design process they use been successful in reducing fire deaths in hospitals? The academic training of architects and engineers provides the foundation for their understanding of fire safety. During the period of apprenticeship, which generally follows graduation, the intern architect comes in close contact with specific building and fire safety regulations and standards. The National Council of Architectural Registration Boards (NCARB) licensing examination used by many States tests candidate architects on their knowledge and understanding of fire and life safety codes.¹⁵

Upon entering practice, the apprentice or intern architect finds that every nonresidential building design must pass the review of government examiners, who enforce fire and life safety codes. Complementing this system are the efforts of manufacturers, trade associations, and specialty consultants, who develop, test, and produce systems and materials that are classified by independent testing agencies as to their fire performance characteristics. Some of these systems are for active fire suppression and others for containment, depending on the requirements stated for occupancies defined in the codes. The added cost attributable to life and fire safety characteristics is enormous, yet there is little recognition and no complaint. The standard for performance has been set very high.

Since architecture schools train generalists not specialists, freshly minted architecture graduates are not likely to have been exposed to the issues of design for health care services, let alone the problems associated with medical error and mistakes. During their apprenticeship period, following graduation and preceding licensing, graduate architects might have an opportunity to work on health care projects. Others might start doing health care projects later in their professional careers. It is through this experiential avenue that most of those who ultimately become health care specialists begin receiving their training in this field. In the United States,

only two university programs have a graduate level curriculum in health care planning and design. Neither of these programs has a track that focuses on design for patient safety. Unlike life and fire safety, no regulations or codes are devoted to patient safety—i.e., freedom from medical errors and mistakes. Furthermore, architecture students get little training in ergonomics, process modeling, psychology, and anatomy that would help them understand how the users of the buildings would react and interact with their designs.

Subjects—such as structures, the mechanics of materials, and history—are taught in a lecture and recitation format, whereas design is generally taught in an experiential studio format. Studio classes might have some lecture periods, but most of the attention goes to student exercises. These could be 1-day quick studies or the focus of an entire class term. The student is given or develops a program for the proposed project and is asked to produce a design concept. The studio director typically visits with each student on a periodic basis and gives a critique that is intended to raise questions that the student explores through self-directed study. The work may be graded individually by the studio director or may be “juried” by the professor and fellow students.

One consequence of this format is that, while all students start with the same program, their resulting solutions may be quite different. This strategy is intended to develop the individuality and personal analytic skills of each student.

Now, picture the medical analogy: A group of interns is each directed to perform an appendectomy or to place a central venous access line, and each cuts the patient in a different location, in a different direction, and to a different depth. The chief medical resident concludes the exercise by telling the students that “each of these solutions is fine, although I like some better than others.” The learning process for architects emphasizes individuality, intuition, and self-expression, but it excludes some helpful tools and disciplines. These can be hindrances when designing medical buildings.

Although architects are subject to legal liability for negligence in designing life safety features for a building, the legal system has paid little attention to exploring potential liability for designs that contribute to medical mistakes and errors. For damages and injuries resulting from structural failures, water migration (mold and mildew), and similar causes, the architect has the restraining benefit of the tort bar. Cases against architects alleging harm due to medical errors caused by the building environment are rare if not nonexistent.

The one area that does receive interest is that of hospital-acquired infections resulting from construction operations, but those cases typically involve the constructors and the owners because of their proximity to the causes and their deeper pockets. It is ironic that some practitioners tout the beneficial effects on staff and patients of well-designed environments, deplore the stress and fatigue caused by poorly designed environments, but yet are silent about their attendant responsibility for errors and harm, which may be attributable in part or in total to the environment.

Furthermore, many architects are trained in what Robert Sommer described as “formalistic design.”¹⁶ In contrast to “social design,” formalistic design emphasizes rules, dictums, and

aesthetics for the sake of aesthetics. Social design focuses on the needs of users, on human scale and human interaction with the built environment, and especially on usability. An excellent (nonarchitectural) example of formalistic design is the work of the artist Mondrian. His paintings are composed of lines and rectilinear forms in rigid structures, which emphasize the relationship of the elements to each other by the use of various proportional schemas.

Given the proposition that the training of architects lacks information on subjects that would improve their ability to design safe medical environments, it is important to review the etiology of the factors in building designs that contribute to accidents:

1. Designer lack of knowledge of medical care systems.
2. Designer lack of knowledge of human factors.
3. Design process that limits comprehensive problem solving and devalues or ignores certain relevant disciplines.
4. External forces and limitations, such as regulations, budget, and schedule.
5. Limitations of available systems, designs, and materials.

Of these factors, we have addressed the first two in a limited way; we find that the fourth and fifth are beyond the scope of this paper: it is the third that we will now address in detail.

Problems with the Current Design Process

While the educational system for architects creates latent deficits for the aspiring health care facility designer, its most damaging effect may be the perpetuation of design processes that are inappropriate or inadequate for health care facility design. The conventional design process used by American architects has evolved into a unique system of project delivery. In many businesses, including some that utilize professional services, a single business entity undertakes product research, design, and production. The aircraft and automobile industries are excellent examples.

In architecture and medicine, the system of design and production is different. By the 20th century, the practice of architecture had separated from building construction. Just as physicians are “independent consultants” representing the patient, so architects are the agents of the client or owner, rather than the construction contractor. This process is dubbed “design/bid/build.”¹⁷

During the last quarter of the 20th century, a system of project delivery, in which designers and constructors posed as a single business entity with respect to their client, gained some prominence. This method, described as “design/build,” was touted as being able to deliver projects faster. Despite this methodology’s continuing gains, most major commercial and institutional projects continue to be delivered by the conventional design/bid/build method.

The design/bid/build process is linear. It starts with the development of a project scope; continues with the creation of a conceptual design; progresses through the preparation of construction documents, which are given to prospective contractors for competitive pricing (bidding); and then proceeds through the construction phase. In health care projects, the client, the architects, or a specialized consulting firm might prepare the “scope statement,” sometimes called a “functional program.” This document could be just a list of spaces by department and

usually does not include medical process information, flow diagrams, or information regarding patient safety issues.

During the conceptual design phase, the architects may interview clinicians and other staff to validate the program, to learn about special requirements, and to understand departmental and room adjacencies. If the owner has engaged a consultant to manage the project, contact between the designers and users might be limited.

During the conceptual phase of the project, disciplines other than architecture play a limited role, but this changes as the project begins to require greater detail. Structural, mechanical, and electrical engineers join the procession in order to design the systems and features for which they are responsible. At some point, equipment planners and information technology experts become part of the team. We use the term “team” loosely because nearly everyone sticks to his/her assigned “silo.”

When the architects are nearly done, interior designers might be invited to select furnishings, artwork, and special finishes. The strength of this process is that it is highly structured and organized. No more information is developed at any one time than is needed for the particular design questions being studied. Inconvenient concepts or facts can be shunted away. Almost everyone in the design and building sectors understands this process and has some conception of its strengths and weaknesses.

The weaknesses of this process are exactly the opposite of its strengths. Because of the rigid structure, disciplines that would benefit by cross-pollination and collaboration never have that opportunity. For instance, a decision about a medical process might be made before all available technologies and equipment are considered. Opportunities to improve process to achieve greater efficiency and quality are artificially limited. Rarely in these instances have we seen adequate research. Because the design/bid/build process is led by a representative of either the architect or the owner, there is little incentive to engage specialized consultants.

One example of this is in the area of human factors, or ergonomics, research. Although health care buildings contain hundreds of workstations, many of which are used day and night, the extent of design research typically involves asking a few users in a nonscientific manner how high the counter should be. That same counter is typically designed without specific knowledge of the monitor and computer or other devices to be installed into it and to be used by staff members. It is also designed without consideration of the physical characteristics of the staff who will use it. Engaging human factors engineers, medical informaticists, and other specialists at the outset of the project where they would have a chance to be effective would disrupt the rigid structure of the conventional project delivery system.

The design/build delivery system, which is an abbreviated form of the traditional design/bid/build approach, is even less flexible and more averse to user-tailored design.

A Proposed Solution – A Conceptual Model of a New Design Process

If the conventional system were malleable, adding the appropriate additional disciplines at the correct time might be possible. However, the process is not malleable because its very rigidity

creates its structure. The solution is to create a new system of project delivery that is not bound by the constraints of the old system.

If the conventional system can be visualized as linear, a better process or system could be visualized as a series of concentric circles, as shown in Figure 1. In the center is a circle that represents the functional systems of the organization: medical care systems, administrative systems, and support systems. The rings around the center represent increasing amounts of knowledge and increasing levels of decisionmaking about the project. Each ring is populated by representatives of each of the disciplines appropriate for the questions at hand. In addition to the architect and engineers, there would be risk managers, clinicians, human factors engineers, medical informaticists, equipment specialists, interior designers, and it is hoped, past and present patients. The concept is to look at all problems and issues with a very broad perspective, so that all kinds of solutions can be developed and tested.

For example, an owner may wish to switch from paper-based to electronic medical records. This switch could have implications for the amount of (electronic) storage space needed, where it should be placed, and the type of environment needed for preservation. It could also affect the way physicians and nurses complete charts and write clinical orders. It might mean that work environments would need to be suitable for computer monitors rather than paper forms. The number and location of charting monitors would have a significant impact on the way doctors care for their patients. In the process, the change from paper-based to electronic medical records might seem at first glance only an “information technology” issue, but in fact it has a huge impact on the workflow and quality of clinical decisionmaking.¹⁸

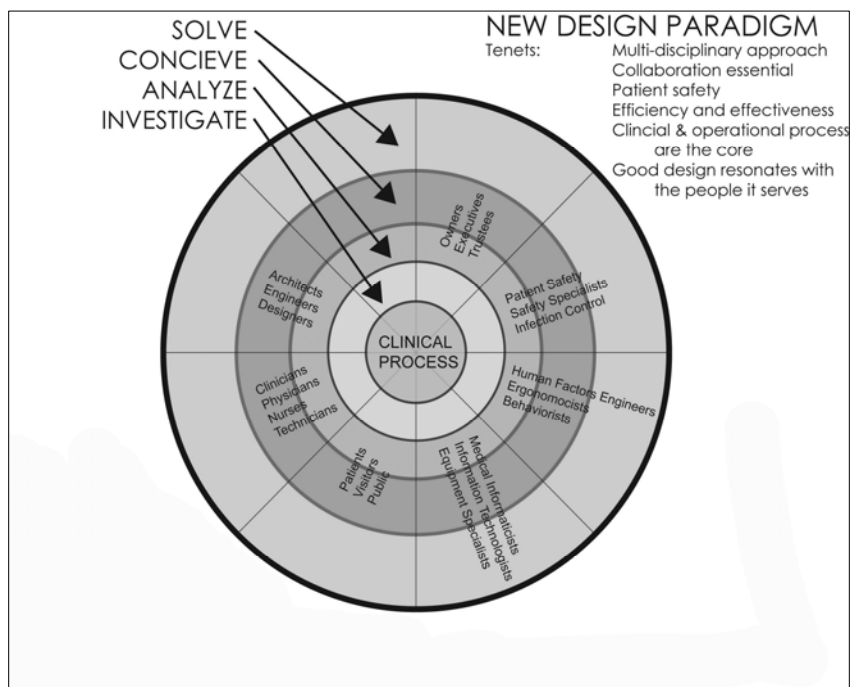


Figure 1. New conceptual model for design process.

In fact, the physical environment would have a significant impact on the success of introducing electronic medical records. New computers might add significant heat load, lighting that was appropriate for working with paper could be totally inadequate for viewing computer screens, and the number of input locations might be insufficient. The best way to avoid these and many other mistakes is to have a project team composed of individuals who understand the interrelationship of systems and have a sufficient voice in design decisions to forestall poor choices or inadequate research.

Patients should be a part of the design team. Designers, builders, administrators, and even clinicians have objectives and agendas that might obscure astute and appropriate observations from the customers of the health care enterprise. Health care now tends to focus on the illness of the patient rather than on his/her care. Talking to patients and their families might reveal valuable insights about the layout and design of the care environment.

Conclusion

Managing a large and diverse design team is a challenge, even on the smallest project. Leadership is needed to give the team a few, tangible, overarching objectives and guidelines for participation. We believe that highly diverse teams, if properly managed, have the best chance of producing health care environments that not only foster the culture of patient safety, but also support the mission of caring.

We also contend that education about patient safety, reallocation of certain building design resources, and fundamental changes to the design process used to create health care buildings are required in order to correct the disparity between life safety and patient safety. Both types of safety involve cultural issues or characteristics of health care institutions; neither type is achieved solely by application of isolated, nonconnected protection or regulatory features. Both types of safety have aspects of interdependence with the environments in which operations are conducted. In the case of fire and life safety, significant changes to design concepts and methods were part of cultural changes to organizations. On the other hand, health care has not undergone such a transformation to date. The need is compelling and immediate.

Next Steps

We propose a design process that has significant differences from the most common current process. These differences, which are characteristics of the new process, include the following:

- A high degree of collaboration is required among design team members.
- The design team comprises a very wide range of stakeholders, including disciplines not normally part of current design commissions (i.e., human factors).
- The entire design team must work together from the start of the project.
- The entire design team must complete various levels, or stages, of the project simultaneously so that information can be shared.
- Advanced techniques must be used to obtain information regarding process and user performance.
- Project leadership concepts and techniques must be suited to the new design process.

Assuming that a particular institution might wish to use a design process of this type for a project, we would offer several first steps and suggestions.

1. An institution should be aware that any new process or technology might have both latent problems and obvious advantages. Institutional management must assess their culture and capabilities to assure that they are willing and able to work through these during the course of

the project. The process we have proposed is not designed to minimize “first costs.” The goal of this new process is to provide safety for patients primarily and safety for staff and operational efficiency as secondary by-products.

2. Team members should be selected based on their willingness to work under the new process and their understanding of its goals.
3. All stakeholders should be willing to develop contractual and relational incentives that support the objectives and the new process. No problem is more intractable in a building project than having team members who are “incentivized” in different ways and toward different goals. Conventional, “industry standard” contracts should be examined carefully.¹⁹ It is natural for parties to want to separate their risks from those that might be borne by others. A highly interdependent and collaborative approach might threaten the “comfort levels” of some.
4. The project execution plan should be created with the informed input of all stakeholders and should address the work of all stakeholders and team participants. The schedule should allow time for completion of each level of detail before proceeding with the next. The schedule should allow time for testing of concepts through simulation, mock-ups, or other tools.
5. The design team should engage regulators by explaining the proposed design process, schedule, and objectives and by requesting waivers or exemptions where necessary. (We are not suggesting waivers to life or public safety requirements, but rather to the review process and requirements.) The design process would produce a set of documents that describe the proposed project, just as the conventional process has done. However, with the proposed process, more information in greater detail would be available.

Our concluding suggestion is that AHRQ expand its role as a catalyst in this area by extending its outreach and its research on the relationship of the design process to the “production” of buildings that enhance safety. Of particular importance is the impact that an organization like AHRQ can have in avoiding certain pitfalls, such as creating “design fads,” which should be recognized as a serious threat in an industry (design) that traces many of its current stylistic roots to the “compounds” of the 19th century.²⁰

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Implementation of Systems Redesign: Approaches to Spread and Sustain Adoption

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Abstract

The widespread gap between evidence and practice for clinical and preventive services argues for a deeper understanding of effective quality improvement (QI) and system change. Using implementation and system redesign sciences, we have developed and used an effective strategy to enable robust implementation of QI initiatives, including clinical practice bundles, within a health care setting. Our program, which applies Lean and systems engineering methodologies, is specifically designed to exploit the five characteristics of effective innovations, as outlined by Berwick. This strategy has been applied in over 21 hospitals (six hospital systems) throughout the State of Indiana and is currently being used as part of the Radically Reducing methicillin-resistant *Staphylococcus aureus* (MRSA) initiative funded by the Agency for Healthcare Research and Quality (AHRQ). The benefits of the process redesign activities are detailed at the business level through a business case analysis. Additionally, benefits at the personal level are quantified through workflow analysis (prior to and following the interventions). The intervention strategy is integrated into the current quality framework for each organization to ensure compatibility with existing organizational programs. Our staff engagement, training, and educational programs make systems engineering methodologies and principles readily accessible to frontline staff. Additionally, each project session requires immediate application of tools and techniques. This article will discuss our implementation strategy, provide examples of Lean and systems engineering tool applications, and provide an assessment of spread adoption and sustainability as a function of this implementation strategy.

Introduction

Quality improvement (QI) initiatives within health care facilities are often designed to improve the safety and reliability of patient care processes. Unfortunately, as detailed in several studies,¹ health care organizations often cycle through the multiple QI initiatives without sustained improvement in either process effectiveness or patient outcomes. The result is often increased staff fatigue, a more stressful work environment, and increased patient care costs.

The challenges of transitioning from the decision to utilize an innovation (adoption) to skilled and consistent use of an innovation (implementation)² are well documented in health care and non-health care organizations.^{3, 4, 5, 6} These challenges or barriers include lack of sustained leadership support, inadequate resources allocated for implementation, insufficient staff time to participate, failure to develop robust measurement and data feedback systems, misalignment of

incentive structures, and cultural resistance to change. It is estimated that fewer than 40 percent of health care initiatives successfully transition from adoption to long-term, sustained implementation.⁷

According to Rogers' "Diffusion of Innovations" model, specific characteristics of innovations influence the rate of spread.⁸ Rogers describes the characteristics of an initiative affecting the perceptions of an innovation as "predict[ing] between 49 and 87 percent of the variance in the rate of spread." Moreover, in adaptating this model specifically to health care, and citing works by Van de Ven,⁹ Berwick notes five characteristics of innovations that are particularly influential among potential adopters within a health care setting: (1) the "perceived benefit of the change," 2) "observability" of the innovation, (3) "compatibility" of the change with the current organizational culture and personal belief systems, (4) level of "simplicity" of the innovation, and (5) "trialability" of the innovation.¹⁰

In 2003, the Institute of Medicine's (IOM) report "Crossing the Quality Chasm"¹¹ recommended the use of systems and industrial engineering techniques to systematically examine and redesign clinical processes. A subsequent National Academy of Engineering report made the same recommendations.¹² Lean is a QI methodology based on systems and industrial engineering techniques. Lean techniques have been empirically documented as highly effective for systems redesign within manufacturing environments. Moreover, ample evidence suggests that appropriately developed and optimized Lean techniques are effective within health care settings.

Since 2004, faculty from the Purdue University College of Technology, Indiana University-Purdue University Indianapolis (IUPUI)'s School of Engineering and Technology, Purdue University-Calumet College of Technology, the Regenstrief Center for Healthcare Engineering (RCHE), and the Indiana University Center for Health Services and Outcomes Research at the Regenstrief Institute, Inc. have partnered with several Indiana hospitals and hospital systems to create Lean and Six Sigma[®] health care programs. As a part of this program, we developed, implemented, and refined strategies to enable robust QI implementation through application of Lean and Six Sigma tools, methodologies, and techniques.

Our program was specifically designed to incorporate findings from the implementation science literature and to exploit the five characteristics of successful innovations as defined by Berwick.¹⁰ As a result of this program, over 40 projects are ongoing or completed across 21 hospitals and 6 hospital systems. These projects have shown remarkable success; more than 78 percent of completed projects exhibit sustained improvement of at least 6 months, with our longest running projects now in their second year of sustained implementation.

This article discusses our Lean Healthcare program and implementation strategy, provides specific examples of Lean and systems engineering tool applications, and assesses sustainability and spread adoption as a function of this implementation strategy.

Methods

Lean Healthcare

Lean is derived from methodologies developed in the Japanese automobile industry. It is a systematic approach to improving the reliability of processes through the identification and elimination of operational barriers and sources of variability within a process or system.

Within health care processes, the application of Lean tools involves an in-depth examination of the clinical and operational processes from the perspective of the patient or staff member in order to identify value added and non-value added steps—i.e., “wasteful” processing steps within the system. This analysis is limited in scope to the process under investigation and might include qualitative and quantitative assessments.

Our Lean Healthcare methodology utilizes a project team that is typically composed of frontline staff (e.g., nurses, clerks) and area supervisors from the project focus area. The project team is responsible for redesign of current processes or systems to meet the objectives, timeline, and deliverables set out by an administrative Champion Team. The Champion Team is typically composed of hospital administrators and department managers for the process under investigation. Our current strategy calls for a 12-week implementation cycle, composed of eight 3-hour project team sessions, held approximately 1 week apart, with 4 weeks of pilot implementation. Additionally, we are currently developing and testing a rapid cycle (5-day) implementation process.

Each project session incorporates approximately 1 hour of instruction in systems redesign and implementation science principles, methods, and tools, including practical examples based in health care and case studies. Then, hands-on exercises are used to reinforce principles and provide a mechanism for more active engagement. Following the instructional portion of each session, the team members apply these systems engineering and Lean techniques to the assessment and redesign of current processes associated with implementation of a set of clinical practice guidelines or operational improvements. Intersession deliverables are assigned to accomplish project tasks not completed during team sessions.

The objectives for the project team sessions included the following:

1. Define the problem/processes under investigation.
2. Collect baseline data on current systems and processes.
3. Identify operational barriers and failure modes in current processes.
4. Develop the “Future State Process” through application of basic and advanced Lean tools, systems engineering, and implementation of science principles to redesign current processes to eliminate or mitigate failure modes; design and perform an implementation pilot to test process redesign.
5. Implement new processes/systems with a robust control strategy and integrate them into practice in order to insure long-term sustainability of improvements.

The techniques and methodologies utilized within our Lean Healthcare program are outlined in Figure 1.

Implementation Design

Improving the perceived “benefit” of the change. QI initiatives within health care are, by definition, developed to benefit the patient through improved quality of care. In spite of the potential to improve patient outcomes significantly, these initiatives are often perceived in a negative manner as being just another “flavor of the day” management activity. Both individual (staff member) and administrative (business) perspectives might not appreciate these initiatives for their true purpose. These negative perceptions can develop prior to or during implementation.

Why does this negative perception exist? The reality is that implementation is time- and resource-intensive both from an organizational standpoint and an individual staff member perspective. The enthusiastic fervor that initially accompanies the introduction and adoption phase of an apparent innovation wanes as the burdens of implementation and sustainability are realized.

Furthermore, QI activities often fail to integrate changes within workflow or to adequately assess and provide feedback on progress to staff involved in making the changes. Additionally, health care administrators often hesitate to fully support implementation unless these efforts can be directly linked to a positive financial impact within their organizations.

Without strong administrative support, the time and resources required for full implementation might not be allocated, and the organizational climate needed to drive the transition from the adoption phase into sustainability might not be fully realized. The result is that the sustained system

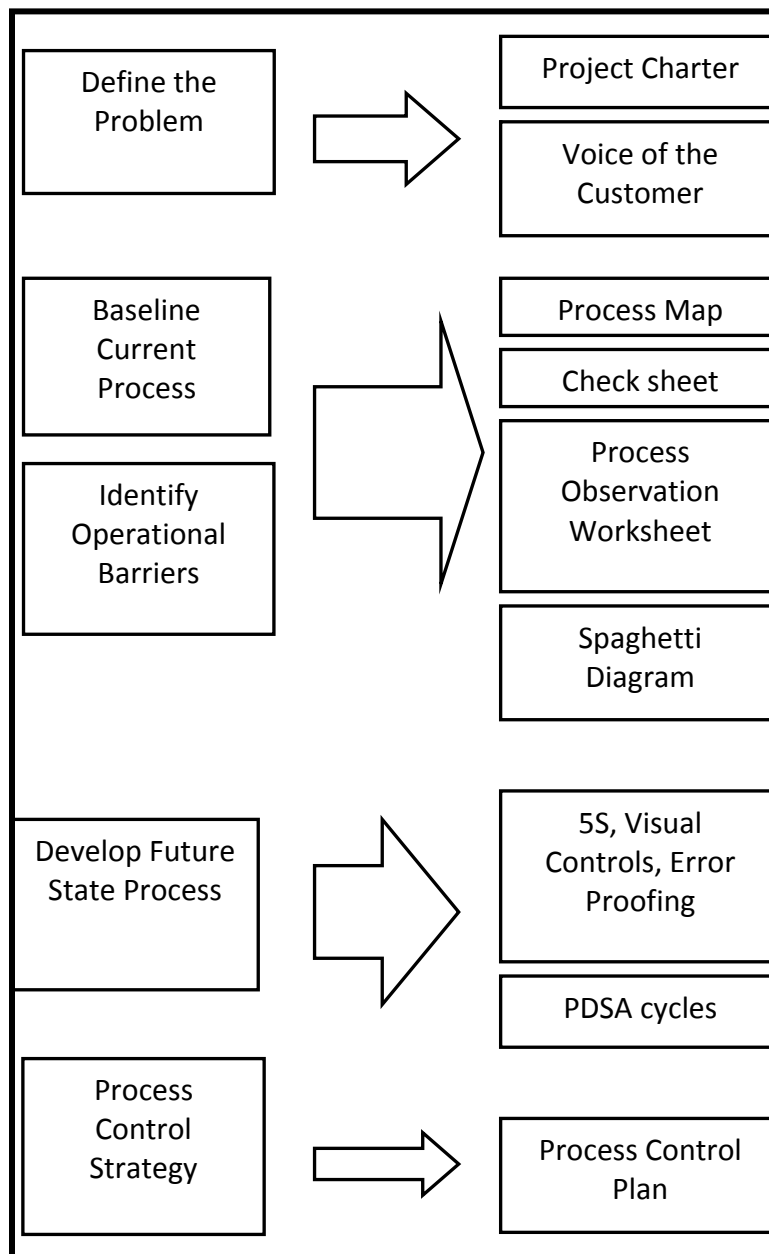


Figure 1. Techniques and methodologies utilized within the Lean Healthcare program.

changes needed to establish the innovation into workflow and the organization do not occur, and the implementation eventually fails. This cycle of failed implementation ultimately jeopardizes the interest of the organization and individual staff members in investing in future initiatives.

The focus of our work in this area has been to fully inform administrators of the organizational benefits of the initiative. This alliance with administrators is accomplished through the engagement of a project champion team to align the initiative with organizational strategic goals and the introduction of economic assessment tools that allow the champion and project teams to directly link the initiative's bottom-line cost savings to improved patient outcomes and staff workflow. This methodology has been termed "building the business case" for QI within health care. The lack of this "business case" has repeatedly been cited as a limiting factor to sustainable implementation within health care.^{13, 14, 15, 16}

The project champion team is typically composed of hospital administrators, department managers, and key clinicians (or opinion leaders) who are stakeholders for the process under investigation. During a series of project champion meetings, open discussions are held with respect to the proposed QI initiative, the evidence supporting the innovation, data on relevant local processes and procedures (if any), anticipated barriers and challenges with respect to implementation, and whether an imperative exists within the organization leadership to provide the necessary support (e.g., resources, time) to ensure a successful implementation.

Project champions are also tasked with building an initial business case for the initiative utilizing an economic assessment template [or other internal return on investment (ROI) template]. The business case analysis includes anticipated expenditures resulting from the intervention/implementation (including training costs), as well a summary of potential economic and strategic benefits to the organization.

As a result of this process, the champion team occasionally decides not to pursue the initiative or to delay until another project cycle, and no further action is taken. Once a decision is made to move forward, the champion team develops the initial project scope, identifies project goals and objectives, and develops a list of expected project deliverables.

Once the project team is chartered and the project initiated, project leaders and team members are expected to appropriately quantify potential project ROI prior to project implementation and validate ROI following implementation. To provide a mechanism for project team members to confidently link their project implementation to direct and indirect economic impacts, we have developed a practical, accessible methodology for standardized evaluation of the financial impact of health care improvement projects.¹⁷ The methodology developed includes Excel[®] spreadsheet-based ROI tools, accompanying training materials used to enable project leaders and team members to suitably quantify potential project ROI prior to project implementation, and to validate ROI following implementation.

The objective of the ROI tool and exercises includes providing project team members with an in-depth understanding of the importance of appropriate financial analysis in achieving management support of operational and patient care improvement efforts. This understanding is reinforced through a hands-on training exercise that provides practical application in

identification and quantification of financial impact, productivity impact and materials, equipment, and purchased services cost savings.

“Observability” of the initiative. Theories of diffusion of innovation within organizations categorize the personality characteristics of potential innovation adopters into five clusters:⁴

1. Innovators.
2. Early adopters.
3. Early majority.
4. Late majority.
5. Laggards.

Within this framework, innovators are estimated to represent about 2.5 percent of the general population, early adopters about 13.5 percent, early majority about 34 percent, late majority about 34 percent, and laggards the remaining 16 percent. Rogers⁸ asserts that the transition between adoption and implementation develops a self-sustaining momentum, when 15 to 20 percent of individuals have embraced the initiative (i.e., the “tipping point”). Berwick¹⁰ describes this phenomenon as being dependent on the interactions that occur among innovators, early adopters, and the early majority during the adoption phase.

Unfortunately, the typical model for implementing change within health care organizations provides very little interaction or dialogue between the supervisors planning the initiative and the health care professionals who must sustain the initiative. For example, meetings to plan clinical practice implementations or to improve clinical processes are often conducted well outside the patient care environment without an appropriate team of health care providers who would be responsible for adopting the processes. Staff input may be obtained, but this often occurs on a superficial level after key decisions have been finalized. Additionally, staff members who express concerns about deficiencies in new processes or procedures are often marginalized or ignored, limiting their capacity or interest in actively engaging in the implementation process and systematizing the changes to the organization.

Our focus in this area has been to develop implementation strategies that (1) promote positive engagement and interaction of the project team with staff members, (2) maximize the “observability” of the project team work, and (3) measure progress and provide feedback regularly.

Within our Lean Healthcare program, the engagement cycles of project team members with outside staff members begin immediately through a series of informal staff interviews know as “Voice of the Customer” Analysis. Within this exercise, “customers” are loosely defined as any individuals who would be affected by the adoption and implementation of the program. In addition to staff members (nurses, physicians, pharmacists, clerks, and others) within the patient care areas, customers might include representatives from environmental services, materials management, ancillary services, physicians, managers and supervisors, and administrators. Additionally, project teams often elect to include patients and their families within this process. Typically, each project team member interviews three to four individuals. The project team members are instructed to briefly introduce the initiative and then conduct an informal 5- to 10-minute interview while taking careful notes.

Sample questions for “Voice of the Customer” analysis include:

- What do you like about the current processes/procedures/policies related to the specific QI initiative?
- What do you think needs improvement?
- What would you recommend to improve the current processes/procedures/policies?
- What could potentially threaten the success of this initiative?

The notes from these interview sessions are discussed and summarized during the subsequent project team session. In addition to providing an opportunity for active engagement with staff members, the Voice of the Customer interviews are essential for understanding and validating customer requirements, expectations, and areas of dissatisfaction with the current processes. The most frequently occurring “needs improvement” and “recommendations for improvement” areas are prioritized. Plan-do-study-act (PDSA) cycles to develop, test, and implement solutions are often initiated immediately following this project session. This rapid resolution of “low hanging fruit” issues within the processes also provides a valuable opportunity to positively affect perceived benefit of the initiative.

Although several engagement activities, such as Voice of the Customer analysis, are intentionally built into the implementation, the project team is also challenged in each project session to develop and test innovative methods of engaging staff members and customers. Multiple techniques have been found to effectively increase project team and staff member interaction and to make the work of the project team highly “observable.” These techniques include encouraging project team members to identify innovators and early adopters outside the project team and to include these individuals in workflow analyses and Lean tools applications during the PDSA cycles. Additionally, physical process changes are often developed initially as prototypes and are displayed in break rooms for staff feedback.

Ensuring “compatibility” of the change and reducing complexity of the innovation. QI initiatives—such as those for implementing clinical practice guidelines or new health informatics technologies (e.g., clinical reminders)—are often introduced during the adoption phase, utilizing a series of policy and procedure modifications and educational inservices, with minimal consideration for organizational culture, current workflow processes, and the level of engagement of the frontline staff members.¹⁸ What results is often a set of policies, procedures, and processes that might be overly complex, impractical, and difficult for frontline staff to successfully apply and integrate with current patient care practices, regardless of their commitment to improving patient outcomes.

