

Advances in Patient Safety: New Directions and Alternative Approaches

Volume 3. Performance and Tools

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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

The Shift toward Performance and Tools

Margaret A. Keyes, M.A.

The articles in this volume provide a number of perspectives on performance and tools used to improve the safe delivery of health care. They include a wide variety of approaches that underscore the importance of teamwork and communication, the incorporation of human factors and ergonomic principles, and the use of various tools and best practices that steer us in the direction of more accurate, increasingly reliable, and safer health care delivery.

Historically, knowledge acquisition has been considered the essential ingredient for ensuring highly qualified clinicians and safe, high quality medical care. However, over time it has become abundantly clear that knowing the right thing to do and doing the right thing (i.e., performance) do not necessarily go hand-in-hand. The old adage of “see one, do one, teach one” tended to minimize the indispensable role of skilled performance and practice. While patients certainly want highly knowledgeable clinicians, they also expect their health systems to perform on par with the Nation’s better run organizations. Hence, there is an increasing focus on performance and the skilled use of tools in support of the optimal delivery of care.

As medicine has moved from the independent solo practitioner, low tech model involving long hospital stays to a high tech, complex, systems-based model reflecting increased use of specialists, shorter hospital stays, limited work hours, multiple hand-offs, and growing use of non-hospital settings, it has become ever more apparent that health care delivery in today’s environment requires excellent teamwork and communication skills. Evidence of this can be found in the volume’s first section. Here the authors address various approaches to teamwork and sets of tactics to enhance communication, empower teams, and make the best use of technology to enhance the safety of care.

The performance-based component of clinical competency is further illustrated in the set of papers that focus on simulation. Given advances in medical simulation technology, a lowering of associated costs, and a national spotlight on patient safety, the recent growth of simulation centers in schools of medicine and nursing, and its increasing migration as a training tool to other clinical settings, is indeed impressive. Just as other hazardous environments—e.g., aviation, military operations, disaster preparedness—have reduced the risk of achieving high levels of individual, team, and system performance using simulation, so too are health care practitioners finding a diverse range of application involving simulation. The authors in this section describe their efforts in using various forms of simulation to improve proficiency, reinforce behaviors, and identify both individual and systems issues in a range of environments and settings. The use of in situ techniques—i.e., bringing the simulation on site to the place of patient care—is quite evident. In brief, these authors do a nice job of demonstrating the potential of simulation as a valuable tool for improving patient safety without minimizing the challenges yet to be addressed.

Following the simulation section, the reader finds papers on human factors. Since World War II, the role of human factors in high performance and high stress environments has been recognized. Likewise in health care, it is essential that human capabilities and limitations be taken into account in the design of interactive systems of people, tools, technology, and work environments to ensure their safety, effectiveness, and ease of use. Far too often, the fit between practitioners and the systems within which they must function is less than optimal. In this section, the authors of five papers, representing different clinical settings, address a range of human factors issues and their impact on the safe delivery of health care. These papers address topics such as safe operating rooms of the future, transitions of care, the use of resilience engineering, and human factors impact in specific treatment environments and with selected technology.

Tools can be viewed as a way of extending and enhancing human and system performance. It is thus appropriate that the volume concludes with a series of articles focused on tools and best practices that support the safe delivery of health care. Some of the authors focus on clinical processes—such as anticoagulation management and the prevention of pulmonary emboli—while other authors focus on administrative processes such as leadership, discharge procedures, work process control methods, and standardization of critical laboratory values. Yet another paper describes the development and value of a widely-used, government-sponsored patient safety Web site.

Given the increasing complexity of medicine and the health care system in general, it is gratifying to witness the growing awareness and interest in the performance-based aspects of health care delivery as found in this volume. However, having access to a performance-enhancing technique or tool is not the same thing as using it effectively. There is a significant learning curve to many of the techniques described here. Proficiency takes practice. The authors in this volume are to be applauded for their willingness to master the learning curve.

Teamwork and Communication

TeamSTEPPS[™] : Team Strategies and Tools to Enhance Performance and Patient Safety

Heidi B. King, MS, CHE; James Battles, PhD; David P. Baker, PhD; Alexander Alonso, PhD; Eduardo Salas, PhD; John Webster, MD, MBA; Lauren Toomey, RN, BSBA, MIS; Mary Salisbury, RN, MSN

Abstract

Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS[™]) is a systematic approach developed by the Department of Defense (DoD) and the Agency for Healthcare Research and Quality (AHRQ) to integrate teamwork into practice. It is designed to improve the quality, safety, and the efficiency of health care. TeamSTEPPS is based on 25 years of research related to teamwork, team training, and culture change. As a direct outcome of the 1999 Institute of Medicine (IOM) report, *To Err is Human*, TeamSTEPPS introduces tools and strategies to improve team performance in health care. This article describes the evolution of the TeamSTEPPS program and its research foundation, development, and implementation. To date, the DoD has taught TeamSTEPPS at over 68 facilities, creating approximately 1,500 trainers/coaches, who have trained over 5,000 staff members. Beginning with the public release of TeamSTEPPS resources in November 2006, AHRQ began its effort to disseminate TeamSTEPPS nationwide. To support this plan, a national infrastructure is being established for long-term sustainment through collaborative efforts of several Federal agencies, academic centers, and health care networks, aiming for wide-scale dissemination.

Introduction

Public reaction to problems associated with patient safety reached a critical mass with the 1999 publication of *To Err is Human*, which concluded that medical errors cause up to 98,000 deaths annually.¹ Since the release of this Institute of Medicine (IOM) report, the Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense (DoD) have been Federal leaders in the patient safety movement. A major focus of these agencies has been supporting research and development activities centered on improving team performance in the delivery of care. Many organizations—such as the Joint Commission, Institute for Healthcare Improvement (IHI), the National Quality Forum (NQF), and the Accreditation Council for Graduate Medical Education (ACGME)—have cited the importance of teamwork in patient safety. Through the Floyd D. Spence National Defense Authorization Act (NDAA) of 2001,² Congress mandated DoD's Military Health System (MHS) to implement a Patient Safety Program (PSP); thus establishing the Healthcare Team Coordination Program (HCTCP). This mandate requires implementation of a team training initiative within Military Treatment Facilities (MTFs) and Combat Casualty Care arenas.

In November 2006, AHRQ, in collaboration with the DoD, released Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™) as the national standard for team training in health care. TeamSTEPPS is the result of a multiyear research and development project jointly funded by AHRQ and DoD.^{3, 4} Since 2005, numerous organizations and individuals have contributed to the refinement of the TeamSTEPPS curriculum. (For a complete list of contributors consult the TeamSTEPPS™ Instructor Guide which can be ordered from <http://www.ahrq.gov/qual/teamstepps/>.) Within the DoD, TeamSTEPPS has been introduced (and is in various phases of implementation) at over 68 MTFs. Within these facilities, approximately 1,500 trainers and coaches have been fully trained to deliver TeamSTEPPS and implement teamwork principles into practice.

The purpose of this paper is to describe the TeamSTEPPS initiative, including its history, present status and update, and future direction. An earlier paper appeared in the *Human Resources Management Review* in 2006 and provides a similar review.⁵ With the release over the past year of TeamSTEPPS as a public domain resource, AHRQ and the DoD anticipate that much will be accomplished over the next several years as “early adopters” create an “early majority” of health care institutions that have implemented this initiative.⁶

Teamwork and Health Care

Physicians, nurses, pharmacists, technicians, and other health care professionals must coordinate their activities to make patient care safe and efficient. Health care workers perform interdependent tasks while functioning in specific roles and sharing the common goals of quality and safety in care. However, even though the delivery of care requires teamwork, members of these teams are rarely trained together; they often come from separate disciplines and diverse educational programs.

Given the interdisciplinary nature of the work and the necessity for cooperation amongst those who perform it, teamwork is critical to ensure patient safety. Teams make fewer mistakes than individuals, especially when each team member knows his or her responsibilities, as well as the responsibilities of other team members.^{7, 8, 9} However, simply conducting training or installing a team structure does not ensure the team will operate effectively. Teamwork is not solely a consequence of co-locating individuals together. Rather, it depends on a willingness to cooperate, coordinate, and communicate while remaining focused on a shared goal of achieving optimal outcomes for all patients. Teamwork does not require that team members work together on a permanent basis, yet it is sustained by a commitment to a shared set of team knowledge, skills, and attitudes (KSAs), rather than permanent assignments that carry over from day to day.¹⁰

Team Knowledge, Skill, and Attitude Competencies

The importance of teamwork in health care emerged in anesthesiology over a decade ago with the work of David Gaba and colleagues who developed Anesthesia Crisis Resource Management (ACRM).^{11, 12, 13} ACRM was designed to help anesthesiologists effectively manage crises by working in multidisciplinary teams that include physicians, nurses, technicians, and other medical professionals. ACRM provides training in specific technical skills and in generic

teamwork skills using patient simulators. The team skills were adopted from research on aviation teams and include developing a thorough case orientation, making inquiries and assertions, communicating, giving and receiving feedback, exerting leadership, maintaining a positive group climate, anticipating and planning, managing workload distribution, maintaining vigilance, and re-evaluating actions.

In the late 1990s, Dynamics Research Corporation (DRC) conducted a DoD-sponsored randomized controlled trial to study team training in emergency departments as an error-reduction strategy.¹⁰ More recently, research on teamwork in health care and its requirements has spread to other disciplines. For example, Healey, Undre, and Vincet developed Observational Teamwork Assessment for Surgery (OTAS), a behavioral rating scale that can be used to assess cooperation, leadership, coordination, awareness, and communication in surgical teams.¹⁴ Thomas, Sexton, and Helmreich have developed 10 behavioral markers for teamwork in neonatal resuscitation teams,¹⁵ and Flin and Maran have identified nontechnical skill requirements for teams in acute medicine.¹⁶

In 2005, Baker and colleagues reviewed the above literature and other relevant information in an attempt to define important elements of teamwork in the professional education of physicians.¹⁷ Baker argues that the KSAs advocated by Salas and colleagues were directly relevant to health care.⁹ These competencies must be possessed by individual health care providers to perform on a variety of teams with which they interact on a daily basis, as well as the numerous tasks that require coordination by health care workers. As discussed below, these competencies served as the foundation for the TeamSTEPPS Initiative. Table 1 presents each KSA, its definition, behavioral examples, and the supporting evidence references.

Table 1. Team KSAs and the coordinating mechanisms of teamwork

Teamwork	Definition	Behavioral Examples	Selected Citations
Team leadership	Ability to direct and coordinate the activities of other team members, assess team performance, assign tasks, develop team KSAs, motivate team members, plan and organize, and establish a positive atmosphere.	• Facilitate team problem solving • Provide performance expectations and acceptable interaction patterns • Synchronize and combine individual team member contributions • Seek and evaluate information that impacts team functioning • Clarify team member roles • Engage in preparatory meetings and feedback sessions with the team	• Cannon-Bowers, et al.¹⁸ • Salas, et al.¹⁹ • Barach, et al.²⁰ • Healey, et al.¹⁴ • Thomas et al.¹⁵ • Flin & Maran¹⁶
Mutual performance monitoring	The ability to develop common understandings of the team environment and apply appropriate task strategies in order to accurately monitor teammate performance.	• Identify mistakes and lapses in other team members' actions • Provide feedback regarding team member actions in order to facilitate self-correction	• McIntyre & Salas, 1995²⁰

Table 1. Team KSAs and the coordinating mechanisms of teamwork (continued)

Teamwork	Definition	Behavioral Examples	Selected Citations
Backup behavior	Ability to anticipate other team members' needs through accurate knowledge about their responsibilities.	Recognition by potential back-up providers that there is a workload distribution problem in their team	- McIntyre & Salas²¹ - Porter, et al.²²
	The ability to shift workload among members to achieve balance during periods of high workload or pressure.	- Shifting of work responsibilities to under-utilized team members - Completion of the whole task or parts of tasks by other team members	
Adaptability	Ability to adjust strategies based on information gathered from the environment through the use of compensatory behavior and reallocation of intra-team resources.	- Identify cues that a change has occurred, assign meaning to that change, and develop a new plan to deal with the changes - Identify opportunities for improvement and innovation for habitual or routine practices	- Cannon-Bowers, et al.¹⁸ - Kozlowski, et al.²³ - Klein & Pierce²⁴
	Altering a course of action or team repertoire in response to changing conditions (internal or external)	Remain vigilant to changes in the internal and external environment of the team	
Team/collective orientation	Propensity to take other's behavior into account during group interaction and belief in the importance of the team's goals over individual member's goals	- Taking into account alternative solutions provided by teammates and appraising that input to determine what is most correct - Increased task involvement, information sharing, strategizing, and participatory goal setting	- Driskell & Salas²⁵ - Shamir²⁶ - Wagner²⁷
Shared mental models	An organizing knowledge structure of the relationships between the task the team is engaged in and how the team members will interact	- Anticipating and predicting each other's needs - Identifying changes in the team, task, or teammates and implicitly adjusting strategies as needed	- Cannon-Bowers, et al.¹⁸ - Klimoski & Mohammed²⁸ - Mathieu, et al.²⁹ - Stout, et al.³⁰
Mutual trust	The shared belief that team members will perform their roles and protect the interests of their teammates	- Information sharing - Willingness to admit mistakes and accept feedback	- Bandow³¹ - Webber³²
Closed-loop communication	The exchange of information between a sender and a receiver, regardless of the medium	- Following up with team members to ensure message was received - Acknowledging that a message was received - Clarifying with the sender of the message that the message received is the same as the intended message sent	McIntyre & Salas²¹

KSAs = knowledge, skills, and attitudes

TeamSTEPPS™ : A 3-Year R&D Project

TeamSTEPPS is the result of a 3-year research program funded by the DoD Patient Safety Program (PSP) within the TRICARE Management Activity (TMA) and AHRQ. Using a collaborative model, AHRQ and DoD brought together experts in team training, health care, aviation human factors, and change management, all of which contributed critical expertise. Most noteworthy was the DoD Healthcare Team Coordination Program (HCTCP) cadre of Master Trainers who have been involved in the instruction of TeamSTEPPS since its onset in early 2005. Each session results in new insights into the curriculum and effective implementation strategies that enable the resource materials to be current and appropriately focused. The DoD and AHRQ continue to assess and evaluate effectiveness and potential correlations to clinical process and outcome measures.

TeamSTEPPS was initiated in January 2003, when AHRQ and DoD convened a national panel of experts on human factors, human error, and medical team training. At this meeting, approximately 30 of the Nation's leading experts discussed the needs, requirements, and strategies for effective teamwork in health care. Topics included competency requirements for medical teams, appropriate training strategies for teams, how to reliably measure teamwork, and what health care could learn from aviation and other disciplines. The result was a roadmap that helped guide the research that followed.

A comprehensive review of the literature on the evidence-based relationship between teamwork and patient safety was conducted. An earlier review by Pizzi and colleagues³³ had been published in an AHRQ report,³⁴ which identified patient safety practices in other fields that should be tested in health care. Pizzi and colleagues argued that crew resource management training (CRM) has a great deal of promise for addressing teamwork in health care. Because this review focused only on CRM, a broader review was needed. Therefore, Baker and colleagues⁴ reviewed the larger discipline of teamwork and team training. Because much of this work had been accomplished in the military, AHRQ and DoD felt this research could be directly extended to health care.

In addition to the literature review, DoD sought to examine their existing medical team training programs to identify any changes or updates that might be required. The DoD HCTCP has been conducting medical team training since 2001. By 2003, a number of different medical team training programs existed within the DoD. To assess the strengths and weaknesses of these programs, Baker and colleagues³ conducted a case-study analysis of three existing DoD medical team training programs: MedTeams®, Medical Team Management, and Dynamic Outcomes Management® (Note: Dynamic Outcomes Management has since been renamed *Lifewings*).

Although the results revealed that each program possessed strengths, the issued report called for the development of a medical team training specification that was evidence-based and would guide developers of medical team training programs. Baker and colleagues³ recommended that this document be constructed like a Federal Aviation Administration (FAA) Advisory Circular. Such FAA documents specify the requirements carriers must meet when implementing certain programs, such as CRM training (e.g., refer to FAA AC120-51E). In the end, AHRQ and DoD decided that a new, updated, evidence-based program wholly owned by the Federal Government was warranted to enable wide-scale dissemination.

The Evidence-Base for TeamSTEPPS™

The teamwork competencies presented in Table 1 and their research basis served as the foundation for TeamSTEPPS. With that information as a starting point, the goal of AHRQ and DoD was to take this academically oriented information and convert it to a framework that was meaningful from an instructional standpoint. As an example, theories of teamwork point to the importance of adaptability/flexibility as a central skill.^{35, 36, 37} Yet, it is difficult to directly train the skill of adaptability/flexibility, which is required when responding to unpredictable situations teams may encounter. Therefore, TeamSTEPPS instructs team members to monitor the performance of others and provide assistance, plan and organize team roles, and communicate with one another efficiently and effectively. Combined, these skills yield a highly adaptable and flexible team.

To develop the TeamSTEPPS instructional model, teamwork competencies from the literature were classified as trainable or as competencies that are the result of employing these trainable skills (i.e., outcomes). For example, shared mental models were viewed as an outcome of using monitoring and back-up behaviors. The resulting TeamSTEPPS instructional framework is presented in Figure 1, where the core competencies include the trainable skills of leadership, situation monitoring (mutual performance monitoring), mutual support (backup behavior), and communication. These core competencies are encircled by the patient care team, which encompasses the patient. Performance, knowledge, and attitudinal outcomes are then depicted in the corners, resulting from proficiency on the central skills or core competencies.

Course Description

The TeamSTEPPS curriculum (Figure 2) contains an introductory module relating to the history of team training, a testimonial from Sue Sheridan, and the structure of teams. The introduction provides participants with insight into the importance of teamwork in health care. Formation and formal definition of different team types are discussed. Four didactic-based modules discuss the core competencies/skills (Figure 1):

1. Leadership.
2. Situation monitoring.
3. Mutual support.
4. Communication.

Emphasis is placed on defining team skills, demonstrating the tools and strategies team members can use to gain proficiency in the competencies/skills, and identification of tools and strategies that can be used to overcome common barriers to achieve desired outcomes. Specialty case scenarios and video vignettes are used to further reinforce the learning. Figure 2 summarizes the entire curriculum with respect to the barriers discussed, tools and strategies taught, and outcomes that can be achieved.

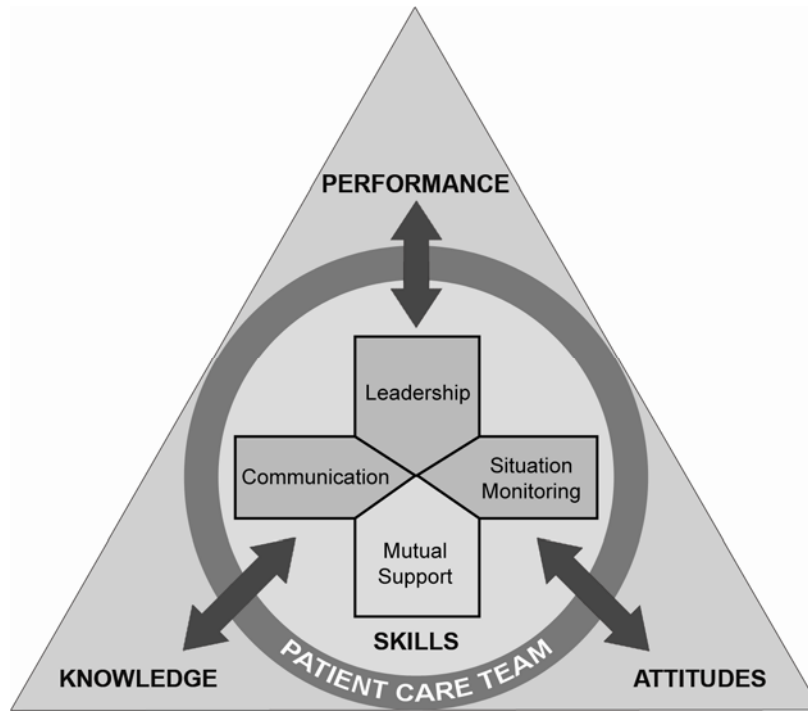


Figure 1. The resulting TeamSTEPPS instructional framework.

BARRIERS	TOOLS and STRATEGIES	OUTCOMES
• Inconsistency in Team Membership • Lack of time • Lack of Information Sharing • Hierarchy • Defensiveness • Conventional Thinking • Complacency • Varying Communication Styles • Conflict • Lack of Coordination and Follow-Up with Co-Workers • Distractions • Fatigue • Workload • Misinterpretation of Cues • Lack of Role Clarity	• Brief • Huddle • Debrief • STEP • Cross Monitoring • Feedback • Advocacy and Assertion • Two-Challenge Rule • CUS • DESC Script • Collaboration • SBAR • Call-Out • Check-Back • Handoff	• Shared Mental Model • Adaptability • Team Orientation • Mutual Trust • Team Performance • <i>Patient Safety!!</i>

Figure 2. TeamSTEPPS™ Curriculum

The Delivery System

The TeamSTEPPS initiative also includes several sessions devoted to Implementation, a multiphase process based on John Kotter's model of organizational change.³⁸ The process is carried out by a cadre of trainer/coaches who champion the effort within their unit, department, or institution. A successful TeamSTEPPS Initiative requires a carefully developed implementation and sustainment plan that is captured in Figure 3. It is based on lessons learned, DoD experience, the literature of quality and patient safety, and culture change.

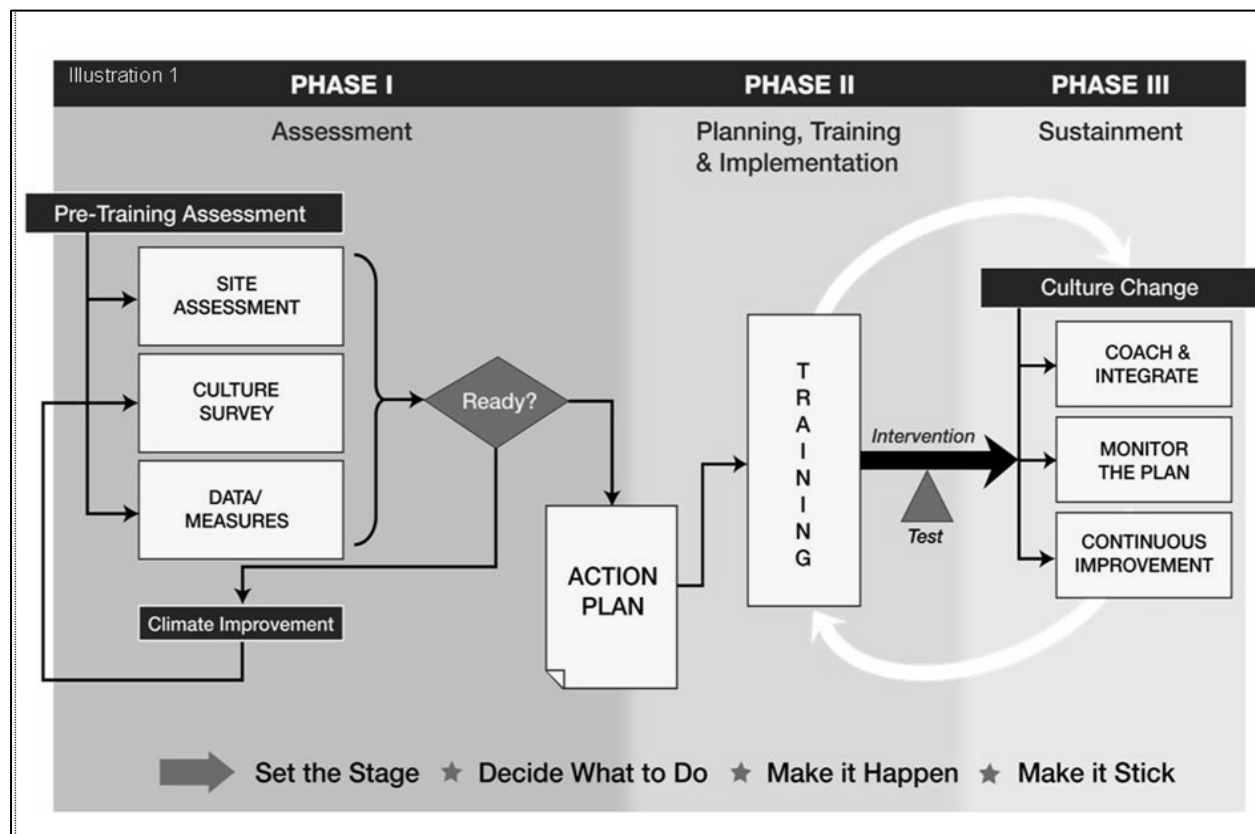


Figure 3. A shift toward a culture of safety

Phase I: Assessment – set the stage. The goal of Phase I is to determine organizational readiness for undertaking a TeamSTEPPS initiative. During the pretraining assessment of Phase I, the organization or work unit identifies leaders and key champions that will make up the organization-level change team. The role of this organization-level change team is to identify specific opportunities for improvement that can be realized by employing a teamwork initiative. A site assessment is conducted to determine the readiness of the institution to include vital support of leadership, potential barriers to implementing change, and whether resources are in place to successfully support the initiative. Such practice is typically referred to as a training needs analysis; it is a necessary first step to implementing a teamwork initiative.³⁹

The AHRQ Hospital Survey on Patient Safety Culture⁴⁰ is a tool that is available to the public to conduct a site assessment. This survey can assist health care organizations and systems in evaluating employees' perceptions and attitudes about the existing culture and issues related to patient safety. Information gathered from this assessment enables leaders to evaluate a variety of organizational factors that have an impact on patient safety to include:

- Assessing awareness about safety issues.
- Evaluating specific patient safety interventions.
- Tracking of change in patient safety over time.
- Setting internal and external benchmarks.
- Fulfilling regulatory requirements or directives.

To further demonstrate the need for improved teamwork and the importance of acting now, facility-specific data (e.g., root cause analyses, occurrence reporting, and patient and staff satisfaction questionnaires) can be used to further support the cause.

A final determination is based on whether improved team performance—to include employing a TeamSTEPPS initiative—is the appropriate intervention necessary to impact change. A thorough needs analysis may uncover many underlying issues within the institution (e.g., systems problems, equipment problems, staffing shortages). The role of leadership is to assess the overall needs of the organization based on the analysis and determine the appropriate interventions.

Once organizational readiness is determined and a decision to proceed with a TeamSTEPPS Initiative is made, the role of the organizational level change team is enhanced. Usually appointed by facility leadership, the change team will:

- Determine the unit or departments in which the initiative should be deployed.
- Develop an implementation and action plan for the organization.
- Train the staff or other trainers.
- Serve as the champions responsible for ongoing coaching and reinforcement of the team behaviors and skills on the unit or department.
- Include feedback on successful use of the tools and strategies, and how best to improve.

Phase II: Planning, training, and implementation – Decide what to do

and make it happen. Phase II is the planning and execution segment of the TeamSTEPPS Initiative. Typically, the change team (or specific designees) complete a 2½-day intensive TeamSTEPPS train-the-trainer session (as described later, AHRQ is developing an infrastructure to support such training). Provided in this session is the core TeamSTEPPS curriculum to include scenarios, case studies, multimedia, and simulation. Culture change and coaching workshops that entail the provision of skills and strategies necessary for implementation, sustainment, and spread of the initiative are introduced. A 4-hour block of time is devoted to participant development of a customized TeamSTEPPS Implementation and Action Plan. Each unit or department produces a tangible report detailing exactly how the initiative will be executed to best meet their unique circumstances. At the end of the session, participants are provided an opportunity to practice teach a module of the core curriculum using specialty-specific scenarios

appropriate to their units or departments. Peer and instructor feedback serves to reinforce understanding of the content, along with refinement of presentation skills.

TeamSTEPPS was designed to be tailored to the organization in which it is being implemented. Options include implementation of all tools and strategies throughout the entire organization, a phased-in approach that targets specific units or departments, or selection of individual tools introduced at specific intervals (a dosing strategy). As long as the primary learning objectives are maintained, the TeamSTEPPS materials are extremely adaptable. Two different versions of the materials are available from AHRQ (i.e., the full course TeamSTEPPS Fundamentals and a shorter Essentials course).

Phase III: Sustainment—Make it stick. The goal of Phase III is to sustain and spread improvements in teamwork performance, clinical processes, and outcomes resulting from the TeamSTEPPS Initiative. During this phase, users will:

- Integrate teamwork skills and tools into daily practice.
- Monitor and measure the on-going effectiveness of the TeamSTEPPS intervention.
- Develop an approach for continuous improvement and spread of the intervention throughout the organization or work unit.

Sustainment is managed by the designated change team through coaching and active observation of team performance. It involves continuing training of the core curriculum through refresher courses and newcomers' orientation, conducting continual evaluations of teams throughout the organization, and providing meaningful, ongoing feedback to staff members in the workplace, where day-to-day health care is provided.

The key objective is to ensure that there are opportunities to implement the tools and strategies taught, practice and receive feedback on the trained skills, and continually reinforce the TeamSTEPPS principles in the unit or within the department.

DoD Initiatives

Numerous Military Treatment Facilities (MTFs) throughout the Military Health System (MHS) are in various phases of the TeamSTEPPS initiative. The HCTCP continues to assess readiness of facilities interested in undertaking a TeamSTEPPS initiative, provides ongoing followup through coaching and consultation, and holds bimonthly Learning Action Network (LAN) teleconferences. Training and implementation have been provided as a whole-hospital approach, within specific specialty units and departments and in ambulatory clinics. Approaches to implementation have included selection of the entire suite of TeamSTEPPS tools and strategies, as well as a phased-in approach of specific tools. The spread of TeamSTEPPS has been evident with the migration of the initiative to additional specialty units and departments within several facilities.

TeamSTEPPS has been incorporated into several other curriculum milieus within DoD to include training at simulation centers, education courses at the Uniformed Services University of the Health Sciences (USUHS), and military operational units. Overall reaction to the TeamSTEPPS initiative has been favorable. Participants in the sessions have provided comments that the

specific teamwork behaviors and skills are pertinent, useful, and applicable to their setting. Many of the tools and strategies (e.g., DESC [Describe, Express, Specify, and Consequences] script for conflict resolution) have been immediately transferable and applicable to situations encountered within participants' work settings. The biggest challenges within the DoD relate to deployments and staff turnover.

AHRQ Initiatives

AHRQ held a 3-day train-the-trainer workshop in spring 2007 with representatives from over a dozen health care systems and hospitals within the High-Reliability Organization (HRO) network. Focus was on development of customized TeamSTEPPS Implementation and Action Plans to support the particular needs of the organizations. Further support is provided by AHRQ through a bimonthly teleconference. A sharing of success stories and lessons learned related to implementation strategies occurs during these calls.

A TeamSTEPPS Collaborative in May 2007 brought together approximately 30 health professionals and researchers. Further clarification regarding requirements for implementation and dissemination of TeamSTEPPS was presented. Participants were in various phases of implementation and shared numerous challenges and experiences. Participants agreed to regular sharing of information, constructing a research agenda for the future, and conducting an annual meeting. Each participating institution will report their progress and findings related to the TeamSTEPPS initiative.

Establishing a National Support Network

Since the release of TeamSTEPPS in late 2006, AHRQ has received numerous requests for the materials and guidance on implementation strategies. To address this need, AHRQ and DoD are establishing a national support network for TeamSTEPPS through the Centers for Medicare & Medicaid Services (CMS) Quality Improvement Organizations (QIOs). Following an agricultural extension model, the intent is for QIOs to serve as partners in the diffusion and adoption of TeamSTEPPS, further aiding health care entities in improving patient outcomes through the tracking of multiple performance metrics. QIOs will be trained and supported via an AHRQ grant through the American Institutes for Research (AIR), which has teamed with Booz Allen Hamilton, Delmarva Foundation for Medical Care, Lumetra, Carilion Clinic, Creighton University Medical Center, Duke University Health Systems, and the University of Minnesota Medical Center – Fairview.

At the core of the AHRQ/DoD national implementation plan are Duke, Carilion, University of Minnesota, and Creighton. These medical centers, which are in various phases of implementation and sustainment, will act as Team Resource Center training sites for the national implementation project. QIO staff and representatives from other health care organizations will be able to enroll in regularly scheduled TeamSTEPPS Master Training Programs. The week-long sessions will provide not only training but also demonstrations as to how TeamSTEPPS was effectively implemented at the host training center. Because each center is different in terms of capabilities, resources, size, and location, the four organizations will provide a variety of training settings for addressing different needs, yielding a greater degree of flexibility in providing training and support to other organizations. A dynamic learning opportunity exists for participants attending a

TeamSTEPPS Master Trainer program, exposing participants to both a classroom learning environment and actual observation of the TeamSTEPPS behaviors and skills applied within a health care setting.

Future Directions

TeamSTEPPS represents a significant advancement in addressing team performance issues in health care. Nonetheless, a critical question remains: Does TeamSTEPPS produce the outcomes hypothesized in Figure 1? Does training in the core curriculum of leadership, communication, back-up behavior, and cross-monitoring lead to more adaptable, safer health care teams? Alternatively, do the tools and strategies presented in TeamSTEPPS lead to enhanced team performance and desirable outcomes?

Similar debate has raged over the impact of team-training programs of all kinds in all industries.^{4, 8, 41} Our goal here in raising these issues is not to question the efficacy of TeamSTEPPS or team training in health care – it works – but to continue to stimulate research. Such research and innovation is the basis of TeamSTEPPS itself. The progress that has been made since the IOM report is tremendous, but there is still much to learn, particularly in health care.

Outside of health care, Salas, Burke, Bowers, and Wilson⁴² have investigated the impact of Crew Resource Management (CRM) training in the aviation community. These researchers compiled information from 58 published accounts of CRM training to determine its effectiveness within aviation. Emphasis was placed on evaluation of CRM training using Kirkpatrick's hierarchy of training evaluation. Results indicated that trainees had positive reactions and enhanced learning that resulted in behavioral change on the whole.

However, establishing a link between CRM and safety was not possible due to limitations in the number of incidents reported. It is very difficult to link interventions to low base rate events, such as incidents and accidents, because of their infrequency. Nonetheless, as Salas and colleagues point out, aviation has accepted the efficacy of CRM training despite being unable to show a direct effect on the ultimate criterion: a reduction in aircraft accidents.⁴² CRM makes sense, and there is little debate that process and performance are improved.

Within health care, Salas and colleagues (2004) updated the 2001 meta-analysis by conducting a systematic review of CRM in the health care industry, which yielded similar results. Twenty-eight accounts (11 within the medical community) of the implementation of CRM training in hospitals and clinics were systematically reviewed. Just as in previous work, links between CRM training and reactions and declarative and procedural knowledge were established. However, like in the aviation industry, a limited number of organizational safety outcomes could be established, preventing researchers from identifying an impact of CRM on safety.

Based on the above results, the evidence supports the efficacy of TeamSTEPPS. However, direct empirical evidence for the TeamSTEPPS initiative's impact on safety outcomes has yet to be presented. Both AHRQ and DoD are actively pursuing this question, and we believe the evidence will emerge in the near future. As part of the national implementation, AHRQ and DoD have requested such studies, and the participating institutions are working on this challenge. For

example, Duke University Medical Center, in partnership with the University of North Carolina, administered a variant of TeamSTEPPS to over 400 graduating medical and nursing students, collecting data on the performance of four-member physician/nurse teams interacting with standardized patients. Carilion Clinic is planning to examine the relation between TeamSTEPPS and hospital-acquired infection rates and patient satisfaction, while Creighton and Minnesota are testing specific tools in the curriculum and studying how to embed TeamSTEPPS principles into medical education.

Another area we believe has a great deal of potential for future research is the sustainment phase of TeamSTEPPS training. Presently, too little is known about the best strategies for sustaining teamwork principles in the workplace. To date, the approach has been to provide coaching and feedback related to specific cases observed by champions. Nonetheless, research suggests that distributed practice may very well be the best strategy for sustainment.⁴³

However, practice in this setting is most effective when a realistic treatment situation is reenacted that provides opportunities for learning and skills reinforcement. This suggests the need to involve simulation in the sustainment phase to guarantee realism without jeopardizing the safety and security of actual patients. Still, the impact of simulators for sustainment needs to be assessed carefully in order to offset the cost of such systems. As such, research evaluating the impact of simulators on team training sustainment would go a long way towards providing insight into the importance of practice.

A second issue associated with sustainment of team training is the cycle with which practice and/or skills reinforcement should take place. Given organizational demands associated with hospitals, it is crucial to find the appropriate interval for providing skills reinforcement in order to optimize the utility of such programs.

Finally, the differential impact of TeamSTEPPS tools and strategies, or any team training program, should be continually investigated. In order to identify and further develop the most crucial tools and strategies for reducing medical error, researchers should embark on the evaluation of individual strategies and tools in the workplace. This might entail looking into the impact of such strategies and/or tools by skill (e.g., assessing the impact of only communication-related strategies on reduction of medical error).

Summary

In summary, TeamSTEPPS is the outcome of a multi-year research and development program led by DoD and AHRQ. DoD has used the curriculum successfully throughout military health care and shown that it works. Now AHRQ is developing an infrastructure to support the implementation of the TeamSTEPPS program nationally. This effort is, in part, the result of the overwhelming response of the health care community to the TeamSTEPPS initiative. Health care institutions see its utility, value the TeamSTEPPS principles, and want to use them. As these early adaptors implement, test, and refine the program, there is anticipation that much will be learned to advance to field of teamwork and its relation to patient safety. Achievement since 2003 has been notable, and we hope that these accomplishments stimulate future research and development innovations. It is only through such work that programs like TeamSTEPPS emerge.

Acknowledgments

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Understanding Quality and Safety Problems in the Ambulatory Environment: Seeking Improvement With Promising Teamwork Tools and Strategies

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Abstract

Despite 1.2 billion ambulatory visits in 2005, from a health care quality and safety perspective, the ambulatory setting has been less subject to research and scrutiny, compared to high-risk inpatient areas like surgery, perioperative and perinatal care, and the emergency department (ED). The ambulatory environment is prone to problems and errors that include missed/delayed diagnoses, delay of proper treatment or preventive services, medication errors/adverse drug events, and ineffective communication and information flow. Once there is clarity about the nature of outpatient errors, evidence-based teamwork tools, strategies, behaviors, and principles can be implemented as countermeasures to elements of the error chain. From the resources of the TeamSTEPPS™ initiative, six effective and evidence-based tools and strategies are offered for use by clinicians in the ambulatory setting to improve the quality and safety of patient care by improving teamwork and communication.

Introduction: Realities and Harm in the Ambulatory Care Setting

Patients and health care providers have become increasingly aware of medical error and system problems causing poor outcomes in high-risk inpatient environments, including surgery, perinatal care, intensive care, and the emergency department (ED). In contrast, care provided in the ambulatory setting has received less scrutiny and is often perceived as safe and routine, focusing on relatively healthy patients. The volume of care within the United States for outpatient services is estimated at 1.2 billion visits to physician offices, clinics, and emergency rooms in 2005,¹ a rate of four visits per person annually.

Trends indicate increasing numbers of outpatient visits for primary and specialty care over the past decade, with similar trends in ambulatory procedures, which numbered 31.5 million in 1996.² Compared to inpatient hospital care, the outpatient environment often is dispersed geographically and lacks infrastructure support. For patients, this potentially creates problems with continuity of care and confusion.

A better understanding of the quality, safety, and system problems clinicians face while providing outpatient care will allow focused application of an increasing array of patient safety solutions, including effective communication and teamwork.³ Recently developed medical error taxonomies^{4, 5, 6} for the ambulatory care environment create structured, meaningful categories and bring greater clarity and understanding to this previously understudied area.

Quality and Safety Problems Experienced by Providers and Patients in the Ambulatory Care Setting

Missed or delayed diagnoses. One of the leading allegations in liability lawsuits is that the clinician “failed to diagnose” a significant condition (e.g., cancer), a claim made in nearly 75 percent of radiology cases, 64 percent of pediatric cases, and in about 50 percent of cases involving family medicine providers and internists.⁷ Analyses of this problem have focused on the frequency, impact, causes, and potential for prevention of missed/delayed diagnoses. Analysis of closed-claim cases identified common factors, including failure to have or adhere to a cancer screening protocol, failure to include cancer in the differential diagnosis, and inadequate followup.⁸

In the ambulatory setting, a review of 307 closed claims⁹ revealed that 59 percent of diagnostic errors harmed patients; of those, 59 percent caused serious harm, and 30 percent resulted in death. In these cases, common process problems included failure to order an appropriate test, create a proper followup plan, obtain an adequate history, or perform an adequate physical examination, as well as incorrect interpretation of diagnostic tests. Further analysis revealed judgment error (79 percent), failure of vigilance or memory (59 percent), knowledge deficit (48 percent), patient-related factors (46 percent), and handoffs (20 percent) as causal factors. The authors comment that no “silver bullet” can solve such complex problems. Instead, successful interventions focused on improving quality and safety will most likely target portions of the error chain.⁹

A literature review and collaborative project,¹⁰ “diagnosing diagnosis error,” formulated potential solutions to include reengineering processes for followup of abnormal tests, delineating “red flag” and “do not miss” diagnoses and situations, and standardizing the interpretation of tests/imaging, particularly after hours and in residency programs. These authors acknowledged the relationship of diagnostic errors with the cognitive process and complexity of the problem.

Cognitive errors and the decisionmaking process can be seen as failures in perception, failed heuristics, and decisionmaking biases, as recently popularized by Groopman in his book, *How Doctors Think*.¹¹ These failures are further explained in detailed articles,^{12, 13} with thoughtful analysis recommending countermeasures to known biases and the useful suggestion to routinely ask during the diagnostic process, “What else might this be?”

Despite the seemingly esoteric view of cognitive failures, often problems seen in offices and clinics are as mundane as misfiled papers, unavailable charts and records, poorly distributed workload, ineffective communication, and reports not acted upon—system defects that can lead to potentially tragic outcomes for patients. Available solutions should address the human factors issues, system problems, ineffective communication, and information flow.

Delay in proper treatment or preventive services. Certainly, if there is substantial delay in diagnosis, there may be a corresponding delay in initiating proper treatment. However, treatment delays have many causes, some of which may or may not be preventable. Patients may not seek care in a timely manner; system issues can delay appointments, testing, or notification of results; or communication may fail along a potentially convoluted continuum of care (e.g., patient to primary care provider to diagnostic testing to and from specialists). According to The Joint Commission (2005),¹⁴ root causes of sentinel events specifically related to delay in treatment focused on the top four problems: communication, patient assessment, procedural compliance, and continuity of care. Recent statistics reveal that only 2.7 percent of sentinel events reported to The Joint Commission occurred in the ambulatory setting, not including the ED.¹⁴ However, underreporting is frequent outside of the hospital environment.

Similarly affected is the delivery of preventive services, such as mammograms, PAP smears, fecal occult blood testing, colonoscopies, and other monitoring/screening functions that are performed in the ambulatory setting. The failures¹⁵ may be related to faulty processes, information technology support, time pressures, inadequately trained personnel, financial constraints, organizational culture, teamwork, and communication, as well as ineffective communication with the patient and family, which may be secondary to language and literacy issues. Solutions must address ineffective communication, lack of teamwork principles, clinical leadership failures, the apparent normalization of ineffective processes, patient-clinician roles and responsibilities, failure to followup, and mutual understanding/decisionmaking.

Problems with medications: Adverse drug events (ADEs). Extensive work has been done in the area of medication errors, including a recent comprehensive evaluation of the evidence and recommendations, broadly applicable across all domains of health care, for actions to prevent these errors.¹⁶ The evidence for harm is extensive, with estimates in one study of 27 ADEs per 100 adult ambulatory patients, of which 13 percent were serious, 28 percent ameliorable, and 11 percent preventable.¹⁷ For older individuals, the rate of ADEs was 50 per 1,000 person-years, of which nearly 14 percent were preventable, and 38 percent were considered serious, life-threatening, or fatal.¹⁸ In this group, the medications most involved with preventable ADEs were cardiovascular drugs, diuretics, nonopioid analgesics, hypoglycemics, and anticoagulants. Recommended prevention strategies have focused on the prescribing and monitoring stages of pharmaceutical care.

Misunderstandings between patients and doctors were identified in a study of general practice medication use in the United Kingdom. This report¹⁹ revealed multiple modes of failure on the part of both the physician and patient in sharing information, beliefs, and decisionmaking. A national surveillance study²⁰ of ED visits identified ADEs from the outpatient setting, which represented 2.5 percent of ED visits, 6.7 percent of hospitalizations for unintentional injuries, and an extrapolated annual national estimate of more than 700,000 individuals treated in EDs for unintentional problems related to medications.

Additional investigations focused on interventions and strategies in primary care and ambulatory practices to reduce the incidence and severity of ADEs,^{21, 22, 23} but the systematic review²⁴ concluded that these interventions had little measurable effect, except for weak evidence that pharmacist medication reviews were effective in reducing hospital admissions due to ADEs. Stronger evidence¹⁶ identifies fewer ADEs with electronic prescribing, particularly with built-in

decision support and technology-based checks for allergies, drug-drug interactions, dosing, and patient-specific information.

Solutions must address inaccurate understanding, the communication process, medication reconciliation, and interactions among providers and other health care professionals, particularly nurses and pharmacists. In addition, the human limitations to vigilance and the presence of complacency, even with high-alert medications, must be considered. The possibility of using back-up behaviors, mutual support within the care team, and standardized communication techniques may offer partial solutions.

Communication and information flow processes. The following are problem areas that can lead to medical error in the ambulatory setting:

- Ineffective communication between patient/family and clinician and among office/clinic staff members.²⁵
- The communication chain: patient → primary care provider → specialty or subspecialty referral.^{26, 27, 28}
- Primary care to hospital and hospital to primary care.^{29, 30}
- Handoff communications along the continuum of care.^{31, 32, 33, 34}
- Missing reports³⁵ from laboratories, imaging and other tests, consultants, procedures, and correspondence.

These problem areas would benefit from structured handoffs, proactive sharing of the patient care plan, improved feedback, and standardized processes for information handling. In addition, clinical leadership has opportunities to set expectations, use the whole team to focus on quality communication and process improvement, and expand the definition of the care team to include consultants, ancillary services, and the patient and family.

Approaches to Improve Quality and Safety in Ambulatory Care

Many organizations have developed and published important concepts, approaches, metrics, and recommendations for improving care in the outpatient setting, all ideas that deserve close attention from those trying to improve quality and safety of care. These excellent resources are summarized in Figure 1:

- AHRQ Conference on developing a strong research agenda for ambulatory patient safety.³⁶
- The Joint Commission: 2008 Ambulatory National Patient Safety Goals.³⁷
- National Quality Forum: National Voluntary Consensus Standards for Ambulatory Care.³⁸
- American College of Physicians (ACP), an online continuing medical education series³⁹ on patient safety, providing seven modules:⁴⁰ Systems, Medication Errors, Idealized Office Design, Electronics, Communication, the Role of the Patient, and Human Cognition.

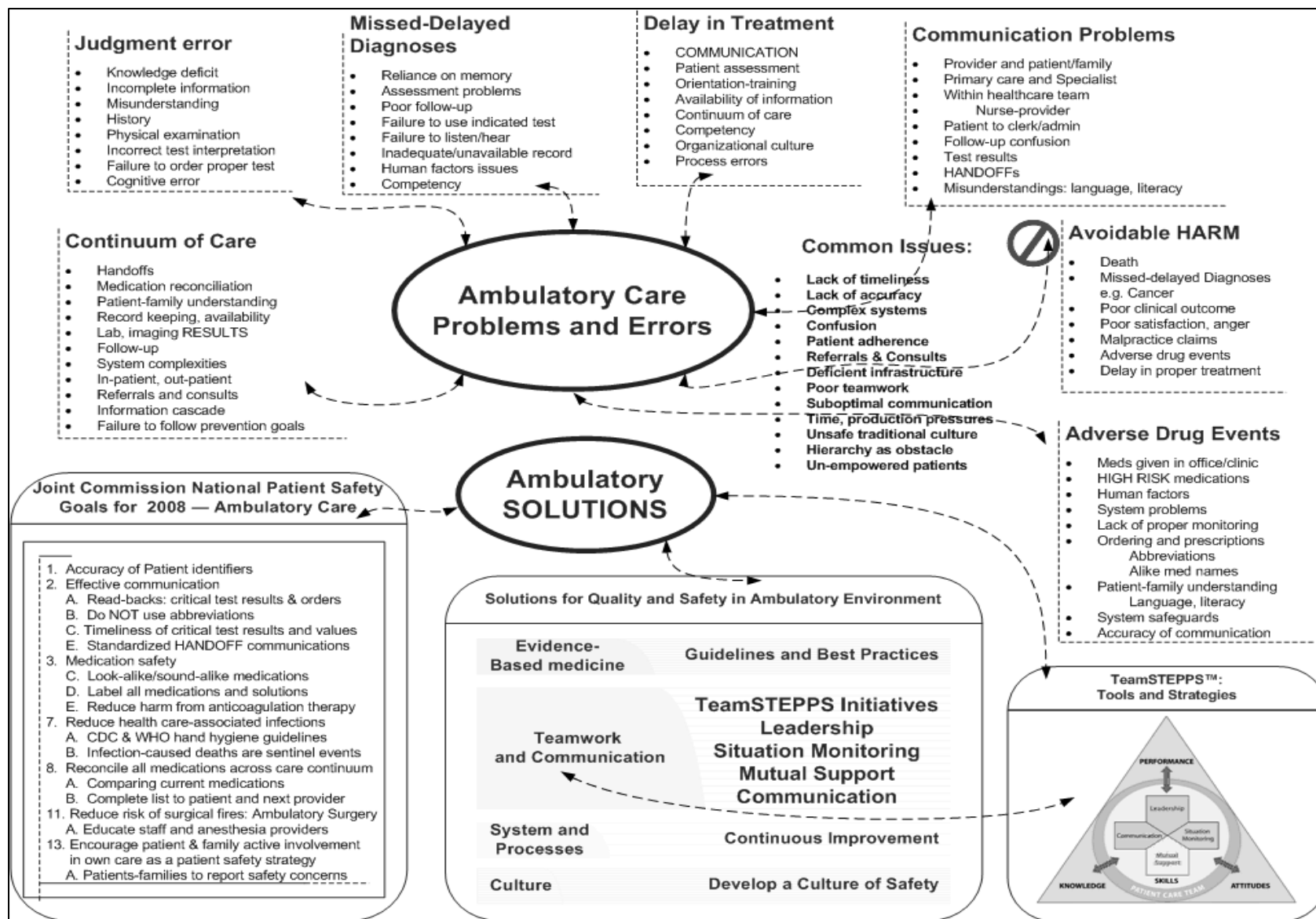


Figure 1. Diagram of resources designed to improve health care quality and safety.

- Focus on measures and reporting:⁴¹ AQA Alliance,⁴² a collaborative of the ACP (and the American Academy of Family Physicians (AAFP), America's Health Insurance Plans (AHIP), and Agency for Healthcare Research and Quality (AHRQ).
- Extensive redesign and "New Model of Practice" from The Future of Family Medicine Collaboration.⁴³
- Institute for Healthcare Improvement's "Planned Care Innovation Community,"⁴⁴ championing a comprehensive redesign of office-clinic practices based on a reliability concept that "...every patient should have a plan for his or her care." Changes in four key elements of care delivery are required: (1) the care team, (2) patient activation to participate in their own care, (3) effective clinical information system, and (4) leadership.
- Enhancing interdisciplinary team collaboration⁴⁵ to improve primary/ambulatory care⁴⁶ and promote a culture of safety,⁴⁷ often by implementing patient safety projects and initiatives.⁴⁸

Relationship of Change Initiatives to Teams and Teamwork

Three important aspects of teams and teamwork in health care must be identified and clarified in order to recognize potential applications to the ambulatory care setting for quality and safety improvements:

- **Improvement teams:** Interdisciplinary teams have long worked together on improvement projects and problem solving, for example, using the PDSA (plan-do-study-act) model cycle to improve processes of care delivery. This would involve identifying a problem and bringing a team together (e.g., physician, nurse, practice manager, physician assistant, and technician) to solve the problem, such as inaccurate lab report handling. The goals might be to ensure that a laboratory report is received accurately and delivered to the provider; its information is properly acted upon; the patient is notified; the report information is recorded/documented; and appropriate decisions and plans are made. The impact could be studied for 3 to 6 months; the results could be analyzed, tracked, and evaluated; and a decision could be made about further lab report handling changes or about moving on to another problem for the team to evaluate and solve.
- **Care provision team:**⁴⁹ A multidisciplinary team within a clinic or practice that collaborates, for example, on the chronic care of a patient (or group of patients) with diabetes and comorbid conditions. This group effort—focused on diagnostic, therapeutic, preventive, and social dynamics—can be seen as effective teamwork, when the members are interdependent, proactively share information, collaborate in the decisionmaking process, and successfully relate to each other respectfully, with each having an expertise to bring to the table. This team might include the patient, family, physician, office nurse practitioner, nutritionist, social worker, home care nurse, foot care specialist, and specialty consultant(s). In fulfilling a dual mission, these team members could certainly combine their wisdom, clinic data, and process improvement knowledge to function as a diabetes care improvement team for all clinic patients with diabetes, in addition to providing daily care.⁵⁰
- **Science of teamwork:** Based on solid behavioral research on effective teamwork, the primary focus of this article pertains to the application of evidence-based tools, strategies, behaviors, and principles of care provided in the ambulatory environment. Seemingly neglected in most of the studies on the effectiveness⁵¹ of interdisciplinary teams on the quality of delivered care are two very basic questions: (1) whether the care providers (in the

studies) were actually using effective teamwork skills and (2) whether they were practicing in a climate that fostered effective teamwork. Recent adaptation of the Safety Attitudes Questionnaire⁵² (SAQ-A) to the ambulatory arena has improved the ability of researchers to explore the safety culture and climate in offices and clinics. This third aspect of teamwork is starting to be valued as teamwork experts “team up” with medical experts and identify opportunities to augment medical knowledge with principles based on the science of human factors,⁵³ system and reliability theory, and team performance.^{54, 55, 56} The benefit in turning a team of experts into an expert team on behalf of patient care quality and safety is significant.

Six Promising Tools and Strategies to Improve Quality and Safety in Ambulatory Care

Based on collective experience over the past 3 years of using TeamSTEPPS™ materials within the Department of Defense (DoD) and a broad range of institutions around the world, the following strategies, tools, behaviors, and principles, selected from dozens within the initiative, are offered as potentially the most useful for making an impact in the ambulatory setting. Their selection was based on these factors and considerations: usability, implementation effort, understandability, acceptance, rationale, usefulness, potential positive impact on quality and safety, ability to improve communication and team performance, impact on staff satisfaction, role in meeting regulatory goals, leadership support, and patient satisfaction.

Team Events: Briefs, Huddles, and Debriefs

Briefs. To create a shared mental model that enables all team members to “be on the same page,” a leader conducts a briefing: bringing team members together, sharing important information, seeking input from others, and creating a plan for an event, procedure, shift, or day. The classic example for a briefing would be a “preflight” brief in aviation. Important information shared with all team members includes environmental conditions, status of the crew and plane, a clearly stated plan for primary mission and destination, and contingency plans. This translates well to a (pre-procedure) brief prior to a surgical case, outpatient procedure, clinical shift, or review of patients to be seen in the office/clinic that day. Discussion may include expectations, the plan, and any contingencies or risks.

It is important to note that a brief is not a meeting, and it must efficiently focus on the quality and safety of patients, roles and responsibilities of team members, input from the leader, and pertinent contributions from team members. Typically, when a brief does not occur, staff members presume what is going to happen; new or inexperienced team members miss an opportunity for learning and planning; and the case, shift, or day unfolds as it may—more reactive than proactive, more on “autopilot” than with adaptive decisionmaking.

Initial responses among staff about conducting briefs could include negative comments, cynicism, and resistance related to time constraints, scheduling issues, and questionable added value. Possible strategies for managing this resistance include an educational event focused on patient safety, medical error, and harm in the ambulatory setting; portrayal of the leadership vision; stories or data from the practice; and agreement on a trial period.

Compelling reasons for conducting briefs should focus on the premise that “as is” needs to change, and time spent performing the brief will be seen as an investment. The resultant payoffs are efficiencies based on clarity of the plan and team roles, fewer reworks, better communication, less confusion, and improved staff satisfaction, resulting in retention of personnel.

Several publications clarify successes from briefing interventions,^{57, 58, 59, 60, 61} and one clearly identifies the opportunity for “next steps” in spreading the briefing project to the ambulatory care setting. Specifically within the DoD, ambulatory clinical leaders almost always choose the briefing tool as the starting point for their teamwork and communication interventions. When roles and responsibilities are clarified, problems are identified/prevented/mitigated, all of the professionals are clear about patient plans, contingencies are considered, accuracy is emphasized, information is gathered from all sources, the climate is conducive to questioning and clarifying, the outcome is enhanced quality and safety for patients in the ambulatory setting.

Huddles. Huddles differ from leadership-driven briefs, in that any member of the team may call a huddle to address new or changing circumstances and to problemsolve about adapting the earlier plan. There may be urgency with an emergent patient, workload issues, unpredicted staffing challenges, environmental problems related to weather or traffic, or unexpected delays in clinic/office operations. In any case, a new plan is needed, and it generally takes a very short amount of time once “the right people” (generally multidisciplinary) gather for a “huddle.”

The focus might be on developing quick evaluation plans for some patients. This is not rocket science, and most ambulatory staff members already do meet to solve problems. Giving it a name, clarifying the purpose, making it a standard process in the work day, distinguishing it from a “meeting” or “brief,” and mimicking the speed and efficiency of a sports huddle allow people to trust that it will be ultrafocused and ultrabrief, yet effective in solving the problem(s).

Much that is written about huddles does not distinguish the rapid huddle, just described, from a pre-procedure briefing, a short safety meeting,⁶² a process-improvement PDSA event,⁶³ or a brief prior to a shift, case, or day. Some authors have used the term huddle for the time-out prior to a procedure, as per the Universal Protocol.⁶⁴ This interdisciplinary event, immediately prior to the procedure, verifies the correct patient, correct site/side, the intended procedure and possibly the correct implant. It is useful to distinguish among a brief, huddle, and time-out, each of which adds significant value to the care quality and safety for patients in many venues, including ambulatory settings.

The team huddle is powerful and effective, but the keys are: short, patient-focused, efficient, problemsolving, information sharing, and action oriented. The huddle is a tool for getting the team to work together effectively; it is easy to implement and a great team-builder. Huddles can change a practice, improving teamwork and communication on behalf of patient care quality and safety. These team events become partial solutions to the ambulatory error chain by proactively sharing information, clarifying patient care issues, providing back-up behaviors with nurses, technicians, and providers, and helping each other with error avoidance.

Debriefs. The debriefing process is central to improving team performance, yet it is seldom used in health care, in marked contrast to other high-reliability teams and high performance teams, for

which debriefing is expected and used routinely. Although supervisors typically give individual performance feedback to employees as a managerial function, the idea of high quality feedback, in real time, focused on team performance, is foreign to most health care team operations, with the exception of code team or resuscitation team debriefs.

When communication and feedback are open, fair, respectful, and focused on team performance improvement, the enhanced learning environment creates remarkable opportunities for the team to improve. A report describing benefits of the debriefing process⁶⁵ in the operating room and intensive care unit settings, indicated a rapid spread to hospitalwide implementation following a grand rounds and information campaign. In aviation, the crew debriefs after every flight so as to incorporate lessons learned in real time. In health care, there is great opportunity to increase use of debriefs with very little burden, with the benefits being improvement in team performance.

In the ambulatory environment, making these team events—briefs, huddles, and debriefs—the usual way of working together could result in improved care, decreased error, learning from mistakes and near misses, and possible disruption of the error chain for the problems of missed diagnoses, medication errors, and ineffective communication that are so prominently presented in the literature and medical-legal arena.

Communication: Closed loop and structured techniques. Communication skills are the lifeblood of teamwork, yet communication failures^{66, 67} are the root cause of nearly 70 percent of sentinel events reported to The Joint Commission.⁶⁸ When information is critical, it should be verified so that both the sender and receiver clearly have the same understanding of the situation. For the pilot cleared by the air traffic controller to ascend to 35,000 feet, the “check-back” includes an exact identifier for that specific plane/flight and a restatement of what was heard, “cleared to three-five thousand feet.”

For medication orders—given verbally in an emergency or written for routine orders, even in the ambulatory setting⁶⁹—an exact repeat of the patient, medication, dose, and route of administration and a further acknowledgment of accuracy by the original sender complete the verification process. After the order, the nurse says, “Let me repeat that. Mrs. Getta Medication, ID number (stated) to receive 40 (four-zero) milligrams of drug X-Y-Z subcutaneously now.” “Yes, that’s correct.” This process is easy to do but requires some discipline. Institutionalizing the process in one’s practice avoids some of the problems with wrong medication, wrong dose, wrong person, and wrong route problems that may result in ADEs.

For telephone orders, actually writing down the exact order then reading back what is written and verbally acknowledging accuracy completes the “read-back” and ensures accuracy of the information exchange. Read-backs have also been effective in giving and receiving critical lab values⁷⁰ and other reports, with minimal time investment. Simple advice: agree as a team what key operational orders will be checked/read back, practice doing this, and take pride in checking back and verifying that what was heard was exactly what was said. Another part of success with this process is for the receiver to speak up if there is any concern with the order creating a quality or safety problem.

In many organizations, staff members use a tool known as the “two-challenge rule,” in which the receiver states two times, if necessary, the safety concern, and the sender is obligated to

acknowledge the concern. Typically, a misstated dose or erroneous drug order results from a momentary lapse or slip, and the sender is appreciative of the assistance and avoidance of error. This is particularly true when the team has agreed to the process, practiced it, and all members see the direct benefit to patient care quality and safety by taking the “ego problem” and hierarchy out of the interaction. Using these methods of closed-loop communication methods, check-backs, and read-backs offer the benefits of redundancy and engagement to decrease medication errors.

Structured communication and handoffs: SBAR. A key lesson from high-reliability organizations is to standardize processes to decrease error and improve performance. SBAR (Situation, Background, Assessment, and Recommendation) is a structured communication technique that allows information to be packaged in an expected and accepted format, which is concise, pertinent, and well-framed for the receiver of the information. SBAR is a superb tool⁷¹ for updating clinical circumstances or relating patient information. In the ambulatory setting, among DoD personnel, SBAR has been used effectively in emergency transport settings, provider-to-provider, nurse-to-provider, technician-to-provider, and telephonically in nearly every clinical scenario.

The following is an example of a telephonic communication using SBAR:

S **SITUATION:** This is (medic) John Smith in the field. I’m calling about a patient we are dressing and splinting for transport shortly to your clinic with an apparent isolated open
B fracture of the left ankle. **BACKGROUND:** Mr. XXX is 22 years old, otherwise healthy,
A who was playing basketball, twisted his ankle and fell. **ASSESSMENT:** Open fracture of
the ankle. The alignment is satisfactory, and the pulses and sensation are normal, and the
R pain level is tolerable, now that the splint is on. **RECOMMENDATION:** We will keep
the patient from eating, have the leg at neutral elevation, run the IV at 100cc/hour, and
transport in the next 5 minutes to your location. Tetanus status is up to date, but on
arrival, suggest IV antibiotics, immediate x-ray, repeat neuro-circ checks, and immediate
orthopedic consultation for wound and fracture care. We’ll monitor for any other injuries.

This is a tool that allows concise, focused transfer of information. SBAR may need to be expanded with disease-specific, age-specific, or circumstance-specific agreed upon data sets for handoffs and referrals for more complicated patients. Clinicians in both inpatient and outpatient settings are designing handoff and referral forms based on SBAR or the mnemonic I PASS THE BATON.⁷² For the perioperative arena, including ambulatory surgery, the Association of peri-Operative Registered Nurses (AORN) has provided online examples of handoff tools prepared by its members.⁷³

Clinical Team Leadership and Membership

The major goals of health care teamwork are to reduce clinical error, enhance patient outcomes, improve process outcomes, raise the level of patient and staff satisfaction, and reduce

malpractice claims. While these are admirable goals, how does a clinic or office begin to apply the strategies and tools that teamwork science suggests are effective? Much is written about models for change.^{44, 74} Consistently recommended, key in the TeamSTEPPS curriculum, and fundamental to success in implementing and sustaining teamwork innovations are the actions of clinical leaders.⁷⁵

As a strategy, frontline physicians, nurses, and other professionals in the ambulatory setting have a great opportunity to fully understand the problems/solutions, create a vision for staff related to quality and safety, demonstrate the “will” and cultivate staff buy-in for change, keep the patient and family central to the process changes, commit time and resources to the change effort, and encourage the open feedback that improves care delivery and team performance. The role of an effective team leader is to organize the team, articulate clear goals (e.g., via briefs), make decisions with collective input from the team, empower members to speak up on behalf of patient safety, promote and model good teamwork, encourage feedback about team performance, and develop the team’s ability to handle conflict.

In turn, effective team members are better able to predict the needs of others on the team, including the patient. They are better able to provide quality information and feedback and engage in higher level decisionmaking. Once trained, they manage conflict skillfully and clearly understand their roles and responsibilities (clarified by the leader). When effective members are led by team-committed leaders, the behavioral evidence strongly suggests improvement in team performance. When teamwork knowledge, skills, and attitudes improve, patient care quality and safety are enhanced, and the known errors and problems described earlier potentially can be avoided or mitigated by disrupting the error chain.

Discussion and Conclusion

For the ambulatory health care setting, the opportunity is ripe for comprehensive change, much of which will depend on the clinicians working as teams, both for care delivery and for quality improvement efforts. Both of these efforts depend on working together effectively and using principles founded on teamwork science. In applying team strategies, tools, behaviors, and principles in DoD and civilian facilities around the world, it has been helpful to clarify the problems faced in the ambulatory setting: delay and missed diagnoses, delay in proper treatment and preventive care, medication errors and ADEs, and communication and information flow problems affecting patient care quality and safety along the continuum of care.

Because of the complexity and the inability to correct all of the problems at once, the rational approach is to seek meaningful interventions that will target portions of the error chain. Within the resources that constitute TeamSTEPPS reside numerous evidence-based strategies and tools, which have the potential to improve many of the practices that have made the ambulatory environment difficult and error prone. Usable tools and strategies are described—real opportunities, with relatively low burden—for ambulatory clinicians to adopt and use on behalf of patient care quality and safety. Each targets a portion of the error chain and offers countermeasures to aid in the prevention, avoidance, and mitigation of medical error and help to create a safer environment for patients and families.

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Building Self-Empowered Teams for Improving Safety in Postoperative Pain Management

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Abstract

Objective: The objective of this project was to test, in a residency training context, a novel methodology based on failure modes and effects analysis (FMEA) to improve postoperative pain management in older adults. The methodology forms adaptive self-empowered learning teams that prioritize and address the threats to quality they face in their own unique setting. **Methods:** On a postoperative floor at a teaching hospital, an Error Reduction Intervention Cycle was implemented, including an FMEA-based survey that elicits perceptions of frequency and severity of various types/causes of pain management errors, followed by meetings to reach consensus regarding priorities and feasible solutions. **Results:** The floor team developed a common set of priorities for improvement. Team members jointly developed solutions that are currently being implemented, including both system changes and educational interventions. **Conclusion:** This proactive methodology actively engaged surgical residents in quality improvement as part of an interdisciplinary team and has the potential to foster a culture of safety.

Introduction

Pain management in general, and postoperative pain management in particular, remains unsatisfactory despite: (1) the worldwide promotion of pain as the “fifth vital sign” (where pain is added to the traditional four vital signs to encourage its routine assessment), (2) technologic advances in medicine, and (3) enhanced guidelines.^{1, 2, 3} The situation is worse in the case of older patients.^{3, 4, 5, 6, 7, 8, 9, 10, 11} Deficient pain management may result in psychological and physiological changes resulting in morbidity and mortality and a decrease in patients’ quality of life; increased financial burden on the patients and the health care system due to extended lengths of stay and readmissions; and patient dissatisfaction.^{12, 13, 14}

The gap between what is delivered and what can be delivered in health care has been termed the “quality chasm” by the Institute of Medicine (IOM).¹⁵ Deficiencies in postoperative pain management can be seen as part of this “chasm.” Areas that require attention in order to close this gap include pain assessment and monitoring; familiarity and availability of a variety of pain management strategies (including nonpharmacologic and pharmacologic); teamwork/coordination; patient/family involvement; respect for the integrity and dignity of patients; and systematic continuing quality improvement.

In response to this need, the Accreditation Council for Graduate Medical Education¹⁶ has called for residents to be trained in practice-based learning and improvement and system-based practice. The Academy of Medical Royal Colleges¹⁷ and the World Health Organization¹⁸ have called for placing patient safety at the heart of medical education and practice.

In any setting, one of the most important barriers to reducing errors and improving quality of care is the lack of awareness of the type, incidence, and consequences of these errors. The most commonly used method for estimating vulnerabilities in health care is to retrospectively collect and count errors through voluntary reporting systems (often referred to as incident reports). These are fraught with difficulty due to underreporting (according to the IOM's 1999 report, only 5 percent of known errors are typically reported, and then there are unknown errors) and abuse (e.g., reports filed and counterfiled as a means of retaliation against colleagues).¹⁹ Error reporting often does not promote understanding of the organizational structure and processes of care. Instead, it tends to be associated with blame and shame and frequently results in antagonism among team members, undermining mutual respect, trust, and cooperation. Bates and colleagues have described the difficulties involved in defining and quantifying errors. They reported that even direct observational studies, which are highly labor intensive, often miss errors.²⁰

An alternative approach that is prospective, rather than retrospective, and permits involvement of all team members in identifying and prioritizing safety and quality problems is failure modes and effects analysis (FMEA). This has been widely used in other high-risk industries and has been advocated by the IOM as a means of analyzing a system to identify its weaknesses (failure modes) and possible consequences of failure (effects) and to prioritize areas for improvement.¹⁹ We have adapted this methodology and shown it to be effective in a variety of complex ambulatory settings.^{21, 22, 23, 24, 25}

The proposed methodology, invoking the paradigm of complex adaptive systems, is designed to aid formation of central "attractors" in the form of self-empowered effective learning teams with a common vision to help their complex microsystems adapt and thrive.^{26, 27, 28, 29, 30} Thriving systems are endowed with simple rules, shared vision, and opportunities for team members to innovate.

The paradigm of complex adaptive systems suggests that each health care setting can be viewed as a complex adaptive microsystem. To survive and thrive, hospital floors have to be adaptive. That is to say, they must: (1) generate information about the vulnerabilities of their microsystem and promote dissemination of this information to aid learning about these vulnerabilities (the hallmarks of safety culture, as pointed out by the National Health Care Safety Council of the United States National Patient Safety Foundation); (2) pool diverse resources to generate options for responding to unpredictable external and internal stimuli/pressures; and (3) create good teams to perform tasks 1 and 2 successfully and keep the prevailing anxieties in check.³⁰

The objective of the work presented here was to test our FMEA-based safety improvement methodology in a teaching hospital setting for improving postoperative pain management, focusing on older adults, with surgical residents as integral members of the team. The methodology was intended to form adaptive, self-empowered learning teams motivated to

prioritize safety problems and to devise feasible interventions, thereby fostering a sustainable culture of safety.

Methods

Adaptation of Failure Modes and Effects Analysis

Traditional FMEA is a labor-intensive process that comes in several varieties but essentially involves the following parts:

- a. Choose a specific process to study.
- b. Assemble a team to conduct the analysis.
- c. Identify the steps in the process.
- d. Identify all the possible failure modes at each step.
- e. Estimate the consequences (effects) of each failure mode.
- f. Prioritize areas for improvement.
- g. Design interventions and/or system changes to address the highest priority areas.
- h. Implement and measure the effects of these interventions.

FMEA is time-consuming, costly, and requires considerable expertise and experience. In most settings, the scarcity of necessary resources and expertise is particularly problematic. Even in hospital settings, trained quality improvement personnel are not always available (especially at the individual floor level), despite the fact that leadership is mandated (in the United States) by the Joint Commission (formerly known as JCAHO) to provide the necessary resources for this type of activity.

A further problem with the traditional FMEA approach is that it focuses on a very specific process (e.g., the medication prescribing process) and, therefore, has potential only to improve a small part of the system. Individual floors/settings cannot afford to limit their quality improvement efforts to such a narrow area at the exclusion of other potentially fruitful ones.

In an attempt to overcome some of these practical barriers and while maintaining the essential thrust of FMEA, our process is designed to give a broad overview of the problem at hand. We include almost all of the entities and their interfaces/interactions in the setting under study.³¹ This avoids the problem of having to choose a very specific process to study (part “a” of the traditional FMEA). Instead, one can take a broader view and study a problem that is wider in scope. Postoperative pain management, for example, is a complex problem that involves many different processes and personnel and would be beyond the scope of traditional FMEA.

In our process, steps “g” and “h” of the traditional FMEA are unchanged, but steps “b” through “f” are achieved via a single step that consists of an anonymous survey of all staff. This survey, known as a “Safety Enhancement and Measurement Instrument – Patient Centered” (SEMI-P), serves as a proactive risk assessment tool.^{21, 22, 23, 24} It is designed to generate a hazard profile (“snapshot”) of the setting at any given time. Considerations leading to its development are described below.

Design of SEMI-P: Macrosystem and Microsystem Level Considerations

The SEMI-P is broadly structured on a visual model³¹ of the whole continuum of health care (Figure 1). The model is a systematic, patient-centered representation (based on safety engineering principles) of health care settings. The concentric circles represent the various domains of care in which a patient can transition, including the home/community (at the center), the primary care office, the emergency department, long-term care, and the inpatient setting.

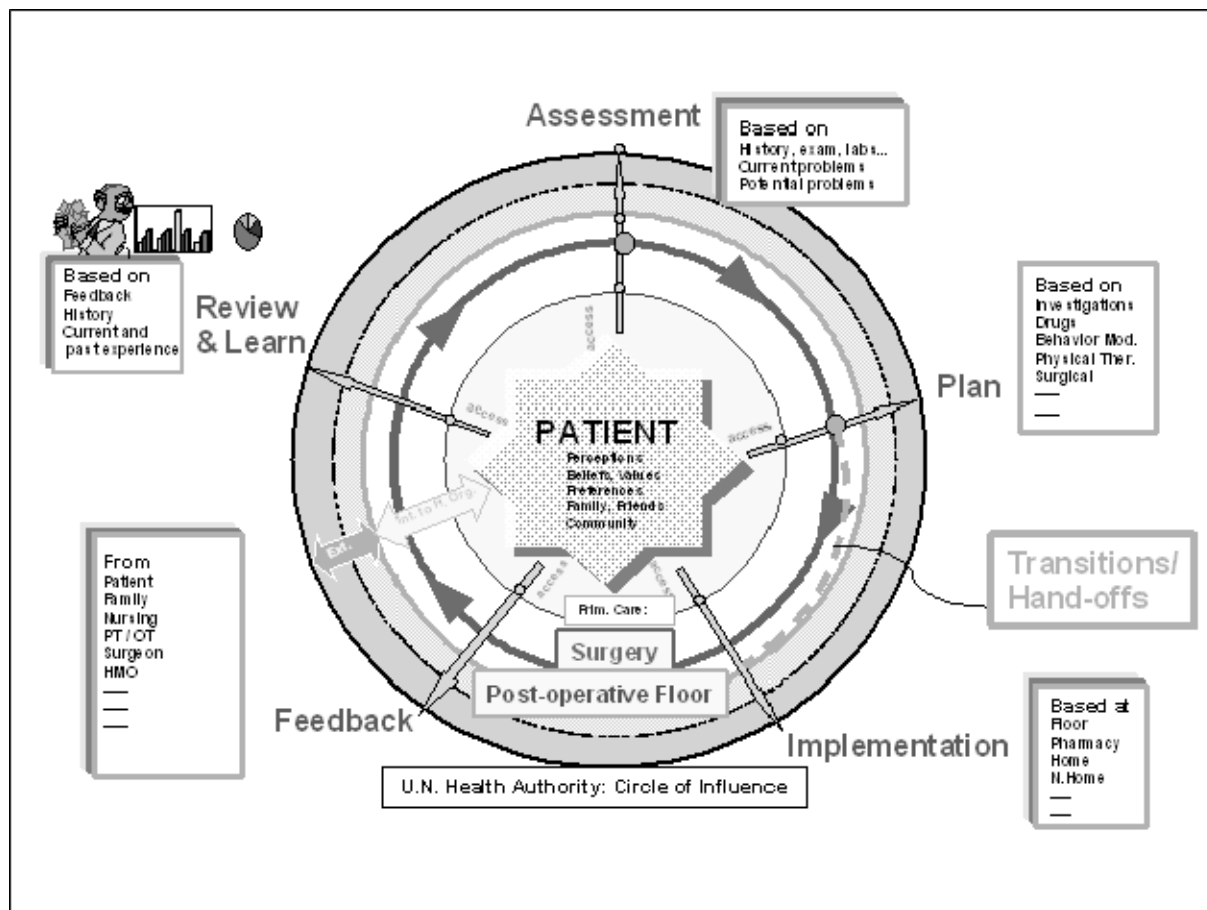


Figure 1. Model of the whole health care system. Adapted from Singh R, Singh A, Fox C, et al., *Inform Prim Care* 2005; 13: 135-144.

A cycle of care takes place in each circle, consisting of the following processes:

1. **Assessment.** Accurate collection, review, and documentation of history, physical exam, laboratory results, medications, and current and potential problems.
2. **Plan.** Accurate prescription of appropriate medications, dosage, timing, and combinations (avoidance of unnecessary polypharmacy) and ordering of appropriate, timely, and sufficient monitoring and other appropriate interventions.
3. **Implementation.** Accurate completion of orders, including transcription, dispensing, and administration of medications, laboratory testing, and other interventions.
4. **Feedback.** Accurate feedback from the patient, family, doctor/nurse/pharmacist/staff, lab, and medical record.

5. **Review and learn.** Systemic learning from process evaluation (without assigning blame).

Each point of intersection between a circle and a process represents a specific set of processes of care. For the purposes of the present work, the circle shown in bold in Figure 1 represents pain management on the postoperative floor. Therefore, the five points around the circle represent the steps in postoperative pain management. These steps need to be examined closely in the SEMI-P. This is achieved by creating a microsystem view, as will now be discussed.

Figure 2 represents a detailed (microsystem) view of inpatient postoperative pain management. It includes all the entities and interactions that together achieve the cycle of care (e.g., assessment, planning, implementation). The microsystem view provides a natural structure for identifying failure modes. The SEMI-P is structured around this micromodel. It dedicates a separate page to each of 18 entities/interactions within the system. Each page includes a list of failure modes that can occur in that specific part of the system. The micromodel and the lists of failure modes were developed by review of the literature and consultation with the setting/floor leaders. The questionnaire contains 153 failure modes. When responding to the survey, participants are encouraged to add to the lists of failure modes as they see fit. Figure 3 shows an example page.

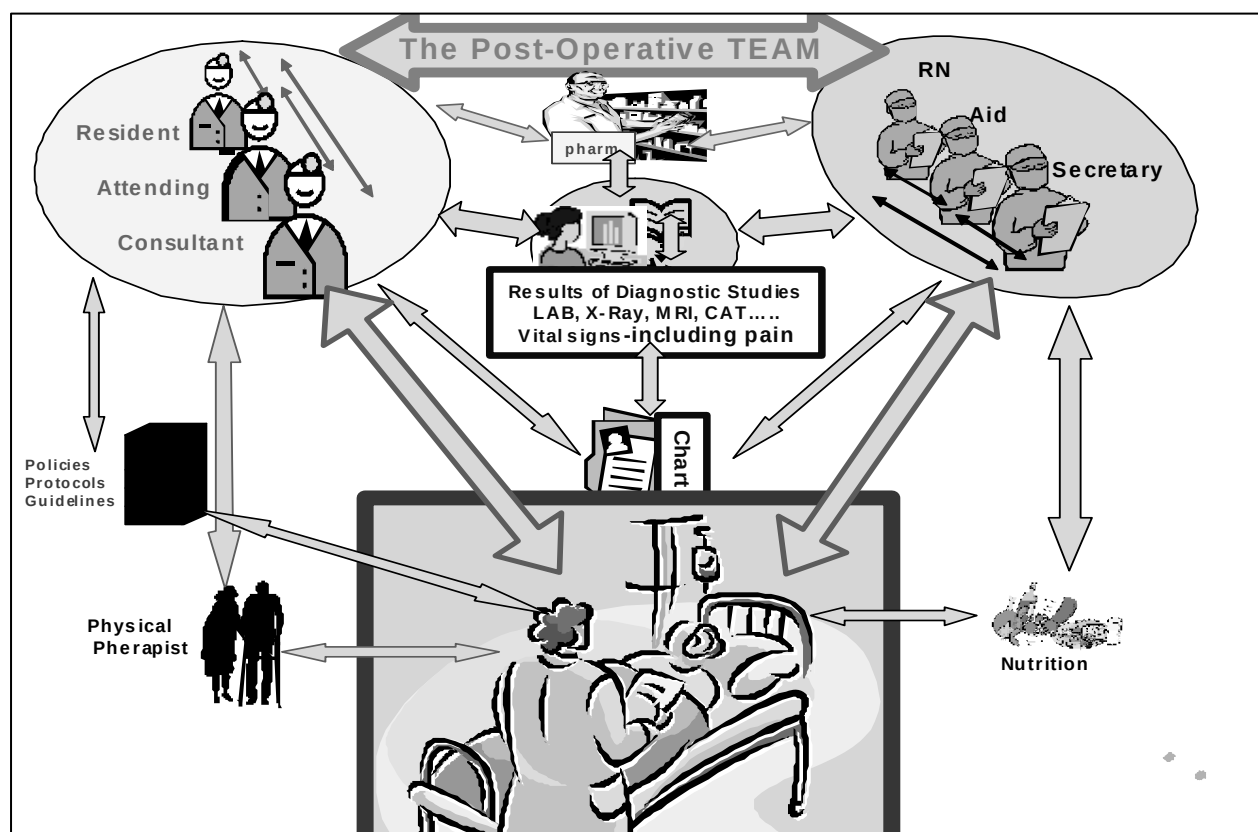


Figure 2. Visual micromodel of the entities and interfaces/interactions for postoperative pain management.

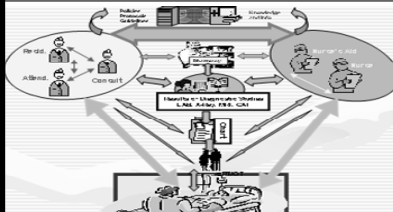
Type/cause of Error : Patient	How often does this happen?				What is the usual consequence?			
	Frequent	Occasional	Uncommon	Remote	Severe	Moderate	Mild	Minimal
Patient does not complain (stoic)								
Unable to explain pain due to cognitive impairment								
Unable to explain pain due to sedation								
Unable to explain pain due to language barrier								
Does not provide accurate information about:								
medical problems								
prior medications								
allergies								
substance use / abuse history								
Does not seek clarification when needed from Dr/Nurse								
Does not provide/participate in self-assessment of pain								
Patient unfamiliar with pain management strategies								
OTHER								
	One or more times in a day	One or more times in a week	One or more times in a month	Less than once a month	Severe or irreversible complications (eg delirium, disability)	Mild or moderate reversible complications unrelated to the natural course of the illness	Increased length or severity of illness	No increase in length or severity of illness

Figure 3. Survey example page.

Participants anonymously and confidentially expressed their perceptions of the frequencies and severities (as defined on each page) of the various failure modes in the setting where they work. These answers were transposed onto numerical scales and then converted to relative hazard scores by taking the product of frequency and severity for each failure mode (see Table 1).

Instead of asking staff about their own personal error experiences, which likely would have been uncomfortable for some respondents, the SEMI-P asked them about their perceptions of the floor as a whole.

This approach took advantage of local experiential knowledge and, like the highly acclaimed Aviation Safety Reporting System (ARS), had three important attributes; safety (immunity from blame and punishment), simplicity and convenience, and worthiness and value (provided

Table 1. Relative hazard matrix used for transposing qualitative frequency and severity into numerical values

Severity(s)	Probability of occurrence			
	Remote	Uncommon	Occasional	Frequent
Minimal	0.01	0.02	0.24	1
Mild	0.03	0.10	1.20	5
Moderate	0.10	0.40	4.80	20
Severe	0.50	2.00	24.00	100

feedback and served as a tool for development of improvement strategies and enhancement of staff self-esteem).

Intervention Design

The intervention design applied an Error Reduction Intervention Cycle (ERIC), as illustrated in Figure 4. The process was carried out on two postoperative surgical floors at an urban teaching hospital. The two units were run by the same nursing manager and were viewed as one unit for this study. All staff—including nursing, administrative and support staff, surgical attendings, and surgical residents—were invited to participate. The hospital quality improvement committee approved the protocol. The steps in the intervention (Figure 4) are described below.

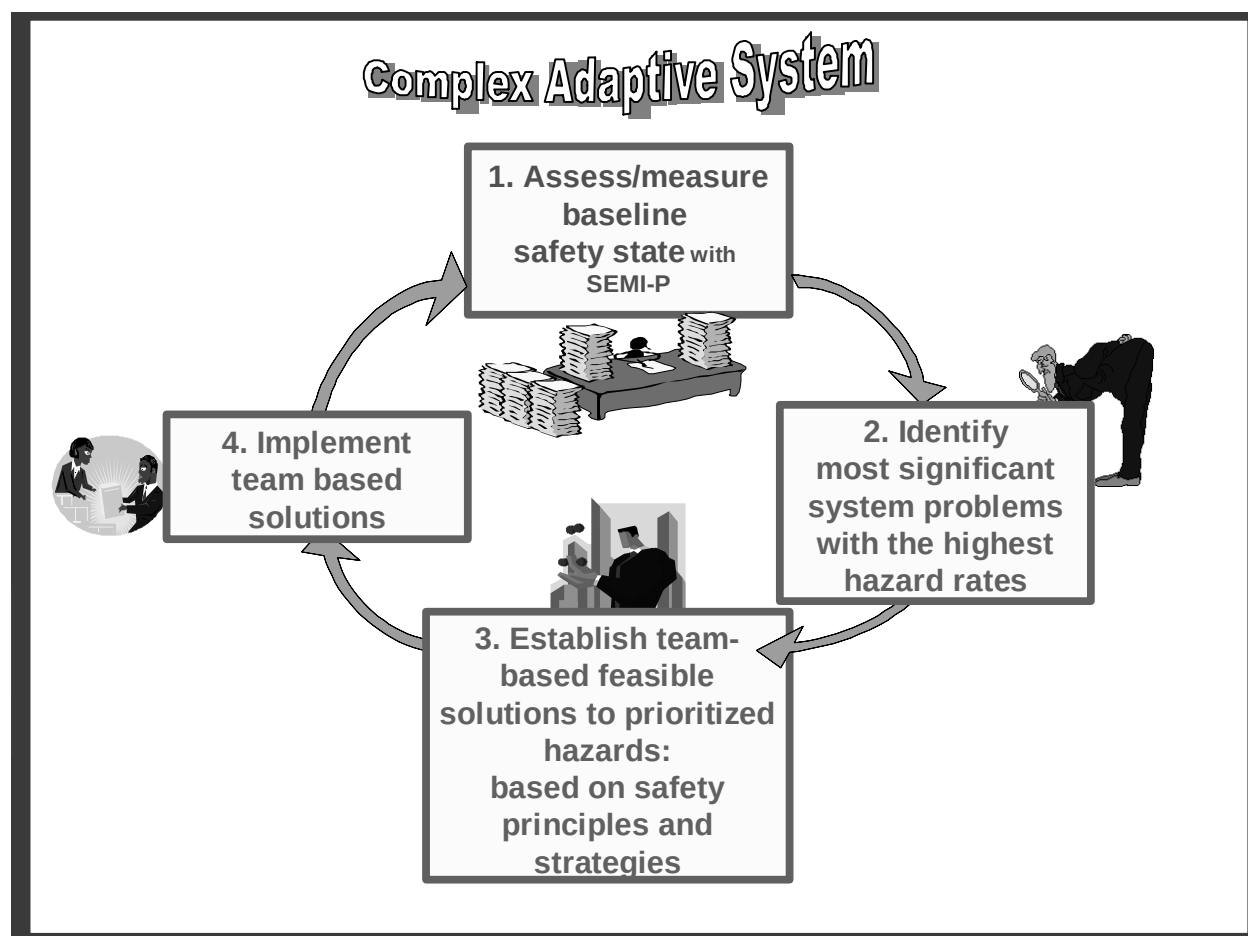


Figure 4. Error Reduction Intervention Cycle (ERIC) using Safety Enhancement and Measuring that is Patient-Centered (SEMI-P).

Step 1: Assess the Baseline Safety State

Prior to administration of the questionnaire, participants attended a 20-minute orientation session that explained the rationale behind the approach, the visual model, the intended cyclic process of improvement, and the format of the survey. Specifically, the following aspects were reviewed with the aid of slide show and flip charts:²³

- The importance of reducing errors for improvement of quality.
- Avoidance of individual blame when errors occur – *To Err Is Human*.
- The importance of focusing on team learning from errors.
- The superiority of a safety culture over a culture of blame and other possible strategies.
- The important contributors to this culture were described and explained in detail.

For floor staff, this orientation was done in small groups at lunchtime meetings (with lunch provided). Surgeons (residents and staff) were oriented during existing scheduled meetings. Immediately after orientation, each group received the SEMI-P survey together with an envelope to facilitate anonymous return of the survey. Meetings were scheduled to include sufficient time to complete the survey. Following the methodology outlined earlier, hazard scores were calculated for each failure mode. Failure modes were then ranked according to their means.

Step 2: Identify the Most Significant System Problems

Ideally, all floor staff and surgeons would have met together to establish priorities based on the survey results. However, this was not feasible. Therefore, two separate meetings were arranged, one with floor staff and one with surgical residents. Each meeting was conducted using the following structure:

- Brief review of the orientation material.
- Presentation of SEMI-P results in detail, including comparison of hazard scores assigned by surgeons vs. floor staff.
- Prioritization discussion, using the SEMI-P results to encourage a common vision and as a starting point for discussion.
- Creation of a mutually agreed upon list of top priorities for improvement in postoperative pain management.
- Where time permitted, preliminary discussion of solutions to the identified priorities (i.e., the beginning of Step 3).

Step 3: Establish Feasible Team-Based Solutions

A joint meeting was convened with representation from surgeons, floor staff, and hospital administration to review the priorities identified in Step 2 and reach consensus regarding appropriate solutions. In keeping with the philosophy of using internal expertise and promoting group ownership of problems and their solutions, the group was encouraged and helped to develop their own solutions based on their intimate knowledge of their own unique microsystem. To aid and guide the design of safety interventions, the staff was shown a brief slide presentation covering basic strategies and principles of system redesign based on IOM recommendations.

Step 4: Implement Team-Based Solutions

Team members collaborated as needed, with input and approval as necessary from within the administrative hierarchy of the hospital, to implement the solutions identified in Step 3, modifying them as needed to overcome the barriers they faced.

Results

Results of each step in the ERIC process are described below.

Step 1: Assess the Baseline Safety State

During a 2-month period, 36 floor staff and 53 surgical staff (including residents and attending surgeons) completed the SEMI-P. Those respondents who completed the survey during the assigned meetings were observed to take between 20 and 30 minutes.

Step 2: Identify the Most Significant System Problems

Approximately 2 months later, two prioritization meetings took place independently, one for floor staff and one for surgeons. The meeting for surgeons was attended by 45 surgical residents and one surgical attending (the residency program director) and was limited to 20 minutes due to scheduling constraints. The SEMI-P results were presented and discussed. The meeting took place in a lecture hall, a setting not conducive to open discussion. Therefore, to allow for maximal participation in the prioritization decisions, 14 items (including those with the highest hazard scores and others raised in discussion) were presented to the group for a vote, based on a show of hands. The four items with the highest number of votes became the surgeons' priority list, as follows:

- Misunderstanding of written pain management orders due to poor handwriting.
- Inadequate information from patients regarding prior medications.
- Poor access to the current medication list.
- Limited knowledge among surgical residents regarding appropriate medication dosages for older adults.

Prioritization by floor staff took place at a 2½-hour dinner meeting with a roundtable format that was conducive to discussion and debate. The nursing manager, nine floor nurses, three nurse's aides, one physical therapist, and one secretary participated. As with the surgeons' meeting, the data were presented, and a discussion was facilitated by one of the authors. The problems the staff identified as having the highest priority were:

- Misunderstanding of written pain management orders due to poor handwriting.
- Shortage of time for nurses to adequately assess and manage pain.
- Use of intravenous bolus dosing of opiates for pain (felt to be inappropriate in most cases by nursing staff).
- Poor communication of pain symptoms by patients to physicians.
- Junior residents sometimes uncomfortable changing the pain medication prescribed by their attending, even if it was not effective.
- Difficulty in reaching the appropriate resident covering a patient.

The time available permitted extensive discussion of the prioritized issues including details of perceived reasons for problems, discussion of previous attempts to address them, and preliminary discussion of new solutions. This discussion format, although more labor-intensive, was more helpful overall than the "voting" method employed with the surgical residents because of the rich

exchange of ideas that occurred. In addition, the detailed records of the discussion served as a useful reference document during Step 3.

Step 3: Establish Feasible Team-Based Solutions

At a 1-hour breakfast meeting held 1 month later, seven surgical residents, the surgical residency program director, five floor nurses, the unit nurse manager, three nursing administrators, and the hospital's chief of geriatrics met to review the priorities identified by the two groups in Step 2, to reach consensus regarding these priorities, and to plan interventions to address them. As a result of this meeting, a summary document was produced, listing the planned interventions and assigned responsibilities. The following is an excerpt from that document [names edited out]:

Planned interventions to improve postoperative pain management:

- 1. Create a standardized postoperative progress note form** that contains prompts reminding residents to check for pain, functional status, and other relevant parameters. A group of surgical residents/attendings could work together to develop this form under the supervision of the surgery residency program director. Examples of such forms used in other facilities may be readily available and could serve as a starting point.
- 2. Work with surgery residency program director to identify training opportunities** for surgical residents and attendings regarding:
 - a. Management of acute pain in the elderly, including:
 - i. Appropriate medications and dosages.
 - ii. Alternative routes of administration.
 - iii. Management of patients who also have underlying chronic pain.
 - b. Medication reconciliation; this is already implemented but not all physicians are aware of how it works.
 - c. Preoperative discussion of postoperative pain management options (for elective surgeries). Residents might have limited access to preop patients, so this may be more of an attending issue.
- 3. Consider increased availability of patient-controlled analgesia (PCA) pumps** as an option for postoperative pain management. [Nursing administrator] will explore whether there are any administrative barriers. Unfamiliarity with ordering PCA pumps (due to prior history of this being done only by anesthesiology at this hospital) is another barrier that might need to be addressed with residents and attendings as part of item 2 above. Similarly, nursing staff will require in-service training.
- 4. Create a preprinted postoperative order form that includes pain management** and other post-op orders. Experience with the postop order form used on the orthopedics floor could help inform the development of this. Surgeons and nurses will need to work collaboratively to develop this. [Unit manager] will create an initial draft as the basis for further discussion.
- 5. Improve access to resident schedules.** Nurses do not find the current schedule user-friendly. They need a list of who is covering each team each day. Some nurses create their own list each day; this helps. This process could be institutionalized so that one list is made and

distributed. Alternatively, this information could be available online. [Unit manager] will explore these two possibilities.

6. **Put in place a system to encourage premedication (when appropriate) to reduce pain prior to physical and occupational therapy.** [Unit manager] will discuss with the relevant therapy departments the possibility of posting schedules so that nursing has enough advance notice so they can premedicate. The preprinted postop order set (item 4) could include the option of a standing order to “Premedicate with _____ prior to therapy.”
7. **Make current medication lists more easily available to residents.** The [specific document in the hospital computer system] was felt to be the most useful document. This has to be requested from pharmacy. [Unit manager] will investigate the possibility of making this available in the chart for every patient on a daily basis.

Step 4: Implement Team-Based Solutions

All of the above action items are currently being implemented. Barriers encountered include resistance from practicing surgeons to change their prescribing habits, unfamiliarity with PCA pumps and how to order them, and competing demands.

Discussion

Each health care setting is a unique and complex microsystem and should be respected and treated as such. This means that off-the-shelf solutions seldom work. We have presented a novel approach, adapted from the method of FMEA intended to be used by each unique health care setting to identify its own set of priorities and to internally develop feasible solutions based on the team members’ intimate knowledge of their microsystem. We have described our experience with using this approach to address postoperative pain management in a hospital setting. The diverse members of the postoperative team were able to work together to develop and implement solutions. However, it is not yet known whether the implemented solutions will lead to improved care and/or outcomes. This clearly requires further study. A variety of effectiveness measures will likely be needed, ranging from simple rates of use of the interventions (e.g., order forms, PCA pumps) to patient satisfaction with pain control, rates of pain-medication-related adverse events, and length of stay.

A further intended effect of the methodology presented here is the fostering of a culture of safety. The ERIC process aims to incorporate change management strategies through a motivated guiding coalition of all staff with a clear, shared vision and shared goals.³² Empowerment, ownership, good team formation (that fosters mutual respect, trust, understanding, collaboration, cooperation, and work satisfaction) are sought to be the driving “strange attractors” of a learning, self-directed, adaptive, and evolving organization^{26, 33, 34} leading to a culture of safety.

This philosophy contrasts with the prevalent approach, often referred to as “Taylorism,” (described by Frederick Taylor in his influential 1911 book, *The Principles of Scientific Management*)³⁵ in which, in its extreme form, only management is empowered to make decisions while workers are expected to follow unquestioningly. The fact that team members worked constructively together in this study is one sign of staff empowerment and a developing safety culture, but further studies are needed. For example, safety climate/attitude surveys might

be used to attempt to measure changes in safety climate that might occur because of the team's participation in the ERIC process.

Although some items were the same between the two groups (surgeons vs. floor staff), most of the priorities initially identified by the two groups were different. This highlights the need to incorporate the perspectives of the whole range of workers in a system. Ideally, team meetings should have involved all staff to maximize the opportunities to discuss similarities and differences of opinion, build a common vision, and take advantage of as many people's experience and insights as possible. While this ideal will likely not be achievable in most settings (as was the case in this study), we suggest that management show their overt support for this kind of approach by facilitating group meetings and exchange of ideas as much as possible. Other methods of exchanging ideas, such as online discussion forums, offer possibilities that should be explored.

The residents' participation as key members of the quality improvement team was an important aspect of this study. Residents participated actively in discussions regarding priorities and contributed much to the development of the interventions. We have not formally evaluated the residents' experience with the process, but our observations are that the residents who participated most actively began to understand better the nursing staff's perspectives, developed a greater understanding of the need for teamwork in pain management, and gained an appreciation of the methods and challenges involved in system improvement. Furthermore, the SEMI-P instrument, in addition to its role in identifying opportunities for system improvement, served as a needs assessment for resident, attending, and staff training.

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Beyond Rapid Response Teams: Instituting a “Rover Team” Improves the Management of At-Risk Patients, Facilitates Proactive Interventions, and Improves Outcomes

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Abstract

Objectives: The objective of this paper is to describe how a Rapid Response System with a proactive Rover Team and a complementary reactive Pediatric Rapid Response Team (PRRT) had positive effects on patients and providers in one children’s hospital. **Background:** Rapid Response Teams (RRTs) are “reactive,” and their effectiveness depends on recognition of the problem and activation of the system. **Methods:** The Rover Team expands the PRRT to include a proactive assessment of patients at risk for clinical deterioration. **Results:** After PRRT/Rover Team implementation, non-intensive care unit pediatric codes dropped from 1 code/month to 0.16 code/month. The Rover Team was most commonly utilized by the nursing staff to deliver time-sensitive therapies, allowing for patients to remain in their current care environment 90 percent of the time. **Conclusion:** A Rover Team identifies at-risk patients and facilitates the prompt administration of time-sensitive therapies. This proactive approach supports the reactive PRRT, provides a critical-care resource, and improves clinically important outcomes.

Introduction

In response to challenges from the Institute for Health Care Improvement and “The 100,000 Lives Campaign,”¹ many hospitals have spent considerable resources developing, implementing, and reviewing Medical Emergency Teams (METs) or Rapid Response Systems (RRSs). Because of growing interest in these systems, experts in the field of patient safety and critical-care medicine have converged in specialized conferences for Medical Emergency Teams.

The First Consensus Conference on Medical Emergency Teams defines the RRS as having a specific structure that includes two distinct pathways. On the “afferent” limb, a critical event is identified, and a systematic response is triggered. The “efferent” limb involves the team—the MET, Rapid Response Team (RRT), or the critical care outreach (CCO) team—that responds to an identified patient need with triage, direct patient care, or escalation of patient monitoring.² Patient safety, evaluations of in-hospital emergencies, and availability of appropriate resources have emerged as important threads in the evaluation of RRSs by both the MET consensus conference and in the adult and pediatric literature.^{2, 3, 4, 5}

As is often the case, many of the early reports described the advantages of METs in adult patient populations. The primary outcomes in these reports described effects of MET implementation on the incidence of out-of-intensive care unit (ICU) cardiac arrests and the number of unplanned readmissions to the ICU.^{2, 5, 6} Recently, data from pediatric studies have begun to emerge. Brilli and colleagues provide the first pediatric report about the implementation of a MET and its impact on out-of-ICU respiratory and cardiac arrests.³ Previous adult and pediatric investigators have included information only about cardiac arrest rates.² Tiballs, et al., described the development of a MET in a pediatric hospital in Australia. Cardiac arrest and death after introduction of a MET were evaluated, as were admissions to the ICU and changes in clinical practice.⁴

RRSs have been developed to bring critical care expertise to patients who demonstrate clinical changes that might herald an acute deterioration outside of the ICU setting. The reactive component of these teams has been described in the literature.² More proactive CCOs have emerged in Europe. These teams not only focus on emergency visits in response to a change in patient status, but they also provide followup visits to patients discharged from the ICU.⁶

Despite improving the timeliness of treatments for patients in non-critical care settings, the Rapid Response model contains one major weakness: its effectiveness depends on an individual first activating the system. This person might not have the clinical expertise or, as the result of other patient care obligations, the time to recognize important changes in a patient's clinical status.

Adding a proactive component to the RRS allows for a systematic review of patients at risk for clinical deterioration and provides clinicians caring for patients in non-ICU settings the resources to help identify these at-risk patients. Rather than depending on an individual to recognize that a patient meets Rapid Response criteria, this RRS includes a collective evaluation of patients who might be at risk for meeting these criteria. This proactive "Rover Team" makes scheduled visits (Roves) to each non-ICU inpatient pediatric ward to provide a critical care resource to the medical and nursing staff outside of the ICU and to systematically review patients at risk for clinical deterioration.

We hypothesized that implementing a "Rover Team" as part of a pediatric RRS would add a proactive component that would result in patients receiving necessary treatments prior to meeting RRT criteria, improve clinical outcomes, such as increasing patient throughput and decreasing number of readmissions to the ICU, and decrease the number of emergency responses from the pediatric ICU (PICU) to non-ICU areas (i.e., Code Blue responses).

Methods

Pediatric Rapid Response Team

Our PICU is part of a 153-bed children's hospital within the Duke University Health System. The 20-bed combined PICU and pediatric cardiac ICU provides critical care to patients for all medical and surgical subspecialties. The children's hospital also includes two inpatient pediatric intermediate care units, a nine-bed pediatric progressive care/step-down unit (PCU), a 16-bed Bone Marrow Transplant Unit (PBMTU), and the Children's Health Center outpatient clinic.

The Pediatric Rapid Response Team (PRRT) was developed through an interdisciplinary process that included collaboration with pediatric critical care faculty, PICU nursing staff, respiratory therapists, pediatric residents, nursing leadership, and pediatric critical care nurse practitioners and fellows. Activation criteria were established according to age-based norms, pediatric advanced life support, and previously published criteria.^{3, 4, 7} Optimal care delivery also depends on effective communication between the bedside provider and the responding team.⁸

To facilitate the many interactions necessary in a rapid response, all the members of the PRRT and the multidisciplinary team participated in team-training activities to develop expertise in the use of SBAR (Situation, Background, Assessment, Recommendation) communication. In addition, prior to implementation of the PRRT, the pediatric house staff and nursing staff also participated in focused educational sessions.

The PRRT comprised a pediatric critical care nurse practitioner or fellow, the PICU charge nurse, and a PICU respiratory therapist. Prior to implementation of the PRRT, the pediatric house staff and nursing staff participated in a 45-minute educational session. The PRRT was implemented on a trial basis in the progressive care unit (PCU) in January 2006. The PRRT was put into place to respond to patients whose clinical status had deteriorated based on an objective set of activation criteria.

Over a very short period, it became apparent that the PRRT was also being utilized as a critical care resource for patients identified by the ward providers as having potential for clinical change. Therefore, to improve patient safety, we attempted to proactively survey care providers on the wards in order to seek out those patients at greatest risk of clinical deterioration.

Initial reviews of PRRT responses and discussions of anecdotal feedback regarding the PRRT at weekly multidisciplinary evaluations revealed that while the team was involved in a response, providers for patients not in the PCU would stop the team to solicit input on the care of their patients or to clarify the plan of care for patients who had been recently transferred from the PICU. A tracking tool was put in place to record these encounters, and from these, the Rover concept emerged. The Rover role became a prequel to a rapid response.

In April 2006, the RRS incorporated a proactive Rover Team component to complement the reactive PRRT. This care-delivery model was then made available for all inpatient pediatric patients and providers outside of the PICU.

The Rover Team

The Rover Team expands the PRRT responsibilities to include a proactive assessment of patients at risk for clinical deterioration, such as acutely ill children admitted to non-ICU inpatient areas or those recently transferred from the PICU. To ensure that these patients are evaluated systematically, a member of the Rover Team meets with the on-call senior resident and the charge nurses of inpatient intermediate care units at scheduled intervals (Figure 1). During these scheduled evaluations (i.e., “Rover Rounds”), the Rover reviews the clinical data, evaluates the patient, provides a critical care perspective, and coordinates transfer to a higher level of care if needed. If necessary, these patients are then targeted for further evaluation by the Rover Team

and scheduled for followup by the primary team. In addition to these scheduled patient identification rounds, the Rover Team evaluates two other patient populations identified as potentially high-risk: all children who have been discharged from the PICU within the prior 12 hours and all patients admitted to the PCU within 1 hour of admission. This process allows for continuity of care as the patient transitions out of the PICU and ensures that these high-risk patients are assessed on a timely basis.

Data Collection

Data were collected on all PRRT activations and Rover Team interventions to any pediatric patient in the Children's Health Center outpatient clinics and all children admitted to either of the inpatient pediatric intermediate care units, PCU, or PBMTU between April 2006 and June 2007.

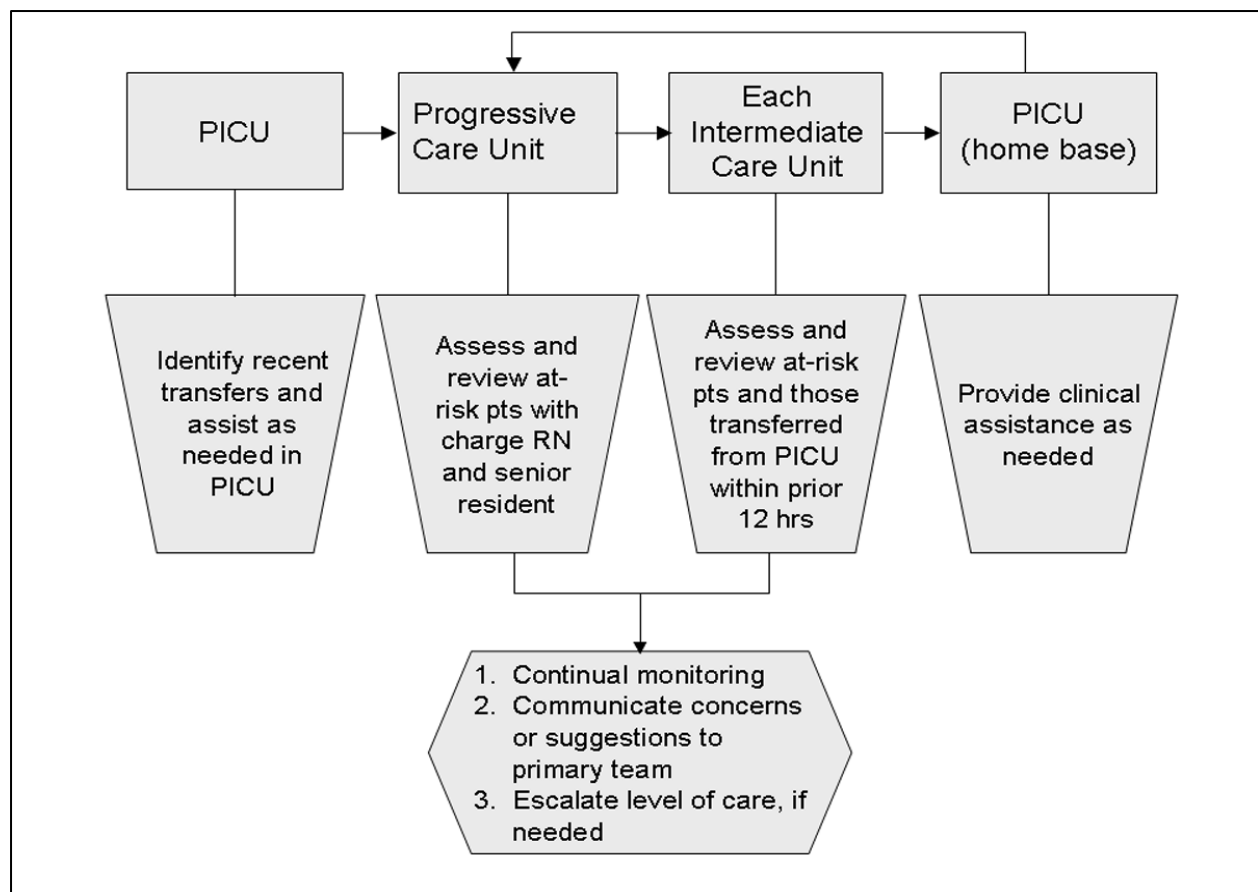


Figure 1. Rover Team process map. Scheduled rounds are made to each of the pediatric inpatient care areas to discuss at-risk patients with the charge nurses and senior resident on-call. The Rover Team representative (NP or fellow) is available for clinical assistance in the PICU, answers Rapid Response calls, and fields questions and pages to the PRRT when not doing rover rounds.

Data collected from rapid responses included time, day, and location of the call; who initiated the call; primary and secondary reasons for team activation; and a list of interventions performed by the PRRT. The data also captured whether the patient was transferred to a higher level of care because of the response.

Rover activities were recorded using a tracking tool to further analyze the system of identifying at-risk patients and the scheduled followup. In addition, the data captured when the Rover was called or paged to solicit critical-care input for medical or nursing assistance. When “Rover Rounds” did not identify at-risk patients and no critical care input was necessary, these rounds were not counted in the total number of Rover interactions.

Feedback

To assess the perceived effectiveness of the PRRT and Rover Team and to determine whether they had contributed an overall feeling of safety within the Children’s Health Center, the nursing staff from all of the intermediate care units and the PBMTU were surveyed. This 12-question survey was sent by e-mail to 132 staff RNs. Respondents had the opportunity to e-mail their responses or to respond anonymously by returning a hard-copy of the survey to their manager. The survey measured responses on a 6-point scale and elicited general comments to questions regarding the staff’s use of the PRRT/Rover Team and the Team’s contribution to an environment of patient safety.

Results

Emergent PICU Calls or Transfers to PICU

Rapid Response and Rover Teams offer a critical-care resource to non-ICU providers for systematic review and prompt evaluation of patients at risk for clinical deterioration. They also allow for delivery of time-sensitive interventions to these patients. Prior to the implementation of the RRS, this critical-care support was obtained by calling the PICU or initiating a Code Blue. Such a system was subjective and inconsistent. Establishing specific criteria to identify at-risk patients would be expected to standardize the response and offer opportunities to assess and monitor those patients by the Rover Team, the non-ICU patient care team, and the responding PRRT.

Analysis of the number of days between Codes is one way to evaluate the effectiveness of the PRRT and Rover Teams. Concurrent with the initiation of the PRRT and Rover teams, the number of in-hospital cardiopulmonary arrests on the pediatric wards has decreased and the number of days between Codes has increased. Prior to PRRT/Rover implementation (July 2005 – February 2006), an average of one non-ICU pediatric Code occurred per month. After activation of the RRS, the average number of Codes dropped to 0.16/month, with not more than one non-ICU Code in a single month (Figure 2). For the same timeframe, the average daily census in the inpatient pediatric patient care areas increased 4.9 percent. The largest percentage of growth within these units was in the PICU and PCU, while the proportion of patients on intermediate care units decreased. This describes an overall more acute patient population compared with the 18 months prior to PRRT initiation.

During the pilot phase, it was noted that the RRT was being utilized in the PCU for much more than responding to a change in patient status in an isolated area. Medical providers and nurses were activating the RRT to clarify patient care plans and to seek ICU guidance on patient care scenarios outside of the PCU. After the pilot period ended, pediatric inpatient implementation of the PRRT and Rover Team evolved simultaneously.

Therefore, data collected reflect both the proactive and reactive components of our RRS. Because both components were so closely linked in the initiation phase, and because the personnel of the PRRT and the Rover Team are one in the same, we were unable to determine whether the proactive education and interventions of the Rover Team altered the number of rapid response calls.

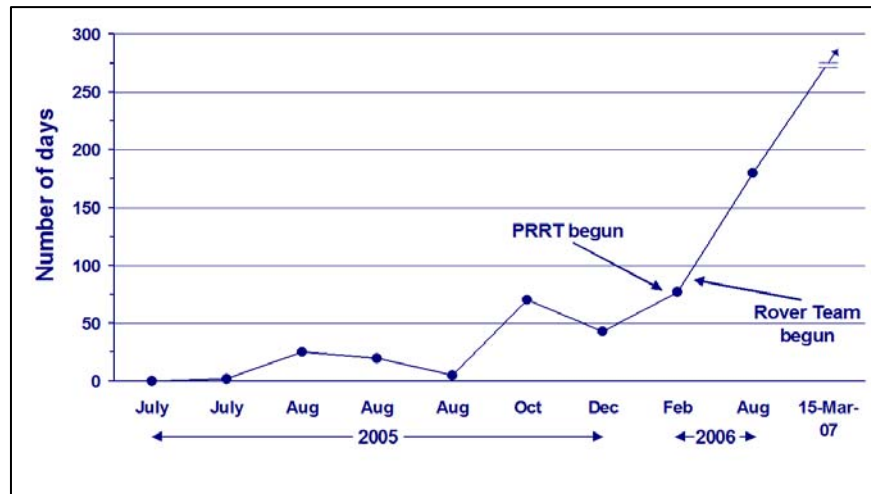


Figure 2. Days between Codes before and after PRRT and Rover implementation

Patient Throughput

Since the team was called upon to evaluate the appropriateness of resource allocation and patient placement, an unanticipated benefit of the Rover implementation was a positive effect on patient throughput. For example, the Rover Team was often called upon to evaluate the appropriateness of continued stepdown (PCU) monitoring.

Through systematic evaluation of the clinical climate of intermediate-care units, the Rover Team not only gained an awareness of patients whose clinical status could deteriorate, but they were able to intervene early and thus avoid transferring the patient to a higher level of care. Figure 3 illustrates the disposition of patients after PRRT and Rover interaction.

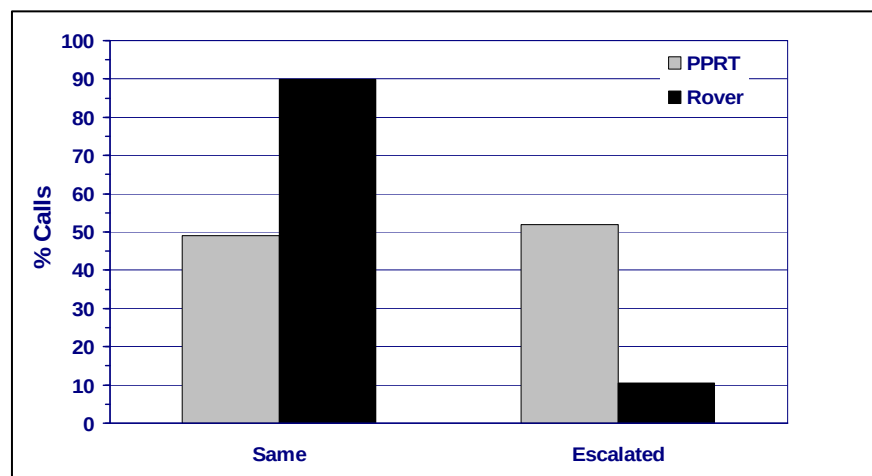


Figure 3. Disposition after PRRT and Rover interaction. Utilization of the Rover Team by both medical and nursing staff has allowed a greater portion of patients to remain in their current inpatient units. In contrast, waiting until the patient has a change in status before calling a rapid response has resulted in escalation of the patient's clinical care status 50 percent of the time.

The proactive Rover Team was able to identify and assist in the care of at-risk patients early, avoiding transfer to a higher level of care 90 percent of the time. Examples of these proactive interventions by the Rover Team include assisting with venous access, clarification of orders, and educating staff about equipment. In response to a change in patient clinical status, activation of the Rapid Response Team resulted in patient transfer to a higher level of care (floor to PCU, floor to ICU, or PCU to ICU) over 50 percent of the time.

Proactive Interventions

A total of 281 rapid responses were documented during this 14-month period, along with 291 Rover interactions. The total number of Rover interactions did not include times when the Rover Team contacted either the senior resident or intermediate care unit charge nurses, but no high-risk patients were identified. Even though no patients were identified, these encounters still allowed for review of the patients, education about transfer criteria, and the opportunity for critical care input, as well as support of the patients and the nursing and medical teams outside the PICU. While not measured or recorded, this opportunity for critical care input and teamwork might have been an additional positive effect of the Rover Team.

Consistent with its name, the PRRT was activated due to a change in patient status in 100 percent of activations. The most common reason for PRRT activation was a change in respiratory status with triggers, such as tachypnea, increased work of breathing, and respiratory distress. Physicians activated the PRRT more frequently than the nursing staff, although this may have reflected the patient's RN first calling for physician assistance, followed by both the RN and MD deciding to call the PRRT. The PRRT was also activated by respiratory therapists and other clinical support staff. A formal mechanism for the family to activate PRRT is still in development, but families have asked the nursing or medical teams to initiate a PRRT call.

Approximately 40 percent (115/291) of interactions occurred during the Rover Team's scheduled rounds with the senior resident and intermediate care unit charge nurse, during which they identified and evaluated at-risk patients. Sixty percent of Rover interactions were initiated by a page or phone call from a member of a non-ICU medical or nursing team seeking critical care input due to a change in patient status or assistance with the development of the patient's care plan. To facilitate continuity of care, these discussions included information sharing regarding a transferred patient's ICU stay and clarification of ongoing clinical issues. Other interventions by the Rover Team included facilitating communication between members of the multidisciplinary team; escalating respiratory therapies; establishing intravenous access; assisting nursing staff with patient medical equipment (e.g., Hemovac[®] drainage systems, noninvasive positive pressure devices, chest-tubes, and central line maintenance); and followup on high-risk patients, including those whose status had necessitated a previous rapid response and patients who had been transferred out of the PICU.

Positive Feedback

Of the 132 nurses surveyed, 36 responded (27 percent response rate). Additional feedback about the RRS has come from conversations during Rover Rounds and through e-mail and discussions with other patient care teams. Returned questionnaires revealed that 80 percent of responding

nurses had activated the PRRT or interacted with the Rover Team (Figure 4). Nurses who had not activated the RPRT indicated that this was due to a lack of necessity rather than a hesitancy to activate the system. Overall, the vast majority of the nursing staff polled felt that the presence of the RRS made them feel more comfortable and confident in caring for their patients and that it greatly strengthened the environment of safety within the Children’s Hospital; 100 hundred percent said they would recommend using the PRRT/Rover Team to a colleague and would encourage or assist others in activating the team.

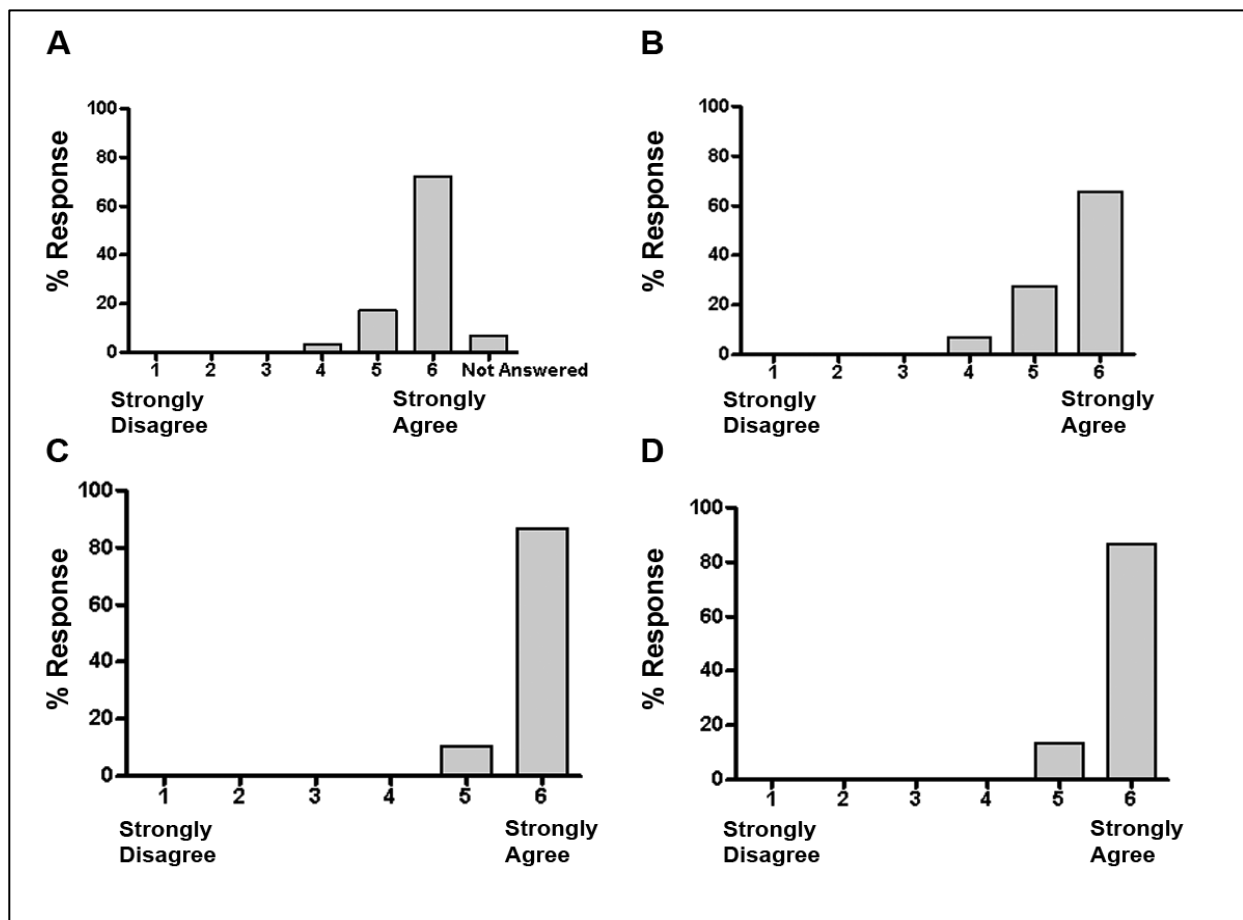


Figure 4. RN feedback:

- A. By working with the Rapid Response/Rover Teams, nurses felt more comfortable and confident managing patients in crisis.
- B. The PRRT and Rover Teams contributed to an environment of patient safety.
- C. Nurses who utilized the PRRT/Rover system felt comfortable with the system and would activate the PRRT or Rover team again.
- D. Nurses would recommend the use of the PRRT/Rover Team to a colleague and have encouraged or assisted others to activate the PRRT.

Because any provider could activate the PRRT or Rover Team at any time, patients had the opportunity to receive time-sensitive therapy before an emergent transfer back to the PICU became necessary (Figure 5).

While some “Rover Rounds” resulted in no at-risk patients being identified, the medical and nursing staffs came to expect “Rover Rounds,” and often these predictable systematic interactions between the critical care staff and the non-ICU staff led to welcomed educational sessions. Non-ICU medical and surgical teams and nursing staff provided positive feedback about these “Rover Rounds.”

Examples of responses: “It’s nice to know that the Rover Team will be around soon; we save many of our questions for them.” “I appreciate knowing that there is someone I can call at any time to help me.”

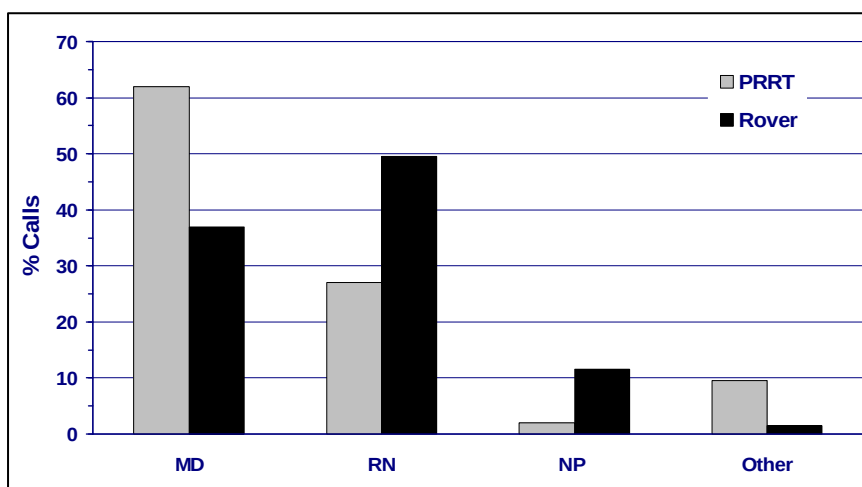


Figure 5. Providers activating PRRT and Rover Teams. Both the PRRT and Rover Team provided critical-care support for medical and nursing staff outside the PICU. The PRRT primarily supported the medical staff in response to a change in patient status. The Rover Team supported personnel by answering questions and scheduling a time to bring up concerns prior to a change in patient status or a situation becoming an emergency. Patient families, respiratory therapists, and physical therapists have also utilized the PRRT and, to a lesser extent, the Rover Team.

Discussion

A Rapid Response System that included a proactive Rover component and a Reactive Response Team was found to contribute to an environment of patient safety. Pediatric patients have significantly worse outcomes if readmitted to the PICU during the same hospital admission.⁹ Readmitted patients were more likely to be brought back to the PICU emergently and had higher severity of illness scores, compared to patients not readmitted to the PICU. The Rover Team was responsible for evaluation of patients transferred out of the PICU at least once within 12 hours of PICU transfer, facilitated communication with the accepting, non-ICU team, and assured a smoother transition of care during this critical transfer period.

It has been reported that, during a 6-year study period, a greater number of readmissions to the PICU occurred during the summer months (July to September) than during other times of the year, presumably because of the number of novice providers present during these months.⁹ When faced with patients whose clinical exams are deteriorating, a less experienced provider might feel more comfortable transferring those patients back to the PICU rather than monitoring them in their current location. Again, the Rover and Rapid Response Teams offered an opportunity to

provide a critical care resource to these patients and providers in their current location and might have decreased the number of unnecessary readmissions to the PICU (Figure 3).

Successful transfer of a patient out of the PICU reflects a balance of avoiding premature transfers and resisting the urge to keep the patient in the ICU for a prolonged stay with the attendant risk of ICU-related complications. PICU readmissions often occur due to progression of the patient's disease process or development of complications from the illness or from the treatment.¹⁰

Collaboration with the Rover Team allows non-ICU providers caring for these at-risk patients the opportunity to seek critical care guidance before the patients' clinical status deteriorates and to avoid PICU readmission. The proactive component of the RRS contributes to an environment of patient safety and improved communication, helps maintain that tenuous balance of successful patient transfer out of the PICU, and facilitates the patient's progress toward hospital discharge.

The inability of medical or nursing staff to recognize serious illness, a delay in calling for assistance, and a delay in arrival of assistance have been described as perceived reasons for unexpected deterioration, cardiac arrest, and/or death on pediatric patient care wards.⁴ Scheduled, proactive "Rover Rounds" allow for expected, timely consideration and evaluation of potentially at-risk patients. The medical and nursing teams expect a call or visit from the Rover Team and prepare for this interaction by reviewing their patients and communicating their concerns regarding patients that have required their recent attention. Staff education is ongoing to ensure that a rapid response is called and to reinforce staff awareness that they can call "at any time," rather than wait for "Rover Rounds," should a question or situation require an immediate response.

Furthermore, establishing specific criteria and education programs to improve staff's abilities and timeliness in recognizing early signs of clinical deterioration can empower nursing and medical personnel to request urgent medical assistance in a more timely fashion.⁴ The nonthreatening presence of the Rover Team, which, through scheduled rounding times, is available for discussion and education when a patient's status is stable, provides non-ICU providers with a resource they can feel confident in calling about a patient's status change.

The implementation of both the RRT and the proactive Rover component was received positively by medical and nursing staff for several reasons. The proactive approach allowed a number of patients to be evaluated prior to the initiation of a rapid response. Additionally, the formalized interaction between the Rover Team members and medical and nursing staff provided a welcome educational opportunity. Identifying concerns about a patient during Rover rounds allowed for clinical discussions about the pathophysiology of the patient's underlying condition and expected clinical progression. These conversations helped to improve continuity of care as the multidisciplinary team of critical care provider (Rover representative), intermediate care provider (ward resident), and nursing created a shared mental model of the patient's current clinical status.⁸

Future Directions

Further evaluation is needed to determine whether mortality, hospital and ICU length of stay, hospital mortality, and PICU readmission rates will be significantly altered by establishing and utilizing a comprehensive RRS. We are currently examining all non-ICU Codes for the presence of PRRT or Rover Team involvement in the 12 to 24 hours prior to Code events. In addition, for all patients transferred to the PICU because of PRRT or Rover interaction, we would like to evaluate patients' subsequent PICU stay for the need for intubation, the presence of an ICU Code event, length of that PICU stay, and the patient's post-ICU disposition. A more comprehensive post-PRRT or Rover Team interaction survey is being developed to gather feedback from all members involved in PRRT or Rover Team interactions. Such ongoing and multidisciplinary feedback should help PRRT and Rover Teams to improve.

Conclusion

The Pediatric Rapid Response System with the proactive Rover Team and rapidly-reactive PRRT helped reduce patient cardiac arrests outside the ICU setting, improved patient continuity between the critical care and non-ICU inpatient areas, and strengthened multidisciplinary team culture and communication. A proactive Rover Team more easily identifies patients at risk for clinical deterioration and more quickly administers time-sensitive therapies. This proactive approach helps support the reactive RRT, facilitates care throughout Children's Service, and improves clinically important outcomes.

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Improving Referral Communication Using a Referral Tool Within an Electronic Medical Record

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Abstract

Objectives: Poor outpatient referral communication is an important quality and safety issue. We implemented an electronic referral tool to analyze its impact on communication between primary care physicians (PCPs) and specialists. **Methods:** We studied one practice site that implemented the referral tool and one that did not and surveyed affiliated specialists, PCPs, and patients about referral communication. **Results:** Specialists more often received information before the referral visit from intervention PCPs versus nonintervention PCPs (62 percent vs. 12 percent, $P < 0.0001$), a finding that persisted after adjustment (OR = 3.3, $P = 0.008$). Intervention PCPs more often received return communication from specialists (69 percent vs. 50 percent, $P = 0.08$), a finding of borderline statistical significance. Finally, patients of intervention PCPs were more likely than patients of control PCPs to report that specialists had received information before their visit (70 percent vs. 43 percent, $P = 0.007$). **Conclusion:** Referrals are a key outpatient transition of care. Facilitating transmission of referral information electronically can improve physician communication.

Introduction

Communicating patient information at the time of specialty referral is essential to high-quality consultation and coordinated, safe patient care. Both primary care and specialist physicians value this information exchange for shared patients,¹ but dissatisfaction with the current referral process is widespread among primary care physicians (PCPs) and their consultants.^{2, 3, 4} About half the time, the reason for dissatisfaction is a delayed or missing referral letter and reports. Other reasons include dissatisfaction with redundancies in the referral process, missing information in the referral communication, time required to write a referral note, and difficulty in finding a specialist.^{3, 4, 5, 6, 7, 8, 9} Studies have highlighted the problem of poor communication between PCPs and specialists in terms of timeliness and content. This represents a major opportunity for improvement.¹⁰

Strategies for improving communication of referral information have been proposed, including scheduling the specialist appointment from the referring physician's office and providing pertinent information to the specialist, which have been shown to increase referral completion.² Specialists who received timely patient referral information reported providing optimal care twice as often as specialists who did not.¹¹ Other studies have looked at the benefits of physician

training on how to write letters¹² and the value of form letters and standard templates to improve letter quality from both PCPs and specialists.^{13, 14}

Few studies have examined the effects of electronic medical records (EMRs) on care coordination in general or on the referral process in particular.¹⁰ Computer access to chart notes was associated with increased communication between referring physicians and specialists, with specialists receiving written or e-mail referral letters more than twice as often as by telephone or other verbal communication.¹¹ Benefits of e-mail communication about referrals include the option for asynchronous communication, increased flexibility, and opportunities for back-and-forth interchange and enhanced rapport.¹⁵ To our knowledge, no controlled trial of electronic communication of referral information has been performed.

We hypothesized that electronic communication via a referrals tool embedded within an EMR has the potential to improve the timeliness and quality of referral communication and may also improve patients' referral experiences. In this study, we used an electronic application, Referral Manager, within an ambulatory EMR, to optimize delivery of the referral and supporting patient information to the specialist. We then surveyed specialists, PCPs, and patients about their referral experiences.

Methods

Study Setting

We studied two community health centers in the Partners HealthCare System in Boston, MA. As members of the Partners system, these practices are part of an integrated care delivery system, connecting two academic medical centers to outpatient primary care and specialist practices in the greater Boston area. Both practices use the Partners' Longitudinal Medical Record (LMR) system, an EMR that allows Partners' practices to share patient information, such as medications, problem lists, and visit notes.

One adult primary care practice used a Referral Manager application (described below) as an additional module within LMR (intervention arm); a second adult primary care practice referred patients in the usual manner without access to the module (control arm). The PCPs and administrative staff that managed the referral process at the intervention practice were trained in the use of Referral Manager. This study was approved by the Partners Institutional Review Board and was registered at ClinicalTrials.gov (ID NCT00129064).

Referral Manager Application

The Referral Manager application is an integrated module of the LMR system.¹⁶ Designed to fit into the referral process workflow, the application has the following features:

- PCPs may initiate, approve, or deny a request for a referral.
- Users are prompted to fill in basic referral elements as listed below. *Italicized items are required elements completed by PCPs; a practice referral manager usually completes the remaining information.*

- o *Reason for referral* (drop-down lists of relevant issues appear based on the specialty chosen).
- o Drop down lists of relevant issues appear based on the specialty chosen.
- o Information to include with the referral letter (e.g., patient's medications, allergies, problem, procedure lists, and visit notes in LMR; default preferences are available).
- o Pertinent past medical history and question(s) to be answered.
- o *Specialty* (from a drop down list) or name of specialist (from a drop down list).
- o Appointment date and time.
- o Number of visits approved and the level of urgency for the referral.
- o Special instructions for the office staff and patient.
- o Method by which to send information to specialist: e-mail or fax.
- Referrals may be routed for further actions (e.g., authorization by physician, completion of appointment details by administrative staff, etc.) to different users within a practice through the use of queues for administrative staff and physician users.
- Referral letters are created from the information that is entered by users and are e-mailed to the specialists on the day prior to the patient appointment. E-mails among study practices are within the Partners' firewall and therefore secure.
- PCPs and practice staff may track referrals, determine referral status, and be notified about the presence of a consultation letter in the LMR.

The Referral Manager application performs background procedures, such as searching specialist schedules to match a specific patient referral with its corresponding specialist appointment; sending e-mails of referral letters to specialists automatically at the appropriate time to ensure that the information reaches the specialist before the patient appointment; determining if patients keep their appointment with specialists; and determining if and when a consultation note has been returned by the specialist.

Data Collection

Referral identification. As a standard part of Referral Manager, data entered into the referral screen is stored in the LMR database. The date and time for each step of the referral process is captured and recorded. Supplemental data stored for each referral includes the initiator of the referral, types of information included in each referral, coded diagnoses selected, clinical questions, and "no-shows" for appointments.

For each referral in the intervention arm, a new referral to a provider of the same specialty was identified for the control arm based on matching by specialty. The primary exclusion criteria for referrals in both arms included:

- Patient did not attend specialist appointment.
- Patient was not yet 18 years of age at the time of the appointment.
- Specialist was not part of Partners HealthCare system.
- Patient had seen the specialist within the past 12 months or had seen the specialist more than 12 months ago for the same problem.

- Referrals to urology, gynecology, reproduction, psychiatry, infectious disease, physical therapy, gastroenterology for screening colonoscopy, or ophthalmology, due to the routine nature of many of these referrals and privacy issues.
- Appointment was changed or did not appear in the LMR system.

In the control arm, in order to verify that the visit was a new referral from a study PCP (rather than one initiated by the patient or another provider), patients were excluded if they had not seen their PCP in the last 12 weeks.

Physician survey. For referrals meeting the inclusion criteria, surveys were sent in the body of an e-mail message to the specialist and the PCP involved in the referral. Specialists were surveyed the day after their appointment with the patient. Nonresponders were sent one reminder survey 3 days later. PCPs were surveyed 2 weeks after the patient's visit with the specialist. Nonresponders were sent one reminder survey 3 days later. If PCPs responded to the 2-week survey saying that they had not yet heard from the specialist, they were surveyed again 4 weeks after the specialist visit, with a reminder survey 3 days afterwards to nonresponders. The number of PCP surveys is a subset of the total referrals because we set a maximum of five surveys per physician. Physicians who refused the surveys were placed on a "do not survey" list, and referrals involving their patients were excluded from future contact. Each PCP and the matched specialist physician who saw the patient received no more than one original survey and one reminder survey per day.

PCPs and specialists associated with the intervention practice were surveyed from November 2005 through July 2006, with surveys conducted daily. PCPs and specialists associated with the control practice were surveyed from January 2006 through July 2006, with surveys conducted weekly to match the number of referrals in each specialty in the intervention arm for the previous week.

Patient survey. After their visit to the specialist, patients with eligible referral visits were mailed an informational letter providing them an opportunity to opt out of a telephone survey. Research assistants made up to 10 attempts to contact patients by telephone within 3 weeks of the referral visit to the specialist. Letters and surveys were available in Spanish for Spanish-speaking patients. Patients provided consent when contacted by phone. Patients were excluded if they did not speak English or Spanish; could not complete the interview; or were deceased, hospitalized, out of the country; or had mental status limitations. Surveys were conducted from August 2006 to February 2007.

Outcomes

Our principal outcome for the specialist surveys was specialist receipt of referral information from the PCP prior to the patient visit. For the PCP surveys, the primary outcome of interest was PCP receipt of information back from the specialist after the patient's specialist visit. For the patient survey, the primary outcomes of interest were specialist awareness of the reason for their visit prior to the visit and overall patient rating of specialist-PCP communication.

Data Analysis

Data were collected, entered, and analyzed using Microsoft Access[®]. Additional univariate and multivariate analyses were performed using SAS[®] (Cary, NC). We performed a multivariate logistic regression using the stepwise method, including variables in the model with a P value <0.1. We started with patient age, patient sex, insurance status, intervention status, and specialty. Sex, insurance status, and intervention status remained in the model.

Results

A total of 430 referrals made up the physician survey component of the study (261 interventions and 169 controls). Referral characteristics are shown in Table 1. Orthopedics and gastroenterology were the specialties referred to most often. Characteristics of the two participating practices and their patient populations for the specialist survey are also shown in Table 2. Of note, there were more PCPs and specialists in the intervention practice, and intervention patients were younger. Demographics of patient survey respondents are shown in Table 3; the control and intervention practices differed somewhat in terms of overall health and ethnicity/race.

Table 1. Types of referrals

Types of referrals	N (%)			
	Intervention specialist survey sent (N = 261)	Control specialist survey sent (N = 169)	Intervention specialist survey responses (N = 141)	Control specialist survey responses (N = 94)
Orthopedics	36 (13.8)	56 (33.1)	19 (13.5)	31 (32.9)
Gastroenterology	56 (21.5)	27 (16.0)	36 (25.5)	13 (13.8)
Neurology	10 (3.8)	24 (14.2)	6 (4.2)	12 (12.7)
Rheumatology	9 (3.4)	19 (11.2)	7 (4.9)	12 (12.7)
Cardiology	10 (3.8)	14 (8.3)	6 (4.2)	7 (7.4)
Dermatology	33 (12.6)	0 (0.0)	21 (14.9)	0 (0.0)
Endocrinology	4 (1.4)	13 (7.7)	3 (2.1)	11 (11.7)
Other	103 (39.5)	16 (9.5)	43 (30.5)	8 (8.5)

Table 2. Specialist survey practice and patient characteristics

	Entire referral sample		Referrals with specialist survey responses	
	Intervention	Control	Intervention	Control
Number of PCPs	12	7	10	6
Referrals per PCP				
Mean	21	24	14	16
Range	1 - 78	1 - 43	2 - 42	3 - 24
Number of Specialists ^a	104	94	70	57
Patient characteristics				
Age (mean, SD)	46 (0.8)	52 (1.2) ^b	46 (1.1)	52 (1.7) ^c
% Female	69	74	73	74
% Insured	79	80	77	76

a Total for unique specialists was 113; 14 (12%) saw patients from both practices

b $P \leq 0.0001$

c $P = 0.003$

Table 3. Patient survey respondent demographics

Demographic	N (%)		P-value
	Intervention ^a (N = 113)	Control (N = 30)	
Overall health			
Very good-excellent	23 (20)	7 (23)	0.67
Good	32 (28)	9 (30)	
Fair	46 (41)	9 (30)	
Poor	12 (11)	5 (17)	
Education			
Less than high school	46 (41)	9 (30)	0.11
High school graduate	24 (21)	5 (17)	
Some college/tech education	23 (20)	5 (17)	
College graduate and beyond	18 (16)	11 (37)	
Employment			
Yes	56 (50)	13 (43)	0.54
No	57 (50)	17 (57)	
Ethnicity/Race*			
Hispanic	92 (81)	9 (30)	<0.0001
White	12 (11)	14 (47)	
Black	7 (6)	4 (13)	
Other	2 (2)	3 (10)	

a Percentages may not total 100 due to rounding and missing responses.

Response Rates

As shown in Table 4, the response rate for specialists was 55 percent (235/430). Of the 113 specialists who responded, 12 percent saw patients from both the control and intervention practices, accounting for 34 percent of survey responses (Table 2). The PCP response rate was 46 percent (54/117). The absolute response rate for the patient survey was 36.2 percent, although the participation rate after successful patient contact was 68 percent (143/210).

Physician Surveys

Specialists seeing patients referred by intervention PCPs were significantly more likely than those seeing patients referred by control PCPs to have received information from the PCP prior to the referral visit (62 percent vs. 12 percent) (Table 5). When specialists did receive information, it contained all the necessary information in 93 percent of intervention referrals and 91 percent of control referrals. On multivariate analysis controlling for patient sex, insurance status, and intervention status, specialists were more likely to have received information on patients referred by intervention PCPs compared with control PCPs.

Of the 83 control specialists who reported that they did not receive information, 20 percent felt that additional information would have been helpful. The additional information most often requested by control specialists was the problem to be addressed (53 percent), more patient history (41 percent), and question to be answered (35 percent). Intervention PCPs were more likely to receive communication back from the specialists (69 percent vs. 50 percent), although this finding was of borderline statistical significance ($P = 0.08$).

Table 4. Response rates

Measure	Intervention	Control	Total
Specialist survey sent	261	169	430
Specialist survey responses [N (%)]	141 (54)	94 (55)	235 (55)
PCP survey sent	68	49	117
PCP survey responses [N (%)]	36 (53)	18 (37)	54 (46)
Patients we attempted to contact	269	126	395
Patients who were contacted [N (%)]	165 (61)	45 (36) ^a	210 (53)
Patients who completed survey [N (%)]	113 (69)	30 (67)	143 (68)

a $P < 0.0001$

Table 5. Physician survey results

Measure	N (%)			P- value
	Intervention (N = 141)	Control (N = 94)	Total (N = 235)	
Specialist received information prior to visit	88 (62)	11 (12)	99 (42)	0.008 OR 3.3 ^a
Specialist did not receive information prior to visit	53 (38)	83 (88)	136 (58)	NS
Information would have been helpful	10 (19)	17 (20)	27 (20)	NS

a Multivariate analysis controlling for patient and referral characteristics.

NS = not significant

Patient Surveys

As summarized in Table 6, intervention patients were significantly more likely to report that specialists had received information prior to their visit (70 percent vs. 43 percent), and they heard information from their specialist that conflicted with their PCP significantly less often than did control patients (6 percent vs. 20 percent). There were also trends toward intervention patients reporting that the specialist was aware of the reason for the visit more often (76 percent vs. 60 percent) and rating specialist-PCP communication higher (58 percent vs. 43 percent) compared with control patients.

Of the 30 patients who had returned to see the PCP by the time of the survey, 61 percent (14/23) of intervention patients reported that their PCP had heard back from their specialist compared to 43 percent (3/7) of control patients.

Table 6. Patient survey results

Measure	N (%)		P-value
	Intervention (N = 113)	Control (N = 30)	
Specialist received information prior to visit	79 (70)	13 (43)	0.007
Received conflicting information from specialist and PCP	7 (6)	6 (20)	0.02
Specialist aware of reason for visit	86 (76)	18 (60)	0.08
Rating of specialist-PCP communication as good, very good, or excellent	66 (58)	13 (43)	0.14

Discussion

We found that when PCPs used an electronic referral tool within an EMR, the chances that information would be communicated to specialists prior to the patient's referral visit were three times as high as when PCPs did not use the tool. In addition, when the electronic referral tool was used, intervention patients were significantly more likely to report that specialists had received pertinent information prior to their visit and significantly less likely to have received conflicting information. There was also a trend towards intervention PCPs being more likely than control PCPs to receive information back from the specialists. These three findings strongly suggest that communication between PCPs and specialists was improved in our trial.

Our results also strongly suggest that the electronic referral tool was the source of the improved communication because the content of communication, once received, was equivalent between control and intervention practices. Therefore, the key to improving PCP-specialist referral communication is ensuring that communication occurs, rather than specifying the content of the communication. Our Referral Manager application helps ensure that communication occurs by allowing the PCP to specify the referred-to specialty and the reason for the referral and by automatically sending the referral question and supporting medical information in a timely fashion.

The intervention also tended to improve communication from the specialist back to the PCP, although this finding was of borderline statistical significance. While Referral Manager did not specifically address this return path of referral communication, this trend suggests that a specialist who receives communication is more likely to try to “return the favor” by initiating return communication. Such two-way communication is essential for clinical care, as poor communication is consistently a leading cause of medical errors.^{17, 18}

Only 20 percent of doctors who did not receive communication felt that it would have been helpful. This surprising finding may be explained by specialists' lowered expectations for information from PCPs, a dysfunctional consequence of the culture of poor communication around referrals that our study seeks to redress. The benefits of the referral tool for referrals in this subset of specialists may have been large, as suggested by the fact that the information specialists sought involved required fields in Referral Manager, such as “the reason for the referral.” Our design of Referral Manager appears to provide the right balance of required and optional fields, thereby laying the foundation for future design of these kinds of tools in EMR systems.

Our referral tool also fits into clinicians' workflow. This was evidenced by a referral tool adoption rate of greater than 99 percent at the intervention practice, according to the practice manager, even though its use was not required (data not shown). Perhaps in the future, use of this kind of tool for all referrals will help close some of the information gaps and improve tracking of referrals, while ensuring flexibility, since referrals to some specialties for routine care (e.g., ophthalmology) probably do not need the same level of detail. In the future, we plan to explore customizing the referral information according to the needs of different specialists.

Many patients could clearly identify when effective communication had occurred between their PCP and specialist; intervention patients were significantly more likely than control patients to

report that the specialist had received prior information. Our data suggest that this realization might influence patients' referral experiences, especially their ratings of the quality of PCP-specialist communication. Patients expect rapid communication between the specialist and the PCP, and they often have questions for the PCP that cannot be resolved if this communication has not occurred.⁴ These findings underscore the importance of improving communication to improve clinical quality and patient care experiences.

Widespread use of an electronic referral module could provide additional benefits. Electronic referrals can facilitate the inclusion of decision support into the referral process. For example, referring to cardiology for a coded diagnosis of new "atrial fibrillation" could trigger decision support suggesting that certain tests be ordered prior to the specialist appointment. In addition, systems could display clinical guidelines for certain common diagnoses, which might prevent unnecessary referrals. Practices also could track the reasons referrals are made to ensure standardization and appropriateness of referrals and to promote benchmarking and related quality improvement activities. To enhance the security of interprovider communications outside of a practice's firewall, applications could create secure Web pages that could be accessed via e-mailed hyperlinks, thereby avoiding transmission of health information. Enhanced security of interprovider communications would be an integral component of a next-generation referral application.

The ability for PCPs and practice staff to track referrals is another potentially important benefit of an electronic referral module. As many as 20 percent of patients referred to specialists do not follow through with the visit.¹⁸ In one study of missed and delayed diagnoses in the ambulatory setting, 5 percent of cases involved the failure of a requested referral to occur, and 2 percent involved failure of the referred-to clinician to send results to the referring clinician.¹⁹ At one malpractice insurer, when looking at high-severity, missed-diagnosis malpractice claims, referral tracking issues came up in 55 percent of cases.^a A tool that allows PCPs and practice staff to electronically track referrals and be notified of no-shows could reduce some of the risk in the referral process. This aspect of our electronic referral tool could benefit from further study and evaluation.

Implementation of an electronic referral tool is challenging. It is critical to ensure that the application fits well into the workflow of the physicians and practices' administrative staff. Usability is also important, and we consciously decided to limit the number of required fields to strike a balance between obtaining useful (coded and free-text) information, while not making data entry too onerous for the clinician. Adoption has been strong at the practice that has used the tool, and clinician response has been very positive. Plans are currently underway to implement the referral tool at other primary care practices in the system.

Limitations of this study include the potential for response bias, especially due to the difficulty in obtaining survey responses from PCPs. In addition, because of difficulties in contacting patients (especially controls, who were harder to reach), our patient survey numbers are low, limiting our

^a Personal communication from A. Puopolo, Harvard Risk Management Foundation Director of Loss Prevention, 2007.

ability to draw strong conclusions from this part of the study. We also do not have a good explanation for the difference in response rates between control and intervention patients, given that we attempted to contact them in the same manner. Finally, for logistic reasons, our study was not a randomized controlled trial or crossover trial. Although we tried to match the intervention practice with a similar type of practice (both community health centers that use the same EMR) and we controlled for differences in the primary outcome with multivariate analyses, unmeasured confounders could account for the differences we observed. Further studies with randomized controlled trials, using a larger sample, could be done to verify our results.

Conclusion

Referral communication is a critical, yet unevenly accomplished part of ambulatory care. Ensuring that this communication happens reliably is an essential component of the safe transition of patient care among providers. We found that an electronic referral tool improved communication from the PCP to the specialist. Further studies should be done to better understand adoption strategies and potential benefits of this technology.

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Improving Patient Safety Through Provider Communication Strategy Enhancements

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Abstract

The purpose of this study was to develop, implement, and evaluate a comprehensive provider/team communication strategy, resulting in a toolkit generalizable to other settings of care. The specific aims included implementation of a structured communication tool; a standardized escalation process; daily multidisciplinary patient-centered rounds using a daily goals sheet; and team huddles. The study setting was the 477-bed medical center of the Denver Health and Hospital Authority, an integrated, urban safety-net system. Utilizing a pre-test/post-test design, baseline and post-intervention data were collected on pilot units (medical intensive care unit, acute care unit, and inpatient behavioral health units). Analysis of 495 communication events after toolkit implementation revealed decreased time to treatment, increased nurse satisfaction with communication, and higher rates of resolution of patient issues post-intervention. The resultant toolkit provides health care organizations with the means to implement teamwork and communication strategies in their own settings.

Introduction

Current research indicates that ineffective communication among health care professionals is one of the leading causes of medical errors and patient harm.^{1, 2, 3} A review of reports from the Joint Commission reveals that communication failures were implicated at the root of over 70 percent of sentinel events.⁴ When asked to select contributing factors to patient care errors, nurses cited communication issues with physicians as one of the two most highly contributing factors, according to the National Council of State Boards of Nursing reports.⁵ In a study of 2000 health care professionals, the Institute for Safe Medication Practices (ISMP) found intimidation as a root cause of medication error; half the respondents reported feeling pressured into giving a medication, for which they had questioned the safety but felt intimidated and unable to effectively communicate their concerns.⁶

The growing body of literature on safety and error prevention reveals that ineffective or insufficient communication among team members is a significant contributing factor to adverse events. In the acute care setting, communication failures lead to increases in patient harm, length of stay, and resource use, as well as more intense caregiver dissatisfaction and more rapid turnover.^{7, 8, 9, 10, 11, 12} In multisite studies of intensive care units (ICUs), poor collaborative communication among nurses and physicians, among other specific factors, contributed to as much as a 1.8-fold increase in patient risk-adjusted mortality and length of stay.^{13, 14, 15}

Analysis of 421 communication events in the operating room found communication failures in approximately 30 percent of team exchanges; one-third of these jeopardized patient safety by increasing cognitive load, interrupting routine, and increasing tension in the OR setting.² The researchers found that communication problems were relatively straightforward and fell into four categories: (1) communications that were too late to be effective, (2) failure to communicate with all the relevant individuals on the team, (3) content that was not consistently complete and accurate, and (4) communications whose purposes were not achieved—i.e., issues were left unresolved until the point of urgency.²

Examining the outcomes of communication, other researchers have found associations between better nurse-physician communication and collaboration and more positive patient outcomes, i.e., lower mortality, higher satisfaction, and lower readmission rates.^{16, 17, 18}

Effective communication among health care professionals is challenging due to a number of interrelated dynamics:

- Health care is complex and unpredictable, with professionals from a variety of disciplines involved in providing care at various times throughout the day, often dispersed over several locations, creating spatial gaps with limited opportunities for regular synchronous interaction.⁷
- Care providers often have their own disciplinary view of what the patient needs, with each provider prioritizing the activities in which he or she acts independently.⁷
- Health care facilities have historically had a hierarchical organizational structure, with significant power distances between physicians and other health care professionals. This frequently leads to a culture of inhibition and restraint in communication, rather than a sense of open, safe communication (psychological safety).
- Differences in education and training among professions often result in different communication styles and methods that further complicate the scenario and render communications ineffective.
- Although teamwork and effective communication are crucial for safe patient care, the educational curricula for most health care professions focus primarily on individual technical skills, neglecting teamwork and communication skills.

A cultural barrier can be found in many organizations that can be traced to the belief that quality of care and error-free performance result from professional training and effort, ignoring the inherent limitations described in human factors science.³ In fact, human factors such as cognitive overload; the effects of stress, fatigue, distractions and interruptions; poor interpersonal communications; imperfect information processing; and flawed decisionmaking are all known to contribute to errors in health care and other complex environments, such as aviation.^{3, 6} Failure to recognize and understand these issues can lead to a culture of unrealistic expectations and blame, diverting efforts away from effective team-based error management strategies.

Intervention-focused research that seeks to improve collaborative communication is lacking.¹⁹ As a means of improving patient safety and outcomes, interventions should focus on integrating the critical attributes of collaboration, including open communication, shared responsibilities for planning and problemsolving, shared decisionmaking, and coordination.^{19, 20} Additionally,

translating the theories and practices of teamwork and communication from aviation to health care is gaining support from a number of researchers citing common elements in both industries. Training efforts—such as crew resource management (CRM) and a focus on the key concepts of leadership, briefings, monitoring, cross-checking, decisionmaking, and review and modification of plans—have enhanced communication and teamwork, thus providing a mechanism for increased safety and a change in crew attitudes and behavior.²¹

Drawing on current research, the purpose of this study was to develop, implement, and evaluate a comprehensive team communication strategy, resulting in a toolkit that can be generalized to other settings of care. The specific aims included:

1. Implementation of a standardized communication tool, the SBAR (see description on next page), as a guide for communicating changes in patient status.
2. Implementation of an escalation process tool to facilitate timely communication.
3. Daily multidisciplinary patient-centered rounds using a daily goals sheet.
4. Team huddles during each shift.

Methods

Utilizing a pre-test/post-test design, this study incorporated baseline data collection and implementation of team communication interventions, followed by data collection and analysis over a 24-month period. The goal of developing a user-friendly toolkit was accomplished as feedback and findings from this study were revised and adapted.

Study Setting

Denver Health Medical Center, an urban public safety-net hospital, provided the site for this study, with specific focus on three care settings utilized for pilot testing. These settings were selected because they each provided a different type of unit organization and staff.

- Phase 1 focused on two settings: the Medical Intensive Care Unit (MICU) and the Acute Care Unit (ACU). The ACU was selected because it had a very diverse patient population, with multiple physician teams and services assigned to the unit at a given time. The MICU was selected because it was a closed unit with fewer physician teams and one primary service with more accessibility to physician consultation.
- Phase 2 focused on behavioral health units: an Adult Psychiatric Unit, an Adolescent Psychiatric Unit, and an Acute Crisis Service (psych ED). The behavioral health units were characterized by a unique patient population and unit milieu, with a more consistent physician group.

Since post-intervention data collection has been completed on the Phase 1 units, this report is focused on specific outcome measures based on Phase 1 results.

Interventions

The following communication strategies were included in the toolkit interventions and can be accessed on the Denver Health Medical Center Web site (www.safecoms.org) for further detail:

Situational briefing guide: SBAR. A standardized communication format, the SBAR, was utilized as a situational briefing guide for staff and provider communication regarding changes in patient status or needs for nonemergent events, related issues, or for events on the unit, in the lab, or within the health care team. SBAR is an acronym for:

- **Situation:** What is going on with the patient?
- **Background:** What is the clinical background or context?
- **Assessment:** What do I think the problem is?
- **Recommendation:** What do I think needs to be done for the patient?

Since SBAR provides a standardized means for communicating in patient care situations, it is effective in bridging differences in communication styles and helps to get all team members in the “same movie.”³ SBAR provides a common and predictable structure for communication, can be used in any clinical domain, and has been applied in obstetrics, rapid response teams, ambulatory care, ICUs, and other areas. SBAR also presents guidelines for organizing relevant information when preparing to contact another team member, as well as the framework for presenting the information, appropriate assessments, and recommendations.⁶ SBAR has been utilized in Institute for Healthcare Improvement (IHI) collaboratives and has been endorsed by the American College of Healthcare Executives and the American Organization of Nurse Executives.

One important aspect of SBAR is its inherent recognition of nurses’ and other care providers’ expertise so that they are encouraged to assertively make recommendations to physicians, thus facilitating a nonhierarchical structure. In a recent study of nursing home transfers from acute care settings to skilled nursing facilities (SNF), SBAR implementation helped avert breakdowns in communication that had previously resulted in patients arriving with incomplete information and the need for important medications that were not available.³

In the current study, SBAR was used initially to organize and present information to communicate changes in patient status. It was also found to be useful in preparing information and for an anticipated difficult conversation with another staff member or provider. As implementation of SBAR expanded across units, a number of various uses were established. It was utilized to provide “kudos” for staff accomplishments, as a framework for reporting on patients, as a means of structuring assessments, and to structure succinct e-mail communications. A diagram of the SBAR process form and guidelines for use are presented in Table 1.

Team huddles. Provider and staff team huddles were implemented on the pilot units as a way to communicate and share information concurrently with the team early in the shift. A team huddle was defined as a quick meeting of a functional group to set the day/shift in motion via commentary with key personnel. Huddles are microsystem meetings with a specific focus, based on the function of a particular unit and team. Although both joint rounding and huddles aim to

improve team communication and patient safety and care, huddles differ in that they have a primarily operational focus. They are interdisciplinary and include operational and care personnel.

Current literature indicates daily team huddles result in fewer interruptions during the rest of the day and immediate clarification of issues.²² Team members know there is a fixed time when they will have everyone else's attention. Daily briefings (similar to those used in huddles) have been shown to be useful for a team to quickly assess changes in clinical workload, identify relevant issues of the day, and provide a means to prioritize.³ In a very short time, members of a care team can all be "on the same page" for the day and be ensured that relevant issues are being addressed.³

Guidelines for huddles include the following:

- Set a standard time each day.
- Use a consistent location.
- Stand up, don't sit down.
- Make attendance mandatory.
- Limit duration to 15 minutes.
- Begin and end on time.

Table 1. SBAR Practice Sheet

S • B • A • R	
Before you call, be prepared! Be clear, concise, focus on the problem & only report what is relevant to the current situation!	
<u>Be sure you do the following:</u>	
• Assess the patient. • Review appropriate parts of the medical record (eg, flow sheet, MAR, physician notes/orders, labs).	• Determine the appropriate person to call. • Have the medical record available when you call. • Use the following form to organize your conversation.
Situation: 5-10 second "punch line" – What is happening now? What are the chief complaints or acute changes? <i>This is _____.</i> <i>I'm calling about _____</i> 	
Background: What factors led up to this event? Pertinent history (eg, admitting diagnosis) & objective data (eg, vital signs, labs) that support how patient got here. <i>The patient has _____</i> 	
Assessment: What do you see? What do you think is going on? A diagnosis is not necessary; include the severity of the problem. <i>I think the problem is _____</i> 	
Recommendation: What action do you propose? State what the patient needs (get a time frame). <i>I request that you _____</i> 	

- Attempt to have the same structure every day.
- Keep the agenda to limited items.

Initial pilot testing of huddles occurred within two departments: radiology and laboratory services. Huddle participants included all departmental and unit level staff members present at the time. They typically occurred at the beginning of the day or shift, lasted approximately 9 to 20 minutes, and were led by a shift supervisor or department head.

Huddles were utilized to review pertinent issues of the day (e.g., inoperable equipment or rooms), to go over the day's schedule, and to plan for possible variations/problems. Information sharing included relevant system-level messages of the day, information from recent management meetings, and departmental issues or problems. Brief discussion of specific issues, such as errors (e.g., mismarked films) was integrated with a review of the process, system issues, and reminders on how to avoid the errors. On nursing units, huddles typically were led by the nurse manager, charge nurse, or clinical nurse educator. Interviews revealed several benefits of huddles, including:

- Preparing staff for the shift/day.
- Face-to-face communication.
- Immediate response to questions.
- Streamlined resolution of issues or concerns.
- Timely response to issues or concerns.
- Efficient dissemination of information.
- Improvement in teamwork and effective communication.
- Staff involvement in decisionmaking.

In some instances, if a huddle had been skipped for a particular shift/day, staff members took notice and inquired about it. Huddles also served to enhance teamwork and the staff's sense of cohesion.

Multidisciplinary rounds using Daily Goals Sheet. Multidisciplinary rounds were implemented in the MICU with the leadership and support of the unit medical director and nurse manager. Rounds were patient-centered and could include any staff member or provider involved in the patient's care, such as a physician (e.g., attending, resident, intern, and fellow), respiratory therapist (RT), physical therapist, occupational therapist, social worker (SW), pharmacist, charge nurse, individual patient's nurse, and pastoral care provider.

Rounds were focused on open and collaborative communication, decisionmaking, information sharing, care planning, patient safety issues, cost and quality of care issues, setting daily goals of care, and communicating with patients and/or family members as they were able. Information shared during rounds was supplemented by communication at shift changes between the incoming and the outgoing care providers.

The Daily Goals Sheet was an interdisciplinary communication tool that served as a simple way of clarifying work goals among providers. It provided the means for the care team and patient

(when able) to explicitly define the goals for the day. The form was typically completed during rounds on each patient, signed by the fellow or attending physician, and given to the patient's nurse. The care team—physicians, nurses, RTs, and pharmacists—provided input and reviewed the goals for the day. The form was updated as the goals of care changed.

Current literature supports the value of multidisciplinary rounding. In a study of multidisciplinary rounding focused on daily care goals in intensive care, the results showed improved communication among providers, significant improvement in the proportion of physicians and nurses who understood the goals of care for the day (from 10 to 95 percent), and a 50 percent reduction in ICU length of stay.²³

Prior to utilizing the patient-centered daily goals format, patient care rounds were provider-centric and lacked clarity about tasks and care plans for the day. Staff often lacked understanding of the tasks they needed to accomplish and the plan for communicating with patients, families, and other caregivers. Physicians and nurses perceived that using this format improved communication and patient care. The benefits of the goals sheet are founded on the theories of CRM (crew resource management) and are currently used in a number of ICUs participating in IHI and Veterans' Health Administration improvement efforts.²³

Escalation Process

The intent of the original study proposal was the development and implementation of an escalation process algorithm for provider communication regarding changes in patient conditions for noncode situations. The goal of the escalation process was timely, appropriate communication between nursing staff and providers as changes in patient conditions occurred. Previously, no standardized process existed at Denver Health for this purpose, resulting in ambiguities in the decisionmaking process for each type of patient situation.

Peer-reviewed case studies revealed that the absence of a standardized and well-defined communication process had led to confusion and delay in appropriate and adequate patient care, when the need for escalating a concern existed. These issues are particularly relevant at academic medical centers similar to Denver Health, since the organizational structure includes layers of providers, such as attending physicians, fellows, senior and junior residents, and interns.

However, concurrent to the implementation phase of the project, the Department of Patient Safety and Quality developed Rapid Response Escalation Criteria, which provided nurses with patient parameters for escalation and an outline of providers to call along with a timeframe; the criteria utilized SBAR for communicating changes in a patient's condition.

The Rapid Response form served both as a guide for identifying a patient's condition that could trigger a Rapid Response call and as a communication tool for physicians to convey their assessment and plan of care. Instructions were also provided for physicians for followup with senior/attending physicians within a 4-hour timeframe. This well-documented, standardized escalation process provided role clarification and clear patient parameters within a realistic timeframe, defining whom to call and when, in a way that could be understood by all health care team members.

Implementation

Staff and provider education and development were primary components of the communication strategy implementation. An “Implementation Toolkit” was developed to serve as a guide for the education and integration of communication and teamwork factors in clinical practice. Although specific units served as pilot areas for pre- and post-data collection, it was necessary to involve all departments and a maximum number of staff members due to the interdepartmental nature of communication. The challenge to capture a broad audience of health care team members mandated the creation of a standardized curriculum, teaching materials, and methods that could be used by multiple disciplines in a variety of forums (e.g., new employees, department orientation, student rotations, initial education, and ongoing refreshers for current employees). Health care team members participating in this intervention included nurses, unlicensed assistive personnel, physicians, respiratory therapists, occupational/physical therapists, dietitians, social workers, pharmacists, chaplains, clerical/support staff, and radiology and laboratory staff.

The nature of the acute care hospital setting presented particular challenges that required multiple teaching strategies to introduce the concepts, reinforce learning, facilitate translation of the concepts into practice, and sustain the practice changes (Table 2).

The goals of the education program included:

- Provide consistent education for all members of the health care team on the concepts of teamwork, psychological safety, and open, effective communication and its impact on patient safety.
- Integrate safe communication strategies into the organizational culture.
- Sustain the culture of teamwork, psychological safety, and open, effective communication.
- Maintain consistency and high quality in all educational efforts.
- Develop educational tools that allow for flexibility in use and application in diverse practice settings.

Table 2. Implementation methods for provider/staff education

	Individual education	Unit/department education	Organization education
Initial expert presentation	•	•	•
Video presentation	•	•	•
Fast talks	•	•	•
Communication education notebook	•	•	
Practice scenarios (multidisciplinary)	•	•	
SBAR practice worksheets	•		
Concept poster campaign		•	•
Visual reminders (bookmarks, cards, lanyards, T-shirts)	•	•	•
PowerPoint® presentation		•	•
Champion role		•	
Web-based training	•		

The education plan was composed of two parts: one, initial education and two, followup education.

The initial (interdisciplinary) education component engaged team members and introduced the foundational concepts of human factors, effective teamwork, and communication. More than 650 health care providers (representing all health care disciplines) attended presentations by a nationally recognized patient safety expert, Michael Leonard, MD. Using “real-life” anecdotes and an evidence-based approach to factors that influence health care workers’ practice, Dr. Leonard fostered a commitment from providers to work toward improving the organizational culture of patient safety.

In addition to the lecture portion of the presentation, attendees also participated in interactive group activities. They applied the SBAR format to “real-life” patient situations and coached each other in communicating patient needs. Involving an outside expert created a certain “buzz” throughout the staff and organization that facilitated interest and involvement in the topic. Feedback surveys of the initial education/presentation were overwhelmingly positive (Table 3).

Table 3. Feedback from initial expert presentation

Question prompt	Agree^a (%)	Strongly agree^a (%)	Positive responses^a (%)
This presentation increased my awareness of how human factors can affect errors and patient safety.	29.8	67	96.8
This presentation helped me understand the need for open, effective communication in the health care team.	27	70	97.0
This presentation helped me realize there may be times when others on my unit do not communicate openly.	30.4	66.4	96.8
This presentation helped increase my awareness of barriers to effective communication.	29.1	68.1	97.2
I think using SBAR would help facilitate better communication with other care providers or staff.	31.5	66.5	98.0
SBAR is easy for me to understand.	33.2	64.9	98.1
SBAR will be understood by others on my unit.	44.5	50.9	95.4
SBAR could help decrease communication problems.	35.7	61.8	97.5
SBAR could be rolled out on my unit with few problems.	48.7	42.6	91.3

a N = 564 respondents

Source: Analysis of feedback from presentations to health care providers at Denver Health made by Michael Leonard, MD, Physician Leader for Patient Safety at Kaiser Permanente.

The followup (unit/department) education component focused on a review of the initial concepts, practice of effective communication skills, and strategies to create and sustain a culture of patient safety. In contrast to the initial “kick-off” education sessions, the followup education was a sustained effort over an extended period of time (months). Ongoing education and reinforcement of learning were achieved through formal and informal sessions on the patient care unit. A number of educational strategies were utilized including: “fast talks,” worksheets, posters, visual cues and reminders, PowerPoint® presentations, unit-level champions, and a video of Dr. Leonard’s initial presentation (see Table 2).