Additionally, in spite of the success of systems redesign methodologies (e.g., Lean and Six Sigma) in manufacturing environments, these tools often are not directly applicable within a health care setting.¹⁹ They also might be difficult for frontline staff members with no formal systems engineering background to utilize. The absence of the “translation” to the health care language for Lean and the need for developing relevant case studies and examples into a health care dialect have been cited as factors limiting the adoption of these practices within health care.

In order to increase the “compatibility” factor of implementation efforts, our work has strongly focused on the design of systems engineering methodologies and principles that are readily

accessible and relevant to health care frontline staff members with little or no prior background in application of these tools and the use of these “translated” systems-engineering methodologies to assist frontline staff members in the redesign and optimization of staff workflow practices to complement components of the quality initiative.

Within our Lean Healthcare program, a technique called Workflow Analysis is used by the project team to examine the clinical and operational processes from the perspective of the patient or staff member and to identify opportunities for systems redesign. Workflow analysis is derived from human factors engineering, where this term describes the study of the human-computer interaction with software and hardware systems. A workflow analysis study²⁰ is typically used to obtain data on baseline existing clinical processes prior to the improvement cycle and to validate process outputs following system redesign. While conducting an analysis study, direct process observation techniques are used to physically observe the process under investigation. Lean tools and techniques, such as process flow diagramming, direct process observation, spaghetti diagramming, and checksheets, are used by the project team members to collect data to identify and quantify the impact of operational barriers.

An example of workflow analysis outputs from a project to implement intensive glycemic control in a critical care unit is shown in Figures 2a-c.¹⁹ These figures are from a published case study detailing the implementation of several clinical care bundles on a critical care unit. This particular workflow analysis examined the process of performing a glucose test on that unit. Note that the process observation worksheet (Figure 2b) indicates that, for this particular observation, the nurse spent 10 minutes searching for a glucometer to perform the glucose test on a patient. As published in this case study, the average time to find a glucometer on this unit was 11 minutes. The path the nurse took during the search for equipment and supplies is shown in the spaghetti diagram (Figure 2c).

Following identification of operational barriers, Lean tools and concepts—such as 5S, visual controls, and constraint management—are introduced to the project team through the use of health care-based case studies and hands-on simulation exercises. The latter exercises are developed specifically to mimic actual health care situations, such as locating equipment and supplies on a nursing unit and patient flow through an emergency department. Multiple rounds are conducted to simulate actual process improvement and to build team members’ confidence in applying Lean tools. These tools are then directly applied to the project team members systems and processes in order to improve the functionality of clinical processes associated with practice bundles.

Within our Lean Healthcare program, the faculty facilitator typically allows 1 week between the training session and a designated “report out” session. Each training group is given a stopwatch, multiple process observation worksheets, and a digital camera.

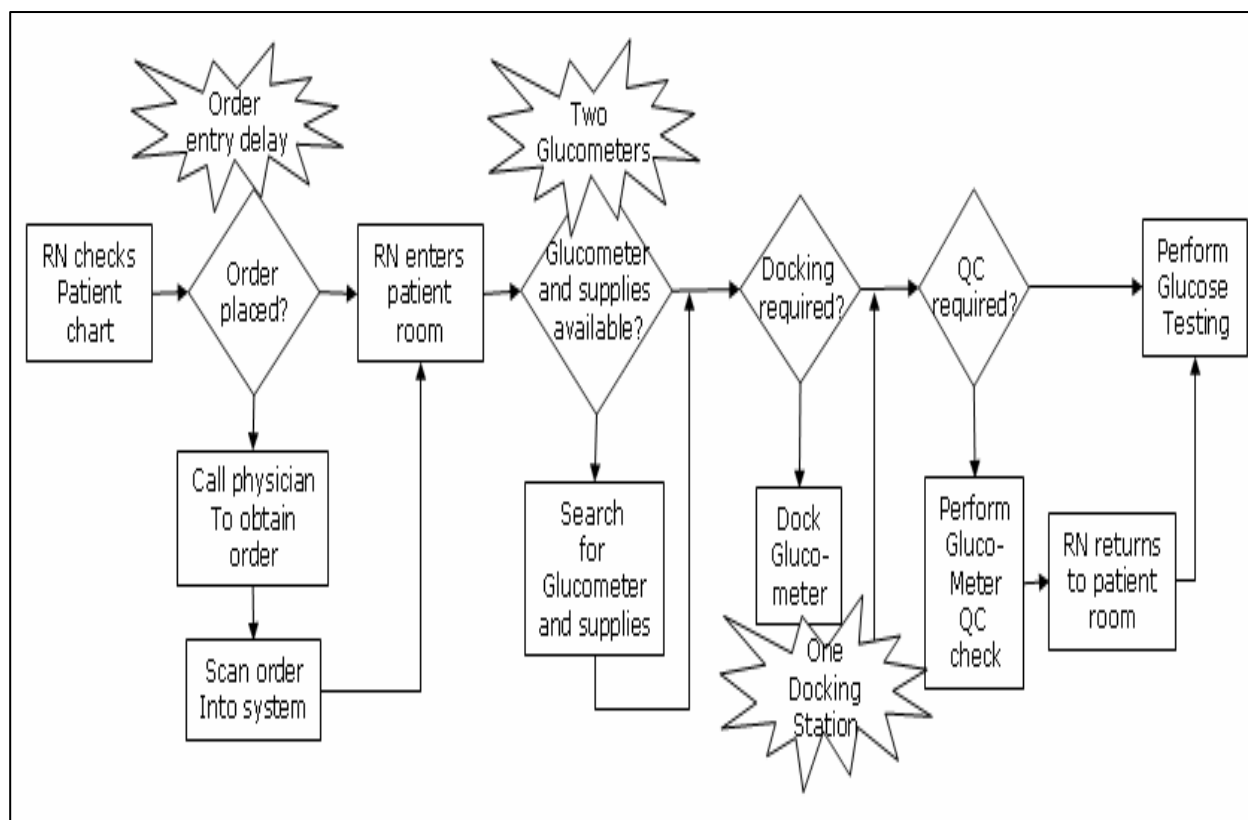


Figure 2a. Process flow diagram for performing a glucose test on a critical-care patient. Adapted from Woodward-Hagg H, El-Harit J, Vanni C, et al. Application of Lean Six Sigma techniques to reduce workload impact during implementation of patient care bundles within critical care – A case study. Proceedings of the 2007 American Society for Engineering Education Indiana/Illinois Section Conference; 2007 Mar; Indianapolis, IN. Used with permission.

Process Observation Worksheet

Step #	Description	Distance	Clock Time	Task Time	Wait Time	Observations
1	RN checks patient chart	0	0			
2	Order Obtained? - If No, call physician to obtain order, scan order		2:00	2:00		
3	RN enters patient room	20	2:30	0:30		
4	Glucometer and Supplies available? - If no, then search for Glucometer and Supplies.	500	12:30	10:00		entered 4 rooms to find glucometer
5	Docking required? - If Yes, then goto Docking station.					
6	QC? If Yes then find QC equipment. - If Yes, then perform QC. - RN Returns to patient room	20	13:00	1:30		
7	Perform Glucose testing	0	13:30	0:30		

Figure 2b. Example of process observation worksheet used during workflow analysis for Glycemic Control Project. Adapted from Woodward-Hagg H, El-Harit J, Vanni C, et al. Application of Lean Six Sigma techniques to reduce workload impact during implementation of patient care bundles within critical care – A case study. Proceedings of the 2007 American Society for Engineering Education Indiana/Illinois Section Conference; 2007 Mar; Indianapolis, IN. Used with permission.

The training groups apply workflow analysis techniques to baseline their current processes, identify an area or instance of “waste” within their processes, and apply Lean tools to improve the processes. The groups are then expected to collect processing time information for the improved process in order to quantify the improvement.

The results are also translated into cost impact as part of the business case analysis, quantifying the benefit on an individual and organization level. The digital camera is used to record processing conditions prior to and following improvements. Team members are encouraged to summarize their results, including photos, into a 5- to 10-minute presentation or storyboard for the report-out session.

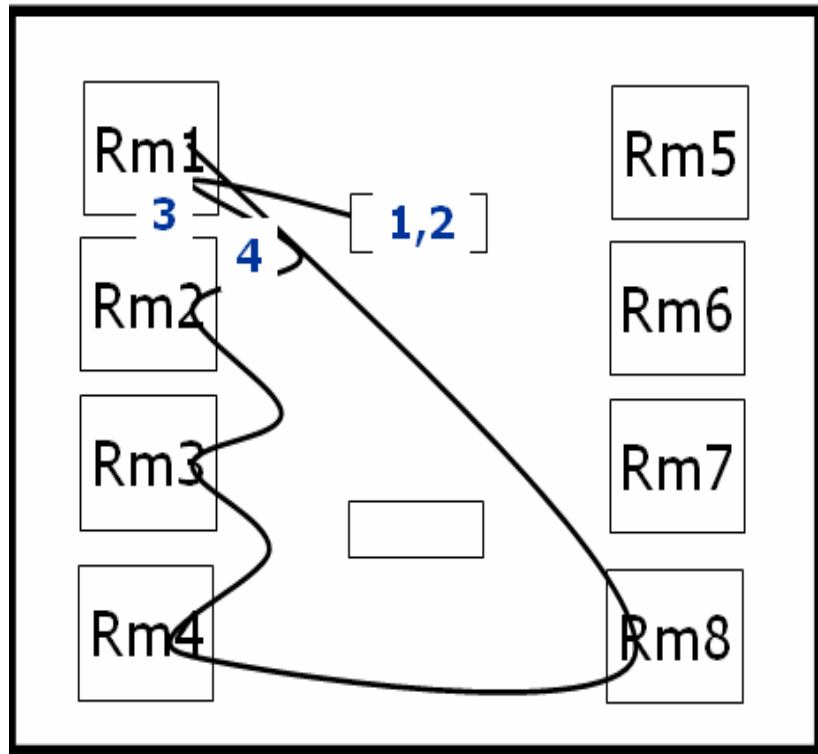


Figure 2c. Example of “spaghetti diagram” used during workflow analysis for Glycemic Control Project. This diagram depicts the movement of the nurse while searching for a glucometer. Adapted from Woodward-Hagg H, El-Harit J, Vanni C, et al. Application of Lean Six Sigma techniques to reduce workload impact during implementation of patient care bundles within critical care – A case study. Proceedings of the 2007 American Society for Engineering Education Indiana/Illinois Section Conference; 2007 Mar; Indianapolis, IN. Used with permission.

“Trialability” of the Initiative

Throughout our experiences in facilitating health care teams in systems redesign, our faculty facilitators have consistently noted that when project team members were encouraged to immediately apply Lean tools introduced during the project sessions to “test” improvements within their own work environments, these teams were more successful with respect to long-term retention and application of these tools, compared to those who might have delayed implementation. The facilitators also noted that these applications were more likely to be sustained over the duration of the implementation if the team went through several test cycles prior to final implementation. Additionally, solutions following these multiple tests of change were often highly customized in comparison to solutions generated by other project teams implementing similar QI initiatives.^{20, 21}

The need for adaptation and customization to sustain change in health care is well documented and is believed to be the one of the fundamental requirements for spread of innovations.²² However, Lean and systems engineering techniques, as applied within manufacturing, rely heavily on a foundation of standardization of processes and systems. As engineering and technology faculty with backgrounds in manufacturing applications of systems redesign, we

initially struggled to reconcile the level of customization necessary to provide sustainability and the level of standardization that is often a characteristic of successful Lean process design in a manufacturing environment.

However, the more we investigated this phenomenon, the greater our understanding that the complex and dynamic nature of health care systems and processes often precludes standardization at a level that is typically required within manufacturing applications of systems redesign. As a result, within our program, we have opted to include both customized and standardized components. The general guideline we have developed is that standardization of processes, policies, and procedures must occur where evidence-based literature exists, linking specific clinical practice to patient outcomes.

All other clinical workflow processes related to implementation (and for which no evidence linking to patient outcomes exists) can be customized to best fit the needs of a particular project team or organization. For example, within a recently AHRQ-funded MRSA (methicillin-resistant *Staphylococcus aureus*) collaborative, the requirements for when a patient should be placed in isolation were standardized among participating hospitals because there was evidence to suggest that contact isolation reduced the likelihood of transmission. However, the processes and procedures that have been developed associated with placing colonized and infected patients in contact isolation vary greatly across participating health care facilities and even within facilities. Therefore, customization of these processes and procedures is necessary to compensate for systematic, cultural, and organizational differences.

For aspects of the implementation not requiring standardization, project teams are encouraged to optimize workflow practices through application of Lean and systems engineering principles by utilizing small, incremental tests of change, also known as PDSA cycles. An added benefit of this technique is that allowing project team members to optimize their own workflow processes through the PDSA cycles ensures that the resulting process and system changes fall within the project team members' capacity for technical complexity and within their confidence level to implement the changes successfully.

Additionally, as the complexity of the interventions increases, project pilots are often utilized to provide a test bed for parallel implementation of multiple PDSA cycles. A pilot implementation plan is generated to test the solutions through a 4- to 6-week timeframe. Often, during the pilot, the scope of the implementation can be reduced to a specific patient population or unit. A pilot implementation plan is created to detail actions that must occur prior to implementation of a specific aspect of the process redesign. Project team members are assigned as owners for individual action items, and dates for completion are determined.

The project team also develops a process control plan prior to implementation. This plan includes components of data feedback from the processes and creation of an administrative infrastructure to encourage sustainability of process improvements.

The control plan is developed to ensure regular feedback of process performance data during and following implementation. Typically, daily data collection and feedback are used throughout the pilot implementation, with the frequency of feedback decreasing as improvements are sustained and the implementation "tipping point" is reached as the project is adopted and integrated.

To continue project observability following implementation, results from daily data collections are often displayed prominently within the process areas to encourage staff discussion of progress and to foster awareness among staff members, including those not on the process team.

Results and Discussion

To date, the implementation strategies outlined above have been used in over 40 QI projects, 21 hospitals, and 6 hospital systems within the State of Indiana.

To evaluate the effectiveness of our implementation strategy, each of the 36 completed

projects was retrospectively evaluated to assess the sustainability of improvements over time and the extent of spread of Lean and systems engineering techniques beyond the initial project focus area. Table 1 outlines the evaluation criteria used in this assessment, and Table 2 presents a list and count of projects by topic.

As shown in Table 2, 89 percent of projects (32/36) have been implemented and improvements sustained for at least an initial 4-week pilot period. A summary of the sustainability and spread assessment results is presented in Table 3. Of those projects that were implemented, 78 percent (25/32) were found to have sustained the majority of project goals for more than 6 months. Additionally, 75 percent of projects (24/32) resulted in the spread of Lean, systems engineering, and implementation science principles beyond the initial project focus area with limited faculty assistance.

Of the four projects that failed to make the transition from adoption to implementation, one failed due to the complexity of the proposed redesign; the other three failed due to lack of administrative support during the pilot phase, which likely reflected a failure of perceived benefit to the organization.

Table 1. Assessment scales used in this study

Sustainability assessment scale	
Excellent	Initiative sustained to goal for majority of primary control metrics for >9 months following implementation
Good	Initiative sustained to goal for majority of primary control metrics for >6 months following implementation
Fair	Initiative sustained to goal for majority of primary control metrics for >3 months following implementation
Poor	Initiative did not sustain to goal for majority of primary control metrics for ≤3 months following implementation; other significant implementation issues existed
None	No implementation occurred
Spread assessment scale	
Excellent	Systems engineering principles spread to other unit or project focus with no faculty assistance
Good	Systems engineering principles spread to other unit or project focus with limited faculty assistance
Fair	Some evidence of application of systems engineering principles beyond initial project area
Poor	No evidence of application of systems engineering principles beyond initial project area

Conclusion

Our program for successful implementation and sustainability of QI initiatives in health care emphasizes principles of Lean manufacturing, systems engineering, and implementation science. This approach specifically emphasizes+ working to incorporate staff engagement and ownership, including training programs that make these methodologies and principles readily accessible to frontline staff with little or no prior experience. Furthermore, each project session requires immediate application of tools and techniques to the processes under investigation with ongoing measurement and feedback of the impact. The benefits of the process redesign activities are detailed through a business case analysis and through quantifying the impact of process redesign utilizing workflow analysis. Through a consistent application of these principles, we have found that interventions are integrated into workflow, adopted, and sustained over time.

Table 2. Completed projects by category

Project categories	Project implemented? (N)	
	Y	N
ED patient flow	1	2
Surgical flow	3	
Outpatient scheduling/registration	2	
ICU admission process redesign	1	
Hospital lab process redesign	4	
Discharge process redesign	2	
IT process redesign	2	
Medication delivery process redesign	2	
Equipment/supply area redesign	2	
ICU LOS reduction (incl VAP / glycemic control bundles)	5	
Implement central line bundle	1	
Implement MRSA bundle	6	
Patient fall reduction	1	
Radiology capacity optimization		2
Totals	32	4
Percent projects implemented (%)	88.89	

Table 3. Summary of project sustainability and spread assessment

Project categories	Sustainability ^a				Spread ^a			
	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor
Number of projects	14	11	7	0	12	12	5	3
Total projects (%)	44	34	22	0	37.5	37.5	16	9
% projects sustained >6 months	78							
% projects exhibiting spread with limited or no faculty assistance	75							

A Sustainability and spread assessment performed only on projects that were implemented.

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Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement

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Abstract

Objective: The morbidity and mortality conference (M&MC) is a traditional forum that provides clinicians with an opportunity to discuss medical error and adverse events. In an effort to promote patient safety at our institution, we implemented a monthly interdisciplinary morbidity, mortality, and improvement (MM&I) conference, which focused on systemwide problems. The participants included physicians, nursing staff, pharmacy, and other clinical departments, as well as senior hospital administrators. **Methods:** A Mortality Review Task Force selects cases for presentation at the monthly MM&I. A resident representative presents the case, and a designated senior faculty member facilitates a discussion of the case with audience participation. Key issues that contributed to the undesired outcome of the case are identified and outlined on a cause-and-effect diagram (Ichikawa diagram). Workgroups are created to target systems-based problems. At the end of the conference, attendees are asked to complete an evaluation and provide feedback for subsequent consideration by the task force. **Results:** Twenty-one cases (12 medical, 9 surgical) representing adverse events were presented at the MM&I conference from January 2005 to February 2007. The mean number of participants per session was 88 (range, 62-115). Adverse events triggering case selection included unexpected deaths (six), unplanned intubations (two), prolonged medical care in the setting of poor prognosis (one), delay in care (nine), and procedural complications (three). The most common factors contributing to adverse or “near-miss” outcomes in these cases were communication failures and inadequate coordination of care. In all, 33 action items were created, and 23 (70 percent) have been completed to date. **Conclusion:** A structured hospital-wide MM&I conference is an effective means of engaging physicians, nurses, and key administrative leaders in the discussion of adverse events. The identification of potential system failures and the creation of workgroups to address specific systems-based problems can promote initiatives to improve patient care and safety.

Background

In order to provide high quality patient care, members of a multidisciplinary health care team must engage in objective, nonjudgmental review of adverse outcomes and commit to systematic process change. The morbidity and mortality conference (M&MC) is one forum that provides clinicians with an opportunity to discuss medical error and adverse events. The M&MC became a major part of physician education in the early 20th century, following the publication of the Flexner report on medical education in 1910 and the creation of the American College of

Surgeons in 1912.^{1, 2} These early conferences were attended primarily by surgeons and anesthesiologists and were used to examine medical errors and adverse outcomes in an attempt to improve surgical practice.

Over the years, the M&MC has evolved into a forum for resident education. The conference is now a required component of surgical resident training, mandated by the Accreditation Council for Graduate Medical Education (ACGME),³ and it is also widespread among internal medicine and pediatric training programs. Despite the extensive presence of the M&MC, the format of the conference varies tremendously among academic programs, and the goals of the conference often are not clearly defined.⁴ Many of the cases presented for discussion are selected because of their educational interest or potential teaching value and often lack identification and discussion of adverse outcomes.^{5, 6, 7} Biddle reviewed cases presented at the anesthesia M&MC at his institution and found that 72 percent involved neither morbidity nor mortality.⁶ In a cross-sectional review of the medicine M&MC at four major hospitals in California, Pierluissi found that most of the allotted time was spent on case presentation and guest speaker commentary, with very little audience participation or discussion of error.⁷

When error is discussed in the M&MC, the focus is often on an unexpected adverse outcome instead of events related to processes of care that might have contributed to the error.⁵ Physician trainees attending the M&MC often feel that the purpose of the discussion is to assign blame for an error rather than to improve patient safety.^{5, 8} Systems-based issues are rarely identified, and often there is not enough time to discuss specific interventions to improve patient care across systems of care.

In an effort to promote patient safety at our institution, we implemented a monthly hospital-wide morbidity, mortality, and improvement (MM&I) conference, which focused on systems-based problems at our hospital and included representation from multiple clinical departments, as well as from senior hospital administrators. Here, we describe our first 2 years' experience with the MM&I conference and discuss the lessons learned.

Process and Methodology

The Monroe Carell, Jr. Children's Hospital at Vanderbilt (MCJCHV) is a 222-bed tertiary care children's hospital that is part of a large academic medical center. The MM&I is part of our formal peer review and quality improvement processes sponsored by the offices of Performance Management and Improvement (PMI) and Risk Management.

Case selection. A Mortality Review Task Force reviews potential cases and selects cases to be presented at each conference. Eligible cases include all deaths, significant patient injuries, and near-miss situations that could have resulted in death or patient harm. Any member of the health care team at any level or location in the institution can recommend specific cases to the Mortality Review Task Force. The referral remains anonymous in order to encourage submissions of cases that might involve emotionally charged or difficult situations. Other sources of potential cases include departmental or unit-based M&MC and the office of Risk Management.

The Task Force is composed of senior attending physicians and residents from pediatric surgery and pediatric medicine, community pediatricians, hospital administrators, and leaders in nursing, pharmacy, and radiology. Two pediatric resident volunteers serve as conference coordinators

each academic year. Rather than focusing on individual caregiver errors, the Task Force selects cases that potentially involve systemwide problems or issues that affect more than one patient care population or single hospital unit. The case selection is made by consensus of the Task Force.

Case preparation and presentation. A core team—consisting of senior quality consultants from PMI, the resident coordinators, and a senior attending facilitator—is responsible for preparing the case for presentation. In the month preceding the MM&I conference, the core team meets to gather and review pertinent documents from the patient’s hospitalization from the initial encounter until disposition from the hospital or clinic. In order to highlight specific systems issues that might have contributed to the adverse event, the case details are then summarized in a time series flow diagram. This process generally requires two to three 60-minute meetings. The resident coordinators also spend an additional 2 to 3 hours preparing a brief literature review of the disease or illness specific to the case.

All clinical faculty and staff are invited to attend the conference. Health care providers involved with the case receive a special invitation to participate in the conference. In addition, subspecialists are invited to comment on specific aspects of the case. For example, pediatric radiologists are asked to review the appropriate imaging studies related to the case. The presentation is organized in slide format for presentation with Microsoft PowerPoint®.

Conference. Attendance at the MM&I is encouraged for all hospital physicians, residents, nursing staff, and clinical support staff, regardless of level of training or provider status. As part of the institution’s peer review and quality improvement processes, the MM&I discussion is considered privileged and confidential.

Table 1 shows the conference outline. Every conference begins with a reminder of the systems-based approach to identifying problems and the confidentiality of the discussion. One of the pediatric resident coordinators presents the patient’s management and hospital course in a timeline format. Appropriate data are reviewed, including vital signs measurements, nursing

Table 1. Conference outline

MM&I conference outline	Time allotted	Participants
• Opening: Reminder of systems-based approach and confidentiality	5 min	Leader
• Review of task force progress from prior conferences	10 min	MMI task force
• Case presentation (timeline format)	10 min	Resident leaders
• Brief literature review relevant to case in question	5 min	Resident leaders
• Identification of key issues leading to undesired outcome	25 min	All participants
• Identification of workgroups to address the key issues	10 min	MMI task force
• Reminder of confidentiality	5 min	Leader
• Evaluation of conference	5 min	Leader

assessments, laboratory and radiographic data, and physician physical examinations. Deidentified records from the patient's chart are used throughout the presentation as appropriate. A computerized system (Turningpoint, Turning Tech, LLC) prompts the audience to consider which management decisions they would have made at key points in the patient's clinical course. The system provides an immediate summary of their responses, encouraging further discussion.

Throughout the discussion, a cause-and-effect diagram (Ichikawa diagram⁹; Figure 1) is used to identify specific factors that might have contributed to the adverse outcome in the case. The cause-and-effect diagram is a standard process improvement tool for facilitating identification of potential failure points.

These factors are assigned to one of six broad categories: (1) procedure, (2) environment, (3) equipment, (4) people, (5) policy, or (6) other. All participants have an opportunity to identify systems-based issues and recommend potential solutions. After these issues are identified, the discussion leader selects the key contributing factors that need to be addressed.

"Action plans" are created, and specific workgroups are assigned to implement the corrective actions. The action plan identifies a concise intervention, assigns accountability (including completion target timeframes), and tracks the status of implementation. The Task Force is responsible for assisting the workgroups in completing the assigned tasks, and the progress of each workgroup is presented at subsequent conferences.

As the conference is adjourned, the confidential nature of the proceedings is again reinforced. Attendees are asked to complete an evaluation and to provide feedback for subsequent consideration by the Task Force. Evaluations consist of eight questions using a 5-point Likert scale, ranging from "Excellent" to "Poor," with space available for free-text comments. Completion of the evaluations is voluntary and is done anonymously.

MM&I Results

Twenty-one cases representing adverse events were presented in the MM&I conference series between January 2005 and February 2007. Both medical (N = 12) and surgical (N = 9) cases were represented. Adverse events triggering case selection are listed in Table 2. An unexpected death, as identified through root cause analysis (RCA), was the most common reason for case selection. At our hospital, the RCA process is multidisciplinary and interdisciplinary and draws on the expertise and clinical opinion of all participants. Other cases were selected based on

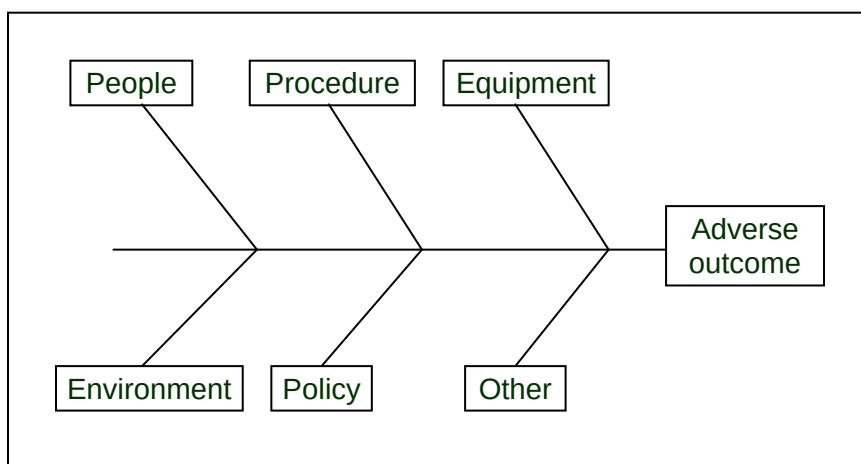


Figure 1. Ichikawa ("fishbone") cause-and-effect diagram.

undesirable outcomes not typically addressed in traditional M&MCs, such as prolonged medical care with poor prognosis.

The presentations also included cases from multiple care sites, including the emergency department, outpatient clinics, inpatient wards, and the operating room.

Table 2. Adverse events triggering case presentations

Case	N
Unexpected deaths	6
Unplanned intubation	2
Prolonged medical care in setting of poor prognosis	1
Delay in care or diagnosis	9
Procedural complication	3
Total	21

Conference participants identified the leading contributors to adverse or “near-miss” outcomes. These contributing factors were categorized by the core team and are summarized in Table 3. Inadequate or incomplete communication among members of the health care team was the most common contributing factor, cited in over 60 percent of the cases.

Attendance. In all, 1,323 participants attended 19 conferences during the 2 year period. The average number of participants per session was 88 (range, 62-115). Attendees included faculty and resident physicians, community physicians, medical students, nurses, pharmacists, case managers, social workers, and senior hospital administrators.

Impact of the conference. The MM&I conference represents an ongoing commitment of The Monroe Carell, Jr. Children’s Hospital at Vanderbilt to improving patient care and safety. During the 2-year period, 33 action items were created to address specific systems-based issues; 23 action items (70 percent) have been completed to date. The action plans developed in the MM&I conferences and the subsequent activities of the workgroup are among the mechanisms by which process improvement occurs.

Example case and action plan. In April 2005, the MM&I conference presented a case in which a postoperative patient experienced respiratory failure on the acute care floor. Excerpts from the

Table 3. Factors contributing to adverse outcome

Factor	% Cases
Communication: e.g., inadequate handoffs; incomplete clinical information	64
Coordination of care: e.g., involving multiple services and/or care sites	36
Volume of activity/workload: e.g., increased clinical volume and/or perception of workload	18
Escalation of care: e.g., delay or failure to involve more senior physician or nurse	14
Recognition of change in clinical status: e.g., delay or failure to recognize changing clinical signs and/or symptoms	14

patient's medical record—including vital signs, nursing care notes, and physician's progress notes—were presented and demonstrated a continued decline in the patient's clinical condition throughout the day, with increased respiratory rate, increased work of breathing, and persistent hypoxia, despite supplemental oxygen. The patient subsequently required emergency intubation and was resuscitated before being transferred to the critical care unit.

After reviewing the available records, the MM&I conference attendees identified multiple contributing factors. From an “environment” standpoint, attendees noted that the timing of the patient's deterioration occurred at nursing shift change, and that likely was a contributing factor. From a “people” standpoint, conference attendees also noted that there was a delay in recognition of changing vital signs by multiple members of the health care team. The attendees identified additional issues under “communication,” including incomplete exchange of key clinical information (i.e., vital signs) between nursing staff and resident physicians and inadequate communication between multiple services involved in the patient's care.

Because of these concerns, an action plan was created to implement the SBAR communication model within our hospital. SBAR (Situation, Background, Assessment, and Recommendation)¹⁰ is a structured communication technique that allows for concise but thorough communication among members of the health care team. The pediatric chief resident and a member of the PM&I office were initially assigned to execute the implementation of SBAR. Ultimately, numerous staff members contributed to this action plan, including members of hospital administration and nursing leaders. This action plan has led to hospital-wide implementation of SBAR as the standard mode of communication among members of the health care team. The SBAR model has been promoted during orientation for new residents and nurses and reinforced during resident didactic conferences and subsequent MM&I conferences.

Limitations

While the MM&I has led to several process improvements at our institution, these process changes have not yet been rigorously evaluated to determine their effects on patient safety, morbidity, and mortality. Our current study is largely a qualitative study that focuses on the MM&I process at our institution. Future research is needed to provide quantitative data on the impact of MM&I-based initiatives. Another limitation of our current study is the low percentage of evaluations completed by conference attendees. While these evaluations provided valuable feedback to the Task Force, the paper forms were completed by only 28 percent of attendees during the first 2 years of the MM&I. In order to elicit more feedback from conference attendees, a new approach to the evaluation process was initiated in May 2007. Conference attendees now utilize the audience response system (Turningpoint, Turning Tech, LLC) to evaluate the conference before the conference is adjourned. This new strategy has resulted in a dramatic increase in the number of evaluations completed by attendees.

Conclusion

The structured hospital-wide MM&I conference is an effective way to engage multiple members of the health care team in a discussion of adverse outcomes, while collaboratively focusing on potential systems-based improvements in patient care and safety. Nonjudgmental case discussion

helps overcome the individual's fear of accusation and criticism, which can stifle honest exchange of information and hinder improvement initiatives. Identification of potential system failures by participants, empowerment of workgroups to address specific systems-based problems, and transparent accountability for regular followup can lead to improved patient safety.