Fast talks. Feedback from direct caregivers, managers, and clinical educators indicated a need for practical teaching strategies that could fit into staff’s daily work and routine. “Fast talks,” a format that is concise (15 minutes), focused, and taken directly to staff members on the unit fit these criteria. Key selected topics were presented and discussed with staff as they gathered informally at convenient times during their shifts. Whenever possible, effort was made to include a multidisciplinary group.

The implementation toolkit included a fast talk notebook of teaching materials for discussion topics on concept review, practice scenarios, and practice implementation. Key concepts were presented on 1 to 2 pages that included a headline sentence to convey the essential implications for practice. Brief bulleted statements served as a guide for more detailed review. Discipline- and patient population-specific practice scenarios were also included in the notebook. A narrative described a scenario followed by appropriate SBAR format prompts. Participants worked either as a group or individually to structure the required communications. A facilitator guide included examples of potential communications.

SBAR blank communication forms/worksheets. Pads of tear-off sheets that included the SBAR, instructions for use, and a guide for preparing to contact another team member or provider were created (Table 1). Feedback from staff indicated the importance of meeting the needs of both novice and expert team members. “Novice” forms included expanded cues for section content. “Expert” forms were more streamlined. These sheets were used for practice/learning and to prepare/organize upcoming communications about actual patient situations. Tablets of the communication forms were placed on units in strategic locations (e.g., near the phone) and utilized in presentations as handouts.

Concept posters. One-line headlines capturing key concepts were developed into laminated posters and placed on units in strategic locations (e.g., nurse’s stations, staff bulletin boards, and resident work stations). Clinical nurse educators, managers, and unit champions used the posters to review key concepts and reinforce previous teaching during staff meetings, huddles, and/or on an individual basis.

Visual reminders. Visual reminders—such as phone cards, bookmarks, name badge holders, T-shirts, pocket cards, and pocket notebooks—were developed to provide ongoing reminders and maintain awareness until practice changes were incorporated into unit/organization culture. These items were also used as incentives for participating in education events and to reward observed practice changes. Visual reminder “giveaways” were particularly effective because

staff members and providers were eager to obtain them, and because they reinforced previously presented concepts, providing reminders throughout the day.

PowerPoint® presentation. Developed for use in unit meetings, orientation classes, and other occasions, these presentations provided a standardized introduction and brief overview of key concepts. PowerPoint presentations were typically utilized during staff meetings and new employee orientations.

Champion role. Unit-based champions were identified by unit leadership and served as implementation “experts,” reinforcing effective learning strategies and culture changes. Champions embraced the key concepts of teamwork and communication, sharing their strategies with other units. Examples included advertising educational events using SBAR format and developing an “SBAR Kudos” form to recognize coworker contributions to the unit.

Data Collection

This implementation project was evaluated using several different approaches:

- Process analysis of communication events, based on observations of communication between health care providers.
- Evaluation of patient occurrence reports: hospital data from the University Healthsystems Consortium Web-based occurrence reporting system (Patient Safety Net).
- Hospital Survey on Patient Safety Culture: staff survey responses to the Agency for Healthcare Research and Quality (AHRQ)-developed patient safety culture survey.²⁴
- Evaluation of staff understanding of patient daily goals: a brief self-report survey on individual providers’ understanding of the patient plan of care.
- Focus group interviews with hospital staff.

This report will focus on the process analysis of communication events, both pre- and post-implementation on Phase 1 units. Further results from other evaluation methods will be reviewed in future publications.

We defined process analysis as focused observations that utilized trained data collectors to record their observations on the communication process within the health care team. Our process analysis data collection methods were founded on the concepts of industrial engineering and observational research methodology. The data collection team—which was made up of nursing staff from various clinical, research, and administrative backgrounds—worked closely with an industrial engineer, who was trained in analyzing and improving processes. Guided by the study’s co-principal investigator and industrial engineer, the team developed standard data collection guidelines, data collection tools, and coding guides.

Initial training involved observation of communication on units in teams of two or more, pilot testing the data collection forms and tools, and debriefing the data collection process. Particular attention was given to team consensus on the various components of the communication events. Observations were also reviewed to ensure inter-rater reliability.

The team defined a “communication event” as nurse-initiated communication with another health care team member (e.g., physician, respiratory therapist, pharmacist) regarding an existing or potential problem/issue related to a patient’s health status or plan of care. The communication event was considered complete once an answer or resolution of the particular patient issue was received. An “event” may not necessarily end in an immediate treatment. However, it can give the nurse further direction for the plan of care (Figure 1).

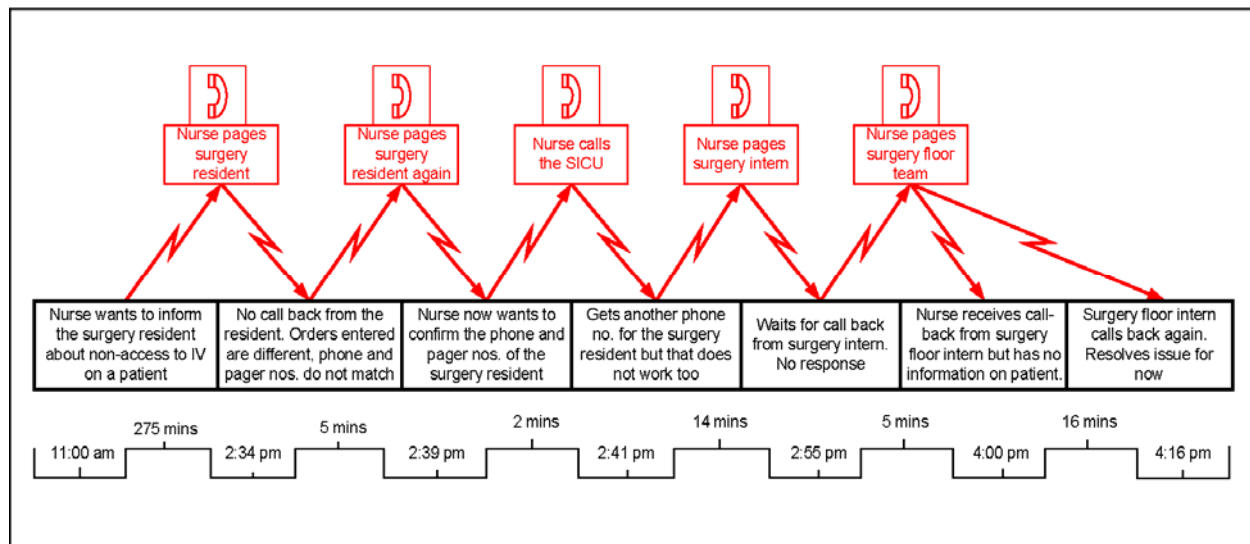


Figure 1. Graphic presentation of a process analysis communication event

Observations were made by one or two data collectors, who remained on the study unit for 1 to 4 hours at a time at different periods throughout the day and night shifts. Stationing observers on the nursing unit allowed data collectors to record communication events from multiple nurses at one geographic location. Data collectors took field notes on their observations using a standard form, asked questions of health care team members to clarify what they were observing, and asked nurses their perceptions of the communication event.

Data collected about the communication event included: who was communicating; the patient’s issue or problem; method of communication (e.g., phone, page, face-to-face contact); any activities taking place during the event (e.g., searching for a phone number, traveling to a different part of the unit, finding a part of the medical record); the amount of time needed to communicate and resolve the issue; and followup questions on the nurse’s perceptions about the resolution of the issue, including his/her satisfaction with the communication. Following observation of a communication event, data collectors asked nurses two questions:

- To what extent do you think this patient issue has been resolved?
- How satisfied were you with the interaction/communication?

Nurses answered on a 3- or 4-point Likert scale, depending on the question: 1 - not resolved; 2 - somewhat resolved; 3 - resolved; and 1 - not satisfied; 2 - somewhat satisfied; 3 - satisfied;

4 - very satisfied. Resolution and satisfaction scores were then recoded into positive and nonpositive responses (i.e., resolved, satisfied, or very satisfied).

The data collection team observed and analyzed 495 discrete communication events: 224 (112 pre-intervention and 112 post-intervention) on the MICU and 271 events (135 pre-intervention and 136 post-intervention) on the ACU.

Results

Data Analysis

Communication events were reviewed and coded by the data collection team *post hoc* and then entered and analyzed using SPSS® 15.0 software. Initial descriptive statistics and frequencies were analyzed for each coded category.

During any given communication event, multiple forms of communication and activities could be evident, such as an initial phone call with a followup face-to-face conversation. Thus, communication types were not mutually exclusive categories and were coded as either present or not present for each event. Most communication events on the MICU (74.6 percent) involved verbal or face-to-face communications, whereas most such events on the ACU (61.6 percent) involved numeric pages with followup/return phone calls. The most common nurse activities observed in both the MICU and ACU pre- and post-intervention were waiting for a return phone call after a page was sent or traveling to a different part of the nursing unit, either to speak with a provider or to find information (e.g., the on-call physician's phone number or a patient's bedside medical record). Of the 495 communication events observed in both the MICU and ACU, 123 (24.8 percent) involved a nurse communicating with another team member to clarify a patient's orders or plan of care.

One of the key elements observed in the process analysis was the time it took health care providers to communicate and resolve a patient issue. [Due to a violation of assumptions for parametric statistics (t-test), we used nonparametric statistics (Mann-Whitney U) to compare pre- and post-intervention times.] In the MICU, we observed a significant post-intervention decrease ($P < 0.01$) in the mean communication/issue resolution time (Table 4). In the ACU, we observed a decrease in mean time that, while not statistically significant ($P = 0.27$), may have been clinically significant due to a reduction in time to treatment and nursing time spent away from other patient care activities. Given the volume of patients and daily communications that occur on the ACU, a 21 percent decrease in mean time for post-intervention communications could have positive effects.

Each communication event was further analyzed for "problematic" time that contributed to the total event time. Problematic time was defined as time that nurses spent attempting, but failing, to communicate with the correct provider (e.g., paging/calling the incorrect team) or searching for information to determine the appropriate provider or phone number (system issues). When problematic time was deducted from communication events, we reasoned, the resulting "adjusted" time was a more accurate representation of provider-to-provider communication time.

Table 4. Results of communications process analysis

Time for resolution of communication/issue	Pre-intervention	Post-intervention	<i>P</i>-value (1-sided)^a
MICU			
Time for communication (min)	(N = 112)	(N = 112)	
Mean	7.19	3.69	0.007
Range	1 - 312	1 - 51	
Adjusted mean	4.52	3.37	0.01
Adjusted range	1 - 55	1 - 51	
ACU			
Time for communication (min)	(N = 135)	(N = 136)	
Mean	8.29	6.51	0.27
Range	1 - 136	1 - 61	
Adjusted mean	6.63	5.27	0.31
Adjusted range	1 - 135	1 - 60	
Resolution and satisfaction			
MICU			
Positive nurse responses (%)	(N = 99) 67.7	(N = 111) 80.2	0.04
Satisfied/very satisfied nurse responses (%)	(N = 103) 85.5	(N = 111) 92.8	0.08
ACU			
Positive nurse responses (%)	(N = 135) 66.7	(N = 136) 75	0.13
Satisfied/very satisfied nurse responses (%)	77.1	80.1	0.53

a t-test
b chi-square

As shown in Table 4, the results were similar for adjusted communication time: a significant decrease ($P = 0.01$) in mean adjusted communication time for the MICU and a nonsignificant decrease ($P = 0.31$) in mean adjusted communication time for the ACU. The ranges for post-intervention times—both total and adjusted—were narrower, had smaller standard deviations, and were therefore more closely clustered around the post-intervention means, indicating a decrease in the lengthy outlier communications found in the pre-intervention data.

In addition to decreased time for communication/issue resolution, there was also an increase in the overall nurses' positive perception of communication events. Chi-square analyses of pre- and post-intervention positive resolution and satisfaction scores revealed a significant increase in positive resolution scores ($P = 0.04$) and a difference in satisfaction scores approaching significance ($P = 0.08$) in the MICU and nonsignificant increases in resolution and satisfaction scores ($P = 0.13$, $P = 0.53$, respectively) in the ACU. Positive responses to both the resolution and satisfaction questions in the post-intervention period increased.

Discussion

Our study demonstrates the value of utilizing teamwork and communication strategies among health care team members in the patient care setting. After implementation of team/communication strategies, communication time surrounding a patient concern or issue was decreased, thus bringing resolution and treatment in a timelier manner. Post-intervention, nurses (the communication initiators) perceived increased satisfaction with communication and higher rates of resolution of patient issues. Further collection and analysis of additional data measuring staff perception of the organizational safety culture, the effect of team and communication factors in patient occurrence reports, and staff and provider focus group interviews are ongoing and will provide further insight into the effectiveness of the study interventions.

The toolkit developed as a result of this study offers other health care organizations a means to implement teamwork and communication strategies in their own settings and is available on the Internet at www.safecomms.org. The intervention tools are adaptable and easily modified for use in a variety of settings. In addition, the toolkit includes an education plan and facilitator guide; fast talk book with case scenarios for nursing, medicine, lab, physical therapy, social work, dietary, and spiritual care; and templates for SBAR communication forms/worksheets, concept posters, bookmarks, pocket cards, and PowerPoint® presentations. The toolkit also includes guidelines for the data collection methods used in this project, should an organization wish to evaluate its own implementation.

Throughout the study, a number of “lessons learned” provided insight that could be useful for other organizations considering similar implementation of teamwork and communication strategies. First, it is paramount to secure administrative and clinical support on all management levels, from the executive to the unit level support. It was important for management and leaders to demonstrate that teamwork and communication were valued as important factors contributing to patient safety and staff satisfaction. Furthermore it was important that they provided the means for staff to attend presentations, encouraged further unit level education, and facilitated integration of the concepts into practice.

The degree of leadership support varied from unit to unit and clearly made a difference in the integration of the communication strategies into practice. Those areas with less leadership support for the project required more mentoring and coaching from the study team over a longer period of time. In contrast, when leaders embraced the concepts of teamwork and communication, units integrated the practices into their daily functions in a variety of ways. Engaged leaders “role-modeled” the use of the communication strategies, and their staff responded in like fashion. The degree of leadership support may be one of the important factors contributing to variations in the findings among the Phase 1 units.

We also found that staff members were acutely aware of the culture within an organization and on their unit as it related to psychological safety, reporting patient occurrences, and team communication. Once again, those leaders who were committed to teamwork and open communication set the tone for psychological safety and created an environment for staff to communicate freely and professionally without fear or inhibition. Other units required additional efforts on the part of the study team to help create and point out experiences that demonstrated a safe culture and additional mentoring for the unit leadership.

The issue of “problematic time” (i.e., the time nurses spent attempting, but failing, to communicate with the correct provider or searching for information to determine an appropriate provider or phone number) was an important system-related finding that warrants further investigation. As data collection progressed, it became apparent that “communication events” were complex and included time spent “hunting and gathering” for the correct information related to whom to call, how to best contact them, and what to do when the primary person was not available. On average, “problematic time” consisted of 10 to 40 percent of total communication time, indicating a clear need for clarification in communication procedures that are unit-specific and easily implemented. It is likely that other academic medical centers face similar challenges and that this project could provide further insights and guidance toward potential solutions. Updates on this topic will be included on the www.safecomms.org Web site as they are developed.

There are also a number of other challenges to achieving interdisciplinary education and training in an academic setting such as ours. Physician engagement is particularly challenging due simply to the nature of the academic setting, with resident rotations, various levels of providers, and the number of physician teams. Our study team developed specific educational strategies that could be presented during existing meeting times, such as noon conferences, resident orientation, and outcomes conferences. The support and engagement of the chief medical resident and chief hospitalist were instrumental in these efforts. In addition, we integrated the perspectives of other disciplines/departments by eliciting their participation in the development of discipline-specific case scenario examples for the curriculum.

Finally, as with other new practices and skills, an important consideration in the overall implementation plan is keeping the strategies and practices going. The ability to educate new staff and continue integrating communication practices presents a challenge that should be considered early in the planning stage. Since few formal education programs across disciplines include teamwork and communication strategies in their curricula, it is particularly incumbent upon health care organizations to incorporate them into staff education and training. We have integrated teamwork and communication concepts and skills into department- and unit-level orientation for new staff and nursing skills fairs for current staff, and we are working on integrating them into competency skills testing.

Conclusion

Our study suggests that strategies to enhance teamwork and communication can be successfully implemented in the acute care setting, and that they result in more efficient and effective communication. Because ineffective communication among health care team members contributes to patient harm and adverse events, interventions and implementation methods become instrumental in preventing negative patient outcomes. This project provided the opportunity to develop, implement, and evaluate an educational program and interventions using multiple measures across diverse patient care units. The resultant toolkit is available on the Internet and can be adapted for use in a variety of settings. Further efforts to evaluate the strategies using additional measures are ongoing. Recommendations for future research include implementation of the strategies in different health care settings (e.g., outpatient clinics, rural

hospitals, and nonacademic settings); integration of the strategies into simulation projects; longitudinal studies to determine the effectiveness and sustainability of the strategies over time; and utilizing specific patient-centered outcome measures and staff-related measures, such as satisfaction, recruitment and retention.

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Improving Clinical Communication and Patient Safety: Clinician-Recommended Solutions

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Abstract

Background: Teamwork and good communication are essential to providing high-quality care.

Methods: We examined clinician perspectives on clinician-to-clinician communication in the context of pediatric patient safety using 90-minute focus groups comprising representatives from varied clinician groups (physicians, nurses, pharmacists) in the five Chicago area hospitals of the Pediatric Patient Safety Consortium. Using a standardized protocol, we asked participants to address effective and problematic communication related to patient safety risk and any recommended solutions to address these risks. Verbatim transcripts of the focus groups were analyzed to identify major themes. In this article, we focus specifically on the potential patient safety solutions clinicians recommended. **Results:** Sixty-five clinician focus groups were conducted. The key solution-oriented themes included: (1) technology, health information technology (HIT), and electronic medical record (EMR) elements and organization; (2) coordination of care and communication around care plans; (3) communication in transitions; (4) knowledge and experience gaps; (5) team-oriented solutions; (6) orders and consultations; (7) organizational responsibility and communication about errors. **Conclusion:** Improving the understanding of clinician-recommended solutions to address risk related to clinician communication will direct targets for communication-related patient safety improvement.

Background

The burden of harm from patient safety events pervades the health care system and is directly and indirectly experienced by many health care consumers. A conservative estimate suggests that 70,000 children annually experience adverse events sufficient to extend a hospital stay or cause disability at discharge, and that 60 percent of these are preventable.¹ This is equivalent to 1 in every 100 admissions. Despite significant improvements in adult medical care related to better understanding of patient safety problems and new interventions to mitigate safety risks, there has been only limited understanding and improvement in these areas related to the care of children.

Communication among clinicians in providing health care is a highly complex but important function in the delivery of health care. In fact, clinician communication is consistently the most frequent contributor to sentinel events reported to the Joint Commission.² Sentinel events are the most serious and harmful of patient safety events and are a high priority for intervention and

improvement. Problematic processes and systems for clinician communication have been shown to lead to patient safety risk for children as well as for adults.^{3, 4, 5, 6}

Given that teamwork and good communication between and among clinicians is central to the provision of high-quality health care for all patients, the processes and systems designed to enhance such communication remain understudied. This multisite study was designed to explore the contexts, processes, and systems of communication among pediatric clinicians and to elicit clinicians' recommendations for effective solutions to improve communication and enhance patient safety. The results of this investigation should provide information that directly translates to the development of interventions for improving the processes and systems of clinician communication in a wide range of contexts and across a wide range of pediatric health care organizations (e.g., community hospitals, academic institutions), ultimately reducing the risk of serious patient safety events in pediatric health care.

Methods

The Chicago Pediatric Patient Safety Consortium

The Chicago Pediatric Patient Safety Consortium (Peds Consortium) was established to conduct research concerning pediatric patient safety. The Peds Consortium consists of a group of five Chicago area hospitals, including Advocate Hope Children's Hospital, Advocate Lutheran General Children's Hospital, Children's Memorial Hospital, John H. Stroger Jr. Hospital of Cook County, and Mount Sinai Children's Hospital. Such a consortium is necessary in order to have a sufficiently large and varied population of pediatric patients for research findings to be generalizable, to provide information about different pediatric health care settings (e.g., teaching hospital, community hospital, freestanding children's hospital, general hospital), and to provide sufficient confidentiality protection to the participating institutions. In total, Peds Consortium member institutions admit over 46,000 pediatric patients each year.

Data Collection

To examine clinician experience related to pediatric patient safety, a series of focus groups was conducted at each site. Focus groups have been shown to be an effective method for identification of systemic patient safety risks.⁷ Data collection for this study consisted of focus groups that comprised hospital-based attending physicians, residents, nurses, and pharmacists; transport teams; and respiratory therapists currently involved in the delivery of pediatric patient care in one of the five Peds Consortium hospitals. Clinicians in each of the participating institutions were invited to participate in a focus group regarding effective and problematic communication in providing patient care.

We convened focus groups within each discipline (e.g., neurology, neurosurgery, surgery, intensive care unit [ICU], emergency medicine, etc.) by profession and professional level (nurse managers, staff nurses, attending physicians, fellow/resident physicians, advanced practice nurses, and nurse administrative coordinators). This group composition was intended to enhance the participants' comfort level and willingness to speak freely about communication with staff from other disciplines. Clinicians were selected based on their service, profession, and

professional level (e.g., a group of neurology attending physicians, a group of neurology residents and fellows, and nurses from the pediatric ICU).

Trained facilitators conducted the 90-minute focus groups using a standardized protocol that directed the group's discussions toward the processes of communication (i.e., in person, telephone, medical chart) and the contexts that resulted in either effective or problematic clinician-to-clinician communication leading to patient safety risk. Clinicians frequently offered solutions to the problematic communication contexts, processes, and systems they described. The focus groups were audiotaped then transcribed. The number of focus groups was determined by "saturation," the point at which additional data collection no longer generated new understanding.

Participants in the focus groups were recruited from the above targeted services and professions. Recruitment included a presentation of the project in departmental and unit meetings and a letter sent to selected clinicians. The letter and presentation provided an overview of the study and informed the individuals that someone would be contacting them in order to schedule their participation in a focus group. Focus group participation was voluntary, and the focus group discussions were confidential. No participant names were recorded; participants identified themselves by using a colored card to indicate when they were speaking (e.g., Dr. Pink, Nurse Blue, etc.) The audiotaped discussions were transcribed in such a way that no identifiable information regarding patients, clinicians, or institutions was included.

The Institutional Review Boards for each of the participating institutions and for Northwestern University approved this study.

Analysis and Interpretation of Data

The focus group transcripts were reviewed by two investigators to inductively develop codes for effective and problematic communication using the Constant Comparative method⁸ and included the following iterative steps:

1. Overall review of the transcripts.
2. Detailed review of a few text reports to formulate meaning.
3. Review of additional reports to develop preliminary categories.
4. Coding of data by category and determination of the need for new categories and grouping of related categories to develop overarching categories (any discrepancies in coding were resolved through consensus based on the transcript language).
5. Sorting of data by category, and review of the performance of preliminary analysis of each category.
6. Deductive review for parallelism and clarity of categories.
7. Classification of all data into the developed categories.

These were refined through review by the remaining Peds Consortium investigators (Steps 4–6). The focus group transcripts and the classification taxonomy of patient safety-related effective and problematic communication were entered into the analytic software *ATLAS.ti* (ATLAS.ti

Scientific Software Development, Berlin, Germany; www.atlasti.com/index.html) for the final classification (Step 7) and to conduct the analysis. The reliability of the categories was assessed through a process that involved independent coding of the textual data by at least two independent reviewers. When discrepancies occurred in the coding, reconciliation of these discrepancies was finalized through consensus according to the transcript language and code definitions. An additional (third) cross-institutional reviewer also reviewed four to five transcripts to further ensure consistency of the code application across the Peds Consortium.

The analysis identified patient safety-related effective and problematic communication scenarios. Clinicians linked solutions to the problematic scenarios, and these were associated with codes related to the problematic communication code(s) they were intended to address or to code(s) for effective communication, for which an additional application to reduce risk was described. The recommended solutions were then aggregated according to the patient safety-related problems for which they were proposed.

Hierarchy of Interventions

To further assess the clinician-recommended patient safety solutions, the transcript sections of recommended solutions were reviewed and classified by the theoretically derived hierarchy of safety interventions developed by Vaida in 1999.⁹

Results

Focus Groups

Sixty-three focus groups were conducted, which included 274 participating clinicians across all of the focus groups. Focus groups included 2 to 11 participating clinicians, with a mean of 4.4 and a median of 4.0 participants. A 90-minute standardized focus group protocol was used for all the focus groups in each of the five Chicago area Peds Consortium hospitals. Table 1 shows the distribution of clinicians by profession and level.

Coding of focus group transcripts resulted in the identification of 252 clinician-recommended solutions to address the patient safety-related communication problems described in the provision of health care. A review of the transcript of recommended solutions revealed three transcript excerpts that were workarounds, done to cope rather than address the safety problem. This resulted in 249 clinician-recommended solutions for analysis.

Table 1. Number of focus group participants by clinician type

Clinician type	Number of focus group participants
Attending	66
Residents/fellows	70
Nurses	107
Nurse managers	12
Other (e.g., respiratory therapists, transport team, pharmacy, imaging technicians)	19
Total	274

Recommended Types of Safety Solutions

Table 2 shows the types of interventions recommended to address specific patient safety-related communication problems and the number of times, across all of the focus groups, that these solutions were recommended. Recommendations fell into four primary domains of solutions, and these applied to many different types of patient safety-related communication problems. The primary domains of solutions included: technology-oriented, team-oriented, educational, and clinical or organization-related. The most frequently suggested technology-oriented solutions involved defining effective elements and organization of the electronic medical record (EMR) system, followed by the use of cell phones and text pagers for accessing clinicians and prioritizing calls. The most frequent team-oriented solution applied to rounds, suggesting that for rounds to be maximally effective and to reduce the opportunity for miscommunications, rounds should be scheduled, structured, of a set duration, and should most importantly involve all key team members. A recurrent recommendation was that nurses be notified of new orders or a change in the management plan, whether in person or through the use of technology. The recommendation to add advanced practice nurses or hospitalists to the clinical team to provide pediatric-specific medical knowledge and coordination was also common.

Table 2. Clinician-recommended solutions for patient safety-related communication problems

Communication problem	Solutions		Number of times suggested
	Types of solutions	Description of solution	
Fragmented medical record information	Technology, EMR elements, & organization	Consolidated clinical information in the EMR including medications, labs, imaging, orders – “one source of truth”	25
		Computerizing the ED “white board”	2
		Cell phones and text pagers; computerized clinical information – EMR	22
Coordination of care & communication around care plans	Technology	Computerized, current, accurate on-call lists with phone numbers in the computer	4
		Voice recognition software for documentation, to improve documentation	4
		Automatic faxing of notes for a patient's hospitalization to their community pediatrician	2
		GPS for transport	1
		Remote technology enabled care conferences	1
		Rounds: Structured, scheduled, interdisciplinary rounds at the patient's bedside with all key team members present (e.g., attendings, nursing, pharmacy, RT)	26
	Team-oriented	Conduct rounds in a quiet space	1
		Role clarity in general and particularly in emergencies	5

Table 2. Clinician-recommended solutions for patient safety-related communication problems (continued)

Communication problem	Solutions		Number of times suggested
	Types of solutions	Description of solution	
Coordination of care & communication around care plans (continued)	Team-oriented (continued)	Care conferences	3
		Verification of problems and completed orders	3
		Cross-departmental meeting of clinicians and staff	3
		Someone taking charge in a conflict	2
		Coordination regarding medical equipment needed for surgical procedures	1
		Observing the processes of other services/units	2
Communication in transitions	Technology	Accurate clinician contact information in the computer	2
		Standardized sign-out	3
		Accessible clinicians with needed knowledge on nights & weekends	3
		Standardized sign-out which includes "why this plan"	1
		Protocol for determining admitting service in transfers from the ED and PICU	2
	Team-oriented	Attending-to-attending communication for inter-facility transport	2
		Relationships across services	2
		Proactive notification of a problem with test or sample	2
		Update on delays	1
		Staggering shift changes	1
		APN to coordinate discharge	1
		Role model respectful communication	1
Orders	Technology-oriented	CPOE	11
		Decision support	5
		Automatic notification of an order made and completed	5
		Automatic weight-based dose calculation and checking	2
		Automated order tracking	2
		Order lists in one place in EMR	2
		Accurate, accessible on-call lists	2

Table 2. Clinician-recommended solutions for patient safety-related communication problems (continued)

Communication problem	Solutions		Number of times suggested
	Types of solutions	Description of solution	
Orders (continued)	Team-oriented (continued)	Provide and make information about the specific prep needed for specific tests easily accessible in computer	1
		Notifying nurse of an order or change in plans	19
		Indication included on orders	7
		Double-checking orders	5
		Attending-to-attending communication to resolve patient management conflicts	4
		Establishing a central line service	1
		Change imaging order form to standardize the communication to include needed information	1
		Consult service to write orders, managing service to sign	1
Consultation	Technology-oriented	Consultations typed in EMR for accessibility and legibility	3
	Team-oriented	Acknowledge consult and provide feedback	4
		Standardized and clarified pre-anesthesia assessment	4
Knowledge experience gaps	Technology-oriented	Palm Pilots® with PDR for surgical residents	2
	Team-oriented	APNs, hospitalists, pediatric liaison	17
		Going up to the next level in the clinical hierarchy	5
		Attending to attending communication	5
		Clear roles	2
		Standardized sign-outs	2
		Tiered consultation intensity	2
		Orientation for surgical residents	5
		Attending availability on nights weekends and holidays	3
	Education	Screening resident read imaging results before releasing	1
		Motivate residents by giving tests	1
		Comanagement of surgical patients in the PICU for educational requirements	1

Table 2. Clinician-recommended solutions for patient safety-related communication problems (continued)

Communication problem	Solutions		Number of times suggested
	Types of solutions	Description of solution	
Clinician availability	Technology-oriented	Cell phones and text pagers	7
	Team-oriented	APNs as physician extenders	2
		The night operator knows who to call	1
		Attending physicians on call making it clear they want to be called	1
Organizational responsibility for safety	Clinical organization	Standardizing processes	4
		Effective computer systems to facilitate clinical thinking	2
		Role clarity	2
		Availability of knowledgeable staff at night and on weekends	2
		Policy for resolving a conflicts regarding admitting service	1
	Learning from errors	Multidisciplinary discussions of errors and solutions	3
		Thank people for reporting	2

EMR = electronic medical record; ED = emergency department; GPS = global positioning system; RT = respiratory therapist; PICU = pediatric intensive care unit; APN = advanced practice nurse; CPOE = computerized physician order entry; PDR = physician's desk reference

Some unique yet interesting recommendations could prove useful. For example, the use of a global positioning system (GPS) to locate and track patients in intra- and interfacility transport; having clinicians from one unit or service observe the operations in another unit or service to better understand the processes, perspective, and priorities of the other; the suggestion of a specialized central line service; and facilitating patient care conferences involving multiple services by conducting them remotely. Table 2 provides a template of ideas for safety improvement investigation.

There were many contexts of problematic communication for which no solutions were recommended. Of 180 possible classifications for problematic or effective communication, 133 were linked to a solution or referred to as a solution. A few examples of codes for which no solution was offered include the following:

- Lack of notification of responsible clinicians: "Clinician has difficulty, cannot, or fails to identify or notify other responsible clinicians about patient care issue."
- Acuity assessment: "Lack of recognition of signs and symptoms of acute clinical status."
- Orders not understood: "Insufficient communication to the responsible clinician or insufficient knowledge base of clinician responsible for carrying out the order to understand order."

- Consultations for surgical patients: “Insufficient pediatric knowledge base of surgical clinicians caring for surgical patients with medical conditions, leading to missed indications for consultation or lack of understanding or misunderstanding the recommendations.”
- Lack of participation in discharge planning: “Failure to prepare and/or communicate adequate and relevant discharge information for the patient’s discharge.”

Hierarchy of Intervention Effectiveness

The hierarchy of safety interventions developed by Vaida⁹ was slightly modified through the analysis of these data in order to appropriately classify solutions not addressed by the existing hierarchy of interventions. Additions included staff organization, risk assessment, learning from errors, and personal initiative. The frequent identification of the addition of advanced practice nurses (APNs), hospitalists, and occasionally, pharmacists as a method to improve communication suggested the need for this addition. There were also recurrent suggestions of utilizing individual initiative or individual vigilance. While recommending individual initiative be applied to improve the safety of a particular system is not a highly effective systemic intervention, it bears reporting that this was a recurrent recommendation from clinicians to improve communication. The resulting hierarchy of interventions is as follows:

1. Forcing functions.
2. Automation, computerization, and technology.
3. Standardization and protocols.
4. Staffing organization.
5. Policies, rules, and expectations.
6. Checklists and double-checks.
7. Risk assessment and learning from errors.
8. Education and information.
9. Personal initiative – vigilance.

As presented in Table 3, automation, computerization, and technology were the most frequent levels of intervention recommended by clinicians to improve communication effectiveness related to patient safety. These were followed by standardization and protocol implementation, which combined, represented more than half of the suggestions. Twenty-one percent of clinician’s recommendations were related to personal initiative. Forcing functions were infrequently recommended or described.

Table 3. Hierarchy of interventions

Hierarchy of interventions	Frequency (%) intervention suggested	Type	Examples of interventions
1. Forcing functions	3 (1%)	Auto-faxing medical information	"When we sign off, the report can be auto-faxed to the referring physician."
		CPOE	"Computer ordering systems... you do not have to do a lot of calculating, you are confirming right there that the dosage is correct. It has limits that won't let you order too large a dose. I think that is a huge issue."
2. Automation, computerization, & technology	69 (28%)	Computerized EMR	"...The institution that I trained at had a much more advanced system. So the resident at night at 2 in the morning admitting a patient had every clinic note, every discharge summary on the computer, every radiologic procedure, medication list, discharge from every prior hospitalization....."
		Automated access to information for sign-out	"There should be a way I could say to my computer, this is my subset of patients, and the computer has all the names, and have it generate a list for me, name, current vitals, or abnormal vitals for the last 24 hours, current medications, location of patient, and a big black box for me to write my to-do stuff. That would save an enormous amount of time for all the residents, because we spend a lot of time doing data entry."
		Technology – voice recognition software	"That's not here. The Wednesday before last, I was the operating surgeon at that hospital, and every note I dictated in the operating room was on the system in the recovery room when I left with the child (<i>inaudible</i>), so there are ways to do this, and I've been to other hospitals, and they are using them now."
3. Standardization & protocols	61 (24%)	Protocol	"So setting up some sort of a protocol for transferring patients from the ED to the floor or from out of the PICU."
		Standardized communication	"When they sign on (<i>inaudible</i>) each other, I think we need to have a standardized form, the nurses, so they can transmit information the same day; every nurse signing off to the next nurse will have the same form just as the physicians have, and they are getting the same information, rather than some signing off elaborately and some signing off very brief, and then information getting missed; and that happens when we shift, when one nurse transfers it to the other nurse, information does get missed."

Table 3. Hierarchy of interventions (continued)

Hierarchy of interventions	Frequency (%) intervention suggested	Type	Examples of interventions
4. Staffing organization	21 (8%)	Advance practice nurses	"I have been a big proponent of a lot of hospital having more nurse practitioners, because I think nurse practitioners have a lot of things to offer, that this is their base, they are staying here forever, communication can be much better. For example, if residents were in the ER for 2 hours, they could know that their floor was being taken care of, which that is not always the way it is right now, because I may be in clinic, I may have gone home already. So I think the hospital, in general, particularly our service, could benefit from having more nurse practitioners."
		Hospitalist	"He made a decision, a bad decision in terms of communication. Whereas, if you have a hospitalist, a physician, and if they know what the protocols are, they probably have a less chance of making a mistake, in terms of who to call, who not to call, what to do, what not to do."
5. Policies, rules, & expectations	26 (10%)	Policy for the determination of the inpatient admitting service	"There is the issue of which service they are getting admitted...if we call a service because we think a patient should be admitted...and they said that that is not an appropriate admission for their service, it is then their responsibility to find another service for the patient to go to. I think it is good, because it gets us out of trying to go back and forth and be mediating something that needs to be worked out amongst the individuals involved."
		Expectations: Nurses and nursing input included in rounds	"I'm thinking to improve this situation, it's important that during rounds, between us, that a nurse clinician, a nurse manager, or a charge nurse would make rounds with us, so if there's a problem with a patient the nurse knew about it, she related it to the charge nurse, and if the charge nurse makes rounds together with us right then and there, she can tell us what is the patient's problem."
6. Checklists & double-checks	18 (7%)	Checklist	"Or even if they sent their orders down from the floor and put 'child needs sedation, child NPO'd, or child has an ID.' Put it in the check-in, on the check-in document...They actually should have to check-off that these things have been accomplished....even if they put on there, you know, the patient is intubated, the patient has an IV – give us the information that we need to complete the study."

Table 3. Hierarchy of interventions (continued)

Hierarchy of interventions	Frequency (%) intervention suggested	Type	Examples of interventions
6. Checklists & double-checks (continued)	18 (7%) (continued)	Double-check to make sure nurse is aware of the order	"The problem right now in our hospital is that now everything is on the computer, so if you do write it down, and you do want an order executed, I know the nurses check it every hour, 45 minutes, hour and a half, something like that; but it still depends on when they check it...but that is when I think the verbal system is even more important to tell them, 'Hey, I put in this order.'"
7. Risk Assessment & communication errors	6 (2%)	Discussing errors	"We addressed system issues every month as a medical practice review of cases discussed. Where did treatment fall down? What are the system issues that are responsible? And it is really just not doctors miscommunicating that is the issue. It is really what systems are in place that we have for our patients' treatment."
		Acknowledge reports	"Somebody noticed and some action was taken – even with a note, 'Thank you for letting us know about that,' would be fine."
8. Education & information	25 (10%)	Education	"We had a couple of issues with anesthesia communication. We have to go back to the OR with certain cases for the heart patients, and they had actually, for specific instance, they were getting new circuits for their ventilator, and the specialty gas we needed to bring back our attachments did not fit onto their ventilator circuit. So that was just a big... they did not tell us. We were back there ready to go, and this child has got an open heart, and we are not following through with anything, we cannot do anything. So we did do an education piece that they needed to be informed... We needed to be informed of things."
		Information	"Especially when you are calling to find out about some obscure test and what kind of tubes do they need it to go into. Sometimes, that is a much more laborious process than I think it should be...I requested something, but I never heard anything.... go into the lab portal; there could be a place where you can type in the test that you want, and then they can give you the test color...before you draw; it does not have to be fancy."

Table 3. Hierarchy of interventions (continued)

Hierarchy of interventions	Frequency (%) intervention suggested	Type	Examples of interventions
9. Personal initiative	21 (8%)	Personality	"...and then again it depends on the bedside nurse's personality. Some of the more difficult subspecialties, I do not take them personally, and I go up to them, and I have no trouble talking to them, even if they are in a bad mood."
		Individual initiative	"Different things that should have been done were not done for the baby, and that you have to take initiative, especially if you are following a baby to look, to see what was done...and therefore, I had to come to the conclusion that I have to go by my own mind..."
Total	249		

Discussion

Technology Solutions

Health information technology (HIT) and suggestions for the organization of the EMR information were the most frequent safety solutions recommended by clinicians to address problems in clinician-to-clinician communication. HIT and EMR solutions were recommended to address many disparate types of communication problems. Entire fields have grown up around the best methods for development and implementation of HIT and the EMR. This literature generally recommends substantial involvement of frontline clinicians in EMR development and organization of HIT and EMR applications to enable the effective expansion of electronic tools that would support the work flow of medical practice and facilitate clinical thinking. Clinicians describe multiple communication problems and patient safety risks that would be addressed specifically by organizing medical information in such a manner to systematically provide easily accessible summary lists of all orders, labs, and consults (with contact information for the consults). Likewise, clinicians frequently recommended compiling a complete list of a patient's medications in one place, with the capability to check and reconcile these. Clinicians discussed the potential for the EMR to become the desired "one source of truth"⁸ for medications and other medical information. This notion of a "one source of truth" did not apply just to patients' medical information, but also to accurate on-call lists and clinician contact information.

HIT solutions thought to address patient safety risks also included the use of automated functions and decision support within the EMR to remind and support memory, check calculations, limit dosages, and bring forward information (e.g., an allergy or a potential drug-drug interaction). Automation was also recommended as a tool to support communication between residents and nurses (e.g., to provide alerts of new orders or to support cross-departmental communication with the lab regarding problems with a specimen for a lab order, blood samples, or verification of results from completed lab work).

Voice recognition software was advanced as a tool to facilitate one's own and other clinicians' documentation of needed clinical management information. GPS systems were described as promising for locating and tracking patients for both intra- and interfacility transport.

Cell phones and text pagers were described by clinicians as tools to locate clinicians and to provide a vehicle for needed communication. These tools can enable the receiver of the communication to prioritize a particular communication and to indicate the need for emergent or routine response as appropriate. Cell phones and text pagers were described as having the additional advantage of providing verification of the receipt of information, developing expectations for the initiator of the response, and in the case of cell phone, providing the ability to ask on-the-spot questions, clarify issues, and develop a plan. Cell phones were suggested as a potential tool to establish a clinical case conference by enabling several clinicians to be brought together over the phone for remote case conferences, which would facilitate communication among the clinicians caring for patients who have multiple services involved in their care.

The potential of HIT to assist the processes of communication and decisionmaking and to overcome many of the problems with hard-to-read, inaccessible, and fragmented medical records is great. However, there were significant drawbacks in the current organization of the systems

that were currently deployed that led to new risks and challenged clinicians' ability to deliver safe care.

Team-Oriented Solutions

Rounds. In addition to technologic solutions, clinicians thought many team-oriented solutions might hold promise for improving clinician communication and patient safety systems. Rounds—a time-honored method of clinical communication—were described as effective because this method of clinical communication brings together the group of clinicians caring for a patient and enables discussion of the patient's status and the care plan for that day. In addition, when rounds take place at the patient's bedside, senior clinicians could easily verify the information presented. However, the effectiveness of rounds would quickly diminish if all key team members were not present or included, and when appropriate preparation is not made. Furthermore, clinicians described additional advantages to rounds that occur at regularly scheduled times, take place in a structured format, and include all key team members.

Including information, knowledge, and the perspective of all team members represents an important safety challenge that was commonly expressed as potentially a significant safety solution. Scheduling of rounds was described as helping to minimize the need, particularly by surgical clinicians, to leave before all patients have been discussed. Having structured rounds would enable an easy-to-follow flow of information and encourage preparation. Defining and including key clinical team members is an important aspect of team communication.

Both physicians and nurses acknowledged the importance of the clinical information and perspective on the patient that nurses can provide to the development of the patient's care plan during rounds. Several methods were recommended to include nurses or nursing input—e.g., residents getting reports from nurses prior to rounds, scheduling rounds so that nurses could participate for their patients, and having the charge nurse participate in rounds.

Clinicians suggested the inclusion of pharmacists and nutritionists into interdisciplinary rounds to address particular patient safety risks in pediatrics. Respiratory therapists were thought to provide needed clinical information and perspective for their patients. It was suggested that there be more than one service round for patients when multiple services were actively involved in the patient's care.

Communication in transitions. Clinicians had comparatively few suggestions for addressing the problem of communication across transitions of care. Most transitions are very complex and actually involve multiple transitions. A change in unit (the place where the patient is being cared for) also involves a change in the managing service (the specific medical specialty caring for the patient), and a change in the specific nurse, specific resident physician, and specific attending physician in charge of managing the patient's care. Clinician shift changes involve at least one clinician but frequently can involve transitions of several clinicians at the same time. At the time of a nurse shift change there also may be a change in the resident and attending physicians. Standardization and protocols were the most frequently recommended solutions for sign-out as well as determining the admitting service from the ED, but other team-oriented suggestions, such as the availability of senior clinicians, good contact information, relationships across services, and respect were also considered to be of assistance.

Gaps in Knowledge and Experience

Most inpatient care for children is provided in general hospitals with a small pediatric service. These institutions may have no pediatric physicians on staff, and indeed, they may lack basic pediatric equipment and skills.¹⁰ Furthermore, resident physicians must receive training in pediatric health care, but these resident physicians have had minimal or no previous pediatric training. During this “rotation,” residents provide care to pediatric patients and are supervised by trained pediatric attending physicians. Pediatric care involves caring for children of varying ages and stages with varying normal ranges of clinical values and test results and care processes and priorities. This variability of signs and symptoms for different age groups of children provides a challenge. In addition, the medical requirements of children with special health care needs (e.g., feeding tubes, oxygen, shunts) that increase complexity and need for expertise further intensify these challenges in institutions with nonpediatric-trained clinicians, including nonpediatric-trained residents and nurses.¹¹

Knowledge and experience gaps are a challenge of particular importance in pediatrics. Communication in the context of inexperience and lack of contextual knowledge is complicated and can easily lead to miscommunications and misunderstandings. Of the many solutions to communication problems related to lacking requisite knowledge and experience in the health care of pediatric patients, most frequently suggested were supplementing the team with additional types of clinical positions to provide supportive knowledge assistance, such as APNs, hospitalists, or pediatric surgical liaisons. The substantial pediatric knowledge base and experience of these clinicians provides an additional teaching function and an important safeguard for the recognition of “when a clinician doesn’t know what they don’t know.” It was also recommended that nurses “jump over” the traditional hierarchy of communication in medicine and speak directly to attending physicians if they believe a resident does not understand the pediatric clinical picture. Direct attending-physician-to-attending-physician communication was also suggested as a vehicle to address these knowledge and experience gaps.

These proposed additions to the clinical team—APNs, hospitalists, and pediatric surgical liaisons—have also been identified as resources for filling the needed role among clinicians involved in the care of pediatric patients, particularly pediatric surgical patients, for coordinating care by different levels of physicians across services.

Recommended Organizational Responsibility for Safety

Clinicians recognized the broader role of the overall organization and organizational leadership to effect improvement, and they attributed the responsibility for many specific solutions to the institution. Examples include the responsibility for standardizing processes; the effectiveness of computer technologies, such as the EMR; role clarity, including the establishment and enforcement of the “chain of responsibility,” and how and when to circumvent this for the safe care of pediatric patients.

Ultimate accountability for clinician availability and for methods and systems for avoiding and resolving conflicts in care management was considered an organizational leadership responsibility. Finally, clinicians ascribed the responsibility for institutional learning from errors to leadership and suggested that cross-departmental, multidisciplinary contexts for learning about

errors as a potentially meaningful approach. Furthermore, they suggested that positively acknowledging the reports of problems is important and should be embraced.

Levels of Intervention

It is encouraging, in the current sociohistorical context of medicine, to find that clinicians frequently recommended use of standardization and protocols. After decades of resistance to standardization and protocols, these findings suggest that the safety value of standardization of systems and processes and proscribed protocols may be rising in clinicians' awareness, with the recognition that medicine is no longer "an individual sport but a team sport."

Conclusion

Involvement of frontline clinicians in the development and deployment of patient safety interventions is essential to understanding the contextual environment in which the risks exist and the impact of change on that environment. Clinicians have important contributions to make to inform interventions for patient safety improvement and the redesign of safer health care. Furthermore, according to the hierarchy of interventions, the clinician's safety recommendations in this study were largely at the more effective end of the hierarchy.

Improved understanding of the role of clinician-to-clinician communication in patient safety and clinicians' recommendations for solutions is a first step to effectively implementing interventions to improve communication between pediatric clinicians and thereby improve the safety of care delivered to pediatric patients. These findings provide a roadmap to direct the next round of efforts to improve the safety and reliability of systems and processes for clinician communication in pediatric health care.

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Simulation

***In Situ* Simulation: Challenges and Results**

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Abstract

In situ simulation, simulation that is physically integrated into the clinical environment, provides a method to improve reliability and safety in high-risk areas. Deliberate practice and integration of teamwork skills in the time-pressured clinical environment provides great realism and is a rich resource to identify latent threats and system issues that can compromise patient safety. However, powerful cultural and logistic challenges impede implementation of this practice. Issues related to culture, performance anxiety, time pressures, and patient perceptions that can interfere with successful implementation of *in situ* simulation are explored. The experiences and lessons learned during implementation of three pilot *in situ* programs are reviewed. Qualitative data, including feedback from health care providers and patients on the value and concerns related to this practice, are presented. Lessons learned provide guidance that is intended to increase the future success and implementation of *in situ* simulation.

Introduction

Human patient simulators are currently utilized in a number of medical settings. Although available simulators do not reproduce the critically ill patient in his/her entirety, they do represent a giant leap forward from static mannequins. In addition, standardized scenarios that exert real-time pressure are easily developed. Anesthesia, critical care, and trauma teams have employed simulation training with a positive effect on procedural and cognitive skills in the simulated setting.^{1, 2, 3} This intervention also combines the opportunity to practice technical and teamwork/behavioral skills.

The pediatric human patient simulator creates a realistic experience for the learner and increases the likelihood that the training experience accurately reflects the clinical environment. The realism of clinical simulations with human patient simulators makes it an extremely valuable tool in a curriculum based on experiential learning. It appears that human patient simulation is effective in developing the cognitive, procedural, communication, and teamwork skills that can improve patient safety.^{4, 5} However, while performance is clearly enhanced in the simulated setting, there is little information available on the translation of these skills to the actual patient care environment.

In situ simulation has evolved as a particular form of simulation, distinct from simulation that is conducted in a simulation center. *In situ* simulation may be defined as, “Simulations that occur in the actual clinical environment and whose participants are on-duty clinical providers during their actual workday.” An alternative definition would define *in situ* simulation as, “Simulation that

occurs in the actual clinical environment, regardless of whether the participants are participating, during the course of caring for actual patients.”

In situ simulation does not replace simulation conducted in the simulation center. In fact, the objectives of training conducted in a simulation center are likely to be very different from the objectives of *in situ* simulation. Training based at a simulation center is often related to a curriculum or course and has objectives related to both technical and non-technical proficiencies (e.g., communication and teamwork). On the other hand, *in situ* simulation allows teams to review and reinforce their skills and to problem-solve in the clinical environment. Given that the simulation occurs in the clinical environment, there are opportunities to identify hazards and deficiencies in the clinical systems, the environment, and the provider team.

The facilitator and the debriefing are critically important in both center-based and *in situ* simulations. Given the time pressures associated with *in situ* simulation, the debriefing in this setting is by necessity brief and concise. Standardized debriefing formats ensure that critical components are covered in a relatively short time frame. The facilitator also plays a critical role in observing communications, interactions, and body language for the debriefing. Again, given the time pressures associated with *in situ* simulation, the use of video for the debriefing may not be possible, although video taping for later review and research purposes is desirable.

Rationale

Conducting simulations in the clinical environment can be justified by a number of rationales. These include everything from training efficiency to the underpinnings of adult learning theory.

Experiential adult learning theory serves as one basis for *in situ* simulation. Kolb’s theory of experiential learning provides a rationale for conducting *in situ* simulation from the perspective of the educator and the participant. This is especially true in that this theory relies on concrete experiences, reflection on the experiences, and “active experimentation” so that “new ideas and concepts can be used in actual practice.”⁶

As an educational tool, *in situ* simulation promotes experiential learning by training the health care provider in the actual environment in which the provider is expected to use these skills. Experiences in simulation labs may accomplish this to some degree, but *in situ* simulation, by definition, is more closely aligned with the actual “work” of the health care provider and is more likely to achieve success for certain training objectives.

In situ simulation also offers the advantage of training efficiency for the health care provider and the organization. *In situ* simulation occurs during the actual workday, utilizing on-duty clinical providers, which alleviates the need to schedule health care workers on nonclinical days, pay overtime, or schedule additional providers to “backfill” the clinical unit while one team of clinical workers is off the unit for training. It also provides an opportunity to review at frequent intervals the skills related to high-risk or infrequent events. Frequent reinforcement of the skills needed for these types of scenarios will likely result in better retention. However, this enhanced efficiency must be balanced by the necessity of conducting *in situ* simulations for all shifts, not just the day shift, in order to achieve competency for the entire provider team.

For those institutions that are just beginning to develop simulation programs, *in situ* simulation offers an opportunity to begin to expose clinical personnel to simulation even before a “bricks-and-mortar” center is constructed. The development of an *in situ* simulation program potentially provides some cost savings, but it is unlikely to meet all the institution’s needs in the long run. Nevertheless, the implementation of simulation in an unoccupied treatment room, patient room, operating room, or emergency bay provides a number of opportunities to begin to realize the benefits of simulation. Aside from safety and educational benefits, this approach has the potential to stimulate providers’ interest—and ultimately that of the institutional leadership as well—in further development of a simulation program.

It is likely that the most valuable benefits of *in situ* simulation are related to the identification of latent hazards, knowledge gaps, and opportunities for clinical teams to rehearse infrequent and/or high-risk clinical scenarios. In this respect, *in situ* simulation has been compared to “crash-testing the dummy” in automobile safety testing. In order to determine the safety of a particular vehicle, the National Highway Traffic Safety Administration does not drive a car around a neighborhood for several hours. Rather, the evaluators crash the vehicle into a wall to determine how well the car withstands the crash and what damage to the “dummies” (and by extension their human counterparts) results from the impact.

In situ simulation offers a diagnostic method to identify clinical providers’ knowledge and technical proficiency gaps. This is particularly valuable for those infrequent and/or high-risk scenarios that most providers do not experience often enough to remain proficient. *In situ* simulation also offers a method to identify latent hazards in clinical systems. In emergency department (ED) *in situ* simulations at Cincinnati Children’s Hospital Medical Center (CCHMC), *in situ* simulations have identified resource issues related to personnel, medication, and equipment—whether missing or an inability to use—that were secondary to knowledge gaps.

Realistic but intentional equipment malfunctions, deliberate errors (especially common errors), missing information, or even the simultaneous introduction of more than one simulated patient reflect a naturalistic approach. These types of simulations also offer the opportunity to stress the system and identify those areas that are highest in risk and have the greatest need for remediation. An example of the use of this type of simulation also combines a usability-testing facet to the *in situ* simulation. Kobayashi et al., used simulation as a means to test the safety of a newly designed ED prior to its occupation as clinical space. As a result of this evaluation, 18 latent hazards were identified and remedied before patients used the space.⁷

Challenges

Despite the many benefits associated with *in situ* simulation, there are at least an equal number of challenges. These can be classified as technical issues, logistics, cultural obstacles, and medical-legal concerns.

Technical issues. The first issue related to the implementation of *in situ* simulations is the use of the simulator. Currently available simulators may be somewhat portable, but they require the ability to transport the simulator, compressor, and laptop computer to the selected location and a method to shield or mask the ancillary equipment from view during the simulation. This problem might be somewhat alleviated if the *in situ* simulations are conducted in the same clinical unit routinely, and storage space is available in the unit. However, the majority of programs are not

able to devote a single simulator to a clinical unit. Thus, the need to transport the simulators and set up and dismantle the equipment is obligatory. The simulators and equipment do not perform perfectly in all circumstances, and the additional jostling related to multiple relocations can contribute to further equipment malfunctions.

During implementation of *in situ* simulations, the use of medical supplies and equipment required for clinical scenarios can be approached in two ways. One approach is to use the medical equipment already in place in the clinical setting, such as angiocaths, intravenous fluids, endotracheal tubes, bags, masks, monitor leads, pulse oximeters, and others. This is obviously a desirable approach, but it does beg the question of paying for the replacement of this equipment, whether through educational funds or by the clinical unit that benefits. Replacement costs can be substantial, depending on the cost of restocking and the frequency of the *in situ* simulations.

An alternative approach requires the simulation team to replace the equipment in the clinical unit with reusable equipment used only for simulations. For example, equipment carts stocked exactly like those used in a particular unit can be placed and removed before and after an *in situ* simulation. This does require additional storage space and transport, but all the reusable equipment needs to be clearly labeled to indicate that it is to be used for training purposes only. A safety risk posed by this method is that equipment intended to be used for training could inadvertently be used on actual patients.

Infection control is another concern raised by the transport of simulators and medical equipment into a clinical setting. Although *in situ* simulation implementation in the ED might not be expected to raise these issues, it might do so in an operating room or critical care unit. The storage of simulators and other necessary equipment also can raise these issues.

Finally, *in situ* simulations can be extremely labor-intensive for the simulation team. The resources and time necessary to transport, set up, conduct, and dismantle an *in situ* simulation can be substantial. It might require half an hour on either side of the *in situ* simulation to account for the transport, set up, and take down. If the simulation is videotaped, three people might be necessary to conduct the simulation: one to videotape, one to run the equipment, and one to observe and facilitate. This kind of resource commitment could strain even large centers and needs to be scheduled with respect to other ongoing simulation activities.

Logistics. The units that often derive the greatest benefits from *in situ* simulations are—at baseline—high-acuity, high-census areas. These include critical care units, operating rooms, and EDs, all of which are areas that are subject to large surges of patients and seasonal variations in census and acuity. The conduct of *in situ* simulation should stress the system, but those conducting the simulations also need to be sensitive to the system stressors already in place. This might mean that the simulation team consults with the charge nurse and/or physician prior to conducting an *in situ* simulation during a particularly busy time.

On the other hand, it is important that *in situ* simulations be conducted on a continuing and relatively frequent basis. At CCHMC, we have found that 10 to 15 percent of *in situ* simulations are cancelled due to volume and/or acuity. This number might fluctuate, particularly during times of extremely high census. When simulations typically occur in empty patient rooms, these rooms might be occupied by actual patients, calling for the creative use of treatment rooms,

trauma bays, or other spaces. *In situ* simulations might be more acceptable at these times by imposing a time limit on them and the debriefings that follow to minimize any negative clinical impact.

In the ED at CCHMC, *in situ* simulations are limited to 10 minutes and the debriefing to 7 minutes. This sometimes necessitates initiating a simulation mid-scenario or presenting a patient that has deteriorated in another area of the ED or hospital. Standardized debriefing formats ensure that all the critical areas are covered during an abbreviated debriefing. A followup survey requests any additional observation or comments from the participants.

A significant concern of health care providers is the delay or perception of delay in actual patient care during the conduct of an *in situ* simulation. Again, limiting the length of the simulation and the debriefing is helpful for preventing a negative impact on clinical care. At CCHMC, we addressed this question with our ED family advocacy group. The family advocacy group is composed of family members with children who have been patients in the CCHMC ED or who are patients with chronic illness and require ED resources several times per year. Despite providers' anxieties, these families reported that they were supportive of *in situ* simulations. They stated that they were glad the health care teams were practicing for high-risk situations and that the additional time spent waiting because of a simulation was not significant in the context of an ED visit. For these families, a brief delay in care was outweighed by the value of the team's training.

Cultural Obstacles

Patient and family perceptions. Family-centered care has become a legitimate focus for many health care delivery systems. Some health care providers express concerns that *in situ* simulation might be perceived as either disruptive or intimidating to patients and their families. For example, mock emergency rehearsals and observation by patients and families of their trusted health care providers performing interventions, making mistakes, receiving coaching and debriefing, and asking questions (i.e., appearing less than perfect) could theoretically undermine patient and family confidence, and it might serve to remind families of the worst potential problems the patients will face.

Other health care providers express the opposite opinion. They acknowledge that *in situ* rehearsals might be stressful for families, but with proper support and explanation, the family can be reassured that their health care providers have recently been refreshed on the interventions and procedures that might be needed. In particular, they are aware of and prepared for the worst emergency that could happen to the patient.

Experience at the Children's Hospital of Philadelphia (CHOP) has reflected the latter attitude. When patients' families and staff have been exposed to an extensive daily bedside "rolling refresher" CPR and defibrillator update and mock emergency for the five sickest patients in the pediatric ICU, the response has been positive. Families have expressed appreciation for the training and preparation (much as is done on a daily basis in the airline industry on flights every day). This suggests that, with proper attention and provision of information to patients and families, integration of *in situ* simulation (even at the bedside) can be accomplished with respect to family-centered care.

On-Duty Clinical Practitioners as Study Subjects

Medical research involving human subjects has traditionally assumed the subject to be a patient with a medical ailment. However, patient safety research is performance research and studies the clinical care system. In this context, clinicians serve as study subjects. The clinicians, the local clinical context, and the organizational institutional culture represent psychosocial dimensions that can become evident when performing *in situ* simulation, whether for training or for assessment. In our different institutions when first implementing *in situ* exercises, we all underestimated: (1) the psychology of being a videotaped professional in a simulation exercise looking at performance, (2) the complexity of classifying “whole system” investigations appropriately and how to approach health care worker participation, and (3) the medical-legal/risk management dimensions of exposing care systems’ vulnerabilities during training and assessment exercises. The analysis that follows is based on our experience with psychosocial/cultural barriers; similar problems should be anticipated by involved in patient safety research. The expression of these issues and the solutions will vary depending on factors specific to the host organization, State law, safety culture, and other local factors. In addition, the shifting regulatory environment and Federal mandates regarding human subject research also affect this type of program.

These psychosocial factors we have categorized as:

- Voluntary research vs. mandatory training.
- Video recording performance anxiety.
- Video recording privacy issues.
- Motivation of clinicians.

Understanding these psychosocial factors prior to beginning *in situ* simulation exercises allows the use of a proactive approach to balance the training and assessment goals against opposing psychosocial factors.

Voluntary Research vs. Mandatory Training or Something Else?

Nationally, many institutional review boards (IRBs) struggle with definitions that differentiate research, quality assurance, quality improvement, and training. The way *in situ* simulation projects are framed can affect their classification and how issues—such as subject enrollment, informed consent, and privacy issues for participants—are approached. Consultation with hospital risk management, legal counsel, and the Committee for the Protection of Human Subjects (CPHS) experts suggests that *in situ* simulation is a hybrid. To paraphrase the consensus opinion, *in situ* simulation is a complex, nontraditional piece of research that arguably includes a quality assurance (QA) component in the conduct of the research and might yield significant training benefits, all in the service of quality improvement. There are good reasons to consider this activity a combination of research, QA, training, and quality improvement (QI).

Research. *In situ* simulation is not consistent with classical clinical research (e.g., a study of a new chemotherapy protocol for a specific form of cancer). Traditional clinical research requires a full CPHS review. The Federal Common Rule: 45 CFR §46.102; defines research as “...a systematic investigation, including research development, testing and evaluation, designed to

develop or contribute to generalizable knowledge.”⁸ Thus, this work is, technically, human subject research. But it is not traditional “human subject research” on patients, of the kind the Federal Common Rule was designed to regulate and the IRB (CPHS) is normally asked to approve. This is human factors research into the performance of clinicians under (simulated) stress, rather than an inquiry into the effects of an experimental treatment on patients themselves. Still, we believe CPHS review should be sought, and requirements must be met if academic funding and publication are anticipated.

Training. In contrast, pure training is typically an expectation of employees and requires no approval by the CPHS. Indeed, performance in mandatory training is often linked to performance evaluations and might be linked to employment. Consequences for nonparticipation in required training are standard in medicine and other industries (i.e., firemen cannot refuse to participate in “fire drills”). We have framed standardized exercises as mandatory training once a validated intervention has been developed and deployed. Many institutions are developing assessment simulations as a prerequisite to privileging clinicians for specific clinical activity. This strategy allows regulatory requirements for a demonstration of competency to be met.

Quality assurance and quality improvement. Between these two extremes of classical clinical research on informed patients and pure employee mandatory training lie quality assurance investigation and quality improvement activity. Quality assurance (QA) activities and records are defined by State law. In New Hampshire, RSA 151:13-a defines QA as the activities and records of a hospital committee organized to “evaluate matters relating to the care and treatment of patients, or to reduce morbidity and mortality.”⁹ *In situ* exercises, such as mock codes, do not legally qualify under the first part of this definition because care and treatment are given not to patients but to a mannequin. However, the activity clearly is organized to reduce morbidity and mortality, and the performance of providers during the mock codes is peer reviewed, so arguably it could qualify as QA if one desired to keep the videotapes and performance confidential.

Unlike QA, quality improvement (QI) records do not have any clearly defined legal meaning and are not given any particular legal privilege, nor should they be, because while QA only works well if its confidentiality is protected, QI materials should be disseminated as widely as possible in the hope that the materials are used to educate providers and improve the quality of care. The purpose of *in situ* simulation is to improve the quality of care, and the research and training aspects of this activity are completely consistent with this end. Furthermore, if participants are deidentified before using the videotapes with subsequent generations of students/trainees or publishing the results—and thus removing any cause for professional anxiety—there would be no reason not to use the tapes as widely as QI training tools.

Unfortunately, consensus on definitions for research, QA, QI, and training do not exist. The general themes described here should provide guidance for how to frame *in situ* simulation to meet local goals and objectives. Each activity needs to be assessed with regard to current Federal and State laws, institutional bylaws and local CPHS policies and procedures. Navigating the complex hybrid aspects associated with *in situ* simulation is a significant challenge.

Video Recording Performance Anxiety

The Hawthorne effect,¹⁰ in which performance while being studied tends to be superior to usual performance, has been well described. However, performance anxiety is also clearly associated

with the use of videotape in medicine and can significantly degrade observed performance and affect participants' motivation. Being observed while working, even by those with no expertise, can be stressful.¹¹ In a survey that reviewed family-witnessed resuscitation, medicolegal concerns and performance anxiety affecting the CPR team were listed by 24 and 27 percent of respondents, respectively, as the reasons they disapproved of this practice.

The magnitude of videotaping's effect on clinical performance has not been well studied. However, performance studies acknowledge that video has the potential to produce anxiety in the subjects of the recording. For example, in a study of emergency medicine resident communication skills, the authors note, "... considerable initial resistance to videotaping ... among the ED nursing staff"; and "Our residents reported an initial discomfort with the possibility of being videotaped, but this diminished with time."¹² This finding—that one limitation of videotape recording is its influence on behavior—has been described by psychiatric, behavioral medicine, and other experts.¹³ The phenomenon of social anxiety is aggravated by infrequent and unpredictable exposure to the stressful stimulus (as occurs with some study protocols; e.g., random once per month mock codes that are videotaped and reviewed for errors in performance). The more predictable and frequent a stressor is, the more rapidly social anxiety dissipates.^{14, 15} In addition, informing subjects that the focus of the videotape review is directed toward team and systemic performance rather than individual error can further reduce anxiety.

Video Recording Privacy Issues

Although video is a powerful vehicle for capturing performance in complex, high-hazard domains, privacy issues emerge when it is used for *in situ* simulation. When patients and family are in the clinical domains of interest, it is common to accidentally record them. This is especially true in exercises in which transports and handoffs are of interest. A STAT cesarean section simulation requires organizing a patient for transport, movement through potentially crowded hallways, and transfer to an operating room table. It is important that the videographer be aware of privacy regulations and avoid taping bystanders. In some systems, it might be possible to obscure participants' faces.

Since simulation training involves forced error in the service of learning, it is important that the video be used only with the individuals participating in the exercise. Trust is a critical factor for all simulations and is especially hard to protect when the simulation is *in situ*. If any permanent record of the video is maintained, explicit permission from each individual as to the purpose and use of the tape must be obtained. Use of the video for education of others without the consent of the participants should not occur. If video is to be used for public presentation at academic conferences, explicit permission from each individual visible on the video should be obtained. Often, it is more acceptable to re-enact the interesting segment with "actors." If privacy is not respected from the perspective of the participants, trust will be lost, and motivation will be a major barrier to continued exercise.

Motivation of Clinicians

Since *in situ* simulation is performed in the clinical domain with clinicians on duty, motivation to participate can be a major obstacle. While groups of individuals can be motivated through edict and threat of punitive action, such as one might use for mandatory training, self-motivation is preferable. The lack of motivation is not always due to performance anxiety. Models of

individual motivation suggest an important first step is helping potential participants to move from the pre-contemplative state (“There is no problem. Why should I waste my time on this?”) to the contemplative state (“There is a significant problem with the status quo, and change is needed.”). Although originally described in relation to motivating individuals to change behaviors like smoking, this model is robust.^{16, 17}

Education on the rationale for crisis training *in situ* should provide sufficient information for clinicians to understand the problem with current practice and see the benefits of participating in such exercises. Further steps toward individual motivation include determination, action, and finally relapse vs. maintenance of the new behavior. *In situ* simulation is a powerful motivator because it reveals less than optimal adverse event management due to flaws in the status quo.

After participating in an exercise, clinicians universally request feedback on their performance. Although immediate debriefing can be difficult, the information provided is ideal for helping individuals determined to change their behavior. Debriefing in the form of video feedback is a well-established methodology in simulation centers to facilitate and motivate learning, but the efficacy of this approach is difficult to demonstrate. In a multicenter trial attempting to show that videotape feedback improved learning compared to a matched group of trainees not given feedback, the measured differences in performance were not statistically different.¹⁸ However, since performance is difficult to measure, it may be that the impact of video feedback was simply obscured by the variability of the measures and a relatively small sample size.

Video feedback is also used in “real world” settings to facilitate learning (e.g., videotaping of trauma resuscitations in emergency rooms). A multi-State survey of videotaping practices for major trauma resuscitations found that of 45 hospitals that videotape, 75 percent used the tapes for teaching, and 45 percent used them in morbidity and mortality (M&M) conferences.¹⁹

Sustaining motivation to participate in *in situ* exercises over time requires feedback that system failures are being addressed by the organization. If debriefing includes individual, team, and systemic contributors to failure, the participants know that these latent conditions will exist until corrected. Individuals tend to normalize deviance and, with repeated exposure over time, fail to notice all the “accidents waiting to happen.” *In situ* simulation makes these conditions explicitly visible and can lead to frustration and anger that the organization is committed only to patient safety on the backs of hypervigilant individuals, rather than to robust supporting systems

In addition, immediate rewards for participation often include small local incentives (e.g., food, coffee, chocolate, badges, trinkets) and more professional outcomes (e.g., documentation of mandatory competencies, fulfillment of unit based CEUs). This latter reward system can serve to promote the utility of *in situ* simulation for both initial orientation training and refresher training documentation, either of minimal competency or level of excellence.

Medical-Legal Issues

Previously, we described the legal issues associated with the use of video, privacy concerns, and consent. A less obvious issue is the influence on liability of *in situ* simulations and the findings associated with them. What is the potential liability and ethical/moral responsibility associated with discovering an “accident waiting to happen” that goes unchecked, only to “happen” a year

later because corrective action was never taken. Organizational patient safety leaders will be extremely supportive of *in situ* simulation as a proactive patient safety investigation. However, they will expect that the identified hazards and threats be an impetus to change systems and protect patients and not just a research endpoint. It is important and responsible that findings from *in situ* simulation be forwarded into existing QA and QI structures in the same way as other identified safety concerns, so that appropriate review and corrective actions can take place. A mechanism is needed to track critiques of the exercises and demonstrate that identified hazards are prioritized (like any risk surveillance data) and acted upon.

Typical reasons for classifying *in situ* simulation exercises as carrying legal liability do not exist. Since the patient is a dummy, at first blush there does not appear to be a likely risk. However, one should at least consider the question that has been raised: Had an actual patient had a serious adverse event in the course of care, and had it become known to the patient or his/her attorney that the hospital had made tapes of closely related mock situations, they might very well want to review those tapes. Furthermore, if the tapes established that there were certain likely risk scenarios (including the one that happened to the patient) that the hospital knew about and could have prevented (through training, systems changes, etc.), this could be evidence of liability to a malpractice plaintiff.

For this reason, one could decide to try to protect the *in situ* simulation exercises, the video, and the critiques of the care displayed on the video as QA. The usual reason for wanting to qualify an activity or a record as QA is to allow candid peer review in order to improve care without exposing the results of that review to discovery and potential litigation. Legal opinions suggest there would be some technical difficulties in defending *in situ* exercises as QA activities. The exercises include a very large number of participants, which is not consistent with a confidential peer review activity held within a designated hospital QA committee. In addition, if one wants to use the video to educate future students/trainees beyond the original participants (even if participants are deidentified), they would be disseminating the “QA records” beyond any group that could conceivably be considered a hospital QA committee, thus waiving any QA confidentiality privilege that might be attached to the tapes. The exercises, tapes, and analysis would still clearly be QI (quality improvement) but not QA (privileged quality assurance).

You can’t have it both ways; before implementation, you should decide about the potential value of the tapes as training material vs. as data in research that might be published vs. assessment data to be used for QA. Practically, it is important to collaborate with hospital patient safety leaders and risk managers. Liability is unclear; still, it is prudent to establish a mechanism to have critiques that identify and forward extreme competency issues and/or system flaws into existing QA systems that are structured to track threat information and take corrective action.²⁰

Overcoming Barriers to *In Situ* Simulation

As mentioned earlier, numerous potential or perceived barriers to *in situ* simulations exist. Strategies for success often require tailoring simulations to the local environment and multidisciplinary staff, particularly when using bedside rather than adjoining (but physically separated) simulation areas for mission rehearsal.

Some consistent themes that emerge for facilitating successful *in situ* simulation experiences include garnering dedicated equipment storage and equipment space in or near the site of

simulation (rather than requiring laborious transport of equipment and support). In addition, the facility to rapidly put up and take down the simulation equipment to convert simulation space to usable patient care space can add to the realism of rehearsals and to the functionality of the dedicated space. Simulation working groups are helpful when they are unit-based, multidisciplinary in nature, highly integrated into the continuous quality improvement (CQI) fabric of the unit, linked to incident reporting and patient safety initiatives in the unit, and conducted in conjunction with efforts for mandatory nursing education within a hospital.

Key to successful implementation of *in situ* simulation is integration of *in situ* simulation with the involvement of those who are responsible for credentialing and orientation of unit staff and familiarization for rarely used or new equipment. At CHOP, prospectively designated standards and limits set by staff leadership consensus for conducting *in situ* simulation based on volume and acuity of patient care needs have been helpful for obtaining support for the program and avoiding concern about interference with unit function. These processes further serve to engage health care providers in the process of simulation, and they solicit objectives and training outcomes that help meet the needs of providers and the administrative network.

Outcomes Associated with *In situ* Simulation

As researchers using *in situ* simulation, we have had to address the various challenges described in this paper. The effort is significant. However, we have seen a variety of outcomes that are extremely exciting, albeit preliminary. Our collective research supports that:

- Individual participant technical proficiency is improved.
- Desirable individual and team behaviors are reinforced.
- Active and latent systems issues are readily identified.
- *In situ* simulation can be a catalyst for change in clinical care systems and improved clinical outcomes.

We highlight these findings with deep respect for the complexity of whole-system research and the limitations of forming direct cause-effect linkages. Still, we report these findings to fortify those embarking on what can be classified as field research.²¹

Outcome #1: *In Situ* Training for Technical Proficiency and Measurable Changes in Clinical Competency

Tracheal intubation. Appropriate airway management is the initial and most critical step for pediatric resuscitation: prevention, initial stabilization, and optimized resuscitation from acute respiratory failure and cardiac arrest. It is one of the core skills to be learned by pediatric residents during their pediatric intensive care unit (ICU) rotation as defined by the Accreditation Council for Graduate Medical Education (ACGME).²²

Studies have shown that psychomotor skills start to decay as soon as 3 months after the training and decay much faster than knowledge-based skills.^{23, 24} The effectiveness of high fidelity simulations was evaluated in achieving and measuring competence in initial airway management

skills in medicine interns (PGY-1) using a computer-simulated training process involving a respiratory arrest scenario in an adult patient. The investigators developed essential and nonessential steps of initial airway management and showed improved performance in those steps in the training group. Although they also suggested an excellent clinical performance in actual airway events in this intern group, they could not evaluate the effect of simulation-based training on the clinical practice directly.²⁵

An evaluation of the reliability and validity of simulation-based acute care skills in medical students and residents found that the reliability was most strongly influenced by the choice and number of simulated encounters. The validity of the simulation scores was supported through comparisons of the performance of students and residents in relation to their clinical backgrounds and experience.²⁶

Refresher training based only on cognitive knowledge review does not improve psychomotor skills,²³ and it remains a challenge for pediatric residents to learn and retain this critical skill. NEAR-4-KIDS (National Emergency Airway Registry for children) has been implemented in our pediatric intensive care unit (PICU) to capture the unit's airway management practices.²⁷ Since 2004, NEAR-4-KIDS has successfully captured more than 200 intubation events (97 percent of all intubation events). It describes characteristics of intubation, operator factors, patient factors, and associated events that might be related to patient safety issues. We came to know that our residents did not participate in the majority of orotracheal intubations (28 percent), and the success rate of the selected cases was still significantly lower than that of our fellows (38 percent).^{27, 28} Based on this knowledge, just-in-time training on psychomotor skills—such as resuscitation and airway management—immediately before the work makes sense. However, no study has yet tested the efficacy of just-in-time resuscitation/procedure training.

To improve the operational performance (i.e., first attempt success rate) and safety (i.e., minimal associated events that could lead to adverse events), a clinical study was conducted to test the association between simulation training and improvement in patient outcomes and patient safety and the impact of “fidelity” on the effectiveness of simulation training.

With IRB approval, experienced nonanesthesia pediatric providers with airway management responsibility serially refreshed orotracheal intubation skills in six simulated infant trauma airway scenarios involving cervical spine stabilization. Time (T) to successful completion of key actions was measured by computerized mannequin and debriefing. The ratio of time to successful tracheal intubation from end of bag-mask ventilation to confirmation of correct tracheal placement was recorded for each scenario.

A total of 26 skilled providers (pediatric transport nurses, pediatric emergency medicine fellows, pediatric critical care fellows) performed 156 intubations. Overall, time to successful tracheal intubation (mean $\pm$ SD) was $T1 = 33.8 \pm 9.4$ seconds for the first scenario. For subsequent scenarios: $T2 = 29 \pm 6.4$ seconds, $T3 = 27.4 \pm 5.6$ seconds, $T4 = 29.8 \pm 9.2$ seconds, $T5 = 28 \pm 5.4$ seconds, and $T6 = 25.6 \pm 5.1$ seconds. Immediate effectiveness of refresher training assessed by the individual provider's ratio of $T2/T1$ was associated with recent intubation training within 3 months ($P = 0.025$) but not with provider clinical experience >3 years ($P = 0.93$) or discipline ($P = 0.40$). Recent intubation training (<3 months) remained significant ($P = 0.017$) in multivariable linear regression adjusted for years of previous experience and discipline.

Recent tracheal intubation training, but not clinician years of experience or training discipline, was significantly associated with the ability of refresher training to improve provider excellence and patient safety in simulated advanced pediatric airway management.

CPR training. Another example of successful *in situ* simulation training involves “training to excellence” in cardiopulmonary resuscitation (CPR). It is widely recognized that high-quality CPR skill retention is poor. We hypothesized that “just-in-time” and “just-in-place” refresher training programs would be effective and well-accepted to maintain CPR skills among pediatric ICU staff. Each day, five ICU patients at highest risk for cardiac arrest were identified by clinical staff, and “rolling refreshers” were implemented to multidisciplinary bedside providers.

A trainer and portable mannequin/defibrillator system with force transducer and accelerometer provided individualized review of CPR skills with automated corrective feedback to optimize CPR skills. Each provider practiced CPR with corrective feedback until he/she had attained skill success, defined prospectively as >90 percent proficiency for a chest compression (CC) rate of 90 to 120/min and CC depth of 38 to 51 mm during 60 seconds continuous CPR. Providers who completed two or more refreshers per month were compared to providers completing less than two refreshers per month in terms of time to achieve prospectively defined CPR skill success. Also, following real-life cardiac arrests in the ICU, resuscitation participants were surveyed for subjective feedback on the efficacy of the training approach, using a 5-point Likert scale.

Over 15 weeks, 420 multidisciplinary PICU staff were “refreshed,” including 340 nurses, 34 physicians, and 46 respiratory therapists; 100 percent of participants met CPR skill success targets during refreshers. A convenience sample of 20 PICU staff was assessed before subsequent refresher sessions. The time to achieve CPR skill success was significantly lower in those refreshed more than twice per month (median, 21 seconds; range 7-30 seconds), compared to those who were refreshed less often (median, 67 seconds; range 30 to 116 seconds; $P < 0.001$).

Following real-life resuscitations, participants rated “rolling refresher” *in situ* training as effective (mean = 4.2 ± 0.67). From this experience, the staff concluded that this novel “rolling refresher” CPR skill training approach using “just-in-time” and “just-in-place” simulation could be effective and well-received by a multidisciplinary pediatric ICU staff. More frequent refreshers resulted in significantly shorter times to achieve proficient CPR skills.

Outcome #2: Teamwork and Desirable Communication Behaviors Reinforced

In situ simulation might stand alone or complement center-based simulation. One of the primary advantages of *in situ* simulation is the opportunity to review and reinforce teamwork and communication behaviors that are critical to a high-functioning, high-reliability health care team. The conduct of an *in situ* simulation allows for the partial scripting of deliberate errors, authority gradient issues, and equipment malfunctions. For example, in the CCHMC ED, one partially scripted simulation involved the attending physician deliberately failing to follow new Pediatric Advanced Life Support (PALS) algorithms for ventricular fibrillation. The facilitator observed that the body language of members of the health care team indicated discomfort with the actions of the attending physician, but no one spoke up during the simulation.

During the debriefing, it emerged that four team members knew that the algorithm had been violated but did not question the attending physician. Subsequently, several alternative methods of addressing these concerns were explored. During the debriefing, team members were encouraged to explore and practice these methods of questioning the team leader. In addition, the health care resuscitation team was observed referencing and researching the most recent PALS algorithms during lulls for the remainder of the day.

Outcome #3: Identification of Active and Latent Conditions

The identification of latent conditions using standardized assessment type *in situ* simulation has been reported previously.²⁹ When used to test pediatric sedation rescue capability, *in situ* exercises exposed substantial variation between different care settings and different clinical teams in caring for the same simulated patient. In addition, these exercises identified 5 to 10 care-management problems and 20 to 40 contributory factors (i.e., latent conditions predisposing systems to fail).

Active failures by clinicians due to knowledge deficits and technical incompetence were also readily identified. For example, clinicians had little knowledge of how to administer narcotic reversal agents (e.g., indications, contraindications, and dose) during an overdose scenario. Technical proficiency in effective positive pressure ventilation and use of bag-mask was lacking in all clinicians—except for respiratory therapists and anesthesiologists—studied in this hospital, which cares for pediatric and adult patients. The opportunities for improvement exposed by just 10 *in situ* simulations has led to several years' work to implement corrective actions to the sedation rescue systems.

In situ simulations also can be presented with malfunctioning or missing equipment. Sometimes this occurs by design, but on other occasions, it might occur serendipitously. For example, a foreign body airway obstruction scenario was carried out in the CCHMC ED. During the course of this simulation, it was discovered that the McGill forceps (used for removing foreign bodies from the posterior pharynx or airway) was missing from the trauma bay. This forced the team to quickly locate backup equipment. However, it also emerged during the debriefing that staff from a particular subspecialty was known to remove these tools from the shock trauma bay, thereby putting critical patients at risk.

Outcome #4: Opportunity to Improve Clinical Outcomes

The empiric research performed in the pediatric sedation domain has been used to design a high-reliability sedation/analgesia care microsystem. The design consisted of specifying the components that support sedation, analgesia, and movement control and respiratory depression control (i.e., rescue). The resource specification included the people, tools, and environmental components that afford control (also known as an affordance map, Tables 1, 2, and 3). These tables demonstrate the specificity of the microsystem that can be created using simulation as a tool to develop and test systems. Some of the implemented changes included:

- Establishing a specialty service for pediatric deep sedation and anesthesia.
- Establishing standard rescue equipment.
- Establishing privileges for sedation with explicit competencies.

- Correcting deficits in the emergency response communication paging system.
- Establishing a specific simulation-based sedation rescue training intervention.
- Establishing better metrics of performance and outcomes.

Within-hospital variation of pediatric procedural sedation has led to benchmark performance relative to other sedation services. These changes resulted in improvements in:

- Pain/sedation management.
- Safety from the life-threatening side effects of sedatives and pain medications.
- Conditions for diagnostic or therapeutic procedures.
- Patient experience.
- Efficiency and access to procedures.

The program was reviewed in the *Joint Commission Journal on Quality and Safety* in a series describing the implementation of high-reliability clinical microsystems.³⁰ While we do not claim to have Class A evidence that clinical outcomes have been improved, the face validity is very strong. Specifically, use patterns by physicians practicing at our hospital support a strong belief that the changes have improved the safety and efficacy of the care provided.