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Collaboratives and Patient Involvement

The Patient Safety Education Project: An International Collaboration

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Abstract

The Patient Safety Education Project (PSEP) aims to advance the shift to patient-centered, systems-based care through high-impact education of health care workers using a superior “train-the-trainer” dissemination mechanism. Employing a core curriculum that includes practice improvement toolkits, PSEP develops “safety trainers,” who teach patient safety and foster its practice among “end-learners” in their own institutions. From 2005 to 2006, PSEP gathered support from leaders and identified learning topics. In 2007, the core curriculum was developed. In 2008, PSEP will be piloted before proceeding to rollouts in the United States and Australia. PSEP will be a course-driven college without walls that works with partner organizations; it will use a nonprofit, cost-recovery, sustainable economic model. Evaluation of PSEP’s impact will measure change in attitudes, knowledge, and simulated skills at our courses. We will also evaluate practice change, patient outcomes, and practice norms in service delivery settings.

Introduction

Since the 1999 publication of the Institute of Medicine’s (IOM) landmark report, *To Err is Human: Building a Safer Health System*, health care institutions have sought solutions to managing newly appreciated sources of risk.¹ These sources of risk include poor systems design, increased technology and complexity, poor teamwork and communication, variations in health literacy among patients, a culture of blame that buries lessons learned, and others.

Although the United States, Australia, the United Kingdom and other nations have made patient safety a clearly articulated national priority, progress has been slow. Fundamental patient safety practices—such as learning from adverse events, working in effective teams, standardizing tools and procedures, and open disclosure of adverse events—are far from universal in health care organizations.

Four fundamental challenges confront us:

- First, despite the existence of considerable information about how to improve care, most health care professionals are not sufficiently educated in patient safety.
- Second, even when existing knowledge is taught, the problem of how to actually use that knowledge to change practice still looms large.^{2, 3} Knowing the universal protocol for preventing wrong-site surgery (or having a policy in place to follow the protocol) is not

effective if staff do not follow the protocol.⁴ Communities of practice that adopt the standards are necessary.⁵

- Third, obtaining knowledge from reporting efforts remains inadequate. Biomedical progress develops from a well-accepted process that begins with basic research, followed by phased clinical trials and health services research. Patient safety, though, relies on methods that make use of reporting and analyzing adverse events and problem solving in real time. Berwick⁶ and Leape⁷ have argued that evidence-based medicine needs to broaden its scope, particularly in relation to quality and safety, and to acknowledge the importance of such approaches to learning, growth, and development. These are very different categories from those found in traditional clinical research.
- Fourth, as articulated in the IOM's 2001 report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, progress in safety and quality depends on alignment among microsystems within the health care workplace and among the organizations in which those microsystems are contained.^{8, 9} These microsystems must, in turn, align with external forces, such as regulatory bodies and payment mechanisms. Examples of misalignment include a legal system that fosters blaming people who make mistakes and a payment system that rewards unsafe care. In the absence of alignment, changes in culture or practice at the microsystem level will most likely neither be accomplished nor sustained.

The Patient Safety Education Project (PSEP) was designed to address these challenges by combining dissemination of existing knowledge with steps to translate this knowledge into better practice outcomes. PSEP was developed by a core team of educators in the United States and Australia. Its target audience includes all health care professionals who have gaps in their knowledge and skills in patient safety competencies. This paper provides an overview of PSEP's development and organization, its strategic vision, and its educational and practice-change methods.

Development and Design of the Patient Safety Education Program

Oversight Structure and Its Role in Program Design and Curriculum Development

In February 2005, a meeting of patient safety leaders was convened at Northwestern University in Evanston, IL, to discuss the need for, and potential design of, a program to bridge existing gaps between current and possible patient safety training. The group found that first, while quality patient safety curricular materials had been produced by a number of highly regarded organizations, no consensus existed regarding a basic, core patient safety curriculum for use in the United States. Second, as evidence of a strong need for such training, they noted that large numbers of health care providers still had not been trained in the basics of safety science or patient-centered care.

The group felt that the general design of PSEP should emulate an education-dissemination project in palliative care that has been recognized as successful: Education in Palliative and End-of-life Care (EPEC), which began in 1997 and is currently housed at the Buehler Center on Aging, Health & Society at Northwestern University. Since the 1990s, EPEC has reached

millions of health care workers.¹⁰ The EPEC program uses a curriculum-driven approach grounded in adult learning methodology to teach content about palliative and end-of-life care to physicians and other medical team members. The EPEC education-dissemination approach utilizes the best adult teaching methodologies and practices and is structured so that course attendees can return to their home institutions to teach others what they have learned.

The group also agreed to use the Australian National Patient Safety Education Framework (ANPSEF) as a starting point to identify core learning topics.¹¹

It was agreed that building on existing curricula resources would avoid duplication and that broad dissemination of a core curriculum had the potential to drive new engagement. The PSEP would be maintained and kept up to date by processes established by a core team that was formed to develop the initial PSEP proposal.

Aware that practice change depends on having broad stakeholder support and leadership, as well as grass roots activity and suitable expertise, a governing council and an expert advisory group (both made up of experts and major thought leaders in patient safety) were established. The governing council convened in Washington, DC, in May 2006, and was hosted by the IOM. The council provided its approval for the PSEP project design and content of the draft core curriculum. The advisory group provided additional input.

As the PSEP project moves forward through pilot, roll-out, and evaluation, the governing council will be consulted periodically at important junctures; the advisory group will be kept informed and involved in their areas of expertise or interest. These bodies will play lead roles in spreading the word about PSEP and its relevance, importance, and availability; and many of their members will become master facilitators or mentors for those engaged in PSEP activities.

Organizational Structure and Programming

The organizational structure of PSEP reflects the needs of its programming design. The core curriculum forms the foundation for PSEP's main offering: 2½-day "Become a PSEP Safety Trainer" immersion courses. These courses are to be held several times a year to generate multidisciplinary teams of safety trainers who will deliver the curriculum content to "End-learners" at their home institutions. End-learners may be clinical, administrative, or executive professionals or other individuals who have a role in implementing patient safety practices or improvement projects in their health care communities.

Safety trainers. "Safety trainers" are professionals, who are involved in health care education or health care delivery—whether as clinicians, administrators, or professionals in related disciplines—who qualify to teach the core curriculum. To become safety trainers, they must take the PSEP course, "Become a PSEP Safety Trainer."

Applications for this course are competitive. To be eligible, applicants must have a commitment from an executive leader in their organization to attend the last half-day of the immersion course, as well as demonstrated support at the executive level of their institution for dissemination within their home organization. Applicants must come as a team that includes at least one physician,

one nurse, and one health care administrator. Others, such as pharmacists or information technology directors, are also encouraged to attend as part of the team. These safety trainers will be trained in both core curriculum content and teaching skills to effectively equip them to convey the core curriculum to end-learners in their home institutions.

End-learners, safety professionals, and practice communities. The ultimate target of PSEP is its end-learners, a category that is broadly construed to include frontline clinicians, managers, a full range of ancillary health care workers (such as receptionists or information technology workers), and executive leadership. Depending on the organization, end-learners may also include governing body members active in patient safety oversight or policy setting. The intent is to create patient safety communities and thereby thoroughly spread effective patient safety practices.

End-learners can become PSEP “safety professionals” by taking all of the plenary and modular units in the core curriculum. Once exposed to the discipline of patient safety, it is expected that some patient safety professionals will be motivated to attend a “Become a PSEP Safety Trainer” course or to pursue further educational opportunities offered by others to develop deeper expertise.

Master facilitators. Master facilitators are safety trainers, who have taken additional training focused on teaching skill development and have been recognized by the core team as competent to teach safety trainers. Initially, they have been recruited based on their experience in patient safety education or practice, as well as their interest in and ability for teaching, mentoring, and quality improvement activity. After establishment of the program, master facilitators will be drawn from safety trainers who have taken additional training in our professional development workshop (discussed later in this paper). As PSEP matures and spreads, master facilitator candidates will emerge from the expanding cadre of safety trainers and end-learners. The program will attract and identify future patient safety leaders and nurture them.

Core team. The core team comprises the lead editors of the safety curriculum from the United States and Australia. Core team members also have administrative responsibility for PSEP and are active in the development, maintenance, and evaluation of PSEP as it matures.

Types of training. As described above, “Become a Safety Trainer” courses will be held several times annually in diverse locations. Approximately 400 safety trainers are expected to be trained during the first 2 years of PSEP; these in turn will teach an average of 100 others. Within the first 5 years of the program, we expect that about 40,000 end-learners will have been trained throughout the United States. A similar roll-out in Australia is planned for 2008, to be followed by roll-outs in other countries.

Based on experience with EPEC, the PSEP dissemination process differs from traditional train-the-trainer models, which suffer from attrition and lack of quality control as layers of hand-me-down training continue. A key difference lies in the distinction between what the master facilitator delivers to the safety trainer and what the safety trainer delivers to the end-learner. The safety trainer will teach patient safety content and implementation to the end-learner without

trying to make end-learners into safety trainers. In other words, safety trainers will not deliver those parts of the core curriculum (described later) that deal with how to teach and mentor.

Safety trainers are encouraged to present sessions to end-learners at their home institutions that fit with local and institutional routines and learning opportunities already scheduled into the health care providers' work lives. Modules can be delivered at grand rounds, seminar series, or purpose-designed settings. Since many modules will take place at the home venue of the safety trainers and participants using local resources, they can be delivered with no special budget.

Safety trainers will select their audience to match the needs and capacities of the setting and the people involved. For instance, this might entail having a safety trainer work with a group from a specific discipline, department, or location. If the safety trainer needs to educate a target group that comes from diverse disciplines, he/she is encouraged to use a team approach.

Teaching to a group that recognizes the safety trainer's authenticity helps establish an informal learning contract—that is, a social expectation that the teaching-learning group can make effective learning progress. Safety trainers can adapt or limit the amount of material they deliver to a portion of the full core curriculum content. For example, if an organization has already invested in a robust program of open disclosure, it might be appropriate to do an overview only on this topic and use the bulk of the session time to explore specific topics included in the disclosure module. Alternatively, if “reducing falls” has been designated a safety priority in the safety trainer's own organization, more depth and analysis of the topic may be desired. In such situations, the resources specifically developed for each module, including implementation kits, should be helpful to safety trainers.

In addition to the “Become a PSEP Safety Trainer” course, safety trainers are eligible to take an annual Professional Development Workshop” designed to foster participants' teaching skills, their capacity to mentor the implementation of safety improvement projects, and their advancement to master facilitator level. The bulk of the 2- to 3-day professional development workshop is devoted to practicing teaching and mentorship skills and to using clinical practice improvement (quality improvement) methods.

To advance, safety trainers also must co-teach with an existing master facilitator, receive excellent teaching evaluations of their teaching sessions, and then be invited by the PSEP core team to become master facilitators. Each teaching session will be evaluated for content and delivery and evaluations will be provided to the safety trainer.

The College-Without-Walls Model

The training opportunities described in the previous section generate a perpetual process of patient safety knowledge dissemination, as illustrated in Figure 1. This has been sustainable in the EPEC program, which serves as the dissemination model and precedent for PSEP. The key to sustainability is a small core team, supported by a few staff members.

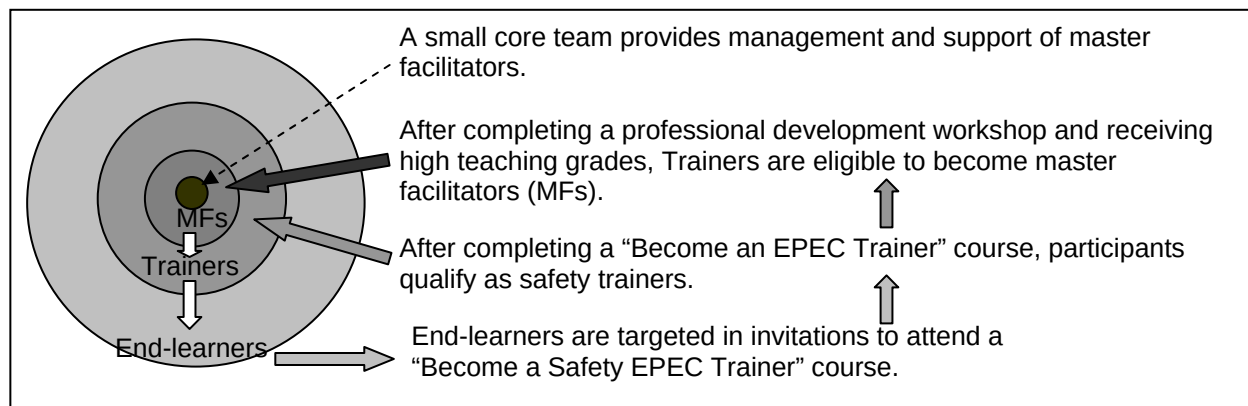


Figure 1. Schematic representation of the perpetual process of knowledge dissemination in the EPEC program.

This training formalizes achievement and stature, creating a collegiate form of merit-based advancement. This college-without-walls model facilitates learning and professional growth in the company of professionals from a range of disciplines; some will become career-long, trusted colleagues, and most will become part of a network of similarly motivated patient safety change agents.¹⁰ The participants will be able to derive a sense of community and mission loyalty from the experience that can be gratifying and professionally exciting.

The PSEP Financial Model

PSEP development and pilot testing has been supported by grants, as will be any subsequent developments and adaptations. In the post-development, self-sustainable phase, core support will come from registration fees, sale of educational materials (although the complete curriculum will also be available to download from the Internet at no cost) to safety trainers and master facilitators, and contracts with institutions that want to roll out PSEP.

Sustainability is accomplished via a lean business model based on a small core team and dispersed faculty who are paid not for full-time work but for services spent specifically on PSEP. The faculty comprises core team members and support staff, master facilitators, and safety trainers. Members of the faculty are drawn from diverse institutions, as are members of the governing council and expert advisory group. They are paid either for time spent on the project, by honorarium, or as part of a subcontract in accordance with normal academic procedures. Master facilitators are paid by honoraria for teaching safety trainers at each "Become a PSEP Safety Trainer" course or professional development workshop.

Legally and structurally, PSEP is designed as an independent program housed in an academic center. PSEP copyrights and trademarks its intellectual property for the purpose of ensuring attribution and preventing other claims to exclusive ownership. Core curriculum materials will be free on the Internet (www.patientsafetyeducationproject.org) to safety trainers with automatic permission to use them and adapt them with attribution.

The key feature retained as the exclusive function of the PSEP is the offering of “Become a PSEP Safety Trainer” courses and the designation of the title of “PSEP Safety Trainer.” The purpose of this is to maintain quality control and standards necessary for long-term evaluation and measurement of impact. It is expected that the program will be independently evaluated at key milestones.

Credentialing

Based on the EPEC precedent, it is anticipated that a generation of patient safety teachers and learners will emerge from PSEP implementation. Certificates will be awarded to PSEP’s master facilitators, safety trainers, and to those end-learners who have become “safety professionals,” which should prove to be a valid and meaningful educational qualification. Many programs require trainees to demonstrate a range of patient safety competencies.

With time it is hoped that, in addition to college programs, home organizations, and educational institutions recognizing PSEP certifications, relevant institutions will use them as quality indicators or as a prerequisite for more formal educational qualifications, such as master’s degrees.

We envision that institutions with teams of safety trainers may one day be recognized as having demonstrated capacity to implement innovative improvement programs, such as the Jewish Healthcare Foundation/Pittsburgh Regional Health Initiative’s “Perfecting Patient Care” program, or IMPACT hospitals designated by the Institute for Healthcare Improvement.^{12, 13}

The PSEP Educational Strategy

Stages of Impact

An increasing focus on performance, as well as understanding and knowledge, has been a welcome change in the field of education.³ Properly understood, the goals of education have long been known to impact much more than knowledge. Dixon¹⁴ and Davis and colleagues¹⁵ have described a cascade of steps for education:

- Knowledge and attitudes precede the learning of new skills.
- If desired outcomes are to occur, new skills must be translated into behavior.
- Once sufficient people are experiencing the desired outcomes, community-wide improvement will be reflected in norms of practice.

These stages of change are readily comparable to changes often identified in management literature and are increasingly used to promote changes in health-related behaviors among patients. These stages include:

- Precontemplation: The person or group has a nonreceptive disposition or attitude toward the potential change.
- Contemplation: The person or group is ready to think about the potential change or issues related to it.

- Preparation: The person or group begins acquiring what they will need to accomplish the change.
- Action: The person or group engages in activities that reflect the change.
- Maintenance: Norms are set up that reinforce and maintain the change.

Figure 2 maps this six-step conceptual framework that informs PSEP strategy and design. Consider the necessary steps in accomplishing medication safety improvement. According to this conceptual framework, the attitude that “medication errors are preventable” and the knowledge of how to prevent these errors come first. Attitude change requires a motivating experience and knowledge uptake requires a teachable moment, both of which can be generated in the PSEP program, as described below. The next step in educational impact is to acquire the necessary skills to reduce medication errors. Some skills, such as aspects of communication and prescription writing, can be taught well in the classroom setting; others can begin in the classroom but require practical application for complete learning.

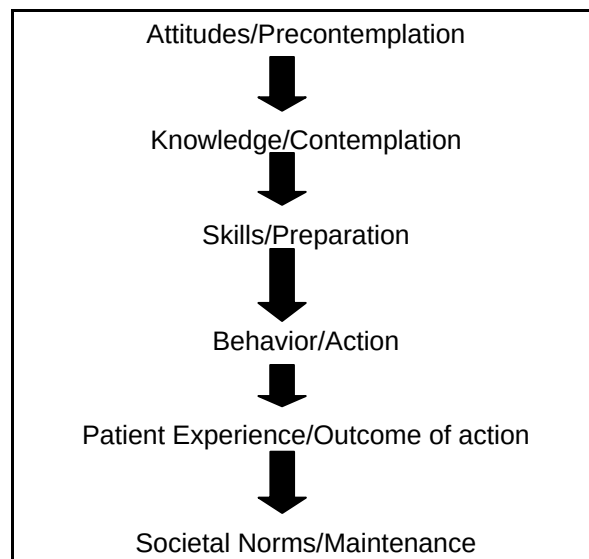


Figure 2. Conceptualization of education-driven performance change.

Changes in actual behaviors in the clinical setting must occur for the fourth step in the cascade of educational impact. These involve applying skills to generate good habits in, for example, prescription writing. Only when these behaviors have improved patient outcomes can the fifth step (patient experience/outcome of action) be accomplished. The final step is accomplished when behaviors that produce good outcomes are systemized into organization-wide norms of practice.

These last three stages all occur outside the classroom. To foster these later stages of change, the core curriculum incorporates toolkits that comprise slides, videos, protocols, templates, measurement tools, and other items that safety trainers can use in their own institutions. The core team culled through the many patient safety toolkits available on the Internet, gathered these into a user-friendly PSEP Toolkit Compendium, and mapped the tools to core curriculum modules.

The “Become a PSEP Safety Trainer” Course

The typical schedule of PSEP courses runs from Friday through Sunday morning, a format that the EPEC project has shown to be optimal for health care worker schedules and attendance. About 11 master facilitators can teach the total number of plenary and concurrent breakout module sessions in any given immersion course. The EPEC experience demonstrates that the best teacher-to-learner ratios sustainable for delivering high-impact education material is a cap of about 100 participants per course, with smaller breakout sessions of up to 20 people. Table 1 lists core curriculum plenary sessions and breakout modules, in the order in which they are designed to be taught, in the “Become a PSEP Safety Trainer” course setting.

Executive Track

Bringing patient safety to the point of real progress in the clinical setting requires crossing social divides within health care communities to create teamwork and support among different clinical professions and across the continuum from frontline microsystems to organizational middle management, executive leadership, and governance.

Table 1. Core curriculum plenary sessions and breakout modules as taught in the “Become a PSEP Safety Trainer” course setting

Setting the scene, gaining core knowledge		
Plenary 1	General session	Why patient safety? Why now?
Module 1	Breakout session	Moving beyond blame to systems thinking
Module 2	Breakout session	Applying human factors in the workplace
Module 3	Breakout session	Communicating effectively with patients and caregivers
Module 4	Breakout session	Being an effective team member and understanding teamwork
Module 5	Breakout session	Organization and culture
Module 6	Breakout session	The impact of technology on patient safety
Plenary 2	General session	Law and other influences in the external environment
Contextualizing knowledge, preparing to change		
Plenary 3	General session	Conceptual framework for patient safety
Module 7	Breakout session	Effectively engaging patients and families as partners in care
Module 8	Breakout session	Leadership and organizational support
Module 9	Breakout session	Scientific methods for improving safety
Plenary 4	General session	How to teach and implement patient safety
Module 10	Breakout session	Acute care settings: rapid response teams, ICU, ER, etc
Module 11	Breakout session	Chronic care settings: palliative care, pressure ulcers, falls, etc
Module 12	Breakout session	Interventional care settings: surgical care; infection control, (e.g., hand hygiene), medication safety, etc
Action		
Small group session		Practicing your teaching skills
Small group session		Planning your PSEP program
Final session		Next steps: Senior execs/trainer teams at roundtables with group work and general session

Note: ICU = intensive care unit; ER = emergency room; PSEP = Patient Safety Education Project.

To assist in aligning leadership support for safety trainers, the “Become a PSEP Safety Trainer” course has a half-day executive track in its course agenda, which has two aims: it provides health care organization executives with essential knowledge about patient safety, and it brings them up to speed with regard to what has been learned and planned by their participant teams.

The final session of the “Become a PSEP Safety Trainer” course is combined with the final session of the executive track. During this combined module, executive leaders and their teams collaborate about intended plans for improvement at the home setting and contract with one another to implement the plan. Executive leaders become invested and supportive, leading to the formation of connections between safety trainer teams and executive leadership.

The Core Curriculum

The core curriculum was designed using adult education methods (described below) with specification for health care settings, to particularly accommodate the needs of the first three of the six steps in the educational impact framework described earlier (Figure 2). Also, as discussed above, the core curriculum prepares safety trainers and their executive leaders for the last three of the six steps.

Structurally, the core curriculum is divided into four plenary sessions, which are delivered in lecture settings, and 12 content modules (Table 1), which are arranged as small group settings in which a safe, active learning environment can be created. Three additional modules are devoted to planning and practicing delivery of the core curriculum to end-learners. The agenda follows adult learning principles, which call for allowing the brain to rest after active learning. Accordingly, each plenary or modular unit of the curriculum is designed to be no longer than 45 minutes.

The first set of plenary and module units cover fundamental safety science and patient-centered care material, such as systems thinking, human factors theory, and teamwork. A middle group of plenary and modular units progresses to specific areas in which practical approaches to improvement are established, such as hand washing or rapid response teams. The final set of units is concerned with the implementation of PSEP teaching and safety improvement projects in the safety trainers’ institutions.

The Core Curriculum is provided in two forms. The *PSEP Participant’s Handbook*, designed for end-learners, contains only the plenary and modular content of patient safety. The *PSEP Safety Trainer’s Guide* contains all the content of the *Participant’s Handbook*, and it provides guidance and comprehensive materials on how to teach each portion of the curriculum and how to mentor implementation of the integrated toolkit resources.

The curriculum is an accordion curriculum; it can be taught in expanded or contracted form. It is provided in modular form, so that units can be taught as a free-standing 45-minute unit or in a workshop-like series of sessions. All modules contain a section on how a trainer can evaluate the impact of their PSEP teaching on end-learner knowledge and skills and benchmarks for desired behaviors, patient outcomes, and institutional policy. The PSEP toolkit compendium and a glossary of terms are integrated as resources. Each unit also has some essential heuristic features in common, as described in the sections below on each educational step.

Generating attitude change. The objective of the plenary sessions is to motivate a change in disposition and/or transmit information that is needed as background or preparatory material. “Become a PSEP Safety Trainer” courses are structured to start each course day with a plenary session that is designed to bring about a change in participants’ attitudes about or engagement in safety work.

Conveying knowledge. Every module uses “trigger tapes” to depict a vignette that participants will recognize as a familiar situation that needs a solution and is designed to trigger a teachable moment. In keeping with adult learning literature among clinicians, these trigger tapes are designed to create the need-to-know sense among participants.

Modules are used to convey knowledge, with an emphasis on content that is needed to effect practice change. Accordingly, each module provides the end-learner with two to five key learning points, which is all that typically can be retained in an hour, according to adult learning theory. PowerPoint® slides crisply reinforce this small number of key points. Language is accessible but balanced with the need to use enough discipline-specific jargon to allow participants to identify and trust the authority of the material.

Skill building. Each module suggests options for interactive exercises, such as virtual patient exercises and role-plays, which enable participants to practice skills. However, skills must eventually be practiced and refined in the clinical setting. The toolkit implementation feature of the core curriculum is designed to help foster skills development. The PSEP’s ability to train safety trainers to be quality mentors who are well supported in the workplace is another key feature.

Teaching Methods

Adult learning is the bedrock of the PSEP. To be effective, it requires familiarity with a suite of teaching methods. During the “Become a PSEP Safety Trainer” course, participants are coached in core methods and when to use them, depending on the subject matter, setting, and teaching abilities. The methods we use in the PSEP include interactive lectures, small group learning, and role play. We also include instruction on how to teach and implement projects.

During the “Become a PSEP Safety Trainer” course, participants deepen their understanding of the different methods and what fits best with what content. Safety trainers are also informed about teaching styles and receive analytic feedback on their own strengths and weaknesses in using the different teaching methods. With some preparation, and using the *PSEP Safety Trainers’ Guide* as a resource, safety trainers should be able to present all core curriculum modules. Practice helps, and safety trainers are reminded to continue practicing until they are comfortable enough to teach a group of end-learners.

Adult learning literature holds that any learning must be relevant to end-learners’ needs. Accordingly, safety trainers are asked to conduct a needs assessment in order to select or refine their teaching goals. Toolkits for conducting a needs assessment are provided.

Methods for Practice Change

As discussed earlier, a principle PSEP strategy for achieving change in skills, behaviors, and practice norms is training in how to use toolkits for patient safety projects. Toolkits are provided in areas such as:

- Improved teamwork.
- Communication techniques.
- Assessing an institutions safety needs.
- Hand washing.
- Medication safety.

Methods for developing patient safety improvement projects are also taught and include:

- The plan-do-study-act improvement method
- Failure modes and effects analysis.
- The “breakthrough technique.”
- Root cause analysis.
- Clinical practice improvement methodology.
- Implementing a guideline.
- Applying human factors engineering principles.

Although a PSEP toolkit resource has been compiled to assist educators and health care professionals in delivering the PSEP program in their workplaces, few of the tools have been rigorously validated. We define a tool as any Web-based resource (e.g., guideline, checklist, Web site, database, report, fact sheet, guide, outcome-focused quality improvement initiative, “how-to” directive, or other mechanism) designed to help health care teams, health professionals, and health administrators implement a patient safety activity or lead an organization toward a safety culture.

A surge in quality measures in health care has generally been in processes of care and quality that apply to small groups of patients in highly contextualized environments. Encouraging health professionals to measure care delivery processes has been a necessary and important step in teaching the importance of measurement in patient safety. These tools provide guidance on approach, understanding, and implementation of a specified patient safety area or activity. At the same time, more evidence is needed on which improvement methods work.

Balancing these features of the field, we have included more than 100 toolkits (freely available on the Internet) and at the same time, we join others, who are disappointed in our ability to track much progress to date in making health care safer and call for the establishment of measures that are practical, valid, and capable of providing relevant findings.¹⁶ This resource of toolkits will be updated continually to reflect progress.

Methods for Evaluation

It is anticipated that the rollout and implementation of the PSEP to end-learners will be measured for the impact of the teaching sessions, so that trainers, providers, and managers can assess the extent of the improvements brought to patient care at their institution.

The core curriculum provides pre- and post-test questions that evaluate attitudes, knowledge, and some skills, as well as an evaluation of the “Become a PSEP Safety Trainer” course. Measures of some skills, behaviors, outcomes, and standards are provided as part of the “resources” section of the modules and, when possible, as part of the PSEP toolkits. Safety trainers decide whether to evaluate the impact of the educational rollout separately or together with the practice improvement project. PSEP aims to create a data bank of de-identified project improvement data.

PSEP Processes for Design and Development

Taken as a whole, the method used for developing PSEP fits nicely into what has been articulated as the ADDIE method, a guide for the development of educational programming.¹⁷ ADDIE is an acronym that stands for:

Analysis: Our first tasks included analyzing existing patient safety knowledge in the health care workforce and the learning needs of the targeted end-learners. Existing patient safety curricula and competencies were reviewed and included recommendations of think tanks and oversight groups, with the final selection of the Australian National Patient Safety Education Framework.¹¹ The second important task was to analyze delivery methods, with final agreement on the highly successful EPEC model. A core team of patient safety experts and medical educators, guided by a blue-ribbon governing council and a highly qualified expert advisory group, finalized the learning objectives and outcomes for each of the instructional units.

Development: The core team met regularly and worked together to develop the curriculum and resources.

Design: PSEP has an innovative design that blends and builds on two strong approaches to program and curriculum design: the EPEC model and the Australian National Patient Safety Education Framework.¹¹ Further, it is designed as a system for education that is tailored to its target population(s) and settings.

Implementation: The train-the-trainer method underpins PSEP. International collaboration ensures opportunities for wide dissemination. The train-the-trainer method relies on the axiom (also underpinning the tipping-point principle) that broad social change occurs when one leader’s thoughts filter down to a few opinion leaders and then to a large number of people who normalize the knowledge and practices.

Evaluation: Built into the program are evaluation tools relevant to the curriculum, learners’ knowledge outcomes, teachers, teaching methods, and instructional design. Furthermore, toolkits are included to help measure practices and patient outcomes.

Conclusion

Patient safety needs a boost. Progress has been slow. Implementation of patient safety practices has fallen short of expectations, despite the existence of good educational materials. Not only does patient safety face the same challenges as other efforts to translate education into practice, patient safety knowledge is derived in ways that are characteristically different from traditional clinical health services research. A new emphasis on types of learning and change is necessary.

The PSEP strategy is to involve the maximum number of people in an organization until a tipping point is reached, and patient safety practices are integrated into the culture. Instituting new norms of clinical care requires that a community of practice adopt the new behaviors. PSEP is designed to use optimal methods to widely disseminate and integrate new knowledge and skills into everyday practice.

This safety trainer-based program provides a conceptual framework for approaching patient safety and a step-by-step guide to patient safety learning areas and coaching techniques, showing how to apply workplace practice change. The PSEP approach of linking to other educators also allows for the important step of connecting with other programs that are working to change core delivery systems.

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Harnessing the Potential of Health Care Collaboratives: Lessons from the Keystone ICU Project

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Abstract

In October 2003, the Quality and Safety Research Group of the Johns Hopkins University School of Medicine, the Michigan Health and Hospital Association, and 108 intensive care units (ICUs) from 77 hospitals began a collaborative improvement project. Goals to improve care included creating a culture of safety, reducing central line-associated bloodstream infections (CLABSI) and ventilator associated pneumonias (VAP), and improving compliance with evidence-based practices for ventilator care. Improvement teams were assembled in each ICU to do the work, and the chief executive officer of each hospital partnered to support project efforts. The teams achieved a 50 percent improvement in safety climate, attained a median CLABSI rate of zero, and reported 99 percent compliance with evidence-based ventilator care practices. Understanding how and why this collaborative succeeded may expedite progress in other improvement efforts. In this article we present some of the lessons we learned while leading the Keystone ICU project.

Introduction

In October 2003, 108 intensive care units in 77 hospitals, the Michigan Health and Hospital Association, and the Quality and Safety Research Group at The Johns Hopkins University School of Medicine embarked on a collaborative journey with bold but focused goals. Our purpose was to improve intensive care in Michigan by creating a culture of safety, reducing central line-associated bloodstream infections (CLABSI) and ventilator associated pneumonias (VAP), and improving compliance with evidence-based ventilator care. By September 2005 in participating units, the median rate of CLABSI was zero, safety culture had improved more than 50 percent, and compliance with evidence-based ventilator care was 99 percent. Additional data on these measures were recently received but have not been analyzed as yet. VAP rates also fell, but those data are not yet published.