Table 1. Best/safe practice specifications for sedation/analgesia

C2 Undertreatment Errors			
CONTROL LOOP COMPONENTS	PROBLEM STATE	STRUCTURES ASSOCIATED WITH CONTROL	
Detection	Pain	Direct observation	
		EKG	
		BP	
	Anxiety	Direct observation	
		EKG	
		BP	
Diagnosis	Pain	Direct observation	
		Test results	
	Anxiety	RN w/ moderate sedation training	
		Anesthesiologist, CRNA	
		Child Life Specialist	
Treatment	Pain	Parents	
		Procedure operator	
		Local anesthesia	Lidocaine/insulin needles
			EMLA
			Numbey
		Non-opioids	Tylenol oral, rectal
			NSAIDs
		Opioids	Fentanyl
			Remifentanyl
		Inhalational	Nitrous
			Sevoflurane
			Isoflurane
	Anxiety	Parental presence	Clear role
		Desensitization (education)	Procedure specific
		Distraction	DVD/goggles
		Choice	A vs. B
		Nitrous Oxide	Face-mask training
		Benzo	Versed/IM/oral/IV
	Dangerous Movement	Mechanical	Arm boards
			Papoose/Velcro
		Airway	Oral/nasal/LMA
		Muscle relaxants	Rocuronium, Vecuronium

Table 2. Best/safe practice specifications for rescue

C3-Over and Mis-treatment errors

CONTROL LOOP COMPONENTS	PROBLEM STATE	STRUCTURES ASSOCIATED WITH CONTROL	
Detection	Obstructive or Central Apnea	Direct observation	
		EtCO ₂	
		Cont. auscultation	
	Hypoxia	SpO ₂	
		Cont. tone/beep	
		Alarm for SpO ₂	
	Hypoperfusion	SpO ₂ pleth	
		SpO ₂ HR	
		EKG HR	
		EKG trace	
		NIBP	
	Deep Sedation/GA	Verbal	
		Pain	
Diagnosis	Obstructive or Central Apnea	RN w/ capnograph	
	Hypoxia	RN w/ pulse oximeter	
	Hypoperfusion	RN with non-invasive blood pressure monitor	
	Deep Sedation/GA	RN w/ moderate sedation training	
Treatment	Obstructive or Central Apnea	RN	w/ oral airway
			w/ suction/yankauer
	Positive Pressure Ventilation	RN call for help	Back-up available
			Access mechanism
		Respiratory Therapy/Anesthesia Provider	Bag
			Mask
			O ₂ source
			Oral airway
	Definitive Airway	Anesthesiologist	LMA
			Laryngoscope
			ETT
	Deep Sedation/GA	RN w/ reversal drugs	Stylet
			Narcan
			Flumazenil

Table 3. Measured competencies for rescue

COMPETENCIES

Video-markers of best/safe practices for managing respiratory depression			Scoring Criteria (seconds)		
			Good	Adequate	Poor
Phase I	<i>Monitoring</i>	Apnea diagnosed (no chest movement)	0-30	31-60	>60
	<i>Mobilizing help</i>	PPV call (from time apnea detected)	0-30	31-60	>60
	<i>Basic Airway Tx</i>	Supplemental O ₂ (from time apnea detected)	0-15	16-60	>60
		Jaw Lift (from time apnea detected)	0-15	16-30	>30
		Oral Airway (from time jaw lift)	0-15	16-30	>30
		Bag/Mask Ready (from time requested)	0-15	16-30	>30
Phase II	<i>Advanced Airway Tx</i>	PPV expert arrives (from time called)	0-120	120-240	>240
		Expert BMV (PPV attempts from when arrived)	0-15	16-30	>30
		Two Person (from when one person failed)	0-15	16-30	>30
		Intubation (from when two person failed)	0-60	61-120	>120
		Failed intubation "call for back-up" (from when failed)	0-15	16-30	>30
		Succinyl Choline (from when laryngospasm dx)	0-60	61-120	>120
	<i>PALS</i>	Atropine (HR<60)	0-60	61-120	>120
		Epinephrine (Atropine, HR<60)	0-60	61-120	>120
		Compressions (no pulse)	0-15	16-60	>60

Conclusion

In situ simulation is a relatively new and rapidly evolving tool with the potential to improve patient safety through the identification of latent hazards and knowledge gaps and by strengthening the communication, teamwork, and technical skills that are critical to high-functioning health care teams. The challenges to the use of *in situ* simulation are many and might seem daunting. However, early evidence suggests that efforts to overcome these challenges will yield a rich return in benefits for improved patient safety.

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The Nature, Characteristics and Patterns of Perinatal Critical Events Teams

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Abstract

The Institute of Medicine has released several important reports strongly recommending team training to improve patient safety. Most team theory assumes that teams are stable, and leadership is constant. However, there are numerous instances in health care where teams are not stable, and leadership is constantly changing. A growing body of evidence has documented the complexity of interdisciplinary health care teams, particularly in critical events. This study uses *in situ* simulation to better understand the nature, characteristics, and the communication patterns of health care teams. We conducted 35 obstetrics emergency simulations at six different hospitals, involving over 700 physicians, nurses, and support staff. These simulated emergencies were videotaped, and 16 were analyzed extensively by medical, human factors, and safety experts. Our findings indicate that during health care emergencies, critical events teams are not stable, and their leadership changes constantly. Important areas for team training and future study are identified.

Background

Within the last decade, interest in communication patterns and performance of health care teams has re-emerged. A growing body of evidence indicates that interprofessional team communication plays a significant role in ensuring patient safety during critical events. In the early 1990s, research on nurse-physician interactions on critical care units indicated that nurse-physician communication and collaboration had an important effect on patient morbidity and mortality, establishing a link between critical care team performance and patient outcomes.^{1, 2, 3} Recent research, using the concepts of crisis resource management (CRM) (derived from crew resource management in aviation) and critical event team training (CETT) (primarily in health care), has refocused attention on the complexity of interprofessional health care team composition, leadership, communications, and performance. CRM and CETT have also provided a conceptual foundation for understanding team performance during critical events in health care.

In its examination of medical errors and patient safety, the Institute of Medicine (IOM)^{4, 5, 6} concluded that although important, the nature, characteristics, and communications patterns of health care teams remain poorly understood. The IOM indicated that the quality of communication among health care team members varies significantly and that this variability has

serious consequences for patient safety. For health care organizations and professionals to improve their performance in critical events, team dynamics must be understood better, and strategies for more effective communication must be described. Although interprofessional teams consist of individuals who are expert in their respective disciplines, they do not always bring effective interprofessional skills to the team. A “team of experts” is not necessarily an “expert team.”⁷

In this paper, we present findings from an observational study about the nature, characteristics, and communication patterns of interprofessional, critical events teams as they form and reform during critical obstetrical events. Unlike conventional teams, these teams come together to perform a specific task, and they reform when the task or mission changes significantly. We examined the videotaped performance of these critical events teams in 16 *in situ* simulations of obstetric emergencies. Critical events teams, which are also referred to as contingency teams,⁸ temporary teams,⁹ action teams,¹⁰ or rapidly formed teams¹¹ change their structure dynamically in response to stressful and unpredictable circumstances, assembling for a limited time, based on the task requirements of the emergent situation, and disbanding once the emergency is over. In this paper, these teams will be referred to as “critical events teams.”

We used high fidelity, *in situ* simulation—simulations in the real-life clinical setting—to examine patterns of team communication and performance during obstetric critical events. Our aims were to describe the stages of team formation and reformation (points at which the team assembles, reconfigures, or reassembles to complete a task during a critical event); the team composition at each stage; team situational awareness, shared mental model, establishment and transfer of leadership and teamwork, closed-loop communication, SBAR-R; and latent conditions.

We selected obstetrics crises to study team performance for several reasons:

- They occur in a compressed timeframe, typically lasting less than 30 minutes from the time an emergency is declared, until the baby is delivered by cesarean section (C-section).
- They can be readily replicated with *in situ* simulation.
- Team communication failures can be readily observed and documented through video.
- Root cause analysis indicates that over 70 percent of sentinel events in obstetrics result from communication failures and poor team functioning.¹² Although tremendous advances in perinatal outcomes have occurred over the past 40 years, the incidence of serious injury remains high at 6.3 birth traumas per 1,000 live deliveries.¹³
- Team and leadership communication patterns found during obstetrics crises are similar to those among members of other types of health care teams.

Concepts and Framework

Recent work in CRM and CETT has provided a conceptual foundation for this study. An interprofessional health care team consists of two or more individuals who perform some work-related task, have a shared past and foreseeable future, and share a common fate.^{14, 15} Teamwork is a composite of behaviors that facilitate effective team member interaction¹⁶ throughout the performance of a team task. In addition to expert technical skills, team members must possess specific nontechnical knowledge, skills, and attitudes (e.g., monitoring each other’s

performance); knowledge of one's own and one's teammates' responsibilities; and a positive disposition toward working as a team.^{17, 18, 19}

Conventional team theory assumes most professional teams are established formally and intentionally and have extensive training and stable membership.¹⁴ It includes nuanced analyses of team evolution, such as stages of forming, norming, storming, and performing;²⁰ team development and leadership;²¹ and situational leadership.²² However, conventional team theory does not adequately describe the dynamics of contingency teams common in health care emergencies. A core team is a group of caregivers who work independently to manage a set of assigned patients from point of assessment to disposition; a contingency team is a time-limited team formed for specific, circumscribed events and is composed of members from various teams.²³

The members of critical events teams might or might not be familiar with each other or each other's work and communication styles.⁹ Health care teams have demonstrated remarkable abilities to function together, even without a prolonged process of team building.²⁴ However, the patterns of a critical events team's performance are far less predictable than those of a conventional team. These patterns are not well understood, and therefore, training of such teams has not been grounded in a scientific understanding of effective nontechnical teamwork behavior.²⁵

In order to examine the performance of critical events teams, we applied the evidence-based teamwork framework developed for AHRQ's TeamSTEPPS^{®26, 27} training program. In this paper, the term "nontechnical teamwork behavior" refers to a team's performance relative to five core concepts: situational awareness, shared mental model, establishing leadership, transfer of leadership, and closed-loop communication.

Methods

This descriptive study used content analysis of 16 randomly selected videotapes taken at 35 *in situ* simulations. The settings were the perinatal units and operating rooms of six hospitals of the Fairview Health System in Minnesota. Table 1 shows the hospitals, annual number of deliveries, and the *in situ* simulation trials held at each facility.

Table 1. Participating hospitals and number of *in-situ* simulation trials

Hospital	Description	Annual deliveries	Number of simulations (used in study)
A	Suburban	~3,200	10 (4)
B	Major teaching	~3,300	6 (1)
C	Rural	~500	5 (3)
D	Suburban	~3,000	7 (3)
E	Rural	~700	4 (2)
F	Rural	~900	4 (3)
Total		~11,600	36 (16)

In developing the *in situ* program, we secured all necessary approvals to conduct the research and invested significantly in audiovisual recording capability. Fairview Health Systems committed substantial resources by reserving operating rooms, perinatal rooms, and space for observation and debriefing. The private medical staff voluntarily participated in the *in situ* simulation training, while nursing staff and support staff rotated into the training during scheduled work hours.

Subjects

The *in situ* simulations involved two classes of personnel from the hospital staff: direct team members and indirect team members. We recruited direct team members, and they were informed about the *in situ* simulation ahead of time and agreed voluntarily to participate in a simulation trial. Each simulation included an obstetrician, labor and delivery nurses, neonatal nurse practitioners, an anesthesiologist, certified registered nurse anesthetists (CRNA), a health unit coordinator, and operating room staff. During the team briefing prior to each simulation, direct team members were instructed to call upon any indirect team members, such as blood bank and laboratory staff, backup surgeons, central supply, extra personnel, code teams, language interpreters, and respiratory therapists to treat the patient, just as they would during a true obstetric emergency. Indirect team members did not know in advance about the simulation or their possible involvement. Each simulation involved an average of 20 individuals. Overall, approximately 700 medical and hospital staff participated in the simulations.

Scenarios and Event Sets

Our *in situ* simulations were based on three scenarios composed of six to eight validated event sets. We created each scenario based on sentinel events that occurred within the previous 5 years at the six participating hospitals. Each scenario was designed to prompt nontechnical teamwork behavior. The event sets were designed to prompt behavioral markers or nontechnical behaviors that contribute to a team's performance in a given situation.^{28, 29} Behavioral markers for situational awareness, shared mental model, establishment and transfer of leadership, teamwork, and closed-loop communication⁸ are provided in Table 2. Definitions of several of these behavioral markers were adapted from existing literature.^{23, 30, 31, 32}

In this study, we defined the “leader” as a person who is physically present and performs three specific tasks: (1) prioritizes decisions, (2) coordinates activities, and (3) communicates a shared mental model. “Leadership transfer” is an explicit handoff of leadership from one team member to another. “Situational awareness” is conscious recognition of salient factors and conditions that contribute to safe practice; it comes from monitoring one's surroundings and continuously facilitating the design and redesign of the care plan with changing conditions. “Closed-loop communication” consists of verbal exchanges between parties who acknowledge receipt of information with reciprocal verbal interactions, in which there are no failures in exchange of key information, and recommendations are acknowledged. A “shared mental model” is a common understanding of the situation and plan by all members of the team.

Table 2. Behavioral markers included in the observation instrument

Behavioral marker	Definition	Examples
Establishing leadership	A participant who is physically present and performs three specific tasks: 1) prioritizes decisions, 2) coordinates activities, and 3) communicates a shared mental model	• Assigns tasks • Gives instructions • Gives orders • Clarifies roles
Leadership transfer	Explicit handoff of leadership from one team member to another	Between surgeon and anesthesiologist at the initiation of surgical procedure
Situational awareness	Conscious, accurate recognition of salient factors and conditions in one's current environment	Managing distractors
Closed-loop communication	Verbal exchanges in which parties acknowledge receipt of information and assure that the exchange is resolved and complete	• Questions answered • Answers acknowledged verbally
Shared mental model	A common understanding of a problem and the plan	• Verbalize plans and rationale • Call outs

Data Collection and Analysis

We conducted 35 *in situ* simulations at six hospitals over a 13-month period from January 2006 to February 2007. All simulation trials were videotaped for use in debriefings and for content

analysis by the researchers. Cameras and microphones were strategically placed to capture physical and verbal action and interactions during the simulations. Due to the time intensive nature of the analysis, we randomly chose 16 of the 35 *in situ* simulations for study. Specifically, we selected videotapes from each of the six study sites without prior knowledge of the trial drawn for analysis.

We used the video recordings of the *in situ* simulation trials to study the critical events teams during the emergency C-sections. Video recordings have been used to study team performance successfully.^{33, 34, 35, 36} Unlike direct observations,³⁷ video recordings allow close scrutiny and repeated inspection. Furthermore, they capture much of the richness of human interactions and of the context in which activities are studied.

To analyze the videos, we used an assessment instrument with three sections: (1) five behavioral markers, (2) duration of each stage of the obstetrics crisis, and (3) the number and type of team members at each of six stages.

The assessment instrument was developed based on an in-depth analysis of the existing literature⁹ and the results of four expert group meetings. The expert group consisted of two physicians (including one obstetrician), two nurses (one maternal-child CNS and one PhD-prepared nurse researcher), and two human factors engineers.

After the initial development of the assessment instrument, the expert group reviewed five randomly selected video recordings (these were not used in the actual data analysis) to test and validate the instrument. Based on the findings of the pilot testing, the group modified and finalized the assessment instrument.

We conceptualized three ways to measure “leadership transfer”: (1) explicit, (2) implicit observable, or (3) failed to observe due to assessment limitations. “Team formation” occurred when an interprofessional group of individuals with special expertise assembled to execute a specific task, whereas “team reformation” occurred when team membership changed in a significant way by the addition or deletion of team members and a significant change in the task. Through a cycle of team formation and team reformation, a critical events team assembles and then adds and releases members as appropriate to the situation. Each behavioral marker was scored using the following scale:

- “0” Behavior occurred at or below 50 percent of the times when prompted by the event set.
- “1” Behavior occurred between 50 percent and 90 percent of the times when prompted by the event set.
- “2” Behavior occurred more than 90 percent of the times when prompted by the event set.

A score was assigned for each behavior at each stage through consensus among the raters present. Each rater scored independently; then the raters discussed the rating and achieved agreement. Every session included at least one research team physician and one research team nurse.

Inter-Rater Reliability

We used the Kappa (κ) statistic to evaluate the inter-rater reliability for each behavior. Two experts viewed the same videos and independently rated team performance using the observation instrument. A $\kappa \geq 0.61$ was considered to be satisfactory.³⁶

Results for the inter-rater reliability of the measures in the observation instrument ranged from $\kappa = 0.67$ to 1.00 (Table 3). All measures had a κ value above the satisfactory level (>0.61).

Results

We identified six distinct stages during simulated emergency C-sections. New stages of the critical event scenario were evidenced in significant changes in the team’s task. In three phases, the change in task was accompanied by a change in team membership and leadership. The specific tasks associated with the beginning of each stage were:

Table 3. Kappa (κ) scores for each measure of the observation instrument

Behavior marker	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
Situational awareness	1.00	0.79	0.86	1.00	0.75	0.89
Shared mental model	0.81	0.71	0.75	0.84	0.67	0.80
Closed-loop communication	0.76	0.69	0.67	0.71	0.84	0.78
Leadership transfer explicitly conceded	N/A	0.75	0.80	N/A	0.80	0.81
Leadership established	0.89	0.82	0.84	1.00	0.81	0.84

- **Stage 1:** Admission and assessment of patient and fetus.
- **Stage 2:** Identification of clinical crisis.
- **Stage 3:** Declaration of emergency.
- **Stage 4:** Induction.
- **Stage 5:** Surgical procedure.
- **Stage 6:** Infant resuscitation.

Figure 1 illustrates the six stages of the critical event, including the composition and leadership of each team as it formed or reformed. In Stages 1 and 2, the task changed: the team included the nurse, patient, and spouse or partner; the RN maintained leadership. In Stage 3, the task changed: the team composition changed, and leadership transferred from RN to the surgeon. In Stage 4, the task changed: the team expanded somewhat, and the leadership remained with the surgeon. In Stage 5, the task changed: the team expanded considerably, and leadership transferred from surgeon to anesthesiologist (or CRNA) and back to the surgeon. In Stage 6, the task changed, and the neonatal team was formed: the neonatal nurse practitioner assumed leadership for the infant's care. The modal group membership ranged from as few as three individuals (Stages 1 and 2) to a high of 13 (Stages 4 and 5).

The Stage 1 team comprised the mother, a spouse or partner, and a primary nurse (RN). The key tasks at this stage were introduction and identification of team members, creation of relationships and trust, and initial assessment of the mother's presenting condition. Stage 1 ended with continuation of the original triad, the arrival of a second RN or, in some cases, a family practice physician.

The Stage 2 team predominantly included the mother, a spouse or partner, the primary RN, and in some cases, an RN who arrived to assist. This stage was characterized by unfavorable changes in the mother's and fetus's clinical condition. The outcome of this stage was contact with the obstetrician or family practice physician to request his or her physical presence and to assume leadership in the impending medical crisis.

The Stage 3 team was reconfigured to add the obstetrician and or family practice physician. At this stage, the mother's condition worsened; decisions were made regarding necessary

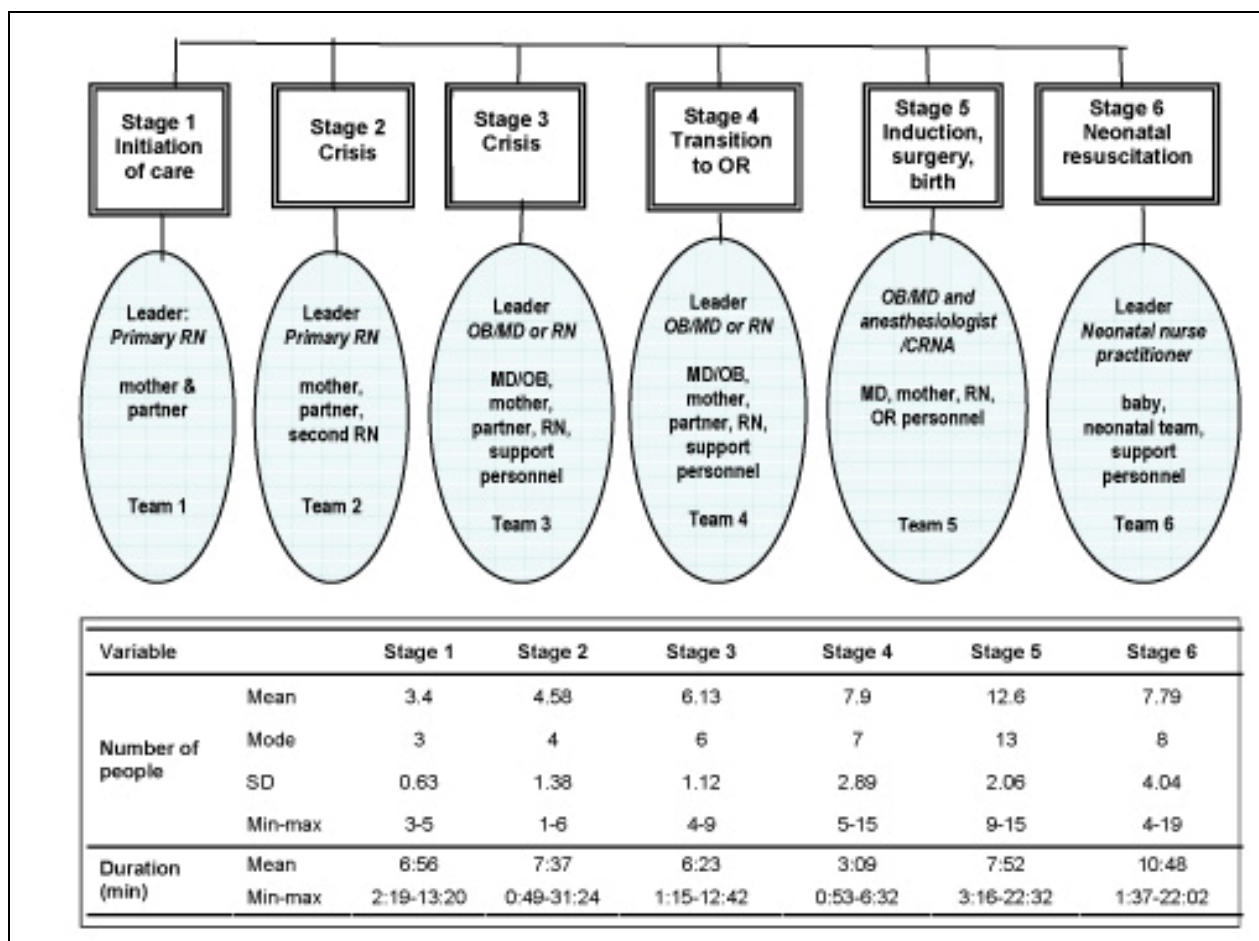


Figure 1. Stages of team formation and reformation with selected team characteristics.

emergency measures; and planning for an emergency intervention occurred. This stage was characterized by high team coordination and communication demands. Stage 3 ended with the calling of a Code C-section.

The Stage 4 team included the mother, spouse or partner, at least two RNs, the obstetrician, and additional personnel, who responded to the growing crisis. Stage 4 was focused on preoperative preparation of the mother for immediate transport to the OR. This stage ended at the time of entrance to the operating room. The Stage 5 team was substantially reformulated. In addition to the mother, obstetrician, the primary RN and/or an RN circulating nurse, the entire operating room staff was present, including an anesthesiologist and/or CRNA, OR technicians, and the neonatal team. This stage was distinguished by two tasks: anesthesia induction and the surgical procedure to deliver the infant. The exchange of leadership from MD/OB to anesthesiologist or CRNA and back, the initiation of the surgical procedure, and the birth of a compromised infant were important leadership and team-formation and reformation incidents. Stage 6 focused on the neonatal team. The neonatal nurse practitioner assumed leadership of this team. The main task for this team was initiation of the infant Code Blue and resuscitation. This stage ended with the stabilization of the infant.

Team Behaviors

After establishing the stages of the team formation and reformation, we examined the performance of key behavioral markers in rapidly formed teams. Table 4 shows five team behaviors classified by stage of team formation, according to the percentage of time that the behavior occurred in relation to the number of times the behavior was prompted (or called for) during the stage.

Table 4. Proportion of “excellent” behavioral markers by stage (%)

Behavior marker	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	Average
Establishing leadership	69	54	64	60	36	64	58
Leadership transfer	N/A	14	13	N/A	27	22	20
Situational awareness	69	58	67	56	44	57	50
Closed-loop communications	19	17	40	27	0	25	21
Shared mental model	44	33	40	50	25	17	36

These findings indicate that leadership and situational awareness were maintained at a better than 50 percent level across all stages. However, neither leadership transfer nor closed-loop communication reached an incidence level of 50 percent. At Stages 2 and 4, overall team behaviors were at their lowest. These two stages involved significant changes in task and reconfiguration of the teams. During Stages 3 and 4, where the emergent nature of the crisis was most evident, the overall team behaviors bumped up to nearly the 50 percent level. At Stage 5, team behaviors declined as the team prepared to move the mother to the operating room. In Stage 6, we observed substantial improvement in team leadership (from 36 to 64 percent) and closed-loop communication (from 0 to 25 percent).

Discussion

Critical event teams in health care face significant complexity and time pressures, which challenge safe patient care. Our findings indicate six distinct stages of team formation and reformation within an obstetrics emergency, during which team membership was fluid. Unlike with conventional teams, these findings show that the critical events teams for obstetrical emergencies were not constant. Regrouping occurred from one stage of care to another, assuring that the right personnel were available to do the right thing at the right time. These teams formed and reformed without the luxury of deliberate selection, lacking a shared history as a team, and exhibiting minimal stable team member composition within a single event or over several critical events.

The temporary nature of rapidly developing teams during a critical event creates difficulties in applying traditional leadership definitions. To accommodate their special nature, we emphasize

the importance of the leader as the person who is physically present and who prioritizes decisions, coordinates activities, and communicates a shared mental model. This was essential because in our study, only a leader who was physically present could establish a shared mental model effectively for the team. Without a shared mental model, team performance deteriorated, and safe patient care was jeopardized.

The only individual present at each stage in every simulation trial was the mother. This finding indicates that including the mother as a team member was an essential aspect of delivering patient-centered care,⁵ while using all resources available to the team³⁸ for ensuring safety and optimal care. To what extent this is fully recognized and utilized to the greatest patient safety benefit is an unresolved issue.

The findings show that one consistent leader was not present throughout the entire critical event. At each stage, leadership was established by different individuals on the team and transferred between team members in predictable ways. Leadership transfer occurred continuously throughout an obstetrics emergency. For example, in Stage 1, the primary nurse was always the team leader, and this leadership was transferred to the obstetrician upon entering the patient's room at the beginning of Stage 3. At this moment, the nurse was the leader with current situational awareness that had to be transmitted during the leadership transfer. Leadership was established in an "excellent" manner 58 percent of the time during these six stages of team formation and reformation, yet "excellent" leadership transfer was performed only 20 percent of the time.

The performance of these teams throughout the critical event was sporadic and uneven. The patterns of "excellent" team performance regarding situational awareness, closed-loop communication, and shared mental model were not consistently observed (overall average of 50 percent, 21 percent, and 36 percent, respectively). This lack of highly reliable performance could be a function of the complexity of the team dynamics in a critical event. Traditional team training theory is based on the assumption that teams train together until they achieve high performance. However, in critical events, the number of teams potentially needing training is impossibly large.

For example, Figure 2 shows that in the labor and delivery unit of one of the hospitals in this study, 208 total staff members made up the six categories. At least one person from each of these disciplines was called upon to participate as a member of a critical events team during an obstetrics emergency. This yields a total of *381 million possible combinations* of teams that could respond to a critical event, suggesting that any team consisting of the same individuals is very unlikely to happen more than one time and illustrating the impracticality of training each specific team combination until it achieves high performance.

Obstetricians	81	Total combinations of possible obstetrics teams = 381 million
L&D nurses	50	
Anesthesiologists	16	
NNPs	12	
Scrub techs	14	
CRNAs	35	
Total	208	

Figure 2. Staff in six categories and total team combinations for an obstetrics emergency.

Decades of research document a science of team performance and team training that is perhaps unknown in health care settings, especially among the medical staff.^{25, 39} These findings add to the large body of teamwork research into the nature and complexity of critical events teams in health care. The current study contributes a framework for new theoretical development regarding the nature of team formation and reformation in health care and leadership transfer that occur during each of these phases. Without a better understanding of team behavior in rapidly formed teams and the predictors of leadership transfer, improvements in patient safety and team training are hampered. These results stress the need for individual team members to possess competence in critical events-team behaviors, not just in team-related competencies.

Implications

Our study of rapidly formed critical events teams helps explain where certain team and leadership behaviors might fail.

- First, certain types of critical events teams do not have stable leadership, and the different leaders in the respective stages should know their responsibility for maintaining situational awareness, creating a shared mental model for the other team members, and transferring leadership. Unlike conventional teams, critical event team membership is not constant. The nature of team formation and reformation, combined with leadership transfer, requires substantially different training in team communication in order to improve closed-loop communication, maintain situational awareness, and sustain a shared mental model.

Many of the teams in health care do not meet the criteria of a stable team, and training curriculums for such teams should identify specific areas of team failures. The AHRQ TeamSTEPPS™ curriculum is a comprehensive team training resource. It has a number of specific training areas that can serve as effective countermeasures to the team failures found in this research.²³ A critical events team is a random collection of highly trained professionals, but they might not know each other, might not have worked together previously, and will likely never perform together again in exactly the same work team configuration. Although a critical events team might have a single physician who is responsible, the team structure and leadership configuration is far more complicated than the relationship between a single leader and multiple team members.

- Second, policies and procedures in hospital operating rooms are extensively developed for staff members, but our experience suggests that many are based on the assumption of conventional teams. Operating room policies and procedures might not take into account the various stages of formation and reformation that occurs with critical events teams, causing some policies and procedures to be ignored, forgotten, or not enforced. For example, policies for responding to latex allergy did not provide a means to ensure that the procedure was communicated and implemented during a critical event in the operating room.
- Third, these findings raise the question of what relationship exists between certain characteristics of critical events teams and patient safety. Improved patient safety requires an accurate understanding of team structure and flow at the microsystem level, so that effective interprofessional team training programs can be designed. We recommend more study to understand how critical events teams are different from conventional teams and what team training is needed for each.
- Fourth, hospital work environments might not acknowledge that critical events teams progress through various stages of team formation and reformation. Future research is needed on how to design hospital processes to improve the performance of critical events teams.
- Fifth, using *in situ* simulation, our research helps to better understand the nature and complexity of health care teams and to recommend effective countermeasures through improved team training. Simulation is also a powerful training tool, and applications of *in situ* simulation for training of critical events teams to improve communication should be explored to determine its effectiveness for this type of training. It is not enough to merely identify these behaviors; they also must be corrected by the critical events teams and avoided in the future.^{39, 40}
- Sixth, in conventional teams it might be possible that implicit communication is sufficient for team members to effectively communicate with each other. However, in critical teams, our observations show that implicit communication can be ineffective and possibly dangerous for patient safety. For example, we observed many instances in leadership transfer where the leader made certain assumptions that were erroneous.

Conclusion

We studied *in situ* simulations, rather than actual obstetric crises. Although we endeavored to achieve high fidelity, a simulation does not replicate every aspect of team behavior during a real crisis. During a simulation, “simisms” can arise, which require the participants to suspend disbelief. In addition, some participants might not engage fully in the simulation, which could affect the findings and lead to inaccurate or incomplete conclusions.

The stages identified in this research are based on behavioral markers that emerged from our study of the team formation and reformation patterns observed on the video tapes. These stages could be an artifact of the research design and need further validation by observing real emergency C-sections. In addition, these findings are based on behavioral markers that the researchers were able to observe. It is possible that certain behaviors occurred but were not

measured because of the limitations of our measurements. At the same time, more complications/crisis could occur in real life situations.

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Failure Modes and Effects Analysis Based on *In Situ* Simulations: A Methodology to Improve Understanding of Risks and Failures

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Abstract

Health care failure modes and effects analysis (FMEA) is a widely used technique for assessing risk of patient injury by prospectively identifying and prioritizing potential system failures. In this study, we conducted *in situ* simulations at a major suburban hospital as a novel method to discover latent conditions and active failures and to prioritize these based on the potential severity of risks associated with them. Process failures were analyzed for likelihood, severity, and discoverability of occurrence using the FMEA. We developed a high fidelity simulation by creating scenarios based on actual sentinel events. We then used an event-set model in the scenarios and conducted 10 simulation trials with 200 participants. These data were then categorized and used to create risk priority numbers as part of the FMEA process. Our findings allowed us to identify the primary failure modes and were consistent with the Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS™ training categories.

Introduction

Catastrophic patient injury often occurs because of an unanticipated sequence of active failures and latent conditions that are difficult to foresee.¹ Documenting and analyzing potential risks proactively are essential for improved patient safety. Accomplishing this goal requires an effective method to identify risks and an easily understood approach to manage risks.² In contrast to root cause analysis (RCA) and sentinel event analysis, which are carried out after an adverse event occurs, failure modes and effects analysis (FMEA) is used prospectively to identify possible system failures and to fix these problems to make the system more robust before an adverse event actually occurs.^{3, 4} An FMEA does not focus on a specific event, but rather on a specific process. An FMEA asks, “How could the system fail?” By contrast, an RCA asks, “Why did the system fail?” The analysis of a process that is already in place or one that is to be revised based on FMEA fulfills the Joint Commission accreditation requirement to conduct one proactive risk assessment per year.⁵

In this paper, we present a novel methodology to support the FMEA methodology. Our methodology uses *in situ* simulations in conjunction with the commonly used brainstorming activity of FMEA to proactively identify and assess the severity of risks and prioritize actions.

Our literature review indicates that no published study has ever reported the use of FMEA in conjunction with *in situ* simulation.⁶ Although we followed an FMEA model commonly used in health care, it was supplemented with extensive data derived from *in situ* simulations that uniquely help us understand and prioritize failure modes that might be otherwise unnoticed and unrecognized.

We begin by describing the basic features of FMEA. In FMEA, a multidisciplinary expert team (focus group) is assembled to meet regularly and identify the system risks using the FMEA process. The FMEA process includes five steps: (1) team selection, (2) process identification, (3) process flow diagram preparation, (4) failure mode identification and scoring based on risk priority numbers, and (5) determination of an action plan.⁶ A failure mode is an area where the process can break down and cause poor outcomes.⁷

The primary method used in FMEA to identify failure modes in Step 4 is brainstorming.⁷ Furthermore, risk priority numbers (RPN) are normally derived from expert opinion and statistical estimates and are not typically based on process interrogation under actual operating conditions to uncover and assess process failures. The weakness of this methodology is that assessment of potential risks and their underlying causes is based solely on domain experts' memories and knowledge.⁸ The process is employed remotely from the microsystem where patient care is provided and the risks emerge. To overcome this weakness, we undertook an innovative approach using *in situ* simulations in conjunction with the traditional FMEA.

The use of simulation in health care is becoming widespread and has been developed for numerous applications.^{9, 10, 11} Catastrophic patient injury often occurs because of an unanticipated sequence of active failures and latent conditions, which are difficult to foresee.¹ Such "sentinel" events can be understood by creating similar conditions and studying the team performance to understand the vulnerabilities and the failure modes. Unlike nonmedical industries, health care has no "gold standard" method for employing observations or audits to monitor and improve team processes and communication.¹²

In situ simulation occurs in a patient unit at the microsystem level and involves interdisciplinary teams and organizational processes. Unlike simulations that occur in a laboratory setting, *in situ* simulation is a strategy that takes place on a patient care unit.^{13, 14} This results in much higher fidelity because participants are challenged in their normal work environment, so that the simulation model mimics real world experiences more realistically.¹⁵ *In situ* simulation makes it possible to recreate stressful critical events in a safe situation, which may allow the multidisciplinary FMEA team to identify and prioritize potential failures in a patient care unit in a more comprehensive, systematic, and objective way.

We used *in situ* simulation combined with the traditional FMEA process to proactively identify and assess risks during emergency cesarean sections. We also discuss the advantages and disadvantages of the use of *in situ* simulations in conjunction with FMEA. We selected obstetrics for developing this *in situ* enhancement of FMEA because medical errors are common in the perinatal units. The landmark Harvard Medical study found that 1.5 percent of hospitalized obstetrics patients experienced an adverse event, and 38.3 percent of these adverse events were due to medical error.¹⁶ It is estimated that each year, approximately 22,980 adverse events are caused by medical errors in obstetric hospitalizations.¹⁷ RCA conducted by the Joint

Commission indicated that communication issues topped the list of causes for these sentinel events (72 percent), which prompted the Joint Commission to issue Sentinel Event Alert #30 “Preventing death and injury during delivery.”¹⁸ To target redesigns of care for improved safety, the risks of potential failures in perinatal units that could result in medical errors and patient injury should be systematically and comprehensively identified.

Methods

Setting

We conducted 10 *in situ* simulations in the labor and delivery unit of a full service, 390-bed Midwestern community hospital. This level II birthplace performs approximately 3,400 deliveries per year, with a C-section rate of 32 percent of total deliveries. The unit has 15 labor rooms, two operating rooms, a postpartum unit, and a level II neonatal nursery.

Participants

The *in situ* simulation trials involved two classes of personnel drawn from hospital staff: direct team members and indirect team members. Direct team members were informed about the *in situ* simulation ahead of time and agreed to participate in a particular simulation trial. We recruited direct team members, including obstetricians, labor and delivery and special-care nursery nurses, neonatal nurse practitioners, anesthesiologists, certified registered nurse anesthetists (CRNA), and operating room staff from the hospital for every simulation trial. Two people were recruited to play the roles of a mother and a significant other for each trial (confederates). During the briefing preceding each trial—direct team members were instructed to call upon any indirect team members, such as backup surgeons, blood bank, laboratory, and central supply personnel, as well as extra personnel, code teams, language interpreters, respiratory therapists, and others—to treat the patient, just as they would during a true obstetrics emergency. Indirect team members were included on an as-needed basis, only if drawn into the simulation by the direct team members. Each simulation trial included an average of 20 staff members.

In Situ Simulation Setup

Production of the *in situ* simulation required the use of a labor and delivery room, a fetal heart tone simulator (connected to our usual fetal heart tone monitor), a cervical dilatation box, a confederate playing the mother, other confederates as significant others, an operating room, and two manikins (SimMan[®] and SimBaby[®] by Laerdal). An artificial gravid uterus was made by enveloping a rubber baby toy in a plastic bag with water, sometimes colored red by gelatin (to mimic blood) or green by pea soup (to mimic meconium). This was then wrapped in fabric foam and taped to mimic the uterus. Finally, the “uterus” was placed on the manikin and covered with thin dark fabric to mimic skin. The normal paperwork from labor and delivery was used for documentation. Video cameras were placed in the labor and delivery room and also in the operating room to capture all interactions of the surgical and pediatric teams. A handheld video camera captured all events as the team traveled through the hallways from the labor and delivery room to the operating room.

The stationary video cameras in the delivery room and the operating room were wired to an observation room where nonparticipants—such as our debriefers, the FMEA team (core leadership team), and administrators—could monitor the simulation in real time. This served several purposes, including allowing debriefers to observe and identify active and latent failures in the simulation. It also allowed a simulation director to communicate wirelessly to the obstetrician and describe the operative field during the C-section as dictated by the scenario.

***In Situ* Simulation Scenarios**

Three scenarios based on actual sentinel events created collaboratively by an obstetrician and a clinical nurse specialist served as the basis for our *in situ* simulation trials. Each scenario was designed to prompt nontechnical team behaviors, such as leadership, shared mental model, situational awareness, and closed-loop communication.¹⁹ The scenarios included typical distractions—such as an overly inquisitive or rude significant other, a language barrier, talkative mother, lack of a prenatal record, and other factors that could interrupt team flow—so that the simulation team would be stressed by both the clinical and social aspects of the care.

Each simulation started with a briefing on labor and delivery, including a discussion of the simulation process, its limitations, and the importance of performing as one would normally perform during actual clinical care. Participants were told that observers were looking for teamwork and communication skills, not for technical skills. *In situ* simulations started with the nurse's first encounter with the patient, often walking into the room with the patient. Simulations averaged 45 minutes and typically included such factors as one nurse and the patient; two nurses and the patient; the addition of an obstetrician; taking the patient to the operating room for an emergency cesarean; entering the operating room; delivering the baby; a need for blood products; and neonatal resuscitation. Simulation typically ended after 10 to 15 minutes of neonatal resuscitation or until blood products reached the operating room.

Immediately after each simulation, the interdisciplinary team was debriefed on the following topics related to team performance:

- What went well during the trial?
- What did not go well?
- What could have been better?

Debriefing was facilitated by two experienced debriefers (one obstetrician and one clinical nurse specialist) and the video playback of the simulation trial. The debriefers stopped the playback at any juncture deemed important, such as after a communication lapse or loss of situational awareness, and the issues observed were discussed in detail with the participants. All participants were given an open opportunity to add comments before and after viewing the video playback. Debriefing typically lasted approximately 2 hours.

Conducting the FMEA Based on *In situ* Simulations

To conduct an FMEA on emergency C-sections, we used the six-step model developed by the Joint Commission:⁵ (1) identification of the process, (2) team selection, (3) description of the process, (4) listing and ranking of failure modes, (5) identification of root causes, and (6) determination of an action plan.

Step 1: Identification of the process. We focused on the emergency C-section process because it is a high-risk process with a large amount of variability in the teams that provide this emergent care. This presents a significant opportunity to improve patient safety for laboring mothers and to improve team performance during emergent, high-risk procedures.

Step 2: Team selection. We formed two separate types of teams for the FMEA analysis: a simulation trial team and an FMEA team. There were 10 interdisciplinary simulation trial teams, each consisting of an obstetrician, labor and delivery nurses, neonatal registered nurses, clinical nurse leader, birthplace manager, neonatal nurse practitioner, anesthesiologist, blood bank director, pharmacy manager, certified registered nurse anesthetist, operating room technicians, and numerous personnel drawn into the simulation from various support departments, including the laboratory, rapid response teams, and code teams. During the debriefing stage of the *in situ* simulation, these teams identified failure modes and their reflection of past failure mode experiences triggered by the simulation trial. The interdisciplinary FMEA team consisted of an obstetrician, clinical nurse specialist, birthplace director, neonatal nurse practitioner, and clinical quality consultant. This core team conducted the FMEA analysis based on the data from the simulation trials.

Step 3: Description of the process. The *in situ* simulation (briefing, simulation, debriefing, and debriefing of the debriefing) provided an intense framework for process mapping. The FMEA team studied the process by flow-charting the key process steps, identifying process weaknesses, and analyzing the data gathered from the debriefing phase of the simulation trial. While the flow diagram is an important tool to understand the process steps, it typically is created by a team that is removed from the core process in time and space.

Our process mapping was developed by the FMEA team based on three data sources: (1) the descriptions and analysis of the data obtained from the *in situ* teams at the end of each trial, (2) the detailed and in-depth studies of the video recordings of trials by the FMEA team, and (3) the data obtained through a focus group of the FMEA team. In other words, the process diagram was prepared not only from team members' prior experiences, but also from data collected during *in situ* simulations (recorded trials) and participating team members' recall immediately after each *in situ* trial.

The process mapping identified six major stages of the emergency C-section process: (1) admission of the mother to the unit and initial assessment by the primary nurse, (2) unfavorable changes in the clinical condition of the mother and fetus and arrival of the second nurse for help, (3) assessment of the mother by the obstetrician and the decision for an emergency C-section, (4) transfer of the mother to the operating unit, (5) operation, and (6) infant resuscitation.

Step 4: Listing and ranking of failure modes. Unlike the traditional FMEA, our failure mode identification was conducted in three stages. First, the FMEA team prepared a list of potential failure modes based on the common method of brainstorming. Next, this team reviewed the video recordings of the 10 *in situ* simulations, identified additional potential failure modes using a structured observation form (consisting of a list of known failure modes with room to add new failure modes), and revised the list of failure modes accordingly. Lastly, this revised list was supplemented with the failures identified by the interdisciplinary simulation trial teams during the debriefings. The participant debriefings were facilitated by experts and conducted using a

structured method to elicit team observations. This included reducing the authoritarian gradient between team members and use of the nominal group process techniques.²⁰

All observations were listed on flip charts for team discussion and later categorized according to specific types of active failures and latent conditions. This resulted in comments and feedback from approximately 200 individuals. The participant's identification of failure modes originated from the *in situ* simulation experience. In addition, we learned that the simulation triggered participants' reflections of past failure mode experiences, which they frequently identified during the debriefing. The FMEA team categorized the data from these 10 *in situ* simulation trials and then used this information as the basis for identifying potential failure modes and for developing risk priority numbers. The FMEA team also categorized each failure mode as either an active failure or a latent condition.¹ Next, based on the revised list of failure modes and the process flow chart developed in Step 3, the FMEA team assessed the potential effect of each failure mode on the emergency C-section process.

After developing a list of potential failure modes, the next step was to calculate a risk priority number (RPN) for each potential failure mode. An RPN is the quantitative estimate of the risk associated with each failure mode.⁵ FMEA teams assigned an RPN to each failure mode based on three factors: (1) its likelihood of occurrence (L), (2) its severity if it occurred (S), and (3) the detectability of the occurrence (D). The RPN was calculated using the formula: $L \times S \times D$, where high numbers indicated a high priority for intervention and action. Table 1 defines each of the three factors included in the RPN calculation and the rating scales associated with each factor.

Table 1. The factors included in the risk priority number calculation and their rating scale

Risk priority number	Definition	Description of the rating scales
Likelihood	The perceived chance of the failure happening within a defined period.	Rating of 1-10: from "failure is unlikely" (1 in >5 years) to "very likely or inevitable" (1/day).
Severity	How severe the outcome is to the patient should failure occur.	Rating of 1-10: from "no severity at all" (would not affect individual or system) to "moderate" (significant effect with no injury) to "major injury" to "death."
Detectability	Is the area of failure readily known, or is it discovered only when a bad outcome occurs?	Rating of 1-10: from "almost certain the control will detect potential cause(s)" to "absolute uncertainty that the control will not detect potential cause(s) and subsequent failure mode(s)."

Source: Joint Commission Resources 2005, and *Failure Modes and Effects Analysis (FMEA). An Advisors Guide*, June 2004; Department of Defense Patient Safety Center.

Step 5: Identification of root causes. Based on the RPN scores, the FMEA team prioritized and decided which failure modes to focus on for further investigation. Next, an RCA was conducted for each of these selected failure modes. The RCA was conducted based on the information obtained during debriefings, the FMEA team's review of recorded *in situ* simulations, and brainstorming sessions based on their personal experiences. Each failure mode, with its root cause, was listed in a chart as a summary from the debriefing data (Table 3). This allowed the FMEA team to visualize inter-relationships between process failures and group them into similar categories for action plans that were developed subsequently.

Step 6: Action plan. In this stage, action items were developed for the causes of failure modes.⁵ The RCA indicated two types of interventions: those that could be completed reasonably soon through rapid cycle improvement, and those that required extensive planning and interdepartmental collaboration. Immediately after each simulation trial, to prevent or mitigate failure modes, the FMEA team implemented changes that could be done easily with few resources and without delay using a rapid cycle improvement approach. In addition to these types of interventions, the FMEA team also developed an action plan that required extensive planning based on the traditional FMEA model. An action plan was developed for each failure mode that was identified as needing further action based on RPN scores. A single individual or a group of individuals at the institution responsible for completing or facilitating each action plan was identified and required to periodically report back on set due dates.

A unique feature of our action plan stage was that the effectiveness of the actions taken was re-evaluated in subsequent simulation trials. During followup simulations, we observed in real time and also gathered data from the *in situ* trial participants regarding the influence of any actions taken on the failure modes.

Results

Failure Modes

Results of the FMEA with *in situ* simulation are presented in Table 2. Ten failure modes were identified with RPN values ranging from 40 to 720 points. Five of the failure modes were categorized as latent conditions, and five emerged from active failures.

We distinguished between latent conditions that were created due to decisions at higher organizational levels (where unintended consequences can lie dormant for a long time until triggered by local conditions) and active failures, which are unsafe acts committed by those at the patient/provider interface.²¹

The highest ranked failure mode, with an RPN score of 720, was the “lack of identified and clear roles for team members in an emergency C-section.” The potential effect of this failure mode was identified as “confusion in task assignments” along with “uncoordinated and fragmented care.” This failure mode occurred in every simulation trial, and *in situ* participants repeatedly identified it as a source of poor team performance and recurrent potential for patient harm.

Table 2. Failure modes and effects analysis with risk priority number

Failure mode (What could/does go wrong)	Type of failure	Effect (Outcome from failure)	L	S	D	RPN
Lack of identified role for all team members in a Code C-section.	Latent	• Confusion in task assignment • Uncoordinated and fragmented care	10	8	9	720
Inconsistent process of ordering and receiving blood products and lab results	Latent	• Delay in receiving blood • Mismanagement of clinical situation	10	10	7	700
Lack of closed-loop communication with lab/blood bank	Active	• Delay in receiving blood • Inefficiency of care	10	10	6	600
Nonstandardized communication between RN, OB, and NNP regarding clinical status	Active	• Mismanagement of clinical situation	8	8	9	576
"Dead spaces" noted when Code C-section is called overhead	Latent	• Delay in personnel arriving to the Code C-section	10	9	5	450
Failure to use common language in calling Code C-section	Active	• Delay in personnel arriving to the Code C-section	4	5	9	180
Drugs for treatment of hemorrhage are not located in same place	Latent	• Delay in treatment	10	8	1	80
Anesthesiologist in OR not able to talk directly with the lab/blood bank	Latent	• Delay in receiving blood • Mismanagement of clinical situation	10	4	1	40
Neonatal resuscitation needs not standardized among NNPs	Active	• Variability in care • Delay in care	5	8	1	40
Interpreter services utilized in variable ways	Latent	• Delay in receiving information • Patient rights delayed	8	5	1	40

L = likelihood; S = severity; D = discoverability; RPN = risk priority number; C-section = cesarean section; RN = registered nurse; OB = obstetrician; NNP = neonatal nurse practitioner; OR = operating room.

The next highest ranked failure mode, with an RPN value of 700, was the “inconsistent process of ordering and receiving blood products and lab results.” Again, this failure mode occurred in every simulation and resulted in delays in receiving blood and/or critical lab results with subsequent mismanagement of the clinical situation.

The third highest failure mode ranking, with an RPN of 600, was the lack of closed-loop communication between the operating room and the blood bank. The participants of every simulation identified this failure mode. Although the second and third failure modes both deal with delays in receiving blood for transfusions in a timely manner, an important distinction was recognized regarding the type of failure by the participants. Specifically, lack of closed-loop communication was identified as an active failure, but an inconsistent process to order blood was considered a latent condition. These three failure modes reflected 59 percent of the total RPN values calculated for the entire FMEA (2,020/3,426 points). They required extensive action plans, while the remaining seven failure modes were remediable with more immediate rapid-cycle action plans.

Root Cause Analysis

The RCA of the failure modes by the FMEA team identified three common causes of error: (1) staff misunderstanding of policies/procedures and roles during emergency C-sections, (2) interdepartmental or intrateam communication issues, such as not having a standardized, common language and other human factors, and (3) institutional process failures, such as poor logistics, equipment failures, and poor policies/procedures (Table 3). This categorization allowed the FMEA team to better understand how an action plan could be developed for each failure mode.

The delay in blood getting to the operating room during a maternal hemorrhage deserves further mention and serves as a more specific example of our results. The simulation provided invaluable information regarding this important process that might have been missed with routine FMEA.

The simulation participants’ comments revealed the process to order and draw labs and receive results depended on (1) the obstetrician remembering five different necessary labs (type and screen), hemoglobin, platelets, fibrinogen, and International Normalized Ratio/Partial Thromboplastin Time; (2) the circulator taking the order and calling the health unit coordinator at a desk remote from the operating room to put the order into the computer; (3) the lab technician responding to the operating room to draw the labs and return them for analysis; and (4) the paperwork being completed with correct instructions, or the results could be called in to the main labor and delivery desk and not into the operating room. Routine FMEA and process mapping could determine all of the above.

However, our simulation revealed that successful completion of this process also required closed-loop communication at many different critical junctures (communication). The process of ordering blood was inconsistent between simulations, and confusion existed around the policy and procedure for ordering labs and blood while in the operating room (staff misunderstanding). This process was complicated by the poor placement of the operating room phone, which was distant from the anesthesiologist (poor logistics). Thus, this one process had all three causes of

error present and required simulation to develop a more complete understanding of the failure modes. This understanding would not have been possible with routine FMEA.

The debriefings also exposed staff misunderstanding of the time requirements for blood products to become available. Many staff members did not realize that it would take 40 minutes to obtain type-specific blood, much longer than they thought. Impatient, the operating room teams repeatedly asked, “Where is the blood?” often making frequent calls to the blood bank to repeat that they needed “2 units” of blood. The blood bank personnel often wondered, “Do they need 2 units or is it now 4 units?” One lab technician succinctly summed up the problem in the debriefing, “You called four different times for 2 units of blood, so did you want 2, 4, 6, or 8 units?” Finally, once a blood product was ordered correctly and the blood bank was ready to release the product, no person was assigned (lack of role definition) to retrieve the product. Often, the blood bank assumed that the operating room would be sending someone, and the team in the operating room assumed that the blood bank would be sending the blood, neither of which occurred. The need for clear training, role clarification, and consistent communication regarding the timing of blood products and retrieval of blood products would not have been apparent from routine FMEA carried out remotely from the clinical site.

Action Plans

Rapid-Cycle Improvement

Immediately following each simulation, the hospital instituted numerous interventions to the labor and delivery unit that could be achieved easily with few resources and without delay. Some examples include moving the telephone to the head of the operating room table for direct access by the anesthesiologist; renaming the operating rooms to avoid confusion during an emergency C-section; initiating immediate point-of-care education for staff about how to call the interpreter on the phone, rather than wait for them to arrive on site; and having engineers do a site review to find out where dead zones existed in the hospital for the overhead paging system. Most of these changes were completed within a week.

Extensive Planning

Action plans that required extensive planning involved failure modes that had high RPN numbers. A multidisciplinary team composed of obstetric and other hospital staff met regularly and was held accountable with timelines. The second highest ranked failure mode, “inconsistent process of ordering and receiving blood products and lab results,” had an action plan that required extensive planning with personnel from other departments.

A multidisciplinary team including a pathologist, lead lab technician, clinical nurse specialist, obstetrician, and anesthesiologist developed an “OB hemorrhage panel.” A pre-formatted form was designed on bright lime green paper so that RNs or MDs could order a standard set of labs and blood products for the mother or the baby during an emergency. This paper form is now kept in a zip-lock bag with three blood tubes on the wall in the operating room near the anesthesia table. The paper form has a checklist format and includes the standard orders, instructions

Table 3. Results of root cause analysis

Rank	Failure mode (What could/does go wrong)	Type of failure	Effect (Outcome from failure)	Root cause/action	Accountable person
1	Lack of identified role for all team members in a Code C-section.	Latent	• Confusion in task assignment • Uncoordinated and fragmented care	• No clear pre-assigned roles for each person entering OR during a code • Process map of a person time sequence & task required with assignment	• Manager of LD • Clinical nurse leader • OB MD quality lead
2	Inconsistent process of ordering and receiving blood products and lab results	Latent	• Delay in receiving blood • Mismanagement of clinical situation	• Interdepartmental process failure and lack of assigned task for ordering, communicating with BB labs, blood product for mom and baby, and how to retrieve results/products • Developed "OB hemorrhage panel" order-set with pre-assigned tasks and instructions	• Clinical nurse leader • Director of blood bank • OB MD lead
3	Lack of closed-loop communication (CLC) with lab/blood bank	Active	• Delay in receiving blood • Inefficiency of care	• Lack of knowledge; What is CLC? How is it done? Need to speak directly to someone; could not ID the RN who was the circulator, because all personnel wearing same blue scrubs with mask. • Purchase of red hats for circulator to provide a visual clue as to which RN can take order. New online education re: CLC.	• Clinical nurse leader • OB MD

C-section = cesarean section; OR = operating room; LD = labor and delivery; OB MD = obstetrician/physician; BB = blood bank; CLC = closed loop communication; ID = identification; RN = registered nurse

regarding timing for all blood products (when they can be expected), a place to circle a call-back phone number for the operating room, and instructions to send a runner to the lab to retrieve the product. Since no other form is lime green, it communicates the message that this particular order is “STAT” and therefore should have the highest priority in the lab. When experiencing a maternal hemorrhage, the RN or MD needs only to order an “OB hemorrhage panel,” and there is no need for the RN or MD to remember which labs to order. The blood bank is put on notice immediately as to the clinical situation, and the OR team has a reminder on how long blood products will take, and that a runner needs to be sent for blood.

Discussion

A number of research approaches can be used to identify risks and hazards in patient safety, including medical records, administrative databases, event reporting, direct observation, process mapping, focus groups, probabilistic risk assessment, and safety culture assessment.²² However, the use of *in situ* simulation to supplement FMEA has not yet been done. New methods of research are needed to improve methodologies for identifying potential system failures and estimating error rates.²³ Understanding patient safety risks and hazards is an important outcome for health care organizations that study safety events.²⁴

Advantages of *In situ* Simulation in Combination with FMEA

The application of *in situ* simulation data provided a more objective, comprehensive, and systematic way to identify potential system risks in emergency C-section processes and resulted in a more realistic list of potential active and latent failures. The *in situ* teams identified six failure modes categorized as latent conditions, some of which resided dormant on our labor and delivery desk for many years (for example, the operating room phone being situated out of the anesthesiologist’s reach was a work-around for 40 years).

Four of the failure modes were active failures. Whenever possible, the action step plans developed by the FMEA team were implemented immediately to provide prompt feedback to the teams and microsystem that identified the process failures. Unlike typical FMEA approaches, the *in situ* simulation allowed us to evaluate the effectiveness of the rapid-cycle action steps in subsequent *in situ* simulations.

This new methodology allowed for more open discussion of failure than a typical RCA environment because the guilt, shame, and embarrassment of a recent failure resulting in patient harm was not a factor. Compared to other risk assessment methodologies, a unique advantage of the *in situ* simulation is the safe environment it creates in which health care scenarios—developed based on sentinel events—can be replicated and videotaped. Undetectable failure modes present a higher risk to patient safety than others modes.⁷ *In situ* simulation facilitates the RCA of high RPN failure modes because it allows for more open discussion and encompasses more staff input for understanding failure and its causes.

In situ simulation gives observers a real-time visualization in which to observe both failure modes and the effects of failure at a moment in time. These critical junctures in time, which are important to the patient care process, are much more vivid and analyzable in *in situ* simulations. Both the failure mode and its effects can be immediately analyzed to appreciate how they

influence team performance and possibly result in patient injury. *In situ* simulation views the failure mode in its normal context of place and time.

Using *in situ* simulation, the process diagram was not flow-charted from memory; it was experienced and recalled by the participants immediately after a simulation trial. Through the use of simulation, we were able to systematically interrogate the process to uncover process failures that otherwise would continue to be unknown and undiscovered, remaining dormant until involved in a patient injury.

FMEA with *in situ* simulation permits the evaluation of teamwork and communication skills and provides a concurrent internal audit from staff as to the fidelity of the experience. It links both latent conditions and active failures that are typically not identified in FMEA. One of the prevailing themes of these 10 failure modes was poor team performance.

The foremost action plans included advanced team training using the AHRQ TeamSTEPPS™ training curriculum. Such action plans are not typically found in FMEA-only approaches. Because of this ability to see human factors at important times in patient care, we have found more failure modes than usual. The *in situ* simulation helps us understand team training and performance at a moment in time. Time-dependent communication is appreciated by staff and observers, and the debriefings make its relationship to potential harm apparent. By identifying communication issues, *in situ* simulation helps address the concerns of the Joint Commission's Sentinel Event Alert #30, "Preventing death and injury during delivery."¹⁸ RCA conducted by the Joint Commission indicated that communication issues topped the list of causes for sentinel events at 72 percent.

The advantages of using *in situ* simulation for detecting risk as discussed in this study can be summarized as follows. It is a prospective method used by an interdisciplinary team to uncover and analyze process failures on a care unit and thereby identify and rank failure modes in a way that realistic actions can be taken to create countermeasures for patient safety. Unlike conventional FMEA analysis, the failure modes are isolated by stressing the process in a way that can only be done during an actual emergency, when process failures usually result in creative workarounds to address the problem of the moment rather than deliberate system improvement.

Limitations of *In situ* Simulation in Combination with FMEA

There are several disadvantages of applying *in situ* simulation for FMEA. First, administrative support is required for supplies, equipment, and human resources. Second, *in situ* simulation is time-intensive for both participants and facilitators. Third, it can create confusion for other departments that are drawn into the simulation. Fourth, it can cause disruption in the patient care unit.

Cost is certainly a factor, but as simulation becomes more commonplace, efficiencies will occur. A Hawthorne effect is certainly possible among the participants; they were aware of being watched and filmed. However, despite this knowledge, many process flaws and team failures were identified. Health care workers, even on their best behavior, are not perfect.

Finally, this methodology has not been compared with results from the traditional FMEA technique. The next step in validating the FMEA using *in situ* simulation is to prepare a process map and RPN of the same process with both techniques. This comparison would help to determine which features are identified by the *in situ* simulation in contrast to FMEA without this technique.

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The Mobile Mock Operating Room: Bringing Team Training to the Point of Care

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Abstract

Objectives: We examined the effectiveness of an innovative mobile mock operating room (MMOR) configuration to support realistic interdisciplinary operating room team training implemented at the point of care. **Methods:** The MMOR, created and used to support the System for Teamwork Effectiveness and Patient Safety (STEPS) training program, included a portable high-fidelity, computerized mannequin; an inanimate surgical procedure model; software for simulating mannequin responses; and a computer-based video recording system. Evaluation was based on direct experience with the MMOR and participants' responses to a questionnaire. **Results:** Participants perceived the MMOR as a realistic training environment. Feasibility and effectiveness were further supported by the research team experiences. **Conclusion:** The MMOR contributes to quality training at the point of care. Results suggest that our MMOR model may be useful for supporting simulation-based training in other high-risk settings where effective team functioning is particularly important (e.g., emergency room, intensive care unit).

Introduction

The operating room (OR) is a dynamic work environment in which effective team interactions are critical to safe delivery of care. In this high-risk setting, lapses in teamwork can potentially lead to adverse patient outcomes. Promoting teamwork competencies characteristic of highly reliable teams is essential to ensure the proper and efficient coordination of OR team activities. They include open communication, adaptive response, and the use of a shared mental model.¹ Without such synchronization among members, care within the OR can become disjointed and haphazard.

Today, team interactions in the OR are characterized more by disruptive behaviors² than by the smooth delivery of care. The marked differences in the background of the various disciplines lead to misunderstandings.³ The resultant lack of role clarity^{4, 5, 6} and poor communication⁷ can hinder effective teamwork. In addition, OR team members may not necessarily agree on their perceptions of rules and guidelines within an OR.⁸ Team members often lack insight into their own strengths and weaknesses regarding teamwork abilities.^{6, 9} Consequently, there is considerable variability among disciplines in OR teams regarding what constitutes high quality teamwork.^{6, 9, 10, 11}

Improving teamwork in health care has become a national priority. The Institute of Medicine (IOM) has established the ability to work in interdisciplinary teams as one of its core competencies for health care professionals.¹² In addition, The Joint Commission has emphasized the importance of team training in its patient safety curriculum for institutions.¹³ Finally, the Agency for Healthcare Research and Quality (AHRQ) has sponsored research aimed at defining the current relationship between medical teamwork, team training, and patient safety.¹⁴ AHRQ has even collaborated with the Department of Defense to create TeamSTEPPS™—an evidence-based team-building program designed to promote teamwork skills in health care.¹⁵

High-fidelity simulation (HFS) can be used effectively to create immersive, realistic training environments that are ideal for practicing teamwork skills.^{16, 17} In contrast to real life situations, HFS supports a low-risk teaching and learning environment conducive to reflective and deliberate practice with feedback, making it an ideal teaching tool.¹⁸ Although crew-based training of particular disciplines within the OR is well established,^{19, 20, 21, 22} the current literature has relatively few examples of true interdisciplinary training of entire OR teams.^{23, 24, 25} To date, examples have been limited to single-site training at large academic centers that have affiliated tertiary hospitals.

Based on our prior experiences with HFS-based teaching and learning, we created in 2004 a Virtual Operating Room (VOR) model to support truly interdisciplinary teamwork training. Initial pilot testing of this approach for OR teamwork training occurred in August 2005. Participants' feedback revealed high receptivity and effectiveness for teaching, learning, and practicing interdisciplinary teamwork skills in the OR.²³ However, time away from the work setting and the need to travel to and from remote sites for training were obvious factors that could hinder full participation of an interdisciplinary team member in training.

Building on our initial center-based model, we adapted the VOR to facilitate taking training to OR teams, rather than requiring them to come to the learning center. We developed a mobile mock operating room (MMOR) configuration to support simulation-based training at the point of care in geographically diverse settings.

Our initial full scale use of the MMOR was in the System for Teamwork Effectiveness and Patient Safety (STEPS) program that was funded, in part, by AHRQ. This article describes the results of testing of the MMOR in two hospitals located 80 miles apart. We hypothesized that the MMOR could be used easily to support standardized implementation of the STEPS training sessions in actual ORs. As a result, participants would perceive the training sessions as realistic and effective learning environments for teaching, learning, and practicing teamwork skills.

Methods

In this section, we describe the development and refinement of the MMOR and its component features. We also briefly describe how the MMOR was used to support the STEPS training sessions in actual ORs. Finally, we describe the evaluation methods used to examine the feasibility and effectiveness of the MMOR for implementing high quality simulation-based training at the point of care.

Prior to implementation, we obtained institutional review board (IRB) approval at an exempt status, as part of a larger research protocol targeting simulation-based training and assessment. While similar approval was not required by the hospital-based research and compliance officers, we initiated and maintained open and ongoing communications with these individuals to facilitate positive relationships and cooperation.

Mobile Mock Operating Room Design

The MMOR is an adaptation of the previously described virtual operating room (VOR) concept that we established at the Isidore Cohn, Jr. MD Learning Center on the main campus of the Louisiana State University Health Sciences Center in New Orleans.²³ Key considerations in adapting the VOR to an MMOR configuration included easy and efficient transport, set up, use, breakdown, and storage. To create an authentic clinical environment for training sessions, major features of the MMOR included:

- A portable mannequin capable of simulating physiological responses.
- An appropriate anatomical model for performing a surgical procedure.
- A software interface for enhancing mannequin responses in clinical scenarios.
- A realistic patient scenario.
- A portable, compact, computer-based system to record training sessions and support easy playback of selected video segments in debriefing and teaching discussions with teams immediately after their scenario-based experiences.

MMOR setting. We designed the MMOR to fit within a typical OR and to create an authentic clinical environment for training at the actual point of care. Ideally, this space should be an actual operating room, but any available room of adequate size located near the OR department could be configured to simulate an OR (e.g., an endoscopy or minor procedure suite).

Easy transport and use of the MMOR was facilitated by the hospital providing all surgical and anesthetic equipment and supplies. This allowed participants to perform routine tasks associated with surgical patient care (e.g., prepare and drape the mannequin like a real patient). Additionally, the realism of the training environment was enhanced by participants' access to their own instruments, monitors, surgical towers, and other accessories for the scenario. Situated in an actual OR (or an adapted room nearby), participants already knew which additional items were available and where to access them as needed for managing patient care during training, just as they would in a real patient case.

To minimize expense and use of resources, we salvaged and re-used consumable materials whenever possible for multiple training sessions (e.g., we used the same patient drapes for multiple scenarios and recycled any disposable instruments throughout the training period). Depending on the focus of training, other case- or procedure-specific equipment and supplies might be needed. For this study, each of the four training scenarios we used involved a patient undergoing a laparoscopic cholecystectomy. Therefore, each hospital also provided a laparoscopic surgical tower with camera, light source, and insufflator, as well as a complete open cholecystectomy instrument set with selected laparoscopic instruments.

For the current study, we used actual operating rooms for all STEPS training sessions at both hospitals. Because the MMOR situates training in the actual patient-care environment, training sessions could be scheduled as actual patient cases. Thus, the MMOR was assigned to an OR, just as actual cases were assigned. For example, over a month-long period, the MMOR was assigned to several ORs in each hospital's department. Participants scheduled for training were then assigned to the OR where the MMOR was located, just as if they had been scheduled for an OR for managing patient cases on a particular day. In keeping with our STEPS training program, all training sessions were scheduled during regular daytime elective surgery hours to maximize convenience and opportunity for all OR staff, anesthesiology staff, and general surgery residents and staff participants.

MMOR simulator equipment. As shown in Figure 1, the MMOR for this study consisted of the actual OR setting and equipment mentioned previously, in addition to a portable computer operated mannequin and an inanimate cholecystectomy model to support the specific patient scenarios developed for the STEPS training sessions. Taken together, these simulators provided a



Figure 1. The two main components of the MMOR simulator equipment include a portable computerized mannequin combined with an inanimate cholecystectomy model. The mannequin rests on the OR table with the cholecystectomy model at the foot of the bed. The mannequin control box is placed underneath the OR table and is connected to the computer via an Ethernet cable (lower left) and an air compressor via tubing (middle right).

platform for the interface between the OR team and “patient” during a simulated surgical procedure and managed the unfolding scenario in which the full participation of each team member was necessary.

We placed the portable Medical Education Technologies, Inc. (METI, Sarasota, FL) Emergency Care Simulator[®] (ECS) mannequin on the OR table and connected it to the control box situated below the OR table. The control box was connected via an Ethernet cable to a laptop computer located in the corner of the OR. In addition, the ECS was attached via specialized tubing to an air compressor placed just outside the OR. The computer was also connected to another monitor placed at the head of the bed to display the mannequin’s vital signs and serve as the anesthesia machine monitor during the scenario. We were careful to place the laptop computer in an unobtrusive location, but we made sure that the operator was still able to easily see and hear team performance throughout the training session. Because the compressor is noisy, placement just outside the OR was necessary to minimize sound interference.

The computer-driven software that accompanies the ECS allows it to mimic physiologic responses to team interventions, medication administration, and treatments. In addition, the air compressor enables it to open and shut its eyes, breathe, alter airway size, and maintain palpable pulses. The ECS can support several procedural interventions: endotracheal tube intubation, chest tube placement, intravenous line placement, and urinary catheter placement. Such capabilities make it ideal for simulating different types of patients.

We enhanced the responsiveness of the ECS to various clinical scenarios using the Clinical Model, a proprietary (patent pending) software interface designed by Drs. Kozmenko and Hilton. This software enhances the extent to which the mannequin, as a patient, responds preoperatively to OR team members and perioperatively with appropriate and spontaneous physiologic reactions to actions taken by the team during the surgical procedure. The software interface enhances the realistic progression of patient scenarios during training sessions, contributing to the psychological fidelity of training (i.e., it enhances suspended disbelief).

Because the cholecystectomy model could not be optimally placed in or on top of the mannequin’s abdomen, we chose to remove the mannequin’s legs and place the model at the foot of the OR bed. This strategy enhanced overall placement, and the altered state of the mannequin did not seem to interfere significantly with the realism of the MMOR configuration. In this location, the scrubbed OR team members could assemble around the OR table to operate, just as they would in a real life case. The arrangement of the mannequin and procedure model allowed the major steps of a gallbladder removal to be performed: accessing the abdomen, identifying and dividing the cystic artery and duct, and removing the gallbladder from the liver bed.

Of note, two separate inanimate trainers were used for this study. At the first hospital, we used the Minimal Access Therapy Technique (MATT) Trainer[®] (Limbs & Things, Bristol, UK) that housed a gallbladder replica. When we were ready to implement the MMOR for STEPS training at the second hospital, the MATT trainer was no longer available, so we substituted for it with the Simulab Torso Trainer[®] (STT) (Simulab Corporation, Seattle, WA) containing a laparoscopic cholecystectomy model. The STT has a replaceable outer skin through which laparoscopic ports can be placed. The inner cholecystectomy model of the STT consists of a mold depicting the

upper abdomen with a detachable gallbladder representation in the liver bed. This disposable gallbladder replica contains both a cystic artery and biliary drainage system. The cystic artery and duct can be dissected free from surrounding tissues, clipped, and divided during the course of the scenario. The gallbladder itself can then be removed off the liver bed and extracted. Figure 2, shows the MMOR configuration being used in a STEPS training session that included the ECS and SST in an actual OR.



Figure 2. A mobile mock operating room scenario in progress. The surgeon (second from right) looks at the monitor as she explores the abdomen with a laparoscope with the scrub technologist (left foreground) assisting her. The nurse anesthetist (right) observes from the head of the bed as the circulating nurse (left background) works. The draped mannequin's vital signs are displayed on the monitor at the head of the bed.

MMOR scenarios. The Clinical Model software interface uses preprogrammed algorithms in patient scenarios that cause the mannequin to respond appropriately and spontaneously to the decisions and actions of the OR team.²³ In this manner, the team's decisions and actions directly influence the mannequin's outcome and minimize outside operator intervention that sometimes interrupts participants' suspended disbelief during training. Figure 3 shows a simple example of a Clinical Model algorithm for a particular scenario.

As mentioned previously, four authentic patient scenarios involving a laparoscopic cholecystectomy were created and used for training sessions in this study. Each scenario

involved one of the following intraoperative critical events to act as a catalyst for team interaction and response: onset of malignant hyperthermia, unstable cardiac arrhythmias, anaphylactic shock, or septic shock. All four scenarios also contained specific opportunities for team interaction that occurred regardless of the team decisionmaking. For example, the mannequin experienced bradycardia in response to initial establishment of pneumoperitoneum in each scenario. Two scenarios were selected for use in each STEPS training session. Their selection was based on minimizing participants' exposure to repeating scenarios.

MMOR recording and playback system. We designed a compact, streamlined video recording and playback system to chronicle each scenario. Our experiences quickly taught us that, not only was space at a premium in the OR, but it was a critical logistical factor for both transportation and storage of the MMOR. Our system included a computer-based video camera with a built-in microphone, the iSight® (Apple, Inc., Cupertino, CA) that provided very good quality video and audio recording. Consequently, individual microphones for each participant were not necessary, which simplified the preparation and saved valuable time and storage space. A magnetic base on the camera allowed us to attach it to an intravenous pole located in the corner of the operating room next to the computer.

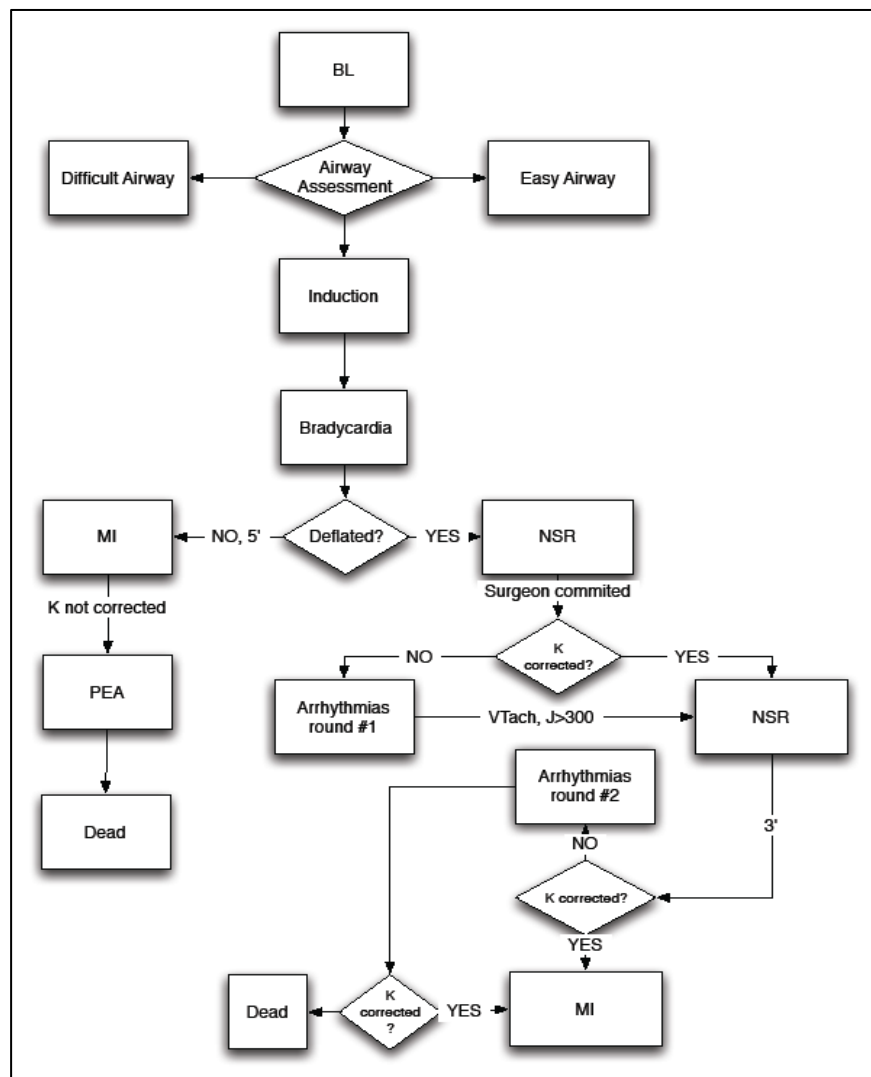


Figure 3. Example of a scenario algorithm used for an MMOR session. The patented software interface supports the development of physiologically complex scenarios involving the mannequin. BL = baseline; MI = myocardial infarction; PEA = pulseless electrical activity; NSR = normal sinus rhythm; K = potassium; VTach = ventricular tachycardia; J = Joules. Copyright pending. Source: Paige J, Kozmenko V, Morgan B, et al. J Surg Educ 2007; 64(6): 369-377. Used with permission.

Video recording and playback was accomplished using Wirecast[®] computer-based video recording software (Vara Software, Poole, UK), an easy-to-use and inexpensive solution that included several features that were important for achieving an effective MMOR configuration. For example, Wirecast can be used to record several data inputs simultaneously (e.g., a room view of the OR team and a view of the vital signs monitor). As soon as the video is recorded, Wirecast formats these data to support a split screen video display, making multiple video views available immediately after a training scenario for use in a debriefing discussion.

In addition, the software includes a bookmarking feature that is quick and easy to use for identifying specific segments that one might choose to highlight in a debriefing discussion. A split screen playback of the two views can then be used in the debriefing discussion to examine team actions and “patient” reactions (and vice versa) during the after-action debriefing and teaching session. Compared with other solutions, our system was very compact, inexpensive, unobtrusive, and easy to use. We found it to be highly reliable in terms of function and quality of video and audio recording and playback across the various ORs in which it was used.

Training Design

As mentioned previously, the MMOR configuration was a major factor in our ability to implement STEPS training sessions that were designed to conduct interdisciplinary OR team training in unique OR departments of geographically diverse hospitals. Half-day training sessions were embedded within the everyday work environment of two busy OR departments that varied physically, organizationally, and culturally in many ways. True interdisciplinary OR teams that work together on a regular basis participated in STEPS training in their own ORs.

In January 2007, pilot testing was carried out at a 179-bed public hospital affiliated with an academic health center. It targeted MMOR portability and technical function, while also testing the STEPS training scenarios and teaching methods. Although the hospital was within walking distance of our center-based simulation programs, issues related to technical function, transportation, set-up, and breakdown logistics were essentially the same as if the hospital had been located 100 miles away.

Full-scale implementation of the MMOR was achieved in March 2007, at a 157-bed public hospital, also affiliated with an academic health center located 80 miles away from our center. This academic health center was the targeted training site for the first year of the STEPS program, which was funded in part by AHRQ. Within 1 month, half-day training sessions were completed to accommodate every member of the OR and anesthesia departments, as well as the general surgery attending staff and all of the general surgery residents rotating at the hospital that month. Few refinements were necessary after pilot testing, so the MMOR configuration, training content and format, measures, and participant composition were very similar at the two hospitals.

Training format. Prior to implementing the training sessions, a general orientation to the simulation equipment, STEPS program, and scenario ground rules was conducted with all participants in a general session. Individuals had an opportunity to interact briefly with the simulator and to learn about its capabilities (and limitations).

For full-scale implementation at the second hospital, orientation was accomplished with a department-wide general session and informal opportunities to “meet” the simulator and ask

questions about the project activities. Each half-day training session began with a brief introduction that revisited simulator function and ground rules for scenarios (e.g., behavioral expectations, confidentiality of training experiences, and security for content of training scenarios). Each training session lasted up to 3 hours and included two simulation-based scenarios, each followed by an after-action debriefing discussion.

Within the training session, each scenario was introduced and initiated by giving the team the patient chart and instructing them to proceed as they would with a real patient. During debriefing discussions, the facilitator used video playback as needed to facilitate reflection on critical events and behaviors as they related to key teamwork competencies and strategies for improvement. While the MMOR could be managed by just two people, we found that a three-member training team worked best. The team included the following roles: a programming expert/mannequin operator, a training (scenario and debriefing) facilitator, and an observer and data collection manager.

Training participants. For the pilot training sessions, teams were volunteer OR and surgical staff, residents, fellows, and students. If a particular discipline was not available, a substitute from another discipline was used (e.g., surgical technologists played the circulating nurse role on two occasions). For full-scale implementation of the STEPS program at the second hospital, the entire OR, general surgical, and anesthesiology staff members and general surgery residents participated in the training. At each session, a representative from each profession was present. A typical team included a general surgery resident, circulating nurse, nurse anesthetist, and surgical technologist. When one of the three general surgery attending staff participated, he/she was paired with a lower level resident [i.e., postgraduate year (PGY) 1 or 2]. Anesthesiologists were available on call into the room during every session, as was typical of their role in everyday practice in the OR department at this hospital.

Evaluation methods. Participants voluntarily completed confidential pre- and post-session questionnaires related to a variety of training features and self-efficacy for teamwork competencies. Individuals were given instructions to generate a record identification code that was used only to match pre- and post-session questionnaires. For the study addressed in this article, only one scale comprising seven items on the post-session questionnaire was related to participants' perceptions of the MMOR configuration for supporting realistic and effective training.

Training participants responded to each item using a 6-point Likert-type response scale (1 = Definitely no to 6 = Definitely yes). Responses were compiled and analyzed after completion of the training sessions at a hospital. Item frequency counts, item mean scores, and standard deviations were calculated. Participants' perceptions were compared for each hospital training site based on a t-test of item means. Evaluation of the feasibility and effectiveness of the MMOR configuration was also accomplished through reflection on experiences and direct observations of actually transporting and using the MMOR to support the STEPS training sessions at the two hospitals.

Results

Data were available for analysis from the last three of five pilot sessions conducted at the first hospital (17 respondents) and all 11 sessions conducted as part of the STEPS program at the second hospital (38 respondents). Disciplines represented in the pilot sessions included upper level general surgical trainees (i.e., PGY level 4 and above), nurse anesthetist staff and students, circulating nurses, and surgical technologists. At the second hospital, all members of the OR and anesthesiology departments and all general surgery attending staff and residents participated in the STEPS training sessions and completed questionnaires.

Table 1 shows each of the seven item statements and summarizes descriptive statistics and results of t-test comparisons. All but one of the item mean scores were >5.0 on a 6-point Likert-type scale. Results obtained during pilot testing at Hospital 1 revealed that item means ranged from 5.00 (Item 5) to 5.56 (Items 2, 6, and 7). For Hospital 2, where STEPS was fully implemented using the MMOR configuration, item means ranged from 4.89 (Item 4) to 5.76 (Items 6 and 7). Only one item mean score was <5.00 (Item 4, mean = 4.89). It was obtained at the second hospital and was related to the extent to which participants experienced the phenomenon of “suspended disbelief” during training scenarios. A review of the individual item statements and corresponding results revealed that participants perceived the training sessions to be realistic, valuable, and effective for examining and enhancing teamwork and patient safety practices.

Table 1. Participants’ feedback on authenticity of the simulation training model

Item statement	Mean ^a (± SD)		P value ^b
	Hospital 1 (n = 17)	Hospital 2 (n = 38)	
1. The physical setting of the training was realistic	5.44 (0.63)	5.39 (0.72)	0.84
2. Patient scenarios reflected realistic situations that teams might face in OR	5.56 (0.51)	5.50 (0.76)	0.77
3. Scenarios were effective for examining teamwork and patient safety practices	5.44 (0.63)	5.68 (0.47)	0.12
4. During scenarios, I momentarily forgot about simulation and acted as if the situation were real	5.13 (0.96)	4.89 (0.92)	0.41
5. The composition of the OR team reflected what I experienced in the real life setting	5.00 (1.10)	5.45 (0.76)	0.09
6. Overall, the program was valuable experience	5.56 (0.63)	5.76 (0.49)	0.21
7. I would encourage colleagues to enroll in this training program	5.56 (0.63)	5.76 (0.43)	0.18

^a Based on 6-point Likert-type scale: Definitely no = 1; Definitely yes = 6

^b t-test

Based on our first-hand experiences, the MMOR configuration was easily handled by two people and transported using a mid-sized sports utility vehicle, negating the burden or additional expense that would be associated with leasing or renting specialized vehicles. The MMOR was also easily transported from the vehicle to a hospital OR by two people. Set-up in the OR and functional testing was easily completed within 20 to 30 minutes. We were generally pleased with the MMOR interface with hospital equipment from the outset. With some minor refinements following pilot testing at the first hospital, accurate and reliable technologic interface (e.g., anesthetic equipment) was achieved.

The compact nature of the MMOR facilitated our ability to position equipment and ourselves unobtrusively within the ORs where we conducted training. This was particularly noteworthy, since the ORs typically were small and—in some aspects—dated (e.g., limited storage and space for movement outside the sterile field area, limited electrical outlets beyond those needed for the MMOR to effectively create realistic clinical settings for the STEPS training without compromising any aspect of the actual OR functionality).

Breakdown of the MMOR was easy and quick and, with some practice, achieved in 15 to 20 minutes. As a result, the amount of OR time needed to support training sessions was minimized. We were able to enter and exit the OR department with the MMOR with a minimum of disruption, even when the OR corridors were crowded and busy. Secure, overnight storage in the OR department was an initial concern when faced with conducting multiple days of STEPS training sessions within a given week at a hospital located 80 miles (one way) from our center. However, despite the OR department being woefully in need of storage space for their own day-to-day operations, the MMOR was sufficiently compact that we were able to find secure storage space in a janitor's closet that was no longer being used, a significant factor in enhancing management of MMOR logistics.

Finally, the video recording and playback solution for the MMOR was a major achievement. From the outset, we were concerned that high visibility of video recording equipment might intimidate or substantially influence participants' involvement in training scenarios. Yet, video recording was important for both supporting after-action debriefing and research purposes. The small scale of the computer-based video recording playback equipment and the ease of use afforded by the Wirecast[®] software produced very good quality video, and participants did not seem to notice the recording equipment at all. Larger scale equipment typical of other types of video recording and playback solutions and the need to place microphones on each participant prior to training would have required considerably more preparation time and taken a much more visible role in the training sessions.

Discussion

Reports in the literature demonstrate that teamwork in the modern OR is plagued by role confusion,^{4,5,6} poor communication,⁷ and tense interactions.²⁶ Furthermore, the hierarchical structure of the OR team is less than ideal for effective coordination among the disciplines.^{4,6} Such dysfunctional team dynamics can negatively impact patient safety, especially during complex procedures.²⁷ In addition, they can result in inter-professional conflicts,²⁸ OR

inefficiency or delays,⁷ and episodes of disruptive behavior characterized by yelling, abusive language, insults, patronizing tone, and a disrespectful attitude.²

Clearly, the need for training to improve teamwork is evident. Although large, group-based, interactive sessions are feasible and have been used successfully for such training,^{29, 30} high-fidelity, simulation-based methods offer several key advantages. First, they create a realistic, immersive learning environment for learning and practicing actual team skills.^{16, 17} Second, they require teams to manage the consequences of their actions in real time, but without risk of harm to the patient.¹⁶ Finally, such training can be used to learn and practice specific team responses that are either difficult or impossible to do in real life (e.g., preparing for rare clinical scenarios that could occur in actual practice).¹⁶ Authentic, simulation-based training can facilitate the use of deliberate and focused feedback and practice to improve critical aspects of communication and coordination that relate to teamwork effectiveness and patient safety.

Involving the entire team in behavioral skills training is essential for achieving highly reliable team functioning in actual practice.³¹ To date, true interdisciplinary team training for OR personnel has been limited to specialized simulation suites located at or near academic health centers and targeted hospitals.^{23, 24, 25, 32, 33} The MMOR model significantly expands the portability of high-fidelity, simulation-based interdisciplinary OR training by taking it to the point of care. In this study, training was conducted successfully at two hospitals located 80 miles apart, demonstrating both the feasibility and effectiveness of the MMOR and its potential for expanding both the geographic and demographic reach of interdisciplinary team training to improve teamwork and patient care.

Fidelity in simulation-based training requires the use of true-to-life equipment in a realistic training environment and the psychological buy-in of participants.^{16, 18} The MMOR configuration allowed us to take the STEPS program “on the road” and retain these essential characteristics. The ability to assemble a realistic OR team composition for training was possible because the MMOR facilitated taking the STEPS program to the point of care, where real teams already existed, and participation in training was convenient. Even when we had to rely on volunteer participants in the pilot testing, we encountered only two sessions in which we needed surgical technologists to play the role of circulating nurses because none were available at the time. The consistency of high item mean scores for the two hospital training sites and the nonsignificant results of t-test analyses were particularly encouraging and demonstrated the effectiveness of the MMOR for reproducing the STEPS training sessions with different OR personnel working in two OR departments that reflected different physical, organizational, and cultural work environments. These results build upon prior studies of simulation-based OR team training conducted near the point of care.^{25, 32}

Given the increasing demands that OR personnel frequently face (e.g., time pressures, short staffing, increasing productivity expectations) and the increasing costs and hassle of travel, individuals are becoming less interested and willing to leave their work settings to attend training elsewhere. Taking the training to health care professionals and conducting it in their own work settings appeared to enhance receptivity and psychological buy-in for simulation-based training. Based on evaluation results, the effectiveness of the MMOR for supporting simulation-based training at the point of care suggests the following design principles:

- Portability increases individual and organizational access to training.
- Adaptability of training to real life OR settings facilitates implementation and minimizes cancellations due to unexpected events (e.g., training is embedded within the everyday routine, making it easy to move a session to an alternate OR when an emergency case arises and alters the training schedule).
- Technologic features of the simulators and their compatible interface with real life settings support use of authentic scenarios.
- Situating simulation in real life settings facilitates standardized training that can offer practical benefits.
- Training in real world environments promotes incorporation of systems-based practice.

Related to systems-based practice, the MMOR configuration facilitates the integrated use of simulated and real elements in training (i.e., a mixed reality environment). Mixed reality methods offer opportunities to examine latent individual and organizational features that either facilitate or interfere with OR team function and the transfer of new knowledge and skills to everyday practice. Paying attention to such features can enhance the potential for long-lasting improvements. For example, new OR staff participating in the STEPS training learned where specific equipment was located before a real life crisis occurred that would have required its use. In addition, team members were made aware of a specialized malignant hyperthermia kit that the anesthesiology staff had created. While these were not objectives-related outcomes of the STEPS training, they did represent intentions for participants to gain such insights as a result of using a mixed reality environment afforded by the MMOR configuration.

Despite the very positive and encouraging results, we identified several noteworthy challenges that include the following:

- Cost.
- Logistics (e.g., transportation).
- Technologic limitations of portable simulators.
- Human capital needed to sustain an MMOR and associated training program.
- Individual, departmental, and institutional commitment or buy-in for training.

First, investing in portable simulation-based training requires substantial commitment of time, people, technology, and finances. Even though we were able to streamline the MMOR components and incorporate some very cost-effective features (e.g., Wirecast[®] video recording software), acquiring and maintaining an ECS alone can run into the tens of thousands of dollars. Despite substantial experience with METI simulators and simulation-based training, creating and supporting rich, authentic training scenarios requires considerable expertise and efforts.

Scheduling our own time to develop the MMOR and implement STEPS activities (e.g., planning, training, assessment, followup, refinement) while holding multiple and competing responsibilities has been a significant challenge. Clearly, one alternative would be to create a core team or set of teams with appropriate expertise that could devote full-time efforts to support ongoing development and enhancements and to provide training to a region, network of

hospitals, or statewide initiative. Such an arrangement could produce synergy and afford a realistic solution to managing costs and logistics effectively, enhancing efficacy, and maximizing assets to achieve optimal benefits to health care providers and ultimately to patients.

We selected the METI ECS as our portable mannequin component of the MMOR. Even with enhancements made possible through our patented Clinical Model software interface, the mannequin itself has certain limitations that continue to challenge achieving optimal levels of authenticity. For example, the ECS cannot interpret the amount and type of “medication” administered because it lacks the bar code reading system that is available on the nonportable mannequin (METI HPS) we use in our center-based simulation suite. As a result, participants must verbalize the type and amount of medication they are administering to the “patient” during scenarios in order to have this information entered into the mannequin software. Once entered, the mannequin gives the appropriate physiologic response to the drug and dose given. However, such verbal drug administration is not representative of what occurs in an actual OR case. Typically, a nurse anesthetist or anesthesiologist is able to and often does give medications without telling other team members. This dynamic is different than in our MMOR. Clearly, a bar code system allowing the nonverbal administration of medication for the ECS would be preferable. Even so, our evaluation results suggest that this technical deficiency did not substantially detract from realistic features of training.

Finally, we recognized that the use of the OR space and personnel who participated in training resulted in reduced hospital revenue that could not be avoided. Such costs and increasing demands for productivity and accountability make it imperative to obtain convincing evidence that the benefits of such training outweigh the real and perceived costs. Results from this study provide only initial evidence of receptivity and satisfaction. Our continuing research efforts are targeting evaluation of learning, behavior change, and ultimately, evidence of impact on outcomes.

Visible support from key leaders is essential to achieving and sustaining buy-in for any type of training, particularly when innovative and performance-based approaches—such as simulation training at the point of care—is proposed.²⁵ In this study, the OR nurse managers at both participating hospitals were essential in the successful use of the MMOR to support the STEPS training. Without their enthusiastic support and assistance, we would not have been able to gain entry to the OR department and access equipment and supplies, much less implement training sessions with interdisciplinary OR teams. At the second hospital where the STEPS program was fully implemented, the hospital medical director, a general surgeon, seized opportunities from the beginning to demonstrate his enthusiasm and support to key hospital leaders. In addition, he participated in a STEPS training session with other OR team members. His actions contributed to developing enthusiasm and support at other levels of the OR department and the hospital, affording us an important opportunity to introduce the STEPS training to staff in the OR, anesthesiology, and general surgery departments. We observed that if individuals were willing to consider such training at the point of care, the MMOR configuration was usually sufficiently captivating to facilitate all or most principals’ buy-in for participating in the STEPS training. With buy-in and participation in training, anticipated improvements in teamwork, for example, can then be recognized and rewarded, and followup strategies can be used to promote long-lasting change.

Our experiences with the MMOR configuration and feedback from STEPS training participants have provided encouraging support for implementing standardized training to meet institutional and regional needs for interdisciplinary OR team training. The outcomes of this study also suggest that the conceptual design of the MMOR and STEPS training could be adapted to expand the availability of team-based training using mixed reality methods to create authentic learning environments for enhancing performance of other types of teams in a variety of settings, (e.g., interdisciplinary teams working in intensive care units, emergency rooms, and even interdisciplinary/interagency first responder teams, which ultimately interact with hospitals, particularly when large scale emergencies and disasters occur). Individuals interested in creating highly authentic and replicable training programs might benefit from adopting or adapting our MMOR configuration and its associated design principles for support of team training initiatives.

Conclusion

Taking high-fidelity, simulation-based training to the point of care requires innovative support structures to achieve realistic, sustainable, and value added training. Our MMOR configuration supports interdisciplinary team training in the actual OR setting. Completion of the STEPS training sessions at two hospitals located 80 miles apart and participants' very high ratings of effectiveness provide evidence that the MMOR has clear potential for increasing geographic- and demographic-based access to authentic simulation-based OR team training via a standardized, reproducible, regional-based team training program. Such a regional approach to training at the point of care would facilitate integrating simulation into actual health care delivery systems and strengthening collaborative partnerships between academia and community practice.

As we continue our refinements of the MMOR and implementation of the STEPS program, we are examining the impact of such simulation-based training on actual transfer of learning and skill development to everyday practice and to the overall culture of teamwork and patient safety in the OR setting. We are also exploring how the MMOR design and implementation principles can be used to support other types of mixed reality training experiences.

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Examining the Effectiveness of Debriefing at the Point of Care in Simulation-Based Operating Room Team Training

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Abstract

Objectives: We examined the extent to which characteristics of effective debriefing were observed when conducting high-fidelity, simulation-based operating room (OR) team training under tight time constraints in the actual OR. **Methods:** The entire OR general surgical staff at an academically-affiliated hospital participated in half-day training sessions. After-action debriefing discussions regarding teamwork followed each of two immersive scenarios. Sessions were videotaped and then assessed by two trained, independent raters using an instrument based on characteristics of effective debriefing. Calculation of Kappa coefficient was used to determine inter-rater reliability. Descriptive statistics were calculated. **Results:** Introductions, rapport-building, and identifying intentions for behavior change were very positive features of the sessions. Most other item mean scores (e.g., process and closure characteristics) were at or slightly below the scale midpoint. **Conclusion:** Effective debriefing can occur even when time and space are limited. However, careful attention to questioning and facilitation skills is essential.

Introduction

Promoting teamwork among health care professionals has become an important national priority. For example, the Joint Commission has included teamwork training as part of its patient safety curriculum.¹ In addition, the Institute of Medicine (IOM) has made interdisciplinary teamwork one of its five core competencies for health care professionals.² The Agency for Healthcare Research and Quality (AHRQ) has supported research into the relationship between teamwork and patient safety.³ AHRQ has also partnered with the Department of Defense (DoD) to create a team-based training system known as TeamSTEPPS[™] to promote behavioral skills among health care providers at the point of care.⁴

Background

The development of teamwork skills has become recognized as a set of learned behaviors and attitudes that should be included in formal education programs. For example, the Accreditation Council for Graduate Medical Education (ACGME) has placed considerable emphasis on teamwork in its expectations for teaching and assessing residents' acquisition of core competencies.⁵ Particular attention to teamwork training has focused on targeting high risk,

highly dynamic health care specialties, such as emergency medicine,^{6, 7, 8} obstetrics,^{9, 10} and surgery.^{11, 12, 13}

Improving teamwork in the operating room (OR) environment is especially important given the role that confusion,^{14, 15, 16} poor communication,¹⁷ and disruptive behavior¹⁸ can play in that setting. Interactive group sessions have been used successfully to promote team-based attitudes and interaction at several institutions,^{10, 11} but high-fidelity simulation-based interdisciplinary team training may offer some significant advantages. For example, it uses realistic scenarios and immediate after-action debriefing discussions. This enables participants to become immersed in a realistic environment where they can learn and practice team skills.^{19, 20} Furthermore, the simulated environment allows teams to fully realize and learn from the consequences of their actions in ways that would not be possible in situations involving real patients.¹⁸ Finally, it exposes teams to rare clinical events in which prior experience could positively impact patient care.¹⁸

To date, most interdisciplinary OR team training has been limited to specially constructed simulation suites.^{21, 22} Only rarely has it been conducted within an actual OR environment.^{23, 24} Such point-of-care simulation training has several advantages, including greater accessibility for clinicians, adaptability in scheduling, the opportunity for systems-based learning, an immersive environment, and standardized regional training.²²

Feedback (including debriefing) has been identified as an essential component of simulation-based training. As an experiential learning approach, debriefing facilitates participants' ability to relate their training experiences to daily practice.²⁵ In fact, debriefing is widely accepted as the most essential component in simulation-based training.²⁶ In simulation-based training, the primary objective of debriefing is to engage participants in reflective critique and discussion regarding their performance during simulation scenarios and how they can improve targeted content and skills. Essential components of debriefing include description, analysis, and application.²⁷

This article presents the results and insights gained from examining the effectiveness of debriefing sessions that were conducted as part of OR teamwork training sessions implemented at the point of care with actual OR teams in a busy OR department of an academic medical center.²⁸ The primary purpose of the study was to examine the extent to which critical characteristics of effective debriefing discussions were observed across the training sessions that were conducted. Each training session (i.e., scenarios and debriefing) was conducted in an actual OR within a time-compressed format that fit within the everyday operations of the OR department. Cramped quarters, time pressures, dynamic schedule changes, and limited access to audiovisual technology were potential impediments to achieving effective debriefing discussions.

Review of Relevant Literature

Learning in simulated environments should be self-directed, and participants should engage in debriefing discussions among themselves with the facilitator serving as a resource person. A facilitator is a helper and enabler who assists participants in achieving learning objectives.²⁹ In most training settings, the facilitator needs to be skilled in managing time and promoting reflection and group interactions necessary for effective debriefing, but he or she does not need

to have the technical expertise of the trainees involved in the scenarios. When participants are not familiar with training content (e.g., specific teamwork competencies and behaviors) or with how to engage in the process of debriefing and reflective practice,³⁰ the facilitator's role becomes particularly important to the reflective practice and performance improvement process.³¹ In a high-fidelity simulation setting, the facilitator often plays the dual role of facilitator and trainer.³²

Relative to the training situation in this study, Smith-Jentsch and colleagues³³ emphasize that the main function of teams engaging in effective debriefing is to integrate experience with concepts transferable to the real OR setting. In effective debriefing sessions, participants are guided to assess the effectiveness of their own performance and that of the team, provide constructive feedback, and correct any unsafe OR teamwork behaviors so that the team will be effective in the real OR setting.

The facilitator plays a key role in focusing the discussion on the training scenario by creating a comfortable environment where the participants are encouraged to self-correct.³³ Most debriefing processes and methods used in health care settings have been adapted from the aviation industry, including the use of a structured method for debriefing.³⁴ Additional insights regarding the characteristics of successful debriefing sessions have been gained from reviewing publications pertaining to effective facilitation techniques and small group learning.

Our review of the literature on aviation, small group teaching, and successful facilitation identified the following common characteristics associated with effective debriefing:^{25, 32, 34, 35, 36, 37, 38}

- Creating a friendly atmosphere.
- Concentrating on key learning objectives.
- Facilitating self-assessment and disclosure.
- Pointing out unsafe teamwork behaviors.
- Having an open discussion with appropriate questions.
- Engaging in shared reflection and critique.
- Employing strategies to facilitate active engagement and ideas for improvement.
- Managing time constraints.

This literature also revealed that effective debriefing sessions include three parts: the introduction, the actual debriefing discussion, and closure. Within the debriefing discussion, four phases are associated with effectiveness: engagement, focus, reflection, and critique.

Although the characteristics of effective debriefing and how it enhances learning have been discussed in the professional literature, how the process of debriefing affects learning in high-fidelity, simulation-based training is still not well understood.^{25, 39} Given the time and space constraints in which our use of simulation-based learning was implemented at the point of care, it was important to systematically assess the extent to which the debriefing component was reflecting the attributes most often associated with effective practice. The next section describes our approach.

Methods

In this section, we describe two sets of methods. First, we provide a brief description of the System for Teamwork Effectiveness and Patient Safety (STEPS) training innovation, including the mobile mock operating room (MMOR) configuration and the formats used for conducting training scenarios and debriefing discussions. Second, we describe the methods pertaining to the evaluation of debriefing effectiveness, including instrumentation, data collection, and data analysis.

Prior to implementation, we obtained institutional review board (IRB) approval at an exempt status as part of a larger research protocol targeting simulation-based training and assessment. Although similar approval was not required by the hospital-based research and compliance office, we initiated and maintained open and ongoing communications with these groups to keep them fully informed and to facilitate positive relationships and cooperation.

STEPS Training

With support from AHRQ, the first training module of the STEPS program was implemented in March 2007 with all staff surgeons, surgery residents, circulating nurses, anesthesiologists, nurse anesthetists, and surgical technologists on the general surgical OR teams at a 157-bed academic affiliated State-run hospital. The STEPS training module targeted nine teamwork competencies as listed in Table 1. In a half-day format (approximately 3 hours), the training session consisted of two immersive high-fidelity, simulation-based scenarios, that were each followed by a focused and structured debriefing discussion to promote reflective practice and performance improvement in teamwork skills. The five debriefing objectives that were targeted are also listed in Table 1.

Each participant attended at least one of the 11 training sessions held over a 30-day period. OR teams consisted of a nurse anesthetist, circulating nurse, surgical technologist, and surgeon. The two staff anesthesiologists were available on call into the simulation environment for each session. This set-up reflected their oversight role within the OR department for actual cases. When the three staff surgeons participated in the training, they were partnered with a junior surgical resident [i.e., postgraduate year (PGY) 1 or 2]. Senior residents (PGY 3-5) participated in training teams as the sole surgeon. Individuals were assigned to training sessions by being assigned to the OR in which the training was scheduled. For example, staff in this OR department check the assignment board each morning to learn in which OR they will work. Two half-day sessions were conducted on each day that STEPS training was scheduled. Thus, two teams were posted for the STEPS designated OR, one for the morning and the other for the afternoon.

Mobile Mock Operating Room (MMOR) Model

Taking the STEPS training module to the point of care and conducting sessions within the actual OR was possible with the use of a novel MMOR model,²² which we adapted from our simulation center-based virtual operating room (VOR) configuration.²⁰ The MMOR combined a portable

Table 1. Teamwork competencies targeted in STEPS training and objectives of debriefing discussions

Teamwork competencies	
	• Shared mental model • Situational awareness • Anticipatory response • Open communication • Role clarity • Flattened hierarchy • Cross monitoring • Resource management • Mental rehearsal
Debriefing objectives	
By the end of the debriefing discussions, participants will be able to:	
	• Engage in shared reflection and critique • Define highly adaptive team function • Define and illustrate teamwork competencies • Compare and contrast effective and ineffective examples of teamwork competencies using their clinical experience • Apply teamwork competencies learned in the STEPS training to their everyday clinical work

computer-operated mannequin (Medical Education Technologies Inc., [METI], Sarasota, FL) with an inanimate laparoscopic cholecystectomy model (Simulab Corporation, Seattle, WA). These two simulators were housed within the actual OR, and all other equipment and supplies were provided by the hospital. A compact video recording and playback system was located unobtrusively within the MMOR. Each training session was recorded in its entirety (both scenarios and debriefing discussions).

Simulation-Based Training Format

Two of four possible patient scenarios were used for each training session. Cases were selected to minimize repetitive exposure to the participants. These authentic patient scenarios were developed using a patented software interface that reduced operator influence on the progress of the simulation.⁴⁰ The scenarios were designed to simulate authentic patient situations and included features that would facilitate observation of OR team members' behaviors associated with teamwork competencies (e.g., shared mental model, mental rehearsal, situational awareness, role clarity, open communication, resource management, anticipatory response, cross-monitoring, and flattened hierarchy).

For example, an airway obstruction would create opportunities for team members to anticipate further problems and engage in communication about how to respond to the next issue. Patient problems and other features, such as issues related to instrumentation, medication errors, or patient chart or laboratory result issues were also included as needed in scenarios to prompt teamwork issues. Among the cases used in training were patient situations that included the onset of malignant hyperthermia, unstable intraoperative cardiac arrhythmias, anaphylactic shock, and septic shock.

Prior to implementation, a general orientation to the simulation equipment, STEPS program, and training session ground rules (e.g., behavioral expectations, confidentiality of training experiences, and security for content of training scenarios) was conducted with all participants in a general session. Individuals had an opportunity to interact briefly with the human patient simulator, learn its capabilities (and limitations), and ask questions about the training that would be implemented.

Each half-day training session began with a brief introduction that revisited the simulator function and ground rules for scenarios. Training sessions lasted up to 3 hours. Each of the two scenarios was followed by an after-action debriefing discussion. Within the training session, each scenario was introduced and initiated by giving team members the patient chart and instructing them to proceed as they would with a real patient.

After-Action Debriefing Format

Each training session included two after-action debriefing discussions within the MMOR, with each one immediately following the completion of a scenario (Figure 1). The same facilitator (JTP), a general surgeon with a background in medical education, led each training session (scenarios and debriefing discussions). Specific open-ended questions were used to target the debriefing objectives and teamwork competencies (see Table 1) and to encourage reflection on specific scenario events and relevant individual and team behaviors preceding or resulting from these events. These team reflections were then linked to nine teamwork competencies and their effects on patient safety. Video-recorded scenarios were used in the after-action debriefing discussions. For example, selected video-vignettes of specific events or behaviors were played to facilitate participants' reflective critique and discussion of key teamwork competencies and strategies for improvement.

Consistent with our findings in the literature, the debriefing component of the training session consisted of three distinct parts: the introduction, the debriefing process, and the summary or closure. The debriefing process was further conceptualized in terms of the following four phases:

- **Engagement.** The facilitator used an open-ended question (e.g., "How did it go?" or "What do you think happened?") to immediately engage the entire team in reflecting on their individual and team performance during the scenario.
- **Focus.** The facilitator quickly introduced and offered brief definitions of specific teamwork competencies and asked participants to identify particular examples of corresponding behaviors from the training scenario.



Figure 1. This photo shows the beginning of an after-action debriefing following the conclusion of a simulation-based scenario. The nurse anesthetist (far left) engages with the facilitator (arms spread in background) as the surgeon (second from right) and scrub technologist (far right) look on. The circulating nurse (foreground) completes breakdown of the field as she listens. An analyst/recorder (behind facilitator) assists with recording the debriefing session and observing interactions.

- **Reflection and critique.** Participants were encouraged to reflect on the various teamwork competencies and how these could be used to enhance teamwork effectiveness.
- **Application to everyday practice.** The facilitator encouraged participants to identify skills or behaviors related to one or two teamwork competencies that they intended to improve in the actual OR environment (e.g., commitment to behavior change).

Evaluation of Debriefing Effectiveness

The data set for examining the debriefing process was made up of the video-recorded debriefing discussions from each of 11 training sessions. Two videos were available from each training session ($N = 22$). All videos were examined for completeness. A video was considered complete if it included all of the debriefing activities from the opening statement to closing comments with clear image and audio quality. Any videos that did not meet these criteria were deemed technically inadequate and excluded from analysis.

To assess the effectiveness of debriefing sessions systematically, a 25-item, observation-based assessment instrument was developed and used to reflect the essential characteristics of effective

Table 2. Summary of descriptive statistics for assessment of debriefing effectiveness during the introduction of debriefing discussions

Item statement	Mean ^a (± SD)	Mode
At the beginning of the session and prior to initiating the debriefing discussion, to what extent was each of the following accomplished effectively?		
1. Purpose and objectives of the debriefing session were clear	3.61 (0.78)	3
2. Facilitator introduced self, including a brief personal background, as needed	4.89 (0.32)	5
3. All participants introduced themselves or they knew each other already	4.94 (0.24)	5
4. Structure and process (e.g., use of a particular approach) of the session was clear	1.44 (0.62)	1
5. Allocated time and planned use of time was clear	1.72 (0.75)	1
6. Participant expectations were clear (e.g., ground rules, engagement, and confidentiality)	1.72 (0.82)	1
7. Rapport was established prior to initiating the debriefing discussion	4.56 (0.62)	5
8. Participants' questions and comments were addressed	4.50 (0.51)	4

a A Likert-type response scale was used for all items (1 = "Not effective at all" to 5 = "Highly effective")

debriefing environments evidenced in the professional literature on debriefing, small group teaching, and discussion facilitation.^{25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39} The instrument included three sections, each one corresponding to one of the three portions of a debriefing session (Introduction, Debriefing, and Closure). Tables 2, 3, and 4 show the instrument items by section.

Using the results of our literature review, the assessment instrument included items that represented the characteristics most commonly associated with effective debriefing environments, regardless of the content, participants, or setting. Conceptually, and consistent with the general research on effective learning environments, the instrument was designed to focus on the debriefing environment as a whole, rather than simply on isolated behaviors demonstrated by the facilitator or participant behavior.

A focus on the environment recognized the interactive and dynamic nature of debriefing as a learning process. A Likert-type response scale was used for all items (1 = Not effective at all to 5 = Highly effective). Item groups on the instrument corresponded to the three parts of the debriefing discussion: the introduction (Table 2), the debriefing process (Table 3), and closure (Table 4).

Table 3. Summary of descriptive statistics for assessment of debriefing effectiveness during the actual debriefing process

Item statement	Mean ^a (± SD)	Mode
<i>Throughout the debriefing discussion, to what extent was each of the following accomplished effectively?</i>		
9. Motivated participants to be actively engaged in reflection, collaboration, and constructive critique	2.89 (0.68)	3
10. Used nonverbal strategies (e.g., appropriate eye contact) to facilitate active engagement	3.44 (0.70)	3
11. Used equipment and teaching/learning materials effectively to enhance learning	3.50 (1.10)	3
12. Solicited strategies and ideas for improvement (and offered suggestions when needed)	3.06 (0.73)	3
13. Used open-ended questions to facilitate appropriate problem solving, divergent thinking, and interaction among participants	3.11 (0.76)	3
14. Clarified content when misunderstanding or confusion occurred	3.83 (0.38)	4
15. Demonstrated priority for self-reflection (e.g., encouraged participants to solve own questions and problems)	2.11 (0.58)	2
16. Did not interrupt participants' contributions or interfere with productive interactions	2.39 (0.78)	2
17. Encouraged participants' critique, enhancement, and expansion of each others contributions	2.11 (0.58)	2
18. The session proceeded at an appropriate pace (i.e., not too fast or too slow)	3.07 (0.77)	4

a A Likert-type response scale was used for all items (1 = "Not effective at all" to 5 = "Highly effective")

Further, assessment decisions were contextually based. For example, if it was clear to the observer that all participants already knew each other and the facilitator (and vice versa), then taking time to conduct personal introductions was rated as ineffective. In the same situation, if the facilitator verified that everyone knew each other and demonstrated familiarity with participants' names and roles, or it was clear to the observer that everyone knew each other already, then skipping the personal introductions would be considered effective. Consequently, there was no need to include ratings on the scale for "not applicable" or "not observed." An iterative process of review and refinement was used to finalize the instrument.

Training in the application of the assessment tool was completed, and supplemental written annotation and guidance were used to structure the videotape assessments. Two researchers completed several cycles of observing and rating videos from pilot training sessions completed prior to the STEPS implementation. Independent ratings were discussed to examine supporting rationales to clarify items and enhance accuracy and inter-rater agreement. Assessments of debriefing discussions were initiated after satisfactory inter-rater agreement for rating decisions

Table 4. Summary of descriptive statistics for assessment of debriefing effectiveness during the closure portion of debriefing discussions

Item statement	Mean ^a ($\pm$ SD)	Mode
At the end of the debriefing session, to what extent was each of the following accomplished effectively?		
19. Participants identified features of the groups' debriefing interactions that were done well	1.61 (0.61)	2
20. Participants assessed factors that enabled or impeded their success, as appropriate	2.78 (0.94)	3
21. Participants discussed ways in which the training could be conducted more effectively	2.33 (0.73)	1
22. Participants revisited important points or asked followup questions to ensure that learning was achieved	2.78 (0.81)	3
23. Participants identified specific intentions or ways to improve future performance using knowledge/skills targeted by the session	3.72 (0.57)	4
24. Summary and closure of the session included specific attention to how learning could be applied to daily practice (e.g., influence of organizational facilitators and barriers)	3.72 (0.89)	4
25. Closure included appropriate communication of appreciation for commitment to learning and participation in training and debriefing activities	1.94 (0.87)	2

a A Likert-type response scale was used for all items (1 = "Not effective at all" to 5 = "Highly effective")

and rationale were achieved. The two researchers observed each videotaped debriefing discussion and then independently completed the assessment instrument before proceeding to the next videotaped debriefing discussion.

Descriptive statistics, including item mean, standard deviation, frequency count, and percentage were calculated. Item mean scores were used as the basis of the debriefing effectiveness evaluation. Inter-rater reliability was examined by calculating a Kappa coefficient.

Results

Ten of the 11 training session videos satisfied the inclusion criteria for analysis. Because each videotaped training session included two debriefing discussions, we were able to complete two independent assessments for 20 debriefing discussions. All of the videos were scored by the same two independent raters within a 1-week period. Good inter-rater reliability was achieved (Kappa coefficient = 0.71).

Descriptive statistics are summarized in Table 2. Five of the eight items included in the "Introduction" part of the debriefing discussions were observed as effective or highly effective (range, 3.61 – 4.94). These items related predominantly to establishing rapport and purposes for learning. The remaining three items represented structural or organizational characteristics (e.g.,

ground rules, use of time) that were either absent or observed as occurring ineffectively in the videotaped debriefing discussions (range, 1.44 – 1.72).

As shown in Table 3, descriptive statistics for the Debriefing Process part of the sessions revealed that 6 of the 10 characteristics of effective debriefing were demonstrated either effectively or highly effectively (range, 3.06 – 3.83). Use of nonverbal strategies to enhance active engagement of participants (item 10) and clarification (item 14) were among the characteristics demonstrated most effectively during the debriefing process. Mean scores were only slightly above the midpoint for management of pace (item 18) and use of strategies to gain participants' commitment to change (item 12). Four items relating to the critical analysis and reflective aspects of debriefing (items 9, 15, 16, and 17,) were observed to be less effective (range, 2.11 – 2.89).

Finally, Table 4 provides a summary of descriptive statistics regarding closure at the end of the debriefing discussion. Positive demonstration of characteristics related to content summary and performance improvement intentions (items 23 and 24) were observed in debriefings across 10 training sessions (mean rating for each = 3.72). Although not completely ineffective, less emphasis was observed for characteristics related to reflection and feedback on the debriefing process itself and how this could be improved (items 19, 20, 21, and 22, range, 1.61 - 2.78). In addition, results for item 25 revealed that debriefing sessions did not routinely include attention to affective elements of debriefing that promote and reinforce learning and participation.

Discussion

High-fidelity, simulation-based training has become a popular strategy for enhancing content knowledge and skill performance across a wide variety of audiences and settings. In recent years, interest in simulation-based training has been increasing as an approach to enhancing teamwork and patient safety. Because of its experiential nature, high-fidelity, simulation-based, interdisciplinary team training requires an effective debriefing for optimal learning and impact on improving everyday practice. In fact, debriefing is often considered the most essential component of simulation-based learning.²⁵ Without effective debriefing, the usefulness of the simulation format is substantially limited.

To date, most initiatives involving high-fidelity simulation have occurred in center-based environments, where training occurs in a simulated clinical setting. In addition, the debriefing is typically conducted in a nearby location (e.g., a classroom or conference room), where a large screen-based video playback system is available, and participants can be comfortably seated and can see and hear each other and the video display easily. Finally, this setting affords considerable flexibility in allocating sufficient time to fully conduct debriefing discussions. For example, debriefing discussions might last anywhere from 30 minutes to 2 hours or more—depending on the length of a scenario-based training experience—in order to allow training participants sufficient time to fully debrief (disclose and discuss) their training experience using video playback of all relevant scenario vignettes.

In contrast, taking the simulation-based training to the point of care requires fitting the learning experiences within the context of the everyday workplace. Despite the perceived benefits of

conducting training at the point of care (e.g., convenience, enhanced authenticity, and potential for impacting everyday practice), implementing the STEPS program meant dealing effectively with significant time, schedule, space, and technologic constraints. Because debriefing was such a critical aspect of learning in the STEPS training and situated in the actual OR via our MMOR configuration, this study sought to identify those characteristics of effective debriefing discussions that were evidenced in the sessions, as well as other characteristics that require further attention and refinement of structure and processes for both scenario and debriefing components of the training session.

While a three-member team managed each training session, one person served in the dual role as trainer for scenario and facilitator for debriefing in our STEPS training. (Another member managed videotaping and data collection, and a third person operated the simulator.) Whether the same or separate individuals fulfill trainer and facilitator roles, there still needs to be a balance between content focus and structure (i.e., trainer role)²⁷ and enabling strategies to enhance participants' reflection and insights from their experiences (i.e., debriefing facilitator).³¹ When a single person fulfills both roles, the complexity of managing multiple tasks simultaneously (e.g., managing organization and implementation of scenarios, writing notes, and/or inserting bookmarks to label video segments for debriefing) can also be quite challenging. In addition, progressing from the scenario immediately to the debriefing discussions leaves little time for organizing key points and selecting video vignettes to structure the debriefing. Breaking down the MMOR to prepare for the next scenario and to quickly vacate the OR at the end of the day sometimes interfered with full participant engagement (Figure 1) and contributed to even less time for the second debriefing discussion in the afternoon training session.

Upon closer examination of the results for all aspects of the debriefing discussion (Tables 2, 3, and 4), coupled with our own debriefing of implementation, it became clear that time and space constraints played a role in the less effective presence of certain characteristics of effective debriefing environments (e.g., strategies to encourage collaborative reflection and participants' expansion of each other's contributions, items 9, and 15-17; characteristics associated with closure, Table 4, items 19-24; higher instances of facilitator interruption of participants' contributions, Table 3, item 16). Consequently, given the time and space constraints associated with debriefing at the point of care, we saw a need to carefully examine the structure of the debriefing facilitator guide and consider how other members of a training team might contribute to preparation and actual facilitation of the debriefing discussion.

Results of this study provide clear evidence that a structured approach to the debriefing process is critically important when time and flexibility are substantially limited.³² That is, much like a teacher's lesson plan, a facilitator guide can enhance effective use of time and space and ensure that sufficient opportunity is afforded for learners to use reflection and critical analysis of their actions.

Similarly, a facilitator guide should not "script" the debriefing process. Instead, it should provide sufficient discussion prompts and tools to ensure that participants are actively engaged in shared reflection, critical analysis, and application to everyday practice, and that time and pace are managed effectively. In this way, debriefing discussions do not become too "stiff" and are less

at-risk for the facilitator assuming a lecture approach. Such a guide would also be important when different individuals fulfill the facilitator role across training sessions.

Finally, a facilitator guide becomes particularly important when facilitators or participants are not highly experienced in using debriefing discussions. Although the facilitator in our study had several years of previous experience in clinical teaching, experience with this specific approach to debriefing facilitation was limited. Consequently, a guide and practice contributed to both increased ease and effectiveness. Thus, regular use of a consistent guide could also contribute to increasing the use and effectiveness of debriefing as a method for enhancing knowledge and skills.

Another key to effective debriefing observed in this study was the creation of a learning environment that was safe, respectful, courteous, and conducive to candid critique and reflective practice. For example, the characteristics of effective debriefing shown in the items in Table 2 contribute to establishing rapport, communicating clear expectations, and providing appropriate assurances for confidentiality. The importance of these characteristics should not be underestimated, especially when new staff members are involved in training and debriefing. While not reflected in the assessment of the debriefing videos, our direct observation during the actual sessions revealed several instances when new OR staff participated in training. Other, more experienced staff members sometimes served an important role in supporting new team members and contributed to the facilitator's efforts to ensure a safe environment for all participants.

Adequate time for debriefing discussions is an important consideration that influences many aspects of effectiveness. A common recommendation that is widely accepted in education and training is to plan debriefing sessions for a time period that is at least equal to or greater than the time spent in the stimulus experience (i.e., simulation-based training scenario).

From the outset, we recognized that we would not have much more than equal amounts of time for the debriefing and scenario components. Variations in the time a team needed to take scenario to its natural conclusion sometimes provided formidable challenges for completing the debriefing discussions. Thus, a clear focus on all characteristics of effective debriefing becomes critically important, and specific efforts to incorporate those characteristics in a structured debriefing facilitator guide are necessary.

In addition, the results of the videotape analyses and our own reflection on participants' contributions to the debriefing discussions suggested that individuals could benefit substantially from prior education and preparation in how to participate in debriefing discussions. For example, clarifying what is expected could streamline the characteristics associated with the Introduction (Table 2). Similarly, education about the various elements of debriefing and how a team engages in this process could facilitate participants' taking a more active role in the various aspects of reflective practice without having to rely on the facilitator to initiate as many prompts (e.g., open-ended questions, Table 3).

Finally, with an enhanced knowledge of how effective debriefing discussions are conducted, participants would come to debriefing discussions better prepared to use reflection and critique

to improve individual and collective performance, both in the debriefing process and in everyday work performance. If participants were well-prepared to use debriefing strategies, the use of available time would be enhanced as well.

Conducting the debriefing discussions at the point of care in the actual OR presented several physical and technologic challenges to achieving an optimal debriefing environment for high-fidelity, simulation-based training:

- The confined physical environment of the OR limited our options for video recording and playback equipment. For example, we could not bring a projection screen into the OR for viewing videotaped team performance. Consequently, we had to rely on viewing selected video vignettes on a computer monitor. In addition, the physical arrangement of the OR limited opportunities to use other teaching and learning materials (e.g., whiteboard or flip chart).
- The physical arrangement of the OR also did not allow all participants to be seated during debriefing discussions. Since the debriefing discussions were rather short, standing did not appear to interfere with participants' involvement in the debriefing process. However, participants sometimes had difficulty positioning themselves to see the video playback, and at the same time, see and hear everyone else in the group. The same was true for the trainer/facilitator. Difficulties related to where participants stood or sat during the debriefing discussion also affected the facilitators' ability to gain and sustain participants' attention and engagement during debriefing.
- Time was a substantial factor for both scenario and debriefing components of the STEPS training. For example, it was important to ensure that training occurred only within the elective surgery hours, avoided the need for employee overtime, and accommodated the regular rhythm of employees, cases, and general operations within the OR department. Consequently, the sessions had to adhere to a strict schedule that did not allow the flexibility for debriefing that has been typically associated with simulation-based training. When scenarios extended beyond their allocated time, after-action debriefings had to be correspondingly condensed to maintain a constant overall time for the session as a whole.

Although the point-of-care debriefing had its challenges, several important advantages were observed:

- Debriefing in the actual clinical environment was useful in promoting self-reflection and linking actual behaviors to teamwork concepts.
- Because debriefing immediately followed completion of the scenario and was conducted in the same setting, participants were able to accurately recall behaviors and events without much reliance on the video vignettes to trigger discussion of teamwork competencies and ways to improve performance.
- Being in the same environment where they worked everyday also facilitated participants' abilities to visualize themselves at work, both in terms of individual and team-related skills.
- The reduced need for video replay proved to be particularly beneficial, given the technologic challenges mentioned previously, and it increased time for discussion that otherwise would have been used to play video vignettes.

- Finally, an important benefit of conducting both scenarios and debriefing in the OR was participants' reflection on and identification of other features influencing effective teamwork and patient safety that were not necessarily directly related to teamwork competency. For example, during debriefing discussions, some teams identified where needed equipment and supplies were located before a real-life crisis occurred for which they might be required. Prior to the training, and particularly the debriefing discussions, these OR staff members did not know where certain equipment and supplies were kept or that they even existed.

In summary, the results of this study suggest that all of the characteristics identified for effective debriefing are important and reasonable to expect in simulation-based training conducted at the point of care, even in the face of substantial time and space constraints. Results of the videotape analysis demonstrated that several characteristics were easier to achieve than others (e.g., rapport, clarification, applying training content to everyday practice).

Because the results and our experiences suggest that the benefits of simulation-based training and debriefing conducted at the point of care outweigh the challenges, we are continuing to evaluate and refine the STEPS training and MMOR configuration to address characteristics that were more difficult to achieve (e.g., increased engagement in reflective practice strategies, preparation of participants in the process of using debriefing, and closure characteristics).

Recently, we completed an end-of-year-1 data collection that included participants' feedback on STEPS training and several measures targeting teamwork effectiveness in the real work setting, including direct observations of patient cases in the OR. Results of these data analyses will begin to show the extent to which training scenarios and debriefing at the point of care influences improvements in OR teamwork effectiveness. In the upcoming year, we will be replicating a refined version of the STEPS program at another hospital and look forward to examining its effectiveness.

Conclusion

Conducting training (and debriefing) at the point of care can present substantial challenges, especially when facing time, space, and technologic constraints. However, careful attention to the characteristics of effective debriefing when planning and implementing training sessions can enhance success in achieving desired outcomes. Effective debriefing is a dynamic process that requires participants, trainers, and facilitators to be actively involved and to contribute specific perspectives and behaviors. In addition, the organizational context in which training scenarios and debriefing are situated contributes substantially to the structure and process of training at the point of care. As simulation-based team training matures and as it becomes incorporated into health care at the point of care, the effective use of debriefing discussions will be important to achieving training and performance goals in a variety of settings. Thus, continued development, evaluation, and refinement of appropriate point-of-care models are needed. Our STEPS program provides one such model from which future development can evolve.

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Effect of Recent Refresher Training on *in Situ* Simulated Pediatric Tracheal Intubation Psychomotor Skill Performance

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Abstract

Objective: Maintenance of competence in orotracheal intubation skills is challenging for non-anesthesiologists who do not practice intubation routinely. We hypothesized that discipline, recent training, and experience would affect immediate skill improvement during refresher training. **Methods:** Experienced pediatric providers refreshed intubation skills in six simulated infant trauma scenarios with cervical spine protection. Time (T) to successful intubation (in seconds) was used to calculate refresher training immediate effectiveness as a function of time to success at second vs. first session (T2/T1). **Results:** Twenty-six providers performed 156 intubations. Time to successful intubation (T1) was 33.8 ± 9.4 seconds (s) for the first scenario and for subsequent scenarios: (T2) 29 ± 6.4 s, (T3) 27.4 ± 5.6 s, (T4) 29.8 ± 9.2 s, (T5) 28 ± 5.4 s, and (T6) 25.6 ± 5.1 s, with the largest improvement between T1 and T2. Immediate refresher training effectiveness (T2/T1) was associated with recent training ≤ 3 months ($P = 0.025$) but not with discipline ($P = 0.40$) or clinical experience > 3 years ($P = 0.93$). Recent training remained significant ($P = 0.017$) in multivariable regression. The number of intubation attempts and the number of tracheal intubation-associated events were not different in recent training, discipline, or clinical experience. **Conclusion:** Recent tracheal intubation training, but not years of experience or discipline, is associated with immediate refresher training effectiveness.

Introduction

High-reliability organization theory supports a high number of operations, intensive training of personnel and teams, and intensive critiques of performance during operations and training in order to maintain a very low failure rate in high-hazard organizations.^{1, 2, 3} However, in busy clinical settings, the allocation of workforce and education resources faces significant challenges. For better allocation of resources to improve patient safety in organizations, it would be helpful to know which factors are associated with the learning effect of refresher training to maintain clinical competence.

Many tasks required to maintain competence in clinical settings involve psychomotor skills with appropriate-level medical knowledge. Several studies have revealed that psychomotor skills

required for crisis management, such as cardiopulmonary arrest, rapidly decay over time,^{4, 5, 6, 7, 8} and do so faster than cognitive skills (medical knowledge).^{5, 6, 7, 8}

Pediatric tracheal intubation is a critical psychomotor skill for pediatric resuscitation.^{9, 10} It is also considered important to decrease the rate of failure to rescue, since many pediatric emergency conditions are associated with respiratory compromise, in contrast to cardiac problems in adult patients.¹¹ Therefore, providing airway training for practitioners to maintain this critical skill is routinely done in clinical settings. For example, competence in this skill is considered essential for pediatric residency training in the United States, as defined by the Accredited Commission for Graduate Medical Education (ACGME).¹²

The acquisition of this complex psychomotor skill requires significant training,^{13, 14} and providers who conduct these procedures on a daily basis, such as anesthesiologists, are considered most competent. Furthermore, maintaining competence may require frequent refresher training,¹⁵ since non-anesthesiology pediatric practitioners and trainees practice this psychomotor skill infrequently in actual clinical settings.^{16, 17} Also, it has been reported that this essential skill is practiced less often by pediatric residents in clinical settings due to practice pattern changes, such as change of guidelines in neonatal resuscitation.¹⁶ To keep clinical practice safe, we need to identify the most effective way for non-anesthesiologists to achieve and maintain psychomotor skill competence in this infrequently practiced but critical procedure.¹⁸

However, we do not know how rapidly pediatric tracheal intubation psychomotor skills decline, how often refresher training should be provided to maintain a high level of competence, or which factors are associated with refresher training effectiveness in non-anesthesiology practitioners who do not practice intubation regularly.

Medical simulation has been recognized as an effective tool to improve patient safety. Recently, the Agency for Healthcare Research and Quality (AHRQ) called for support for medical simulation research to improve patient safety.¹⁹ Simulation has been utilized for various purposes, such as basic-to-advanced task training or team training—e.g., in crisis resource management. Recently, several studies found that simulation-based training effectively improved clinical operational performance with fewer adverse events.^{20, 21} The U.S. Food and Drug Administration (FDA) now requires simulation-based training for a certain intravascular surgery device.²²

Medical simulation has been used often to evaluate competence and training for emergencies.^{23, 24} Objective competence measurement through simulation is more reliable compared to self-efficacy (a trainee's degree of confidence in performing a procedure evaluated by self-assessment).^{3, 25} Recent studies suggest that competence measurement through simulation is valid and translates into operational performance in clinical settings.^{3, 26, 27}

The purpose of this study was to investigate the factors associated with the effectiveness of refresher training in pediatric emergency intubation. Since pediatric intubation is a complex, risky procedure that does not occur on a regular basis for most non-anesthesiology practitioners, medical simulation was determined to be the best technique for this intubation training study. A high fidelity simulator was used in a simulated clinical setting to maximize the realism, to accurately reflect competence, and to maximize the learning effect.²⁸

Methods

This study was conducted in an *in situ* simulation room auxiliary to the pediatric intensive care unit (PICU) of an urban children's hospital.²⁹ The simulation room was originally structured for acute patient care, similar to other PICU patient care rooms with two sets of suction, a monitor, and other patient care equipment in place. Non-anesthesiology pediatric practitioners who are credentialed in tracheal intubation in our institution were asked to participate voluntarily in this study from October 2006 to February 2007. Pediatric residents were not enrolled in this study, since their intubation rate and success rate have been low in the local airway registry data, and they are not the primary intubators on our transport team. A written consent was obtained from each subject.

A priori-defined pretraining data—including discipline, date of prior training involving pediatric intubation, years of experience performing pediatric intubations, and basic demographics (age, sex, and ethnicity)—were collected using a questionnaire at the time of training.

Each subject was asked to participate in six simulation sessions with identical objectives, all of which required pediatric advanced airway management, including orotracheal intubation for an infant trauma patient with C-spine stabilization. In each session, a subject performed as the primary airway provider. The team leader asked the subject to perform orotracheal intubation, randomized to one of three different cervical spine protection techniques: No physical protection (N), C-collar (C), or Manual in-line immobilization (M).¹⁰ Each protection strategy was repeated once in the immediate next session. The order was randomized. For example, one subject performed orotracheal intubation with cervical protection strategy ordered N, N, C, C, M, M, where N = no protection; C = C-collar; M = manual inline immobilization (Appendix 1).

Each session was designed to last approximately 5 minutes, and the entire simulation evaluation consisted of six consecutive sessions and lasted approximately 1 hour in total.

To improve the accuracy of competence measurement and maximize the training effect, this study was conducted using a realistic, high fidelity infant simulator (SimBaby[®], Laerdal, Norway).²⁸ The simulator was programmed to reproduce physical findings, quantify the specific functions, and perform specific prospectively designated measurements for this study (Appendix 2). End-tidal CO₂ was measured by a portable end-tidal detector (Handheld Capnograph/Oximeter Model 715, Respironics Novamatrix, Inc., Wallingford, CT).

Scenario

Briefly, the scenario was as follows: A 6-month-old infant is involved in a motor vehicle crash. She arrives in the emergency department in a car seat and C-collar (Stifneck[®], Laerdal Medical Corp., Wappinger's Falls, NY). She appears obtunded, with oxygen saturation of 93 percent, despite 100 percent oxygen via a properly fitted face mask. She has been moved to a stretcher for primary evaluation and advanced airway management. Minor, prospectively configured variations of this same scenario were repeated identically six times.

The simulator was preprogrammed to demonstrate saturation and heart rate changes during advanced airway management, with realistic timelines and triggers for response (Appendix 1).

For orotracheal intubation, a standard Miller 1 blade and a 3.5 uncuffed tracheal tube with appropriate sized stylet were provided.

The key actions were prospectively identified and defined as follows: Time of initiation of tracheal intubation was cessation of bag-valve-mask ventilation. Initiation of direct laryngoscopy was defined when the laryngoscope was inserted into the oral cavity of the simulator; initiation of tracheal tube insertion was defined when the tracheal tube visibly entered beyond the gum inside the oral cavity. As used in the procedural definitions for the National Emergency Airway Registry (NEAR),³⁰ duration of an intubation attempt was prospectively defined by the process starting at the cessation of bag-mask ventilation to time of confirmation of successful tracheal tube placement. A successful orotracheal intubation was defined as tracheal intubation with confirmed endotracheal tube position with primary (chest rise and auscultation) and secondary confirmation (positive end-tidal CO₂).⁹

The time to each key action (in seconds) was recorded by an investigator at the scene in a simulation event log. This was later reviewed to document the lowest saturation during each scenario and any tracheal intubation-associated event(s) that occurred during the scenario. Tracheal intubation-associated events were prospectively defined as:

- SpO₂ <60 percent.
- Bradycardia: heart rate <60 beats per minute.
- Hypotension: systolic blood pressure <70 mmHg.⁹
- Intubation failure:
 - o No intubation success within 15 minutes.
 - o Esophageal intubation with immediate recognition (prior to removal of laryngoscope).
 - o Esophageal intubation with delayed recognition (after removal of laryngoscope, but recognized by a subject).
 - o Missed esophageal intubation (never recognized by a subject).
 - o Mainstem intubation with immediate recognition (prior to removal of laryngoscope).
 - o Mainstem intubation, with delayed recognition (after removal of laryngoscope, but recognized by a subject).
 - o Missed mainstem intubation (never recognized by a subject).^{30, 31}

The same investigator attended all study sessions, to ensure consistency of simulation and entry of key action.

Statistical Analysis

The immediate effectiveness of refresher training was prospectively defined as the ratio of time required for successful intubation at the second vs. first session (T2/T1).

The time to successful intubation (in seconds) and immediate effectiveness of refresher training were considered as continuous parametric variables. Parametric data were described as mean ± standard deviation (SD); nonparametric data were described as median and interquartile range (IQR). To avoid confounding by intermittent periods of time required for appropriate rescue bag-mask ventilation, the sessions where subjects required more than one intubation attempt for success were analyzed separately.

As safety practice indicators, the number of intubation attempts required for intubation success and the number of predefined tracheal intubation-associated events were also analyzed as a secondary outcome.

Recent pediatric advanced airway management training (within 3 months)¹⁵ and pediatric intubation experience (>3 years) were analyzed as dichotomous variables as defined *a priori*. Demographic data were compared with Fisher's exact test. Parametric variables were analyzed with unpaired Student's t-test or ANOVA. Nonparametric variables were analyzed with Wilcoxon rank-sum test or the Kruskal-Wallis test. Multivariable linear regression analysis was conducted to evaluate the impact of *a priori* selected independent variables. All statistical tests were performed with two tails, alpha = 0.05 as significant. STATA® 9.0 (Stata Corp, College Station, TX) was used for statistical analysis.

Results

Twenty-six skilled non-anesthesiology providers with a duty to provide advanced airway management at our tertiary care children's hospital (16 pediatric transport nurses, 4 pediatric emergency medicine fellows, and 6 pediatric critical care fellows) performed 156 intubations. The median length of pediatric intubation experience was 3.5 years (IQR: 2 - 5); the median duration from the most recent intubation training was 3.5 months (IQR: 0 - 8.5) (Table 1).

Three transport nurses, no emergency medicine fellows, and no pediatric critical care fellows needed two intubation attempts for successful orotracheal intubation at the first session ($p=0.272$, Fisher's exact test, among disciplines). All participants were successful at the first attempt in the second session. Overall, time (mean $\pm$ SD) to successful tracheal intubation (limited to those with first attempt success) at the first session (T1) was 33.8 ± 9.4 seconds (s), and for the subsequent sessions: (T2) 29.0 ± 6.3 s; (T3) 27.4 ± 5.6 s; (T4) 29.8 ± 9.2 s; (T5) 28.0 ± 5.4 s; and (T6) 25.6 ± 5.1 s (Figure 1). The largest improvement was seen between the first (T1) and second sessions (T2). T2, T3, T5, and T6 were significantly shorter compared to T1 (t-test, $P < 0.05$, $P < 0.01$, $P < 0.01$, and $P < 0.01$, respectively); however, T4 was not (t-test, $P = 0.14$). The

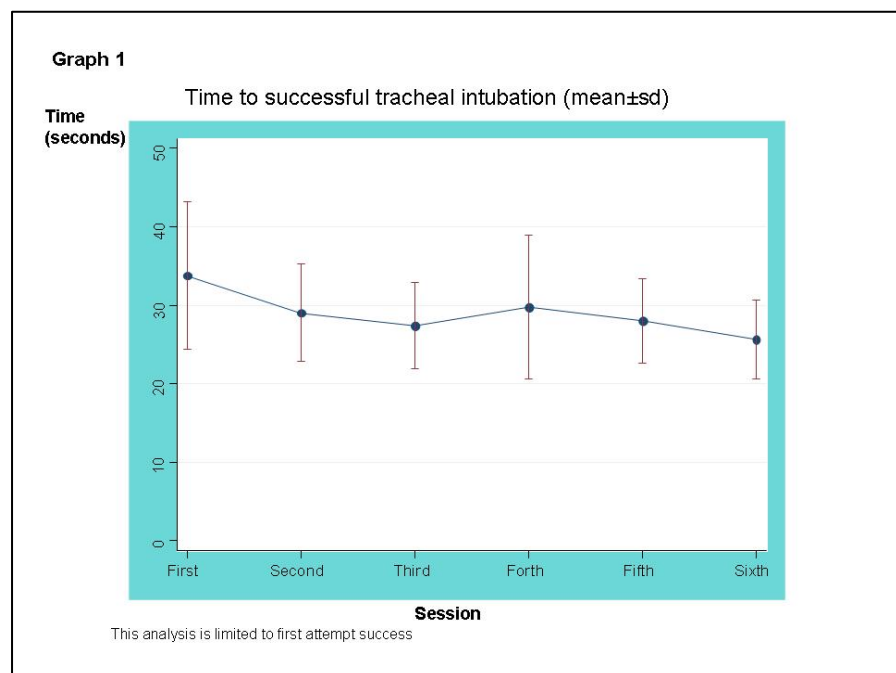


Figure 1. Time to successful tracheal intubation (mean $\pm$ SD).

improvement between two consecutive sessions was only significant between T1 and T2 (t-test, $P < 0.05$); subsequent improvement was not statistically significant (T2 vs. T3: $P = 0.36$; T3 to T4: $P = 0.29$; T4 to T5: $P = 0.41$; T5 to T6: $P = 0.11$).

Overall immediate effectiveness of refresher training assessed by T2/T1 was 88 ± 24 percent, indicating that a 12-percent reduction in time (seconds) to successful intubation was observed at the second scenario compared to first scenario.

Univariate analysis revealed the immediate effectiveness of refresher training was significantly associated with recent pediatric advanced airway training (with recent training 0.74 ± 0.17 vs. no recent training 0.98 ± 0.26 , $P = 0.025$, unpaired t-test) but not with provider clinical experience in pediatric intubation >3 years (with >3 years experience, 0.88 ± 0.23 vs. ≤ 3 years experience, 0.89 ± 0.26 , $P = 0.93$, unpaired t-test) or discipline (transport nurse 0.94 ± 0.24 vs. emergency medicine fellow, 0.81 ± 0.18 ; critical care fellow 0.80 ± 0.29 , $P = 0.40$, ANOVA) (Table 2).

Recent pediatric advanced airway training (within 3 months) remained significant ($P = 0.017$) in a multivariable linear regression model with *a priori* selected variables (discipline, recent pediatric advanced airway training, clinical pediatric intubation experience). However, discipline and provider's clinical intubation experience remained nonsignificant (Table 2).

The number of intubation attempts for a total of six sessions did not differ significantly among disciplines (transport nurse: median six attempts, IQR (6 - 6.5) vs. emergency medicine fellows: six attempts vs. critical care fellows: six attempts, $P = 0.57$, Kruskal-Wallis), with or without provider clinical experience >3 years (Wilcoxon rank-sum, $P = 0.87$) or with or without recent (within 3 months) pediatric advanced airway training status ($P = 0.48$, Wilcoxon rank-sum) (Table 3).

Table 1. Demographics of participants

Discipline	Subjects (N)	Median age (IQR)	Sex (M vs. F)	Median years experience in pediatric intubation ^a (IQR)	Median months from last intubation training ^b (IQR)
Transport	16	40 (37 – 47)	4 vs. 12	3 (2 - 5.2)	2.5 (0 – 9)
PEM fellow	4	31 (30 - 38)	1 vs. 3	3.5 (1.8 - 5.8)	5 (2 - 9)
PCCM fellow	6	31 (30 – 32)	3 vs. 3	4 (3 - 5)	3 (0 – 4)

a Experience in pediatric intubation was not significantly different among three disciplines ($P > 0.5$, ANOVA)

b Duration from last intubation training was not significantly different among three disciplines ($P > 0.5$, ANOVA).

PEM fellow = Pediatric Emergency Medicine fellow.

PCCM fellow = Pediatric Critical Care fellow.

IQR= Interquartile range.

Table 2. Univariate and multivariate analysis for immediate training effectiveness (T2/T1)^a

	Univariate analysis		Multivariate analysis ^b	
Variable	T2/T1	<i>P</i> -value	Coefficient (95% CI)	<i>P</i> -value
Discipline				
Transport nurse	0.94 ± 0.24	<i>P</i> = 0.40	0 (Reference)	<i>P</i> = 0.16
PEM fellow	0.81 ± 0.18		-0.199 (-0.483, 0.086)	
PCCM fellow	0.80 ± 0.29		-0.141 (-0.386, 0.104)	
Previous experience				
≤3 years	0.89 ± 0.26	<i>P</i> = 0.93	0 (Reference)	<i>P</i> = 0.79
>3 years	0.88 ± 0.23		-0.027 (-0.245, 0.190)	
Last training				
≤3 months	0.74 ± 0.17	<i>P</i> = 0.025 ^c	-0.274 (-0.494, -0.055)	<i>P</i> = 0.017 ^c
>3 months	0.98 ± 0.26		0 (Reference)	

a Analysis restricted to first successful intubation attempt.

b Linear regression model. R square = 0.3576, number of observation = 21, probability >F = 0.112.

c *P*-value <0.05,

PEM fellow = Pediatric Emergency Medicine fellow.

PCCM fellow = Pediatric Critical Care fellow.

The frequency of tracheal intubation-associated events did not differ significantly among disciplines (transport nurse: median 2 events, IQR (1.5, 2.5) vs. emergency medicine fellows: 2 events (1.5, 3.5) vs. critical care fellows: 1.5 events (0, 3) *P* = 0.72, Kruskal-Wallis); provider clinical experience (*P* = 0.49, Wilcoxon rank-sum); or recent pediatric advanced airway training (*P* = 0.78, Wilcoxon rank-sum) (Table 3). The most common intubation-associated event was mainstem bronchus intubation without immediate recognition, which was observed in 42 sessions.

Discussion

Psychomotor skill is a critical component for crisis management in clinical settings.^{23, 32} Several studies have examined skill retention after cardiopulmonary resuscitation training. Those studies showed that both cognitive and psychomotor skills decay over time, but psychomotor skill decays faster.^{4, 5, 6, 7, 8} This finding is critical from a training implementation standpoint, since this will determine how frequently trainees need to take refresher training.

Although under some circumstances the initial training effect can be augmented by initial intensive overtraining,³³ the intensity of refresher training required to maintain competence is still unknown. It is also unclear what factors influence the effectiveness of refresher training.

Table 3. Number of intubation attempts and tracheal intubation-associated events

Variable	Median intubation attempts (IQR)		Median tracheal intubation-associated events (IQR)	
Discipline				
Transport nurse	6 (6, 6.5)		2 (1.5, 2.5)	
PEM fellow	6 (6, 6)	$P = 0.57^a$	2 (1.5, 3.5)	$P = 0.72^a$
PCCM fellow	6 (6, 6)		1.5 (0, 3)	
Previous experience				
≤3 years	6 (6, 6)	$P = 0.87^b$	2 (1, 3)	$P = 0.49^b$
>3 years	6 (6, 6)		2 (2, 2)	
Last training				
≤3 months	6 (6, 6)	$P = 0.48^b$	2 (1.5, 3)	$P = 0.78^b$
>3 months	6 (6, 6)		2 (1.5, 2.5)	

a Kruskal-Wallis test.

b Wilcoxon rank-sum test.

IQR = Interquartile range.

PEM fellow = Pediatric Emergency Medicine fellow.

PCCM fellow = Pediatric Critical Care fellow.

Tracheal intubation is a complex psychomotor skill, similar to cardiopulmonary resuscitation; there is a learning curve to acquire intubation skills, and it usually requires significant practice.^{14, 34} Furthermore, this complex skill decays over time if not practiced repeatedly.¹⁷

Initial and refresher tracheal intubation training using patients may be challenging, since intubation by trainees may have higher complication rates,³⁵ patients may not tolerate the long duration of the procedure, and the learning effects may diminish under high-stress clinical situations.³⁶

Our study was conducted to investigate factors associated with the effectiveness of immediate refresher training in an attempt to overcome the challenges described above and to improve safety in pediatric advanced airway management. Determining the effectiveness of immediate refresher training in intubation skills is clinically important because many actual intubations require more than one attempt,^{16, 30} and it is reasonable to assume that clinical providers are actually “refreshing” at their first attempt. Since multiple attempts at intubation may be harmful, the immediate refresher effect is critically important. Therefore, we chose this as a primary outcome of our study design.

This study showed that the effectiveness of immediate refresher training was significantly associated with recent psychomotor training. Unlike many studies in cardiopulmonary

resuscitation training with volunteer lay rescuers, all participants in this study were credentialed in pediatric advanced airway training—including orotracheal intubation—and many had received training relatively recently (Table 1). The transport team members participated in bi-annual intubation training in the operation room. The pediatric emergency medicine fellows and pediatric critical care fellows perform advanced airway management as a part of their fellowship training, although it is less frequent, compared to that of anesthesiologists.

Our local airway registry data in Pediatric Intensive Care Unit showed that tracheal intubation occurs every 3 to 7 days in a busy tertiary PICU with 45 beds (data not published). Despite that training, the intubation in the first session took significantly longer compared to other sessions.

This study finding was similar to the recent report on chest compression refresher training for pediatric in-hospital staff.³⁷ Those researchers compared the time to achieve simulated high quality cardiopulmonary resuscitation (CPR) with an automated feedback system among providers who received frequent “rapid 3-minute refresher” CPR training (two or more times a month) vs. providers trained less than two times a month. The group with more frequent “rapid refresher” training had significantly shorter times to achieve excellent chest compression performance evaluations.^{38, 39}

Since the improvement after the second session was smaller in our study, it is prudent to say that short refresher psychomotor training—even as short as two sessions—is effective. The first session serves as refresher training and the second as a competence measurement. The second session needs to be repeated for those judged not sufficiently competent.

We also should consider that the required number of refresher training sessions might change, when we have absolute competence cutoff (e.g., 20 seconds for neonatal intubation),⁴⁰ since participants improved their skills as the number of refresher training sessions increased. Therefore, this goal is achievable.

Woollard, et al., studied skill retention and skill reacquisition at the time of refresher classes in Basic Life Support with Automated External Defibrillator classes for lay volunteer rescuers.⁴¹ They demonstrated psychomotor skill decay over time. However, skill reacquisition did not differ between a group that received training 7 months earlier compared with a group that had previous training as much as 12 months earlier. This finding is different from our study, in which the recent training was positively associated with an immediate learning effect.

Although the reason for this difference is not entirely clear, it is possible to speculate that: either the effect of previous training on immediate training effectiveness did not last longer than a few months in a difficult, complex psychomotor skill (i.e., intubation), or the refresher training was thorough enough so that the educational effect was maximized at each participant’s capability, regardless of the other factors associated with refresher training effectiveness in Woollard’s study.⁴¹

Kovacs, et al., studied the maintenance of airway management skills in emergency medicine residents.¹⁵ They provided an initial 2-day intensive airway training course followed by 3 weeks of subsequent practice sessions. They then randomized participants to three groups: (1) no feedback at the time of testing nor further practice sessions, (2) feedback at followup testing and eight practice sessions over 10 months, and (3) feedback at followup testing without further

practice sessions. They found that the group with feedback and subsequent practice sessions maintained their airway skills without decay and performed significantly better than the other two groups. The score of the airway skills dropped significantly at the first followup test (16 weeks) and stayed at similar levels in the control group (the first and the third group).

The study by Kovacs, et al., demonstrated the rapid decay of intubation skills within 4 months and the effectiveness of frequent refresher training in advanced airway management.¹⁵ Although we are not able to quantify the effect of time on intubation skill competence (since we do not have their previous competence level), we are able to quantify the effect of recent training on the immediate refresher training effectiveness at the time of refresher training (27 percent improvement in time to intubation success at the second session, compared to first session with recent training). Based on those findings, we conclude that previous training effect still exists up to 3 months later, and that frequent pediatric intubation refresher training every 3 months can be brief, since practitioners regain the skill quickly. Future study in pediatric intubation refresher training at various intervals with immediate training effectiveness measurement is warranted to further quantify the effectiveness of refresher training.

This study has some limitations. It was conducted with each participant performing tracheal intubation without feedback using any of three different C-spine stabilization techniques. Although this was randomized, this technique might have biased the results. We performed an ANOVA with repeated measures to evaluate the effect of C-spine protection method on time to successful intubation, which showed no significant effect ($P = 0.39$).⁴²

The time to intubation was longer in T4 compared to T3, but T4 was not significantly different from T1. The reason for this is unclear. However, it is possible that this was due to the relative performance improvement of “less skilled” intubators. Their performance was eliminated in T1, since they required more than one attempt for intubation success, but it was included in T4, since they no longer required more than one attempt. There was a statistically significant difference between T1 and T4 ($P < 0.05$) when all time-to-intubation success was analyzed, regardless of the number of attempts, which supports this speculation.

The fidelity and realism (face validity) of the simulation used in the study was an important consideration. To enhance realism, we used the high fidelity simulator with real-time feedback in a simulation room similar to a patient care room and provided physiologic parameters that were prospectively set as triggers for success or failure. The realism of intubation with this simulator (SimBaby[®]) under similar conditions was demonstrated in another study to evaluate pediatric resident intubation skills.²⁸ Those investigators found the resident intubation attempt success rate to be 56 percent, which correlated with pediatric residents’ performance in the emergency department (first intubation attempt success rate of 50 percent).³⁰

Furthermore, one recent study showed that learning orotracheal intubation on simulators is equally as effective as learning on human subjects,⁴³ suggesting that our study results might be generalizable to the clinical setting. The potential for ascertainment bias (using volunteers from the pool of skilled practitioners) is possible, as for any convenience sample.

It also is possible that more “self-confident” practitioners volunteered for this study. This effect is unclear, since several studies suggest self confidence does not correlate well with objective

competence measurement in medical practitioners.⁴⁴ In addition, in order to quantitatively measure refresher training effectiveness, we eliminated those events where tracheal tube intubation success required more than one attempt. This could potentially confound the results, since more skilled practitioners might not attempt to intubate with limited laryngeal visualization and would not attempt it a second time. However, the number of intubations was not associated with discipline, recent intubation training, previous experience, or any other demographic data that might be associated with intubation skills.

Conclusion

For non-anesthesiology pediatric providers who do not routinely perform tracheal intubation, recent tracheal intubation training within 3 months, but not practice discipline or previous years of experience, was significantly associated with the effectiveness of refresher training to rapidly improve provider excellence and patient safety in simulated advanced pediatric airway management. The training effect was the largest between the first and second scenario, suggesting that frequent short episodes of refresher training (e.g., as few as two scenarios, with the first session for refresher training and the second session to confirm competence) might be necessary to maintain complex psychomotor skill competence, such as that involved in orotracheal intubation. Long sessions or multiple repeated scenarios may have little incremental benefit for experienced providers. For practitioners who frequently refresh their psychomotor skills through either training or clinical practice, short and frequent refresher training with simulators may be effective.

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This study was approved by the Institutional Review Board of the Children's Hospital of Philadelphia.

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Appendix 1

High Fidelity Infant Simulator Function Utilized in this Study

Simulator Capability

- Trainee to perform bag valve mask ventilation.
 - Trainee to perform tracheal intubation properly or improperly.
 - Simulator to demonstrate chest rise with spontaneous ventilation or positive pressure ventilation.
 - Simulator to demonstrate breath sounds.
 - Simulator to demonstrate palpable pulses in left brachial, radial, and bilateral femoral artery locations.
 - Simulator to exhale CO₂ from trachea with CO₂ tank.^a
-

Monitor Capability

- To demonstrate pulse oximetry saturation number and waveform.
 - To demonstrate heart rate and electrocardiography waveform.
 - To demonstrate respiratory rate.
-

Simulator Measurement/Record Capability

- To measure cervical spine extension angle at every second.
 - To detect appropriate ventilation after intubation.
 - To record a simulation log with vital sign changes, with key actions recorded by an investigator during simulation.
-

a Exhaled CO₂ after appropriate endotracheal tube placement was detected by an end-tidal CO₂ detector.

Appendix 2

Simulation Scenario

A 6-month-old infant was involved in a motor vehicle crash and is restrained in an infant safety seat without obvious signs of traumatic injury. The infant is unconscious with labored breathing and coarse, equal breath sounds. There is no evidence of hemothorax or pneumothorax. The infant has no evidence of increased intracranial pressure. The attending physician requests that you prepare to perform tracheal intubation prior to CT scan evaluation of the brain.

The infant is given appropriate rapid sequence intubation medications, including appropriate paralytics and sedatives, and is currently unconscious and paralyzed. With preoxygenation and good bag-valve mask ventilation technique, the SpO₂ has risen to 92 percent, but you are unable to achieve higher oxygen saturation.

You are instructed by the attending physician to intubate the infant's trachea using an appropriate laryngoscope and endotracheal tube (e.g., Miller 1 laryngoscope blade and 3.5 mm cuffed tracheal tube). Please pay particular attention to cervical spine immobilization, confirm correct tracheal position (using clinical and exhaled CO₂ capnography) and oxygenate and ventilate the infant.

Given this scenario, participants will then perform tracheal intubation on the infant simulator with one of the three cervical spine protection methods:

1. Nonrestricted neck mobility.
2. Immobilization using manual inline stabilization by a second "rescuer."
3. Immobilization using a rigid cervical collar.

Order of Tracheal Intubation			
Group	1 st Set	2 nd Set	3 rd Set
1	No protection	Cervical collar	Inline manual
2	No protection	Inline manual	Cervical collar
3	Inline manual	No protection	Cervical collar
4	Inline manual	Cervical collar	No protection
5	Cervical collar	No protection	Inline manual
6	Cervical collar	Inline manual	No protection

Table key:

No protection (N) was defined as no particular cervical spine immobilization technique is applied to manikin during the scenario. Each subject was reminded to "pay attention to" the potential cervical spine injury, but a person was not assigned to immobilize the neck.

Cervical collar protection (C) was defined as a rigid cervical collar in place during the orotracheal intubation. Proper C-collar placement was confirmed before each scenario by a single investigator.

Inline manual immobilization (M) was defined as a second person holding both hands on the manikin's head, with the index or middle finger held approximately at the opening of the auditory canal to maintain the cervical spine in a neutral position without movement, as taught in the American College of Surgeons Advanced Trauma Life Support course. The person performing inline immobilization crouched to the directed side of the intubator.²¹

Programmed Saturation and Other Vital Sign Changes

Time since last oxygenation (seconds)	Oxygen saturation (%)	Event (precipitated by SpO ₂)	Time to reach SpO ₂ 90% once reoxygenation is reached (seconds)
10	99		--
30	98		--
60	90		--
90	80		10
120	70	Bradycardia	30
180	60	Hypotension	80
240	50		240

Columns 1 and 2 (time since oxygenation and SpO₂) will be collinear. Hypoxia-induced events (column 3) will be entered into the simulation at predetermined SpO₂ levels as indicated in the table. The time to reach an SpO₂ of 90 percent after reoxygenation is reestablished will be collinear with SpO₂.

Simulation-Based Education Improves Patient Safety in Ambulatory Care

Beth A. LaVelle, PhD, RN, CEN; Joanne J. McLaughlin, MA, BSN, RN

Abstract

High-fidelity simulations of patient scenarios have been used successfully to promote critical thinking and staff teamwork in emergency departments, critical care, and medical transport. In contrast, this strategy has been little studied in ambulatory environments. *The First Response: The First 10 Minutes*, a two-phase, simulation-based education program, was designed to help staff from 21 primary/specialty clinics and five urgent-care clinics improve the immediate care of patients with chest pain or anaphylaxis until the arrival of ambulance crews. Key components included updated standing orders, easy-to-use documentation tools, interactive learning stations with expert faculty, on-site education, and scenarios based on real-life situations with immediate debriefings. The effects of this program on clinic staff were increased knowledge, confidence, and skills that translated into better management of actual patient emergencies. An unanticipated benefit of the *in-situ*, simulation-based education was the discovery of 40 safety concerns that were readily addressed.

Introduction

In response to the Institute of Medicine (IOM) report “To Err is Human: Building a Safer Health System,”¹ “Crossing the Quality Chasm,”² the 5 Million Lives Campaign,³ and the Joint Commission’s National Patient Safety Goals,⁴ many initiatives have been developed to improve care in acute care inpatient facilities. However, most patient care is delivered in ambulatory care settings.

Although clinic staff are not expected to be experts in emergency care, they must be able to readily recognize emergent situations, assess the level of intervention needed, provide appropriate care to prevent deterioration in a patient’s condition, and determine the need for activating a call to emergency medical services (EMS) responders. These abilities require a major commitment from staff and their leadership to provide education, analyze processes, identify safety concerns, and put into place many “hard and soft stops” to ensure the delivery of safe, effective patient care and to transfer patients to higher level facilities as needed. Although high-performance team behavior and crisis resource management (CRM) are often cited in the acute care literature,^{5, 6, 7, 8, 9, 10, 11, 12} they are also appropriate frameworks for ambulatory care, and medical simulation with debriefing is an efficient, effective, and safe strategy to facilitating those skills.^{13, 14, 15, 16}

HealthPartners, a consumer-governed family of nonprofit health care organizations, has 21 ambulatory care clinics and five urgent care clinics. Nursing leaders recognized discomfort

among clinic staff in assessing and managing patients with emergent needs. Wide disparities in approaches, unfamiliarity with equipment, lack of skills, and low confidence in handling these situations were noted, particularly during the two most common high-risk events: patients with chest pain and those experiencing anaphylaxis. Both situations require excellent assessment skills, psychomotor skills, critical thinking, and teamwork.

When considering how to improve care of these patients, three concerns were identified:

1. Past traditional “skills days” and learning packets had not been particularly effective in improving staff competence and practices.
2. Despite “standardization,” the contents of code carts and pharmacy emergency drug boxes varied among clinics.
3. Roles and expectations needed to be clarified in order to improve communication and teamwork.

To better prepare clinic staff to work as a cohesive team during the first 5 to 10 minutes between recognition that patients are in trouble and arrival of the ambulance crews, an alternative educational strategy was explored.

In 2003, the medical education branch of HealthPartners collaborated with Metropolitan State University to create a Simulation Center for Patient Safety. The high-fidelity, very realistic simulation-based education provided at this site was primarily directed at teams working in critical care. Learning experiences were designed to accelerate the integration and application of knowledge, skills, and critical thinking without endangering patients. Use of the center has helped prepare these teams to respond to situations that are infrequently encountered in actual care settings. Despite the Center’s primary focus on critical care, the clinics had successfully used simulation for intensive communication courses and new employee orientation. They thought that this hands-on approach could be adapted to teach clinic staff how to manage emergent situations as well.

The nurse leaders partnered with the center’s PhD-prepared nurse coordinator to develop and implement a simulation-based program using a more transportable, moderate-fidelity manikin (Laerdal Mega Code Kelly™). Learning stations and scenarios were developed to provide unique opportunities for ambulatory care staff to safely try new skills and practice teamwork, help leaders discover how human factors and systems issues affected their staff’s ability to deliver safe patient care, and evaluate the effectiveness of new protocols and documentation tools.

A grant from the Minnesota Job Skills Partnership was obtained to help cover some of the expenses of developing and implementing the program.

Methods

Originally designed to facilitate staff education, this project evolved into a quality assurance/patient safety initiative. There was no risk to patients. Data were summarized by clinic, by urgent care, and as a whole (HealthPartners ambulatory care), but only aggregate data and unidentified

quotes were included in publications. We obtained Institutional Review Board approval to share the results.

Design and Implementation of Training

Ninety percent of Advanced Cardiac Life Support (ACLS) ambulance crews arrive at our clinics within 10 minutes of the call for assistance and often within 5 minutes. Therefore, our focus was *First Response: The First 10 Minutes* – the recognition of patients in distress, initial management, and readiness for seamless transport.

Patients with chest pain and anaphylaxis were selected as the target populations. Through collection of verbal feedback from clinic staff and observation of actual critical events, the Nursing Education Committee identified learning gaps related to initial patient management. Five learning units were identified: (1) basic airway management/oxygen delivery, (2) use of automated external defibrillators (AED)/cardiac monitoring, (3) knowledge of emergency medications available on code carts and pharmacy emergency drug boxes, (4) establishment of peripheral IV access, and (5) awareness of processes/protocols/documentation.

Clinic staff would rotate through the five stations as assigned according to their positions (RNs all stations; LPN/certified medical assistants [CMAs] airway, oxygenation, documentation; MDs/nurse practitioners drop-in). Simulated patient events would begin with the patient's arrival at the reception area, continue through emergency management (with or without a physician), and end with documentation and hand-off to the paramedics (Figure 1). Learning activities would take place *in-situ* at each of the clinics so that participants could work with their own equipment, facilities, and staff.

Preparation for the workshops included review of standardized medications and supplies. Protocols and standing orders were updated to reflect current best practice. Worksheets and other educational tools were developed and supplies purchased to support the learning activities (Table 1).

Education at the primary/specialty clinics occurred in two phases:

- **Day 1 skills stations** were available from 0830 to 1600, so that staff could rotate in and out. Faculty (paramedic educator, certified registered nurse of infusion [CRNI], and the emergency nurse/simulation coordinator) taught, discussed, demonstrated, and observed return demonstrations (e.g., basic airway management, oxygenation, AED, IV manikins) at five stations. Most medical assistants completed their assigned three stations (airway, AED, policy/documentation) within 30 minutes. RNs generally needed 2.5 hours to complete the basic three stations, in addition to peripheral IV insertion and emergency medication updates.

To facilitate attendance during clinic operations, some clinics added personnel, while others had clinic educators or managers cover for staff. The faculty also inspected code carts and pharmacy emergency drug boxes for adherence to the clinic-approved lists, ensured inclusion of appropriate supplies, checked for outdates, reviewed medications for congruence with

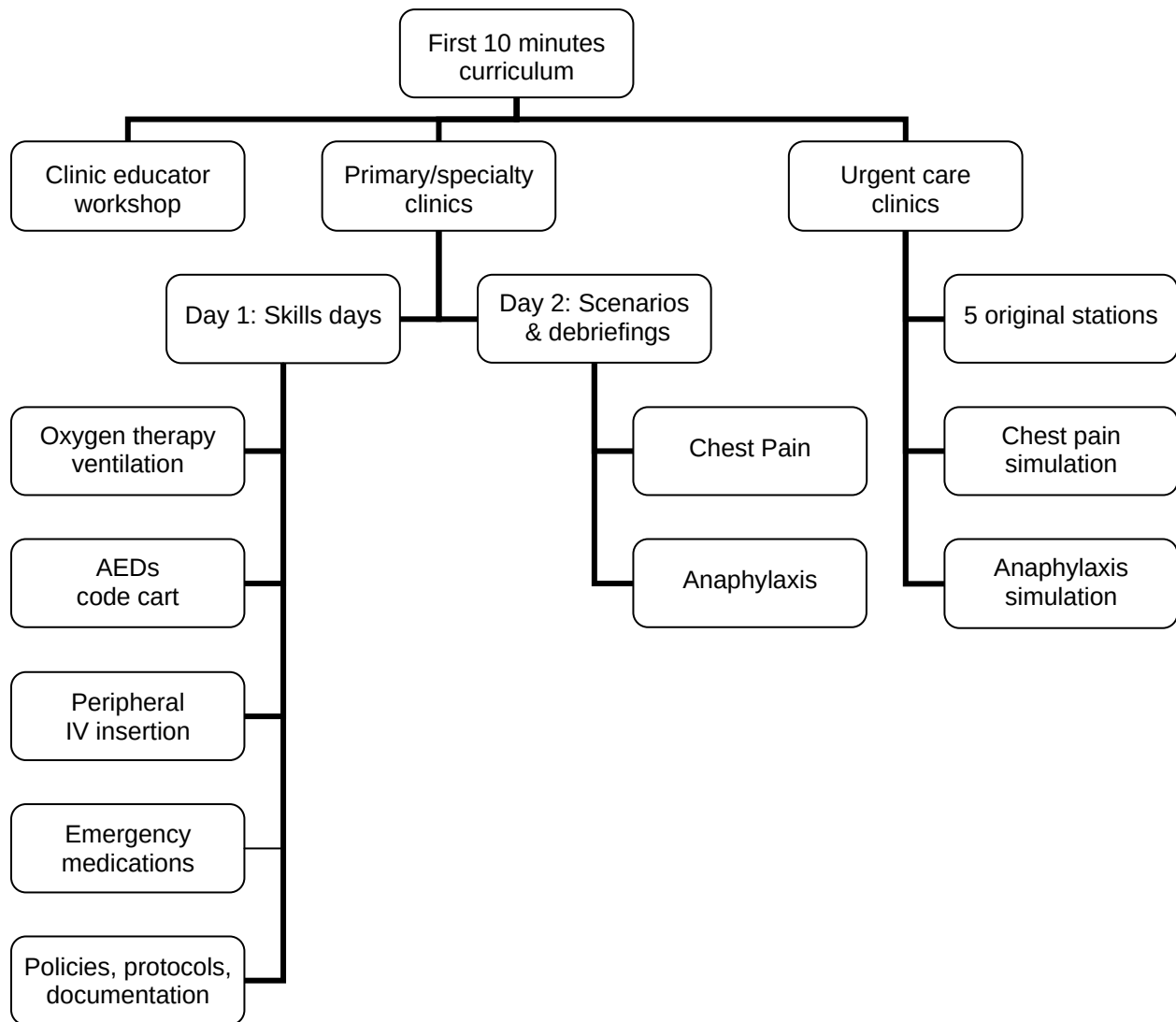


Figure 1. Schematic of training curriculum.

national standards, identified safety concerns, and 6) outlined potential solutions to discuss with clinic leaders.

- **Day 2 scenarios** occurred 1 to 4 weeks later, depending on the clinic's schedules. Over lunchtime, or occasionally dinner, staff (receptionists, nurses, assistants, pharmacists, lab technicians, and sometimes physicians) applied their skills during chest pain and anaphylaxis scenarios. Protocol-driven worksheets were used to guide staff implementation of the revised protocols and to increase accuracy of documentation. The paramedic skillfully guided the simulations with a moderate-fidelity, costumed manikin, while an educator or manager quietly observed and compared staff response with the desired actions (Figure 2).

Staff debriefings followed immediately to identify what went well, what could be improved, and to suggest potential solutions. Because so many staff needed to participate and the exam rooms in which the scenarios took place were small, each scenario was offered at least twice.

The largest clinic had 60 participants over 2 skills days and 57 participants over 2 evenings of scenarios.