Given the effectiveness of these interventions and the potential for replicating this project (the Keystone ICU project), it is important to understand how this program differed from other quality improvement efforts and why it was successful. The limitations of qualitative reports of “lessons learned” from quality improvement collaboratives are widely acknowledged in the literature.^{1, 2, 3} However, a more complete picture of the collaborative process is possible when qualitative reports are coupled with complementary, objective, and rigorously conducted outcome evaluations.^{1, 4, 5} The significant improvement in CLABSI rates achieved by the Keystone ICU teams has been published.⁶

Thus, the specific aim of this paper is to present some of the lessons we learned as coleaders of the Keystone ICU (KICU) collaborative. Our intention is to further the dialogue and advance the science of large-scale quality and safety improvement projects. Given the magnitude of improvements in quality of care in this collaborative relative to improvements with pay for performance,⁷ use of this collaborative model may increase in frequency. Strategies to improve the efficiency and effectiveness of collaboratives will therefore be an important research priority.

Lessons Learned from the Keystone ICU Collaborative

A virtual learning community evolved during our work with the Keystone ICU teams, with frequent dialogue occurring among teams outside the formal collaborative structure. Thus, we recognized that the perspectives of other health care organizations or researchers regarding what contributed to the success of this project were important and could vary from the perspectives we present in this article. We offer the following lessons, not as an exhaustive list, but as a starting point for others to consider when embarking on a large-scale initiative (Table 1).

Understand the Differences Between Leadership and Authority: Cultivate Leaders

Leading change efforts (e.g., an improvement collaborative) is a challenge that benefits from an understanding of the differences between leadership and authority. Social psychology literature describes five bases of social power in organizations: legitimate power, referent power, expert power, reward power, and coercive power.⁸ Individuals with legitimate power (also referred to as “position power”) have organizational authority and are typically expected to control conflict, maintain norms, and provide direction, protection, and orientation to role and place. Within the collaborative structure, the engagement and support of organizational authorities are necessary but not sufficient for success.⁹ Authorities may or may not exhibit strong leadership skills.

Leadership is often independent of authority. In collaboratives, changes in practice and adherence to measurement criteria are often led by staff who exhibit strong informal leadership traits. Such individuals share knowledge (“expert power”) and build

Table 1. Lessons from the Keystone ICU Collaborative

1. Understand the differences between leadership and authority: cultivate leaders.
2. Get both the technical and adaptive work right.
3. Strive to find the “sweet spot” between scientifically sound, yet feasible, measures and interventions.
4. Match project goals, objectives, and database design at the outset.
5. Stay focused on original aims.
6. Link culture improvement and clinical outcomes.
7. Reduce bias in data collection.
8. Reduce the quantity, not the quality, of collected data.
9. Keep a “laser-sharp” focus on patients.
10. Expect the project to occasionally stall.
11. Improve upon quality improvement models.

consensus (“coercive power”), even though they are not in a job position that provides them with formal authority.^{8, 10}

Leaders involve other people in setting directions, facing challenges, adjusting values, changing perspectives, and developing new behaviors.¹⁰ Within the context of the KICU collaborative, we encouraged teams to acknowledge and support both formal (e.g., CEO) and informal leaders (e.g., bedside nurse) at every level of the organization. For example, to help facilitate engagement, we asked for input and recognized the perspectives and contributions of everyone involved in the project. As a result, leaders on the frontlines—such as attending physicians, nurses, therapists, pharmacists, unit coordinators and environmental health workers—and organizational leaders with formal authority—such as ICU medical directors, managers and hospital executives—were all well-informed. They understood the goals of the project, recognized why these were important, supported the interventions, believed the performance measures were feasible and valid, and committed the effort needed to improve care.

Get Both the Technical and Adaptive Work Right

Conceptually, technical and adaptive challenges are separate beasts to conquer, yet they often intersect in the process of completing work in a collaborative. Technical problems are those that can be clearly defined and most often have existing solutions. Technical work (content) can certainly be difficult, but we typically know what to do or can solicit the assistance of an expert for advice.¹⁰ In an improvement collaborative, technical work enlists all participants.

Examples of technical work at the team level in the KICU project included stocking chlorhexadine in their respective ICUs; developing a method to procure and organize the supplies needed for a line-insertion procedure using evidence-based practice guidelines; educating everyone involved with line insertion on the evidence supporting the project interventions; reliably collecting required data elements; and reporting the results.

Examples of technical work at the project coordinator level for any collaborative initiative include:

- Defining the focus for improvement.
- Selecting the measures to assess this improvement.
- Defining the variables and data collection methods.
- Developing a database and data management plan.
- Analyzing data and generating reports.
- Providing feedback to local leaders and frontline staff
- Determining the consequences if teams do not consistently meet project participation requirements.

In KICU, the stringent technical work described above resulted in reliable data we could analyze to track safety culture, CLABSI rates, and compliance with the evidence-based ventilator care bundle.¹¹

Adaptive challenges are often difficult to clearly identify. Yet, the ability to pinpoint and manage these challenges is critical to the success of any improvement initiative. Adaptive work (context) involves changing hearts, minds, and behaviors and typically takes longer than technical work, since it generates disequilibrium in existing systems. Individuals who care deeply but may not have formal authority to mandate change are often the champions of adaptive work. Adaptive challenges share several properties:¹²

- There is a gap between aspirations and reality.
- Narrowing the gap requires difficult changes.
- The people with the problem are the problem as well as the solution. Problem-solving responsibility must shift from authoritative experts to those required to change their hearts, minds, or behaviors for resolution to occur.
- Solving adaptive challenges requires moving beyond a comfort zone or “stepping outside the box.”

In KICU and our other collaborative initiatives, the adaptive challenges far outweighed the technical work. We believe success was tied to addressing both effectively. As an example, disseminating the evidence supporting strategies to reduce CLABSI and the methods to measure these infections was a technical problem, but getting clinicians to ensure that every patient reliably received these evidence-based interventions was an adaptive challenge.

Teams were encouraged to share data showing the gap between the project goals and the unit’s current performance. Many teams reported sharing data throughout their unit, often posting performance reports on unit bulletin boards or in staff lounges or conference rooms. We also heard from teams that routinely reported their data at medical and nursing staff meetings, project team meetings with their executive partner, and management and board meetings. Thus, the technical work of rigorous data collection and transparency of performance reinforced the need to modify practice behaviors.¹³

The importance of addressing both content (“technical work”) and context (“adaptive work”) in quality improvement studies is not new, although most published studies have focused on content (e.g., evidence-based medicine).^{14, 15, 16} During this project, we developed a change model designed to help participants understand and address both technical and adaptive challenges.¹³ This model targets senior leaders, team leaders, and staff through four phases of work. The first and third phases are primarily, though not exclusively, adaptive; the second and fourth are primarily, though not exclusively, technical. The phases are:

1. Engage staff in the importance of the work through stories, sharing of baseline data, and identification of performance gaps.
2. Educate staff about the evidence supporting practices known to improve outcomes.
3. Execute the work to ensure patients in the organization receive these evidence-based practices.
4. Evaluate the outcome to answer whether we are safer.

Each phase of the change model is important. But, the engagement phase deserves detailed discussion here because it provides the foundation for all other phases and relies on a role-specific understanding of how the requested interventions will make the world better. To achieve engagement requires capturing both the “head” and the “heart” of individuals.¹⁷ Our cognitive engagement strategies included use of baseline performance reports to estimate the number of preventable infections, deaths, and potentially avoidable ICU days, compared with optimal performance. While such estimates are helpful as tools for engagement, they are fraught with bias and should be used cautiously, if at all, to evaluate outcomes of a collaborative. Effective engagement strategies included the use of stories about patients who developed a preventable complication (e.g., CLABSI) and the impact it had on their lives.

It is critical to communicate regularly and transparently with project leaders and frontline staff both to establish and maintain this engagement. Enthusiasm is often easy to muster at the beginning of a project because it is new and offers hope for better clinical outcomes, camaraderie, and improved teamwork. However, sustaining this enthusiasm requires real and constant work at the project leadership and local levels.

Teams that consistently reported their data to all levels of the organization (from senior leaders to bedside staff) perceived the data as valid, continued to bring forth stories of harm, and seemed to build an institutional support network that sustained project vitality. Moreover, the collaborative created a virtual learning community that enabled teams to learn together and from each other. This support system helped many solve local adaptive challenges. As coordinators of the collaborative, we periodically sent aggregate project updates to hospital leaders and ICU teams. We also encouraged local teams to provide monthly project updates to their senior leaders.

Strive to Find the “Sweet Spot” Between Scientifically Sound and Feasible Interventions and Measures

We learned that an important principle for effective collaborative work, and likely quality improvement in general, is to find a balance between what is scientifically sound and what is feasible. We selected interventions with the strongest evidence (e.g., the lowest number needed to treat) and the fewest barriers to implementation. For example, we culled out of a nearly 100-page guideline to prevent catheter-related infections (from the Centers for Disease Control and Prevention) five behaviors that were closely associated with reduced infection rates and were also easy to implement with few barriers.¹⁸ Educating staff about these five simple behaviors that are associated with reduced infection rates was sound, feasible, and effective.⁶

Accurately evaluating the impact of any quality improvement collaborative is contingent upon the data teams provide. Thus, respecting the importance of science, while at the same time the realities of data collection burden, we chose to minimize the quantity of data collected without sacrificing data quality. For example, we used a rigorous definition for CLABSI data, but we did not collect data on the types of organisms causing the infection. We also implemented a robust data quality control program that sought to reduce measurement error and missing data.

Match Project Goals, Objectives, and Database Design from the Outset

A major challenge for quality and safety improvement projects is the eagerness of teams to forge ahead without clearly defined goals, a plan to measure progress toward those goals, an estimate of baseline performance, and a system for measuring performance.^{2, 5} In our experience, the “just do it” mentality hinders or precludes the ability to estimate whether or not an intervention is associated with improved performance. On the contrary, before any work is done, it is important to spend ample time conveying explicit objectives and goals to teams and collecting a sufficient amount of baseline data to make a precise estimate for each measure. A database that allows you to efficiently and effectively manage your data is most often worth the time and resources required to develop or purchase and install it. Perhaps the best test of the database and the team’s ability to collect and submit data is to ensure that you have collected valid baseline data and can produce performance reports.

Stay Focused on Original Aims

A team’s enthusiasm to improve care or its frustration with the challenges of redesigning care often results in a desire to “add on” to a project, perhaps before the original goal is achieved. From our experience, project leaders should be clear and consistent, focus on the original project aims, and caution teams about adding more work. “Scope creep” will deplete scarce resources and add ambiguity when evaluating the impact of the original intervention(s) on the collaborative’s goal.

Moreover, when teams struggle to implement significant system redesign or achieve results, they often become frustrated and move on to a new intervention. In this collaborative, we asked teams to refrain from starting a new intervention until they achieved the stated goal(s) for the current intervention. For example, if teams were working on the CLABSI interventions, we urged them not to begin working on VAP until they had significantly reduced or eliminated CLABSI.

Link Culture Improvement and Clinical Outcomes

Organizations need to learn how to influence cultural change, just as they need to learn how to eliminate infections. Creating a culture of safety and teamwork can enhance a team’s capacity to implement clinical interventions and increase the likelihood of sustaining the results achieved.^{19, 20} Culture and climate are used interchangeably in many industries, yet they are conceptually distinct. Culture is the underlying values, beliefs, and assumptions that make an organization or group distinct, whereas climate is a snapshot of culture at a specific point in time. Climate can be measured using survey instruments

At the beginning of the KICU project, teams measured safety and teamwork climate using the safety attitudes questionnaire (SAQ).²¹ Teams were presented their SAQ scores relative to an aggregated score of the other ICU teams in Michigan and were asked to meet with their CEOs to review the results. Following this meeting, teams implemented the Comprehensive Unit-based Safety Program to improve culture.²²

We found that teams wanted to understand why safety culture was important, identify their current culture, and implement interventions intended to improve culture. Culture change is not likely to occur by ordering clinicians to cooperate, work more collaboratively, or communicate more effectively. SAQ scores provided a context for teams to discuss their safety culture and evaluate their annual progress. Teams with the best safety and teamwork climate also demonstrated the most rapid improvement in CLABSI rates.^a Additional analyses suggest similar associations between safety climate and other clinical outcomes.

Minimize the Bias in Data Collection

Because quality improvement studies are often conducted with less rigor and resources than clinical studies, and because we have a strong desire to improve safety, there is a propensity to perceive that an intervention improved safety when, in reality, it may not have (i.e., type I error).^{2, 5} Project leaders can take several steps to help reduce these errors:

- First, create a manual of operations that includes a data dictionary with explicit definitions for each variable. The numerator (events), those at risk for the event (denominator), and methods to monitor both variables should also be explicitly defined.
- Second, create, pilot test, and revise data collection forms.
- Third, create a data quality control plan. At a minimum, this plan should include a process to train data collectors and evaluate their reliability, imbed range checks in the database, generate monthly reports of missing data and outliers, and strategize ways to minimize missing data.²³

Reduce the *Quantity*, Not the *Quality*, of Data

The quality of data is more important than the quantity of data when evaluating the impact of your intervention(s). Yet, many projects collect relatively large amounts of poor quality data. In evaluating whether an intervention was associated with improvements in quality or safety, we believe that biased data are worse than no data at all. Our efforts to engage and maintain physician involvement with this project were tied to our capacity to collect and report data that had face validity (i.e., the data are important and useful to those who are collecting and using the data). Nevertheless, we recognize that it is often difficult to find the correct balance between data that are feasible to collect and also scientifically sound. Quality improvement studies would be better served by collecting a smaller amount of high-quality data than a large amount of biased data. In the KICU project, we repeatedly had to scale back our desired list of data elements to those that were meaningful and feasible.

Keep a “Laser-Sharp” Focus on Patients

Hospitals, clinicians, and local cultures are unique, and sometimes conflict will arise. By keeping a “laser-sharp” focus on what is best for patients, project leaders can help overcome political and power struggles. At the beginning of our collaborative, we asked hospital leaders and local ICU

^a Bryan Sexton, PhD, unpublished data, September 1, 2007.

teams to publicly commit that harming patients was untenable. This statement galvanized our virtual learning community to keep patients first.

Because poor communication is a primary cause of many sentinel events (www.jointcommission.org), and because we know that physicians and nurses often have different mental models that result in communication lapses, we introduced tools to improve patient-focused communication, teamwork, and ultimately, patient safety. One tool, called “the goals sheet,” focused attention on the patient by prompting clinicians during morning rounds to clearly outline a plan of care and identify potential safety hazards for each patient.²⁴ This tool and others (e.g., multidisciplinary rounds, morning briefings) provided safe methods to practice teamwork behaviors that kept the patient as the central focus.

Another example was the CLABSI checklist. The goal of this tool was to reduce or eliminate the possibility of a patient developing a preventable blood stream infection. CLABSIs are common, costly, and often lethal and are best reduced or avoided by following the CDC guidelines to prevent infections. The CLABSI checklist provides an independent check, in which the assisting nurse checks off each evidence-based step that should be completed for line insertion. We asked executives to support the authority of nurses to “stop the line” if evidence-based practices were not followed during line insertion, and each executive complied.

This shift in authority has the potential to create conflict between the nurse and physician or other provider inserting the line. However, we learned that executive support, the ability to reference an organizational commitment to the concept that harm is untenable, and use of the CLABSI tool helped clinicians stay focused on the patient. While we do not pretend culture change is easy, maintaining a focus on what is best for patients often dispels any role-related tensions.

Expect the Project to Stall at Times

Rather than becoming frustrated or moving on to a new intervention when projects stall, leaders should listen to “the music beneath the words,” as Heifetz¹⁰ has explained. Hear what teams are struggling with and why. With a better understanding of local needs, leaders can work in concert with project staff to develop and implement a go-forward strategy. Not surprisingly perhaps, it seemed that a project would lose momentum most often because of adaptive challenges (e.g., changing behaviors).

When the local KICU teams appeared unusually overwhelmed, we put a hold on any new project activities, allowed the atmosphere to calm, and listened. Adaptive leaders do not provide answers. Instead, they frame the right questions, identify the current realities that need to be addressed, and challenge people to identify creative solutions.

We routinely tried to role-model adaptive leadership by leading with a single question. If the project was struggling, the question was often “Why?” Starting a dialogue about barriers with a wide participant audience allowed potential solutions to surface. In reflecting on why momentum periodically faltered, it was helpful to recognize and remember that change in and of itself is not a barrier to improvement. We know that if change is perceived to be positive, like winning the lottery, we welcome it with open arms. What people fear more than change is loss.^{10, 12} When

teams reported local resistance to change, we suggested they try to bring to the surface and openly discuss what individuals or groups anticipated losing as a result of the change. These forums often resulted in a realization that loss(es) were more perceived than real. Often, projects fall apart because leaders assume tension means the project is not working. In fact, we observed that the tension points were where the greatest learning and forward momentum were occurring.

For example, at one point, teams were invited to voluntarily beta-test the Joint Commission ICU measures. A subset of teams agreed to do so, but it took far more work than many teams realized. Once the beta-test was completed, the test teams requested time to recoup their energy and catch up on local efforts. While adhering to the project plan was important, and some teams urged moving forward, we had agreed at the outset of the project that no one would be left behind. In spite of the tension, once reminded of our commitment to each other, all teams agreed to slow down implementation of the project plan.

During the hiatus, several teams developed internal project newsletters and shared project-related protocols they had developed with other KICU teams. This short but forced hiatus taught many teams the value of what Heifetz¹² would describe as stepping off the dance floor and moving to the balcony—that is, observing the project from an objective distance, rather than from the day-to-day flow of activity. It also resulted in some new communication tools and project vitality.

At another juncture, many teams were experiencing physician leadership change and did not know how to cultivate a new leader. Engaging new physicians in an existing project was an important pause point for us. We did not modify expectations; we modified our project plan by adding coaching calls on physician engagement. During the calls, we provided tools (e.g., shadowing another practice domain) to facilitate mutual appreciation of roles and time demands. We also refined our monthly team checkup tool to collect additional team turnover information, so we could more effectively anticipate team needs.

Delays also may be caused by project management issues at the collaborative level. Well into the first year of the project, just as things were implemented and running smoothly, we experienced a turnover in project management at the hospital association's Keystone Center for Patient Safety and Quality. This turnover resulted in missed project deadlines. Rather than exhibit frustration, however, we viewed it as an important opportunity to examine the departing project manager's tasks and determine if any could be automated.

Our leading question was “How?” How could we continue this important work with fewer disruptions the next time we experienced the inevitable staff turnover? It was during this unexpected stall that we created new electronic capabilities for communicating with participants and for receiving local data, including an enhanced participant Web site.

Improve Upon Quality Improvement Models

Quality improvement methods have varied over the past two decades, but most have incorporated a bias toward action over evidence. In spite of weak study designs, the effectiveness of these studies was often accepted based on anecdotal accounts of success and intuition.^{1, 3, 4, 5, 14} Given the urgency to improve quality and the scarce resources devoted to quality improvement, we needed to improve the efficiency and effectiveness of quality improvement efforts.

Our goal in conducting collaborative projects with methodologic rigor and strict data management is not to conduct research for the sake of publication or to impose burden on caregivers. Our goal is to learn with confidence what works to improve clinical outcomes and patient safety to benefit all patients.

The KICU project reinforced our belief that inferences regarding the benefit of a quality improvement intervention must be made with scientific rigor. We learned from participants that our approach was different from many, and in some cases all, previous quality improvement efforts in which they had been involved. We had a clear and articulated project plan, including a hypothesis/objective, study design, explicit interventions with timeframes for implementation, and valid outcome measures. Data collection forms and procedures were thoughtfully developed and pilot-tested for clarity and reliability. As these evolved during the project, we noted when and why so changes could be accounted for in the analysis. We provided training for personnel collecting the data. The research team regularly reviewed submitted data to minimize the risk for data entry errors and contacted teams for resolution when data were missing or suspect. Similar to clinical research, we committed to describe, conduct, and report the analyses appropriately. This included reporting missing data, accounting for nonindependence of outcome data, adjusting for confounders, and providing an estimate of precision for results. We understand that the knowledge or skills within an institution to adhere to these criteria may not always exist.

However, suggesting that data for quality improvement can be held to a different standard than data for research does not serve patients or the goal of improving care.² In our experience, we observed that teams follow in the shadow of the leader. Within a supportive shadow, where rigorous study constructs are provided, expectations are clear, and those with analytic skill provide regular feedback and support, all teams are capable of rising to the challenges and expectations of collecting and submitting valid data.

Conclusion

The science of how to broadly improve quality of care is growing. We believe that these efforts require both technical and adaptive work, and both need to be done well. In this paper, we outlined some of the insights we gained while leading a large and successful collaborative. We learned lessons from the KICU teams that have infused all of our subsequent patient safety efforts.

Resources are too scarce and the need to improve is too great to support quality improvement activities that are inefficient or ineffective. Project coordinators should strive to make certain that frontline wisdom is respected and reflected in the work; that resources needed to conduct the work are part of leadership's commitment to participate, a commitment that must be honored; and that the impact of each intervention is measured in a manner that will allow the industry to understand whether clinical outcomes improved and whether patients are safer because of our efforts.

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VHA's National Falls Collaborative and Prevention Programs

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Abstract

Falls are a high-volume, high-cost problem in health care. This article presents three successful patient safety fall prevention projects completed within the Department of Veterans Affairs Healthcare Administration (VHA): the National Falls Collaborative Breakthrough Project, the development and deployment of the National Falls Toolkit, and the National Falls Data Collection Project. Each of the projects enrolled VHA medical centers from across the country. These three projects demonstrate VHA's leadership in evidence-based practice, data and outcomes management, and reliability and sustainability of innovations. The National Fall Collaborative Breakthrough Project involved 40 participating facilities and achieved remarkable results (62 percent reduction from baseline for major injuries). The National Falls Toolkit is a compendium of useful references, resources, presentations, posters, and spreadsheets that were culled from existing research and the Falls Collaborative. The National Falls Data Collection Project occurred over a 2-year period and analyzed multiple indicators of a fall prevention and injury reduction program for 65 medical centers.

Introduction

This article describes the veterans Affairs Healthcare Administration's (VHA's) experience with three unique, interrelated projects over a 6-year period to build capacity, improve practice and expertise, and collect national outcomes data related to patient falls in inpatient settings. While each project stands alone, the combined effect and interrelationship of each initiative showcases the success that large-scale health care systems can have with regard to patient safety and fall prevention in general and to injury reduction in particular.

The first of these, the National Falls Collaborative Breakthrough Project,¹ involved 40 hospitals and State veterans homes, which focused on reducing injuries associated with falls. This section identifies factors associated with successful teams, as well as those program interventions associated with dramatic decreases in injury rates.

The second section describes development and deployment of the National VHA Falls Toolkit, which is a compendium of information, sample policies, templates, presentations, posters, and videos. This resource has been publicly available since 2004, and is widely accessed by the general public (www.patientsafety.gov).

The third project, an evaluation of the impact of the National Falls Toolkit, details an outcomes project involving 65 VHA facilities that reported quarterly information over a 2-year period (2004-2006). An analysis is provided on their results, why people participated, and what changes were implemented.

Falls are a high-volume, high-cost problem in health care with severe personal and health consequences for the elderly, and they result in significant consequences that add to the burden of care for elders in health care systems. Approximately one-third of all adults over 65 years of age are reported to fall each year.^{2, 3} National data indicate that falls are the largest single cause of restricted activity days among older adults,⁴ and they are a leading precipitating cause of nursing home admissions.⁵ In addition, falls account for 6 percent of all medical expenditures for individuals over age 65. Direct care costs of fall injuries for people age 65 and older are expected to reach \$32.4 billion by 2020,⁶ when 20 percent of Americans will be over the age of 65.

Despite considerable research devoted to falls, little progress has been made to significantly decrease falls and their potentially devastating consequences. Until recently, falls were viewed simplistically, not as complex problems with multiple risk factors. Current evidence suggests that falls prevention and fall-injury protection requires interdisciplinary health care providers who understand the complexities of fall risks among varied populations, evidence-based fall risk assessments, and multifactorial interventions. Additionally, evidence-based tools are needed nationally for our health care systems to implement fall prevention programs. This article provides some models of activities that others can use as learning tools.

National Falls Collaborative Breakthrough Project

Although research on preventing patient falls is widely available,⁷ implementing effective fall prevention programs at the local level is a major challenge. To help local programs implement effective fall programs, we conducted a facilitated quality improvement effort designed to reduce falls and injuries due to falls within the VHA. The following section describes the process, outcomes, and team-level success factors of that effort.

Methods and Process—Breakthrough Project

In its Collaborative Breakthrough Series (BTS) Model, the Institute for Healthcare Improvement (IHI) outlined a method to rapidly implement change in health care systems.^{8, 9} This method relies on adaptation and dissemination of existing knowledge to multiple settings to accomplish a common aim. It calls for careful research with subject matter experts to identify the knowledge available for use; ideas for change worth testing are developed from that knowledge base.

Over a 6- to 9-month period, multidisciplinary teams that want to achieve much higher levels of performance work on a common aim under the guidance of faculty members who are expert in the topic area or in change theory. Teams come together for two, 2-day educational and planning sessions that are conducted by the faculty. Between these sessions, teams implement some of the suggested changes, measure the results of those changes, and report back to the larger group. Teams are supported through monthly educational and troubleshooting conference calls, individual coaching by faculty members, and an e-mail LISTSERV[®] designed to stimulate interaction among teams.

We chose to focus this effort on reducing falls and injuries due to falls because within VHA, patient falls are the leading cause of reported adverse events and result in significant morbidity and mortality.¹⁰ In May 2001, the project was marketed to the directors of VHA facilities and State veterans homes. Forty teams were accepted into the project and attended the learning sessions. Throughout the duration of the project, teams provided monthly reports to their leadership and to project faculty on the changes they were making and the results of those changes. Prior to the first learning session, the teams collected baseline data and analyzed their systems for assessing and treating patients at risk for falling.

Learning sessions. The first learning session, conducted in July 2001, focused on teaching teams key changes designed to reduce falls and injuries. The teams were taught a model of improvement in which they defined clear aims, measured progress, and implemented changes by using small (plan-do-study-act) cycles of change.¹¹ The teams also worked to develop specific action plans to implement improvements in their systems for assessing and treating fallers.

During the second learning session, conducted in March 2002, the teams continued to learn strategies for reducing falls and injuries, presented their results, taught each other, integrated their findings to identify best practices, and developed further action plans to consolidate their gains and spread changes to new areas in their facilities.

Measures. Teams collected and reported the following data on falls and injuries at baseline and monthly thereafter throughout the project's 8-month duration:

- Monthly fall rate, calculated as the number of falls/bed-day of care x 1,000.
- Monthly fall injury rate, calculated as the number of injuries/number of falls x 100.
- Severity of injury for each fall, defined as no injury, minor injury (e.g., abrasion, bruise, minor laceration), or major injury (e.g., hip fracture, head trauma, arm fracture).¹²

Team characteristics. We collected information from a questionnaire that we previously used to assess each team's sense of learning, leadership support, and progress.⁹ At both face-to-face learning sessions, participants from each working team were instructed to circle their agreement or lack of agreement to an accompanying statement from the perspective of the team.

Assessing individual team performance was challenging because some teams found that fall reporting had improved, thereby increasing reported fall rates, and major injuries were rare events, rendering their tracking over such a short term unreliable. We therefore determined overall performance based on three factors:

1. Decrease in fall rate, calculated as the average fall rate for the first 3 months of baseline data compared with the average fall rate for the last 3 months of data collection.
2. The absence of major injuries for the last 5 months of data collection.

3. Active change participation, determined by whether teams had implemented more than four interventions during the project. Four was the median number of interventions implemented, as determined by examining team storyboards that summarized their changes.

Overall team performance was calculated by assigning one point for each factor achieved.

Results—Breakthrough Project

During the project, three teams dropped out; therefore, we had the potential to analyze results from 37 teams. Three teams did not submit any data, and three teams submitted incomplete data. Consequently, our analysis was limited to results obtained from 31 teams. The overall major injury rate decreased 62 percent (our method for calculating this change was described earlier), from 2.14 major injuries per 100 falls at baseline to 0.82 major injuries per 100 falls near project completion (paired t test $P = 0.097$). This difference represents an average reduction of 40.9 major injuries per month for the group of 31 teams analyzed. The overall fall rate decreased slightly over the project's duration from 6.84 to 6.42 falls per 1,000 bed-days of care.

By the second learning session, more teams reported a better understanding of team members' strengths and weakness (paired t test, $P = 0.06$), a view of problems as everyone's responsibility rather than someone's fault ($P = 0.04$), and more data collection from patients ($P = 0.04$).

During the first learning session, most of the teams felt mutual respect and were comfortable expressing their opinions. Fewer than half of the teams had previously worked together as a team, worked on improvement projects, or were familiar with process measurement. At the second learning session, virtually all of the teams reported learning new ideas and methods and indicated that the project added value to their facilities. Most teams also reported that they used information from other teams and shared information with others.

Several important differences in team characteristics were evident between the lowest performing teams (0 on our performance scale) and the higher performing teams (2 or 3 on our performance scale). High performers were much more likely to turn in their first monthly progress report ($F = 8.2$, $P = 0.01$) and, at the second learning session, to report better conflict management skills ($F = 6.08$, $P = 0.03$), more frontline support ($F = 14.5$, $P = 0.001$), more use of information from other teams ($F = 5.3$, $P = 0.03$), and stronger team leadership ($F = 4.9$, $P = 0.04$) than low performers.

We discovered that teams that used toileting interventions reduced their major injury rate by 2.7 falls per 100 (1.4 falls above the average). Similarly, teams that used signage, used or evaluated hip pads, or implemented environmental interventions reduced their rates of major injuries by 2.3 (almost 1.0 above the average). Teams that used staff education and postfall assessments also had reductions that were above average by 0.8 and 0.7 major injuries per 100, respectively.

We found that a team's performance scores were positively correlated with adoption of signage programs ($r = 0.567$, $P < 0.001$), postfall assessment programs ($r = 0.342$, $P = 0.05$), environmental safety programs ($r = 0.330$, $P = 0.05$), and toileting programs ($r = 0.325$, $P = 0.05$). We also found a positive, but not statistically significant, relationship between

performance scores and the use of the Morse fall scale,¹³ staff education, and utilizing or evaluating hip pads.

Also, large differences in the major fall-related injury rates existed between the higher performers and lower performers who submitted data. While lower performers decreased their major injuries by 11 percent, the higher performers decreased their major injury rate by 82 percent, to only 0.39 major injuries per 100 falls. By January 2002, the difference in major injuries per 100 falls reached statistical significance ($P = 0.032$).

We interviewed the teams 1 year after project completion to assess sustainability of their success. The majority of teams (82 percent) reported that they had stayed together as a team; 97 percent continued to collect data; 94 percent reported that they had maintained their gains; 82 percent said that they had spread changes to new locations; and 85 percent had begun to work on new topics. At followup, team performance was correlated with leadership support ($r = 0.614$, $P < 0.001$) and teamwork skills ($r = 0.377$, $P = 0.033$).¹⁴

Discussion—Breakthrough Project

As part of a facilitated quality improvement effort, 37 teams worked to reduce falls and fall-related injuries. There was a collective reduction in major injuries, and 78 percent of the teams were successful on at least one measure of performance. Participants reported learning from the project and found it valuable, despite the perception that they did not have enough time to achieve their aims, and that they lost some support from their leaders.

As we have found in previous interdisciplinary collaborative projects, teams that “hit the ground running” are the best performers in the long run. In this study, top performers not only turned in early progress reports, but also had more staff support, stronger leadership, and better conflict-management skills. While high performers were not more likely to have worked together as a team before the project, they seemed to come together as a working unit more quickly and did a better job of gaining a broad base of support from other staff at their facilities. Sustained improvement is also important, and we found that leadership support and teamwork skills were valuable for continued success.

Our analysis of the types of interventions that were associated with larger reductions in major injury rates may shed some light on which interventions a facility may want to try first. Teams that were the most successful at reducing major injuries were those that were able to identify systemic problems through the use of postfall and environmental assessments and then enact specific solutions, such as toileting programs, staff education programs, and the use of signs and hip pads.