To accommodate staff scheduling, the format of the program was altered slightly for the urgent care clinics. A 4-hour, evening workshop was held at each of the urgent care clinics. The staff rotated through all five learning stations (2.5 hours) but practiced on the more difficult geriatric IV manikin arm. After a 30-minute dinner break, they took part in the two simulation scenarios (1 hour). Staff were encouraged to attend workshops at their home sites. However, if they had a scheduling conflict, they had the option of attending a workshop at another urgent care clinic.

As the workshops rolled out, the curriculum was modified to meet newly identified needs, particularly related to the emergency medications.

Three critical safety concerns were noted across all clinics:

- Most staff did not understand the potential interaction between oral nitroglycerin (NTG) and Viagra® or Viagra-like medications, nor were they skilled in soliciting information from male or female patients about their use of such medications.
- A staff member had accidentally injected an EpiPen® into himself/herself rather than the patient.
- A recent sentinel event involved a pediatric epinephrine order that fell between the two standard EpiPen doses.

Table 1. Preparation for workshops

Review

- List of standardized medications on code carts and in pharmacy drug boxes.
 - List of standardized supplies and equipment on code carts.
 - Competency checklists for inserting peripheral IVs, using AEDs, placing airways, and ventilating via bag-valve-mask.
-

Update

- Chest pain standing orders.
 - Emergency management procedures using standard template.
 - Emergency management record.
-

Create

- Chest pain worksheet to match the standing orders.
 - Competency checklists for delivering oxygen, changing regulators.
 - Education module for emergency medications, charts, and quiz related to dosages, formats, and patient and nursing implications.
 - Posters of documentation tools and protocols.
 - Photos of each crash cart drawer and medication box.
 - Two clinic patient scenarios flowing from arrival at the reception area, through emergency management, with or without a physician, and ending with documentation and hand-off to the paramedics.
 - Apply for continuing education hours (CH for nurses, assistants; CME for physicians).
 - Contract for paramedic educator.
-

Purchase/organize

- Supplies for oxygenation and IV stations
 - Moderate-fidelity manikin (Laerdal's Mega-Code Kelly™).
 - Clothing, wigs, props (e.g., bifocals, purse, winter jacket, billfold).
-

It quickly became obvious during the first workshop that the content of the original medication template and quiz was critical, but that discussion rather than a self-study module was needed for staff to synthesize the information and demonstrate correct usage. During that session and all others, we changed the format and added more detailed information about medication interactions with NTG, role-playing exercises for obtaining accurate information about current medication use, critical thinking about nonstandard doses, how to clarify questionable medication orders, examination of the medications on the code cart and in the pharmacy drug box, identification of outdates, “look-alike”/“sound-alike” medications, standard dosages of emergency medications, and demonstration/return demonstration of EpiPens. Although this station was required for RNs and optional for LPNs, all LPNs did participate.

Several modifications were implemented during the simulations. The American Heart Association-revised CPR recommendations were implemented. A new chest pain worksheet, specifically designed to complement the updated standing orders, was piloted and successfully integrated into the electronic medical record as “Smart Text.” We also noticed that at some clinics, nursing staff were reluctant to actively participate in the scenarios once clinic physician(s) arrived. Therefore, we occasionally limited physician involvement and increased our discussion of principles of high-performance team behavior (i.e., role clarity, communication, resource utilization, global awareness) and SBAR communication (Situation, Background, Assessment, Recommendation) during the debriefings.

Design and Implementation of Evaluation

Written evaluations of the experiences were kept very brief so that staff could complete them quickly and return to their patient care duties. For the Day 1 skills sessions, the questions addressed baseline comfort with emergency situations at their clinic, a post-workshop increase in confidence about their ability to perform in an emergency situation, effectiveness of instructors, clinical value of material learned, topics/content deemed to be the most valuable, topics thought to be least helpful, and identification of which stations had been completed. Additional space was left for comments. A similar tool had been successfully used after continuing education workshops for more than 4,000 nurses over the past 4 years.

Although not sophisticated, this simple tool provided valuable information in a minimum amount of time. Comfort and confidence are both affective constructs: comfort reflects a state of ease, low anxiety; confidence reflects certainty, assurance. At baseline, we wanted to know how comfortable staff were with emergency situations. A post-workshop increase in comfort, while desirable, was not as important as an increased confidence in the ability to perform effectively. It was anticipated that those who were very uncomfortable in emergencies would become more confident. It was hoped that even those who were already very comfortable in emergencies would find the sessions helpful and have increased confidence in their ability to perform. A total of 485 participants signed in for skills sessions; 454 evaluations were completed, for a return rate of 94 percent.

Figure 2. Sample scenario for patient with chest pain

A woman wheels a man up to the check-in desk: “Can you help my husband? He’s been having chest pain for hours and just wouldn’t go to the hospital.” Patient (fully clothed, jacket, glasses; skin pale, sweating): “Woke up with pain in my left arm. Kinda sick to my stomach, & it’s a little hard to catch my breath.”

Actions

- ☐ Receptionist: notify staff per protocol; then assist family member(s) & print a copy of pertinent patient information (history, insurance, etc) for EMS.
- ☐ RN: Patient in wheelchair to cart in exam room; staff notify physician that patient with chest pain needs evaluation.
- ☐ Instruct staff to call 911.
- ☐ Identify staff roles within the clinic.
- ☐ Assess pain/intensity (1-10 scale).
- ☐ Assess pulse (apical preferred), BP, RR.
- ☐ Ask for code cart.
- ☐ Check O₂ sat. Start O₂ by cannula (2-4 LPM); simple mask (6-10 LPM), or nonrebreather (10 LPM)
- ☐ Pull up chest pain protocol & worksheet.
- ☐ Notify lab that 12-lead ECG needed.
- ☐ Check history, meds, allergies.
- ☐ ASA 325 mg (or 4 low-dose ASA) chewable. Use chest pain standing orders if MD not available.

“The pain started out at about 4 o’clock this morning –woke me up...it’s stayed about the same except when I walked up the steps, it went to a 6.” Patient has no medical problems; takes no daily meds; no allergies; doesn’t smoke. His dad had a heart attack at age 62.

VS: BP 110/70; P 92 (irreg); R 24; O₂ sats 94%.

Actions

- ☐ NTG 0.4 mg SL, if systolic BP >90 AND patient is NOT on a Viagra-like medication.
- ☐ Start peripheral IV (saline lock).
- ☐ Call for AED & 12-lead ECG (begin continuous monitoring once it arrives).

As you are taking a repeat set of VS: “Oh man, it’s really hurting. Now it’s an 8...I can’t breathe...Give me a pan, I’m going to throw up.” He vomits twice, and then loses consciousness.

- ☐ Actions.
- ☐ Open airway, assess for patency.
- ☐ Suction oropharynx.
- ☐ Assess breathing.
- ☐ Place oral airway.
- ☐ Hook up O₂ at 15 LPM to bag-valve-mask; then ventilate at 8-10 breaths/minute.
- ☐ Assess carotid pulse. If no pulse, begin chest compressions.
- ☐ Apply AED as soon as it is available; follow AED instructions.
- ☐ Update EMS.
- ☐ Assure that personnel are waiting at door to escort EMS to patient's room.
- ☐ Assure appropriate documentation of assessments & interventions.

Figure 2. Sample scenario for patient with chest pain (continued)

After 1 shock, the AED announces, “No shock indicated, check pulse.” Carotid pulse is present. He is making minimal attempts at breathing & moans to painful stimuli.
VS: BP 94 palp; P108; R assisted; SpO₂ no reading; Skin color improving as EMS arrives.

Actions

- ☐ Consider continuing CPR x 1 minute while assisting ventilations.
- ☐ Give brief SBAR report to EMS.
- ☐ Assure that pertinent information is documented for EMS & update family.

EMS leaves for hospital

Actions

- ☐ Escort EMS out of the building.
- ☐ Call report to receiving hospital/emergency department.
- ☐ Debrief event with all involved staff/leadership.
- ☐ Restock emergency supplies.

Since continuing education hours (CH for nurses and assistants; CME for physicians) were awarded for participation in the simulation scenarios, Day 2 evaluations followed the standard CME format: overall reaction, effectiveness of learning activities, relevance to practice, commercial bias, and whether the course objectives had been met. Additional space was left for comments. Evaluations were handed out and completed during the post-scenario debriefings. Staff who responded to the “codes” but had to immediately return to their work areas were offered evaluations to complete but rarely did so. No attempt was made to match individuals’ skills session evaluations with their post-scenario evaluations. A total of 431 participants signed in at scenarios, including 27 physicians who had not participated in the skills sessions. Additional ancillary staff attended but did not sign in; 302 evaluations were completed, for a return rate of 70 percent.

The evaluation tool for the urgent care sessions included all five CME components: pre-session comfort, post-session confidence, the most valuable/least helpful topics, and space for comments. A total of 65 participants signed in; 64 evaluations were completed, for a return rate of 98 percent.

Results

More than 500 staff participated in the *First Response: The First Ten Minutes* program during a 12 month period. All but one person attended sessions at their home clinic or urgent care.

Immediate Self-Report and Evaluations

At baseline, 53 percent of clinic staff stated that they were “uncomfortable in my role when a patient is critical or requires immediate transfer,” or that they “really hate code-like (or potential code) situations.” After completing training, participant self-reported confidence increased “very much” (51 percent) and “somewhat better” (48 percent); 86 percent of participants indicated that they had “learned a lot” that would help them clinically, and 13 percent “learned some.” As expected, staff who were uncomfortable at baseline increased in confidence after the program (96 percent). However, 65 percent of staff who indicated that they were very comfortable at baseline also noted that their confidence had increased “very much.” Only three staff members, all medical assistants, who “really hated” code-like situations, indicated that their confidence level had not improved.

Urgent care staff were slightly more comfortable with emergency situations at baseline than clinic staff (“very comfortable” – 55 percent vs. 47 percent, respectively); they also had slightly more confidence after the workshops (“very much” – 59 percent vs. 51 percent, respectively). Mean scores for overall reaction, effectiveness of learning activities, and “relevance to my practice” were all 4.6 (5 = excellent, 1 = poor; N = 320-329). Self-reported levels of learning for urgent care and primary/specialty clinic staff were similar.

Approximately 20 percent of all participants wrote comments and suggestions on their evaluation forms. These included 10 suggestions on how to improve the process (e.g., scheduling, practice ideal codes on skills day, have more scenarios with fewer staff). The rest of the written comments about the experience were overwhelmingly positive, such as “More self-assured. Really reinforced learning with mock situations”; “Love that it was focused on the first 10 minutes”; and “This was a very good learning experience since our clinic doesn’t see much of each problem.” Ten percent of participants requested more frequent mock codes. Many asked for future scenarios related to obstetric and pediatric emergencies (e.g., seizures, airway obstructions, asthma, unplanned clinic delivery).

Subsequent Application of Learning in Clinical Settings

Even more important than participants’ subjective evaluations immediately after the program were the unsolicited e-mail reports from clinic supervisors that indicated the skills had been successfully transferred to actual patient emergencies. For example:

- “Today we had quite a serious medical emergency and one of my medical assistants thanked me for the mock code experience. Patient ...was having an anaphylactic reaction... [we] knew what to do with the epi because of that drill.”
- “He was pretty bad off...with a heart rate of about 212. Within minutes we had vitals done; EKG in progress; the doc summoned; nitro given; ASA given; an IV in (first try!); and an ambulance called. It was a great team effort. It wasn’t until the dust settled that I realized that all four of us had gone through the training for *First Ten Minutes Response*. It was very valuable training, and that really proved true yesterday.”
- “A man walked into the ... clinic having a heart attack ... [staff] promptly got him aspirin, oxygen, nitroglycerin, and an EKG and summoned me [the doctor]... Less than 15 minutes after walking through our door, he was leaving in an ambulance. Less than an hour after

walking through our door, he was in the cath lab having the blocked artery opened and having the blood supply to that part of the heart restored. He is now stable in ICU. Your work had a profound effect on this man's life! I thank you for that. It is easy to see that effect when it happens so dramatically."

Over 40 patient safety concerns, primarily related to medications, were identified at the various clinics, and plans for corrective action were developed (Table 2). One year later, the Emergency Management Record and new revisions of the chest pain standing orders and chest pain worksheet continue to be used. Paramedic crews have noticed improvements in hand-offs from the clinics, many stating that transfers of care have been "flawless." Although there is still room for improvement, some clinics continue to have admirable chest-pain management with "door-to-EMS transport" times of less than 20 minutes.

Comparing Clinic and Urgent Care Staff

The self-reported baseline level of comfort and post-workshop confidence for clinic staff and urgent care staff were surprisingly similar (Table 3). Since many urgent care facilities in Minnesota had been staffed in the past with ACLS-prepared physicians and RNs with extensive emergency department experience, one would expect that their baseline level of comfort in emergencies would be greater than that of primary/specialty clinic staff. Perhaps the recent trend towards urgent-care clinics being modeled on "after-hours" clinics and hiring staff with less critical care/emergency department experience has blurred the distinction between clinic and urgent care staff.

Although both staffs requested additional scenarios related to pediatrics, respiratory emergencies, and seizures, the urgent care staff also requested trauma scenarios (e.g., lacerations, fractures, head injuries, spinal cord injuries). Clinic and urgent care staff comments about the simulation experience followed the same themes: "More self-assured. Really reinforced learning with mock situation;" "Reinforcement is always helpful;" "The 'real' dummy was awesome to demo. Thanks!" "Made situations we don't see often very real – opportunity to think through and evaluate reactions."

Discussion

Creating a culture of safety has been a focus for the leadership of the HealthPartners primary/specialty clinics and urgent care clinics. Similar to reports in the literature,^{17, 18} HealthPartners system quality data indicated that the vast majority of our clinic incidents were related to prescriptions, but only a handful of reported incidents were associated with actual medication administration (primarily immunizations). The corrective action plan for pharmacy-physician prescription concerns had very limited involvement for the nursing staff, so the Nursing Education Committee focused on providing safe, effective care of two high-risk but relatively low-volume types of patients who receive emergency medications: those with chest pain and those experiencing anaphylaxis.

Table 2. Patient safety concerns and corrective action plan

Potential safety risk	Corrective action plan
Airway/oxygenation safety risks	
Intubation supplies on code cart; but few ACLS-trained staff; intubation not in clinic protocols; and supplies not on standardized list; leaders concerned about liability	Remove intubation supplies from code carts
Staff not sure which sizes of oral airways to use; some sizes missing	Demonstrate/return demonstration; containers with slots for each size airway
Infant oral airways in front of code cart drawer, but most oral airways are used for adults; displaced infant airway can obstruct adult airway	Label and place infant/pediatric oral airways in container in back of drawer
Four different oxygen regulators made it difficult for staff to remember how to attach; tanks run out of oxygen when valves are left open	Use Praxair Grab N' Go™ all-in-one portable medical oxygen system
Suction catheters too small; suction machines require electricity, but some clinic areas don't have outlets within reach	Add inexpensive turkey basters to quickly clear mouths; add second heavy-duty extension cord to code cart
Medication safety risks	
Dangerous to give oral nitroglycerin (NTG) if patient has taken Viagra® or Viagra-like medication within previous 24-36 hours	• Update chest pain protocols to include contraindications to oral NTG administration • Discuss: 1) risk of dangerously low BP if NTG is given within 24-36 hours of Viagra-like med; 2) med names; 3) types of patients (male & female) who are prescribed these meds; 4) role play ways to solicit accurate information from patients
NTG expiration dates unclear	• Label with date expired, not date opened • Clarify whether to use manufacturer's expiration date or 6 months from opening NTG bottle
Sound-alike meds: "Nitro spray" vs. "Nitro" (topical) in large silver canisters	• Nitrolingual® Pumpspray currently not available in clinics • Providers request "nitroglycerin sublingual"
Difficulty injecting dextrose through small IVs	• Review needle-less systems • Administration rate of meds related to IV catheter size
No filtered needles to draw up meds from ampoules	Add filtered needles to code carts and emergency drug boxes
No injectors (cartridge holders) to administer meds	Add injectors to code carts and emergency drug boxes

Table 2. Patient safety concerns and corrective action plan (continued)

Potential safety risk	Corrective action plan
Medication safety risks (continued)	
Staff drew up meds through metal bottoms of cartridges	Review how to “seat” and twist to engage cartridge
Staff member accidentally triggered EpiPen® auto-injector into his/her own finger	- Review administration; demonstration/ return demonstration with trainer device - Discuss emergency measures if EpiPen® accidentally discharges into healthcare provider
Look-alike meds: - Diazepam, midazolam, and morphine in green-capped cartridges with purple-hued lettering - Magnesium sulfate, furosemide, and midazolam all in small vials with orange caps	- Remove meds not on standardized list from code carts and emergency drug boxes - Physically separate look-alike meds - Alert staff to potential look-alike meds
Enteric-coated, low dose aspirin in code cart	- At least 4 <i>regular</i> low-dose tablets – <i>not enteric coated</i> – in aspirin bottle during code cart checks - Review why it is not called “children’s aspirin”
End-of-month, routine checks by pharmacy staff missed some outdates around holidays	- Reminders for pharmacists - Consider best time of the month to check for outdates
Medications not on approved list (e.g., Depacon®, paraldehyde, lorazepam); only 6 meds on emergency drug box standardized list, but requests resulted in up to 4 tackle-box drawers filled with meds	Review and limit meds in emergency drug box to those on the standardized list
Staff and pharmacists unfamiliar with doses of emergency meds given infrequently	Add med chart to top of emergency drug box; include names (generic & brand; note version in box), format, usual dose, & admin instructions
- Variable med format and names (brand vs. generic) secondary to med cost and availability - Unfamiliarity with meds delays administration	Indicate current format (e.g., cartridge, ampoule, vial) on the medication grid
Wrong concentrations &/or route on code cart: - Epinephrine with intracardiac needle 1% lidocaine for joint injection vs. 2% for cardiac	Change to standard prepackaged emergency meds: - Epinephrine (1 mg, Abboject®, needleless) - Lidocaine (100 mg, Abboject®, needleless)
Right concentrations but too much available: - Adenosine IV 60 mg/20 ml vials - Diazepam IV 50 mg/10ml - Outpatient pharmacists not always aware of usual emergency med doses	- Store only two doses of each med on code cart; obtain additional doses from pharmacy - Add usual med dosages to standardization charts
Small, difficult-to-read fonts on med containers	- Tie magnifying glass and/or “cheaters” to code cart - Large print instructions

Table 2. Patient safety concerns and corrective action plan (continued)

Potential safety risk	Corrective action plan
Equipment and supply risks	
Code cart drawers not labeled	Standardize labels (e.g., medications in top drawer; then airway, breathing, circulation)
Staff unfamiliar with emergency documentation forms; tendency to jot notes on scrap paper	• New emergency med form piloted/revised • New chest pain form follows standing orders – available in hard copy and computerized “Smart Text”
Difficult to find current ACLS protocols during an emergency	• Hang enlarged, laminated copies of current algorithms from IV pole on code cart • LABEL and tab the most common protocols in spiral ACLS resource book
Wheelchairs unavailable (missing, locked up, on a different floor)	• Minimum of 1 wheelchair per floor • 3-4 wheelchairs in reception area including an extra-wide wheelchair
Only regular size adult and pediatric BP cuffs on code cart	All code carts have a range of cuffs, including extra-large adult or thigh cuffs for bariatric patients
Monitor/defibrillators being replaced with AEDs in all clinics except those that use moderate sedation and urgent-care clinics; however, nurses and physician uncomfortable when unable to see cardiac rhythm	• Continue to have monitor/defibrillators in urgent-care clinics and areas where patients receive sedation • Lab brings ECG machine if 12-lead ECG is needed or actual rhythm needs to be observed
System and process risks	
Unable to hear overhead pages in pharmacy, exam rooms, conference rooms	• Add audio speakers • Adjust speakers in conference room so they can't be turned off during meetings
Missing “tasks”: obtain information from family members, address family needs	Assign staff to attend to family: offer phone; gather information; escort to patient care area
EMS unable to find patients in large clinics	Assign staff to clear hallways, wait by entrance that EMS crews use, and escort them to patient room
Delayed pharmacist arrival in multilevel buildings	Receptionist holds elevator, escorts pharmacist to patient floor, returns immediately to ground floor to await ambulance crew, accompanies EMS to patient floor, holds elevator for EMS return with patient to ground floor
Staff unable to find patient location in new building	Identify floor, corridor, and room number during overhead page
Staff unaware of standing orders or did not know where to find them	• Place chest pain standing orders on code carts • Keep “chest pain packets” at reception desk and hand to nurses responding to code blue

Table 2. Patient safety concerns and corrective action plan (continued)

Potential safety risk	Corrective Action Plan
System and process risks (continued)	
Staff reluctant to speak up when MDs order incorrect doses of medication or deviate from protocols	Discuss hierarchy, “assertion” communication, and responsibility of staff to speak up
Original documentation lost; unavailable for entry into charting system (tend to “go out door” with ambulance crews)	• Receptionist prints patient information (e.g., allergies, meds, insurance) to give to EMS crew • Photocopy/print emergency management/chest pain flow sheets • Worksheets in “Smart Text”
Roles unclear; staff hold back until they receive clear directions	• Clarify roles • Educate about delegation; RNs practice directing, delegation, and SBAR hand-offs • “Job cards” – individual roles during an emergency
Exam rooms small; unable to have ECG machine and code cart in room at the same time; crowded with staff responders	• Bring patients with chest pain or allergic reactions to larger procedure rooms • Leave code cart in hallway outside exam room • Crowd control: ancillary staff (pharmacist, lab, extra CMAs, nurses) stay outside of room until invited in
Staff uncomfortable with ECG rhythms	• Review dangerous rhythms for clinic RNs • ACLS courses for urgent-care RNs and MDs
Some clinics do not have a pharmacy; controlled substances (e.g., morphine) must be locked up	• Lock emergency drug box in wall unit • Consider if locked code cart drawer is secure
Inconsistent process/overhead page script to initiate emergency responses	• Standardize meaning and protocols across all clinics for “Code Blue,” “Nurse,” “STAT,” “All available staff” • Create standard script for staff
• Many staff haven’t seen a smoothly managed patient emergency • Not all staff could attend First Response workshops	• Create “gold standard,” clinic-based video • Periodic staff review of protocols • Repeat clinical scenarios every 6 months

Table 3. Relationship between pre-workshop comfort level in emergency situations and post-workshop increases in confidence about ability to perform

Comfort level before skills day	Increase in confidence after skills session? [N (%)]			
Primary/specialty clinic staff (N = 399)	No, not really (N = 7)	No, fine before (N = 8)	Some (N = 181)	Yes, very much (N = 203)
Really hate (N = 52)	3 (0.8)	1(0.3)	29 (7.5)	19 (4.5)
Uncomfortable (N = 180)	4 (1.0)	0 (0)	90 (22.6)	56 (14.0)
Very comfortable (N = 197)	0 (0)	7 (1.8)	62 (15.5)	128 (32.1)
Urgent care clinic staff (N = 61)	No, not really (N = 0)	No, fine before (N = 0)	Some (N = 27)	Yes, very much (N = 34)
Really hate (N = 7)	0 (0)	0 (0)	4 (6.7)	3 (4.9)
Uncomfortable (N = 22)	0 (0)	0 (0)	13 (21.3)	9 (14.8)
Very comfortable (N = 32)	0 (0)	0 (0)	10 (16.4)	22 (36.1)

* Note: In-between scores were moved to a lower level. Pairwise deletion was used so that only respondents who answered both items would have his/her data included in the chi-square.

χ^2 Primary/specialty clinics (6, 399) = 46.22, $P < 0.01$; χ^2 urgent-care clinics (6, 61) = 4.63, $P = 0.59$

Drivers for Using Simulation

The primary drivers for using a simulation-based learning strategy to address emergent care were prior success in using simulation to improve patient safety, consistency with adult learning principles, and practicality. Patient safety concerns were identified through a review of the clinic quality incidents, observations by the clinical supervisors, the National Patient Safety Goals, and the ISMP Medication Safety Alerts.¹⁹ The Simulation Center had already established that high-fidelity simulation with debriefing was a safe, effective, and efficient way to expose critical care staff to high-risk/low-volume situations, observe staff behavior under stress, and promote critical thinking. Our challenge was to adapt simulation to outpatient settings and to obtain a more easily transportable, moderate-fidelity manikin with heart/lung sounds and blood pressure.

The use of simulation with immediate debriefing was also supported by principles of adult education:

- Adults often learn most effectively when they can participate in interactive environments.
- Immediate feedback during debriefings is more valuable than delayed feedback.
- Consistent messages and standardized protocols reduce ambiguity and variation in practice.
- Concrete applications increase learner engagement and retention of information.
- People learn from their mistakes and, with simulation, mistakes can be allowed to lead to natural consequences without harming actual patients.

Finally, simulation was a practical approach. Since traditional skills days and learning packets had not been very effective or well-received by the clinic staff, the Nursing Education Committee was searching for an engaging strategy that could be used for efficiently teaching large numbers of staff. The Simulation Center not only had expertise in creating emergent scenarios, but it had secured grant funding to support the project. Providing education at the clinics made staff participation easier and less expensive than if staff had to travel off-site to the Simulation Center. On-site education also supported the discovery of clinic- and system-based issues and the implementation of corrective action plans. We concluded that simulation-based learning at the clinics would be an effective, efficient, and safe way to meet our educational goals.

Curriculum

The basic curriculum for the *First Response: The First Ten Minutes* program was effective. Each of the five learning stations was rated “most valuable” by a large number of the participants. Faculty were also well-received. The moderate-fidelity manikin was sufficient for the scenarios. The sessions were praised as being “nonthreatening,” and additional scenarios were enthusiastically requested. Adjustments to the program included:

- It was more effective for managers to observe a workshop prior to it coming to their site than to attend an instructor class off-site; therefore, the second instructor class was canceled.
- Only a paramedic, an infusion specialist (for 2 hours over lunch), and an educator from each clinic were in the original staffing plan for implementation. When few educators could be freed up from patient care duties and it became apparent that a high level of expertise was needed at the emergency medication station, the simulation coordinator supplemented the team, taught most of the medication stations, and evaluated the code carts and pharmacy drug boxes.
- The format for the medication station was changed from a self-study module with quiz to a half-hour discussion based on the quiz, demonstration/return demonstration, and analysis of code cart and pharmacy drug box contents.
- New documentation forms and standing orders were piloted during scenarios.
- Because some staff avoided participation when physicians were present, the paramedic was selective about which clinics allowed their physicians to take part in the scenarios.
- Additional skills days and scenario sessions were needed to accommodate the number of staff in the larger clinics.

Lessons Learned

Most of our “lessons learned” were associated with implementation rather than planning. First, the supplies, equipment, and manikins that filled the back of a stationwagon were heavy, and because they were not dedicated solely to this project, had to be transported from the Simulation Center to each clinic and back again. A dedicated manikin and supplies would reduce that time and labor.

Second, clinic staff were not experienced in patient simulations, so they were not sure what they should do compared to what they should verbalize. They had a tendency to want to fabricate the

lab results and change the flow of the scenarios. Increased exposure to simulation and this particular manikin would help clarify faculty expectations and increase staff comfort.

We also realized that the advantages of doing the scenarios on-site definitely outweighed the disadvantages. We would not have identified the majority of the safety concerns noted in Table 2 had we offered the program off-site. Although on-site education provides an opportunity to involve the staff physicians and nurse practitioners, most providers were booked with patients and only expressed an interest in participating “after the fact.” Earlier involvement and engagement of providers in the learning stations and scenarios would help encourage high-performing team behaviors, particularly role clarity and communication.

Medication “lessons learned” included:

- Since most pharmacists and nurses are outpatient-based and unfamiliar with the administration of emergency medications, the corrective action plan must have “hard stops” to reduce the risk of medication errors.
- Despite overall excellent relationships with the physicians, nurses sometimes did not question them when they requested an incorrect medication or dose during scenarios. Whether this reluctance was due to the clinic hierarchy or nurses’ insecurity, several actions (e.g., “pause for the cause,” practice “assertion language”) and an understanding of the responsibilities involved in being on a high-performance team are needed.
- Vigilance is critical, even when medications and supplies have been “standardized.” The variability that occurs naturally when large numbers of staff are spread over multiple sites should trigger frequent, routine examinations of code carts and pharmacy drug boxes by clinical experts who can quickly spot potential problems. Except for purchasing additional wheelchairs and reinstalling overhead speakers in some clinics, most of the suggested corrective actions were both inexpensive and relatively easy to implement.

Safety Concerns

Since the clinics’ supplies, equipment, emergency medications, and protocols had been previously standardized, the large degree of variation among the clinics came as a surprise to everyone. The 40 safety concerns fell into four broad categories: airway/oxygenation, medications, equipment/supplies, and system/processes (Table 2). Of particular concern were the emergency medications in the pharmacy drug boxes. Although only six medications were on the standardized list, some clinics had up to four tackle-box drawers filled with additional medications, such as Depacon[®]. The most distressing example was related to the stocking of adenosine. A pharmacist had stocked adenosine 2 mg/mL as directed by the standardized list, but each of the 6 vials contained 60 mg. The initial adult dose is 6 mg IV. How easy it would have been for a nurse inexperienced in giving adenosine to hear “60” instead of “6” and administer the entire vial.

Sound-alike medications were not an issue, but some pharmacy drug boxes had look-alike medications in near proximity, such as midazolam, magnesium sulfate, and furosemide in small vials with orange caps, and midazolam cartridges labeled with pink-purple print, much like nearby meperidine and morphine sulfate. In addition, medications on the code carts were not

always the appropriate dosage, concentration, or formulation, and some carts were missing the injectors or filtered needles needed for medication administration.

Next Steps

The *First Response: The First 10 Minutes* simulation-based strategy can be modified to address multiple safety concerns and patient situations. For HealthPartners, the focus of Season 1 was the emergent identification, management, and seamless transfer of patients with chest pain or anaphylaxis. Season 2 focused on first response to alterations in levels of glucose, particularly hypoglycemia. Standing protocols for adult and pediatric hypoglycemia were revised, and corresponding worksheets were created. The clinical scenarios included the management of a young woman with hypoglycemia and a man with diabetes who was experiencing chest discomfort but had a normal blood glucose. It is anticipated that subsequent seasons will address management of pediatric respiratory distress and seizures. The success of the *First 10 Minutes* program has stimulated interest in adapting the curriculum for the staff of the HealthPartners dental clinics and the outpatient pharmacies.

Conclusion

Simulation-based education was a well-received, effective strategy to enhance patient safety in ambulatory care. Implementing *First Response: The First 10 Minutes* at each primary/specialty clinic and urgent care clinic resulted in identification of multiple safety concerns that would not have been discovered had the training occurred off-site. Increased staff knowledge, competence, confidence, and teamwork skills improved their ability to manage chest pain and anaphylaxis in real-life patient situations. Key components of the program included careful planning, revisions of standing orders, easy-to-use documentation tools, on-site education via interactive learning stations and simulated patient scenarios with immediate debriefings, faculty who were expert teacher-clinicians, team training, and a firm commitment by nursing leadership to make the safe delivery of care in emergencies a priority. The program format can be readily adapted to address other patient safety concerns.

Finally, and perhaps most significantly, is the enhanced awareness that even well-run, standardized ambulatory care environments can benefit from careful, *in-situ* scrutiny of their medications, supplies, equipment, and processes.

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Human Factors

Pillars of a Smart, Safe Operating Room

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Abstract

Major gains in patient safety can be achieved through development of innovative approaches to the care of surgical patients. Investigators and clinicians have conceived an “operating room of the future” (ORF) that epitomizes those current and future enhancements that can contribute to patient safety in the operative environment. In this article, we explore these enhancements in the context of their development as University of Maryland (UM) ORF initiatives. We discuss the four “pillars” of our research that affect patient safety: (1) surgical simulation, (2) “smart image,” (3) informatics, and (4) ergonomics/human factors. In surgical simulation, in addition to virtual reality and physical trainers of surgical skills, we are developing a cognitive simulator for teaching clinical decisionmaking in a manner that emulates the actual surgical and clinical experience. Smart image uses computer-enhanced imaging to provide safe rehearsal before surgery and image-based guidance during operations. Informatics analyzes and improves the processes within the perioperative environment, including accurate identification of the patient, care providers, and tools; establishment of clear communication among the surgical team members; and provision of real-time, graphically presented feedback. Ergonomics and human factors are used to design physical and informational workplaces for better outcomes, both for patients and care providers. Research in regard to these pillars shows the promise of an ORF as a vital component of a pervasive patient safety environment.

Introduction

Almost two decades ago, Sir Alfred Cuschieri, one of the true pioneers of minimally invasive surgery (MIS) and the operating room of the future (ORF), asserted that laparoscopic surgery represented “a rare instance in surgical history where an advance in patient safety and surgical technique has been so rapid and so profound.”¹ Today these words continue to ring true and bring inspiration to those who seek to move beyond laparoscopy, to probe, discover, and invent the ORF in anticipation of the patient benefits that will follow. Surgeons and researchers at the University of Maryland (UM) have contributed significantly to the growth and evolution of laparoscopic surgery and to the development of the concept of the ORF.

The state of the art in operating room (OR) safety, while always evolving, can be revolutionized through smart application of technology and knowledge. Recent advances in technology have moved us from a traditional surgical suite toward one that is more efficient and safe. That evolution continues in the ORF, where research seeks to identify and address novel approaches to an array of domains often overlooked in the safety literature. While the ORF has been embraced by many institutions in unique ways, the advantages of a number of promising

approaches to safety can be exemplified through the UM ORF initiative. Our approach has been to identify strategic areas for which solutions to problems would be significant, even disruptive, in the advancement of the concept of ORF. Of the many fields of investigation to be pursued under the rubric of ORF, we have focused on four key areas. Broadly titled, these focus areas are (1) cognitive simulation, (2) informatics, (3) “smart image,” and (4) ergonomics/human factors. Considerable overlap is found among these complementary research fields. In this article, we describe the aim of each of these four pillars and the work that we are doing within each pillar to improve patient safety. We conclude each section with an idealized view of what the future may hold.

Cognitive Simulation

As new surgical technologies and techniques emerge, patients are often torn between wanting to avail themselves of the latest therapeutic options, yet wanting to be reassured that their surgeon is adequately trained and has already ascended the requisite learning curve. Surgical educators have been hesitant to mandate simulators for the training of surgical novices even as they recognize the need to separate surgical trainee learning from direct patient contact. The cautious approach to acceptance of simulation training was based, in part, on the initial lack of robust scientific evidence to support the use of medical simulation for skills training and also on the lack of knowledge of how to effectively apply simulation to a surgical skills training program. Fortunately, the acceptance of simulation training by boards and certifying agencies is on the rise.²

Simulation represents a valuable alternative to using patients as hands-on training material for care providers. It improves patient safety by moving the learning phase away from patients.^{2,3} Typically, simulations allow the practice of manual skills or procedural steps involved in a discrete medical event or team-based activities, such as a trauma admission, airway management, or surgical crisis.⁴ Simulation practice has steadily gained credence as a method of improving knowledge and performance. Additionally, the use of simulation for credentialing and assessment of competencies is acquiring acceptance as a means of improving patient safety.⁵

Many patient safety issues arise not out of poor manual and procedural skills, but rather from lapses in clinical judgment leading to adverse events (AEs). Simulation can provide time-effective experience and training to residents on restricted work-hour schedules. In particular, cognitive simulation can provide clinicians with the opportunity to rehearse and explore the process of diagnosis and treatment.

Given the effect the development of a cognitive simulator can make in regard to training and patient safety, the UM ORF simulation team has created a “Maryland Virtual Patient” (MVP) prototype. This multivariate cognitive simulation possesses the ability to grow, change, and experience biologic functions, to allow trainees to experience realistic interactions with a simulated patient. The UM ORF has developed this working prototype as an automated tutor for medical students. It currently functions as a clinically accurate and computationally tractable model of human physiology, both normal and pathological, that emulates some six to eight gastrointestinal diseases at levels of detail sufficient for the needs of training medical students. A broader range of disease models is being developed.

The MVP automatically undergoes physiologic processes over time and can communicate its symptoms to trainees, which makes it a combination of an intelligent cognitive agent capable of understanding, reasoning, and responding in English and a physiologic agent—i.e., a patient with a disease. With the MVP, just as with an actual patient, the trainee can practice communicating, ordering tests, prescribing treatments, and observing treatment results. The MVP includes a language recognition and text generation component to generate relevant statements: the MVP can understand the user's questions and statements and also decide what to communicate back to the student. This decisionmaking process is akin to the reasoning process guiding the “life” of this physiologic agent.

Significant to this MVP project is the use of artificial intelligence so that learners can interact with the simulation using natural language. This dynamic represents a considerable advance over other simulations, which depend on a prescribed “script” of events or preset branching points in a scenario. The MVP can be given a variety of treatments at any time and in any doses, appropriately or inappropriately, and it responds as a typical patient. The potential benefits of using the type of dynamic simulation represented by the MVP are improved clinical decisionmaking, provision of realistic experiences for training clinicians, and the provision of well-trained care providers for patients.

Simulation is gaining wider acceptance for credentialing procedural skills, supplying criteria-based certification of safety-critical skills, and providing opportunities to improve clinical judgment through the practice of cognitive skills. It is expected that future clinicians will gain experience during training less on animals, cadavers, and real patients and more on realistic simulations of clinical experiences. Because simulation faithfully reproduces a variety of clinical challenges, the likelihood increases that a surgeon will have familiarity with a multiplicity of patient-specific problems.

Smart Imaging

Medical practice is considered among the most complex and difficult fields. That no two patients are exactly alike is one of the challenges that makes it so. Anatomic and physiologic differences make each case unique. In surgery, these variations can complicate an operation; the discovery of unexpected anatomical variations often requires a surgeon to stray from standard, well-practiced techniques to attempt a novel approach to the procedure. With novelty comes a reduced margin of safety. This situation is exacerbated by a trend toward further physical separation between the patient and interventionalists (e.g., surgeons, endoscopists, radiologists) and a greater dependence on an image of the patient's (target) anatomy to effect therapy or establish a diagnosis.

Recently, a number of innovative approaches to enhance the scope and precision of image-guided surgical procedures have been under development. These include augmented reality images used to guide laparoscopic procedures;^{6, 7} advanced image-guided navigation; haptic (touch-based) feedback; telesurgical capabilities used in robot-assisted procedures;⁸ and even subject-specific anatomical models developed for minimally invasive cardiac surgery.⁹ These approaches have the potential to bring in a new level of sophistication and accuracy to image-guided surgical procedures. Our focus has been on developing a “smart image” to guide the interventionalists.

“Smart image,” as we have defined it, refers either to the process of extracting elements from an environment and imparting them to an image or to acquiring elements from within a scene and enhancing them. The result in either case is a more meaningful visualization of the operative field. Although many applications exist within this definition, Maryland’s smart image team is working toward performing the first laparoscopic surgery guided completely by smart image.

Typically in laparoscopic procedures, diagnostic imaging—including x-rays, computerized tomography (CT), and magnetic resonance imaging (MRI) scans—can provide a preview of patient physiology. Often, however, these diagnostic images are in a static format that does not allow the care provider to interact meaningfully with the information the images contain. Current advances in smart imaging can be used to improve patient safety by providing the caregiver with a more interactive experience. A set of two-dimensional (2D) slices of a CT scan can be transformed into a three-dimensional (3D) computer model so that surgeons can preview a realistic view of the patient’s anatomy before an operation. This type of smart imaging provides an interactive “fly-through” view that allows the surgeon to explore the anatomy in detail.

With advances in computing power, these previews could be mapped more realistically to interactive simulators that would permit rehearsal of a surgical procedure that might include attempts at novel approaches before surgery begins. During real surgery, these smart diagnostic images could be integrated into the surgeon’s actual view of the patient.

At the Maryland ORF project, we are working toward matching the minimally invasive surgeon’s video view of the surgery with computer-generated models from diagnostic imaging.¹⁰ Such imaging could provide the surgeon with real-time “x-ray vision” during the operation. Thus, the underlying structure, such as the position of a tumor beneath the surface of a larger anatomic structure or blood vessels within the liver, could be seen. Vessels could be contrast-enhanced in a single, high-resolution CT scan before the surgery. Then, during surgery, low-dose/low-resolution CT scans could be used to transform the high-resolution CT image to match the movement of the patient’s anatomy during surgery.^{11, 12} This would allow intraoperative visualization of anatomy that retains the enhanced contrast vessels, a unique ability that is not possible at present.

CT scans can provide enhanced intraoperative visualization of deep structures far superior to that of laparoscopes. However, the use of continuous CT exposes the patient and surgeon to a radiation level that remains a concern. Therefore, a major thrust of our work is to design, develop, and test several dose-reduction strategies and to incorporate these into our proposed continuous CT-guided surgical navigation system.^{11, 13} Our preliminary work suggests that our strategies would allow us to lower the net radiation exposure to the patient to levels commonly viewed as acceptable in cardiac catheterization and interventional radiology procedures. In the long term, we also propose using telemanipulators to remove surgeons from the CT room and thereby shield them entirely from radiation exposure while they are performing the procedure.

In the future, we expect that advances in computing power will lead to a routine interactive review of patient anatomy through 3D modeling. Rehearsal of surgery on a detailed computer model of a specific patient would allow a surgeon to work out potential complications through simulated surgery before the actual operation. During surgery, surgeons would have the ability to

see diagnostic images projected onto or viewed next to a patient's actual physiology to provide a synthetic-vision view of the patient's anatomy integrated with additional diagnostic information.

Informatics

The manager of a well run OR suite should maintain an awareness of the surgeons, anesthesiologists, nurses, patients, and major pieces of equipment that are present. The harsh reality in current medical practice is that most commercial warehouses and supermarkets track their assets and inventories in a far more sophisticated way than we do in the perioperative environment. Wal-Mart closely tracks the location of its 99-cent paper towel inventory, but a charge nurse in a typical operating suite might have to search for a C-arm or ultrasound machine.

Well executed process management is a key to excellence in health care. Inefficiency, redundancy, communication problems, usage problems, and system failures are among the issues driving annual health care expenditures to over a half-trillion dollars, or the equivalent of 30 to 40 cents of every health care dollar.¹⁴ The challenge to the health care industry is to understand and improve processes that lead to system failures and lower efficiencies, while simultaneously minimizing risks to patients and caregivers. This challenge must be met in order to offset the growing fiscal demands placed on the health care enterprise. Fiscal, operational, regulatory, and patient safety demands that occur within the constraints of limited resources increase the complexity of both performing a single procedure and of coordinating multiple procedures. A need exists to create a system that can objectively evaluate the efficacy of the many processes that occur in any OR as they relate to time, cost, and patient outcome.

Informatics—the science of collecting, classifying, processing, retrieving, and disseminating data—can be a key to patient safety. Using information technology to improve patient safety has been a hallmark of recent patient safety efforts. These efforts have ranged from the use of barcode IDs for patients to the application of computerized physician order entry systems. Computer systems provide an infrastructure in which patient safety efforts can be implemented through novel uses of information. Process improvement—specifically the identification, evaluation, and quantification of perioperative processes—is the focus of UM ORF informatics research. By studying perioperative workflow at the UM ORF, we hope to track, model, and ultimately better integrate existing and emerging OR technologies in a manner that contributes to patient safety, OR efficiency, and process improvement.

We anticipate that information technology and location-aware tracking technologies will have a valuable and indelible influence on health care, one that results in ensuring that patients receive a care experience characterized by a safe and healing journey through the health care system. Currently, no accepted measure of efficiency exists within the OR environment. There is no quality matrix or framework to evaluate operational processes to determine the level of operational performance. We do not have a means to show the patterns of our efficiencies or failures. We plan to apply a novel approach that integrates technologic components and corporate and manufacturing methodologies, so that system failures are minimized or eliminated, and investment returns are maximized.

Within the informatics pillar, the UM ORF research program is developing three specific applications to improve patient safety. These are smart environments, operational glitch analysis,

and group-based communication technology. All three are potential application areas of informatics technology that hold promise for improving perioperative safety and efficiency.

Smart Environments

In pursuit of this future environment in which patient safety is ever increased and clinician education is ever more successfully tailored, we have designed and implemented a prototype Context Aware Surgical Training (CAST) Environment as part of UM's Advanced Simulation, Training, Research, and Innovation (MASTRI) Center. The CAST goal is to create an intelligent pervasive computing environment that can enhance the training of surgical students, residents, and specialists. CAST research builds on prior work on context aware "smart spaces."^{15, 16} It uses Web-based infrastructure and software applications in academic and professional development programs.¹⁷ A cornerstone of this project is tracking student presence using technology as varied but common as radiofrequency identification (RFID) tags or even mobile phone or personal digital assistant (PDA) Bluetooth[®] signals, so that the smart environment "understands" the access and asset use of students.

Our pilot system integrates training resources available in the MASTRI Center into a context aware training environment that can recognize the presence of a trainee or mentor and take appropriate action based on known training goals and parameters.¹⁸ The success of our CAST "smart environment" would lead to scaling it to meet the needs of an operative environment, where technologic demands are often analogous to those seen in the training environment.¹⁹ Tracked blood product data could be compared to tracked patient data so that, for example, clinicians would be alerted immediately if incompatible blood products were brought into an OR. This type of approach to safety is the goal of advancing interactive information management, resource management, and content management via a seamless process.^{16, 20}

CAST illustrates how potential safety and efficiency issues can be addressed and resolved when surgical training environments and the corollary activities in the ORF are transformed into a pervasive computing environment. In this environment, devices, simulation systems, software agents, and legacy computing components cooperate seamlessly to support the activities of doctors, nurses, other perioperative team members, medical students, and their mentors. A requirement of such an environment is that the constituent systems should be aware of, or have access to, a context model that represents relevant information on the devices, services, people, environmental conditions, tasks, and activities in the space.

Such environments entail many challenges in terms of developing hardware, system, software, and human-computer interfaces.²⁰ One such challenge is that the rapid development of new technologies, combined with iterative introduction of these technologies into the OR, creates a formidable barrier to achieving a well integrated operative information system.

In the future, smart environments would guide the training of medical care providers by tracking their progress, providing feedback, and assuring proper credentialing. Smart environments would also speed training and improve safety. In the operative environment, this same type of tracking would augment human vigilance, further preventing adverse outcomes through automated, context aware safety checks.

Operational Glitch Analysis

Crucial questions facing OR managers and hospital administrators are how to process and analyze the vast array of data being collected and how to use the data rapidly for effective decisionmaking in a large-scale coordinated environment, such as the OR. Building upon the results of smart environment data and models of perioperative workflow, it is possible to identify glitches in any system so as to improve both efficiency and patient safety. Data are often collected about work processes for the purpose of revealing systems vulnerabilities, inefficiencies, or “glitches” in general. Using data collected from the ORF workflow, we can, in real time, generate from that environment pertinent statistics from which we can identify sources of variation and communicate these variations to relevant stakeholders.

The UM Medical Center (UMMC) currently maintains an active glitch database that contains information from its 19-room surgical suite. Among the items reported are reasons for surgical case delays and issues regarding equipment and supplies. This database provides information that is used by senior management for accountability and by line managers for rapid process improvement.

A key to high reliability is reduced variations in the process of care.²¹ Communication, performance feedback, and transparency are all cited as factors that can improve patient safety and create a culture of safety.^{22, 23} In the UM ORF, we have implemented preliminary versions of a system capable of identifying variations in the management and scheduling of the suite of operating rooms. This prototype system includes a Web-based interface to the database that displays a graphic visualization of trends, provides for text-based search, contains automatically generated reports, and allows issue-centered exploration of historical data. Development of key concept graphs and trend presentations is achieved through conceptual modeling based on the patterns and the etiology of glitches. Information about both is considered vital for the determination of the information requirements necessary for rapid institutional learning and is derived from interviews with key stakeholders.

What is the future impact of operational glitch analysis on patient safety? Glitches and delays in the process of running an OR (or any other such venue for care) would be quickly identifiable by both OR managers and hospital administrators. The immediate availability of such information, the ability to instantaneously interact with that information to answer questions, and the data-driven decisionmaking that ensues, would enhance institutional learning. The ultimate hope is that by uncovering sources of variation and by treating the root causes, glitches can be eliminated.

Group-Based Communication Technologies

Miscommunication has been widely cited as contributing to adverse events in medicine. In the OR, AEs are more often related, not to technical competence, but to interpersonal aspects that are part of OR team functioning.^{24, 25} Indeed, “insufficient communication” was the most frequently cited root cause of the nearly 3,000 sentinel events reported to the Joint Commission between 1995 and 2004;²⁶ not surprisingly, over 70 percent of all OR-related sentinel events between 1995 and 2005 cited communication as a root cause.

One approach to addressing communication problems has been through training in team communication and interpersonal communication skills and by formalizing communication procedures. Such strategies have been effectively employed in a number of arenas, including training in “crisis resource management” (CRM),^{27, 28} establishing preoperative “time outs,”²⁹ and structuring work in intensive care units.^{30, 31} While not a replacement for interpersonal improvements in communication skills, communication might also be enhanced through the smart application of technology.

We are currently examining the ability of technology to facilitate one specific aspect of the communications process: How changes to the surgical schedule can be communicated to the necessary parties through a timely and secure method. Such communication is necessary to ensure OR efficiency and patient safety. Many forms of communications are used to convey critical location, scheduling, and patient information to the perioperative team. These communications traditionally have taken place across and through an amalgamation of phones, pagers, computer scheduling systems, printed schedules, and face-to-face communications. Quality of care and safety are influenced directly by this jumble of communications, which often proves inadequate in terms of providing individuals and teams with the real-time knowledge required for high-quality decision support. Additionally, poor management of both the reallocation and replenishment processes in the OR can ultimately lead to interventions that are unsafe for patients.³² Recognizing communication as a significant part of the management process, we contend that flow or process breakdowns that occur in the perioperative environment are often preceded by a variety of communication breakdowns and have collateral repercussions.

Technology can be used to communicate action plans in a concise, up-to-date format to all team members. Technology can facilitate propagation of an initial action plan or alert a team to last minute plan changes. Deployed properly, technology could reduce the time and effort required to coordinate the running of an OR suite safely. Bearing such concepts in mind, we are working to bridge key gaps between information systems and care providers so that the people who need accurate information have timely and ubiquitous access to scheduling and operative plans and to equipment status. Digital solutions can be deployed that will both assist in the communication of operative plans and facilitate acquisition of communications data that can serve as source data, permitting analysis of the communications that occur in the OR. Rapid, automated distribution of accurate, necessary information to all team members can be achieved through a coordinated combination of smart technologies, including the Internet, pagers, and voice-based (phone) applications.

Group-based communication technologies hold great promise for improving patient safety. The multiple OR surgical suite, which often experiences schedule disruptions, would be kept running smoothly as all the team members would be apprised at all times of the plan of action that is the most current. Handheld computers, pagers, and wireless phones would be linked into a centralized Web-accessible schedule and operative plan that all members could access and, if needed, update. Changes will be “pushed” to the relevant team members through automated paging and phone calls, so that the proper equipment, people, and patients arrive in the right OR at the right time. With all team members knowing the plan, there would be fewer surgical complications, the result of team members being freed from solving logistic problems so they can focus on the operation at hand.

Ergonomics and Human Factors

Ergonomics and human factors are two related branches of study that examine the relationship between people and their work environment. Ergonomics often focuses on the physical environment and the human body, while human factors center more on the cognitive aspects of performance. The same ergonomics and human factors techniques credited with making industrial processes safer and more efficient can be applied to the analysis and improvement of OR operations. Tools, such as video analysis and motion tracking, can be used to analyze current practices, identify inefficiencies and dangers, develop solutions, and measure improvement. “Best practices” to maximize safety and efficiency can be developed based on empirical data.

Our discussion of workflow to this point has taken a macro or panoramic view; for example, how might we most effectively track and bring together the people and assets necessary to ensure that a patient’s surgical experience is safe and efficient. Through human factors and ergonomics, we have the ability to focus on a more micro-level analysis, such as how the physical interface between the surgeon and the patient could be improved and the associated work space chaos and stressors of MIS be reduced.

The patient is the center of the ORF.³³ During MIS, the interfaces between the patient and the surgeon are critical to both the safety and quality of patient care and surgeon welfare. Patient-surgeon interfaces are complicated by compromises in equipment design, technology limitations, operating theatre layout, and technical approaches.^{34, 35} In particular, ergonomic problems in the MIS workspace, such as obstructing catheters and cluttering tubes, can elevate the chance for contamination, increase surgical risks to the patient, and reduce work efficiency.³⁶ Optimal workflow during MIS stands to be achieved through better understanding of patient-surgeon interfaces, both intracorporeal and extracorporeal. In the ORF, advanced technology could function as a key enabler, allowing an optimal patient-surgeon interface.

Some of our current work is focused on establishing quantitative, valid measures of workflow within patient-surgeon interfaces, identifying ergonomic problems that result as a consequence of workplace designs (e.g., arrangement or management of cables and catheters), and demonstrating key barriers to optimal workflow that present direct safety and efficiency concerns. One project is based on a collaboration between surgical experts and human factors experts.³⁵ Previous experiences in video capturing³⁷ and analysis³⁸ are being used as a basis for development of workflow measures and identification of ergonomic inadequacies. Time-motion studies³⁹ have been conducted to collect objective data on activities in the patient-surgeon interface. Conceptual workplace layout designs are being developed, based on objective data and simulations of what workflow might be if interfaces were optimized.⁴⁰

In the future, OR workspace layout would be optimized through ergonomic data and human factors analysis, and this optimization would lead to the establishment of “best practices” for an array of surgical operations. Proper layout would reduce risks of infection, speed operations, and reduce fatigue of surgeons and staff, all elements that could contribute to a reduction in AEs and improved patient safety.

Future Vision of the Operating Room Environment

Well-trained care providers, who have reached a level of proficiency on realistically simulated patients, are supported by an array of smart technology enabling surgical procedures to be performed in an ever safer environment. Cases start on time with all team members informed of the goals and possible trouble spots of each operation. Contingency plans are in place for dealing with anticipated complications. The smart environment checks that all required equipment and people are present and cross-checks drugs and blood products brought into the room, ensuring patient compatibility in terms of allergies and blood type. Surgeons do not have to fight fatigue and discomfort during surgery, as the layout of the surgical workspace is ergonomically correct. Thus, the time and effort needed to perform surgery is minimized and improvement of both technique and outcomes is realized.

Data from all aspects of the surgical procedure are collected in real time and combined with data from other processes to help identify safety and efficiency trends. These data are available to all stakeholders and are presented in interactive, graphic formats that aid in tactical and strategic decisionmaking for improved operations. Systemwide problems can be identified and root causes discovered. The transparent nature of both the data collected and the subsequent analysis of the data supports a culture of safety and encourages a systems-based approach to understanding AEs.

Conclusion

This utopian vision of the perioperative environment just described may sound unattainable, but prototype components of just such futuristic systems currently exist in some form. Significant time, effort, and advances in technology are certainly required before such a pervasive, seamless system can be implemented. However, achieving incremental advances is already possible through implementation of any of the systems or approaches described in this article.

Additionally, technology, while certainly not a panacea for patient safety, might well serve to facilitate or augment a culture of safe medical practices.

Future surgical care will be safer and more efficient due, in great part, to simulation training for practitioners. Simulation represents a viable alternative to using patients as hands-on training material for care providers. As discussed, the future will see an increase in the adoption of physical simulation for credentialing procedural skills and for awarding certification of safety critical skills, in addition to the regular use of cognitive simulation to improve clinical judgment. However, this rosy picture is tempered by the need for increased realism of simulators, for the incorporation of automatic assessment into training program modules, and for studies that demonstrate the validity and effectiveness of procedural simulation training.

While many image-guided therapies are already enhancing patient safety and therapeutic efficacy, substantial work must be done to accelerate development of image capture, processing, and display. A strong desire exists on the part of many surgeons to have the capability of rehearsing a procedure on a simulation of the specific patient before performing it. Rehearsal would entail the building of a precise model of the patient's pathology by way of imaging and loading the model of the patient into a simulation system that realistically replicates the patient's condition. The optimum outcome of this development is a surgeon's "practicing" of a procedure

on an exact model of the patient, then entering the OR and performing the surgery. Computer scientists and engineers have not yet incorporated advances in computing power to achieve the level of fidelity necessary to make such rehearsal practical.

Some of the most significant improvements in health care may evolve from refined information systems capable of reducing medical error, improving surgical efficiency, minimizing risks to patients and caregivers, and reducing costs. Yet, challenges still need to be overcome by those engaged in medical informatics. The current state of medical informatics is still one of fragmented information systems and a lack of comprehensive standards for information exchange between information systems. Initiatives are underway for a “universal electronic medical record,”⁴¹ the implementation of which should facilitate progress toward resolving these challenges. However, even achievement of such an initiative can be viewed as only a first step toward using the power of informatics for comprehensive patient safety.

Technology itself can be a barrier to safety if improperly designed or implemented. Application of human factors and ergonomic principles can help ensure that technologies facilitate rather than impede safe practices. Applying human factors to information systems can ensure their usability. Similarly, ergonomics and human factors analysis can achieve proper configuration of the perioperative space to decrease risk of infection, speed operations, and reduce surgeon and staff fatigue, leading to a reduction in AEs and improved patient safety.

The concept of an ORF has, in fact, been embraced by many institutions. Implementing key aspects of ORF practices has already increased patient safety, although other aspects remain, which require much work before realization of tangible safety goals. Given the progress already achieved, the medical community should consider the ORF to be a key component within a broader context of a safety culture.

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High-Hanging Fruit: Improving Transitions in Health Care

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Abstract

Discussions about enhancing the safety of transitions in health care have been disjointed. Respected health care researchers, noting handoffs to be variable in content and process, view improving handoffs as “low-hanging fruit” that can be easily gathered by reducing variability through standardization in a variety of ways. In contrast, human factors specialists express concern about potential unintended consequences of this approach, particularly when it is applied across a wide variety of practitioners and settings, due to factors common to complex domains with high consequences for failure. These factors include the ubiquity of goal conflicts and trade-offs in chronically under-resourced environments; the understanding that imposing simple standards on complex processes will never yield simplicity; and the recognition that communication is not a single function but rather a means to achieve multiple functions in distributed work. Standardization can enhance handoffs, not in the manner commonly espoused in health care, but rather by providing a window of opportunity to restructure how they are normatively conducted. For example, standardization by employing a rigid structure for the content of a verbal update is potentially misguided compared to an adaptive heuristic of “triage (most important first), tell the story, and details on demand.”

Introduction

Transitions in care bridge gaps in health care work that are a consequence of its continuous operation (24 hours x 7 days) and its divisions of labor. These divisions have long been viewed as necessary evils, fertile ground for error, and opportunities for failure.^{1, 2, 3} The large number and wide variety of types of transitions in health care (e.g., like-to-like, like-to-unlike, across specialties) and the myriad contexts within which they occur markedly complicate understanding and attempts at redesign.

There have been three common approaches to transitions, each organized around what is perceived to be the predominate source of vulnerability:⁴

- One viewpoint assumes that the informal verbal format is a significant weakness, and that if information were presented in a standard, clear, and consistent format (either written or electronic), the process would markedly improve.^{2, 5} It is strongly influenced by the information-processing metaphor of human cognition, where the emphasis is on completeness of data transmission.

- In contrast, a second perspective views the loosely structured verbal interaction as a strength, allowing health care workers to perform “real time decoding and synthesis,” while responsibility and authority for patient care are being transferred.⁶ This perspective stems from the belief that data availability is insufficient for effective “sensemaking” to understand the “story” of a patient’s status and predicted future trajectories.
- The third position, based in the emerging “resilience engineering” literature, regards transitions as opportunities for reassessing situations for the explicit purpose of identifying and correcting hazards and failures.⁷

In this article, we discuss the role of standardization for enhancing the safety of health care transitions. In particular, we focus on the most frequently occurring transitions—shift change signovers and handoffs—and the importance of structuring flexibility into any improvement efforts for the preservation of existing but latent safety features.

Standardization

A national experiment is underway to “fix” transitions in health care.^{8, 9} Remediation efforts for signovers have centered around the assumption that a high degree of variability in the method and content of information is a fundamental flaw in the process.^{2, 5, 9} The currently popular modes include uniform patterns of contact in the form of scripting checklists, such as SBAR (Situation, Background, Assessment, Recommendation).

By definition, standardization can be beneficial to any communication process if it provides the “rules” for interaction, so they do not need to be negotiated (including the function, process, content, timing, and who is directly or indirectly included in the conversation); it allows information to be conveyed more efficiently and with higher reliability; and convention can be established, such that the lack of comment on a topic would imply (usually) that there is nothing worthy of mention. From a stance of transitions as “low hanging fruit,” the benefits of standardization are understandably appealing.

The introduction of standardization to the signover process in this manner draws from an elementary understanding of the sociotechnical complexity of the work performed during the signover. Signovers provide more than information (e.g., name, blood pressure, diagnosis); they also support macrocognitive functions, such as problem recognition, problem analysis, sensemaking, and planning¹⁰ (e.g., “If the temperature does not come down soon, she will need a CT scan and lumbar puncture, and her husband is very anxious about it.”) None of these functions is easily conveyed in a structured format (e.g., checklist or scripted).

Written signovers or checklists. Standardization of clinical shift transitions via a written format has been widely recommended and employed,^{11, 12} but there have been a number of unintended consequences. The implementation of a signover form has been observed to supplant verbal updates during times of work overload; forms that are sometimes “pre-prepared” call into question their validity.¹³ Additionally, the role of these signover forms in the documentation of medical care is unclear. Should they be managed as a part of the medical record (discoverable following an unintended outcome), or are handoff forms and checklists merely cognitive work tools, no different than a “to-do” list for tracking tasks?

Danger also lies in the template becoming the script for transitions, thus changing the nature of the event from a “two-way interaction” to a “one-way transaction.” Under increasing workload, it could be easy for the checklist to supplant the interactive aspects of a transition, becoming instead the script from which workers read; or worse, changing the criterion for a “completed” signover into the receipt of a form. In either case, the result would be a reduction in patient safety, with less inquiry and opportunity for clarification. This also undermines workers’ macro-cognitive functions (i.e., problem recognition, analysis, sensemaking, and planning) and also the rescue and recovery opportunities that signover can provide.¹⁴

Written logs or report sheets are another method recommended for handovers in process operations. These have been observed to be routinely used prior to and/or following handover updates in most high-reliability organizations (HROs) as reference or cognitive artifacts for critical data points.¹⁵ In some settings, including NASA space shuttle mission control, written logs contain a short summary to support the handover process but are not all-inclusive. The use of written and electronic cognitive artifacts has shown benefit within specific clinical care settings, such as transitioning to an overnight cross-cover clinician or team.^{16, 17} Since it is hard to know what the equivalent of a “log” would be in most health care settings, new paperwork or software would have to be created for this type of transition improvement. Either medium would be required to briefly capture the “story” in a written format that could be easily referenced if needed.¹⁸

Standard verbal content. Standard ordering of verbal content in patient handoffs has been another implemented strategy for improving shift-change handoffs.¹⁹ Observations of handover updates in other domains have noted an absence of scripting of discrete data elements,⁷ most likely explained by the use of “most important first” as an ordering heuristic for topics in the verbal update.^{20, 21} In addition, space shuttle mission controllers are reportedly trained to “efficiently communicate a bottom line and details when asked,” which enables them to flexibly negotiate the level of detail needed in the update.⁷

Another benefit of ordering by “most important first” is a decreased likelihood that interruptions will occur prior to covering the most critical aspects of the update. Under data-overload conditions—where a massive amount of data is theoretically available but pragmatically impossible to review—the verbal update is used to help the incoming practitioner quickly get a “story” of the situation, which is not easily conveyed in a structured (checklist) format.¹⁰ As yet, no HRO has been found to use a structured verbal update during a handover transition, including the frequently mentioned shift transitions on nuclear submarines (S. Kirschenbaum, R. Severinghaus, Naval Submarine Operations, personal communications, 2007). One way of characterizing the common elements of handoff updates in HROs is “triage, tell the story, and details on demand.”

A consistent feature of signovers across industries is the fact that there is variation in both form and content,²² which is likely a necessary consequence of the variable nature of the work being performed. Research on transitions in emergency medicine and nuclear power plants is illustrative of these variations.^{20, 23, 24} Differences in content or genre of signovers related to the time of the changeover (morning, afternoon, evening) have been observed in both work settings, likely resulting from differences in the volume and character of work being performed (e.g.,

fewer major events on the overnight shift than during the daytime). Content exchanges also varied across skill levels (workers vs. supervisors in nuclear power; physicians vs. nurses).

Information exchanged as part of *in situ* problem solving and planning was observed in both physician and plant supervisor transitions, whereas situational and task updates were foremost in signovers involving plant workers and nursing staff. Shift changeover content appears to modulate based on recent events, the kind and complexity of current problems, the degree of uncertainty, time of day, and the team members present, as well as actual and anticipated competing demands for attention.^{6, 25} Therefore, a single signover intervention cannot adequately support the work and safety of highly dynamic, complex work environments. The inevitable variation of work across health care must be attended to when attempting to standardize verbal content.

Readback. Another recommendation for patient handoffs has been the inclusion of readbacks.^{11, 26} Readbacks in domains outside of health care are associated with very specific tasks, such as verifying discrete, numerically formatted information (e.g., acknowledging correct receipt of a planned altitude change in aviation). However, they have not been observed during HRO handovers, and their use during health care signovers remains equivocal.

Likely beneficial for discrete high-risk pieces of numerical information (i.e., lab values, medication dosing, or equipment settings), the global benefits of readback are less clear, given the true nature of the transitions.^{26, 27} One explanation is that the ability to “read back” information does not verify synthesis and understanding, nor does it ensure remembering and performance of the task. Additionally, with verbal repetition, rather than written transmission of highly specific numerical data, there is a risk of “drift” similar to the phenomenon seen in the game of “telephone.”¹¹

A more general application of readback in signovers, though, is ill advised due to the high likelihood of diverting attention away from conveying the “story” of the situation to that of a periodic test of short-term memory, particularly if documentation specific to readbacks is required during an update.

A variation on readbacks, the “teachback,” has been considered as a tool for including patients in the transition (P. Angood, personal communication, 2007). The word “teachback” emphasizes a divergent audience with variable levels of understanding of medical terminology and the work of clinical care. Additionally, teachbacks endorse the importance of educating patients about their clinical condition, including conveying treatment plans and any deviations, whether due to clinical or systems problems. Because of pragmatic challenges involved in timing a transition update to include patients, particularly when there are linguistic barriers (e.g., medical terminology, spoken languages) and cognitive barriers (e.g., dementia), the inclusion of patients “real-time” becomes unlikely. On the other hand, making plans observable to patients and caregivers, including through verbal interactions, might enable increased robustness across care transitions, particularly during discharges to the home setting.

Latent Properties of Transitions: “Hard-to-See Things”

Observational studies of transitions in health care have elucidated a number of latent or “hard-to-see” properties that are very similar to those in other industries.^{28, 29} Four phases of transitions

have been noted: (1) pre-turnover, during which the individuals involved begin to prepare for transition; (2) arrival, where incoming and off-going workers gather; (3) meeting, during which the transition occurs; and (4) post-turnover or “taking post,” during which oncoming workers assume authority and responsibility. These same phases have been observed during shift signovers in emergency medicine and during transitions of care that cross specialties.^{6, 23} The presence of these phases supports the notion of transitions and signovers as intricate and richly constructed events that provide an opportunity for workers to assemble shared representations of their complex work environment, or to “co-orient.”

Co-orientation theory, a model developed in the 1970s, has at its core the need for shared mental models for effective communication processes.³⁰ Transitions in continuous work environments, such as health care, are vehicles for off-going workers to create shared mental models with oncoming staff, “co-orienting” for future sensemaking and planning. Co-orientation is an implicit and latent feature of transitions, constructed during the two-way interaction of workers with an endpoint of reaching consensus or shared understanding of the issues.³¹ The four phases of a transition provide a platform from which to co-orient for the identification of problems and issues, situation, and resource assessment; planning for the short and long term also can occur between workers at this time.³²

Research on signovers in the nuclear reprocessing industry, anesthesia, and emergency medicine has identified transitions as occasions for highlighting not only failure, but also rescue and recovery.^{14, 21} In these instances, the signover elucidated incorrect or incomplete problem identification and evolving unsafe conditions or plans.^{33, 34} Signovers appear to provide a medium for “fresh eyes” to review the mental models used by off-going workers, in addition to the transfer of responsibility and authority to continue the work underway.

Fundamentals of Health Care Signovers Redesign

The burden of national improvement of transitions has become a local initiative delegated to individual health care organizations that subsequently have assigned the task to their workers. A benefit of the solutions coming from the “sharp end” of care is that they can be tailored to the clinical work setting, where the transitions occur, rather than being mandated from administration or external regulators. The downside is the lack of requisite expertise from human factors engineering, which might result in well-intended but not well-calibrated or well-understood interventions.

Calls for process standardization of transitions in health care abound, yet little research or science is being incorporated into the re-design.³⁵ Studies of transitions in other industries provide a rich collection of successful and failed strategies that would be applicable to transitions within health care based on demonstrated commonalities (such as the presence of the four-phase framework of shift signover noted above). The danger here then is two-fold: first, to avoid the “magpie syndrome”³⁶—i.e., incorporating a strategy because it is “shiny and new” without a good understanding of its fundamental nature and underlying philosophy; and second, to avoid unintended consequences that could undermine latent safety features of health care transitions—“throwing out the baby with the bathwater.”

It is essential to devise solutions thoughtfully. As in many other high-risk industries, the consequences of new implementations are not easily seen, take time to develop, and even then,

are not likely to be easily detected. Failure to invest time here runs the risk of undermining embedded safety features developed ad hoc to bridge the discontinuity of work.

Good design requires identifying fundamental elements and ground rules from which the deliverable can be crafted. The redesign of signovers and handoffs should begin with establishing transitions as non-optional behavior, viewed by the organization on a level with other initiatives, such as proper documentation or reducing patients' fall risk. Additionally, transitions must be synchronous, two-way interactions that include the health care worker who has the primary responsibility for the patient. This will allow opportunities for inquiry and clarification to support co-orientation and the construction of mental models for those assuming care. Finally, the goal for transitions should not be comprehensiveness, but saliency, to avoid swamping the important in a sea of the contextually immaterial.

Universal mandates to eliminate or reduce interruptions during handover updates are unlikely to be effective due to the typical length of transition updates and the high consequence, event-driven nature of health care. However, technologic support could provide for improved timing of interruptions. Pager and cell phone technology might offer an opportunity to negotiate the criticality of interruptions by giving users the ability to communicate their willingness to be interrupted (e.g., placing the cell phone or pager in one of several modes: Available; Busy; Call in 5 minutes, Emergencies only) that would be communicated or displayed to the caller upon first ring. The criticality of an interruption could be similarly encoded for the receiver by annotating calls or pages (e.g., FYI, When available, Respond in 5 minutes, ASAP, STAT).

An interesting strategy employed by most NASA space shuttle controllers is to remotely "listen in" to the primary audio channel ("voice loop") of the individual they wish to contact, allowing controllers to gauge whether their request is worthy of interruption and how to time the interruption.³⁷ This strategy might be copied if practitioners were willing to wear microphones that others could "listen in" on, or Global Positioning System (GPS) trackers that would allow others to "see" an individual's availability for an interruption, not only during transitions but also during other high-consequence activities, such as being in the operating room, in the middle of a procedure, or during a signover.

Additional ground rules for addressing communication issues in the health care setting can be found in the domains of communication and organizational theory.¹¹ These include: (1) limiting the impact of work place noise and other distracting interruptions; (2) limiting cognitive work load and if possible, physical work load (multitasking) during the transition period; (3) ensuring explicit communication between individuals as to who has responsibility and authority during the handoff; and (4) delaying documentation tasks until there is a reduction in high-consequence activities (e.g., medication administration or moving a critically ill patient to a higher level of care).^{38, 39}

Observations of other high-consequence industries (e.g., railroads, ambulance dispatch, NASA Space Center) have found many of these same fundamentals in place.⁴⁰ Features that enhanced co-orientation in these settings included providing time for the incoming staff to review the current state of operations before signover (i.e., brief overlap of shifts) and performing signover where other workers could overhear updates and provide correction as needed with limited external environmental noise. Intuitively, the implementation of these low-tech fundamentals for

effective communication would significantly affect handoff communication. It could be readily instituted at a local level with little impact on existing safety features currently embedded in signovers.

Conclusion

Improving the effectiveness of transitions in care is a complex endeavor; indeed, those who have been conscripted (i.e., health care workers) to improve care transitions are not fully aware of just how complex the task will be. Latent features of the handoffs, coupled with necessary variations to convey effectively the work at hand, reduce the presumed benefits from across-the-board standardization. Standardization is not a “silver bullet,” and improving transitions is not a case of “low-hanging fruit.”⁴¹

Introducing enhancements to existing processes—beginning with ensuring that handoffs occur between the practitioners directly caring for patients and are interactive in environments supportive of communication—are important first steps. Translating human factors principles and methods is not easy and should ideally involve multidisciplinary teams to tailor the transition to specific clinical areas.³⁵

The introduction of limited, well circumscribed techniques at the “sharp end,” such as ordering of content to “most important first,” would allow for some enhancement of signovers while preserving critical features (i.e., co-orientation, problem recognition, sensemaking, planning, and opportunities for rescue and recovery). This approach would initiate the process of “fixing” transitions, as much needed research into understanding the messy details of clinical work gains traction.^{42, 43}

*The high hanging fruit
Hides all the sweetness you sought
In sour low-hangers
Wears-san*

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Minding the Gaps: Creating Resilience in Health Care

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Abstract

Resilience is the intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances so that it can sustain required operations, even after a major mishap or in the presence of continuous stress. As an emergent property of systems that is not tied to tallies of adverse events or estimates of their probability, resilience provides the means for organizations to target resource investments by integrating safety and productivity concerns. Resilience engineering (RE) can enable an organization to cope with and recover from unexpected developments, such as maintaining the ability to adapt when demands go beyond an organization's customary operating boundary. Understanding resilience makes the difference between organizations that inadvertently create complexity and miss signals that risks are increasing, and those that can manage high-hazard processes well. We discuss two examples of resilience: the response of an emergency department staff to surges in patient volume and design improvements to the infusion device control/display interface.

Introduction

Economic pressures to make a system leaner can increase the complexity of interactions among its elements, tighten their coupling,¹ and lead to a system that the slightest disruption can render dysfunctional. The current U.S. air transportation system is a case in point, as a snowstorm in the Northeast can disrupt air travel in the Southwest.

Current Notions of Health Care Safety

Standardization and automation are just a few of the current popular notions about how to improve safety and performance in health care. However, resources that appear to be superfluous in normal operations may have latent value that is realized during crises. Combined with economic pressures, initiatives that seek to simplify and lean down organizations actually whittle down reserves, buffers, and other undervalued resources. This makes it difficult for an organization to tap resources to meet new demands when they arrive.

Resilience engineering is a new approach to this problem that strives to identify and correctly value behaviors and resources that contribute to a system's ability to respond to the unexpected. Put another way, efforts to lean down organizations risk suffering from what an economist would term "cost externalization." For example, a coal-fired power plant does not have to pay for the environmental effect of the acid rain its emissions cause. In a similar manner, the resources that are needed for resilient adaptation may appear to be redundant. Eliminating those resources can

be seen as savings, when in reality there may be unforeseen future costs. Resilience engineering attempts to identify and combat this sort of externalization.

The way we think about systems, system performance, and their outcomes evolves as new insights become available. Hollnagel² has suggested that our understanding of adverse events and their causes evolves through time as we develop and use new ways of thinking about how accidents happen. In the 1960s, technology and equipment were often cited as the attributable cause of adverse events. Attributions to the human performance peaked over the past 40 years, while attributions to the organization have recently been on the increase.

Notions of what to do to improve health care follow such perceptions about systems. The vogue for process re-engineering, for example, reflects a bias toward attributing the cause for adverse events to the organization. Few of these notions, though, are based in scientific study. Lack of system knowledge in health care leaves it without the necessary tools to understand the deeper forces that mold daily operations.

Efforts to improve health care without a basis in science do more damage than good by making systems unable to change in response to circumstances—what Sarter, et al.,³ term “brittle.” For example, Ash, et al.,⁴ found that health care information technology systems that are intended to reduce errors can also foster them. In another instance, Perry, et al.,⁵ found that the introduction of tighter procedures that were intended to improve glycemic (blood sugar) monitoring ironically had the opposite result. In a further example, efforts to standardize between-shift handoffs⁶ clashed with the initiatives that clinicians had developed to cope with the complexity, variety, and uncertainty in their work domain.⁷ Such interventions are not benign; instead, they induce unforeseen outcomes. They waste time, attention, and resources that could be spent more productively. They also delay progress toward genuine improvement.

System-Level Safety

No system has infinite adaptive capacity. Patterns in the way that a system responds to disrupting events provide information about its limits and how the system behaves when events push it near to or over those boundaries.⁸ As a service sector, health care can be understood according to how it responds to changes in demand for output over time.⁹ Demand for care varies widely in volume and type. Resources that are available to respond to demand (e.g., clinicians, beds in acute care facilities, and time) are in limited supply and constrained in various ways. If demand exceeds the ability of a system, three kinds of response may be observed as Table 1 shows.

Table 1. Health care response to demand

Response	Recovery	Demand example	Response example
Limited	Rapid	Large influx of patients	Recruit additional resources
Matched	Delayed/degraded	Extended influx of patients	• Extend work shifts • Work double shifts • Call in post-call staff
Different from usual	Sustained change	Continual excess of patients	• Expand facility • Recruit new staff

1. **Limited response, with rapid recovery**, in which the system is designed to continue on at normal output levels. An emergency department (ED) that experiences a large influx of patients might increase throughput by recruiting additional resources, such as borrowing clinicians from other duties. While this kind of adaptation could not continue indefinitely, operations are able to continue because of it.
2. **Matched response with protracted recovery**, in which the system meets increased demand, is degraded for a short time afterward, and then returns to normal output levels. The same ED faced with an extended flow of patients beyond its capacity might extend shifts, work double shifts, or call in ED clinicians who are post-call. After such a surge, it would take days until the staff could return to normal.
3. **Different demand from usual**, calling for a different set or scale of resources that requires a sustained change to the system. The ED faced with a continual excess of patients might look for a different way to buffer demand. Noting that many of their patients' symptoms resolve after an extended stay in the waiting room, management might agree to make an additional room available to place patients for observation. The change would require recruitment of further staff and facility resources, making it a sustained change.

Authentic improvements to clinical performance and to patient safety must rely on understanding the underlying forces that shape the work environment. For example, in Figure 1, Cook and Rasmussen¹⁰ demonstrate how health care organizations exist at an operating point (the circled dot symbol) within an envelope that is bounded by economic failure, unacceptable workload, and acceptable performance. Management exerts pressure to increase efficiency in order to avoid economic failure. Workers try to find a sustainable level of effort that is sufficient to accomplish tasks and avoid an unacceptable workload.

Pressures to increase productivity and avoid excessive workload push the system operating point away from the boundaries of economic failure and work overload and towards unacceptable performance. Crossing the boundary of unacceptable performance results in an adverse outcome, or accident.

Organizations seek to create a boundary of operations that allows for variable performance

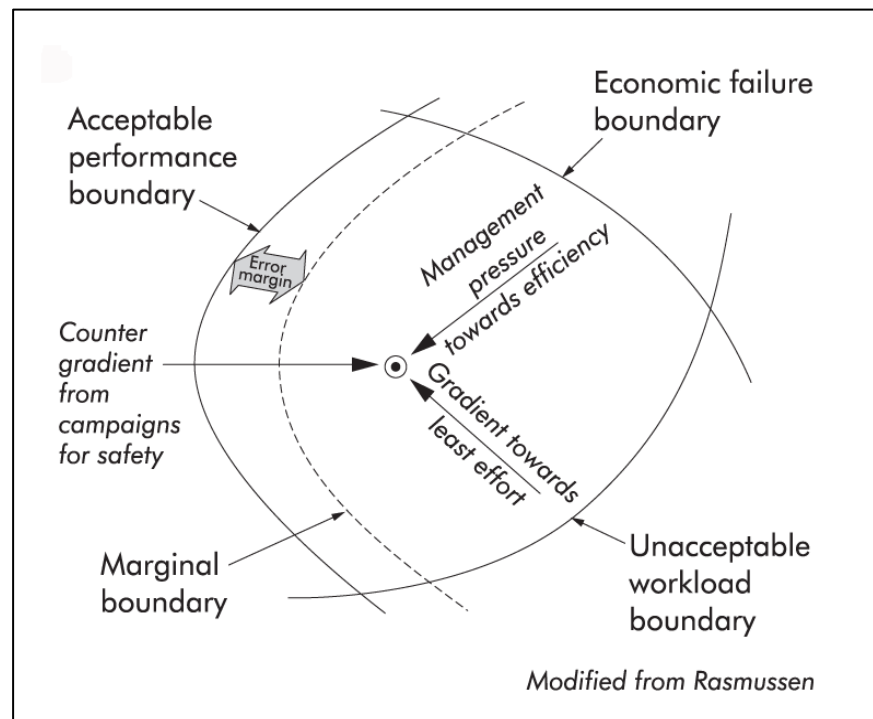


Figure 1. Influences on a system's operating point.

Source: Cook and Rasmussen, 2005. Copyright © 2008 Richard Cook. Reproduced with permission.

without causing loss. However, gradients to reduce workload and improve efficiency continually push an organization's operating point ever closer to the boundary. Understanding where one's operating point is, relative to the margin, requires an organization to cultivate a keen awareness of its operations and variability in performance.

Effective organizations are constantly looking for signs that specify how the organization actually operates and to use this information to be better calibrated.^{11, 12} Studies of high- and low-reliability organizations have documented the problems created when organizations are poorly calibrated with respect to their operating point. Management that correctly understands the operations of any system would also be likely to correctly estimate how well its strategies would work when unforeseen challenges occur.

The remainder of this chapter defines resilience and resilience engineering. Two examples of resilience in health care are provided. The first shows how ED staff members create resilience through the strategies they employ in response to changes in demand for care. The second describes a concept for an infusion device interface, demonstrating how equipment design can improve resilience.

Health Care and Resilience

There is universal agreement that, in fundamental ways, the health care system is not working. This may be the result of large-scale changes to both health care needs and to the efforts to meet those changes that have had varying success.

The U.S. health care systems serve a population that has experienced a decline in acute conditions and a rise in chronic conditions, such as heart disease, human immunodeficiency virus (HIV), methicillin-resistant *Staphylococcus aureus* (MRSA), and drug-resistant tuberculosis. Chronic conditions tend to require more complex medical interventions. Those interventions, supported by technology, increase the risk of misadventures.¹³ Studies of safety in high-hazard sectors,^{14, 15} such as the military and aviation, typically address system-level issues that mold the nature of daily operations and account for success and failure. While some attention has been focused on health care at the systems level, most recent efforts engage safety at a lower level: process redesign or safety engineering.^{15, 16} This is due in large part to the lack of systems safety skills and knowledge in the field, as well as to conventions in health care about what constitutes acceptable scientific activity. It is also due to the practical convenience (if not expediency) of dealing with concrete issues one by one, instead of trying to understand the larger situation.

The cottage industry structure of the national health care delivery system results in what Reid, et al.,¹⁷ term "disconnected silos of function and specialization." An estimated 60 million patients in the United States suffer from two or more chronic conditions and are particularly affected by this disconnection among clinical care specialties. Connectivity, integrated care, and coordination are inadequate nationwide at all stages of illness treatment.¹⁸ As evidence of this breakdown, Asch, et al.,¹⁹ polled 6,712 randomly selected patients who visited a medical office within a 2-year period in 12 metropolitan areas including Boston, Miami, and Seattle. Those patients received only 55 percent of recommended steps for top-quality care among 439 measures, ranging from common chronic and acute conditions to disease prevention.

Health experts blame the overall poor care in the United States on an overburdened, fragmented system that fails to keep close track of patients with an increasing number of multiple conditions.²⁰ Such outcomes beg for an approach that speaks to these problems in a substantive, systematic manner.

Resilience. Resilience is the ability of systems to mount a robust response to unforeseen, unpredicted, and unexpected demands and to resume or even continue normal operations. As an emergent property of systems, resilience is not tied to tallies of adverse events or estimates of their probability. The notion of resilience frees safety research from hindsight bias²¹ by making it possible to understand how workers anticipate possible adverse outcomes and act in advance to avert them. This is what the U.S. Navy terms “being forehanded.”²²

Health care seeks to provide a seamless continuum as the patient transitions among care providers from presentation to diagnosis to treatment and to followup. Gaps in the continuity of care threaten a patient’s well being and introduce the potential for adverse events.²³ Gaps in care continuity are evidence that the health care system is unable to respond with sufficient output to meet demand. Whether, or how, a system responds to fill such gaps in care continuity indicate its resilience. Signs of gap-filling adaptations (e.g., clinician initiatives and improvements to equipment design) indicate classes of disruptions or demands and sources of resilience that are present to help accommodate demands for care.^{24, 25}

Understanding resilience. Resilience provides the means for organizations to target resource investments by integrating safety and productivity concerns. Woods and Wreathall²⁶ have proposed an approach to model resilience based on an analogy from the world of materials engineering: stress-strain. In a manner that is similar to traditional materials performance models, the approach uses the relationship between stress (the varying loads placed on a mechanical structure) and the resulting strain (how the structure stretches in response) in order to understand organizational response to strains.