We were intrigued to discover that the single intervention most highly correlated with our measure of performance was simple: signage that identified patients as being at high risk for falling was an extremely effective method of increasing staff awareness of fall risk and of enlisting the patient in fall prevention. We believe that the intervention was so effective because signage is commonly used in other areas of hospital care (i.e., infection precautions). Also, it was an easy intervention to achieve, it allowed staff to immediately align resources with needs,

and the results were immediately observable—all conditions consistent with factors that increase adoption of innovation.¹⁵

Finally, there is cost savings. While there is a moral imperative to help our patients avoid unnecessary suffering from a preventable fall, there also appears to be a strong financial incentive for facilities to avoid falls and the injuries that result. Using a range of \$16,322 to \$18,727 for the estimated cost of a hip fracture for the first year following injury,¹⁶ the collective avoidance of 40.9 such injuries per month would result in a total cost savings of between \$667,569 and \$765,934 per month.

Development and Deployment of the National VHA Falls Toolkit

In response to the magnitude of the falls problem, and to share tools and successes from the Falls Collaborative Breakthrough Project and current research, the National Center for Patient Safety (NCPS) created a Falls Toolkit. The toolkit is available free of copyright for any individuals or institutions wishing to access it.^a The Falls Toolkit continues to be the most frequently downloaded item on the NCPS Web site.

Staff employed in hospitals and other health care settings are actively engaged in improvement efforts to prevent patient falls. However, development, testing, and dissemination of a comprehensive set of tools for program development (eg, policies, guidelines, checklists, patient and staff education materials [PowerPoint® presentations, posters, pocket cards, technology resource guides]), deployment (conference calls and reporting systems), and evaluation (database management and reports) are beyond the resources of many health care institutions. The VHA addressed this gap through the development and deployment of the Falls Toolkit and the decision to make this compendium of resources publicly available.

In an effort to ensure that the toolkit would be useful, NCPS beta-tested the toolkit within VHA facilities and with subject matter experts. The facilities were asked to review the contents of the toolkit for a month and provide feedback. They found the toolkit useful, practical, and easy to understand. Based on this feedback, NCPS added articles to the annotated resource list, changed the format of the toolkit, modified the videos, and added sections.

Inside the Falls Toolkit

The Falls Toolkit is a boxed set containing a notebook and a media box. All materials are available electronically and free of copyright for use by individuals and organizations.

The Falls Toolkit notebook. The notebook consists of a three-ring binder containing 11 tabbed sections. The inside binder cover includes a CD-ROM that contains the information provided on the Falls Toolkit Web site, a Morse¹³ Fall Scale pocket card, two tri-fold brochures, and three 8½" x 11" posters and fliers. The 11 tabbed sections are as follows:

^a The Falls Toolkit is available at www.va.gov/ncps/SafetyTopics/fallstoolkit/index.html.

1. Contents: the locations of all resources available in the toolkit.
2. Instructions: information on how to use the toolkit.
3. Background: general information on falls and fall prevention.
4. Falls team: how to develop an interdisciplinary falls team.
5. Falls policy: what should be addressed in a comprehensive fall prevention policy and an example policy.
6. Interventions: things to do to reduce the number of falls and fall-related injuries.
7. Measuring success: tools to measure improvement in preventing falls and fall-related injuries due to interventions.
8. Resources: additional articles and resources categorized by topic.
9. Video 1: “Performing a Balance Assessment” (Audience: rehabilitation therapists).
10. Video 2: “Hip Protectors in an Inpatient Setting” (Audience: caregivers).
11. Video 3: “Protecting Your Hips with Hip Protectors” (Audience: patients).

The Falls Toolkit Media Box. The media box contains three 11" x 17" posters; three DVDs, each containing one of the aforementioned videos; one VHS tape containing all three videos; and a small box containing two styles of sample buttons for identifying falls prevention advocates or resources on units or shifts.

The Falls Toolkit Web site. The Falls Toolkit Web site contains all the printed information and tools and some additional materials, such as the Technology Assessment Guide and the Educational Resource Guide.

The Web site is organized into five sections:

1. Getting Started: orientation materials for the Falls Toolkit.
2. Notebook: PDF and MS Word[®] versions of the information contained in the notebook.
3. Media Tools: PDF versions of the posters, fliers, brochures, and button designs.
4. Resources: PDF and Word[®] versions of the additional resources (Technology Assessment Guide and Educational Resource Guide), PowerPoint[®] presentations, Excel[®] files, button designs, and links to relevant Web sites.
5. Contact Information: instructions on how to contact NCPS for more information, questions, or comments.

Using the Falls Toolkit

The purpose of the Falls Toolkit is to help facilities create and improve comprehensive falls prevention programs. Teams examining cases of falls with serious consequences can use the toolkit to analyze the data collected as part of a root cause analysis (RCA) and develop actions and outcome measures to reduce falls and fall-related injuries. The Falls Toolkit guides facilities in organizing interdisciplinary falls teams and in implementing evidence-based interventions based on fall risk or on a patient’s areas of risk.

Toolkit User Ratings

Participants were asked to rate the overall organization of the Falls Toolkit and its impact on their particular facility. The organization of the hard copy version of the Falls Toolkit and the Web site were both rated highly: 4.05 and 4.00, respectively, based on a 5-point scale.

In addition to the overall ratings, participants were also asked to rate the usefulness of the individual portions of the Falls Toolkit. The most popular physical item in the toolkit was the Morse¹³ Fall Scale pocket card, with 30.6 percent of respondents finding it highly useful. The most popular section of the Falls Toolkit Notebook was the interventions section, which also ranked as the section with the highest usage.

The questions regarding the individual portions of the Falls Toolkit were divided into questions about the materials in the media box and the contents of the notebook. The most popular items in the media box were the posters for educating patients, family, and staff. These items had the highest rate of use, and of those who used them, 17 percent found them to be highly useful. The least popular item was the falls advocate buttons, with 42.9 percent of those who used them finding them to be of little or no use.

The materials that are available on the Web site and the CD-ROM were also rated on usefulness. The most popular item that was only available electronically was the Educational Resource Guide. The majority of participants have used it, and of those, 20.3 percent found it highly useful.

The questionnaire asked participants to indicate how they had used the Falls Toolkit, such as for creating or modifying a falls policy or for tracking changes in the rate of falls or fall-related injuries. The most popular use for the Toolkit was creating or modifying the falls prevention policy at the participants' facility (59.3 percent), followed closely by implementing new fall-prevention interventions (54.2 percent) and tracking changes in fall rates or fall-related injury rates (47.9 percent).

The Falls Toolkit consolidates lessons learned from the Falls Collaborative and from current research in an easily accessed and well-organized manner. The electronic version of the contents is available and has been accessed and downloaded thousands of times by individuals, institutions, and agencies focused on falls preventions. The continued popularity of this product substantiates the public interest and desire for tools and products that are practical and field-tested to address the important issue of preventing falls and the injuries that result from falls.

VHA's National Falls Data Collection Project

VHA's Falls Data Collection Project (FDCP) grew out of a desire to create an incentive for people to use the Falls Toolkit and to develop some outcome measures for the effectiveness of falls programs. Participating facilities collected and reported various data elements from January 2004 through March 2006.

Of note for other health care systems interested in initiating a similar project, we were able to voluntarily recruit approximately one-third of the VHA facilities to participate in this project and report data for eight quarters (2 years). Participating facilities were attracted because they could receive their own information back in a useful form (e.g., charts, graphs, tables) and as comparative aggregated data. They also were attracted because they had regular access to teleconferences with falls experts. In addition, we scheduled calls to explain the data and reports and answer logistical questions.

We purposefully kept the number of captured data elements to a small set, focusing on the metrics that seemed most useful. In addition to fall and injury rates, we provided analysis on the following question: Were those that fell previously identified as being high risk, and if so, were interventions in place at the time of the fall? By the completion of the project, we saw a major improvement on this front, reflecting heightened sensitivity to screening for fall risk and implementing interventions. Major injury rates showed modest changes across the 2 years. However, the rates were low to begin with, and selection bias may have led to high-performing facilities self-selecting to participate. Participants' evaluation of the impact of the project was 4 on a 5-point scale (1 = no impact, 5 = highest impact). This project was accomplished with a very small staff of 15 percent FTE project director and 50 percent FTE data analyst/project manager.

Methods—Data Collection

Seventy VHA facilities initially volunteered for the project, and 65 ultimately provided data every quarter for 2004 to 2006. The data were sent to NCPS using a standard data collection tool on the last day of the month following the end of each quarter. At the end of the following month, NCPS sent reports back to facilities that compared the facility data to the aggregated national data. These reports were provided in hard copy and through interactive graphs and tables saved on a CD.

Data were collected, analyzed, and reported for three unit types: acute care, long-term care, and behavioral health. The behavioral health data were separated out because these patients often had a longer stay than acute-care patients and were not as old or frail as long-term care patients. Behavioral health units often had patients whose primary diagnosis was a psychiatric disorder, such as schizophrenia. Facilities provided the following data elements for each unit:

- Bed-days of care (BDOC).
- Number of unique patients who fell, divided into the following categories:
 - Overall number that fell.
 - Overall number that fell more than once in a quarter (repeat fallers).
 - Identified as high risk.
 - Identified as high risk and had interventions in place at the time of the fall.
 - Identified as high risk and unknown whether interventions were in place at the time of the fall.
 - Identified as high risk and had no interventions in place at the time of the fall (calculated rather than collected).

- Number of falls broken out by the following:
 - Absolute number of falls.
 - No injury or minor injury.
 - Major injury.
 - Death.
 - Hip fracture (a subset of the major injury).

These data were analyzed and reported back to facilities each quarter. The following measures were provided broken out for behavioral health, long-term care, and acute care:

- Fall rate per 1,000 BDOC.
- No or minor injury rate per 1,000 BDOC.
- Major injury rate per 1,000 BDOC.
- Hip fracture rate per 1,000 BDOC.
- Percent of patients who fell and were identified as high risk.
- Percent of patients who fell and were identified as high risk and:
 - Had interventions in place at the time of at least one fall.
 - Had no interventions in place at the time of any fall.
 - Unknown whether interventions were in place at the time of any fall.
 - Percent of patients who fell more than once in the quarter.
 - Percent of falls resulting in injury.

Results—Data Collection

Over the course of the 2 years, there was a reduction in major injuries as a percent of falls in all three unit types. This change was especially apparent in the behavioral health setting, with a relative rate reduction of 64.3 percent.

This project had a significant effect on the interventions that were in place at the time of a fall. As shown in Figure 1, the percent of high-risk patients who fell and it was unknown whether interventions were in place at the time they fell decreased substantially over the course of the project.

The fall rate per 1,000 BDOC for all three types of units remained relatively stable over the course of the data collection project. With the exception of the last quarter, the fall rate for behavioral health remained lower than both the acute care and long-term care settings. The smaller population in our study for behavioral health often led to higher variation in the fall rates and injury rates.

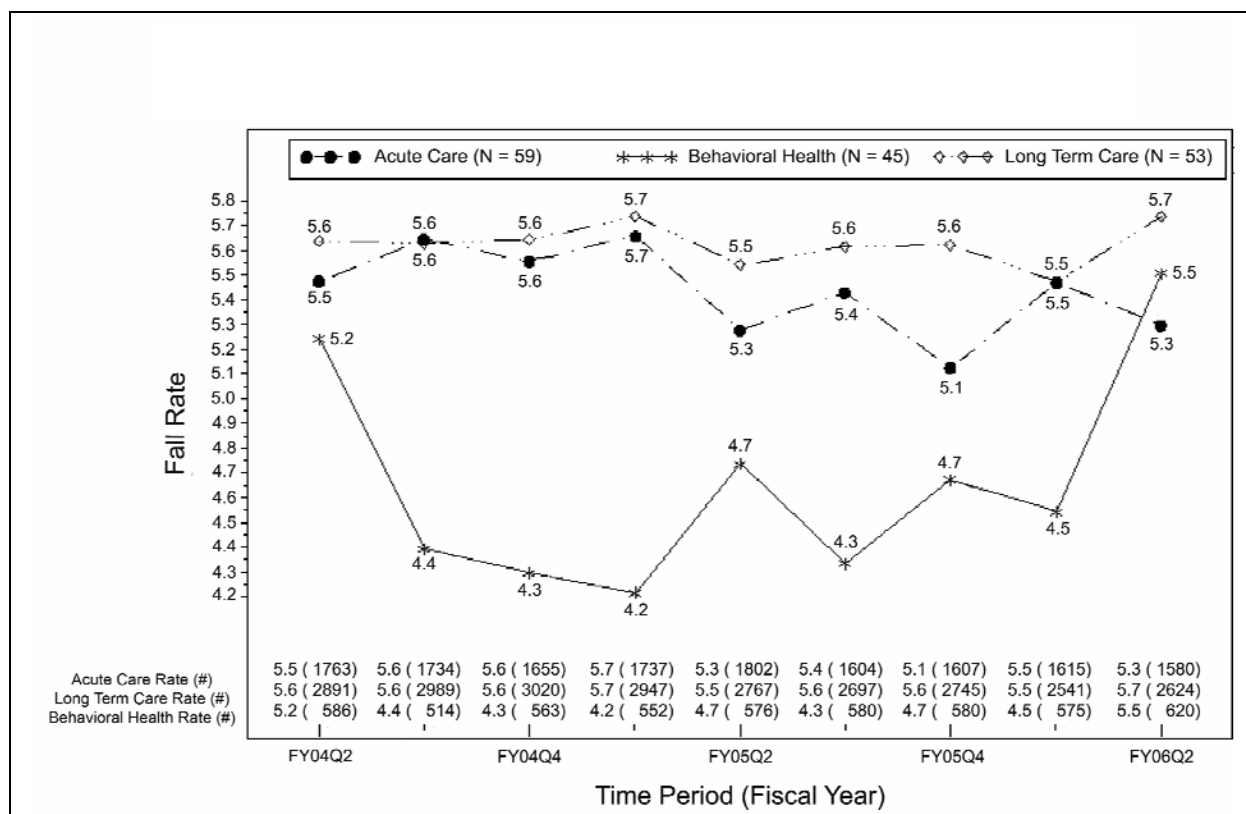


Figure 1. Comparison of national fall rate per 1,000 bed days of care.

Forty-two facilities submitted participation questionnaires, resulting in a 67.7 percent response rate. The mean rating for the overall impact of their participation in the project was 4.00 (0.826 SD) on a scale of 1 to 5 (1 = the lowest impact, 5 = the highest impact).

When facilities were asked about their reasons for participating in the project, they were able to indicate multiple reasons, as shown in Table 1.

Table 1. Reasons for participation in the Falls Data Collection Project

Reason for participation	N (%) (N = 42)
Report of national data	27 (64.3)
Report of own facility's data	25 (59.5)
Ability to opt out of an aggregated review	18 (42.9)
Other:	13 (31.0)
Benchmarking	8 (18.6)
Picture to use for awareness education with staff	1 (2.3)
Decision before I came	1 (2.3)
Help prevent falls	1 (2.3)
Institutional baseline	1 (2.3)
Making business case for changes	1 (2.3)

On the participation questionnaire, patient safety managers were asked three open-ended questions regarding their participation:

- How did you use the information provided to you?
- In what specific ways did you change your program based on this information?
- What actions are you the most proud of?

The responses are summarized here.

How did you use the information provided to you? Facilities had several uses for the information provided as part of the Falls Data Collection Project (Figure 2). Their responses could fall into more than one category. The six “other” responses (14.3 percent) that did not fit into any category included incorporating the data into an RCA, using the data for policy revision or team use, and justifying the need to purchase hip protectors and bed and chair alarms.

In what specific ways did you change your program based on this information? There were many ways that facilities changed their programs based on the information, for example:

- Changed or implemented a fall risk assessment (14.3 percent).
- Changed the system of tracking falls data, either by changing incident report forms or the measures they used (11.9 percent).
- Honed in on an area of vulnerability (9.5 percent).
- Changed or implemented a falls policy (7.1 percent).
- Changed or implemented a falls team (7.1 percent).
- Increased use of documentation or falls prevention interventions (4.8 percent).
- Became more proactive in falls prevention (4.8 percent).

In addition, 21.4 percent of facilities changed their programs in other ways, such as by implementing specific interventions, modifying the change-of-shift report, and changing benchmarking data. Here are some of their responses:

- Changed fall reporting to an electronic form to encourage accurate reporting. Amended policy to include Fall Prevention Toolkit information. Using toolkit guidance, posted on nursing units fall prevention tools based on the Morse¹³ Fall Scale rating.
- Implemented the Morse¹³ Fall Scale, changed the nursing assessment form to include falls risk; implemented visuals for patients at risk for fall to remind them to call for help; implemented a toileting program.
- Established a patient falls committee with stronger interdisciplinary approach to managing patients at risk for fall and improving the falls program.
- Changed from counting falls to a fall rate based on BDOC. Displayed the comparison of the national rate against our rate.

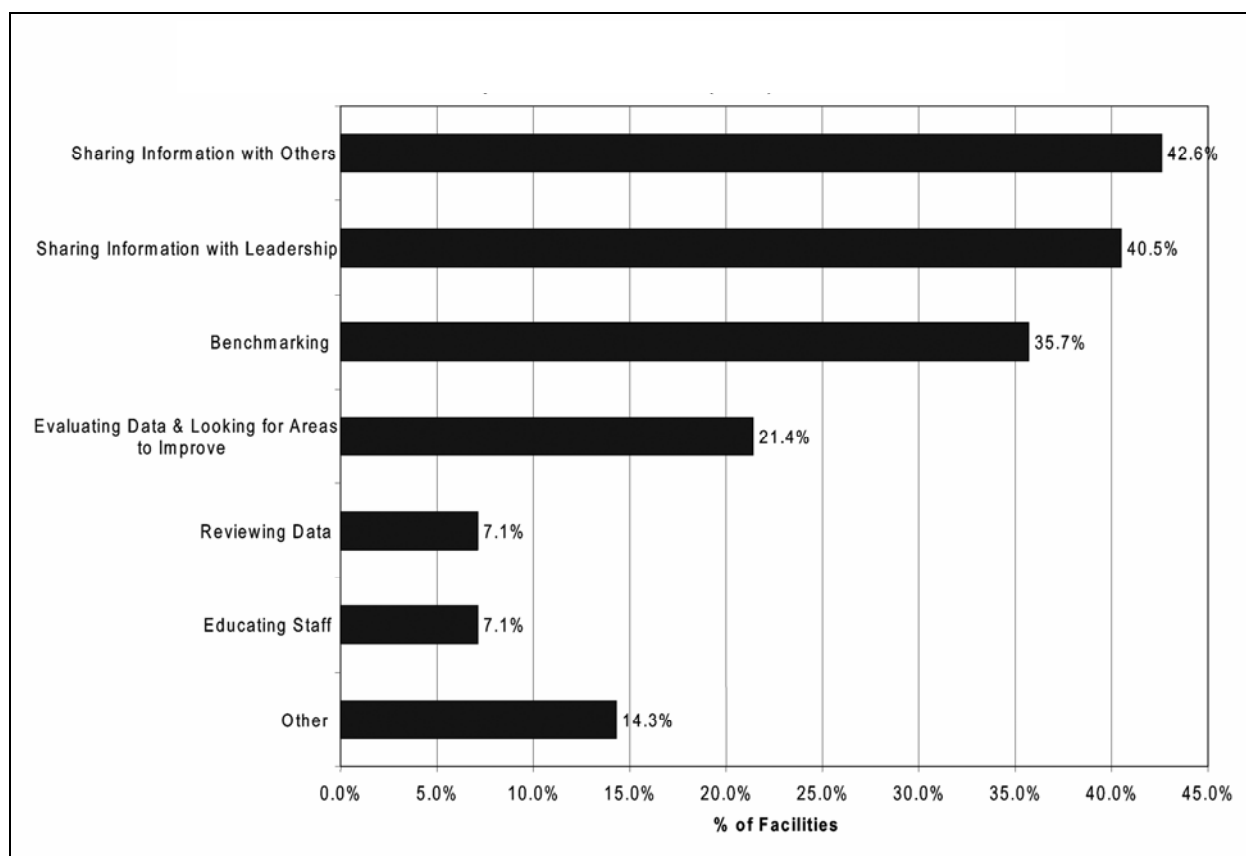


Figure 2. Reasons for participating in the Falls Data Collection Project Participation Questionnaire (n=42).

What actions are you most proud of and why? Several facilities mentioned that the implementation of a specific intervention, such as a transfer protocol or a “fall room,” was the action of which they were most proud (11.9 percent). Other actions included better or increased documentation (9.5 percent); increased awareness or motivation (9.5 percent); decreased injury or fall rates (9.5 percent); better or increased use of interventions (7.1 percent); increased reporting (7.1 percent); and education for patients, family, or staff (4.8 percent).

Patient safety managers were also asked to rate the value of the Falls Data Collection Project products on the participation questionnaire. These products included the data provided quarterly on both CD-ROM and hard copy, two newsletters, and two conference calls on the data. The results are summarized in Table 2. The data supplied on CD-ROM and in print copy and the newsletters were found to be useful or highly useful by 95.2 and 85.7 percent of patient safety managers, respectively. In addition, 80.9 percent of facilities found the conference calls on the data to be at least useful.

Table 2. Usefulness of products provided by NCPS for Falls Data Collection Project participation questionnaire

Product	N (%) (N = 42)			
	Highly useful	Useful	Little/no use	Did not use/attend
Data supplied on CD-ROM & hard copy	20 (47.6)	20 (47.6)	0 (0)	2 (4.8)
Newsletters	15 (35.7)	21 (50.0)	1 (2.4)	5 (11.9)
Conference calls on data	15 (35.7)	19 (45.2)	3 (7.1)	5 (11.9)

Results

This project demonstrated the appeal to facilities of participating in a project that provides falls data on operationally relevant measures in a timely fashion. Substantial improvements were witnessed in the proportion of falls resulting in major injuries, in the identification of patients at high risk, and in implementing interventions. Building upon the falls collaborative and the contents of the Falls Toolkit, this project continued the maturation of the falls programs at various VHA facilities.

Future Recommendations—Falls Interventions

While most studies on fall interventions have focused on reducing the number of falls, we believe that it is injuries that cause problems for our patients. Thus, reducing fall-related injuries should be the focus for future interventions, as well as targeting repeat fallers whose risk for injury increases with each fall. Our recommendation is that institutions move to analyzing falls according to the three categories described by Morse: accidental falls, anticipated physiologic falls, and unanticipated physiologic falls.¹³

Categorizing falls in this manner will allow facilities to direct action plans accordingly.¹ Most falls are accidental, and the environment should be examined for possible causes. However, if the majority of falls are anticipated physiologic falls, the focus should be on protecting the patient from falling by implementing all possible interventions for these high-risk patients. We also believe that more focused research is needed on patients who experience repeat falls, determining the effectiveness of team communication, and care-planning redesign.

These results provide some evidence that facilitated quality improvement efforts are perceived as useful to teams, and they can be successful in helping facilities to reduce major injuries due to falls and prevent loss of function and life due to falls. Falls can be prevented, and severity of fall-related injury can be reduced.

Our results also suggest that patient safety initiatives have the potential to generate organizational cost savings. Furthermore, the evidence indicates that better organized teams with good leadership and staff support are more successful. The evidence also shows that once teams

are established, the most fruitful interventions include conducting environmental interventions, postfall assessments, toileting programs, use of hip pads, and identifying high-risk patients through signage.

Additional leadership investment in teams would continue to advance these patient safety improvements. VHA's leadership and commitment to patient safety is unparalleled nationally, and this project reflects the cooperative efforts of staff, administrators, quality managers, and researchers to promote our veterans' freedom, independence, and safety.

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Hospital Language Services: Quality Improvement and Performance Measures

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Abstract

For a growing segment of the U.S. population, language barriers affect patients' ability to communicate effectively with health care providers. "Speaking Together" is the first national quality improvement (QI) collaborative focusing on improving operations of hospital-based language services. We employed a multistage process to develop quality performance measures for Speaking Together participants to use throughout the collaborative. The measures, which are grounded in the Institute of Medicine's six domains of quality, underwent multiple levels of review prior to pilot testing. Early experiences with the measures highlight challenges with collecting information on patient care that has not previously been collected and the importance of engaging staff, including registration staff and senior management. Speaking Together hospitals have shown that QI efforts to measure and advance the delivery of high-quality language services represent challenging but important tasks for improving delivery of care for patients with limited English proficiency.

Introduction

In the United States, 21 million individuals speak English "less than very well" and are thus said to be limited English-proficient (LEP).¹ For this growing segment of the population, poor health status and diminished access to health care are frequent challenges. As members of a racial, ethnic, or linguistic minority, people with LEP experience disproportionately high rates of infectious disease and infant mortality and are more likely to report risk factors for serious and often chronic diseases, such as diabetes and heart disease.² Furthermore, individuals with LEP are less likely to have a regular source of primary care³ and to receive fewer preventive health services, such as mammograms.⁴

Language barriers can also adversely affect the delivery of care. For LEP populations, followup compliance,⁵ adherence to medication, and patient satisfaction are significantly lower than they are for English-speaking patients.^{6, 7} On the other hand, LEP patients who are provided with an interpreter make more outpatient visits, fill more prescriptions, and have higher satisfaction with care.^{8, 9} Thus, the ability to communicate with a health care provider can mean the difference between receiving higher or lower quality care.

Physicians who are unable to communicate effectively with their patients often compensate by engaging in costly practices, such as using more diagnostic resources or invasive procedures and overprescribing medications.^{10, 11} According to one study, language barriers are associated with

an increased risk for serious medical events during pediatric hospitalizations.¹² For patients with LEP, adverse events occurring during hospitalization have also been shown to be more severe and more likely to be related to communication problems compared with English-speaking patients.¹³ Consequently, individuals with LEP have poorer health outcomes, are at greater risk for medical errors, and place a higher financial burden on the system than patients who can communicate fully with their health care providers.

Medical interpreters can bridge the communication gap between provider and patient.¹⁴ In the context of patient safety, studies have shown that this bridge is critical, particularly in hospital settings. For this reason, many hospitals have built an in-house capacity to provide language services to LEP patients using medical interpreters and other communication modalities. However, as language services programs grow, hospitals are increasingly challenged to determine whether their programs are providing high-quality language services to their patients.

The purpose of this article is to describe the development of a set of quality measures to assess the quality of spoken language services in U.S. hospitals. We also address challenges encountered by hospitals in implementing the measures and identify steps hospitals can take to improve language services operations.

The “Speaking Together” Learning Collaborative

Speaking Together is a national program funded by the Robert Wood Johnson Foundation that integrates quality improvement (QI) with hospital-based language services. The program uses a collaborative “learning network” model to foster shared learning and innovation among 10 hospitals that were selected through an open, competitive solicitation to participate in the program. Working in interdisciplinary teams, health professionals from across the United States learn what is working in other language services programs and draw on the expertise of the collaborative to address their own hospitals’ language services challenges. Program successes are shared across participants, giving hospitals with linguistically diverse patient populations concrete and tested examples of effective language services programs and interventions that they can adopt in their own busy hospital environments.

Speaking Together identifies effective ways to reduce ethnic and racial disparities in the quality of patient care by providing tools that health systems can use to improve the overall quality of care delivery. The project focuses on three areas: (1) improving the quality and accessibility of language services for patients with LEP, (2) using quality performance measures to monitor improvements in the delivery of language services to patients, and (3) identifying the link between improvements in chronic disease management for a set of target conditions (i.e., cardiovascular disease, depression, diabetes mellitus) and improvements in language services delivery.

As Table 1 illustrates, the 10 hospitals in the collaborative are diverse in terms of their location. They also vary in size and the scope of their language services programs, with the size of their employed language services workforce varying from 7.9 to 63.1 fulltime equivalents (FTEs). All have more than 10,000 admissions per year, with volumes of interpreter encounters varying from

Table 1. Summary of hospitals participating in the Speaking Together collaborative

	Bellevue Hospital Center	Cambridge Health Alliance	Hennepin County Medical Center	Phoenix Children's Hospital	Regions Hospital	U. Rochester (Strong Memorial Hospital)	Children's Hospital and Medical Center	U. California Davis Medical Center	U. Mass Memorial Medical Center	U. Michigan
Location	New York, NY	Cambridge, MA	Minneapolis, MN	Phoenix, AZ	St. Paul, MN	Rochester, NY	Seattle, WA	Sacramento, CA	Worcester, MA	Ann Arbor, MI
Number of beds ^a	771	350	434	285	399	973	250	526	731	802
Total admissions ^a	26,068	15,263	22,117	11,712	22,827	36,321	11,608	27,946	44,231	42,811
Annual interpreter encounters ^b	58,962	140,556	120,000	48,043	28,887	14,885	40,690	65,000	59,134	21,503
Total FTE for language services ^b	34.0	63.1	53.0	13.9	12.1	10.4	7.9	22.8	28.5	16.0
Interpretation encounters in top 5 languages ^b	60% Span 6% Mand 6% Cant 3% Polish 2% French	55% Braz Port 24% Span 7% Hait cre 2% Eur Port 2% Hindi	60% Span 12% Somali 4% Russ 3% Hmong 1% Laotian	>99% Span	50% Span 12% Hmong 10% Somali 9% Viet 4% ASL	46% Span 35% ASL 3% Viet 2% Russ 2% Arabic	55% Span 7% Viet 4% Somali 4% Russ 2% Cant	58% Span 20% Russ 8% Mien 5% Hmong 5% Cant/Mand	62% Span 13% Port 7% Viet 5% Albanian 3% ASL	22% Span 18% Chin 14% Jap 12% Arab 10% Russ

a **Source:** AHA Annual Survey Database, FY 2005. See: AHA Trendwatch Reports and Chartbooks. Washington, DC: American Hospital Association; 2005. Available at http://www.aha.org/aha_app/trendwatch/archive.jsp. Accessed May 8, 2008.

b **Source:** *Speaking Together*, 2006.

FTE = fulltime equivalents

Arab = Arabic; ASL = American Sign Language; Braz = Brazilian; Cant = Cantonese; Chin = Chinese; Eur = European; Hait Cre = Haitian Creole; Jap = Japanese; Mand = Mandarin; Port = Portuguese; Russ = Russian; Span = Spanish; Viet = Vietnamese

14,000 to more than 40,000. In all but one hospital, Spanish is the most common language spoken by LEP patients. Many have substantial numbers of patients who speak Mandarin, Cantonese, Portuguese, Haitian Creole, Somali, Hmong, Arabic, and Russian. Most also have many patients who communicate using American Sign Language (ASL), which Speaking Together includes among the other languages requiring effective QI interventions.

Language Services Measures

Speaking Together is the first national QI collaborative focusing on improving operations of hospital-based language services. Speaking Together grantees apply techniques and tools similar to those used in other QI collaboratives, including rapid cycle change, uniform and routine data collection, transparent reporting mechanisms, and learning sessions for sharing strategies. These types of QI activities have proven to be extremely useful in other similarly structured learning collaboratives.

Because the field of language services does not currently have commonly used language performance measures, hospitals customarily report fluctuations in the number of interpreter services encounters as a proxy for evaluating their programs and operations. However, in our examination of the published literature and extensive interviews with field experts, we have found no evidence linking quality of language services to total volume of services provided.

The Speaking Together staff developed a set of performance measures for language services for grantees to use throughout the learning collaborative, with the goal that these performance measures would provide relevant and consistent information about aspects of quality associated with the delivery of language services. The measures address only one important component of communication in the health care setting—i.e., verbal communication. We recognize that other important aspects of communication within the health care arena will require additional performance measures. Nevertheless, Speaking Together provides an opportunity to test the utility and adequacy of this set of performance measures and to determine whether they can be sustained over a long period.

Development of the Measures

We employed a multistage process to develop these measures. First, we used the Institute of Medicine's (IOM's) six dimensions of quality (i.e., safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness) as articulated in *Crossing the Quality Chasm*¹⁵ as a framework for developing language service performance measures. As Table 2 illustrates, we applied these quality dimensions to language services to create guidelines for the measures' development process.

With the IOM framework guiding our work, we conducted an extensive literature search to develop an evidence base that would support measures in language services and identify key quality concerns related to the delivery of language services in hospitals and other health care settings. The literature review formed the basis for developing draft measures and identifying important questions for discussions with experts.

We discussed the findings from the literature review and our own questions developed through field work with approximately 36 researchers, directors of established hospital-based interpreter services departments, and other experts in language services to help identify issues related to quality of language services and potentially valuable performance measures. These discussions, the literature review, and our own observations of language services programs identified similar quality issues and created the empirical basis upon which performance measures could be framed.

Table 2. Applying IOM's six domains of quality to language services

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- **Safety:** Avoiding injuries to patients from the language assistance that is intended to help them
 - **Timeliness:** Reducing waits and sometimes harmful delays for those who receive and those who provide language services
 - **Effectiveness:** Providing language services based on scientific knowledge that contributes to all who could benefit, and refraining from providing services to those not likely to benefit
 - **Efficiency:** Avoiding waste, including waste of scarce language services resources; the time of patients and clinicians, hospital staff, and interpreter services personnel; and equipment, supplies, ideas, and energy
 - **Equity:** Providing language assistance that does not vary in quality because of personal characteristics, such as language preference, sex, ethnicity, geographic location, and socioeconomic status
 - **Patient-centeredness:** Providing language assistance that is respectful of and responsive to individual patient preferences, needs, culture, and values; and ensuring that patient values guide all clinical decisions
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Source: Institute of Medicine, *Crossing the Quality Chasm*. Washington, DC: National Academies Press; 2001.

Identifying a Framework for Organizational Change

After determining that the IOM domains of quality would be an appropriate conceptual framework to identify and define the principles of high-quality language services, we looked to the literature on performance measures to find guidance on how to apply the measures of quality to an organization. We used Nerenz and Neil's paper, "Performance Measures for Health Care Systems,"¹⁶ to help us develop an organizational framework for hospital language services that could be used to encompass the quality measures. Nerenz and Neil ask three key questions that we considered essential for the language services measures development process:

- What is the entity being measured?
- Who is using the information?
- What core organizational processes or skills are the measures designed to reflect?

The first two questions are easily answered by the goals of Speaking Together. The program seeks to measure the quality of language services in an effort to improve those services and the care received by patients who need them. Thus, language services are the "what" that is being measured; and hospital language services departments, QI committees, and clinical staff are all part of the "who" that is using the information.

The Nerenz and Neil article¹⁶ was particularly useful in helping us determine what core organizational processes or skills should be included in the quality measures. Specifically, we used their “domains of performance measurement” to identify the key elements involved in the delivery of language services and to examine how they should be integrated into the quality measures.

We identified the following specific organizational elements related to language services:

- Organizational structure of language service departments.
- Processes involved in the delivery of language services.
- Operational efficiencies of language services.
- Outcomes associated with quality language services.

Once these elements were identified, we used them to help us pinpoint and define the variables that would be included in the actual measurement of quality language services, as identified using the IOM domains of quality.¹⁵

Drafting Performance Measures for Quality in Language Services

Using the quality and organizational frameworks described previously and information from the literature and interviews, Speaking Together staff developed 10 measures for external review. These measures focused primarily on the operations of language services in hospitals, the delivery of verbal and signed interpreter services, and verbal communication with bilingual hospital staff and clinicians.

We developed a glossary of terminology used to describe the performance measures. Many of the definitions were based on those developed by the California Healthcare Interpreter Association,¹⁷ the National Council on Interpreting in Health Care,¹⁸ and The California Endowment.¹⁹ We defined interpreters and bilingual providers as “qualified” to communicate with patients if they were:

- Bilingual staff or providers who have been assessed for proficiency in the language(s) for which they provide care.
- Medical interpreters who have been trained in medical interpreting methods and protocols and assessed for language proficiency.

We did not include specific standards or guidance on the types of assessments used to determine whether bilingual providers or interpreters were qualified, but instead, we left it to health care organizations to determine whether they met their own organizational standards or requirements.

Once we had a set of draft measures, we assembled two groups of experts to review the language services performance measures. The first group comprised individuals who were most likely to ultimately use performance measures in language services. Each of the eight participants in the group was either the director of a large ambulatory care service in a linguistically diverse hospital or the director of a large, established, and complex interpreter services department at a different hospital. Our goal was to capture opinions about the day-to-day challenges of the demand and supply sides of language services in busy hospital environments and to determine

whether the draft language services performance measures would be appropriate for their hospitals. The panel convened to review the measures according to uniform evaluation criteria and to discuss the feasibility of implementing the measures in the context of busy acute care hospitals and outpatient settings.

The second group of reviewers consisted primarily of experts who had contributed to the research in the field of language services. These researchers were well versed in the key issues, methodologic concerns, and challenges facing language services programs. Both groups of reviewers were asked to evaluate the draft measures using four evaluation criteria:

1. **Importance power.** Does the measure address a significant and important quality issue pertaining to delivery of language services?
2. **Proxy power.** Does the measure address the specified domain of quality? Is the measure an approximation of the description in the value of the measure?
3. **Communication power.** Is the measure clearly worded and easily understood by users collecting the data?
4. **Data collection power.** Is the data collection required for the measure obtainable in a format that minimizes bias? Is the data collection required feasible? Are the data reproducible? Are the data reliable?

Based on reviewer discussions and suggestions, five performance measures were selected for field-testing, as shown in Table 3.

Future Measures Development

We were unable to identify a performance measure for “patient-centeredness,” because the scope, design, and timeframe of Speaking Together did not enable us to gather feedback directly from patients in any systematic way. Patient-centeredness is a critical domain of quality. For this reason, the Robert Wood Johnson Foundation has since funded focus groups of patients with LEP across all the Speaking Together hospitals. Thirty focus groups—held in Spanish, Portuguese, Somali, Russian, Vietnamese, ASL, Haitian Creole, and Chinese—were conducted in fall 2007 and provided extremely important information to the hospitals as they developed strategies to improve their language services programs.

Piloting the Measures

The five Speaking Together performance measures were piloted at two hospitals with active and well-regarded language services programs: Boston Medical Center (BMC) and The Children’s Hospital of Philadelphia (CHOP). The two pilot sites received a toolkit designed to assist clinical department managers, language services department managers, interpreters, and others in collecting the required information to calculate the measures. The toolkit included data and information submission templates that served as the paper version of a Web-based data reporting program that participants in the collaborative were to use to submit data and information to the Speaking Together program office throughout the duration of the collaborative. Also included were data-tracking tools, measure specifications, details about variables and metrics required for each measure (e.g., inclusion and exclusion criteria), and information to link how the measure would be useful for patient care and/or language services operations.

Feedback from the pilot sites allowed us to assess the feasibility of collecting the data for the measures and to refine the tools and documents that grantee hospitals would utilize during the collaborative. No substantive changes were made to the performance measures because of the pilot tests at the two hospitals.

Early Experience with the Measures

We introduced the measures to the Speaking Together hospitals at the first learning network meeting in November 2006 and

expected that they would face certain challenges in being able to gather data to report on their performance on a monthly basis. In anticipating some of these challenges, we designed the project as a 16-month collaborative. This would provide a full year for participation in QI activities following a 3- to 4-month period for hospitals to become accustomed to the reporting requirements and to make necessary adjustments to their information systems and data collection practices.

A focus on patients rather than interpreters. As we anticipated, the hospitals encountered a number of challenges during implementation of the language services measures. For example, the measure ST2 requires hospitals to document whether patients who prefer to receive care in a language other than English actually receive language services during two critical points in the health care encounter, i.e., initial assessment and discharge. This is a complicated measure, but we consider it essential to safe, effective, and equitable care. Patients with LEP must be able to communicate fully with their physicians and nurses when complex interactions take place.

We identified two instances in a patients' interactions with their providers—initial assessment and discharge—when adequate communication was essential, and we required hospitals to document that, in those two instances, the LEP patient had either received care directly from a bilingual provider whose language fluency had been assessed or indirectly via the help of an interpreter whose fluency had been assessed and who had been trained in medical interpreting.

Speaking Together takes no position on whether communications take place via bilingual staff, in-person interpreters, telephonic or video interpreting, or through other modalities. Regardless of the vehicle, interpreters must be assessed and trained, and bilingual providers must be assessed to be deemed qualified for the encounter and to “get credit” for meeting the measure.

Table 3. Proposed Speaking Together performance measures

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- **ST1: Screening for preferred language.** The percent of patients who have been screened for their preferred spoken language
 - **ST2: Patients receiving language services from qualified language service providers.** The percent of LEP patients receiving initial assessment and discharge instructions from assessed and trained interpreters or from bilingual providers assessed for language proficiency
 - **ST3: Patient wait time.** The percent of encounters where the patient wait time for an interpreter is 15 minutes or less
 - **ST4: Time spent interpreting.** The percent of time interpreters spend providing medical interpretation in clinical encounters with patients
 - **ST5: Interpreter delay time.** The percent of encounters during which interpreters wait less than 10 minutes to provide interpreter services to provider and patient
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Source: Speaking Together, 2006.

LEP = Limited English proficiency

For initial assessment and discharge, Speaking Together considers the use of family or friends, untrained interpreters, or unassessed providers to be identical to the patient receiving no language services whatsoever.

The ST2 measure required hospitals to collect information on patient care that had previously never been collected, and it often required cooperation and collaboration from clinical staff in inpatient and outpatient settings. Hospitals regularly collect training and assessment information for interpreter staff, but they had not previously collected this information for bilingual providers. To our knowledge, no hospitals in the country systematically documented whether LEP patients received adequate language services during specific encounters or interactions. Thus, this measure required hospitals to change data collection practices to focus less on numbers of language services encounters provided and more on whether each LEP patient received services at certain points during the inpatient stay or outpatient encounter. Such a shift in focus, though completely understood and embraced by the hospitals, remains a challenge for the Speaking Together hospitals and is likely to challenge most hospitals that undertake data collection focused on patients rather than interpreters.

Standardizing definitions. One of the benefits of participating in a QI collaborative is the opportunity to benchmark performance against a group of similar organizations. Without national benchmarks related to quality of care in language services, the Speaking Together hospitals were in a position to set benchmarks for the country, assuming the group could agree on certain basic definitions to enable “apples-to-apples” comparisons in performance. However, we soon learned that although identifying a common set of definitions was possible, requiring all hospitals in the collaborative to adopt those common definitions would create problems that could not be addressed within the scope of the project.

For example, hospital teams struggled with the definition of a language services encounter. Within the collaborative, various hospitals considered the term “encounter” to describe a single interaction among an interpreter, a patient, and a provider; multiple interactions among an interpreter, a patient, and the same provider; and a time-defined (e.g., 22 minutes) interaction among an interpreter, a patient, and a provider, with lengthier interactions among the same three parties constituting multiple encounters.

Similarly, in recording timeliness of interpreter services, hospitals used different definitions for the start time of the encounter. Consequently, they would see their performance rise or fall based on the particular definition chosen. Even without standard definitions, the Speaking Together hospitals were relatively close in most of the variables necessary to report on the measures. For the purposes of the collaborative, we suggested a number of common measures but allowed hospitals to use their own definitions if they felt doing so would be more appropriate for internal reasons.

Engaging staff beyond interpreter services. Reporting on the Speaking Together measures required hospitals to engage the interest and cooperation of other services and departments in the organization, a task that was new to many hospitals. For example, the measure ST1 requires all patients—including English-speaking patients—to be asked about preferred language for health care delivery. While many hospitals ask patients about their primary language, it was unusual for hospitals to query all patients about language preference. Yet, we believe that true demand for

language services cannot be identified without full screening of all inpatients and outpatients for preferred language.

Such a change required hospitals to interact, either directly or indirectly, with registration staff to educate them about the importance of asking about preferred language, offer suggestions about how the information could be recorded, and encourage them to routinely collect the information, despite adding another information field to the registration process. Because many of the registration systems did not easily accommodate this information, language services staff also met with information technology staff to discuss opportunities for adding a field in the registration system for preferred language.

None of these changes could have taken place without the support of senior management in the hospitals. True change in the quality of language services requires the ongoing support and participation of multiple departments, clinicians, and managers; and it hinges on executive leadership embracing the notion of change and its practical implications. Speaking Together benefited from an enormously supportive cadre of forward-thinking chief executives who well understood the safety implications of high-quality language services and the need to facilitate linkages between various support services in the hospital and the Speaking Together team.

Conclusion

The quality of communication between patients and providers is a strong determinant of whether patients receive optimal care. By identifying specific strategies that help hospitals build effective language services programs, health care organizations can improve quality and patient safety for millions of people.

Hospitals have shown that they can undertake serious QI efforts to measure and advance the delivery of language services in hospitals. Advances in improving quality do not come without challenges, but the Speaking Together program illustrates how committed health care professionals and organizations can meet those challenges and overcome substantial obstacles to improve quality for their patients.

The Speaking Together hospitals are poised to set benchmarks for hundreds of other hospitals that are struggling with the challenges of providing high-quality language services to their LEP patients. For the first time, hospitals are gathering information to estimate true demand for language services and to determine whether they are effectively meeting that demand. The result will certainly be better and safer care for patients with limited English proficiency.

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Using Patient Complaints to Promote Patient Safety

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Abstract

Patients can help promote safety and reduce risk in several ways. One is to make known their concerns about their health care experiences because complaints might suggest unsafe systems and providers. Responsive health care organizations can benefit since patient complaints that are recorded, systematically analyzed, aggregated, and profiled by ombudsmen can accurately identify physicians at increased risk of a lawsuit. In this paper, we describe how patient complaint profiles have supported nonpunitive “awareness” feedback and, if needed, “authority” interventions designed to improve safety and reduce lawsuit risk. Experience since 1998 with several hundred such interventions at more than 20 community and academic medical centers shows fewer subsequent complaints associated with most of those receiving feedback. Strengths and limitations of the approach are discussed. We conclude that patient concerns can be an important force for promoting safety.

Introduction

Surveying the patient safety movement in 2002, Vincent and Coulter rightly decried “the lack of attention paid to the patient.”¹ At about the same time, we demonstrated an association between unsolicited patient complaints and physicians’ risk management profiles.² In an accompanying editorial, Sage noted, “It would help to forge stronger links between the ‘customer satisfaction’ side of health care and the ‘clinical safety’ side.”³ However, Hsieh and colleagues noted that many health care organizations do not appear to use patient complaints to promote higher standards of care.⁴ In this paper, we report our experience with using patient/family complaints about their health care experiences to make medicine both kinder and safer.

Over the past few years, various authors and groups have suggested several ways that patients and family members might help promote patient safety and reduce risk. For example, Garbutt, et al., recommended that patient advocates ask hospitalized patients about any concerns they might have about their hospital stay,⁵ and Burroughs, et al., suggested that advocates also inquire about patients’ fears about medical errors.⁶ In a review of studies about multidisciplinary rounding on patients, Gurses and Xiao found that health care team communications with patients uncovered unmet needs and improved clinical outcomes.⁷ Levinson and Gallagher recently suggested that physicians’ error disclosures might create opportunities for patients to help improve safety and quality.⁸ In an overview of strategies for involving patients, Coulter and Ellins suggested several types of patient-focused interventions that could improve safety, including offering information to help patients choose safe providers, involving patients in handwashing and other infection

control processes, encouraging adherence to promotion programs, encouraging patients to check their own records and monitor their care processes, and advising patients to report adverse drug events.⁹ In addition, impressive national and international efforts to solicit patient perceptions of their care have been initiated, particularly the Agency for Healthcare Research and Quality's (AHRQ) Consumer Assessment of Healthcare Providers and Systems (CAHPS™) survey program,¹⁰ the Centers for Medicare & Medicaid Services' (CMS) Medicare Current Beneficiary Survey (MCBS),¹¹ and the World Health Organization's (WHO) Patients for Patient Safety,¹² one of 10 action areas of WHO's World Alliance for Patient Safety.

In the mid-1990s, we began asking whether there might be other avenues by which patients and their loved ones might contribute to safety and risk management improvement efforts. After all, given the large numbers of iatrogenic injuries worldwide,^{13, 14, 15, 16} error-affected patients and those aware of near misses would certainly have many observations about their health care experiences that—if sought, recorded, and analyzed—might help promote positive changes in health care systems, teams, and individual providers. As Sage³ put it, "...health care organizations need to elicit patients' stories, capture information relevant to safety, and feed that information back to the professionals who organize and deliver care." Others agree.¹⁷ This article summarizes our experiences over the past decade profiling patient complaints and using the results to promote safety and reduce risk.

Patient Complaints Are Important

Why be concerned about the experiences of patients and their loved ones, when peer-review programs and safety committees already exist in most health care organizations? First, the substantial literature on patient-centered care and patient empowerment suggests that patients' involvement in their care can improve their medical outcomes. We hypothesized that patient/family concerns would just as likely point to recurring problems that increase risk.

Second, despite legal protections established by Federal and State legislatures to encourage medical peer review, many observers assert that outcomes of peer review fall short of expectations for a variety of reasons that have been reviewed elsewhere.¹⁸ We simply suggest that patient concerns might supplement, not supplant, traditional peer review. We hypothesized that getting peer physicians to provide feedback about patient concerns would help address the malpractice claims risk of their high-complaint physician colleagues.

Finally, our hypotheses assumed that safety issues were embedded in patient complaints and risk management activity, at least in part. Our reviews of risk management files have consistently pointed to doctor-patient, doctor-doctor, and staff-doctor communication problems as disruptors of team function and drivers of risk management activity.^{19, 20, 21} Good teams make for optimal outcomes and patients are integral members of the health care team. When patients are forgotten or not integrated into ongoing decisionmaking, outcomes suffer. Therefore, we believe patient complaints are often markers of dysfunctional teams, and addressing those physicians who are associated with the greatest expressions of patient dissatisfaction might create better teamwork and greater safety. We will return to this issue later.

Unsolicited Patient/Family Complaints as Indicators of Opportunities to Improve Safety

Many medical centers and medical groups employ patient advocates (ombudsmen) to assist families who express concerns about their care. Advocates attempt service recovery (i.e., the process of trying to make right what the patient thinks is wrong), and they document families' concerns. We wondered whether such complaints were randomly distributed, and if not, whether physician-related complaints were associated with one indicator of challenges to patient safety: risk management-related activity.

To assess the potential value of families' observations, our team created a reliable system for coding complaints by type (6 major categories and 34 subtypes), by person or people associated with the complaints, and by the locations—inpatient units or outpatient facilities—associated with the concerns.²² The major categories included concerns about care and treatment, communication, concern for the patient, access, billing, and environment. (Note: Physicians are almost never associated with complaints about environment.) For example, access-related subtypes included such allegations as long waits to be seen, inability to get an appointment within a reasonable time span, failure of physicians to see patients/families after surgery or throughout a hospitalization, failure to return phone calls, and inadequate time spent with the patient. A description of the coding categories has been published previously.²²

Application of the coding scheme to patient complaints recorded by one academic medical center revealed that 35 percent of its physicians were never named in an unsolicited complaint.² In addition, about as many physicians were only rarely associated with a patient concern. However, 9 percent of the group's physicians were associated with approximately 50 percent of all unsolicited physician-related complaints during the study period. This finding has since been replicated at a large regional (nonteaching) medical center.²³

We next demonstrated that an academic medical group's physician-related patient complaints were associated with their malpractice risk.² Specifically, through a series of regression analyses, we identified several independent predictors of claims experience: sex, specialty, volume of service, and unsolicited patient/family complaints. However, complaints accounted for the greatest proportion of the variance in claims experience. Inserting values for each physician's sex, type of practice (medicine or surgery), service volume, and number of unsolicited patient complaints, we used the regression equation to calculate a predicted-risk index for each of the medical group's 644 physicians. We sorted every medical group member into one of five empirically determined predicted-risk categories. Next, we calculated the mean risk-management payouts (dollars and percentage of dollars paid out) for each of the five groups, and we then assessed each group's mean number of complaints per physician.

Our regression equation placed nearly half (49 percent) of the medical group risk in the lowest predicted risk category. Physicians in this lowest predicted-risk group averaged fewer than five unsolicited complaints during the 6-year study period. By contrast, the 8 percent of physicians with the highest predicted-risk scores averaged more than 10 times the number of complaints. With respect to risk management-related expenses (including court costs, attorneys' fees, and payments to claimants), the 49 percent in the lowest predicted-risk group were responsible for

4 percent of expenses, whereas the 8 percent in the highest risk group were responsible for fully 50 percent of expenses. Even more startling to us was the fact that physicians in the highest predicted-risk group had an average payout that was 73 times as high as that of their low-risk colleagues.¹⁸

These findings have been replicated with physicians in a Midwestern community medical center.²³ We concluded that the association between malpractice risk and patients' unsolicited complaints provided a strong foundation upon which to create a system for alerting physicians whose patients and patients' loved ones expressed a disproportionate numbers of complaints.

Patient Complaint Profiles

The literature about effectively changing physician practice behavior teaches that change-related messages must be evidence-based, contain data that compare a physician with peers, be delivered by a respected physician "messenger," and be repeated over time.^{24, 25, 26} In other words, the messages must be delivered in a way that promotes sustained attention, deliberate action, and personal accountability.

Given the association between complaints and malpractice claim risk, the Vanderbilt group developed the Patient Advocacy Reporting System (PARS[®]) to investigate how complaint data might be used to reduce risk and promote quality care. Research using this program has been ongoing since 1997. In brief, patient complaints are reliably coded and analyzed, and a complaint index is generated for each physician and compared with that of other medical group members. A higher index reflects higher risk for medical malpractice claims. Physicians with an index greater than the 95th percentile are candidates for peer-to-peer intervention.^{18, 27}

Small committees of physicians at Vanderbilt and more than 20 other hospitals and medical centers have been trained to deliver what we call "awareness feedback" (or a "Level 1" intervention). Each institution establishes a committee in compliance with its State's requirements for protected peer review. Committee members are nominated to be trained as "messenger peers" based on several criteria: they are distributed among practice types, currently or recently in active practice, respected by colleagues, committed to confidentiality, and willing to serve. Their own complaint scores are mostly satisfactory, but on occasion, some high-risk physicians have served as messengers.¹⁸

Peer physicians receive 6 to 8 hours of training to help them deliver the data and the essential messages to high-complaint colleagues. The training discusses the research background, support data, and feedback materials; essential steps in sharing the complaint data; and how to anticipate and address high-complaint physicians' common reactions, questions, and challenges. The training includes demonstrations, role-play exercises, and substantial time for questions and discussion.

Once messenger training is complete, "awareness intervention" materials are assembled and distributed. Each packet contains a letter from the messenger addressed to the high-complaint (at-risk) physician. The letter describes the process and provides the physician with his/her numerical ranking among all medical group physicians (e.g., "You are number 8 of 280 in your group, and you rank second within your general field of surgery."). The packet of feedback materials also contains a "you-are-here" figure (Figure 1), a table that portrays the types of

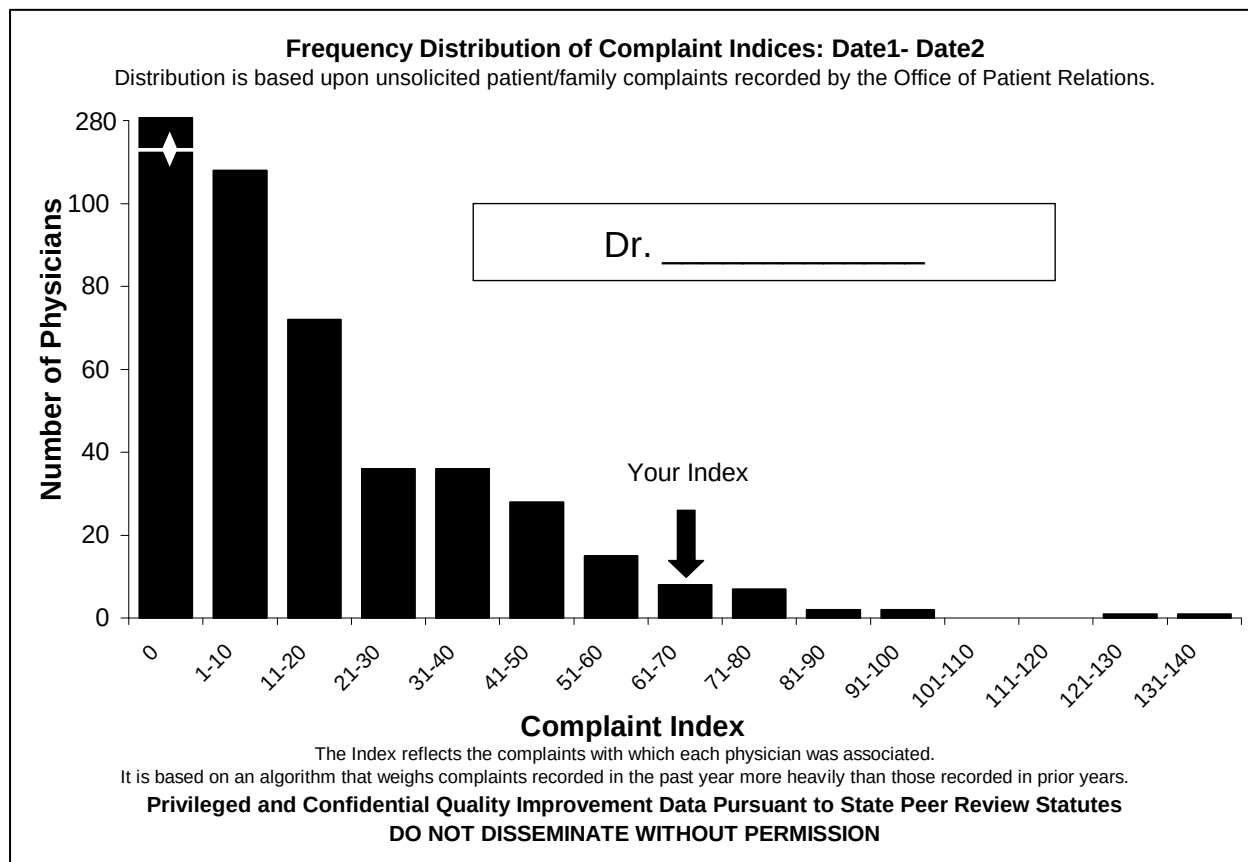


Figure 1. Distribution of complaint scores at one medical center. The arrow identifies Dr. _____’s standing in the large group of physicians with privileges at that medical center.

complaints voiced by patients and families, and individual deidentified complaint narratives. Physicians are assured that the process is confidential and, if applicable, protected from discovery under appropriate peer review or quality statutes. They also are assured that none besides the one or two others named in the letter are or will become aware of the individual’s status unless the risk pattern persists over time. Finally, messengers remind their high-risk colleagues that the process is ongoing, and that they will provide annual followup data.

Figure 1 illustrates calculated indexes for all of a physician group’s members. The index is based on age of complaint (more recent complaints are given more weight) and the specific complaints contained within a complaint report. Physicians are shown where their index lies on the graph, which illustrates that the vast majority of other physicians practicing at the medical center are associated with fewer complaints. For followup visits, a line graph shows change in the physician’s index over time relative to his/her area of practice and facility.

As of this writing, composite results are available for 14 medical centers, several of which are made up of multiple hospitals. To date, 405 initial Level 1 “awareness” visits and more than 600 followup feedback sessions with 336 of those physicians have occurred (69 followup visits are scheduled after this writing). The results have been quite promising (Table 1, previously unpublished data). Overall, after being made aware of their standing and given followup data 1

year later, the mean and median percentage of complaint reduction 2 years after the initial “awareness” intervention are 29 percent and 56 percent, respectively ($P < 0.001$).

Not all improve, of course, but more than half have shown substantial improvement. Specifically, as of this writing, 58 percent

of physicians receiving initial awareness level feedback and one followup have reduced their numbers of complaints by at least 40 percent. The mean and median improvements for these “responders” were 78 percent and 79 percent, respectively. Formerly high-complaint physicians continue to be tracked, but after 10 years of data collection, the “recidivism” rate is less than 3 percent. Most messengers have been well received; fewer than 2 percent reportedly met with overt hostility. Most high-complaint physicians self-identify and self-select issues to be addressed and then do such things as request to be shadowed to get suggestions for improvement, seek resources that will improve their service, reorganize their unit, or seek other assistance.

One unexpected finding has been that roughly 21 percent of the high-complaint physicians have departed their institutions or groups. Perhaps their intention to move or retire distracted them from fully caring for patients, or perhaps they left seeking a “geographic cure” for perceived shortcomings of their practice environments. Because very good doctors can be caught in and decide to leave unsupportive or unsafe environments, we make no judgments about their reasons for departure.

The final noteworthy group consists of approximately 21 percent of the high-complaint physicians whose poor followup results suggested they might be unable or unwilling to respond to “awareness-level” feedback. Such individuals require what we refer to as a “Level 2” or “authority-based” intervention. The persistently high-complaint physician’s leader, however defined, is approached by messenger committee members to review the data and to develop a specific plan to address recurrent sources of dissatisfaction. The plan might include anything from CME courses to practice audits to comprehensive health evaluations. The number of “authority” interventions at this time has been small, but results to date suggest that fewer than half of these physicians remained associated with their medical center and subsequently reduced patient complaints. Unfortunately, failure to respond to the “authority-based” intervention raises the specter of voluntary relocation, nonrenewal, limitation of privileges, or dismissal from a group.

Finally, do feedback interventions change claims history and promote safety? Initiation of feedback sessions in two waves during late 1998 and early 2000 at an academic medical center was associated with reductions in claims and lawsuits adjusted for the medical center’s volume of service.¹⁸ Specifically, rates of the institution’s general liability (e.g., premises liability) and professional liability claims, both adjusted per 10,000 relative value units (RVUs) of care

Table 1. Followup data subsequent to “awareness feedback”^a

Physician status at followup	N (%)
Complaint indexes improved	195 (58.0)
Complaint indexes unimproved or worse	70 (20.8)
Departed after Level 1 intervention(s)	71 (21.1)

a Based on 336 high-complaint physicians associated with 14 health care systems.

delivered each year, were analyzed to understand the institution's trends in risk management activity over time. The trends for general and professional liability claims differed significantly (year x type of liability interaction, $t = 3.5$, $P = 0.006$). The institution's professional liability data showed a significant downward slope ($t = -3.39$, $P = 0.02$), whereas the general liability data showed no significant change over time. In other words, the salutary effects seemed specific to professional liability actions, and the reduction did not appear to be an artifact.

Several factors besides the PARS[®] feedback program may have contributed to the trend, including changes in the risk management process, medical procedures, staff, patient/payer expectations, case mix, legal climate for malpractice claims, institutional marketing, and internal quality and safety programs. Therefore, we carried out a randomized controlled trial involving one institution's high-complaint physicians, who were randomly assigned to a control group (no messages of high-risk status) or an intervention group ("awareness" feedback). Complaints and risk management events for 6 years preceding and subsequent to initial interventions were tracked. The study was only recently closed to data collection, and analysis of the data will be the subject of another manuscript.

Impact of Patient Safety Initiatives Based on Patient/Family Concerns

Complaint-related feedback to physicians reduces patient complaints and may help address litigation-related risks. We believe such feedback also improves patient safety. We recognize, of course, that not all risk management events and not all patient complaints signal safety lapses. After all, many patient complaints might seem to reflect mere annoyances (e.g., "The doctor made me wait well past my appointment time." "The surgeon never visited with my family after my surgery.") rather than specific, valid observations of negligence or unsafe practices^{6, 28} (e.g., "The doctor was rushed, so she didn't listen to us, skimmed on her exam, failed to order appropriate tests, and made an error on my prescription."). Of relevance is that patients define medical errors more broadly than clinical mistakes, extending the concept to communication problems, lack of compassion, and responsiveness failures.⁶ Such problems have been found to be associated with adverse patient outcomes.²⁹ Therefore, if patients and families can identify recurring problems, their observations can point out professionals whose practices might be made safer.