Examination of the way a joint cognitive system of people and machines responds to different demands on work makes it possible to describe it. In other words, plot how a system stretches in response to changes in demands. One use of the stress-strain approach is to guide how organizations search for information and provide a means to integrate the results into an overall picture of changes in adaptive capacity. Wreathall^{27, 28} and Wreathall and Merritt²⁹ have tried to select sets of indicators that map onto aspects of resilience. Such measures point to the onset of gaps in normal work practices as pressures grow and reveal where workers develop gap-filling adaptations to compensate. These indicators are chosen to reveal circumstances in which management may be unaware of such challenges, either in terms of changing demands or in terms of the need for workplace adaptations. They can also reveal situations in which management may be overconfident, and current plans may not suffice for the changing demand profile.

Resilience engineering (RE) is a recent development in risk assessment and system safety.³⁰ RE accounts for the manner in which people at all levels of an organization can try to anticipate paths that might lead to failure, create and sustain strategies that are resistant to failure, and adjust tasks and activities to maintain margins in the face of pressure to do more and to do it faster.³¹ A resilient organization can anticipate, cope with, recover, and learn from unexpected

activities and resources at the same time as they struggle to handle patient load. Making the deliberate decision to forego care for all but life-threatening illness is an example of what some practitioners have described as a “free fall.”³⁵

Table 2. ED staff member strategies

Condition	Strategy	Adaptation
“Run of the mill,” usual conditions	Adapt to changes	Adjust existing resources
Demand increasing	• Recognize degradation • Initiate adaptive responses	Identify and reorganize additional resources
Demand requiring department-level change	Reallocate resources	Forego all care except that for life-threatening illness
Catastrophic event	Reorganize	Completely reorganize work

The final class is qualitatively different from the previous three ordered classes:

4. *Health care organizations plan for but rarely experience catastrophic events such as mass casualties or natural disasters.* These rare but significant occurrences require a complete reorganization of work in their wake. In the absence of an unambiguous external trigger, health care organizations are reluctant to shift to this fourth strategy.

The following real-life example shows how ED staff members employed multiple strategies that increased the resilience of their operations. Recently, at the start of the evening shift (15:00), the ED was boarding 43 patients; 28 of these patients filled the unit reserved for boarders; the remaining 15 were split among the acute care areas and the hallway. The use of the hallway as additional treatment space is an example of resilient adaptation at the departmental, as opposed to the individual, level. This procedure was first used several years earlier. By now, it had become part of normal operations, representing an organizational reconfiguration to establish a new equilibrium.

All four of the acute care unit’s critical care bays were filled with admitted patients on ventilators. The unit was approaching limits to seamless adaptation. As the shift change rounds began, the ED received a critically ill ambulance patient. Over the course of the next 4 hours, five more critically ill patients arrived and required ventilator support and other intensive measures. This was in addition to multiple additional patients, who were seriously, but not critically, ill (e.g., chest pain suggestive of heart attack).

All treatment spaces and all temporary spaces to hold stretchers were filled. The staff identified and employed additional resources. The unit ran out of stretchers and began to store incoming patients in chairs near the nursing station. Congestion was severe, making it physically difficult to move around in the treatment area. This was a particular problem when new critical patients arrived, as they needed to go to spaces outfitted with particular equipment for treatment. Patients who occupied those spaces had to be moved to other locations on very short notice. By this point, the staff could only deal with patients who had life-threatening illnesses. The staff later

developments by maintaining its ability to adapt when demands go beyond the organization's customary operating boundary. RE provides tools to manage safety by assessing changes in the adaptive capacity of an organization as it confronts disruptions, change, and pressures.

Examples of Resilience in Health Care

Two examples, drawn from actual work in the clinical setting, demonstrate principles of resilience in action: the response of an ED staff to surges in patient volume, and improvements to the design of equipment so that it performs as a “team player” among clinicians.

Emergency department response. New patient flows and hospital management responses to financial and other pressures have left EDs brittle; they are less able to respond resiliently when accumulating or cascading demands push their operation into the second ‘extra’ region.³² The system has to stretch in response to increasing demands to avoid an accumulation of gaps that would lead to a system failure. Individuals and groups make it possible for the ED to stretch by adjusting their strategies and recruiting resources to provide additional adaptive capacity. This stretching requires extra work, extra resources, and new strategies.

EDs are well-defined physical units in hospitals. Functionally, though, they are ill-defined, open systems. The ED workers' physical span of control is limited to reasonably small distances—i.e., less than 100 feet. Very large EDs, such as the one discussed in this case, are typically subdivided by function into smaller units. For example, this ED is divided into five contiguous units, including trauma care, pediatric care, severe illness, and mild illness. The fifth unit is reserved simply to hold admitted patients (“boarders”) for whom no bed is available in the hospital. The event described here took place in the 5-bed trauma unit and the 21-bed acute care unit of the ED. Both units are physically adjacent and are generally staffed by separate groups of nurses and a set of physicians that generally flow back and forth between units.

As Table 2 shows, staff members in this ED use four adaptive strategies to cope with the different levels of challenge they face in their daily work:

1. *A routine day, in which the system is operating under usual conditions and practitioners describe as “run of the mill.”* The system anticipates changes outside the routine and adapts in a way that is apparently seamless.
2. *As load and demands increase, a key individual recognizes system degradation and initiates adaptive responses.* For example, practitioners identify and reorganize additional resources, such as buffering capacity, in order to manage the challenges and maintain performance at near normal levels. Adaptations in these two settings include readily available solutions to the expected, normal, and natural troubles that workers have learned by experience and word-of-mouth.³³ For the most part, these adaptations are performed skillfully and unconsciously (almost invisibly).³⁴ They are the usual solutions (e.g., putting admitted patients in the hallway to make room for new patients) that make it possible to contain the usual problems within a horizon of tractability.³³
3. *Demands increase to the point that the required adaptations occur at the level of the whole department.* In this extreme situation, the demands on the organization may cross the horizon of tractability. This challenges its ability to sustain operations and risks escalation to a breaking point. Practitioners have to recognize and anticipate the trend and reorganize

described this situation as a feeling of “free fall”—i.e., a disorganized situation in which they did not know the numbers, types, or problems of the patients in their unit.

The crisis continued until approximately 22:00. By that time the staff felt they had finally gained control of the situation. They had regained a clear picture of which patients were present, where they were located, and at least a vague idea of the nature of their problems. The system had stabilized, and the staff could return to “run of the mill” operations. As far as is known, no adverse events were associated with this episode.

Here, conditions beyond the range of previous operating experience exceeded the horizon of tractability.³⁴ The resources and coping strategies that would normally provide resilience against variation and the unexpected became exhausted. Workers are compelled to invent new strategies on the fly. They also were driven to make sacrifice decisions, abandoning lower-level goals in order to preserve higher ones and regain control of the situation.

Equipment and information system design. Complex equipment and information systems can also contribute to brittleness or resilience. Misperceptions about user-device interaction have substantial consequences for clinical work. Collections of complex electronic information devices occur in acute care, particularly in critical treatment areas, such as the intensive care unit (ICU) and ED. Information technology (IT) systems are often installed in an attempt to fix problems that are actually embedded in the social organization.³⁶ Recent reports of failures³⁷ due to unexpected results from automation surprises indicate that IT demonstrates brittle properties that result from poor understanding of the work settings they are intended to support. Opaque systems that offer poor feedback and low observability undermine resilience and increase brittleness. There is a need to create new visualizations that provide improved feedback and high observability to help people recognize when events challenge current plans in progress.

How can IT, including information systems³⁸ and infusion devices,³⁹ be created so they can adapt to the fluid, variable clinical health care work setting? In the context of research, design, and development, the role of design has the responsibility to connect the adaptive power of people as goal-directed agents to technologic capability.⁴⁰ People actively manage the dynamic characteristics of their work place, drawing on a deep knowledge of their work domain to create and use artifacts.⁴¹ Cognitive artifacts⁴² take the form of physical items, such as order forms, checklists, schedules, and digital equivalents—e.g., the control and display interfaces for information systems and equipment. Artifacts embody only the essential elements of a work domain.⁴³ This makes them useful to both understand⁴⁴ work domains and to derive design guidance for the IT systems intended to support cognitive work. It is a design approach from the user to the system, not the other way around.

The creation of better equipment and information systems makes it easier for workers to anticipate future opportunities and problems ahead of time. How can IT systems be configured in order to support such an approach? Klein, et al.,⁴⁵ have proposed 10 traits that IT systems need in order to participate in any highly adaptive human work domain. These are 10 challenges for automation to participate in joint activity—extended actions carried out by an ensemble of people who are coordinating with each other—that set a longer term agenda for IT system development. Six of those traits inform the following example of how IT can follow these principles in order to develop a more resilient infusion pump interface.

1. *Have the ability to adequately model other participants' actions vis-à-vis the joint activity's state and evolution.* Be able to coherently manage mutual responsibilities and commitments to facilitate recovery from unanticipated problems
2. *Be mutually predictable.* The mental act of seeing ahead, with the frequent practical implication of preparing for what will happen.
3. *Be direct-able.* Be able to deliberately recognize and modify ones' own actions as conditions and priorities change.
4. *Be able to make pertinent aspects of their status and intentions obvious to their teammates.* Make targets, states, capacities, intentions, changes, and upcoming actions obvious.
5. *Have the ability to observe and interpret signals of status and intentions.* Be able to signal and form models of teammates.
6. *Enable a collaborative approach.*

Medical devices, such as infusion pumps, increasingly feature complex control and display interfaces. Even highly experienced clinicians who have used infusion devices for years get “lost in menospace” when they perform even the simplest tasks.⁴⁶ Most infusions in U.S. hospitals are now provided by infusion pumps,⁴⁷ making this device the most widely used IT-controlled equipment in the acute care environment.

Microprocessor-based infusion devices are associated with significant clinical accidents, resulting in patient morbidity and mortality. Problems with current commercially available infusion devices arise from the complexity of clinical care and the need to handle complex infusion programming through a simple interface. This simplicity creates gaps in necessary knowledge about the state of a patient's infusion. The disorientation and confusion it causes makes it difficult to adapt to changes in patient care. This is brittleness in action. Following a 5-year study of commercially available infusion devices, we have developed a concept that provides necessary features that current pumps lack.

The display concept in Figure 2 illustrates how an interface can provide information about device display and control through time, showing operating history, current state, and implications for the future. Including context information makes it possible to interpret device behavior in terms of its clinical use.

In this example, a pediatric patient is receiving an infusion of dextrose that was started at 08:07 and is programmed to be completed at 10:07. At this point (09:10) the infusion is about halfway completed. The display shows volume/time (rate) parameters, current and recent system status, and the expected course of the infusion if current program settings are maintained.

The device controls remain fixed in the display center, while the data scroll from right to left as time passes. The graphic representation makes it possible for clinicians to use pattern recognition to determine how infusions are programmed and progressing. Alphanumeric characters provide values for discrete variables that are necessary for accuracy.

As a predictive display, a clinician can recognize dose-limit errors that plague current infusion displays that are programmed using only numbers. Additional information (indicated by “i” symbols) can be displayed that coincides with the treatment timeline. For example, the “i” at the lower left indicates blood glucose test results that were reported at 08:06. This overlay of

therapeutic activity with results makes it possible for the clinician to make more informed decisions about patient care.

The interface concept reflects many of the 10 traits identified by Klein, et al.,⁴⁵ making it better suited to work jointly with clinicians. Making clinical and programming information explicit makes team coordination easier and prevents coordination breakdowns. Providing past, current, and anticipated states and making connections with related data, such as lab results, makes it easier to recover from unanticipated problems. Showing projected values helps clinicians see ahead and prepare for what will happen. Controls make it possible to explore contingencies before committing to a final decision. This enables the clinician to evaluate multiple options and make trade-off decisions. Integrating controls with displayed information makes it possible to deliberately assess and modify programmed infusion actions as conditions and priorities change. The combination of graphic and alphanumeric information makes pertinent aspects of the device target, status, capacities, programming intentions, and upcoming actions obvious to members of the clinical team. These are the kinds of observable and controllable traits that would improve IT support for health care.

Improving the compatibility between infusion pumps and work requirements is not a matter of fixing a particular aspect of a particular design, such as making type larger. Instead, it is a matter of developing a new approach to representations that aid the work of clinicians who perform infusions. A new design needs to follow the principles of Klein, et al.,⁴⁵ to make the pump's operation evident, demonstrate implications of current programming for the future, and make it possible for others (in addition to the clinician who programmed the pump) to make informed decisions in light of this information.

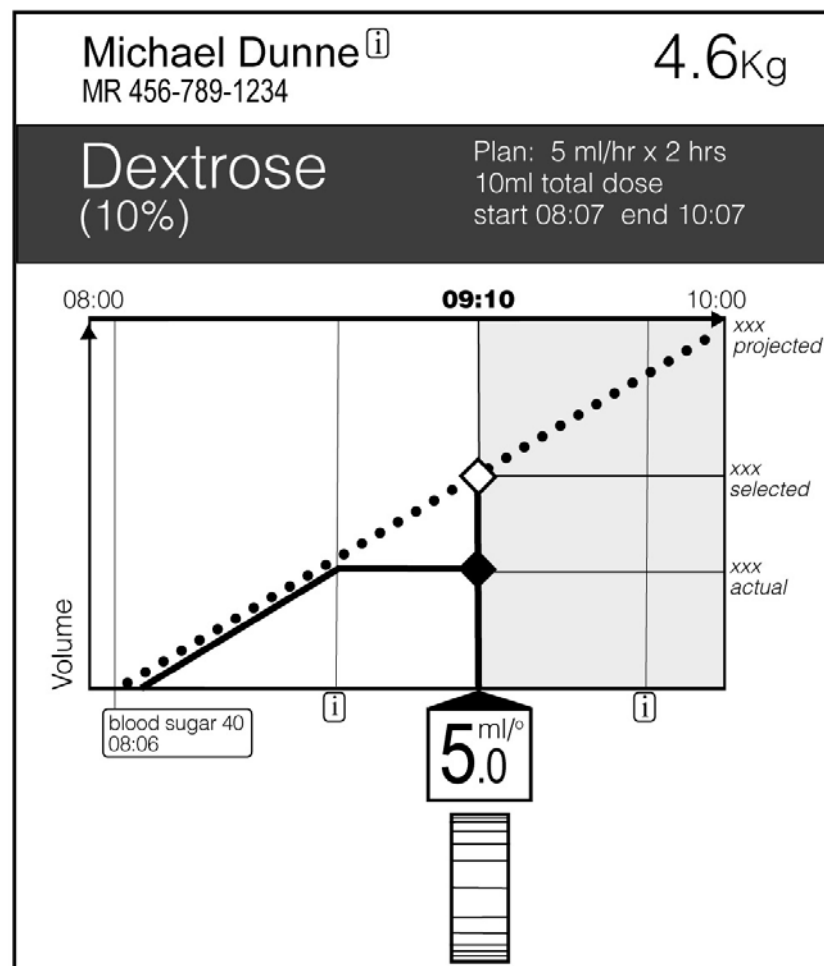


Figure 2. Infusion device interface supporting resilience.

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Conclusion

Current research on resilience seeks to clarify how resilience works, where it comes from, and what factors facilitate or impede it. These and other active steps can improve the ability of health care systems to respond adequately to increasing demands and to avoid an accumulation of discrete, well-intentioned adjustments that can detract from organizational efficiency and reliability. This makes the difference between organizations that inadvertently create complexity and miss signals that risks are increasing and those that can successfully manage high-hazard processes.

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Error Producing Conditions in the Intensive Care Unit

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Abstract

Up to 98,000 patients die because of human error in U.S. hospitals each year. Among the areas where errors occur frequently is the intensive care unit (ICU). Despite the impact of these errors, little research has identified the human factors that contribute to errors in the ICU. The current study uses the error-producing conditions (EPC) approach to help identify device-related factors that contribute to error. One result of the present study was the identification of the extent to which individual conditions contribute to the prevalence of error. In addition, we identified the contribution of certain devices to the prevalence of error. More importantly, the most critical devices for patient care were also identified as the devices that were rated highest in EPC prevalence. Developing medical devices designed to reduce the device-related potential for patient harm should be a primary goal in patient safety.

Introduction

Up to 98,000 patients die because of human error in U.S. hospitals each year.¹ Critical care is one of the areas in which human errors occur most frequently. In their seminal paper, Donchin and colleagues² estimated that the error rate was 1.7 per patient per day in the intensive care unit (ICU). A study 2 years later found that 45.8 percent of ICU admissions (480 of 1,047 ICU admissions) were associated with an adverse event (AE).³

More recently, an investigation of the incidence and nature of AEs and medical errors in a medical ICU and a coronary care unit (CCU) collected data during nine 3-week periods. A total of 120 AEs were found in 79 patients, for an AE rate of 20.2 percent.⁴ The researchers found that 66 of the 120 AEs (55 percent) were nonpreventable, while 54 of the AEs (45 percent) were preventable.

An Australian study suggested that nearly 17 percent of all hospital admissions resulted in an AE, with half of these being preventable.⁵ The same study estimated that in Australia, 8 percent of all hospital bed days were a result of AEs. In addition to the costs associated with a longer stay and other potential costs for the hospital, there were also the issues of disability payments and the associated high personal costs for the patients and staff involved in these cases.

More recently, due to a change in Medicare in the United States, the costs associated with AEs will be redistributed. Previously, the followup costs for treatment of “serious preventable events” were covered by insurance payments. However, as announced in September 2007, Medicare will no longer cover the followup costs of AEs.⁶

Clinical Risk Management

Historically, a human error in clinical settings has been treated as an issue of clinical risk management, the aim of which was to deal with the consequences of AEs by controlling the potential for litigation based on claims of medical negligence.⁷ One problem with this approach, though, was that each AE was treated as a single, isolated event. Underlying influences were not necessarily investigated, and the effects of other factors on the genesis of human error were often ignored. Consequently, errors were seen as an exception in a system that otherwise performed well; no other problems, other than the particular case in question, were typically investigated. Preventable AEs were considered to be the result of an individual making an error or not following standards of medical practice.

Several alternative approaches have been proposed and applied to improve our understanding of human error in health care. Among these is root cause analysis (RCA), a standard approach for the analysis and assessment of processes in the clinical environment. The Joint Commission requires this technique for studying serious and sentinel events. The goal of this resource-intensive method is to identify any aberrant processes that may have contributed to a particular AE. Root causes, which represent the fundamental reasons why the event occurred, are investigated by analyzing how and why the event occurred.

RCA has been criticized for several reasons. First, as its name suggests, RCA posits a single cause leading to an error, which often may be an oversimplification. In most cases, a complex chain of events, including a number of contributing factors, are found to lead to an incident or accident. In addition, RCA often focuses only on the reconstruction of a particular event and not on an understanding of what the event reveals about systemic problems in the health care organization in which it occurred. As a consequence, RCA may only help to prevent the repetition of similar events in the future, and it is uncertain whether it actually does reduce the risk of such events. Finally, RCA often directs its focus on events that are among the most serious, while ignoring events that may be considered less serious. In fact, though, a concentration on less serious AEs may help provide insight into systemic causes of error. Efforts to improve patient safety in health care should go beyond an RCA to incorporate a psychologically based theory of human error in organizational settings.

An alternative to the approaches outlined above is to evaluate human error from a systemic perspective. This would not only document error occurrence, but it would also aim to understand the complex underlying factors that contribute to error in the context of health care. This can be distinguished from RCA's reactive approach because it applies a more proactive strategy of error management; its goal is to anticipate where and how errors may occur. At the core of a systemic approach is identification of conditions under which errors occur and implementation of measures that would protect against such error occurrence. Overall, a system-oriented approach that emphasizes proactive and pre-emptive error management is in accord with the concepts of preventive medicine and patient safety that lie at the core of public health.⁸

Adverse outcomes: The last link in a chain of events. Several authors have developed frameworks that include the elements outlined above. Here we discuss James Reason's model of organizational accidents.⁹ Central to Reason's approach is the assumption that an accident or an adverse outcome is the final link in a chain of events. This implies that it is important to consider

the actions of the people involved and to analyze the conditions and organizational factors under which they were working that may have had an impact on the AE under investigation. Reason distinguishes between two elements present in cases of human error: active failures and latent conditions.

Active failures can refer to several different types of actions:

- Action slips—for example, selecting the wrong menu when programming an infusion pump.
- Lapses—for example, a nurse performs a structured task but does not use a checklist and, as a result, forgets an important step.
- Mistakes—for example, due to an incorrect understanding of a situation, an individual takes actions that may be performed successfully but do not solve the initial problem.
- Violations of operating practices, procedures, or standards—for example, not performing hand hygiene when indicated.

Latent conditions are the result of decisions that were made by people who do not operate at the “sharp end” but are more remote.¹⁰ Latent conditions can be created by management or senior clinicians with responsibility for decisions at the unit level. They also can originate with decisions that are made at a higher organizational level but have direct implications for the way work is performed by staff at the “sharp end.” Latent conditions result in situations from which an active failure may lead to an AE. Common latent conditions include high workloads, insufficient training and supervision, inadequate equipment, or imperfect equipment maintenance.

Although Reason’s approach⁹ provides a theoretical framework for human error, one potential problem is that it does not allow easy identification of influences that increase the probability of error at the level at which errors are likely to occur.

Human Error Assessment and Reduction Technique. An approach that overcomes this weakness is the Human Error Assessment and Reduction Technique (HEART). Developed by Jeremy Williams, HEART has been applied successfully in a wide range of industries.¹¹ HEART provides a set of generic task types and lists error probabilities associated with these tasks. The probabilities for error are identified based on a comprehensive review of the literature on human performance and human factors. In addition, HEART provides a list of error-producing conditions (EPCs) that can affect both task performance and the potential to increase the probability of error when a specific task is performed in the presence of these conditions. Thus, EPCs can be thought of as additional factors that increase the probability of error. Williams conceptualized them as factors that have a consistent effect on human reliability. Thus, they introduce constant error that is nonvariable and therefore can be studied systematically.

Given the importance of EPCs, it is plausible that they should be an integral part of a comprehensive model of human error, including that of Reason (Figure 1). The strength of such an integrative approach is that it is well rooted in the psychological literature on human performance and human factors. Moreover, this integrated approach facilitates the identification of conditions and task characteristics that lead to estimates of the probability of error. A disadvantage of this approach, though, is that it requires a trained observer to visit work places

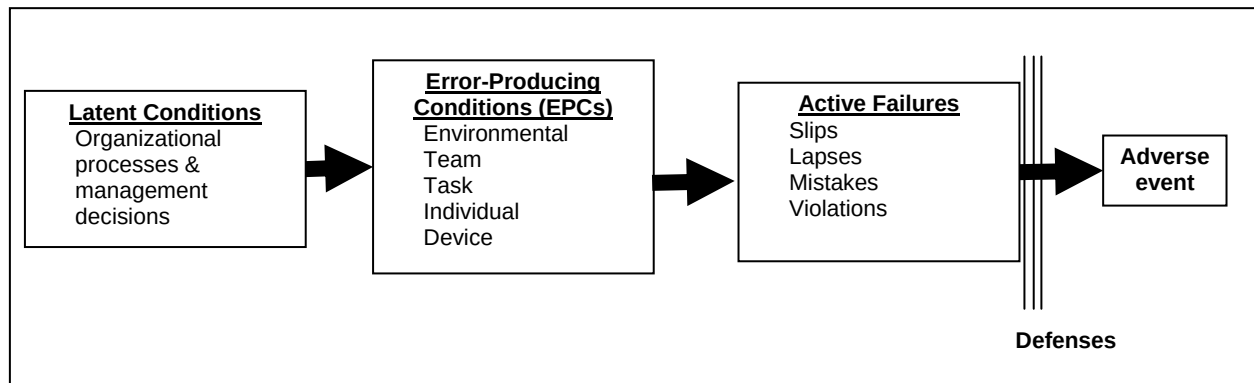


Figure 1. Reason's model of error (modified after Dean et al)¹⁴

under consideration and to categorize the tasks and conditions under which work is performed. Obviously, this makes the approach quite resource-intensive and time-consuming.

Most literature over the last three decades describes the application of systems like HEART in non-health care industries, demonstrating that proactive approaches toward error management have been successfully implemented. However, some encouraging evidence for the successful application of proactive and preemptive error management does come from health care.¹²

The present study focuses on EPCs in the ICU, which is a unique environment due to its complexity and tight coupling. (Coupling refers to the interdependence of different elements in a system.) The complexity of critical care medicine is reflected in the fact that high-risk decisions often have to be made by clinicians very rapidly, and to make matters worse, these decisions often are based on incomplete patient data. The presence of comorbidities in ICU patients only adds to the level of complexity, increasing the difficulty of decisionmaking even further. In addition, critical care patients often have lower physiologic reserves to help them cope with problems that might derive from suboptimal care.

Tight coupling presents other challenges. A tightly coupled system has little room for error because it cannot tolerate delays or variations in sequencing. Taken together, a high level of complexity and tight coupling make critical care medicine an ideal testing ground for the study of human error and the identification of EPCs.

EPCs in the ICU can be broadly considered as factors that negatively affect the reliability of human performance. The construct of EPCs is similar to the construct of latent causes of error, which has been extensively studied in non-health care industry settings, such as aviation and nuclear power plants. Although the notion that medical error arises from latent system-level causes is widely appreciated,¹³ quantitative data regarding the impact of these conditions in clinical settings are scant.¹⁴ To study EPCs, it seems important to focus either broadly on the presence of such conditions in the ICU, or to identify one or more specific domains and to examine their presence there. We have chosen the second approach and focused on devices that are associated with EPCs in the ICU.

Devices

Potential problems with monitoring devices are highlighted by the following case: About 22 minutes after a nurse's last routine bedside visit, an ICU patient was found to be in *torsades de pointes*-type ventricular tachycardia (VT). As a result, the patient experienced irreversible brain damage. The staff noted that the critical arrhythmia alarm had not sounded at the onset of VT. Testing the monitoring equipment revealed that it had been inadvertently placed in "pulse mode," which disabled the arrhythmia alarms. Further investigation found that no critical care supervisors and only 3 of 50 staff nurses were even aware of the pulse mode option; none of the nurses knew of the pulse mode function's effect on alarms.

Sentinel event reports like this one provide much of the information about hazards associated with medical device use. The problem is that comprehensive studies of medical device problems are lacking.¹⁵ That alarms are used unproductively in ICUs is widely appreciated, yet very few data exist about the consequences of ineffective monitoring in critically ill patients.

Poor interface design in health care is a serious problem. The U.S. Food and Drug Administration (FDA) reported that from 1985 to 1989, up to 50 percent of device recalls were due to poor product design, including problems with software and user interfaces.¹⁶ As a result, in 1990, Congress passed the Safe Medical Devices Act (SMDA), which requires device producers to follow good manufacturing practices.¹⁷

In 2002, the Joint Commission issued an alert based on the review of 23 sentinel events involving mechanical ventilators, of which 19 had been associated with death and four with coma.¹⁸ Malfunction or misuse of an alarm or an inadequate alarm was a factor in 65 percent of the sentinel events; 52 percent were related to a tubing disconnect. The analysis of these ventilator events led the Joint Commission to designate improved effectiveness of clinical alarm systems as one of its patient safety goals.

Adapting the EPC framework based on Williams's work, we found it possible to identify a number of conditions that are directly related to the operation of medical equipment in the ICU. These EPCs, which formed the basis for our study, include:

1. Unfamiliarity with a situation.
2. Time pressure in error detection.
3. Low signal-to-noise ratio.
4. Mismatch between an operator's mental model and that imagined by the device designer.
5. Impoverished information quality.
6. Ambiguity in performance standards.
7. Disruption in normal work-sleep cycles.
8. Unreliable instrumentation.

The present study examines the prevalence of error-producing conditions, such as the ones above, with respect to the use of a selected number of medical devices in the ICU. The selection of specific devices was driven by their function (e.g., therapeutic or monitoring devices) and

their criticality for patient safety (Table 1).¹⁹ In addition to EPCs, the study also assessed error prevalence in the ICU based on the subjective ratings of ICU nurses.

Historically, medical research has been focused more on the development of plans (i.e., identifying therapies) than on ensuring that those plans are correctly executed (i.e., therapeutic interventions).²⁰ Focusing on nurses in this study gives us the opportunity to examine performance that is related to the execution of plans.

Based on a literature review, we expected to find that nurses would be able to identify the presence of errors in the ICU. Thus, we expected the presence of error in the ICU to receive moderate to high ratings. We also expected that nurses would be able to identify general EPCs and rate them in terms of their perceived contribution to ICU problems. However, no specific hypotheses were formulated about the ratings of individual EPCs. At least two hypotheses about the relationship between patient safety and EPCs, as they relate to a device's criticality, can now be developed:

- The higher a device's criticality, the lower its rating for individual EPCs should be.
- Based on data about device use in the ICU, the higher the criticality of a device, the higher the rating of the impact of EPCs should be.¹⁹

Methods

The present study employed questionnaires (approved by the University of Utah Institutional Review Board) to determine nurses' assessments of ICU device-related EPCs. Nurse participants were recruited through advertisements placed at several ICUs in Salt Lake City, UT.

To be eligible for the study, nurses had to be active Registered Nurse license holders, have at least 1 year of experience in critical care, and be employed and currently working in an ICU. Nurses completed the questionnaires in the presence of a research assistant.

Data were collected from 25 ICU nurses. The mean age of participants was 39 years (range 22-64, sd = 13.5), and they had an average of 10 years in critical care (range 1-38, sd = 10.25). The majority of participants were female (19), and most were currently working in the medical ICU (68 percent). Other intensive care workplaces included the thoracic ICU (12 percent), the surgical ICU (8 percent), the neurological critical care unit (8 percent), and the burn-trauma unit (4 percent). The demographics of these participants are shown in Table 2.

Table 1. Devices classified according to criticality and frequency of use

Device category	Device	Criticality
Therapeutic	Mechanical ventilators	High
	Bilevel positive airway pressure (BiPAP)	High
	Transvenous pacemakers	High
	Aortic balloon pumps	High
	Chest tubes	Moderate
	Infusion pumps	Moderate
	Feeding pumps	Low
Monitoring	Pulmonary artery catheters	Moderate
	Oximeter probes	Low
	Multiparameter monitors	Low

Materials

To identify general and device-related error-producing conditions, we developed a questionnaire that focused on the eight EPCs mentioned above. The questionnaire consisted of 121 items that were grouped into three sections. Participants rated each statement on a scale from 1 (“strongly agree”) to 9 (“strongly disagree”). After the individual scales were recoded to create unidirectional scales, mean scores across device categories were computed for each question.

The first section focused on errors in the ICU in general. Statements to assess this issue included: “Errors are a problem in the ICU”; “You sometimes find yourself making errors”; and others.

The second section provided statements about devices in general and how EPCs might affect operation of these devices. To assess participants’ attitude about these EPCs, statements included “You are open and willing to ask for help when programming a device”; “You always can tell whether something is malfunctioning or just difficult to use”; and others.

In the third section, statements about specific EPCs had to be rated according to how they applied to individual devices that differed in criticality for patient safety (i.e., low, moderate, and high). Respondents were asked to rate their level of agreement with several device-specific comments, such as “You feel you have received adequate training to use [device]”; “You often see an error message with [device]”; “You feel [device] is designed well”; and others. Respondents also had the option of not answering questions about individual devices if they had had no experience in using them.

After arriving at the Department of Psychology at the University of Utah (or another place of their choosing), nurses completed the consent form required by the University of Utah’s Institutional Review Board. The nurses then completed the questionnaires, which took most nurses approximately 45 minutes.

Table 2. Demographics of participating ICU nurses

Total ICU nurses participating	25
Sex	
Male	6
Female	19
Age (years)	
Mean ($\pm$ SD)	39 (14)
Range	22 - 64
Years in critical care nursing	
Mean ($\pm$ SD)	10 (10)
Range	1 - 38
ICU workplace (%)	
Medical	68
Thoracic	12
Surgical	8
Neurological critical care	8
Burn-trauma unit	3.8

Results

For the purpose of the analyses, the polarity of items was reversed where needed so that high ratings consistently expressed a more negative attitude toward an individual statement. Consequently, aggregated scores on individual scales (e.g., error scale) expressed more negative attitudes and had higher average ratings; i.e., this condition potentially contributes more to error occurrence.

The first analysis focused on participants' subjective assessments of errors occurring in their own behavior or observed in other ICU nurses. The mean ($\pm$ SD) rating on the scale that assessed the presence of error in the ICU was 6.35 ($\pm$ 1.3); range, 3.25 - 8.75. Mean EPC ratings in the ICU in general are shown in Table 3.

Clearly, the EPCs "low signal-to-noise ratio," "unreliable instrumentation," "operator-designer mismatch," and "shortage of time" ranked relatively high in importance. These higher ratings contrasted with the nurses' ratings for "ambiguity in performance standards," which they rated as a less important contributor to error.

The final analysis focused on device-specific EPCs and the relationship between device criticality for patient safety and potential device hazards as contributors to error. For this purpose, we analyzed device-specific answers with regard to the EPCs using an ANOVA with device criticality (i.e., high, moderate, low) as a factor. Individual ANOVAs were performed for each of the eight EPCs.

The ANOVAs identified five device-specific EPCs with significant differences among the three criticality ratings (Table 4). The EPCs with significant differences were "unfamiliarity with situation" [$F(2,71) = 28.9$; $P < 0.01$]; "shortage of time" [$F(2,71) = 5.0$; $P < 0.01$]; "low signal-to-noise ratio" [$F(2,71) = 3.1$; $P < 0.05$]; "operator-designer mismatch" [$F(2,71) = 7.6$; $P < 0.01$]; and "quality of information" [$F(2,71) = 30.0$; $P < 0.01$].

Table 3. Mean ratings for general EPCs in the ICU

Error-producing condition	Mean ($\pm$ SD)
Unfamiliarity with situation	3.08 (1.21)
Shortage of time	4.42 (1.74)
Low signal-to-noise ratio	5.92 (2.02)
Operator-designer mismatch	4.63 (1.31)
Quality of information	3.81 (1.51)
Ambiguity in performance standards	1.13 (0.34)
Disruption of work-sleep cycles	3.81 (1.55)
Unreliable instrumentation	4.82 (1.15)

Table 4. Mean criticality ratings for statistically significant device-specific EPCs

Device-specific error-producing condition	Mean ($\pm$ SD) criticality rating ^a		
	High	Moderate	Low
Unfamiliarity with situation	4.4 (2.9)	2.3 (1.7)	1.3 (0.5)
Shortage of time	3.8 (2.3)	2.1 (1.3)	2.5 (1.8)
Low signal-to-noise ratio	3.3 (2.1)	2.1 (1.2)	3.1 (1.8)
Operator-designer mismatch	4.4 (2.6)	2.8 (1.5)	4.0 (2.3)
Quality of information	4.0 (2.6)	2.0 (1.0)	4.0 (2.4)

^a ANOVA

Figures 2 and 3 illustrate the mean agreement scores for “unfamiliarity” x device criticality rating and “shortage of time” x device criticality rating, respectively.

We performed additional post-hoc analyses to identify which differences in criticality levels for each of the above EPCs were statistically significant. With regard to the “unfamiliarity” variable, the mean rating for high device criticality was 4.4 vs. 2.3 for moderate criticality and 1.3 for low criticality (Table 4, Fig. 2). Tests indicated that differences among all three levels of device criticality were significant for the EPC “unfamiliarity with situation.” In clinical terms, this suggested that unfamiliarity with a device becomes less of a factor in the production of errors as the device’s criticality declines.

Similarly, in the case of “shortage of time,” data analyses indicated a significant difference between high and medium device criticality (mean rating = 3.8 and 2.1, respectively) in the likelihood of causing an error; and between high and low device criticality (mean rating = 3.8 and 2.5, respectively); but there was

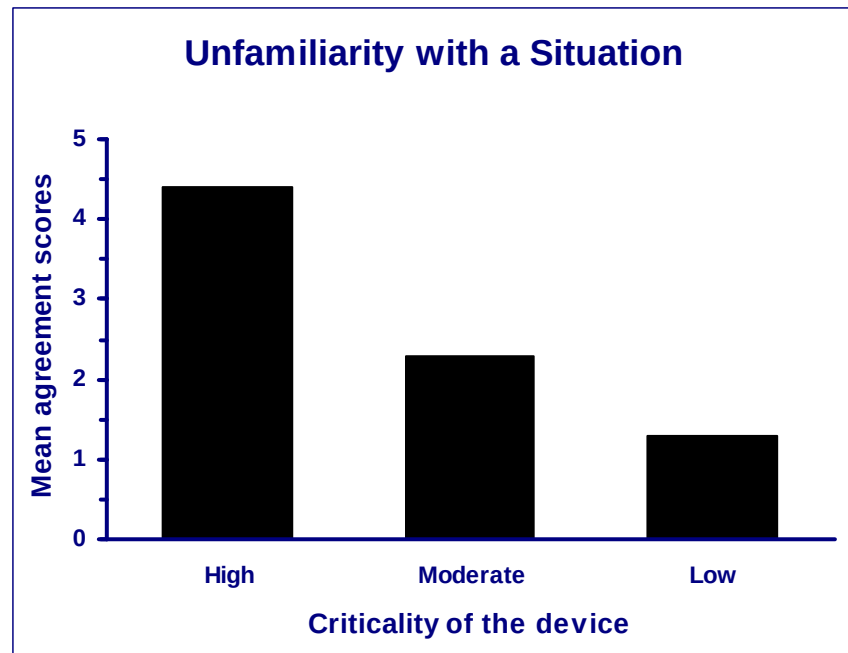


Figure 2. Mean agreement scores of device-specific EPCs for “unfamiliarity with a situation” x device criticality. Results suggest that “unfamiliarity” becomes less likely to lead to error as device criticality declines from high to low.

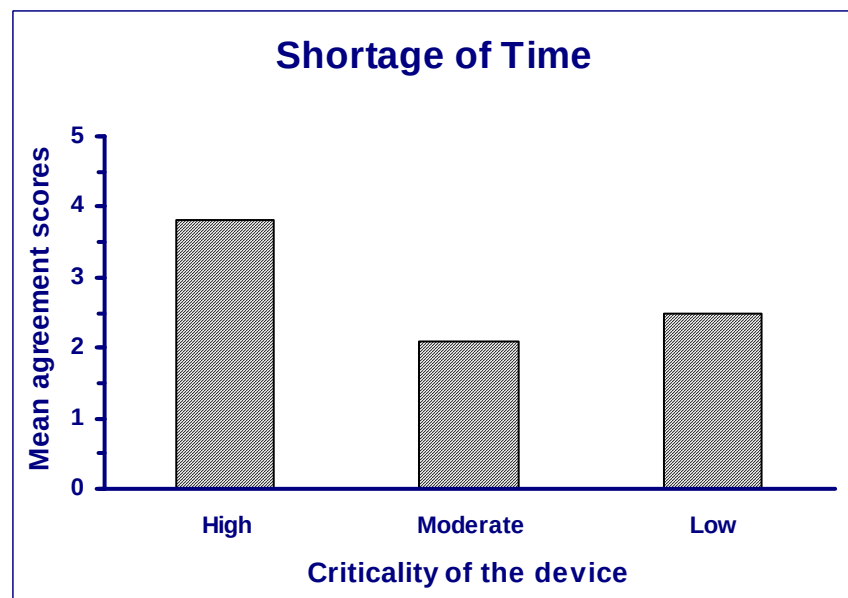


Figure 3. Mean agreement scores of device-specific EPCs for “shortage of time” x device criticality. Results suggest that shortage of time significantly increases the chance of error more with highly critical devices than with devices of moderate or low criticality.

no significant difference between devices that were medium or low in criticality (Table 4, Figure 3). Thus, in clinical terms, the EPC “shortage of time” should have a significantly greater negative impact on the risk of errors when nurses are using highly critical devices compared with devices that are moderate or low in criticality.

In the case of the EPC “operator-designer mismatch,” significant differences in the risk of error were found between devices with high or moderate criticality (mean = 4.4 and 2.8, respectively) and between devices with moderate or low criticality (mean = 4.4 and 4.0, respectively). For the EPC “quality of information,” significant differences were found between devices high or moderate in criticality (mean = 4.0 and 2.0, respectively) and between devices moderate or low in criticality (mean = 2.0 and 4.0, respectively). Interestingly, for both “operator-designer mismatch” and “quality of information,” the risk of errors using high criticality devices and low criticality devices was similar when compared to those of moderate criticality.

For the EPC “low signal-to-noise ratio” no significant differences were found in a device’s risk of errors based on its criticality

Discussion

The first goal of this study was to assess perception of error in the ICU among nurses who had experience working in the ICU. Another goal was to examine device-related EPCs in the ICU, based on the application of a survey methodology. Two aspects were analyzed: What are device-related EPCs, with no focus on specific devices; and how much are EPCs associated with devices according to their criticality?

Our initial finding is consistent with the existing literature on error in the ICU: Errors not only occur in the ICU, but they occur rather frequently, as reflected in the high mean nurse estimates of 6.35 (9-point scale).

A potential criticism of this finding is that the ratings were not especially high, and one might possibly expect higher subjective ratings. However, it is important to keep in mind that error in health care is an issue that clinicians do not necessarily like to discuss. Thus, it may be argued with equal validity that ICU error ratings even this high are rather remarkable. Often, when asking people to respond to statements that measure socially questionable acts or activities, the bias toward the lowest endpoint on a scale is strong. This tendency might even be amplified if people work in an organization marked by a culture of blame. Given that the present study found ratings on statements about error to be relatively high, this finding emphasizes the importance of investigating, in even greater detail, the nature of and contributing factors to error in the ICU.

Device-related EPCs in general shed some light on the contributing factors to error in the ICU. The results of the present study indicate that some EPCs are perceived as having a larger impact on error than others, when focusing on devices across the board. Clearly, low signal-to-noise ratio is one such EPC, indicating that information provided by devices in the ICU is difficult to discriminate from noise. This has serious implications for performance. Even experts experience serious difficulties performing at near optimal levels without interpretable and trustworthy feedback. A low signal-to-noise ratio has the potential to affect performance negatively. Some

support for this finding comes from the observation of the large number of false alarms in the average ICU.²

Related to the problem of low signal-to-noise ratio is the issue of unreliable instrumentation. Nurses experience unreliable instrumentation when they have to deal with false sensor readings or other equipment-related problems that can cause false alarms. In another paper in the current edition of *Advances in Patient Safety*, we note that nurses point to incorrect sensor readings as one of the main problems of patient monitoring in the ICU.²¹

Another problem that ranks high as a potential contributing factor to error in the context of device use is “operator-designer mismatch” as it relates to the mental model implemented in the design of a device. Not only does the relatively high ranking of this EPC indicate it to be a potential hazard, but this finding is also consistent with nurses’ complaints about cumbersome interfaces (e.g., patient monitors) that do not map into the task structure or sequence for which the device is used.²¹ Based on this finding, we can conclude that those involved in device development are not taking into adequate account cognitive analyses of the user’s task and the device’s interface. As a result, the device may not facilitate the task at hand as much as it increases the likelihood of the nurse committing an error.

Another EPC with high ratings was “shortage of time” in dealing with devices. Given the problems outlined above, it is no surprise to find that under time pressure, the operation of devices becomes more of a challenge and consequently increases the chance of an error.

Finally, the present study offers evidence about the relationship between EPCs and devices of varying criticality for patient safety. The results show that devices with high criticality unfortunately have the highest ratings on the EPCs “shortage of time” and “unfamiliarity with the situation.” This finding replicates results from Samore and colleagues¹⁹ to a certain extent, but it also extends these by providing evidence that devices that are among the most important for patient safety also are the ones with the largest potential for patient hazards. Ironically, the use of these critical devices is especially compromised when nurses have to deal with significant challenges (e.g., unfamiliar situations) and are under high time pressure (“shortage of time”).

This particular finding has important implications for the development of devices and their interfaces: only ICU devices that minimize hazards and maximize resilience toward error have the potential to reduce the risk of human error. The development of devices that are consistent with these goals will be a formidable human factors task.

A potential limitation of the present study is the relatively small sample size (25 nurses). To increase the generalizability of our findings, future studies of EPCs in the ICU should employ larger sample sizes.

Based on the present findings, it appears that questionnaires—in addition to observational approaches used in prior non-health care domains—can be used to identify EPCs. By translating the construct “error-producing condition” into easily comprehensible language, it seems possible to collect data on these factors. Validation of these findings using independent observers is still

important, though, because mismatches between a nurse's experience and the conclusions of a trained observer regarding potential EPCs cannot be excluded.

The overall results of this study are encouraging in that they demonstrate the possibility of increasing our understanding of device-related human error in the ICU. This is an important step toward the goal of reducing hazards and improving patient safety.

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Patient Monitors in Critical Care: Lessons for Improvement

Frank A. Drews, PhD

Abstract

Unexpected incidents are common in intensive care medicine. One means of detecting, diagnosing, and treating these events is use of physiologic displays that show the patients' vital signs. Monitors currently in use in intensive care units (ICUs) provide information in numerical and waveform formats, but most such displays originated in patient monitors developed for use by anesthesiologists. The present study focused on problems related to patient monitoring and needs of ICU nurses. Semistructured interviews of 26 experienced ICU nurses were employed to identify monitor usability problems. Among their comments, interviewed nurses mentioned that monitors now in use make it difficult to access vital sign trends and do not permit marking of events or interventions on trend displays. The present results indicate that patient monitoring in the ICU could be improved, but that such improvement will require identification of the tasks nurses perform and the development of new monitoring tools that fit their specific needs.

Introduction

The last three decades have seen significant effort and resources expended toward improving data display design in high-risk fields, such as aviation and power plant control. These efforts have yielded marked improvements in the safety and efficiency of airplane and nuclear power plant operation. Among the commonalities of these two domains are engineered systems. All monitored systems are designed by engineers, and consequently, they are well understood by their designers and to a certain extent by their operators. Sometimes the systems are designed with the goal of making system monitoring less complex. Engineered systems can be contrasted with situations where the task involves the monitoring of a natural system, that is, a patient.

One of the very first technical approaches to monitor patient physiology was the strip chart electrocardiogram (ECG) recorder developed by Sir Thomas Lewis in 1912. Interestingly, even some of today's most innovative monitors still employ elements of Lewis's original strip chart, with some numerical information added.

Development of patient monitors grew out of anesthesiologists' need to improve intraoperative patient monitoring. The complexity of the monitoring task is reflected by the fact that anesthesia monitors currently in use display more than 36 critical physiologic patient variables—often in real time—visualizing them through a combination of numerical data and waveforms.

Physiologic monitoring displays were introduced into the ICU in the 1970s, and they have not changed substantially since then. Patient monitors still employ a conventional format rooted in

anesthesiology to present physiologic variables. The design format for these displays is based on a single-sensor-single-indicator (SSSI) approach, which provides a single indicator for each individual sensor connected to the patient. This approach to monitoring is founded in the domain of engineered systems¹ and has been applied to patient monitoring without significant modification.

The physiologic parameters currently displayed on ICU monitors include blood pressure, acquired from an arterial catheter and external pressure cuff; oxygen saturation of the blood, acquired from a pulse oximeter; heart rate; and respiratory rate, acquired from external transducers and the electrocardiogram waveform. Critically ill patients may also require hemodynamic monitoring using a pulmonary artery (PA) catheter. The parameters obtained from a PA catheter—including central venous pressure, right atrial pressure, PA pressure, cardiac output, and other calculated parameters—are also typically displayed.

ICU nurses monitor physiologic patient parameters on a regular basis to assure the patient's stability. Among the most common problems they face is detecting changes in one or more physiologic patient parameters. Timely detection of a change becomes a potential problem when detection is viewed in the context of all the patient's physiologic parameters and disease history and then must be interpreted and compared with parameters stored in the nurse's recent memory or the patient's records.

Nurses sometimes have to integrate 10 or more rapidly changing physiologic parameters into a clear and qualitative mental representation of a patient's current state. To make matters worse, in the case of an unexpected and potentially life-threatening event, the cognitive demands increase as the clinician must interpret new data for problem detection and rapid intervention.² The high cognitive demand for data integration reduces available cognitive resources for other important tasks (e.g., taking corrective actions, documentation, communicating with physicians and/or nurses). This can lead to other problems or a cascade of errors, such as interrupted tasks or deviations from the treatment plan or necessary interventions.³

Providing nurses with information about the patient's physiologic status in a manner that is easy and fast to interpret should reduce the time needed to detect changes. However, currently available monitors are not explicitly designed as cognitive aids for facilitating the rapid detection of changes in patient status.⁴

Current ICU monitor displays are also deficient in their ability to facilitate an integrated assessment of the patient's status that would enable nurses to develop a high level of situation comprehension.⁵ Designs that follow the SSSI approach tend to yield data in a sequential, piecemeal form that makes it difficult and time-consuming for nurses to develop a coherent understanding of the relationships and underlying mechanisms of the displayed parameters.^{6, 7} However, this situation flies in the face of the fact that a coherent understanding of a system's function and patients' physiologic mechanisms is a necessary precondition for optimum performance.^{8, 9}

In their paper on medical errors in the ICU, Donchin and colleagues¹⁰ reported that nurses performed 87 percent of all patient-oriented activities. Overall, nurses contributed to more than

half the errors observed during the data collection period in this study. One plausible explanation for this high occurrence of error is that nurses have to rely on monitoring equipment that is not optimized for the specific tasks they have to perform. This mismatch between the required task and the cognitive aids available to deal with the task may be partly responsible for the relatively high occurrence of error in the ICU.

A user-centered approach might help optimize the design of physiologic ICU monitoring equipment. For example, iterative, user-centered design strategies for the development of graphic displays in health care have been suggested.^{4, 11, 12}

Despite these problems, very few researchers have actually evaluated new designs for nursing monitors. For example, Effken, et al.,¹³ developed a graphic, etiologic display to support hypothesis testing and treatment. The monitor incorporated elements of ecologic interface design to show causal constraints among key hemodynamic variables.^{9, 14} In their study, critical care nurses and student nurses administered simulated drugs to correct hemodynamic disturbances in simulated patients. Compared to a traditional monitor, the graphic display reduced the time to initiate treatment (i.e., administer drugs), reduced the total number of drugs used, and increased the percentage of time that variables were in the optimal range. Interestingly, the etiologic display did not help clinicians understand the underlying physiologic effects. In fact, student nurses were better than experienced critical care nurses at returning the hemodynamic state to normal by simply focusing on returning the display's shape to normal and ignoring the underlying physiologic models. This display seemed to support treatment but not diagnosis.

The Cognitive Task of Controlling Patient Physiology

To conceptualize the control of a critically ill patient's physiology, several aspects of the control task must be taken into account. Hollnagel's Contextual Control Model (COCOM) provides some guidance and also allows predictions of potential problems that are associated with patient monitoring.¹⁵ COCOM is based on three main concepts:

- Competence—which is what the human-machine system can do based on the recognized needs, the available information, and the range of available actions. It is the combination of information and ability to act on that information.
- Constructs—which are conceptualizations of the situation; also referred to as mental models.
- Control—which characterizes the application of competence in relation to constructs. Control modes correspond to different processes of decisionmaking that vary in several dimensions, including:
 - Determination of outcome—which refers to the operator's ability to detect and interpret a change in system state.
 - Subjectively available time—which refers to the time pressure the controller perceives.
 - Number of simultaneous goals—which is related to the number of objectives a person can maintain.
 - Availability of plans—which is related to an individual's ability to generate an action based on available information. Plans can be generated based either on fast pattern recognition processes or on slow, cognitively demanding problem analysis.

- Event horizon—which refers to the amount of prior information an individual uses in making a decision about an intervention and how that individual extrapolates information into the future based on the current situation.
- Mode of execution—which refers to the type of feedback that influences future behavior; some actions may be executed in a “ballistic” fashion, while others rely on feedback.

Operator control can range between the extremes of absence of control and the highest level of control. Hollnagel¹⁵ outlined four regions of control as areas on this continuum:

- Scrambled control mode. This is the lowest level of control, which is characterized by the absence of any control. An operator acting at this level shows random actions that are characteristic of a trial-and-error approach and the absence of any cognitive schemata that could potentially guide behavior. Consequently, cognitive stress and time pressure experienced by an operator “controlling” at this level are extremely high.
- Opportunistic level of control. This is the next level on the control continuum. The operator at this level has some limited ability to control the system (i.e., actions are not random) but still faces high subjective time pressure. A central characteristic of opportunistic control is the ability to recognize and act on cues in the environment, allowing for feedback that can guide actions. Because the operator is slightly familiar with the environment, it is also possible to apply some cognitive schemata that direct action.
- Tactical level of control. This is the next highest level, in which the operator is capable of short-range planning. An expanded event horizon is available, and the subjective time pressure is less than at the lower levels of control. The user is experienced in acting in this context, making it possible to apply rules and procedures and to anticipate action requirements in the near future. The user operating at this level is able to maintain several goals simultaneously and relies on feedback.
- Strategic level of control. This is the highest level of control. Interaction with the system produces high levels of system stability, based on effective and robust control input. Because operators at this level do not experience time pressure, they can spend more time planning actions, allowing anticipation of future events while integrating past information. Due to the high cognitive load, operation at the strategic level is usually possible only for limited periods of time.

Monitoring Physiologic Parameters

Monitoring patient physiology, as well as planning and executing interventions to stabilize an unstable patient, can be conceptualized as control tasks.¹⁶ Often, nursing activities go far beyond these tasks and include such tasks as assessing patients’ functional and cognitive state. Other necessary activities, such as vital signs assessment and auscultation, require hands-on data acquisition. In addition to these tactile tasks, a significant number of activities involve the acquisition and interpretation of data that are displayed on patient monitors.

Based on a combination of observations and interviews with nurses, Aitken¹⁷ analyzed the nurses’ use of hemodynamic data and developed “concept maps.” These “maps” showed that the nurses were integrating a wide range of physiologic data—e.g., information from the patient’s medical history and current treatment regimens—into concepts to describe the patient’s state.

In another interview study (13 ICU nurses) of hemodynamic monitoring, Doig¹⁸ identified six cognitive tasks that nurses typically perform (Table 1). The concept maps identified in interviews can be used to make inferences about the control of patients and the level of control that is possible based on current monitoring technology.

Table 1. Tasks and issues

Tasks	Examples for issues with tasks
Selective data acquisition	Limited by ability to understand and/or conceptualize variables
Data interpretation	- Visualizing the big picture - Understanding relationships between variables
Controlling hemodynamics	Titrating medications and intravenous fluids to achieve a physiologic goal
Independent interventions	Anticipating the needs of the health care team during emergent situations
Monitoring trends in numerical data	Defaulting to memory for trend assessment
Use of current technologies	Trusting the accuracy of computer-acquired data

Source: Doig A. Graphical cardiovascular display for hemodynamic monitoring [dissertation]. Salt Lake City: University of Utah; 2006.

In the current study, we used a contextual adaptation of the concept maps developed by Aitken¹⁷ and Doig¹⁸ to identify challenges involved in ICU nurses' monitoring of physiologic patient parameters. The goal was to identify the central issues and to relate them to the dimensions of control as identified by Hollnagel.¹⁵

Methods

Semistructured interviews were used to assess issues and challenges related to the use of currently available physiologic monitors in the ICU. Interviews lasted approximately 1 hour and were conducted individually with 26 ICU nurses (Table 2). Most interviews were conducted at the Department of Psychology, University of Utah. The study was approved by the University of Utah Institutional Review Board.

To recruit nurses, we posted advertisements at several ICUs in Salt Lake City, UT. To participate, nurses had to be active Registered Nurse license holders, currently working in an ICU, and have at least 1 year's experience working in critical care.

The mean age of the 26 participants (19 females, 7 males) was 39 years (range 22 – 64, sd = 13.2). Nurses had an average of 10 years working in a critical care setting (range 1-38, sd = 9.86). Most of the nurses were currently working in the medical ICU (65.4 percent); other workplaces included the thoracic ICU (11.5 percent), the surgical ICU (11.5 percent), the neurological critical care unit (7.7 percent), and the burn-trauma unit (3.8 percent).

Interviews were recorded digitally and professionally transcribed (see Table 3 for interview questions). Data analysis began with the identification of themes that emerged in the interviews concerning monitoring of physiologic patient parameters (see Table 4). Analysis was performed according to the guidelines for theme extraction, as per Ryan and Bernard.¹⁹ Category generation was based on prior research regarding general concepts about nurses' use of physiologic monitors.^{17, 18} Emerging themes from the interviews were then identified and consolidated with the list of themes. This was followed by an additional analysis of the data, which focused on identifying individual elements that fit into the theme categories.

Table 2. Demographics of participating ICU nurses

Total ICU nurses participating	26
Age (years)	
Mean ($\pm$ SD)	39 (14)
Range	22 - 64
Years in critical care nursing	
Mean ($\pm$ SD)	10 (10)
Range	1 - 38
ICU workplace (%)	
Medical	65.0
Thoracic	11.5
Surgical	11.5
Neurologic critical care	7.7
Burn-trauma unit	3.8

Table 3. Interview Questions

- Which monitored variables are the most confusing ones?
- Think about information that would make patient monitoring more effective. Which information is currently missing on physiologic monitors?
- What are your main concerns with current patient monitors in general and, in particular, with the specific monitor you are using?
- Think about a situation when you and your colleagues work under serious time pressure. Are there errors you observe in others that are related to or caused by patient monitors?
- Which are the parameters on physiologic monitors for which trend information is, or would be important?
- Is all the trend information that you want available?
- Think about the way trend information is currently displayed. Is this mode of information presentation optimal?
- In order to get other data, you have to go through menus. When you do this, what is the information you are looking for, and how easy is it for you to get through the menus?

Results

The list of themes (task column) that emerged from the interviews is shown in Table 4. Examples of statements concerning these themes are listed in the second column. We will discuss the themes and the issues in more detail in following sections.

Data Acquisition and Processing

False alarms. Some nurses mentioned issues regarding data acquisition of physiologic parameters and data processing of parameters. One frequently described problem in this category is the high frequency of alarms sounded by ICU-based patient monitors, most of which are false alarms. Due to the high workload of ICU nurses (e.g., nurse-to-patient ratios ranging from 1:1 to 1:3), nurses often do not respond to alarms, assuming they are false, with the obvious consequence of missing a real alarm.²⁰

Nurses also expressed a desire to adjust alarm thresholds for individual patients. They often stated that, due to the monitors' complex menu structure and a lack of training, they did not know how to change alarm parameters. The absence of a standardized alarm menu structure increases monitor complexity. Nurses cited this inconsistency as the reason they tend to use default alarm settings, which are based on population parameters and are more likely to produce false alarms in critically ill patients. The application of such broad parameters to a specific patient in the ICU inevitably results in a high percentage of false alarms.

Table 4. Important themes and issues abstracted from interviews with ICU nurses

Themes	Issues
Data acquisition/processing	Data processing leads to frequent false alarms.
Data/event integration	- Marking events as an explanation for changes in vital signs. - Only contextual information allows for detection of artifacts. - Clutter makes data extraction and integration difficult.
Data interpretation	- Applying meaning to variables. - Understanding interrelationships among variables.
Monitoring trends in numerical data	- Trend functions are not routinely used, not accessible. - Need to visualize interrelationships between intervention and physiologic variables. - Defaulting to memory for trend assessment.
Usability issues	- Variables were difficult to read due to small font size. - Color coding of variables is not consistent between manufacturers or even within same manufacturer models. - Cables should be color coded for ease of use and troubleshooting.

Data Integration

Appropriate assessment of a patient's status requires cognitive integration of physiologic patient parameters, as displayed on monitor screens. The nurses identified several issues regarding current monitor technology.

One category of issues involved data artifacts (i.e., when measurements of physiological parameters are incorrect, for example, due to sensor-related problems). Nurses mentioned in the

interviews that they are frequently confronted with these artifacts; correct interpretation of these artifacts requires an assessment of the overall context in which they have occurred. At present, there is no display technology available that would allow nurses to assess a patient's status in a fast and integrated manner. As a result, nurses are forced to process individual physiologic parameters, both past and present, in a piecemeal fashion and then identify any inconsistencies between the patient's history and current status.

The nurses provided the following example that illustrates the shortcomings of currently available monitors: Oxygen saturation monitors are frequently associated with false alarms. When a patient's blood oxygen saturation drops too low, the oxygen saturation monitor sounds an alarm to notify the nurses that an intervention is needed to restore blood oxygen to an acceptable level. When such an alarm sounds, it is only natural for nurses to gravitate toward the alarming monitor. Based on the monitor reading of blood oxygen levels alone, it might be reasonable to assume that an intervention is necessary. However, it is common for an oxygen saturation monitor to report deceptively low blood oxygen saturation levels if the patient's body temperature is low.

It might well be that the patient's blood oxygen saturation values are actually low. However, because the sensor measuring blood oxygen saturation only operates accurately within an optimal temperature range, it is more difficult to obtain an accurate reading of oxygen saturation if the body temperature falls below that range. In the absence of an integrated display, a nurse faced with a low oxygen saturation alarm must remember to first check the patient's body temperature and then create a comprehensive mental model integrating both the patient's blood oxygen saturation levels and body temperature. The benefit of a display that integrates both pieces of information in one location is obvious here.

ICU nurses also expressed a need for information about recent interventions (e.g., drug administration) to be better integrated into trend displays on physiologic monitors. They pointed out that, when looking at trend data to assess the variability of parameters over time, information about recent interventions is not directly available; instead, it is recorded on the paper records or electronic charts, which are not integrated into or accessible on the data monitor display.

Data Interpretation

Interviewed nurses frequently reported observing novice nurses focusing on individual parameters rather than on the overall pattern of physiologic parameters. According to the interviewees, novice nurses experienced difficulties integrating information from available parameters and, consequently, tended to overemphasize the importance of individual parameters. This phenomenon, in which there is too strong a focus on individual parameters, has been termed "cognitive tunnel vision."²¹

To help alleviate "cognitive tunnel vision," some nurses recommended data monitors that integrate individual variables into graphic representations of the data, which would allow an immediate, more holistic assessment of patients' status. At the same time, some nurses mentioned that they also need the ability to focus on individual parameters, with the goal of identifying artifacts and assessing the patient's status.

Interviewees also mentioned two other factors that can influence their data interpretation: the formation of expectations regarding potential problems that facilitate data interpretation, and long years of experience, which allow them to quickly (although not necessarily effortlessly) assess a patient's status, despite problems with monitors.

Monitoring Numerical Data Trends

Almost all of the interviewees mentioned the relevance of information about physiologic patient parameter trends. As one nurse put it, "Trends kill people." The nurses viewed trend information as being relevant in a wide range of situations, from regular monitoring to critical events, or "code" situations, where access to trend information can be crucial when making rapid assessments about the cause of a problem.

Nurses frequently stated that trend information is only available on the main station monitors, and that they can only access the information from there. Many nurses also stated that trend information, despite its importance, is not used often enough, which some nurses attributed to a lack of formal training on the monitors. In addition, they stated that nurses were often unaware that they could access trend information on patient monitors, and that the menu structure on these monitors is too complicated and counterintuitive.

Nurses' suggestions about making trend information more readily available focused on their ability to review alarms and alarm setting changes over time, as well as on their ability to assess trend information. Additionally, nurses mentioned that they would prefer a monitor that allows them to visualize both trend information about physiologic parameters and information about interventions (e.g., drug administration). Such an integrated monitor would help them develop a more comprehensive understanding of both the effectiveness of interventions and the patient's response to them.

Finally, nurses also indicated that it would be helpful, in allowing for artifacts, for them to have the ability to mark events (e.g., "patient is supported in leaving bed temporarily") on a monitor that provides trend information. The nurses said a graphic representation of data over time would be best for displaying trend information.

Usability

The largest group of issues identified by the nurses involved problems with monitor usability. In the following section, we apply the criteria outlined by Drews and Westenskow²² to categorize the usability topics mentioned in the interviews.

Affordance. Nurses frequently mentioned issues of affordance,^a which gives them clues about which interaction with a monitor's interface is required to perform a particular operation. For example, many nurses complained about the difficulties they encountered in finding and selecting various functions on display menus and screens, which often resulted in many of the

^a Affordance is a term used in human-computer interaction to describe the quality of an object or environment that allows an individual to perform an action.

monitor's functions not being used. In a similar vein, nurses mentioned problems with the visibility of certain functions. For example, information about alarm settings was not always directly accessible. The issue of visibility was also mentioned in the context of the clarity of monitor function activation, where it was not always obvious whether a particular function had been activated or deactivated by a previous user.

Clutter. Nurses stated that novice nurses were often overwhelmed by the amount of clutter on the monitor display, making it difficult for them to use the monitors effectively.

Discriminability. Nurses complained about excessively small font sizes used on monitors, which increased the likelihood that numbers would get misread. Abbreviated labels were also likely to be misread, potentially leading to an incorrect assessment of patients' status and certainly to an increase in the time spent interacting with the monitor.

Knowledge. Nurses found fault with the discrepancy between information provided on the monitor to guide nurses vs. knowledge that nurses needed to have previously acquired in order to navigate successfully through a menu (knowledge in the world vs. knowledge in the head²³). They mentioned that the menu structure was often too "deep," making it difficult to find the desired information or menu item. They also complained that some patient monitor models did not provide help menus or a booklet of quick reference functions.

Consistency. Nurses pointed out that monitors were inconsistent in their use of color coding and the organization of menu structures. In some monitors, menu structure changed based on settings, and color mapping of variables varied with different settings, violating the principle of consistency.

Hardware modifications. Most nurses expressed a desire for touch screens to allow a direct manipulation of the displayed information, potentially removing, or at least reducing, the number of complex menu structures. They also pointed out that easy-access buttons would allow them to directly access important information without having to go through menus. Finally, they mentioned that it is essential to always display the alarm status on the main monitor.

The interviewees consistently pointed out that, as a result of these and other usability deficits, it takes a long time for nurses to feel comfortable interacting with physiologic patient monitors. Also, many monitor functions did not get used on a routine basis, possibly depriving nurses of important information.

Discussion

The current study revealed a number of issues related to the monitoring of physiologic patient parameters in the ICU. Nurses experienced a high number of false alarms, which they attributed to alarm settings not adapted to individual patients and to a lack of knowledge about how to change alarm settings, among other problems.

The nurses in this study emphasized the fact that currently available display technology does not allow them to rapidly integrate individual parameters into a coherent, holistic assessment of the

patient. Instead, it forces them to process individual parameters in a piecemeal fashion. This is consistent with the fact that the current data displays were developed using an engineering-based SSSI approach, which provides a single indicator for each individual sensor connected to the patient and makes data integration difficult.

The task of data integration is further complicated by the suboptimal information arrangement on patient monitor displays. Nurses complained about the presence of clutter on monitors. They also expressed a desire for information on physiologic trends, which they do not acquire from currently available monitors because they do not know how to access it.

By far the largest number of complaints about ICU monitor problems fell into the category of usability. In terms of software, nurses mentioned issues of affordance, visibility of functions, accessibility, discriminability of information, and violations of the consistency principle. Also mentioned were issues with current hardware, including a desire for touch screens, easy-access buttons, and clearly displayed alarm status.

These findings strongly suggest that nurses' information needs in the context of patient monitoring are not being completely met. Currently available monitoring equipment seems not to be based on an analysis of nurses' information needs. Information, such as event markers and trend data, often is either not available or not easily accessible.

According to COCOM, these findings suggest that competency is not being fully realized when nurses interact with current physiologic data displays, since competency is a function of the combination between information available and the ability to act.

Hollnagel²⁴ has described the levels of control based on several dimensions. Given the limitations identified in our interviews, it is clear that ICU nurses are not being supported optimally in the determination of outcome of an intervention due to a lack of information integration. This situation could be remedied by making available event markers that indicate the timing of an intervention in the context of physiologic trend information. Better integrated information displays would also help. These changes would also increase the likelihood of available plans, since pattern recognition processes would be better supported.

It is likely that ICU nurses' cognitive load is also increased by the requirement that information be gathered piecemeal, thus limiting the number of simultaneous goals that can be represented cognitively at one time. Moreover, because trend information is difficult to access and consequently rarely used, expansion of the event horizon is not supported. Finally, optimizing the feedback that nurses receive would also allow for a more feedback-based mode of execution.

Future development of physiologic monitors should follow the principles of usability outlined by Drews and Westenskow²² among others. It is also important to emphasize that the task of monitoring a patient differs from monitoring a technical system. If approaches from technical system monitoring are blindly applied to patient monitoring, progress is bound to be short-lived. Thus, only careful application of lessons learned from other domains to health care in general and patient monitoring in particular will lead to improved patient safety.

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Tools and Practices

Developing the Tools to Administer a Comprehensive Hospital Discharge Program: The ReEngineered Discharge (RED) Program

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Abstract

Introduction: The hospital discharge is nonstandardized and marked with poor quality. One in five hospital discharges is complicated by an adverse event (AE) within 30 days, many of which lead to emergency department visits and rehospitalizations. **Methods:** Using an iterative group process, we developed the principles and components of the ReEngineered Discharge (RED), a set of 11 distinct components designed to prepare patients for discharge. Three tools were created: a training manual used to train discharge nurses to provide the RED; an individualized, patient-friendly “After Hospital Care Plan” (AHCP), a booklet used to prepare patients for discharge; and a workstation to integrate all pertinent discharge information used to electronically create the AHCP. **Outcomes:** The RED was adopted by the National Quality Forum (NQF) as one of their “Safe Practices.” Among the intervention subjects, 89 percent were provided with an AHCP at discharge; it required approximately 1 hour for the discharge advocate to provide the RED intervention. **Implications:** Use of the AHCP tool can effectively prepare patients for discharge, as recommended by NQF 2006 Safe Practice number 11. These results have important implications for quality of care at discharge and for lowering costs.

Introduction

The transition process from the hospital to the outpatient setting is nonstandardized and frequently poor in quality.¹ One in five hospital discharges is complicated by an adverse event (AE) within 30 days, often leading to an emergency department visit and/or rehospitalization.^{2, 3, 4}

Many readmissions stem from errors that can be directly attributed to the discontinuity and fragmentation of care at discharge.^{5, 6} High rates of low health literacy; lack of coordination in the “hand-off” from the hospital to community care, gaps in social supports, and other limitations also contribute to the risk of rehospitalization, particularly for low-income urban patients.^{7, 8, 9} Increasingly, as hospitalists provide more inpatient care,^{10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20} it is difficult for primary care physicians (PCPs) to be aware of all the complexities of a hospitalization.^{21, 22}

Compounding the problem, the typical brief post-hospital followup visit does not allow the PCP adequate time to become familiar with the details of the hospitalization. Furthermore, the discharge summary, the main tool utilized by primary-care providers to ensure the continued care of the patient, is often not available to them or is missing key information.^{23, 24} Thus, the transition from the hospital to the ambulatory setting is a “hand-off” that opens the door for many potential medical errors.

There were over 38 million discharges in the United States in 2003, at a total cost of over \$753 billion.²⁵ Patients requiring recurrent hospitalization accounted for only 13 percent of hospitalized patients, but they used up to 60 percent of resources.²⁶ Any successful effort to reduce AEs will likely make care safer and reduce unnecessary rehospitalizations, thereby decreasing costs. A reduction in the rehospitalization rate, even by a few percentage points, would produce profound effects on health care financing.^{27, 28} Eliminating 4.7 percent of hospitalizations, a conservative estimate of the rate of unnecessary rehospitalizations, would save \$5.1 billion annually.²⁹

In its report, *To Err is Human: Building a Safer Health System*,³⁰ the Institute of Medicine (IOM) argued that most medical errors are a result of systemic problems rather than of poor performance by individual providers. The transition from the hospital to the ambulatory setting holds the potential for systemic problems, with numerous inherent possibilities for mistakes, lapses, and AEs. While adequate knowledge, skills, and adherence to established protocols by hospital and ambulatory care physicians can prevent many of these problems, others are the result of flaws in the design and organization of the health care system. These flaws are magnified in safety net hospitals, like Boston Medical Center, where the connection between hospital care and community-based care can be tenuous, and the patient population faces many barriers to care.

This report summarizes the rationale for and development of the principles and components of a comprehensive hospital discharge that we call the ReEngineered Discharge (RED), tools that can be used to administer this discharge, and preliminary results of a randomized controlled trial funded by the Agency for Health Research and Quality (AHRQ), designed to test the effectiveness of the RED.

Medical Errors and Adverse Events at Hospital Discharge

Errors and Adverse Events Are Common on Both Sides of the Transition

A study of a medical service at an urban teaching hospital demonstrated that 49 percent of discharged patients, who followed up with their PCPs, experienced an error in care due to a discontinuity between the inpatient and outpatient setting. Furthermore, patients who experienced “work-up” errors were 6.2 times as likely as those not experiencing these errors to be rehospitalized within 3 months.³¹

In addition, over one-third of recommended outpatient workups scheduled after hospital discharge are not completed. Noncompletion is partially attributed to poor documentation on

discharge summaries.²⁴ From a review of medical charts and structured telephone interviews conducted with patients 3 weeks after discharge, Forster, et al.² concluded that between 15 and 23 percent of patients experienced an AE during the transition from the hospital to the ambulatory care setting. One-third of the AEs were preventable; one-third resulted in disability; and half were associated with use of additional health services. Overall, close to two-thirds of post-discharge AEs were preventable or ameliorable.^{2, 3} As Forster noted,³² “There is good reason to hope that the safety of the discharge process can be substantially improved.”

The five error types most often observed and reported by U.S. family physicians are:^{33, 34}

- Errors in prescribing medications.
- Errors in getting the right laboratory test done for the right patient at the right time.
- Filing system errors.
- Errors in dispensing medications.
- Errors in responding to abnormal laboratory test results.

Patients see multiple providers before, during, and after a hospital encounter, and communication among these providers tends to be inconsistent. The majority of PCPs do not receive patients’ discharge summaries in time for hospital followup visits,^{23, 35} and when they do, it may take as many as 7 days for a PCP to receive it by mail.³⁶ This glaring lack in communication results in difficulty in adequate monitoring of the recently discharged patient’s condition and/or test results.^{37, 38}

During this period of vulnerability, patients often have trouble getting in contact with a physician from the hospital, which they may need to do to discuss new symptoms, the side effects of medications, or deviations from the discharge plan. With the PCP unaware of the patient’s medical condition and hospital physicians unavailable, patients are left in clinical limbo during the precarious days immediately following a hospitalization.

Urgency for Interventions Related to Medication Errors

Nearly one in every five medication doses in American hospitals may be administered in error. The error rate is also high in long-term care centers and small hospitals.^{39, 40} Research suggests that 1.7 to 3.9 percent of patients’ emergency department (ED) visits result from problems with medications, 66 percent of which might have been prevented.^{41, 42}

Estimates of the number of deaths from medication use range from 7,000 to 140,000 yearly. Medication error rates depend on how these rates are measured. Lower rates are found when reporting is passive (e.g., based on incident reports) rather than active (e.g., based on observations).^{43, 44} Many more patients suffer from drug-related morbidity than mortality; the worst outcomes include permanent disability and life-threatening experiences.^{45, 46}

Medication errors also add to costs. The cost of treating an adverse drug event in a hospital averages \$3,244 to \$5,857 per case.^{47, 48, 49, 50}

Adverse Drug Events: Common, Serious, and Costly

Adverse drug events (ADEs) are the most common AEs that occur following hospital discharge.^{2, 3} Annual estimates of the proportion of outpatients experiencing ADEs range from 5 to 35 percent.^{51, 52} A survey of 661 patients found that 162 patients had a total of 181 ADEs. Of these, 13 percent were serious; 28 percent were ameliorable; and 11 percent were preventable. Nearly two-thirds of ameliorable events (63 percent) were attributable to the physician's failure to respond to medication-related symptoms; 37 percent were due to the patient's failure to inform the physician of the symptoms.⁵³

In another study, possible drug-related incidents occurring in the ambulatory clinical setting were assessed using multiple methods.⁵⁴ Of 1,523 ADEs identified in this study, 27.6 percent were considered preventable. Of these, 38 percent were categorized as serious, life-threatening, or fatal; 42.2 percent of these events were preventable. Human error associated with ADEs occurred most often (58.4 percent) at the stage of prescribing. Human error came into play in monitoring, which accounted for 60.8 percent of ADEs. Errors involving patient adherence were also common, accounting for 21 percent of ADEs.

Finally, ambulatory ADEs are costly. One study estimated the annual cost of ambulatory ADEs at over \$76.6 billion.⁴⁶

Developing the RED Toolbox

Re-Engineering the Hospital Discharge

With funds and encouragement from AHRQ's Safe Practices Implementation Challenge Grant Program (AHRQ grant HS-014289), we undertook an in-depth analysis and redesign of the current hospital-discharge process. After reviewing the literature, we used an iterative group process to produce a process map of the discharge.⁵⁵ We reviewed the map with senior administrators, physicians, residents, nurses, pharmacists, and ancillary staff, and revised it based on their feedback. The map was reality-tested by "sharp-end" providers (those closest to the patient directly involved with the discharge process) at weekly meetings of the working group and at nursing, social services, and case management staff meetings. It was modified based on feedback from Boston Medical Center (BMC) administration, BMC senior management, and Boston HealthNet medical and executive leadership (an integrated health service delivery network serving Boston area residents with limited ability to pay for medical care).

We began to investigate what worked, what did not, and how we could improve the discharge process. We identified and categorized potential failures, the likelihood of making a mistake, and potential consequences of the error. We then identified any processes that could help detect errors before they occurred and suggested an action plan for each potential failure that could cause significant consequences. We (representing most key stakeholders within the hospital) then gathered to redesign our discharge process.

Working in small groups, members were instructed to use the information from the research literature, knowledge from the above analyses, and their own creativity to develop a new

discharge process. Each of the groups then described their new map and the themes or principles thought to be important to the discharge process leading to the construction of the principal themes of the ReEngineered Discharge (Table 1). A full description of this process was published in the AHRQ publication, *Advances in Patient Safety: From Research to Implementation*.¹

Table 1. Principal themes of the ReEngineered Discharge (RED) process

1.	Delineation of roles and responsibilities must be explicit.
2.	Waiting until the discharge decision is made before beginning the discharge process can increase the risk of errors.
3.	Patient education must occur throughout the hospitalization, not just at the time of discharge.
4.	Information must flow reliably from the primary-care physician (PCP), to the hospital team, among hospital team members, and back to the PCP.
5.	Information to be included in the discharge résumé (summary) should be available when it is prepared. The discharge résumé must be completed before discharge and updated at the time of discharge. Waiting days or weeks leads to errors.
6.	Every discharge must have a written discharge plan that is comprehensive in scope and that addresses medications and other therapies, dietary and other lifestyle modifications, followup care, patient education and health literacy improvements, and instructions about what to do if the patient's condition changes.
7.	A comprehensive discharge plan must be completed for every patient before discharge, and a copy of the plan should be provided to the patient at discharge.
8.	All patients should have access to their discharge information written in their language and at their literacy level.
9.	Patients at risk for rehospitalization should have their discharge plan reinforced after discharge.
10.	All information about the patient's admission must be organized and promptly delivered to the PCP.
11.	Efficient and safe hospital discharges are significantly more challenging if case management staff members are available only during limited daytime hours.
12.	Discharge processes must be benchmarked, measured, and subjected to continuous quality improvement.

To learn more about the patients being rehospitalized in our community, we analyzed characteristics of patients admitted to the BMC HealthNet inpatient clinical service, which served as the source of study patients for Project RED. In this analysis, we learned that 22 percent of the admissions were followed by a rehospitalization within 90 days. These rehospitalizations were slightly concentrated toward the days immediately following discharge. Thirty-four percent of the rehospitalizations occurred within the first 2 weeks following discharge.

Looking at the day of the week of discharge, we found that discharge over a weekend was a powerful predictor for rehospitalization. Patients discharged on Friday, Saturday, or Sunday were 30 percent more likely to be rehospitalized or seen in the emergency department within 90 days than those discharged other days.

Qualitative Research of the Transition from the Hospital to the Ambulatory Setting

Another study examined the phenomenon of AEs from the perspective of discharged patients.⁵⁶ Twenty-one rehospitalized patients were assessed using semistructured, open-ended interviews during their hospital stay at BMC. The results showed that difficult life circumstances posed a greater barrier to recuperation than lack of medical knowledge. All participants were able to describe their medical condition, the reasons they were admitted to the hospital, and the discharge instructions they received. All patients knew the types of medications they were taking and the conditions for which the medications were prescribed.

The patients' recuperation was compromised by factors that undermined their ability to follow their doctors' recommendations, including support for medical and basic needs, substance use, and limitations in the availability of transportation to medical appointments. Distress, particularly depression, further contributed to poor health and undermined their ability to follow doctors' recommendations and the discharge plan.

Taken together, these results suggest that life circumstances outside the hospital are as critical to recovery as institutional coordination of medical care. Thus, interventions targeting low-income patients are more likely to succeed if they include social and medical support during the transition from hospital to home and if they ease the patient's burden of daily responsibilities.

Depression as a Risk Factor for Rehospitalization

We also conducted a study⁵⁷ that evaluated the utility of adding psychosocial information to more traditional measures to improve the ability to predict rehospitalization among high-risk patients with prior admissions. A logistic regression model that included prior admissions in the last year, comorbidity, physical functional status, and depression showed that depression tripled the odds of rehospitalization (OR 3.3; 95 percent CI 1.2 - 9.3). We concluded from this study that hospitalized patients with a recent hospitalization and a positive screen for depression are three times as likely to be rehospitalized within 90 days as those without depression.

National Quality Forum Endorsement of the RED

In 2006, the National Quality Forum (NQF) Consensus Standards Maintenance Committee was charged with the task of updating the *Safe Practices for Better Healthcare* developed in 2003.⁵⁸ The committee recognized the critical importance of the discharge as a significant patient transition and decided to expand the pre-existing focus on promoting accurate communication about treatment and procedures at discharge to a broader, more comprehensive approach to hospital discharge that would be evidence-based and patient-centered and would target existing systems failures.⁵⁹ The committee undertook a thorough evidence-based review of the domain, followed by consultation with a number of subject matter experts, including primary input from the "Re-Engineered Discharge" project at the Boston University School of Medicine. This Safe Practice largely parallels the components of the ReEngineered Discharge (Table 2). The complete NQF Safe Practice can be accessed at www.qualityforum.org.

Table 2. Operationalized components of the Re-Engineered Hospital Discharge

- 1. Educate the patient about his/her diagnoses throughout the hospital stay.**
 - 2. Make appointments for clinician followup and post-discharge testing.**
 - Make appointments with input from the patient regarding the best time and date of the appointment.
 - Coordinate appointments with physicians, testing, and other services.
 - Discuss reason for and importance of physician appointments.
 - Confirm that the patient knows where to go and has a plan about how to get to the appointment; review transportation options and other barriers to keeping these appointments.
 - 3. Discuss with the patient any tests or studies that have been completed in the hospital and discuss who will be responsible for following up the results.**
 - 4. Organize post-discharge services.**
 - Be the sure patient understands the importance of such services.
 - Make appointments that the patient can keep.
 - Discuss the details about how to receive each service.
 - 5. Confirm the medication plan.**
 - Reconcile the discharge medication regimen with those taken before the hospitalization.
 - Explain what medications to take, emphasizing any changes in the regimen.
 - Review each medication's purpose, how to take each medication correctly, and important side effects to watch out for.
 - Be sure patient has a realistic plan about how to get the medications.
 - 6. Reconcile the discharge plan with national guidelines and critical pathways.**
 - 7. Review the appropriate steps for what to do if a problem arises.**
 - Instruct on a specific plan of how to contact the PCP (or coverage) by providing contact numbers for evenings and weekends.
 - Instruct on what constitutes an emergency and what to do in cases of emergency.
 - 8. Expedited transmission of the Discharge Resume (summary) to the physicians (and other services, such as the visiting nurses) accepting responsibility for the patient's care after discharge that includes:**
 - Reason for hospitalization with specific principal diagnosis.
 - Significant findings. When creating this document, the original source documents (e.g., laboratory, radiology, operative reports, and medication administration records) should be in the transcriber's immediate possession and be visible when it is necessary to transcribe information from one document to another.
 - Procedures performed and care, treatment, and services provided to the patient.
 - The patient's condition at discharge.
 - A comprehensive and reconciled medication list (including allergies).
 - A list of acute medical issues, tests, and studies for which confirmed results are pending at the time of discharge and require followup.
 - Information regarding input from consultative services, including rehabilitation therapy.
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Table 2. Operationalized components of the Re-Engineered Hospital Discharge

- 9. Assess the patients' degree of understanding by asking them to explain the details of the plan in their own words.**
- May require removal of language and literacy barriers by utilizing professional interpreters.
 - May require contacting family members, who may share in caregiving responsibilities.
- 10. Give the patient a written discharge plan at the time of discharge that contains the following:**
- Reason for hospitalization.
 - Discharge medications, including which medications to take, how to take them, and how to obtain them.
 - Instructions on what to do if their condition changes.
 - Coordination and planning for followup appointments that the patient can keep.
 - Coordination and planning for followup tests and studies, for which confirmed results are not available at the time of discharge.
- 11. Telephone re-enforcement of the discharge plan and problem solving 2 to 3 days after discharge.**
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The committee undertook a harmonization approach in order to synchronize the practices across the pertinent requirements or initiatives of the Joint Commission, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Leapfrog Group, and the Institute for Healthcare Improvement. This harmonization effort was termed “the 4Cs” across each of these organizations, including:

- A cross-walk of requirements.
- Cross-language or synchronized descriptions where possible.
- Cross-credit opportunities.
- Cross-communication of common performance targets.

This set of processes was intended to establish the new discharge practice as a clear roadmap for hospitals to satisfy a common set of requirements of major purchasing, accrediting, and quality organizations. In the summer of 2006, the RED project was presented to the national health care community for review and input for revisions. Substantial input from providers and purchasers was received, and a round of revisions ensued.