We recognize that an important limitation of this work is our reliance on patient complaints and risk management claims files as proxies for unsafe health care. Not all patients with valid concerns complain, so those who report represent only the "tip of an iceberg." Perhaps complainers more closely represent those who might be inclined to sue than the larger group of patients who respond to standardized patient satisfaction questionnaires. Despite the value of these questionnaires for other purposes, they have not been shown to date to efficiently identify the highest risk physicians.³⁰

Another limitation is that we did not examine the specific factors and events underlying patients' or risk managers' concerns, nor did we determine the validity of either the complaints or the claims files. The "gold standard" for evaluating the validity of allegations requires exhaustive review beyond the resources available to us. Even if we could do such evaluations, professional reviewers do not always agree.³¹ In spite of the "noise" in patients'/families' expressions of concern, complaint scores based on allegations of both clinical and interpersonal failures are

indeed associated with risk management activity.^{2, 23} Although malpractice claims are not always associated with errors and unsafe practices,³² recent reports suggest that a majority of claims do appear to involve patient injuries and evidence of medical error.^{33, 34}

The bottom line is that many, perhaps most, malpractice claims are reasonably related to medical management injuries and patient concerns about errors and other practices they consider unsafe. While we certainly agree that “reducing lawsuits requires preventing errors and improving safety, not just placating patients,”³ it appears from our experience that keeping patients from becoming dissatisfied in the first place—which, for many patients and families, translates into concerns about what they deem to be unsafe—may well reduce the lawsuit experience for high-risk physicians who act to reduce patient complaints.

Summary and Conclusion

We believe the vast majority of physicians at risk for a disproportionate share of malpractice claims are not aware that they stand out from their physician peers. If they are unaware, they are not likely to address risky or unsafe technical and interpersonal behaviors. Unsolicited patient complaints offer a powerful tool for identifying high-risk physicians. Most physicians respond positively if those complaints are captured, reliably processed, and regularly communicated through a physician-driven feedback process.

Like Vincent and Coulter,¹ Sage,³ and many others who advocate patient “empowerment” or “activation” in health care, we conclude that patients can indeed play important roles in promoting safe medical care. One of those roles is to make concerns about their health care experiences known to appropriate medical center or medical group personnel. To be effective at identifying patterns, medical center and medical group personnel must solicit, value, and support patient input,^{2, 3, 9} especially from populations who are culturally less likely to complain^{35, 36}; centralize complaint reporting for systematic analysis; and institutionalize physician-driven processes for providing constructive feedback to those associated with high complaint scores.

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From Public Testimony to Vehicle for Statewide Action: Experience of the Michigan State Commission on Patient Safety

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Abstract

In 2004, Michigan Governor Granholm appointed the Michigan Health and Safety Coalition (MH&SC)—an already established voluntary collaborative of diverse health care stakeholders—as the Michigan State Commission on Patient Safety. The Commission’s final report, released publicly in 2006, presents a detailed set of objectives and action steps designed to engage the entire State in a coordinated effort to accelerate patient safety improvement and transform Michigan’s health care culture. Through this unique opportunity to provide policy recommendations to State government, the MH&SC increased awareness of patient safety as a statewide concern; demonstrated the value of a transparent, inclusive, consensus-based process for setting a statewide agenda; and identified individuals and organizations committed to non-competitive, collaborative patient safety improvement. Here we summarize the Commission’s methods for transforming diverse public input into a consensus-based policy document; describe the results of its process; and discuss the factors that contributed to its success.

Introduction

The overwhelming majority of people working in health care share a deep commitment to healing; they do not go to work intending harm. Our health care system, however, is far from perfect. Its interdependent people, processes, tools, and environments still do not ensure the safety of every patient every time, despite increased attention since 1999, when the Institute of Medicine (IOM) released *To Err is Human: Building a Safer Health System*.¹ The IOM’s estimates of 44,000 to 98,000 deaths and \$17 billion to \$29 billion in lost income, disability, and health care costs attributable to medical errors each year spurred unprecedented research, activity, and funding opportunities focused on reducing harm caused by the processes of health care.

In many States, public dialogue about health care quality and safety was initiated in the legislative arena.² By contrast, Michigan stakeholders responded to the challenge of the “quality chasm” by forming the Michigan Health and Safety Coalition (MH&SC), a voluntary collaborative developing system-level solutions for making patient care safer. MH&SC participants include the Michigan associations of physicians, nurses, pharmacists, and hospitals;

health plans; consumer and employer groups; MPRO (the State's Quality Improvement Organization); and the Michigan Department of Community Health. Through their participation in the MH&SC, these individuals and organizations have developed constructive, cooperative relationships and have engaged in creative problem-solving in the complex arenas of patient safety and health care quality.

In 2004, Michigan policymakers requested formal guidance from this voluntary coalition. Following legislative action, Governor Jennifer Granholm invited the MH&SC to serve as the Michigan State Commission on Patient Safety (Commission) to "examine means to improve patient safety and reduce medical errors in this State." The Commission's enabling statute provided detailed requirements regarding the Commission's membership, activities, and timeline. The Commission had 14 months in which to take public testimony, conduct a complementary literature review, and issue a report to the Governor containing "recommendations for improvements in medical practice and a system for reducing medical errors, both in health facilities and in private practice."³

The Commission recognized that the credibility of its recommendations—and their influence in fostering behavioral change to improve the quality of health care—would depend on the integrity of the process used to develop them. The Commission met this challenge by developing an intentionally transparent process for considering public testimony in the broader context of health care quality and safety. The results include a detailed health policy agenda designed to involve affected segments of the health care arena in implementation. The Commission's final report, signed by every Commission member, is a road map for improving patient safety in Michigan. It includes both destinations and major landmarks along the way, engaging everyone with a stake in health care safety—whether providing care, paying for it, or depending on it—in navigating toward a safer Michigan health care system.

Anecdotally, the authors are aware that many States have engaged in collaborative efforts to improve patient safety, with or without a joint, consensus-based patient safety agenda. A thorough review of these efforts is beyond the scope of this paper. However, the authors believe that the combination of the following characteristics is unique to Michigan's approach:

- Its genesis as an input to policymakers: The Commission was established by the Michigan Legislature and reported to the Governor.
- The enlistment by policymakers of an established coalition of health care stakeholders with a long track record of trust and collaboration, and the continued efforts of this broad-based coalition to promote implementation after its service was complete.
- The engagement of a team of health care researchers to develop and implement a transparent process to interpret the public testimony collected and incorporate findings from a complementary literature review.
- The presentation of the Commission's findings in a final report combining excerpts of the testimony, narrative rationale, and lists of action steps to be used modularly and over time by various stakeholders.

This paper is not a summary of that final report. Instead, included here is a description of the innovative methods used by the Michigan State Commission on Patient Safety to transform a large quantity of public testimony into a cohesive set of recommendations for coordinated

statewide action, a brief summary of the resulting policy agenda, and a discussion of how and why the Commission's process led to the results it did. We present this information as part of the Commission's commitment to transparency, and so it may serve as a model or starting point for other States or regions interested in building broad consensus for systems-based solutions to health care safety and other critical issues of public concern.

Methods

Context and Overview

The Commission's choice of methods served its public policy purpose. From its inception, the Commission was committed to rigor, credibility, accountability, transparency, inclusivity, and consensus in its work. Commission members' commitment to shared decisionmaking arose not from familiarity with the literature on consensus building, but from an understanding of the likely political and economic implications of its recommendations and recognition that members had to be willing and able to support and implement the proposals they put forward.

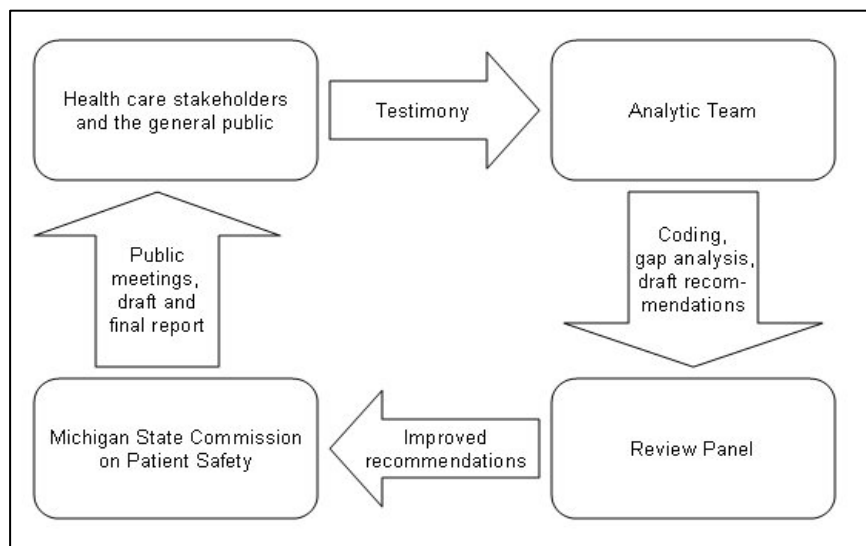


Figure 1. Process overview: Michigan State Commission on Patient Safety.

The core steps of the Commission's process are illustrated in Figure 1:

- Health care stakeholders and the general public provided testimony regarding patient safety concerns and recommendations.
- A team of researchers (the Analytic Team) coded and categorized the testimony, conducted a complementary literature review, and summarized the findings.
- In two rounds of deliberations, a subgroup of the Commission plus two Michigan patient safety experts (the Review Panel) refined and enhanced draft recommendations.
- The Commission oversaw the process, periodically reported progress to the public, invited public comment on the draft report, and issued the final report, signed by all 25 members.

Throughout the process, participants aimed to foster respect, trust, inclusiveness, and openness; create an environment in which differences of opinion could be voiced; and successfully manage conflict.⁴

Preparation

In anticipation of the need to make sense of a large number of diverse concepts and suggestions from public testimony, the Commission engaged a team of nine analysts. This Analytic Team included experienced health policy and health services analysts and clinicians, many with expertise in qualitative and quantitative methods in research, evaluation, and policy settings. Their charge: to gather from the public testimony recommendations for creating a safer health care environment and translate these data into usable information for the Review Panel and Commission. They were expected to develop a valid approach to reduce the volume of information, identify significant patterns in the data, and construct a framework for communicating the essence of what the data revealed. The team also was tasked with consulting published and unpublished sources to determine if what was recommended in the testimony was supported in the patient safety arena and identify areas of improvement discussed in the literature that did not appear in the testimony. Three objectives guided the analysts' approach:

- The Commission should understand the range of patient safety concerns in the State.
- Interested stakeholders should be able to follow how the final report and its specific recommendations emerged from the original testimony.
- The team's methods should enhance the Commission's efforts to build broad-based support for eventual implementation of its recommendations.

To these ends, the Commission and Analytic Team took great care to design processes to convey accurately the words and intent of those supplying testimony and generate results independent of the influence of any individual Commission member or analyst.

A pragmatic mixed model approach⁵—blending qualitative and quantitative methods throughout—was adopted for overall project design, as well as for data analysis and interpretation. Use of a pragmatic approach was dictated by the Commission's limited timeframe, which was established by the Michigan Legislature. As a result, the framework used to structure the request for testimony and guide development of *a priori* codes drew upon the IOM's work in patient safety, rather than relying completely on what emerged from the testimony, as a strictly qualitative research approach would suggest. Four categories suggested by the IOM proved useful throughout the Commission's process—from suggesting topics on which the public might wish to provide testimony to organizing the Commission's final recommendations into a model of safe care in Michigan (Figure 2):

- Develop leadership and knowledge.
- Identify and learn from errors.
- Implement safety systems in health care organizations.
- Set performance standards and expectations.

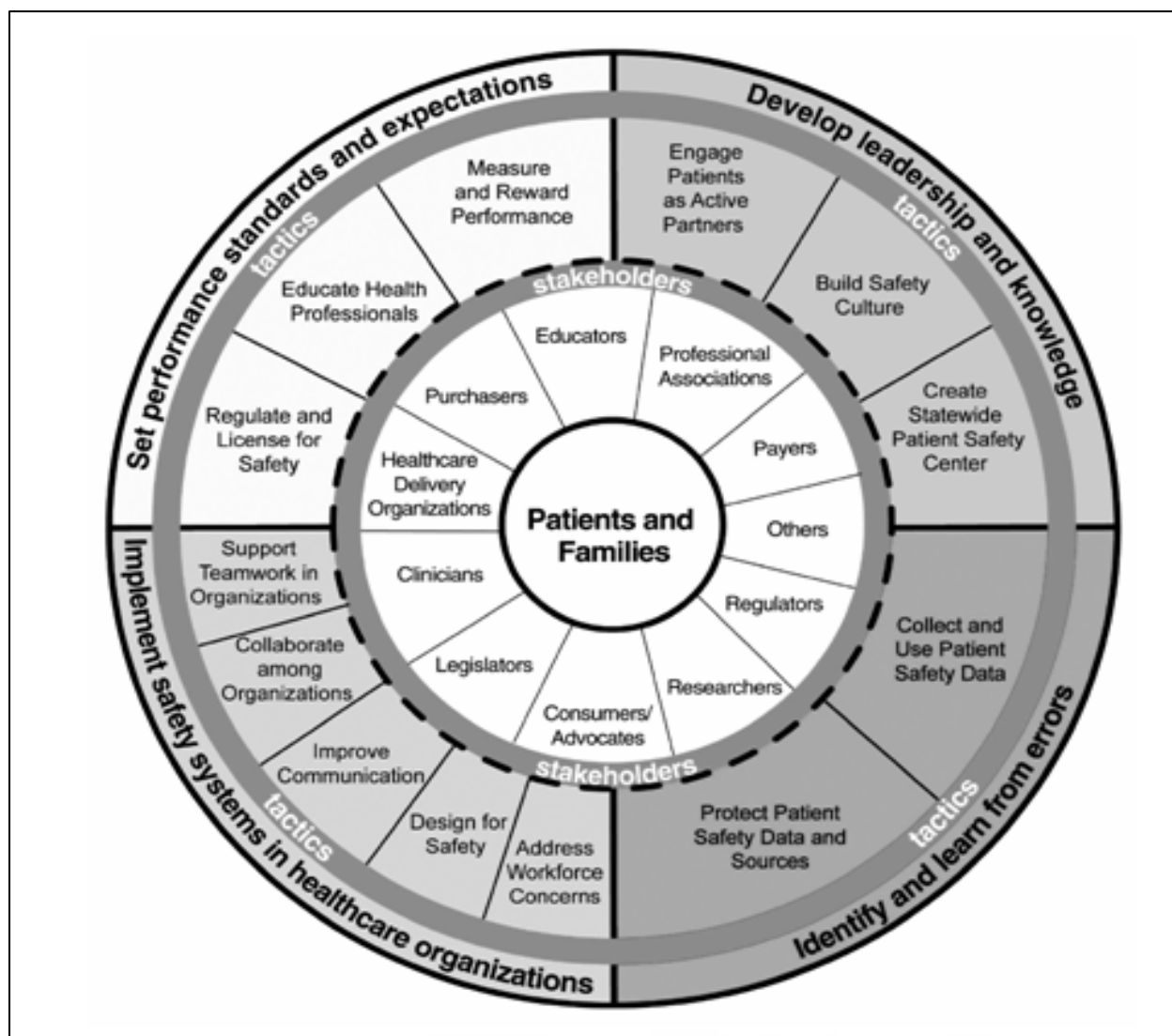


Figure 2. A model for safe care in Michigan. As its framework, the Michigan State Commission on Patient Safety adopted categories suggested by the IOM's report, *To Err is Human*.¹ These categories appear in the outer ring of the model, within which appear the areas in which the Commission developed recommendations. At the center, the diverse stakeholders, who must be united to realize the Commission's vision of a safer Michigan health care system, are arrayed around patients and families, as a reminder that those who receive health care should be at the center of all efforts to improve patient safety.

Data Collection

In October 2004, the Commission extended a request for testimony to 279 health care organizations, associations, professionals, consumers, researchers, and others with an interest in patient safety, some of whom were identified in the Commission's enabling statute. To reach the general public, the request also appeared in major newspapers around the State. Three public hearings were held 1 month later, in Lansing, Southfield, and Traverse City. Those unable to attend were encouraged to supply written testimony.

The Commission received testimony from an impressive array of health care stakeholders, many of whom expressed a desire to continue working with a State-level entity to improve patient safety in a variety of health care settings. A total of 77 informants provided testimony verbally, in writing, or both. Informants included 19 of 43 listed in the Commission's enabling statute. All oral testimony was transcribed by professional services. For tracking purposes, each piece of testimony was assigned a unique 3-digit identifier. Oral and written testimony from one organization was considered one submission from one informant, and this testimony was given a single 3-digit identification code. Informants included seven hospitals; 12 health professionals not representing an organization; five educators, including faculty and schools; 17 consumers and organizations representing consumers; two employer groups; three insurers; 26 health professional associations/organizations; and five classified as other, including research institutes.

Analysis

The major phases of data reduction, data display, and conclusion drawing and verification⁶ are described in the following sections.

Data reduction. The team's first task was to organize and condense the data so meaning could begin to emerge. An initial reviewer's guide provided team members with detailed instructions for close reading of the text, identifying text fragments that contained meaning units, and implementing standardized coding and documentation processes. The first set of *a priori* codes included in the guide was developed to satisfy the policy aims of the analysis; it used as a foundation the IOM's *To Err is Human*,¹ from which the four categories of the Commission's framework were drawn.

Because there are no absolute rules for how to implement a qualitative analytic approach, only standards and principles applied with judgment to a particular situation⁷; and because the analysts brought diverse perspectives and backgrounds to this process, safeguards that supported the analysts' consistency, impartiality, and neutrality were essential. Before coding began, inter-rater reliability was tested at two training sessions. While consistency of coding across analysts improved with the second exercise, additional quality assurance measures were instituted as reviewing and coding got underway: continued testimony review and feedback sessions; a requirement that at least two team members review and code each piece of testimony; and a deliberative process for resolving coding disagreements. Leadership of each of the team's four subgroups by an experienced qualitative analyst, subgroup-to-subgroup support, and inter- and intrasubgroup communication strategies (e.g., regular e-mail and weekly phone conferences) were critical to the successful transfer of information and consistent implementation of quality control measures as they evolved.

The team also established a formal process for adding and clarifying codes for new ideas that emerged from the testimony. Eventually, 30 testimony recommendation codes (for "what" should be done) were identified. Each code was assigned a 2-digit identifier, an abbreviated name, and a narrative description. For example, code 01, labeled "StateFocal," indicated that the testimony recommended "identification and adoption of an institutional focal point for providing State-level leadership related to patient safety."⁸ The team also established nine recommendation target codes for "who" should make a recommendation happen. These included, for example, State government, health professionals, and third-party payers.

From the testimony of 77 informants, analysts extracted and coded 353 unique recommendations. Some testimony fragments were coded with multiple codes. Analysts did not code statements, complaints, observations, and other comments that did not clearly contain recommendations for improving health care safety.

Data display. The coding of testimony recommendations allowed this information to be retrieved and organized so analysts could quickly find, pull out, and cluster segments related to a particular theme or question. To discern patterns and interrelationships in the data, the four major categories of the Commission's framework were used to cluster the 30 recommendation codes. Initial assignments were based on the code's face-value fit with the category definition. Analysts then performed code and data consistency checks on each category, agreed upon the assignment of each code to a framework category, and developed a reliable process for identifying and correcting coding errors.

Conclusion drawing and verification. The team also consulted a variety of sources to identify gaps in recommendations emerging from the testimony and to determine if emerging recommendations were supported in work done by others. For this broader perspective, the team read journal articles, books, and Web sites, and spoke with individuals active in patient safety improvement across the country. In some cases, information from these sources provided external support for recommendations the Commission might otherwise have been reluctant to include. For example, testimony in favor of a statewide focal point for patient safety activities was strengthened by research into the structures, roles, and funding sources of patient safety centers across the country.⁹ In some cases, the gap analysis broadened the scope of a recommendation. For example, with support from the literature, public testimony specific to nursing education evolved into a recommendation to incorporate safety principles in the education of all health professions.^{10, 11, 12, 13} In other cases, the analysts' synthesis of external sources provided needed focus. In the area of statewide reporting of health care errors and near misses, for example, the testimony pointed in many and often conflicting directions. Should a system be mandatory or voluntary? What events should be reported? By whom? To whom? For what purposes? The analysts' research^{14, 15} provided critical information regarding the opportunities and challenges of various approaches.^a

Deliberations

The Review Panel consisted of 15 Commission members and two of the State's recognized patient safety experts. In two rounds of facilitated deliberations, this group considered reports prepared by the Analytic Team, requested further research or clarification, brought additional information to light, and refined and prioritized recommendations for consideration by the full Commission.

In its first round of deliberations, the Review Panel considered a series of reports—one for each of 20 topic areas (some testimony codes were presented together for this purpose)—containing verbatim excerpts from the testimony, draft recommendations and related rationales, evidence

^a Note: Analysts reviewed a variety of texts in each of the areas discussed in this section; only a few of the more helpful texts are cited here as examples.

and information about comparable initiatives in other States, a discussion of benefits and barriers to recommended approaches, and initial thoughts regarding implementation.

A second round of reports (in which 20 topics were reduced to 12) followed a template designed to facilitate consensus-building. All of the relevant information for each subject area was assembled in a single document, and recommendations were developed with enough detail and simplicity to promote thoughtful consideration. These second-round reports included refined recommendations and justifications; expanded supporting evidence and assessment of advantages, barriers, and implementation issues; an overview of related testimony and non-testimony evidence; and notes from the Review Panel's first round of deliberations. Additional information or clarification requested by the Review Panel in its first round of meetings was highlighted.

The group was polled during this second round to gauge the level of agreement with emerging recommendations and to identify areas of concern and the degree to which disagreement existed. The Review Panel's limited discussion time was then focused on modifying or rewording recommendations with promise (those not rejected outright) that had the least agreement.

At the end of its second round of deliberations, the Review Panel used a two-stage structured ranking process to prioritize the 12 broad recommendation categories that had emerged from the original 30 numbered codes. Individual objectives and action steps were not voted on separately.

Initially, each panel member rated each recommendation category on a Likert scale (1 = strongly disagree to 5 = strongly agree) in response to three statements:

- Recommendation has great potential for reducing patient harm.
- Recommendation should be addressed with a sense of urgency.
- Recommendation is a high-priority funding opportunity.

In the final round of voting, each panel member ordered the 12 broad recommendations in terms of importance by using a scale from 0 = least important to 11 = most important. Scores from 11 voting members were totaled, and the results of this prioritization process guided the order in which the Review Panel proposed that the Commission present its recommendations in the final report. (Two codes conflated for this second round of deliberations were restored as separate recommendation areas in the final report, resulting in the 13 report sections listed in Table 1.)

To reach final consensus, the Review Panel and full Commission conducted a piece-by-piece review of a number of draft reports, each more clearly defining the range of underlying concerns and possible courses of action, until a final set of objectives and concrete action steps emerged. The Review Panel, with support from the Analytic Team, used the consistent formatting of the chapters in these draft reports to confirm that action steps for each relevant stakeholder group had been identified. Members were encouraged to share the detail in these drafts with their organizations and constituents to gauge the level of support or concern and to bring any objections to the Review Panel or Commission for discussion.

Table 1. Objectives of the Michigan State Commission on Patient Safety

The substance of the Commission's recommendations is contained in the detailed recommended action steps in each section of the final report. These "to-do" lists—too long to reproduce here—provide the roadmap to accomplishing the objective(s) set out in each section. For this detail, please refer to the Commission's full report, available at www.mihealthandsafety.org/statecommission/barefoot/final_report.html.

Report Section	Objectives	Action Steps Provided For...
A. Build a safety culture	• Continue to transform Michigan's health care culture to one characterized by a commitment to safety, learning, collaboration, and systems thinking. • Reinforce a culture in which the State of Michigan, all clinical and administrative leaders who influence health care delivery, all individuals involved in the caregiving process, and those who use health care services act consistently from a deep commitment to decreasing harm to patients.	• State of Michigan • Michigan Center for Safe Health Care • Health professionals and organizations • All health care stakeholders
B. Establish a statewide patient safety center	• Establish and fund the Michigan Center for Safe Health Care as a statewide center for leadership, information, and advocacy to reduce patient harm across a range of health care settings.	• State of Michigan
C. Collect and use data about errors and near misses	• Establish and fund a statewide voluntary, confidential, peer-protected, nonpunitive error reporting system. Ensure that important findings are disseminated regularly to improve health care safety. Complement, to the extent possible, emerging national data definitions and measurement criteria.	• State of Michigan • Michigan Center for Safe Health Care
D. Protect patient safety data and sources	• Protect patient safety data and reporting activities under statute without denying patients and families access to information through normal channels when medical errors or unexpected events occur.	• State of Michigan
E. Measure and reward performance	• Establish or adopt standards for patient safety performance across the continuum of care, develop or adopt a common vocabulary and standardized data definitions, set dynamic benchmarks to measure progress, use the measured performance of Michigan's health care providers to inform ongoing improvement efforts, and reward excellence.	• Michigan Center for Safe Health Care • Health professionals and organizations
F. Address workforce shortages effectively	• Address health care workforce shortages without compromising patient safety while improving practice environments and the availability of qualified health professionals.	• State of Michigan • Michigan Center for Safe Health Care • Health professionals and organizations

Table 1. Objectives of the Michigan State Commission on Patient Safety (continued)

Report Section	Objectives	Action Steps Provided For...
G. Design facilities and processes for safety	Adapt tools and methods from human factors engineering, facility design, and industries with demonstrated error prevention records to improve patient safety in health care. Prevent or correct system defects in ways that respond to patient and staff needs rather than training staff or teaching patients to accommodate poor system design.	- State of Michigan – Certificate of Need Commission - Michigan Center for Safe Health Care - Health professionals and organizations
H. Improve communication of critical information	Promote improved use of communication and technology to ensure that information critical to patient safety (e.g., health history, medication history, and critical lab values) is available to patients and health care providers within and across organizational boundaries.	- State of Michigan - Michigan Center for Safe Health Care - Health professionals and organizations
I. Involve patients as active health care partners	- Empower consumers/patients/clients/residents and their families/caregivers/advocates to better assume their roles as partners in the health care encounter. - Promote open and clear communication between patients/families and health professionals about health issues, treatments, patient safety concerns, and adverse events. - Embed the consumer/patient voice in the structure and process of designing safe care.	- State of Michigan - Michigan Center for Safe Health Care - Health professionals and organizations
J. Embrace safety in health professions education	Weave the teaching and demonstration of patient safety principles, knowledge, and skills into health professions education and continuing education requirements.	- State of Michigan – Michigan Dept of Community Health working with health professions licensing boards - Michigan Center for Safe Health Care - Educators of health professionals
K. Emphasize collaboration among organizations	Expedite the translation of patient safety-related evidence into practice, accelerate the spread of successful programs and processes for improving patient safety, and promote creative problem solving for patient safety challenges through cross-organization collaboration.	- State of Michigan - Michigan Center for Safe Health Care - Health professionals and organizations
L. Support teamwork within organizations	Improve teamwork across disciplines by providing training and support for cross-disciplinary teams.	- Michigan Center for Safe Health Care - Health professionals and organizations - Educators of health professionals
M. Regulate and license with safety in mind	Explore use of the State's licensing and regulation functions to improve the culture and processes of safety among health professionals and organizations.	State of Michigan – Michigan Dept of Community Health, Bureau of Health Professions

Stakeholder Checks

Ultimate accountability to the public rested with the full Commission, which oversaw the entire process of transforming public testimony into the final report and approved the subprocesses used by the Analytic Team and Review Panel. To enhance the credibility of the final recommendations, the Commission solicited feedback from those who provided testimony and the broader community. Two high-profile public hearings were held in April and June 2005 to summarize the process of obtaining and considering public testimony and additional research, present the Commission's preliminary findings, and invite public comment. These meetings were announced in the press, and notices were sent to those who provided testimony and to those who were invited to provide testimony but did not. The Commission also invited public comment following the final report's public release in March 2006.

Results

Policymakers have to master myriad complex, substantive issues in a short time. Term-limited legislators often are called upon to make decisions based on incomplete or imperfect information. In establishing the Commission, Michigan's legislature requested that the best available information about a pressing public policy issue, along with the best courses of action, be collected and presented in a way that its members could understand and use. The Commission's efforts, therefore, began with the collection of data for a specific public policy purpose and culminated in the organization and presentation of a report that discusses complex issues as simply as possible and provides clear recommendations for action.

The final report of the Michigan State Commission on Patient Safety, *Call to Action: A Plan to Improve Patient Safety in Michigan's Health Care System*,¹⁶ embodies the consensus-based agenda resulting from its 14-month process. In it, the Commission recognizes ongoing efforts to make health care safer and makes the case that Michigan can accelerate system improvement by undergoing a cultural transformation, from blaming individuals to creating organized systems and cultures that lead to more consistent, less error-prone health care services. The Commission goes on to articulate a detailed and workable plan to create this culture of safety focused on learning rather than blaming.

The report contains a set of 16 objectives (Table 1) and nearly 150 action steps organized into 13 chapters. Each chapter begins with a description of the specific concern and a brief summary of what is known about potential solutions; contains one or more clear, concise objectives; and concludes with recommended action steps for relevant stakeholders. Consistent naming conventions allow stakeholders—the State of Michigan, the proposed Michigan Center for Safe Health Care, health professionals and organizations, educators of health professionals, and professional societies and organizations—to access their list of action steps quickly and easily.²

² Note: See sample pages and/or download the Commission's report at http://www.mihealthandsafety.org/statecommission/barefoot/report/SCPS_Final_Report_Vol1_Nov7.pdf.

Rather than include specific action steps for patients and families and for health care purchasers and payers (including health plans, insurers, employers, consumers, and State government in its role as purchaser for State employees and underserved populations), the Commission: incorporated the patient/family voice throughout, to remind health professionals, organizations, and policymakers to make a permanent place for patients and families at the table; and urged purchasers and payers to participate actively by providing incentives, research grants, subsidies, rewards, and public recognition in support of the Commission's recommendations.

Each chapter of the final report also includes verbatim excerpts from the testimony to allow the reader to connect the thoughts of individuals and organizations with the Commission's recommendations. The report also contains a table of milestones for measuring progress toward meeting the Commission's objectives and a chapter highlighting specific areas for future research identified during this process.

The order in which the chapters appear in the report was guided by the Review Panel's prioritization process and further Commission discussion. Chapters were identified using capital letters (rather than numbers) to indicate that recommended objectives and action steps are not, for the most part, sequential; work can begin on many concurrently.

Consistent with the testimony and Michigan's tradition of collaborative approaches to patient safety improvement, the Commission recommended the establishment of an independent, nonprofit Michigan Center for Safe Health Care and a statewide voluntary, confidential, non-punitive health care error and near-miss reporting system. The proposed Center would catalyze, measure, and coordinate progress toward a safer Michigan health care system. It would serve as a primary source of information about the wide variety of successful Michigan patient safety improvement projects and encourage new projects across the continuum of care, particularly among health care stakeholders not yet involved in collaborative efforts. The proposed patient safety reporting system would respond to concerns raised in the testimony by focusing on learning and prevention. While the proposed Center, with oversight responsibility for the proposed voluntary reporting system, would not be a governmental entity, legislative action would be required to authorize its establishment and to assign a source of restricted, dedicated, sufficient, reliable, and ongoing funding. To facilitate legislative action, the Commission included a Model Act in its final report.

Putting these new structures in place will take time. However, progress on many of the Commission's other recommendations need not wait. The Commission urged Michigan stakeholders to begin immediately to work toward a health care system in which:

- Patients and family members are engaged as active, valued members of the health care team.
- Critical information about health status and medication history travels with each patient as he or she moves through the health care system.
- The quantity and qualifications of health professionals on duty are carefully matched with patient need.
- Factors such as light, noise, and fatigue are taken into consideration when facilities and processes are being designed.

- Effective cross-disciplinary teams and cross-organization collaborations flourish.
- Patient safety principles, knowledge, and skills are woven into health professions' education programs.
- The State's licensing and regulation function is used to improve the culture and processes of safety.
- Patient safety standards are established across the continuum of care so that years from now, Michigan can look back and measure how far it has come.

As a result of the Commission's participatory policy recommendation development process, awareness of patient safety as a statewide concern increased among all health care stakeholders, including consumers, providers, purchasers, payers, and policymakers. The Commission also was able to identify individuals and organizations committed to noncompetitive, collaborative patient safety improvement.

Discussion

When the Michigan Health and Safety Coalition first accepted the Governor's invitation to serve as the State Commission on Patient Safety, it had yet to prove that a transparent, inclusive, consensus-based process that started with an invitation for public testimony and synthesized the best from the research and activities in Michigan and beyond could result in a focused, actionable statewide policy agenda. Without a doubt, the Commission delivered just that.

Along the way, the Commission transformed a number of limitations and barriers into strengths and lessons learned. These fall into three broad areas:

- Financing the effort without public funds.
- Collecting diverse points of view and managing data with limited time and resources.
- Strengthening trust and working relationships.

This effort required a total investment of approximately \$400,000, including just over \$10,000 for transcription and printing services and nearly \$257,000 for 3,000 hours of consulting (analysts, meeting facilitator, writer). No State funds were appropriated for this legislatively mandated project. Before accepting the Governor's invitation, the MH&SC secured a generous combination of grants and approximately \$140,000 of in-kind contributions from those acknowledged at the conclusion of this paper. In-kind contributions included the professional and administrative staff at Blue Cross Blue Shield of Michigan, who managed the project, and hundreds of donated hours from two of the consultants. Without these considerable resources, it is likely the project would have floundered.

The Commission also worked within the very tight timeframe established in its enabling legislation. These limitations on time and resources were both a strength and a challenge. The Commission's commitment to timely submission of a final report that respected and incorporated the testimony served as a beacon from beginning to end. It led to tight project management of parallel and iterative processes, affected development of the Analytic Team's mixed methods

approach, focused the Review Panel's deliberations, supported the Commission's consensus-building efforts, and informed both content and layout of the final report.

This short timeframe contributed a sense of urgency about the Commission's work that overcame the potential for "perfection paralysis" inherent in such complex undertakings. Rather than become overwhelmed by the large volume of public testimony with which it started, the Commission chose to view the diversity of perspectives and suggestions as a rich and valuable resource. With unlimited time and financing, additional public hearings might have been held. Instead, the Commission publicized the hearings in newspapers around the State, granted radio interviews, and encouraged statewide associations to promote the call for testimony among their members. Even so, only 77 (28 percent) of 270 entities invited to submit testimony chose to do so. The thoughtful consideration of the public testimony by the Commission's diverse membership, the involvement of additional Michigan patient safety leaders, and the solicitation of further public input in several modes were designed to address this potential limitation.

Most commissions established to develop policy recommendations are assembled for a single purpose and disbanded once their mission is accomplished. This effort, by contrast, both drew upon and strengthened the trust and working relationships among members of the well-established Michigan Health and Safety Coalition, which served as the Commission. This advantage proved extremely useful. Through persistent and patient effort and with respect for all opinions, members faced and overcame conflict, explored potential courses of action, and searched for solutions that went beyond their own limited vision of what was possible.^{17, 18} Through this work, Commission members also developed a higher degree of "political competence":¹⁹ they are better equipped to analyze policy initiatives from a broader perspective and exert influence in the public policy arena. In short, the MH&SC emerged from its service as the Commission stronger, ready to face the difficult issues inherent in implementation of the final recommendations. While the MH&SC's role as the Commission ended in 2005, members remain committed to moving forward individually and together to improve the safety of health care for all who seek care in Michigan.

Conclusion

"The challenge in driving safety and quality improvements in health care is to provide the right information—in the right way, at the right time, and to the right user—in order to maximize uptake and the conversion of knowledge to action."²⁰

In September 2004, Governor Jennifer Granholm designated the Michigan Health and Safety Coalition to act as the Michigan State Commission on Patient Safety. The MH&SC was honored to undertake this important project. The Commission set high standards for itself, working respectfully and collaboratively throughout the process. It captured concerns and suggestions through public hearings, analyzed them within a framework based on the IOM's reform ideas, viewed them through the lens of related research findings and change literature, synthesized them into a manageable number of specific recommendations, reached consensus on the relative importance and potential effectiveness of the proposals, and developed a set of activities designed to involve affected segments of the health care arena in implementation.

The effort's success is measured, most importantly, in the timely submission of a report containing broadly supported, consensus-based, actionable recommendations for a coordinated, statewide approach to patient safety improvement. The Commission accomplished its mission, and every member signed the final report. This process also produced many unintended benefits:

- Strengthening the culture of collaboration among those who served on, assisted, or provided testimony to the Commission.
- Identifying a broad network of health care stakeholders willing to engage in ongoing efforts to improve patient safety.
- Improving the ability of these stakeholders to understand public policy processes and communicate effectively in the public policy arena.
- Discovering the challenges and opportunities involved in using a mixed methods approach for consensus-based agenda setting.

The Commission believes that the innovative processes it used to transform public input into a well-articulated set of objectives and action steps could serve as a model for other States or regions committed to identifying systems-based solutions to issues in health care and other areas of public concern. Documentation of the process, including original letters soliciting testimony, verbatim testimony from the public, and the Analytic Team's reports, are collected in a technical appendix to the Commission's final report.²¹

While the public testimony collected and analyzed in Michigan represented the point-in-time concerns and recommendations of a self-selected group of organizations and individuals in the State, the recommendations that emerged are remarkably consistent with those of other State-level and national policymaking bodies. As a result, other States or regions interested in developing meaningful, integrated, broadly supported solutions to the patient safety challenge may wish to avoid unnecessary costs by using the Commission's report as a starting point for consideration within the context of their own health care infrastructures, adjusting the priorities and implementation strategies in response to local circumstances.

It makes sense that providing safe care in our complex health care system is far from simple. It is also becoming clear that systems and design improvement, no matter how well intentioned, is not enough; cultural transformation is required. Culture change is hard and requires a long-term commitment. As a first step, the Commission asks all health care stakeholders to recognize the complexity of health care interactions, choose to learn rather than blame when the unexpected happens, and set aside competition when it comes to keeping patients safe. In its final report, the Commission presents a road map with a worthy destination. Though its service as the Commission has ended, the MH&SC continues to lead efforts to get everyone in Michigan—whether providing care, paying for it, or depending on it—on the road together, spreading a culture of safety and preventing patient harm across the continuum of care.

The authors hope other States and regions find this summary valuable, because the Commission felt that if its report resulted in a change that saved even one life, whether in Michigan or elsewhere, its effort would have been worth it.

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The Rural Physician Peer Review Model[®]: A Virtual Solution

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Abstract

Evaluating quality of care through peer review is a challenge for physicians. Rural physicians have the added burden of close personal relationships and conflicts of interest. The Rural Physician Peer Review Model[®] presents an innovative solution to these problems that involves utilizing simple information technology to share HIPAA-compliant information, a systems approach to review, principles of patient safety/quality of care, and continuing education. The process involves network hospitals submitting patient cases to the central staff, deidentifying patient information, e-transmitting the cases, meeting by teleconference, and report writing by the physician moderator. Over 3 years, 934 patient cases have been reviewed in 209 teleconferences. Participating physicians report high levels of satisfaction with the objectivity of the reviews and new learning. Written evaluations of the teleconferences document that this impartial process promotes the inclusion of quality improvement and patient safety in peer review. Anecdotal evidence indicates increased use of system improvements.

Introduction

Monitoring and evaluating the quality of care through peer review is a continual challenge for physicians. Peer review is a time-honored tradition for physicians and has been considered by many to be the cornerstone of good quality of care in the United States. However, because of a lack of internal expertise, inadequate capacity for new technology, conflicting interests and recommendations, and a need for expertise in cases of potential malpractice suits, the physician peer review process may be suffering.¹

A culture of “blame and shame” has permeated some peer review activities. Merry and Crago² state, “Physician leaders face an urgent imperative to detoxify peer case review.” They argue that the core professional values that have permeated the medical profession since the time of Hippocrates have not prevailed in the current business climate. By the mid-1990s, there was a realization that hospitals could benefit if quality improvement principles were infused into the peer review process.³ Around this time, Peer Review Organizations (PROs) mandated by Congress to oversee the care delivered to Medicare beneficiaries in each State began focusing on quality improvement. Reports from Europe of “quality circles” indicate that this perspective is becoming increasingly useful in improving quality among family physicians.⁴

In rural hospitals, the problems of traditional peer review are compounded for a number of reasons. First, the small medical staff in most rural facilities leads to partner reviewing partner and physicians reviewing either their direct competitors or those who cover their own practices during time off. These interpersonal dynamics result in a constrained review with inherent conflicts of interest.

If peer review results in an adverse action by a medical staff executive committee, physicians under review frequently seek legal redress, usually claiming restraint of trade, anti-trust violations, intentional torts, or discrimination.^{5, 6} This discourages peer review and removes the opportunity for objective review, learning opportunities, and improvement of care. In small medical staffs, these constraints can obviate meaningful peer review.

The second problem is that often there are not sufficient numbers of physicians in the same specialty to review their peers. Unfortunately, in small hospitals, it is common for family physicians to be reviewed by pediatricians, internists, or even surgeons on their medical staff. This, they claim, is not review by real peers. Other specialists claim that review by someone outside of their own specialty (e.g., family practitioner reviewing a pediatrician) does not constitute fair and objective review by a peer.

A third problem perceived by rural physicians is that significant differences in resources between urban and rural hospitals can produce different diagnostic and therapeutic pathways. When physician reviewers practice under different circumstances, peer review determinations might be affected. For example, many diagnostic techniques and therapeutic options immediately available to urban physicians—such as subspecialty consultation, endoscopy, magnetic resonance imaging, or even basic ultrasound—may be unavailable or only irregularly available to rural practitioners. Thus, rural practitioners often have to render their initial clinical judgments based on less immediate information compared with urban physicians. This has the greatest impact on emergency department care in the rural environment, but it affects all specialties, particularly inpatient care.

Small rural hospitals attempting peer review may also miss the availability of expert opinion in cases involving potential malpractice suits. In addition, they may experience confusion in cases where peer review committee members arrive at conflicting recommendations.

Efforts to reduce these disparities may involve time-consuming and costly “workarounds,” such as transfer protocols that leave both patients and physicians dissatisfied. Such protocols are generally considered highly effective in trauma, but they are much less useful in conditions with an extensive differential diagnosis. One function of the rural peer review network has been to share insights into how these problems may best be addressed.

The Rural and Community Health Institute (RCHI) has developed a virtual peer review process for physicians in rural hospitals in Texas that has alleviated many of the problems described above. RCHI, a component of the Texas A & M Health Science Center, was established in 2003 with the mission of improving access to care and reducing disparities in health status and clinical outcomes between rural and urban communities in Texas. The Rural Physician Peer Review Model[®] has the following objectives:

- Promote incorporation of quality improvement methods into health care delivery in rural hospitals.
- Assist rural hospital staff members in meeting the increasing regulatory requirements of case review and quality of care.
- Disseminate evidence-based practice guidelines and updated information regarding clinical standards, criteria, and “best practices” for quality of care.

This article describes the innovative concepts employed in the Rural Physician Peer Review Model, the current participants and procedures utilized, preliminary assessment results, the barriers that challenge its operation, and the strategies being used to overcome these barriers, as well as plans for expansion of the system.

Innovations

The RCHI leaders have built a number of innovative concepts into the Rural Physician Peer Review Model, including a network of hospitals as its base, with a central staff, a quality improvement/patient safety philosophy, and the use of information technology. Each of these innovations is described in detail below.

Internal Peer Review: A Network

Texas statutes provide for confidentiality and nondiscoverability of peer review deliberations within a hospital’s peer review processes. However, such protection is less certain if outside parties become privy to these data.^{5, 6} Therefore, the decision was made to establish a network of hospitals affiliated with RCHI, and this relationship was incorporated into each of the hospital’s by laws. This internal network shares responsibility in the peer review process and provides legal coverage.

Approach of Quality Improvement/Patient Safety

RCHI leaders searched for ways to implement the hallmarks of the perspective of patient safety and quality improvement. They assumed that quality and patient safety in health care could be improved by introducing organizational learning practices. Organizational learning refers to increasing a health care organization’s capacity to take action based on the cycle of knowledge, understanding, reflection, and implementation. Thus, organizations “learn” by creating channels for information flow and networking.⁷ Peer review presents a valuable learning opportunity for health care organizations to standardize their work practices, make knowledge more explicit, promote collegial learning, alleviate increased service and educational demands, and support physicians in adjusting clinical guidelines to the variance among patients.

Therefore, the learning organization concept is used as a tool to maintain an organization’s learning environment, where education does not add on to the normal time demands of clinical practice. Rather, acquiring new knowledge becomes a natural means of enhancing patient care.⁸ In light of the quality improvement concept, organizational learning requires an understanding of the processes that underlie patient care, teamwork, and deployment of new medical practices.^{9, 10}

The organizational learning approach has proven effective in empowering change in primary health care practice, where resources may be scarce, and information sharing among colleagues may be difficult due to heavy workloads, conflicting priorities, remoteness of practice locations, and lack of effective feedback.^{11, 12, 13}

From the beginning, RCHI leaders conjectured that it might be feasible to utilize patient safety and quality improvement literature during the case reviews. Currently, the RCHI physician who leads a review meeting searches the literature, with the assistance of a reference librarian from a medical college library, and reads pertinent articles prior to the meeting. He/she then reports on the findings of these articles during the discussion. These references are cited in the report written after the discussion. The physician-moderator also responds to requests for specific types of literature from participating physicians. A recent example was a request from a participating physician for evidence about the accuracy of the “rapid strep test.” Participating physicians have been stimulated to share recent articles they thought were worthwhile, and all complete articles are placed in an electronic folder. Currently more than 100 evidence-based articles and guidelines are available to all hospital and physician network participants.

Graber, and colleagues¹⁴ have described the occurrence of three types of medical errors: (1) no-fault errors, when it is medically difficult to make an accurate diagnosis; (2) system errors; and (3) cognitive errors, which are caused by a physician’s cognitive deficits. The Rural Physician Peer Review Model seeks to address system errors and cognitive errors. Introducing ideas and data from the literature has proven beneficial in getting “best practices” used in clinical care. A basic premise of the process is that it is a professional’s right and obligation to examine the care of patients and to ask specifically, “Can we provide better care next time for similar patients?” Thus, physicians can examine errors in light of the system instead of blaming individuals. After each peer review meeting, the RCHI staff members request that participating physicians evaluate the meeting. The results of these evaluations are described in the assessment section of this article.

Use of Information Technology

For practical reasons, it was imperative to provide an affordable, user-friendly, and HIPAA-compliant means of communication within the network, which stretches across the entire State of Texas. One possibility was to use paper and mail with a tracking system (e.g., Federal Express) to disseminate patient cases. However, an electronic system with encryption and password protection was preferable because electronic communication is faster and cheaper. Simple software that provided encrypted transfer of information with password protection was adopted for dissemination. This software required no financial commitments and was easy to install and use with minimal training. The only requirement for installation and use was Internet access and basic computer skills.

Initially, a separate file was created for each hospital (facility) in the network. In 2006, the system was upgraded to a Web-based system that incorporates physician folders, specialty folders, facility folders, and library folders (reference articles). Users were given individual passwords that determined which folders they could access.

In practice, both types of systems (mail and electronic) have been used. Many hospitals send paper patient cases to RCHI by mail with a tracking system; RCHI uses the electronic folders to

distribute the blinded patient cases to participants for the review meeting and also to distribute the reports of the review.

Since in-person meetings were impossible to hold because of the long distances among the hospitals, teleconferencing was selected as the method for holding the peer review meetings. The network participants access the committee meetings via a toll-free conferencing number with a conference ID number. The physicians identify themselves by name at the beginning of the meeting.

Teleconferencing has had the advantage of bringing a degree of anonymity and, therefore, greater objectivity to the patient case reviews than is possible in a face-to-face meeting. The practice of blinding the patient records before transmitting them to the physicians for review adds to the productive anonymity achieved. The teleconferences provide a forum for discussion of ideas without the inhibition of face-to-face meetings. The physicians involved in any meeting are all members of the same specialty. There may be several physicians from a hospital, but in most meetings, the physicians are located in different towns. Thus, they can pay closer attention to the use of practice standards and specialty protocols and far less attention to personal relationships. These regular teleconferences, as an aspect of an educational culture for quality improvement and patient safety, assist physicians practicing in rural areas in overcoming their isolation, an important factor for retention. It serves the same purpose as professional conferences but without the time away from practice and the expenses involved in attending a conference in person.

Category 1 Continuing Medical Education (CME) credit, meeting the requirements of the Texas Medical Board (TMB) for continuing licensure, is designated for physicians who prepare for and participate in the peer review teleconferences. Three CME credits are awarded for each meeting. If ethical issues are discussed, one of the three credits may be designated for ethics credit, another requirement of the TMB. The CME credits are administered through the Texas A & M Health Science Center. The CME credit represents recognition that this peer review activity is a valuable and meaningful educational experience, in addition to serving as an incentive to participate.

Peer Review Within Specialty

A major advantage of the Rural Physician Peer Review Model is that rural physicians are able to hold peer reviews within their own specialty. The lack of a sufficient number of physicians of a like specialty in any one rural hospital is a serious obstacle to holding fair and impartial peer reviews. Family physicians in rural hospitals complain that review of their cases by obstetricians or pediatricians does not constitute review by peers. Conversely, surgeons feel that family physicians cannot adequately review surgery cases. Therefore, aggregating physicians of the same specialty across rural hospitals solves this problem.

Current Participants and Procedures

Currently, 30 of the 188 hospitals located in Texas counties with populations under 100,000 are enrolled in the peer review program. The 30 hospitals are located in 27 different counties (13 of which are considered to be “frontier counties”); 12 of the hospitals are designated as Critical

Access Hospitals (CAHs). The median daily census of participating hospitals is 11 patients (range, 2-54).

All hospitals willing to participate in the Rural Physician Peer Review Model sign a memorandum of understanding that details the purposes and uses of RCHI services and a business associate agreement that covers HIPAA regulation requirements. Multiyear contracts (2-5 years) are prepared and signed. A fee based on the average number of occupied beds in the hospital is charged to defray the expenses. A business plan, developed in 2003, is oriented toward cost recovery only.

Physicians from nine specialties currently participate, each in his/her own specialty meeting: family medicine (without obstetrics), family medicine (with obstetrics), general surgery, pediatrics, obstetrics and gynecology, emergency medicine, anesthesiology, internal medicine, and orthopedics. Requests from hospitals have been received for adding other specialties to the peer review system. The limited types of specialists in each of the rural hospitals constrain the specialties for peer review. Additional specialties can be added only when the number of physicians of a given specialty is sufficient to merit its addition among the participating hospitals in the peer review network. During the period that the Rural Physician Peer Review Model[®] has been in operation (February 2004 through April 2007), 934 patient cases have been reviewed in 209 teleconferences. The peer review teleconferences are held as needed, with family medicine meeting as often as eight times a month; emergency medicine and general surgery weekly; and orthopedics and most other specialties monthly.

Since the inception of the Rural Physician Peer Review Model, individuals who have served as quality directors in their respective hospitals have played an important logistic role. Quality management personnel maintain regular communication with RCHI staff members and physicians; they also identify charts for review, utilizing various screening criteria, in addition to handling all logistic arrangements within their hospitals, such as preparing and transmitting the cases for review. They are welcome to attend meetings, and many take advantage of this opportunity to enhance their understanding of patient safety and clinical standards of care.

Hospitals send patient cases for peer review by the fifth day of each month, to be scheduled for review in the following month. Records are frequently presented for review based on a local facility's established criteria or on a suggested list provided by RCHI. Suggested screening criteria are modified from time to time, depending upon findings identified during the peer review process. The current RCHI list includes:

- Unanticipated death.
- Discharge against medical advice.
- Delay in diagnosis/treatment.
- Validated patient complaints.
- Medical staff referral for any reason.
- Unplanned return to the emergency department.
- Unplanned return to surgery.
- Adequacy of documentation.
- Risk management concerns.

The RCHI staff members blind each patient record (i.e., redact all patient, caregiver, and facility identification) to eliminate bias and to ensure compliance with HIPAA and other RCHI policies. Dates and times relevant for care processes are left intact. Therefore, all records transmitted to physician reviewers provide anonymity during peer review. Two weeks before the teleconference, RCHI staff members post the blinded medical records along with a “face sheet” to the specialty-specific electronic folders. The face sheet contains a summary of the patient case, the reason for referral, pertinent clinical question, medical record comment, if any, and an index to the patient chart.

Once cases are posted, reviewing physicians in each hospital are able to access the cases via the Web to prepare for the teleconference. However, some physicians still prefer to have clerical staff members print out the cases. An RCHI physician-moderator reviews each case before the meeting. This review serves three purposes, to: (1) identify possible systemic failures, medical errors, close calls, issues with communication or equipment, and areas for improvement in the care of similar patients in the future; (2) research and select applicable clinical care guidelines and/or “best practices” for rural hospitals to be discussed by the committee in light of the specific patient chart reviewed; and (3) provide guidance during the peer review meeting in negotiating cumbersome and difficult patient charts.

A typical peer review teleconference begins when an RCHI staff member opens the conference phone line 5 minutes before the appointed time. Physicians from the various hospitals in the network dial in using a toll-free number and the conference ID access code. As each physician dials in, a tone is heard and the name of the physician is noted for the minutes and CME certification at the RCHI central headquarters. A short paragraph about CME credit is read at the beginning of the proceedings. Then the RCHI physician-moderator identifies the first case for review, presents a brief summary of the case, and identifies the reason the case was submitted for peer review. The physician-moderator then calls for open discussion.

Physicians typically conduct a lively discussion about the case and use this time to network with peers, sharing information gleaned from a variety of sources, including scientific and clinical literature, conferences, workshops, and personal communication with other physicians. Teleconferences provide a forum for communication, suggestions for patient care, and venting of frustrations for physicians who may be somewhat isolated in their rural communities. Patient safety issues, Joint Commission requirements, and other regulatory mandates are discussed as appropriate to the case.

After each record has been reviewed, the physician-moderator asks participants for a decision regarding the outcome of the peer review. The decision is made by consensus of the participating physicians. Choices for the peer review outcome refer to whether the care was appropriate, or whether a standard of care was breached. If there was a deviation from the standard of care, it must be classified as “major” (i.e., a substantial risk of potential patient harm) or “minor” (i.e., a recognizable departure from the standard of care, but unlikely to result in significant harm). After a consensus is reached, the physician-moderator moves to the next case.

At the end of the meeting, an RCHI staff member verifies the names of the physicians in attendance, ensuring that all who have participated will be awarded CME credits. If the participating physicians have any questions pertaining to the review or the peer review program,

they are given the opportunity to have them answered at this time. The moderator then closes the meeting and the phone line.

An RCHI nurse takes notes during the meeting and transmits these notes to the physician-moderator, who writes a report that is posted to both the hospital folder and the appropriate specialty folder within 1 week after the meeting. The participating physicians and quality directors are notified via e-mail when reports are posted. The physicians who “attended” the meeting have 1 week to review the reports and submit any revisions they feel are necessary. After 1 week, the reports are considered final reports and are deleted from the specialty folder, but they remain posted in the hospital folder.

During autumn 2006, an external audit of the policies, procedures, and integrity of the electronic firewalls of the Rural Physician Peer Review was conducted by a vendor familiar with HIPAA requirements, electronic security, and other applicable State and Federal mandates. The auditors found the policies and procedures to be sound and recommended only modest process improvements. The recommendations included using a copy machine not linked to the health science center computer network and setting up a separate local area network (LAN) for staff members who do the blinding of the patient cases.

Preliminary Results

Assessment of the Rural Physician Peer Review Model is ongoing. Preliminary results are presented here.

- Of the 934 patient cases that have been reviewed during the first 3 years of operation, from February 2004 through April 2007, the majority—575 cases (62 percent)—received judgments that the standard of care was acceptable.
- Minor deviations from the expected standard of care were noted in 172 cases (18 percent).
- Significant deviations, in which there was substantial risk of patient harm, were identified in 91 cases (10 percent).
- Inadequate documentation for adjudication was found in 18 cases (2 percent).
- No determination was reached due to insufficient information in 78 cases (8 percent).

A detailed review is underway of those cases in which the care was considered inappropriate. Other authors have devised various schema for classification of physician error in patient care^{15, 16, 17, 18} with little agreement among them. We propose that a simplified taxonomy of physician error in patient care may result from our ongoing peer review activities as described here.

The educational approach of systems thinking and improving quality/patient safety through the peer review process is the most important innovation of the Rural Physician Peer Review Model. The awarding of CME credits is merited by the preparation and participation accompanied by use of the library of scientific articles. Table 1 presents the number of credits awarded.

RCHI staff members requested that physicians answer several questions on a 5-point Likert scale using commercially available software. These questions included the following:

Q1: Are you satisfied with the inclusion of quality improvement and patient safety principles in the peer review meeting?

Q2: Was this peer review meeting accomplished in a manner that was impartial and fair?

Q3: To what degree are you satisfied with the systems thinking approach addressed in this peer review?

Table 1. Number of continuing medical education credits awarded by year

Year	Meetings (N)	Physicians (N)	CME credits awarded	Ethics credits awarded ^a
2005	56	53	244	42
2006	83	340	1002	31
2007 (January – June)	70	265	795	48

^a Texas defines and requires ethics credits each year.

The physicians (N = 105) have responded very positively to all three questions, indicating satisfaction with the key elements of this innovative process. Figure 1 shows these results graphically. The mean scores are in the upper range of the 5-point Likert scale (5 = high; 1 = low).

The Rural Peer Review Model emphasizes adherence to CMS core measures (quality of care indicators mandated by Medicare) and Joint Commission mandates, such as the requirement that all physician orders rendered verbally or by phone be documented by nursing staff and confirmed by means of “read back” to the physician. As a value-added service, RCHI personnel have catalogued this measure in all charts for participating hospitals. Review of the data indicated that during 2.5 years, about one-third (36 percent) of the verbal and telephone orders have been read back. Because hospitals can enter the network in any month, new hospitals may need to learn what more experienced hospitals have already learned and implemented. This variable needs to be taken into account when analyzing the data. Improvement in read-back has clearly occurred, but there is opportunity for future improvement.

A survey to obtain feedback from the quality directors was conducted using electronic software during July and August 2007. The survey containing 10 questions

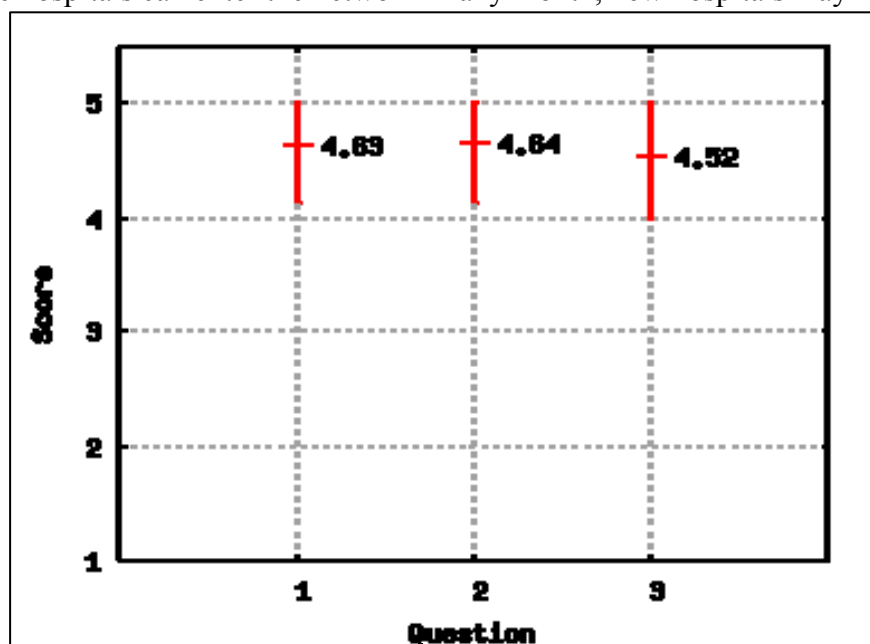


Figure 1. Means (±SD) for the physician scores for each question.

was sent to 40 individuals in 28 participating hospitals. Completed surveys were returned from 16 hospitals, a response rate of 57 percent. The questions included such items as criteria used to send patient cases for review, disposition of the final reports for the hospitals, problems faced by the hospital in participating in RCHI peer review, and hospital gains from the RCHI peer review. In response to hospital gains, the most frequent answers were the objectivity gained by having a group of peers outside their hospital conduct the reviews and the education offered by these meetings.

The physician-moderator and staff members are planning a pre- and post-intervention study of medication reconciliation with the hospitals enrolled in peer review. Using a subset of patient records, they plan to analyze the degree of medication reconciliation utilized, implement a paper process for medication reconciliation in a selected number of hospitals, and analyze the results 1 year later.

Barriers and Strategies

As with any process, barriers to successful implementation of the Rural Physician Peer Review Model are apparent. RCHI staff members have worked persistently to develop strategies to mitigate these barriers, knowing that some challenges will be perennial. Obtaining physician participation is the most important and persistent challenge.

One of the main barriers to physician participation has been overcoming the historic stigma of peer review as traditionally practiced with a “blame and shame” approach. We have found that once a physician attends one or two teleconferences, initial reticence is replaced by an appreciation of the opportunity to network with peers in a meeting that is focused on education and patient safety rather than criticism and finger pointing. The anonymity of the teleconference and the blinded records remove much of the reluctance that physicians often feel in offering criticism face-to-face.

The many competing priorities for physicians’ time represent another persistent challenge. These priorities include patient care, hospital committees, clinic and office management, community and civic leadership duties, and family responsibilities. In rural areas, physicians play important leadership roles in the communities they serve. They cannot partition off and maintain only their patient care duties. Therefore, making time to participate in peer review meetings is difficult.

Quality directors, like most employees of rural hospitals, “wear many hats.” Among the roles they perform in making sure physicians “attend” peer review meetings are selecting charts for review, placing the dates and times of meetings on the physicians’ calendars, providing reminders, printing out a “hard copy” for those physicians who prefer to review away from a computer, protecting the meeting time from interruptions, tracking reports, distributing CME certificates, and conducting the scientific literature search. RCHI staff members send an e-mail message with the cases to be reviewed to the hospital quality director and relevant specialty physicians 2 weeks before the scheduled meeting. Each hospital is called on a monthly basis to determine any special needs the facility may have pertaining to peer review. A monthly calendar is sent to each quality director with all peer review information listed, along with a calendar showing meeting dates that is sent to physicians.

Some difficulties arise from the small number of physicians in each community. Taking time off for vacations, holidays, and urgent family matters depletes the ranks of participants. When even one physician is away, it may not be possible for hospital staff to participate in peer review.

Occasionally, there are technologic challenges for the rural facilities when participating in our peer review program. Many rural hospitals operate on a very limited budget and have little money for frequent technologic upgrades. When presented with large records to print, older computers and printers can create time challenges for the quality directors, since the more voluminous records require extended amounts of time to print.

Another barrier for the Rural Physician Peer Review process is the limited number of some specialists in the rural facilities. For example, RCHI includes in its contracts the specialties of orthopedics and obstetrics/gynecology. Only one board certified orthopedist participates in the reviews, creating difficulty when this orthopedist is away. In this instance, RCHI must contract with an outside orthopedist to critique the charts and participate in the teleconference. This creates an additional expense for the peer review program, since an outside provider must be reimbursed. For a nonprofit entity with a budget already operating on a very thin line, this added expense may be difficult to absorb.

Conclusion

The Rural Physician Peer Review Model is significant because it provides a virtual process to achieve unbiased physician judgments about patient care, and it promotes systems thinking and quality and patient safety improvements for a significant number of rural physicians. This model has overcome some of the traditional problems of peer review, primarily replacing the “blame and shame” culture with a focus on education and system improvement. Challenges of obtaining physician time for participation and limited resources, especially human and technology resources, will continue to demand creative solutions. Nevertheless, the Rural Physician Peer Review Model has the potential to be a genuine advance in enhancing quality of care and patient safety for rural hospitals. Success thus far has stimulated plans to expand the number of hospitals in the Rural Physician Peer Review network.

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