In October 2006, the national members of the NQF voted to endorse the new practice as a national standard.⁵⁸ The stated objective of the practice is “to ensure that effective transfer of clinical information to the patient and ambulatory clinical providers occurs at the time of discharge from the health care organization.” Our current proposal is designed to meet this objective. A manuscript describing the development of the RED and the NQF Safe practice was published in conjunction with the publication of the NQF’s new Safe Practices.⁶⁰

The RED Toolbox

Using resources funded by AHRQ, the research team at BMC operationalized the RED-based NQF Safe Practice and created tools to allow for a safer discharge. Three tools were created: a training manual for discharge nurses to provide a regulated “checklist” for each component of the RED; an individualized, patient-friendly “After-Hospital Care Plan” (AHCP) written at the patient’s appropriate literacy level; and a workstation to integrate all pertinent discharge information and to generate the AHCP.

Training Manual

We have prepared a 30-page training manual and workbook for health care professionals that describes in detail how to deliver a safe and effective hospital discharge, including the following points:

- Instructions and information pertaining to the best ways in which to contact the team providing care for the patient.
- The various components of the RED. For each of the components, the manual contains a detailed script describing how to collect the necessary information.
- Prompts for providers to reconcile the discharge plan with any existing national guidelines for the patient’s diagnosis and general scripts for discussing the diagnosis with the patient.
- Instructions for determining the best time to schedule an appointment through consultation with the patient.
- Prompts to ascertain that the patient has transportation to all appointments, as well as instructions on telling the patient what to do if an appointment needs to be changed.
- Encouragement to the provider to include a photograph of the primary care physician and a map describing locations of appointments in the AHCP, in order to further facilitate the patient’s likelihood of attendance at appointments.
- Encouragement to providers to obtain a list of the patient’s medications that has been reconciled by the hospital team and updated in the patient’s electronic medical record. The reconciled medication list is then included in the AHCP.
- Scripts for discussing the medications with the patient, ensuring that he/she understands how to take them and has a plan to obtain them from the pharmacy.
- Detailed dialogues for each step of the discharge process.

After Hospital Care Plan

One principle of the RED and of the NQF Safe Practice is that all patients should leave the hospital with a discharge plan. We call our discharge plan the “After Hospital Care Plan” because, in the course of our work, we realized that some patients are confused by the word “discharge.”

The AHCP is a spiral-bound, color booklet designed to clearly present the information needed by patients to prepare them for the days between discharge and their first visit with their ambulatory care physician. We worked with consultants from the Rhode Island School of Design to help us with the graphic design. The AHCP is presented in an easily understood chart format. It lists upcoming appointments and tests; provides a color-coded calendar of upcoming appointments,

and includes prompts and questions to help the patient prepare for his/her upcoming appointment (patient activation).

Each AHCP is individualized, including the patient's name, contact information for his/her primary care physician, a color-coded medication schedule tailored to the patient's medication regimen, and an illustrated informational page describing the discharge diagnosis. The information included in the booklet is presented and organized in a manner designed to be accessible to individuals of all literacy levels.

Computerized Workstation to Print the AHCP

Creation of the AHCP is now automated by means of a Discharge Planning Workstation, a dedicated computer workstation. The workstation is the nexus of all information regarding patient discharge and discharge followup. It is a stand-alone tool where the nurse responsible for the discharge (the "discharge advocate") enters the key data into a database. Once this information is entered, the workstation automatically creates a draft AHCP. The discharge nurse then reviews and refines this plan, if necessary. Following this, the discharge nurse prints out the draft discharge plan and takes it to the physician for review and sign-off.

Once the discharge plan has been finalized, it is "published" and a spiral binding is added at the workstation. The discharge advocate then teaches the information it contains to the patient at his/her bedside. One objective over the next year is to integrate the workstation into the hospital's electronic health record (EHR) system (Centricity-Logician™ at Boston Medical Center), exporting the information to the patient's ambulatory EHR and emailing it to the patient's PCP.

Testing the RED

The RED is currently being tested in a two-arm, randomized, controlled trial (ClinicalTrials.gov Identifier: NCT00252057) among hospitalized patients admitted to the general medical service of BMC. This study is taking place on a portion of the inpatient general medicine service at BMC. This service is composed of four teams of residents each plus a teaching-attending physician.

After obtaining informed consent, subjects are randomized to those receiving standard discharge (control group) and an experimental group that receives the components of the RED by a trained discharge advocate. As part of the RED, the discharge is reinforced via a telephone call from a pharmacist with access to the AHCP 2 to 5 days post-discharge. In this report, we provide preliminary information about the first 571 subjects enrolled in this trial (289 intervention subjects and 282 controls).

Participants and Randomization

The study population is 52 percent female, mean ($\pm$ SD) age of 49 ($\pm$ 14); 52 percent African American; 15 percent private insurance; 64 percent high school graduate or less; and 56 percent limited in health literacy (as measured by the REALM score). The distribution of baseline variables (i.e., sex, age, race, education, income, insurance, employment, having a primary care

provider, homeless at any time in the past 3 months, hospital admission in the previous 6 months, Short Form-12 Health Survey, REALM score) is equally divided between the two study arms, suggesting successful randomization. Of the subjects enrolled, 87 percent have been reached for the data collection telephone call at 30 days post-discharge.

The Time It Takes to Administer the RED

An important barrier to providing the RED intervention (at least in our teaching hospital, where residents care for inpatients and are responsible for discharges) is that our discharge advocate needs to coordinate the discharge plan with the resident team. In our experience, residents consider hospital discharge a lower priority than other activities. On average, it requires 3.9 attempts by our Discharge Advocate to contact the resident team on the day of discharge to discuss the discharge plan, reconcile medications, etc. Most patients require three attempts. Excluding the time spent in contacting the resident team and producing the “AHCP,” the Discharge Advocate spends an average of 51.9 minutes in face-to-face time with each patient (median, 45 minutes; range, 15-185 minutes).

Effectiveness of the Delivery of the RED

The AHCP has been given to 89 percent (N = 257) of intervention subjects. Subjects not given an AHCP either left the hospital against medical advice, left at a time that no discharge advocate was available, or were transferred to another hospital service.

Of the subjects receiving the AHCP booklet, 58 percent received a RED medication schedule, 88 percent received a physician appointment schedule, 91 percent received an appointment calendar, and 82 percent received a diagnosis education sheet. Pending hospital tests at discharge and tests to be completed post-discharge are also listed in the AHCP.

Completion of RED Intervention Components

The RED intervention has been successful in completing the specified components of the RED (Table 3) and identifying barriers to completion of these components. Among the 289 intervention subjects, 96 percent (N = 276) were discharged from the hospital with a primary-care appointment, most within 3 weeks after discharge. For 97 percent of the PCP appointments made, the subject’s discharge plan was sent to the PCP prior to their followup appointment. This discharge plan included both the hospital discharge summary and the RED AHCP, if available. Of the intervention subjects, 90 percent (N = 261) were discharged with at least one medication; RED discharge advocates were able to reconcile medication lists with the hospital team for 57 percent (N = 148) of these subjects. For those patients whose medications could not be reconciled by the discharge advocate, the hospital team was asked to complete the medication list prior to discharge and print a copy for the subject.

Table 3. Successful completion of RED intervention components

RED component	Intervention Group [N (%)]
Appointments and tests scheduled	
PCP appointment scheduled (N = 289)	276 (96)
Discharge plan sent to PCP (N = 276)	268 (97)
Medication plan	
Patient has medications at discharge (N = 289)	261 (90)
Medications reconciled with hospital team (N = 261)	148 (57)
After Hospital Care Plan (AHCP)	
AHCP given to patient (N = 289)	257 (89)
Patients with AHCP items included	
Appointment schedule (N = 257)	226 (88)
Appointment calendar (N = 257)	233 (91)
Diagnosis Education Sheet (N = 257)	211 (82)
Patients with AHCP and medications	
RED medication schedule (N = 237)	138 (58)
Electronic medical record med schedule (N = 237)	120 (51)

Barriers to Implementing the RED

Our experience to date has helped identify key barriers to implementing comprehensive discharge programs for hospitalized patients. These barriers include:

- It is not clear who is responsible for all elements of the discharge transition, such as completing the patient preparation and education and communicating with the source of ongoing outpatient care.
- The discharge process receives low priority in the work schedule of inpatient clinicians, leaving little time to create a coordinated, patient-centered, and comprehensive discharge plan.
- The medication plan is regularly changed late in the hospitalization, if not right at discharge. This leaves patients underprepared to address any learning, access, or support issues that the changes may engender (e.g., self-administration of insulin or low molecular-weight heparins, or post-hospitalization monitoring-associated logistics of patients initiated on warfarin).
- The financial pressure to fill beds as soon as they are empty works as a disincentive to give nurses and doctors the time needed to create and teach a complete discharge plan.

- Medication reconciliation with the ambulatory electronic health record is often not done, even when it is required of residents and when our discharge research staff “hound” residents to do it.
- Discharge is relegated to the least experienced members of the team, who are most likely to make medical errors and/or not appreciate the most important elements to include in discharge communications, with plans often not reviewed by attending physicians for days or weeks after discharge.
- Discharges occur around the clock but especially in the late afternoon and evening, when optimal staffing often is not available.

Conclusion

A comprehensive discharge, as endorsed by the National Quality Forum Safe Practice Number 11, can be successfully implemented using the RED AHCP tool. However, about 1 hour of nursing time is needed to create and teach the discharge plan. There is consensus that the RED provides a “checklist” of key processes that should be completed on every patient at the time of discharge. However, in implementing this under a research protocol, it is clear that there are many barriers to a comprehensive discharge inherent in the procedures, processes, and priorities of hospital systems. We are now completing a randomized, controlled trial of the RED compared with usual care. Finally, we are now working on new health information technology systems designed to provide the RED and minimize nursing time.

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Creating an Accurate Medication List in the Outpatient Setting Through a Patient-Centered Approach

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Abstract

Objective: The objective of this project was to evaluate the efficacy of patient-centered strategies implemented in a community-based setting to improve the accuracy of the medication list in the outpatient setting. **Methods:** We conducted a quasi-experimental trial using two waves of cross-sectional data from patients aged 55 years or older conducted in five Aurora Health Care clinics in Walworth County, WI. Interventions included education, personal medication lists, and medication bags. The primary outcome measure was the rate of accurate medication lists in the intervention clinics compared with a group of 68 control clinics. **Results:** After disseminating over 16,600 medication lists and 7,800 medication bags at over 80 educational programs, the rate of accurate medication lists significantly increased from 55 percent to 72 percent ($P < 0.001$). This increase was significantly better than changes seen in the comparison group ($P < 0.001$). **Conclusion:** A community-based initiative providing tools and resources for patient engagement can improve the accuracy of the outpatient medication list.

Introduction

As the rate of drug use continues to grow among Americans, medication safety has become a major concern for both patients and providers. Over 60 percent of U.S. adults aged 65 or older take at least five different medications per week in the ambulatory setting, with 15 percent taking at least 10.¹ Although medication regimens requiring multiple drugs may be clinically appropriate, proper medication management by providers and patients is essential to prevent errors and adverse drug events (ADEs). The reported rate of medication errors and ADEs varies widely, depending on the care setting and the methods used to measure them, with growing evidence that errors and ADEs are common in the ambulatory setting.^{2, 3} The older adult population is at particularly high risk; individuals 65 years and older were shown to be 2.4 times as likely to sustain an ADE and 7 times as likely to be hospitalized as younger patients.⁴

Improving medication safety requires participation of, and interventions for, both providers and patients. A key strategy recommended by national and international patient safety experts is to engage patients in the medication process through a collaborative relationship with their provider.^{5, 6, 7} Providers can promote this relationship by providing patient-centered care that includes effective communication; accurate, accessible information and education; and patient self-care strategies. Research shows that patient-centered care can enhance outcomes of care,

patient adherence to medication regimens, chronic disease outcomes, and patient satisfaction.^{6, 8, 9, 10} Engaged, active patients who are given tools and support for self-management of their medications are associated with better health outcomes.⁶

The process recommended for providers to help prevent medication errors is called “medication reconciliation.”⁶ The first step in medication reconciliation is verification—i.e., obtaining a complete, accurate list of the medications a patient is taking and comparing this to the list documented in the medical record. The few studies conducted in the outpatient setting have identified significant discrepancies in the medication list (defined as inconsistency or lack of agreement between the provider medication list and what the patient is taking, based on comparison between the medical record and the patient’s medication list and/or medication bottles).^{11, 12, 13} An inaccurate medication list can lead to significant adverse events.¹³

Both patient-centered care and medication reconciliation are strongly recommended, but few studies have described how to achieve these goals in the outpatient setting and what their impact is on creating an accurate medication list. The aim of this project was to develop and implement patient-centered strategies to improve medication list accuracy.

A community-based advisory council was established to assist in identifying relevant strategies for patients. Through a collaborative process involving patients, providers, and community members, medication safety tools were created and disseminated throughout the community. The primary interventions focused on patient medication self-management tools. Secondary interventions addressed the redesign of the medication process for providers in the outpatient setting.

This study evaluated the effectiveness of these interventions by measuring the rate of accuracy in the medication lists in the medical records of outpatient clinics over a 2-year period, compared with a control group of clinics. Additional qualitative measures included patient, provider, and community surveys.

Methods

Study Setting, Patient Population

This project was conducted from July 2005 through June 2007 in five Aurora Health Care outpatient clinics in Walworth County, WI. Aurora Health Care is a large, integrated health care system that includes 13 hospitals, over 75 clinics, 120 retail pharmacies, and a visiting nurse program. The physician staff includes approximately 650 employed and over 3,000 affiliated physicians. At the five intervention clinics in Walworth County, the targeted patients were those aged 55 years and older who were seen by any of the 23 Aurora primary care providers (two internal medicine, 18 family practice, and three obstetrics/gynecology). Efforts to engage older adults throughout Walworth County were part of the community-wide campaign. The comparison group included 68 other Aurora Health Care clinics located throughout southeastern Wisconsin. At the comparison clinics, data were collected from patients seen by any of 363 primary care providers, including 136 internal medicine, 171 family practice, and 56 obstetrics/gynecology physicians.

Support for the project was received from two partners, Consumers Advancing Patient Safety (CAPS) and Midwest Airlines.¹⁴ CAPS assisted in the development and facilitation of the council, and Midwest Airlines provided expertise in consumer engagement and marketing.

This project was reviewed and approved by the Research Subject Protection Program, the Institutional Review Board affiliated with Aurora Health Care.

Definitions

An “accurate clinic medication list” was defined as follows: the clinic’s chart medication list contained the same list of prescription medications as the patient’s list (or bag of prescription medications); i.e., none were missing from the clinic list nor were there medications listed that the patient was not taking. For this study, the outcome measure was to have the same medications documented on both the clinic list and the patient list. Dose, frequency, and route of medication administration were not evaluated in the measurement. The definition and measurement activities used in this study were based on a previously reported methodology.¹⁵

Interventions

The interventions consisted of multiple components intended to encourage and facilitate patients and providers to collaborate in the medication reconciliation process. First, the project team established a Patient Advisory Council as a structure through which providers could “partner” with their patients and the community. The Walworth County Patient Safety Council was established in November 2005. The methods used to establish the patient advisory council and develop the interventions have been described previously.¹⁶ To identify specific intervention strategies, the Council and project team conducted patient and provider focus groups, surveys, and interviews. This formative research identified the need for patient education and tools that would facilitate communication between patients and their providers and foster the patients’ self-management of their medications. For providers, interventions were directed at the assessment and redesign of the clinic workflow during the medication reconciliation process.

Patient-directed interventions. The patient-directed interventions developed by the Council included a personal medication list (paper-based) and an insulated bag for transporting medications to their provider visits. In addition, the medication lists and bags were distributed to patients and community members through a variety of venues: clinics, retail pharmacies, hospitals, health fairs, and community organizations. Patients received education and training on medication safety and the importance of communication with providers, as well as instructions on how to complete the medication list and use the bags. Council members and the project team provided the education and training in various settings.

Provider interventions. The provider interventions included education on medication reconciliation and patient engagement, an analysis of clinic workflow during the medication reconciliation process, and identification of “best practice processes” that were most efficient and effective toward achieving an accurate medication list.

Data Collection Method

The rate of accurate medication lists in the five intervention clinics was the outcome measure used to evaluate the impact of the interventions. Accuracy of the chart medication list was measured during two data collection periods, baseline and post-intervention. Targeted patients included all those aged 55 and older who were scheduled for a visit with a primary care provider during the data collection periods.

A member of the clinic staff contacted patients prior to their appointment and asked them to bring a list of their prescription medications (or the medications themselves) with them to their appointments. At the appointment time, the nurse (or medical assistant) interviewed the patient and compared the personal medication list (or the actual medications) the patient brought to what was documented in the clinic chart medication list. (The medication lists in all five intervention clinics were paper-based; none of these clinics had an electronic medical record at the time of the study. In the comparison group clinics, the medication list was either paper-based or electronic, depending on whether they had an electronic medical record.) If the patient forgot to bring their medication list or their medications, the patient was asked to recall the prescription medications they were taking.

The staff completed a data collection tool, which included patient age; sex; whether the patient was taking prescription medications; whether the patient brought a medication list and/or their actual medications or neither to the clinic; and whether the patient used supplements, herbals and/or over-the-counter medications. Although the procedure of reviewing medications at the time of a visit with their primary care provider was routine in Aurora clinics, the documentation of noted discrepancies between the patient list and the clinic chart medication list was only done during this measurement period. The data were scanned into a centralized database.

Qualitative data included patient focus groups, patient interviews and surveys, provider interviews and survey, and a community telephone survey. During the initial formative research, between August 2005 and June 2006, two patient focus groups of randomly selected Aurora Health Care patients from the five intervention clinics and individual patient and provider interviews were conducted.¹⁶ Post-intervention data included a survey of all patients aged 55 and older from the five intervention clinics. A provider survey was sent to physicians, nurses, medical assistants, and retail pharmacists from the five intervention clinics and the four Aurora retail pharmacies in Walworth County. In addition, a community telephone survey measured the project's penetration beyond the intended target group of Aurora patients. The sampling frame of this survey included adults aged 55 or older and residents of Walworth County who had not been Aurora patients within the previous year. All surveys and focus groups were developed and conducted by the project team, assisted by Aurora staff and external agencies with expertise in qualitative research.

The study was designed as a quasi-experimental, prospective, longitudinal trial using cross-sectional data for each measurement point. Individual patients were not linked across waves of data collection. Since a limited set of clinics in a specific county were targeted, a larger sample of comparison sites was used to establish reliable rates for comparison.

Data were collected during two 4-week periods: pre-intervention (baseline) in September 2005, and post-intervention in March 2007. Eligible patients included those aged 55 or older who were

taking prescription medications and were scheduled for a visit with a primary care provider during one of the data collection periods. Patients were sampled within ambulatory care clinics when being seen by primary care providers. In order to reduce staff and respondent burden, sampling from among eligible patients was done at random. Clinic staff (nurses and medical assistants) reviewed patients' personal medication lists and their clinic medical records and invited every other eligible patient to participate. In the intervention clinics, the clinic staff reviewed approximately 60 charts per primary care provider. In comparison clinics, sampling continued until 10 charts for each primary care provider had been reviewed.

Reported results include a descriptive analysis, based on the patient as the unit of analysis, and a final outcome analysis, using a hierarchical model in which patients were clustered within clinics, with the clinic serving as the primary unit of analysis. These models took into account the similarities of people within the clinic—the intraclass correlation. In these models, covariates measured on the patient level (age, sex, and physician specialty) were incorporated as adjustment variables. Condition—intervention site or comparison group—was assigned and measured on the clinic level. Although individual physicians might have had highly variable practice styles within a specific clinic, “physician” was not the unit of analysis, since the number of charts reviewed per physician was too low for reliable statistical modeling, and participation in the intervention was based on the clinic, not the individual physician.

Data were scanned to a Microsoft ACCESS[®] data set. Patients were excluded if they were not taking prescription medications by self-report (even if medications were listed on the clinic record) or if no medication record could be found in the patient's chart. Cases were also excluded if data necessary for the primary outcome measures were missing from the data collection tools. All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS[®], version 15.01). For statistical tests, a 2-tailed test was used with the rejection region set to $P = 0.05$.

Results

The Walworth County Patient Safety Council was established in November 2005. The Council consisted of 11 patients (55 years and older) and 12 health care providers (four physicians, three clinic nurses, one parish nurse, one retail pharmacist, and three community health services professionals). The Council met on a monthly basis from November 2005 through June 2007 for a total of 17 meetings (excepting 3 months due to holiday and summer schedules). The mean attendance rate was 85 percent; evaluations completed by all members after each meeting showed an approval rating of 4.5 on a 5-point scale (5 = excellent).

Formative research conducted early in the project identified barriers and opportunities for improving the medication management process for both patients and providers. Two patient focus groups (with 22 participants combined), 21 individual patient interviews, and 21 provider interviews were completed. As previously reported,¹⁶ patients identified the challenge of effective communication with their health care providers as a barrier, as evidenced by comments such as, “I am timid about asking questions of my doctor;” and “We are speaking different languages.” Some patients were not using any medication self-management tools, as rationalized by one interviewee, who stated, “I don't keep a medication list; my doctor knows what I take.” In

the health care provider interviews, limited time was consistently identified as a major barrier to conducting a complete medication review during an office visit. In addition, providers often complained that patients did not maintain medication lists.

Two tools were created by the Patient Safety Council to improve communication between patients and their provider regarding medications—a personal medication list and a medication bag. The logo “Partners in Safety” was created and selected by the Council with community input and printed on both the tools for easy identification.

The Partners in Safety medication list was sent by U.S. mail to every patient aged 55 or older who was seen in any of the five Aurora clinics in Walworth County within the year ending August 2006. The Partners in Safety lists and bags were also distributed to patients by staff (physicians, nurses, medical assistants, and pharmacists) at the five clinics and through the four Aurora retail pharmacies. Formal presentations on medication safety and instructions on use of the lists and/or bags were given at over 80 community education programs, which drew over 2,300 participants.

Based on the Council’s recommendation, broader dissemination of the medication lists was initiated after the first 3 months of distribution. The Council members, through their links with community-based organizations and social groups, provided access to the community through organizations, such as the Kiwanis, Rotary, and Lions clubs; senior centers; health fairs; churches; and personal social gatherings. Using the PPECA (Partnering for Patient Empowerment through Community Awareness) model,¹⁷ two educational programs were provided at a Walworth County public library. Every member of the Council played an active role in the dissemination and education, with the top three distributors of the tools being the project coordinator, one of the patient representatives on the Council, and a parish nurse. Between August 2006 and June 2007, more than 16,600 Partners in Safety medication lists and 7,800 Partners in Safety medication bags were disseminated to patients and the community in Walworth County.

To address the provider issues in the clinics, a workgroup was created with representatives from each of the five clinics. Patient representatives from the Council participated at the eight meetings held between April 2006 through June 2007. At these meetings, the project team leaders provided education on medication safety, medication reconciliation, and patient-centered care. Barriers and opportunities for improving the medication review process were addressed.

Weekly communication between the project coordinator and staff at the individual clinics provided assistance and support. Physician education and engagement was promoted by the physician project leader through a variety of means, including presentations at physician leadership and management meetings, individual physician discussions, and workshops led by content experts. Additional Aurora staff, trained in conducting work flow analysis, were brought into each of the clinics to evaluate processes used during medication reconciliation that might be most efficient and effective for obtaining an accurate medication list.

“Best practices” identified by the evaluators included reminding patients (via reminder letters or telephone calls) in advance of their appointment to bring in their medication list or bag. This encouraged and enforced the message of patient ownership of their medication list. Those

physicians who had their assisting staff (nurse or medical assistant) verify the patients' medication lists prior to the actual physician encounter had more accurate lists, allowing the physicians time to reconcile the medication lists. Real-time physician documentation in the charts of these reconciled medications (i.e., immediately after the patient encounter) was critical for maintaining accuracy beyond that visit. These findings were shared with staff and physicians, with strong recommendations to incorporate these techniques into their practices.

To evaluate the impact of these interventions, the rate of accurate medication lists in the five intervention sites was measured and compared to the 68 other (control, nonintervention) Aurora clinics. Of the 6,242 charts reviewed at all Aurora clinics during the baseline and post-intervention periods, 845 were ineligible based on the exclusion criteria (exclusion rates were similar in both groups and both data collection periods).

Table 1 summarizes the characteristics of the eligible patients interviewed in the intervention and comparison (control) groups for both baseline and post-intervention periods. The differences between the intervention and control groups on age and physician specialty were statistically significant. The intervention sites served a significantly older population and had a significantly higher percent of visits to family practice physicians compared to the control sites. These variables were subsequently used as adjustment variables in the hierarchic models.

Table 1. Patient characteristics for intervention vs. comparison clinics: Baseline vs. post-intervention periods

Characteristics	Intervention clinics			Comparison clinics			P-value ^b
	Baseline (N = 596)	Post (N = 594)	P ^a	Baseline (N = 2,154)	Post (N = 2,053)	P-value ^a	
Number of clinics	5	5	na	67	68	na	na
Mean participants per clinic	119	119	na	32	29	na	na
Mean participant age (yrs) (±SD)	73.1 (9.8)	72.0 (10.5)	0.07	70.6 (9.9)	69.5 (10.0)	<0.001	<0.001 ^c <0.001 ^d
Females (%)	65	59	0.074	64	63	0.412	0.801 ^c 0.139 ^d
Patients seen by FP physician	74	80	0.022	46	47	.453	<0.001 ^c <0.001 ^d

a Within-group change.

b Intervention clinics vs. comparison clinics; difference between baseline^c and post-intervention^d periods.

na = not applicable

FP = Family practice

Table 2 summarizes the rate of accurate medication lists measured in the intervention and comparison clinics at baseline and post-intervention. The aggregate rate of accurate medication lists in the five intervention clinics at baseline was 55 percent. The baseline rate of accurate medication lists in the comparison group was 63 percent, which was significantly higher

compared to the five intervention sites ($P < 0.001$, Fisher's exact test). The post-intervention rate of accurate medication lists was 72 percent in the intervention sites, a 17 percent improvement from the baseline rate. In the comparison group, the rate of accurate medication lists was 56 percent at post-intervention (significantly lower than their baseline rate, $P < 0.001$). This rate was also significantly lower than what the intervention sites achieved compared to the baseline period ($P < 0.001$). Thus, when the project started, the intervention sites began with a significantly lower medication list accuracy rate than the comparison group; by the post-intervention period, the intervention clinics had improved and surpassed the rate in the comparison clinics.

Table 2. Rate of accurate medication lists at baseline and post-intervention, by patient as unit of analysis

Sites	Baseline	Post-intervention	P-value ^a
Intervention clinics, [no./total (%)]	328/596 (55)	429/594 (72)	<0.001
Comparison (control) clinics [no./total (%)]	1,366/2,154 (63)	1,142/2,053 (56)	<0.001
P-value ^b	<0.001	<0.001	—

a Within-groups difference.

b Baseline vs. post-intervention.

The results of the more conservative, mixed-model hierarchical linear analysis are summarized in Table 3. In this analysis, both the patient level and the clinic level data are used to adjust for between-group differences and to account for the intraclass correlation of individuals within clinics.

Since the same individuals were not measured at both time points, this model used only data collected in 2007. The baseline accuracy rate was significantly less for the intervention clinics than for the comparison clinics.

The mixed model results show a 15 percent difference in accuracy between the intervention and comparison sites, after adjusting for the covariates in the model. The higher rate of medication list accuracy for those patients seen in the intervention sites relative to the comparison sites was significant at $P = 0.034$.

Table 3. Estimated marginal means for rate of accurate medication list (post-intervention results)^a

Type of clinic	Estimated mean (%)	Standard error
Intervention	69.9	6.5
Comparison (control)	54.9	2.2

a Based on mixed-model (hierarchical) regression. Marginal means estimated for clinic as unit of analysis with patient nested within, adjusting for individual patient level age, sex, and family medicine specialist as provider. The difference between conditions was significant at $P = 0.034$.

Patients' rate of personal medication list and bag utilization, measured at both the intervention and comparison sites, is summarized in Table 4. The use of any personal medication list increased significantly in the intervention sites, from 51 percent at baseline to 61 percent post-intervention ($P < 0.001$). Those bringing in their medicines (i.e., use of a medication bag)

decreased in the intervention clinics from a baseline rate of 41 percent to a post-intervention rate of 25 percent ($P < 0.001$). In the comparison group, there was no significant change in the rate of utilizing personal medication lists (49 percent at both data collection periods), but the rate of medications brought into the clinics did increase (from 28 percent to 35 percent, $P < 0.001$). Comparing the intervention sites to the comparison sites, there was a greater rate of personal medication lists in the post-intervention period. (61 percent in the intervention sites, 49 percent in the comparison group, $P < 0.001$). There was no difference in whether patients brought neither a medication list nor their actual medications from baseline to post-intervention, 23 percent vs. 24 percent, respectively).

Use of the project-specific “Partners in Safety” medication list (measured only in the intervention clinics during the post-intervention period) was 31 percent (Table 4). At the intervention clinics, 13 percent of patients brought in the “Partners in Safety” medication bag, and 7 percent brought in both their medication list and a medication bag. Thus, in total, about half the patients at the intervention clinics, who brought in a medication list or bag of medications, used the project-specific materials.

The post-intervention surveys conducted among patients, providers, and the community supported the quantitative results. Of the 7,724 surveys mailed in May 2007, to Aurora patients aged 55 and older 6 months after they were sent the medication list, 1,577 completed and returned the forms (response rate, 20.4 percent). Seventy-six percent of the respondents had documented their medications on the list, and 73 percent had brought this list to their physician appointments; 69 percent felt the personal medication list made it easier to talk with their provider about their medications. Only 23

percent used the medication bag to transport medicines to their clinic visits. Comments from surveyed patients included “The list is a very good idea. Although I had prepared a list for my 91-year-old mother, I had not thought of doing one for myself.” “Having the list of medicines helps me remember to take information to my doctor’s appointment... so I can discuss it with my

Table 4. Rate (%) of patient use of personal medication lists and bags during baseline and post-intervention periods

	Clinic type			
	Intervention (N = 586)		Comparison (N = 2,040)	
	Pre	Post	Pre	Post
Brought personal medication list	51 ^b	61 ^{b, c}	49	49 ^c
Brought medications	41 ^b	25 ^b	28 ^d	35 ^d
Brought neither	18	24	28	23
Brought both ^a	10	10	4	7
Intervention clinics only				
Used “Partners in Safety” medication list	31			
Used “Partners in Safety” medication bag	13			
Used both project materials ^a	7			
Used neither of the project materials	49			

Percentages also included in entries above for use of lists and bringing medications.

$P < 0.001$ Pre- vs. post-intervention.

$P < 0.001$ Post-intervention, intervention vs. comparison groups.

$P < 0.001$ Pre- vs. post-intervention

doctor.” “Being visually impaired, the bag helps me keep my medications in one place and allows me to take it easily when I go visit my family.”

In April 2007, the provider survey was sent to 92 providers—including physicians, nurses, and retail pharmacy staff in Walworth County—through the Aurora e-mail system. Fifty-two providers completed the survey, for a response rate of 57 percent. Of those responding, 85 percent (44/52) agreed or strongly agreed that medication list on file was more accurate because of the personal medication list; only 54 percent (28/52) felt the medication bag improved accuracy. Although 96 percent of respondents (50/52) agreed or strongly agreed that the list facilitated communication, 12 percent felt the bag did not improve communication.

Comments from the providers regarding the project included “I think patients are more aware of how this is a partnership tool for their health.” “It has increased awareness with the patients of the importance of sharing all their meds with all their physicians and pharmacists.” “This project caused patients and health care providers to examine medication administration and its effects on patient health and safety.” “[This was] a collaborative effort that empowers patients to inspire providers to achieve best practice standards.”

In April 2007, 60 Walworth County residents participated in a telephone survey to measure the penetration of the project into the community beyond those members who were patients in the Aurora system. Of these 60 community members, 13.3 percent (8/60) had received a “Partners in Safety” medication list, while 5 percent (3/60) had been given a medication bag. Applying the response rate of 13 percent to the approximately 10,000 Walworth County residents aged 55 years or older who were not Aurora patients,¹⁸ up to 2,600 community members might have been affected by this project.

Discussion

Through a collaborative process involving patients and providers, interventions were developed and implemented at the community level to engage patients in the medication process and foster patient-centered care among ambulatory care providers. By using tools—including personal medication lists, bags, and education—to facilitate patient medication self-management, the rate of accurate medication lists improved by 17 percent in five outpatient clinics. As evidenced by the rate of patient use of a medication list and by providers’ perception of what improves the accuracy of their chart list, the personal medication list was the preferred self-management tool by both patients and providers. Although the use of a medication list in the intervention clinics increased, patients bringing in their actual medications declined. Perhaps the preference of providers for the medication list influenced which tool their patients utilized. Overall, the increased rate of accuracy in the intervention clinic charts, in contrast to the decline in the comparison group clinics, suggests that the aggregate impact of the various interventions contributed to the observed improvement.

This project identified the need to address both patient and provider issues, as well as the importance of community involvement, which is consistent with national and international recommendations.^{6, 7} Patients need to understand the inherent risks related to the complexity of the medication process, but they also need tools to facilitate greater self-management. Education

and training for patients are needed in easily accessible and culturally acceptable formats. Trained community leaders can bring the message and education about medication self-management to older adults in a familiar setting using community-based organizations and social networks.

Our findings are consistent with previous research, which found that the more effective interventions for improving medication adherence included a variety of components.¹⁹ Personal medication lists were utilized at a greater rate and were preferred over the medication bags, but a variety of self-management tools are needed to meet individual patients needs (e.g., visual impairment). The Walworth County Patient Safety Council did not pursue technologic interventions, in part due to costs, but also in recognition of the fact that many older adults are not comfortable with computer-based resources. However, there are many patients—old and young—who would prefer a computerized process for managing their medications. Further research should be done to evaluate the role of a Web-based medication list, accessible to patients and providers.

Just as patients need education and tools to facilitate the medication process, provider issues must be addressed. In order for clinic staff to adopt new approaches to the medication reconciliation process, their system-based issues—clinic workflow, time availability, staff roles—must be modified. Creating an accurate medication list through a collaborative, patient-centered process requires patient participation that is reinforced and encouraged by providers. Patient-centered care should not be interpreted as merely shifting the responsibility onto patients to manage their medications.²⁰ Patients who do not receive positive reinforcement from providers may feel their participation is neither necessary nor valued. One patient representative on the Council expressed frustration after he brought all his medications to three clinic visits, but the staff never asked to check them. To improve the workflow around medication reconciliation in the outpatient setting, “best practices” identified in this study are being further evaluated for replication throughout all Aurora clinics.

The most significant lesson from this project was the important role of community-based and nontraditional partners in creating a collaborative relationship between patients and providers. This study expanded the concept of patient partnering to a broader scale, in both the structure and the process used. The Walworth County Patient Safety Council exemplified the type of partnership relationship between patients and providers that defines patient-centered care but on a community scale. Including health care providers—such as retail pharmacists, parish nurses, and social service groups—as additional partners facilitated the dissemination of a consistent message heard by a wide audience of patients. Partnerships with non-health care providers—such as CAPS and Midwest Airlines—provided expertise and guidance for both engaging consumers and marketing methods.

The processes used—establishing a collaborative structure between the research team and the community, including representatives affected by and concerned with medication safety issues, and involving them in all aspects of the research process with the goal of improving the health of the community—were consistent with the principles of community-based participatory research (CBPR).^{21, 22} As others have suggested,²³ applying public health concepts, theories, and

interventional methods, such as CBPR and social marketing, may be more effective than the traditional medical model for addressing the challenge of medication safety.

By creating the educational message and tools for medication self-management in a culturally acceptable format, then disseminating them through community-based organizations, the community itself became empowered to address the public-health burden of medication safety that affects everyone, either directly or indirectly. This community engagement, led by formal and informal leaders, was evidenced by the measure of penetration of the project beyond just Aurora patients. In February 2007, the Walworth County Board presented a Certificate of Accomplishment to the Patient Safety Council “in recognition of their efforts to improve medication safety through the unique model of a partnership between medical providers and their patients.” The measured success of the Walworth County project suggests community engagement could be a significant component of the patient-provider partnership for medication safety.⁶

Even with the project’s achievements, we recognized several limitations. Our definition of “accurate medication list” required only that the name of the medication was on both the clinic chart and patient medication lists. Route of administration, dose, and frequency—critical details for an accurate medication list—were not evaluated. In addition, measurement did not include a comparison of documented over-the-counter drugs (OTC), herbals, or supplements. With over 65 percent of the Aurora patients surveyed self-reporting use of OTC drugs (2007 data not shown), nonprescription drugs present a significant risk for problems, such as drug-drug and drug-supplement interactions. This study did not evaluate the relationship between an accurate medication list and outcomes, such as errors, ADEs, or medication adherence. Despite this limited definition and analysis, our results are consistent with findings previously reported, which reveal significant discrepancies between patient and provider knowledge of the medication list.^{3, 11, 12, 13}

The data collection process and analysis had the potential for bias and error. Data were obtained by a variety of staff at each clinic. Therefore, variability and inconsistency in the process might have occurred. Relying on a patient’s memory to confirm or deny their current medications might have biased the results. However, this method of measuring the accuracy of the medication list had been used annually since 2004. Therefore, clinic staff had up to 4 years of experience with this process. Data analysis at the clinic level did not account for individual physician practices. The clinic data were linked over time, but patients were not matched over time. To adjust for this discrepancy, a sequential cross-sectional design was used to study outcomes within the same set of clinics.

The relationship between the interventions and the measured outcomes was not defined. The project provided extensive education and self-management tools to the target population, but a direct causal effect on the improved accuracy of the medication lists could not be confirmed. Confounding variables might have influenced the results. Information directed at consumers has become readily available from other sources on medication safety.²⁴ Changing behaviors and practices takes time; measured results might improve as more patients adopt the use of personal medication lists. Some of the patients, who received a medication list or bag, might not have been seen in the clinic during the data collection period. Therefore, the findings might be more

conservative than if they had been measured over a longer period of time. The results of this study suggest that patient self-management tools are important, but broader evaluation is necessary to determine which specific interventions are most effective at improving medication list accuracy.

The interventions identified for providers might not be relevant in other outpatient settings. At the time of the study, the intervention clinics used paper-based charting, not electronic medical records (EMR). The medication reconciliation processes could differ depending on differences in system issues, such as staffing patterns and technology. However, during replication efforts at some of the comparison clinics, the project team identified similar process issues, regardless of level of staff or electronic charting. Although technology, such as EMR, has great potential to reduce the risk of errors in the medication process, process issues—such as medication reconciliation—still need to be addressed.^{25, 26}

As with patients, a behavior change in providers may also take time, and results may improve as processes change. Providers could have been influenced by interventions other than those identified by the project, including recent emphasis and education by professional organizations.^{6, 7} Although multiple interventions were implemented, this study did not assess the effects of each one separately. Therefore, the results might not be attributable to a single intervention.

Conclusion

Patient-centered care strategies, applied at the community level, are associated with significant improvement in the accuracy of the medication list in the outpatient setting. Both patient and provider interventions are necessary to facilitate a collaborative approach to medication management. While a perfectly accurate medication list cannot be attributed to a single intervention or tool, addressing medication safety as a public health problem could be an effective approach. As Americans continue to consume medications with a voracious appetite, humans (both patients and providers) will continue to err. Using a collaborative approach involving education, accountability, and technology, consumers and providers can tackle the public health challenge of medication safety together.

The success of the Walworth County Patient Safety Council in creating an effective patient-provider partnership that improved medication safety was recognized with a 2007 Institute for Safe Medication Practices Cheers Award.²⁷ The methods and tools used in Walworth County are available in two toolkits accessible through the CAPS Web site at www.patientsafety.org.

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The Use of Modest Incentives to Boost Adoption of Safety Practices and Systems

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Abstract

Physician adoption of quality and safety systems has been delayed due to required changes in workflow, up-front investments in training, and shifts in efficiency. Here we report on the application of novel approaches to incentive design, such as the Prospect Theory, and steps to engage leadership and staff physicians in the development of a physician quality and safety incentive program in a large employed physician group. The program couples modest financial incentives along with a broad communications campaign to foster the adoption of electronic health records, the use of electronic decision support for ordering imaging studies, e-prescribing, and department/division-specific quality and safety targets ranging from note completion times to hand hygiene practices. To date over 1,200 physicians have participated in this program, and it has generated unprecedented interest and energy in quality and safety measurement and improvement. Here we report on the impact of the program on systems adoption and meeting specific quality and safety goals, as well as the generalizable lessons learned in the development and implementation of the program.

Introduction

The Institute of Medicine (IOM), among others, has focused on a systems approach to quality and safety, leading to calls for the adoption of electronic medical records, decision-support systems, and electronic prescribing.^{1, 2} To date the adoption of those systems has been delayed by factors, such as standard setting,³ financing,⁴ and the lack of product offerings.⁵ Beyond those challenges, physicians have been slow to embrace new systems, even when they are available, because of the required changes in workflow, up-front investments in training, and shifts in efficiency.⁶ Recent estimates suggest that less than one-quarter of physicians in the United States have adopted fundamental information technology, such as electronic medical records.⁷

As a result of this inertia the spread of important quality and safety systems is caught in an “adoption chasm.”⁸ Addressing the adoption and improvement challenge often requires a fundamental change in physician behavior, a daunting task. A variety of “carrots and sticks” are

available to promote such change.^{9, 10} One of those tactics, the use of focused incentives, has most recently received considerable attention with regard to quality improvement

and systems adoption.¹¹ There have been calls for the Government to help bridge the chasm by providing incentives,^{12, 13} and many private payers have created pay-for-performance incentives¹⁴ around quality in general and IT adoption specifically.

A recent survey of a nationally representative sample of physicians found that three-fourths of respondents voiced support for financial incentives being tied to valid quality metrics, yet they raised significant concerns over potential unintended consequences of such programs.¹⁵ Those concerns include exacerbating health care disparities; driving physicians away from the sickest and most disadvantaged patients; the impact on trust in the physician-patient relationship; generation of unhealthy internal competitiveness; the reduction of intrinsic motivation; over-reliance on incentives as a lever to foster behavior change; diversion of organizational focus; creation of a measurement and accountability bureaucracy; and the impact of the incentives on quality of care outside of the care covered by the incentives program.¹⁶ Even when these issues can be adequately addressed, there is a paucity of rigorous evaluations on the impact of incentives on physician behavior,¹⁷ and where it has been studied, the impact on quality and adoption has been variable at best.^{18, 19, 20, 21, 22}

Although it is clear that incentives are far from a panacea and many aspects of such programs are controversial, they remain important among the levers to change physician behavior. In addition, the existence of financial incentive programs has been correlated with high performance among medical groups.²³ Here we describe the design and implementation of a physician quality incentive program in a large academic multispecialty group. The incentive program was explicitly crafted to address concerns with incentives, and it has had a positive impact on the adoption of quality and safety systems.

Program Rationale

Although our multispecialty group had fared well in commercial payer-based pay-for-performance programs, we found those programs were limited in their ability to promote quality improvement and the adoption of quality and safety systems. The payer-based programs differentially affected some segments of our group, with primary care physicians carrying the greatest burden, while no payer metrics applied to other physician groups. The data lags inherent in payer-based programs were also problematic because they could only serve to retrospectively score performance and were of limited value in managing that performance. As a result, payer-based pay-for-performance, an important contracting mechanism in our market, was not a sufficient catalyst for quality improvement and systems adoption in a climate of increasing focus on quality and transparency.

There were also internal reasons for considering an incentive program. In taking a systems approach to quality and safety, our multi-specialty group had made major investments in electronic medical records, computerized radiology order entry with embedded decision support, and electronic prescribing. However, the adoption of these systems in routine clinical practice

was variable due to requirements to change work-flow, concerns over productivity, and a lack of training. To realize the potential of our systems investments, we required more complete adoption than had been achieved with exhortation, pressure from payer-based contracts, and further investments in making the systems user-friendly and efficient. Taken together, these realities—common to physician groups attempting to promote quality improvement and the adoption of safety systems—created a compelling rationale to engage our physician community in the design of an incentive program.

Design Process

To avoid the pitfalls common to previous incentive programs, we began the design of the incentive program with a comprehensive review of both the clinical and economic literature on the subject. Those results, which often raised concerns without necessarily providing solutions, were then shared with representative physician leadership in a series of meetings over 12 months leading up to the program launch. Those discussions explored key design considerations identified by others as crucial to incentive programs, including a consideration of the institutional culture, community context, organizational strategy and structure, organizational stability, infrastructure, quality measurement, nature and size of incentives, and the sustainability of interventions.²⁴

The involvement and awareness of the physicians who ultimately participated in the incentive program's design have been identified as an essential process component.²⁵ Physician involvement afforded us the opportunity to craft a program with appropriate attention to professionalism and other concerns raised by incentive programs. In addition, it fostered a collaborative approach to quality and safety, which increased the dialogue on that subject among physicians.

Guiding Principles

The explicit goal of our program was to recognize physicians for reaching quality incentive targets and for supporting physician organization goals. From the beginning of the program, we were careful to differentiate this effort from prior payer-based incentives, in that our goal was to avoid creating “winners and losers”; we wanted 100 percent of our physicians to have success because that success was linked to organizational success. We also wanted to avoid the potential negative consequences of payment for performance on disparities²⁶ and therefore decided that all metrics would be “payer-blind.” Based on the literature review and input from our physicians, we developed a simple set of guiding principles for the program:

1. **Involve all clinically active physicians.** We wanted to ensure that all physician groups would be affected fairly.
2. **Focus on activities that are important to our patients and physician organization success.** We chose just a few initial organization-wide adoption targets for our program to keep the organization focused on what it needed to achieve to ensure improved quality and safety for our patients and organizational success.
3. **Differentiate motivation (incentive) from capability (infrastructure and supporting processes).** It is essential that those accountable for performance have the tools to achieve it to avoid a fundamental disconnect.²⁷ The program must recognize that incentives to work

harder and faster are doomed to failure, since they will be unsustainable when the incentive is gone. To help address this challenge, we ensured that physicians would receive the maximal support possible, including training and changes to our software systems, to promote adoption. Such focus allows the program to promote working smarter rather than providing a fee for the service of working harder.

4. **Complement departmental quality and compensation plans.** Some of our physician groups already had systems-adoption and quality improvement goals embedded in their compensation plans. Rather than replace or undermine those existing programs, we focused on areas outside of existing plans.
5. **Design with input from our physicians and departmental chiefs of service.** To ensure the program would be clinically meaningful, we complemented organization-wide targets (e.g., adoption of electronic medical records) with targets chosen by the departments themselves.
6. **Use available metrics.** To avoid the creation of a measurement and accountability bureaucracy and to avoid shifting resources to administering the program, we chose to focus our program on areas where there were either existing metrics or a compelling need to develop them because of upcoming pay-for-performance contracts.
7. **Remain flexible and evolve.** The incentive program was consciously portrayed as a continuing work in progress to explicitly recognize that it would never be error-free. The flexibility in the program allowed for near real-time adjudication of unintended consequences and promoted a sense of fairness. The flexibility and evolution of the program has also allowed us to keep true to the one promise of the program that it will get better.

Program Characteristics

With the guiding principles defined, we sought to take a comprehensive approach to address key aspects of the program. Based on our review of other programs, we focused on four key design issues: (1) eligibility, (2) frequency, (3) size of incentive, and (4) choice of metrics. For each, we conducted a review of the literature for guidance and engaged in an extensive review and revision process with physician representatives.

Eligibility. To be inclusive, we defined eligibility for the program broadly—all physicians who participated in the majority of our managed care contracts and met a minimum level of clinical productivity, measured as at least 50 work Relative Value Units (wRVUs) during the preceding 6 months. Physicians who billed privately were required to submit wRVU data for review to be eligible for the program. Payouts for the program were tiered based on clinical productivity with the tiering structured to ensure that the majority of physicians (65 percent) fell into the highest tier of reward in an effort to fully engage a broad segment of the physician population. Because the incentive program was part of our effort to ensure future success on pay-for-performance arrangements with commercial and public payers, physicians who did not bill for clinical services directly (e.g., trainees) were excluded from the program.

Frequency. As with other aspects of the program, appropriate balances must be considered with regard to the frequency with which the program measures performance and provides feedback/reward. We and others²⁵ have found that commercial payer pay-for-performance contracts, where the withhold return often occurs more than 1 year after the close of the billing

year, are too lagged and infrequent to foster physician focus. Annual payments are too infrequent to solidify the relationship between performance and reward. However, more frequent assessments and payments result in greater infrastructure demands and resource needs. To balance these realities, our program runs on a 6-month basis. This provides an opportunity for the program to improve and evolve yet maintain some stability so that physicians do not perceive it as a case of rapidly changing goalposts or “flavor of the month.”

Size of incentive. A review of the literature on the sizing of physician incentives to achieve measurable behavioral change reveals conflicting recommendations. Some suggest that the incentive should be at least 10 percent of annual income,²⁸ while others admit that no real data suggest a more firm specification beyond “enough.”²⁵ In reviewing the program with our physicians, we learned that no sum would be “enough” to “pay” for adopting some of these systems. For example, the adoption of an electronic medical record system not only means lost time in the clinical setting but often translates into evening hours spent converting old records to the new system, time that would otherwise have been spent with family. As a result we found it useful to move the dialogue from a focus on remuneration (payment for time value) to reward (financial recognition of the effort made). This change in both underlying philosophy and rhetoric was not only key to gaining physician acceptance, it also supported the principle that the incentive is only partly about the money. It was also a clear statement of organizational priorities and values.

Nevertheless we still faced the challenge of trying to keep the program affordable yet powerful enough to promote real change. Here we found the economic literature on the Nobel Prize-winning Prospect Theory,²⁹ which explains the evaluation of risk and utility by individuals, to be helpful. According to Prospect Theory, the risks of gains and losses are evaluated differently from what one would otherwise expect by looking at the expected utility. This explains why individuals would rather take a 50/50 chance on losing \$200 than a guarantee of a loss of only \$100, yet they would accept a guaranteed \$100 gain over a 50/50 chance of gaining \$200.

We applied Prospect Theory to our program design by phasing the implementation of our program. In the first phase, all participating physicians were given the full financial reward (\$500, \$1,250, or \$2,500 depending upon their wRVU tier) just for meeting the eligibility requirement. However, the communication with the check for that reward made it clear that receiving the remainder of that year’s potential reward would depend upon performance. This phasing allowed us to create the sense that underperformance would lead to our physicians not getting something they otherwise should have received. This creation of an expectation of success proved to be a powerful motivation for our physicians.

Choice of metrics. Based on our pay-for-performance contracts and the goals of our quality and safety initiatives, we chose two metrics for organization-wide focus—the adoption of electronic medical records and the use of electronic radiology order entry—for the initial measurement period. In both cases, the incentive program was preceded by over a year of communications with the physician staff on the importance of these two systems to our future success. Nevertheless, adoption lagged. To be equitable across physicians, those departments for which these organization-wide metrics were inappropriate (e.g., radiology and pathology) had to come

up with substitutes where adoption and performance would have an impact on quality and safety (e.g., decreasing turn-around time on final reports).

In addition to the organizationwide metrics, each department was required to develop its own metric related to quality and safety. This ensured clinical relevance and promoted the incentive program as a collaborative effort rather than a central mandate. In the departmental metric selection process, care was taken to avoid selecting metrics that would link incentives to a clinical decision with an individual patient, further reinforcing the systems approach. Some departmental measures were extensions of the organizationwide metrics (e.g., improving the timeliness of electronic visit or operative notes or decreasing the proportion of potentially inappropriate, high cost imaging studies). Others chose metrics related to public reporting (e.g., ACE/ARB use in congestive heart failure or perioperative and pneumonia antibiotic timing); Joint Commission compliance (e.g., hand hygiene and medication reconciliation); or department-based systems adoption (e.g., the deployment of electronic anesthesia flow sheets and electronic prescribing in the emergency department). Table 1 presents the array of metrics used in our first measurement period in the spring of 2007.

Program Implementation

Our reviews of the literature suggested that the implementation of an incentive program might be even more important than design features.²⁵ In an effort to apply “evidence-based implementation,” we identified six key levers for ensuring program success: (1) embedding the program in a larger quality and safety effort, (2) clear and frequent communications, (3) integrity of performance scoring, (4) transparency, (5) identifiable reward disbursement, and (6) the availability of an appeals mechanism.

Embedding in a larger quality and safety effort. The extant literature on incentives is clear on one point: incentives alone are not sufficient to improve quality and promote systems adoption.²⁷ Like Pasteur, we recognized that “the seed is nothing, the soil is everything.” In our case the “seed” (our incentive program) was unlikely to flourish without appropriate attention to our “soil” (our organizational culture). As a result, we approached the development and implementation of the incentive program from the standpoint that this program was necessary, but not sufficient, to improve quality and systems adoption.

Rather than rely on incentives as an all-powerful, stand-alone magic bullet, our program was embedded as an appropriate next step in a quality and safety strategic planning effort that had begun 3 years earlier and was reaching a critical juncture, where our progress was slowed by the adoption chasm. Other components of that strategic planning included safety culture surveys, quality and safety leadership retreats, integrated delivery system-level efforts focused on information systems adoption,³⁰ and a rewriting of the hospital’s mission statement to reflect an emphasis on quality and safety. In addition, we developed complementary incentive programs—many of which were based on aggregations of the physician incentive program metrics—for the senior leadership of both the physicians’ organization and hospital. This reinforced the organizational commitment to quality and safety and aligned all interests to achieve success.

Clear and frequent communications. Keeping the physicians in an incentive program informed is a key success factor cited in the literature.²⁵ As a result, we developed a broad communications

campaign to accompany the incentive program, which included regular newsletter updates; general electronic mail communications to all physicians; targeted electronic mail communications to departments and individual physicians; electronic reminders throughout the performance measurement period; meetings with representative physician groups; updates at “town hall” style meetings; incorporation into regular leadership meetings of department chiefs; and publication of updates, metrics, and targets on the physicians’ organization Web site. The communications program was designed to get the message out “early and often” but to avoid the risk of becoming noisome to busy physicians. As with other aspects of the program, this required a careful balance and two-way communications with our physicians to titrate our strategy.

Integrity of performance scoring. Recent negative experience with a comprehensive program to promote quality in general practices across the United Kingdom illustrates the importance of keeping the scoring of performance simple in order to avoid both confusion and gaming.²² Performance on the two organization-wide performance metrics was evaluated at the individual level and determined 50 percent of the reward payment. These were scored on an “all-or-nothing” basis. The remaining 50 percent was based on the performance on the department’s chosen metric. Here, the unit of analysis varied among the departments, with some choosing to measure at the individual level (e.g., note completion time), while others were at the departmental level (e.g., hand hygiene). In those cases where individual rates were used (e.g., proportion of operative notes completed in 24 hours), there was some room for “partial credit,” although this was limited to maximize the impact of the intervention, and it was neither communicated nor applied until after the end of the measurement period.

We kept the program simple by not using an elaborate scoring algorithm, and thus, we did not need to create a “measurement and accountability bureaucracy.” Also, the 50/50 split on scoring between organizational and more locally defined goals emphasized the collaborative nature of the program.

Transparency. At baseline and after the initial performance measurement period, aggregate data were shared with all of those participating in the program via print publications and on the physicians’ organization Web site. Again, there was a need to strike an appropriate balance, this time between transparency and the appropriate peer pressure it generates with respect to privacy. Based on a previously crafted performance data sharing policy, that dissemination was guided by the application of a “need-to-know” principle. Under that policy—which was adjudicated by the hospital’s and physicians’ organization Medical Policy Committee—all individuals had a need to know their own detailed performance data. Within a department, individual physicians could also see whether colleagues were meeting their performance target (as “Yes/No”) but could not see any individual’s specific performance data. Individual physicians could also see the aggregate performance of other departments. Senior leadership at the organizational and departmental level, whose own incentive program was tied to aggregate performance, had access to individual level performance data.

Identifiable reward disbursement. We took two steps to maximize the impact of the incentive payments. The first was to mail real checks (as opposed to electronic transfers) to physicians’ homes. Although the use of checks required the physicians to get the checks deposited or cashed, the use of actual checks reinforced the distinct nature of the incentive payment. In addition, we

had our initial payments coincide with the end-of- year holiday bonus season. The incentive checks were accompanied by a cover letter from the physician organization’s leadership and the

Table 1. Initial set of incentive program metrics

Measure	Description
# e-prescriptions	Increase number of e-prescriptions (numerator) compared to total prescriptions (denominator) given to patients upon emergency department discharge.
Hand hygiene	Hand hygiene compliance, before and after contact with patient or patient’s environment.
ACE/ARB prescriptions	ACE/ARB prescribed for CHF & AMI patients discharged from cardiac medical services.
Antibiotics to pneumonia patients	Initial antibiotics to pneumonia patients within 4 hours of arrival.
Radiology report completion	Measures the fractional days to bring a study from completed to finalized status.
Deploy anesthesia electronic flow sheets	Deploy charting system in two of the six off-site locations by spring 2007 (i.e., IVF suite and GI endoscopy areas).
Electronic sign-out	Electronic sign-out in pathology system of surgical pathology reports within 4 business days.
EMR use ^a	Outpatient visits are noted in an electronic medical record.
Electronic notes completion	Preliminary notes in the electronic medical record within 120 hours of outpatient visits.
Operative notes completion	Operative notes dictated within 24 hours of surgery.
Medication reconciliation	Pre-admission medication list is ready for review within 36 hours of admission.
Perioperative antibiotics	Appropriate perioperative antibiotic administration.
Reduced inappropriate high-cost imaging	Reduced inappropriate rate for electronic orders for high cost imaging.
Radiology order entry use ^a	High cost outpatient imaging studies (i.e., CT, MRI, and nuclear cardiology) ordered via electronic order entry attributed to the ordering clinician show evidence of direct input from a clinician.
Signed ED notes	Completion (signing) of ED electronic notes within 96 hours of patient visit.
Turn-around time for cardiac enzyme testing	In lab turn-around time of troponin T testing for myocardial infarction complete within 60 minutes.

^a Organization-wide metrics.

Measure	Description
ACE = angiotensin-converting enzyme; ARB = angiotensin II receptor blocker; CHF = congestive heart failure; AMI = acute myocardial infarction; IVF = in vitro fertilization; GI = gastrointestinal; MRI = magnetic resonance imaging; ED = emergency department.	

department chief of service, an individualized performance report (Figure 1), and a notification of future metrics and targets.

Availability of an appeals mechanism. Although we made every effort to keep the incentive program simple and get the assignments of accountability and performance measurement correct, the program explicitly acknowledged that it would not be perfect. Physicians who felt that they had not been treated fairly in the program—whether in terms of eligibility or performance assessment—were provided with clear instructions on how to appeal their incentive assignment and were invited to do so. Those appeals were then investigated individually, data were re-examined where appropriate, and a final decision on the validity of the appeal was then made by the Medical Director and ultimately the Chief Executive Officer of the physician organization. Although the proportion of physician appeals was low, 4.7 percent in the spring 2007 measurement period, the availability of an appeals mechanism was a key design feature, which highlighted the commitment to program improvement over time.

				Name:	
				Department/unit:	
				Eligible for: \$2500	
				Gross payment: \$2500	
Measure	Target	Numerator	Denominator	Percentage	Met Target
EMR Use	80%	150	160	94%	√
ROE Use	70%	30	30	100%	√
Department measure	85%	100	110	91%	√

Figure 1. Example of performance communication to individual physician. (EMR = electronic medical record, ROE = radiology order entry)

Program Results to Date

Although the program is relatively new, we have already had some measurable preliminary results.

December 2006. We had 1,307 physicians participate in the incentive program, representing every specialty in our multispecialty group. The December 2006 payment, which was made solely on the basis of eligibility, returned \$2.6 million to eligible clinicians, with 65 percent of them receiving payment at the highest tier level.

July 2007. The spring 2007 measurement period was the first where performance determined the incentive amount. Of the 1,351 clinicians participating in the spring 2007 program, 1,124 (83 percent) received the full payment, with only one physician missing on all of the targets. Of the two organization-wide metrics, 89 percent of eligible clinicians met the electronic medical record adoption goal (compared with an initial program goal of 75 percent, based on pay-for-performance contracts), and 96 percent met the electronic radiology order entry goal, with only 44 eligible clinicians failing. For the department metrics, all 11 departments that had metrics measured at the group level met their targets. In those departments with metrics measured at the individual level, 70 to 86 percent percent of clinicians met their targets.

We found that many clinicians received “byes” on some of our initial metrics because these did not apply to their particular practice. As a result, we will try to increase the specificity of metrics in future rounds to be more inclusive of our entire physician population.

Collateral Benefits of the Program

In addition to the preliminary benefits of the program in terms of systems adoption and quality improvement, some important collateral benefits of the program have provided value to the physicians organization. The greatest of these was the heightened interest in quality and safety engendered by the program. Examples of that increased engagement included the participation of all departments in defining quality metrics, increased traffic to our quality and safety Web sites, and an unprecedented level of focused inquiries to the program leadership about quality and safety measurement. That interest integrated nicely with the execution of our quality and safety strategic planning.

Other benefits included the development of more accurate lists of clinically active physicians and their practice group/peers; the identification of low clinical volume physicians for future consideration in contract discussions; enhanced data on the physicians in private practice; early identification of potential billing compliance issues, which were amenable to immediate remediation; improved scheduling information; and increased use of radiology order entry decision support.

The measurement process also improved the integrity of the data we use for payment for performance with commercial payers. The increased scrutiny of our data sources to support this program led to the recognition of failures in extant measurement efforts and improved our pay-for-performance results. In addition, the increased attention paid by our clinicians to our quality and safety systems resulted in important enhancements to our information technology and the identification of opportunities to improve our decision support software, which otherwise might not have come to our attention.

Program Evolution

From the outset we recognized that the program was a trial and that it would only continue as long as it provided value to our physicians and the patients they serve. The evolution of the program to date has been illustrative of the flexibility of the initial approach, with the continued focus on remaining true to collaboratively developed guiding principles. It is expected that the program, which is now in its third incentive period, will continue to evolve with our quality and safety agenda.

Future plans include the retirement of some metrics, where our goals for adoption have been achieved (e.g., adopting electronic medical records); raising the bar in some areas (e.g., note completion time); maintaining focus in areas that required sustained attention (e.g., antibiotic timing in the emergency department); development of new metrics to address our evolving pay-for-performance contracts; and calls for transparency (e.g., electronic prescribing rates). To promote greater transparency and maintain focus—particularly in cases where the adoption or improvement goals have been achieved, leading to metric retirement—we plan to incorporate ongoing performance surveillance into the institution’s quality and safety dashboard, which will be reviewed regularly by the senior leadership and trustees.

Conclusion

Although our program is relatively new, we have already demonstrated a positive impact on systems adoption, quality metrics, and some operational gains through collateral benefits. Carefully crafted, modest financial incentives produce incredible interest and, more importantly, action, when embedded in an integrated approach to improving quality and safety. We have shown that collaborative design and implementation guided by the lessons learned in the literature on incentives can strike appropriate balances to avoid the potential perverse consequences of such programs. Nevertheless, we recognize that this experience is early, and we are still in a learning phase. Future program evaluations will examine the sustainability of gains, return on programmatic investment, and overall impact on quality and safety.

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Using Data Mining to Predict Errors in Chronic Disease Care

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Abstract

Development of data mining technologies to predict treatment errors in populations of patients represents a major advance in patient safety research. In the work presented here, we create a simulation test environment using characteristic models of physician decision strategies and simulated populations of patients with type 2 diabetes, employ a specific data mining technology that predicts encounter-specific errors of omission in representative databases of simulated physician-patient encounters, and test the predictive technology in an administrative database of real physician-patient encounter data. Two dominant decisionmaking strategies with different rates of treatment errors are identified: “feedback strategies” that use the results of past actions to guide treatment decision, and “feedforward strategies” that make treatment decisions based on anticipated future patient states. Evaluation of data mining results shows that the predictive tools developed from simulated treatment data can predict errors of omission in clinical patient data. The methods developed in this work have the potential for wide use in identifying decision strategies that lead to encounter-specific treatment errors in chronic disease care.

Introduction

Reducing the incidence of medical errors is an ongoing area of interest to the health care community. Much of the focus in recent work has been on reducing errors of commission (inappropriate actions), such as amputating the wrong limb.¹ Less attention has been given to errors of omission (i.e., failure to act when patients are not at evidence-based goals), a particular area of interest in the treatment of chronic diseases, such as type 2 diabetes.² Two major challenges in preventing errors of omission are (1) identifying patterns of behavior that predict future errors and (2) determining appropriate actions to take to prevent errors when error-prone behavior patterns are identified. Such actions might include changing the way individual physicians manage patients and matching physicians’ abilities to patients with characteristics they are most successful in treating.

The health care community is placing greater emphasis on the use of data sources to improve the quality of care delivered to patients.^{3, 4} Available data sources include administrative and clinical records, particularly with the advent of the electronic medical record (EMR). However, extracting meaningful information from large databases is a challenging task. Data mining, the extraction of useful and potentially actionable information from data, has been identified as a tool for culling health care databases for information to improve the quality of care. The majority

of recent data mining research directed toward improving quality of care has focused on detecting outcomes associated with patient/illness characteristics.^{5, 6} Less work has directly examined outcomes and physician actions.

Methods

The present study applies data mining to identify patterns of physician decisionmaking used to treat patients with the goal of predicting errors of omission. In this approach, we conducted a simulation study of the clinical environment of type 2 diabetes to model alternative physician treatment strategies and develop a representative database of treatment records reflecting the use of these strategies to treat populations of simulated patients. The resulting database was used to employ a specific form of data mining technology—decision trees—that enabled accurate prediction of errors of omission across a range of patients and physician treatment characteristics. The resulting decision trees were then evaluated by using them to predict errors in an administrative database of actual patient records.

Simulation Environment

The simulation environment used in the present work comprised a computational model for patients with type 2 diabetes, plus a set of physician decision strategies for treating patients with this disease. Clinical responses of individual patients and populations of patients' responses to treatment were modeled. Each part of the simulation environment is described here.

Patient model. A computational model of a patient with type 2 diabetes was developed in prior research.⁷ This model is composed of an inference structure and a rule network that responds to treatment actions in a manner characteristic of diabetes patients in real clinical encounters. Changes in levels of blood glucose, blood pressure, and lipids are simulated in response to actions taken over time. The patient model accounts for specific effects on outcomes from various oral medications, insulin, and other treatments, including medical nutrition therapy. The model captures the physiologic effects of drugs in the form of dose-response curves taken from the clinical literature.^{8, 9} The patient model includes three sources of individual patient variation: (1) seasonal fluctuations in adherence to the treatment regimen following a 1-year cycle,¹⁰ (2) daily fluctuations in adherence,¹¹ and (3) an assigned rate of disease progression.¹²

Individual patients. Changes in patient blood glucose values (i.e., glycated hemoglobin and fasting plasma glucose, hereafter referred to as A1c and FPG, respectively) are computed in two parts: (1) the effect of treatment actions (hereafter referred to as “moves”) is computed as determined by a dose-response table, where each medication dose in the table has a maximum expected effect on patient blood glucose values (i.e., A1c and FPG); and (2) the percent of maximum effect is computed at any point in time based on the time-course of respective medications. Time-dependent values for percent maximum effect of medications are computed for both A1c values and FPG values.

Adherence to a treatment regimen indirectly affects A1c level, where the level of adherence assigned to each patient determines the percentage of the regimen followed. For example, if a patient has a prescription for 2,000 mg of metformin and is modeled to be 75 percent adherent,

then the patient model receives $2,000 \text{ mg} \times 0.75$, or 1,500 mg, of metformin throughout the period in question. Blood pressure and lipid values are similarly represented.

Patient populations. Characteristic properties of populations of patients with type 2 diabetes were modeled using an administrative database of treatment records. Working in conjunction with physicians from a major health care organization and their clinical database, 11 key health indicators for patients with diabetes were identified and represented: A1c, low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides, systolic blood pressure, weight, creatinine, height, depression, stress, and level of adherence to treatment regimen (estimated from the timeliness of prescription fills). Generated populations of synthetic patients in the study reported here are based on distributions of these attributes.

Physician Treatment Strategies

Physician process model. The physician process model (PPM) referred to in the present research is a dynamic decision model designed to bring patient blood glucose, blood pressure, and lipid values to evidence-based goals (e.g., A1c values <7 percent). The PPM manages patient state by processing information and making corresponding moves. Moves take three forms: (1) treatment moves, which include medications and referrals to specialists; (2) scheduling moves, which stipulate when future visits will occur; and (3) information seeking moves, which are made up of orders for medical tests (e.g., A1c) to support decisionmaking.

Because patient states change as a function of patient variables and decisions made by the physician model, each treatment strategy requires a series of real-time decisions. As described by Brehmer, making such decisions is analogous to a process of achieving control of a system to obtain desired outcomes (goals).¹³ PPMs for treating patients with type 2 diabetes are based on the internal model control paradigm,¹⁴ shown in Figure 1. This model is composed of processes and computations (represented as squares and circles, respectively). The system being controlled is a patient (model) with type 2 diabetes.

The “inverse model” shown in Figure 1 is a process that generates treatment moves, schedules visits, and orders tests. The inverse model determines what moves to make based on the patient’s “distance to goal” and whether prior moves have had their expected effect on patient state, as

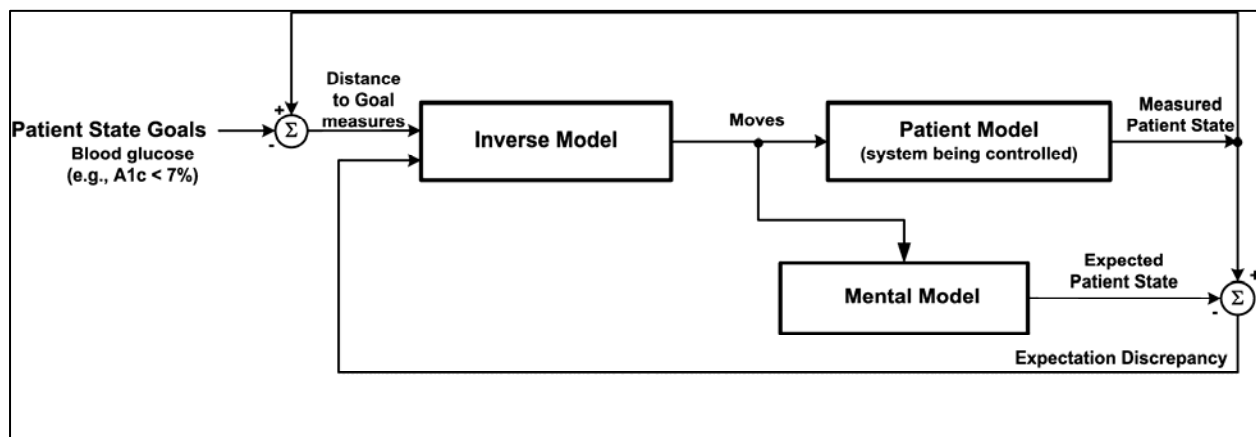


Figure 1. Physician process model for managing patients with type 2 diabetes.

measured by the “expectation discrepancy.” Distance to goal is the amount of change in A1c (or other measures) required to bring the patient to the desired A1c level. Expectation discrepancy is defined as the difference between the patient’s current A1c and expected A1c at a given point in time, as estimated by the mental model. The “mental model” represents parameters that affect estimations of patient state, including patient adherence to treatment (low or high) and dose-response curves (i.e., representations of patient responses to doses of various medications over time). The mental model generates an expectation of patient A1c as a consequence of moves that are made. The “patient model” receives moves from the inverse model and generates the next state of the patient being treated.

Brehmer has suggested two decision strategies to control dynamic processes: feedback and feedforward.¹³ A feedback strategy uses information based on current patient state to make decisions. A feedforward strategy uses current patient state information *and* anticipated future patient states to make decisions. Two versions of the feedback strategy and two versions of the feedforward strategy were created for the purposes of the present study. These versions are labeled “weak” and “strong.” Each version is described in detail below.

Feedback strategies. A common heuristic for feedback control from the literature on decision making is “anchoring and adjustment.”^{15, 16} “Anchoring” is accomplished by selecting a control variable to use as a basis for making decisions. The PPM uses previous blood glucose value as an anchor. “Adjustment” is the process of making decisions relative to past decisions. For the PPM, this equates to titrating (adjusting) the dose of a single medication.

The weak version of the feedback strategy represents a physician who infrequently titrates (adjusts) diabetes-related medications. This version of the feedback strategy involves encounters with the patient every 90 days, but treatment moves are made only when A1c is either above goal (i.e., A1c = 7 percent) and has stopped decreasing, or it is increasing compared to the previous encounter. The strong version of the feedback strategy involves encounters with the patient every 90 days; treatment moves are made at every encounter when the patient is above the A1c goal (7 percent). The 90-day scheduling parameter was chosen because most oral medications require 90 days for complete absorption.

Feedforward strategies. The feedforward strategy estimates the amount of medication needed to treat the patient, based on the distance of the patient’s A1c from the goal. The feedforward strategy has a time constraint of 1 year to reach the A1c goal. Given the time constraint, the feedforward strategy determines whether enough visits can be scheduled to administer the amount of medication needed to reach the goal. If the strategy estimates that time is insufficient, given standard scheduling of visits and titration of single medications, the model would schedule visits more often, and when appropriate, would administer and titrate more than one medication (including insulin).

Unlike feedback strategies that use only A1c values in their decisionmaking, feedforward strategies use both FPG and A1c values when determining progress toward goal. Because feedforward strategies can make medication moves before prior moves have finished taking their full effect, these strategies must manage this “delay of feedback” by combining dose-response

curves in order to prevent overmedicating the patient. The two versions of the feedforward strategy manage this in different ways.

The weak version of the feedforward strategy calls for a single medication move at every encounter when the patient is above goal. When the patient's A1c is ≤ 7.5 percent, the weak version calls for treatment moves only when the A1c has stopped decreasing or is increasing, compared to the previous encounter. By using this rule, the weak version does not need to combine dose-response curves in order to avoid overmedicating the patient, possibly resulting in hypoglycemia. In the weak feedforward version, visits are scheduled every 60 or 90 days. This allows enough time between moves for medications to have the bulk of their effect, thus avoiding the need to combine dose-response curves.

The weak feedforward strategy uses a relatively simple (linear) representation of a dose-response curve to anticipate the amount of change in A1c, which is to be expected for a given treatment move. On each encounter, the weak feedforward PPM compares the anticipated A1c with the measured A1c to infer patient adherence (Figure 1).

The strong version of the feedforward strategy calls for moves at every encounter when the patient is above goal. This version of the feedforward strategy combines dose-response curves in order to estimate delayed effects of medications. Because this version of the feedforward strategy can combine dose-response curves, visits can be scheduled as frequently as every 30 days. If results are less than expected from a prior move, and if patient adherence is not an issue, an additional medication can be introduced. More than one medication can then be titrated during a given visit. The strong feedforward strategy has a more complex (piecewise linear) representation of the patient's responses to treatment moves, which is needed for combining dose responses from more than one treatment move.

Experiment

An experiment was conducted to determine the effect of the two versions of each model when treating simulated populations of diabetes patients. In the research reported here, the focus was on the way each PPM managed patient blood sugar values. (Blood pressure and lipid values were treated but are not reported.) All models were tested on their ability to bring patients' A1c values to < 7 percent within 1 year. Four metrics were used to evaluate each of the models at the end of 1 year of treatment: (1) proportion of patients reaching goal, (2) average final A1c values, (3) average costs to treat patients, and (4) proportion of encounters with errors of omission.

Simulated patients. Using statistical characteristics in an existing database of real patients as a guide, a population of 10,000 synthetic patients was created. Patients were blocked into six cells (or groups) combining their initial A1c value (L, M, and H) and level of adherence (L or H). Initial A1c categories were defined as follows: (1) low A1c: A1c < 8 percent, (2) medium A1c: A1c between 8 and 10 percent, and (3) high A1c: A1c > 10 percent. Adherence to treatment level was divided into two categories: (1) low adherence: adherence < 75 percent), and (2) high adherence: adherence > 75 percent). Each of the six cells was labeled using a two-letter designator, where the first letter specified A1c range, and the second letter specified level of adherence (e.g., cell MH represents patients with medium initial A1c and high adherence to treatment).

The number (percentages) of simulated patients in each cell was as follows: LL, 900 (9 percent); LH, 6,000 (60 percent); ML, 400 (4 percent); MH, 1,900 (19 percent); HL, 200 (2 percent); and HH, 600 (6 percent). These numbers reflect the actual distribution of patients in the administrative (clinical) database. Average initial A1c values within each A1c range were low, 6.7 percent; medium, 8.8 percent; high, 11 percent. Average initial adherence was 60 percent in low adherence cells and 90 percent in high adherence cells.

Procedure. Each physician model treated 10,000 simulated patients for 1 year of elapsed time. Both weak and strong feedback models scheduled visits every 90 days. Weak feedforward models scheduled visits every 90 days, except when results from the past move did not decrease A1c by the anticipated amount. In these cases, visits were scheduled 60 days from the previous visit.

The strong feedforward model scheduled visits every 60 days, when A1c changed by the anticipated amount and 30 days between visits when A1c changed by less than the anticipated amount. All models used the same drug formulary for treating blood glucose. The formulary was composed of metformin, sulfonylurea, thiazolidinedione (TZD), and insulin. The models prescribed medications in the order in which they were listed. Simulation treatment records for each model were evaluated for errors of omission using the following error definition:

- **High and medium A1c cells:** If a patient's current A1c is >8 percent and has not dropped by at least 0.5 percent A1c over the past 120 days, then flag an error on this encounter.
- **Low A1c cells:** If a patient's A1c is <8 percent but above goal (7 percent), and a treatment move has not been made in the past 120 days, plus a treatment move is not made on the current encounter, then flag an error on this encounter.

Results

Table 1 summarizes results for all models at the end of 1 year of treating 10,000 individual patients. The results are summarized in four categories.

Percent to Goal Within 1 Year

Feedforward strategies brought more patients to goal within 1 year than feedback strategies. Within each strategy type, strong versions brought more patients to goal than weak versions. These findings hold for all six patient cells. Feedforward-weak and feedback-strong strategies brought similar numbers of patients to goal in all but the HH cell, where feedforward-weak brought 5 percent of patients to goal and feedback-strong brought 0 percent to goal. In both high A1c cells, only the feedforward-strong strategy was able to bring patients to goal.

Table 1. Performance of physician process models treating 10,000 synthetic patients for 1 year

Cell designation ^a	Feedback		Feedforward	
	Weak	Strong	Weak	Strong
Percent to goal by cell (%)				
LL	84.6	94.8	98.4	100.0
LH	91.9	99.1	99.8	100.0
ML	9.8	26.5	26.5	90.5
MH	20.6	42.9	49.5	98.4
HL	0.0	0.0	0.0	44.5
HH	0.0	0.0	5.0	87.3
Average cost^b to treat by cell (\$)				
LL	811	866	1,210	1,390
LH	791	836	1,165	1,325
ML	1,646	1,697	2,044	2,648
MH	1,639	1,691	2,008	2,303
HL	1,973	2,045	2,526	4,200
HH	1,961	2,033	2,524	3,839
Average final A1c by cell (%)				
LL	6.7	6.7	6.5	6.2
LH	6.7	6.6	6.4	6.1
ML	7.9	7.6	7.5	6.8
MH	7.7	7.4	7.2	6.6
HL	10.1	9.7	9.2	7.7
HH	9.8	9.1	8.5	6.8
Percent encounters with errors by cell (%)				
LL	1.0	0.9	0.0	0.0
LH	1.2	1.2	0.0	0.0
ML	23.6	17.0	9.0	3.0
MH	16.0	7.9	2.3	0.8
HL	53.1	52.2	41.6	19.3
HH	45.8	34.1	27.0	2.4

a Cells are labeled using a 2-letter designator, where the first letter specifies initial A1c range (L, M, or H), and the second letter specifies level of patient adherence to treatment (L or H).

b Average costs included prescription costs, charges for office visits, lab orders, and referrals to specialists; inpatient and emergency treatment costs were not included. Prescription costs were based on Average Wholesale Prices.¹⁷

Cost to Treat for 1 Year

Feedforward strategies were generally more successful in treating patients and required more resources than feedback strategies. Strong versions of strategies required more resources than weak versions. This trend applied to all six patient cells. Even though the feedback-strong strategy and feedforward-weak strategy brought approximately the same number of patients to goal, they did it at very different costs. The feedback-strong strategy incurred 28 percent, 16 percent, and 20 percent lower costs, compared to the feedforward-weak strategy in the low, medium, and high A1c ranges, respectively.

Average Final A1c After 1 Year

Feedforward models outperformed feedback models within patient cells. High-adherence patients also achieved the same or lower A1c than low-adherence patients. These differences became greater as the initial A1c of the patients increased.

Errors of Omission

Feedback strategies committed more errors of omission than feedforward strategies. For a given strategy, weak versions committed more errors than strong versions. All models committed fewer errors in the low A1c cells (feedforward strategies committed no errors). However, in medium and high A1c cells, patients' adherence to treatment influenced the occurrence of errors. Each model committed more errors in low-adherence cells than in high-adherence cells.

In the following sections, treatment data and error patterns were used to develop predictive tools for both synthetic and real clinical patient data.

Predicting Errors in Synthetic Patient Data

Data mining is an area of computer science that uses algorithms to find patterns in datasets. One use of data mining involves the training and testing of classification functions. Common types of functions include decision trees, artificial neural networks, and support vector machines.¹⁸ Each type of function, referred to as a classifier, uses a different method for categorizing input data. A classifier reads a single vector of input data and outputs a classification of these data as one type or another. (For example, in this research, a classifier would predict the presence or absence of an error of omission in the next physician/patient encounter.)

Building classifiers requires a training set of data that forms the classifier and a testing set of data that tests how well the classifier works. Each vector of training data is labeled (i.e., the class label is known). Thus, the classifier is trained by developing a mathematical model that minimizes the number of inaccurate classifications. The present research uses decision trees¹⁸ as classifiers, based on their use of logical rules to discover insights into the relationships between input variables and class labels.

Classifiers are data mining models of relationships between attributes and classes. Such models are considered either explanatory or predictive in nature.¹⁹ Explanatory models are formed to account for patterns in the available data (e.g., a linear regression model that explains some of the variance in the independent variable). Predictive models are formed to predict classes from

input data that have not yet been seen. The work described here develops data mining classifiers using information gathered at a current physician/patient encounter to predict an error of omission on the next encounter.

Predicting errors in real physician-patient encounter databases is often problematic because of missing data, which makes it difficult to identify consistent patterns of physician decisionmaking that lead to error. For example, previous attempts in this research to train classifiers using available real encounter data yielded single-class decision trees that predicted that every next encounter would result in an omission error. An alternative approach for learning predictive patterns of physician decisionmaking is to train classifiers on synthetic data, where issues such as noisy, insufficient, or missing data can be avoided.

To predict errors of omission in a database of physician-patient treatment encounters, the set of classifier attributes was constrained to reflect those data available in both the synthetic and real patient data sets. These attributes were as follows:

Input vector	Classification label
• Time elapsed since last encounter • Time until next scheduled encounter • Monthly rate of change in A1c between last encounter and current encounter • Current reported A1c • Previous medication move • Current medication move	• Error of omission on next encounter

The goal of this work was to predict whether an error of omission would occur on the next encounter. Encounters were defined in terms of clinical visits. The time between encounters was measured in days. A1c was reported when ordered. If a current A1c was not available, the last available A1c was used. Medication moves covered the range of oral medications, including metformin, sulfonylurea, and TZD. A medication move was measured from one encounter to the next by changes in existing prescriptions for each oral medication using values of {-1, 0, 1, 2, 3}. A negative number represented a decrease in the prescribed dose of a medication. A zero indicated the current prescription remained unchanged. Positive numbers indicated the number of medication doses that were increased.

Data on each of the six attributes and the class label (i.e., presence of error in the next encounter) were collected from simulated encounter data and assembled to form vectors of input data to train decision trees. The attributes formed a collection of commonly available information representing a momentary patient state across three clinical encounters (i.e., previous, current, and next) and a set of physician moves connected to that state transition. The resulting set of

input data was combined across all patients with an initial A1c ≥ 8.0 and for all four physician models.

Each of the four previously defined PPMs treated this patient data set for 1 year of simulated time. The resulting encounter data were combined into a database, scored for errors on a per-encounter basis, and conditioned for classification (i.e., the records containing the classifier input attributes mentioned earlier and the class label were created). One decision tree was trained for all physician/patient combinations, where the patient's initial A1c was ≥ 8.0 percent.

A 10-fold cross-validation training method was used to generate a decision tree. Cross-validation is a method that divides the data set into the number of folds (i.e., sub-datasets) specified, using one fold for testing and the other folds for training. The classifier then rotates through the folds, holding each one out as the test set in order to create the best general classifier for the data.²⁰ The decision tree was generated by the J4.8 tree learning algorithm (which is part of Weka data mining tool)¹⁸ that analyzed the input data described above and determined which attributes best predicted errors. This algorithm arranged these attributes into a decision tree composed of a root decision node, subsequent decision nodes, and leaf nodes as shown in Figure 2.

The decision tree shown in Figure 2 is used for prediction by starting at the root of the tree and traversing a series of branches until a leaf node is reached. The value of that leaf node determines

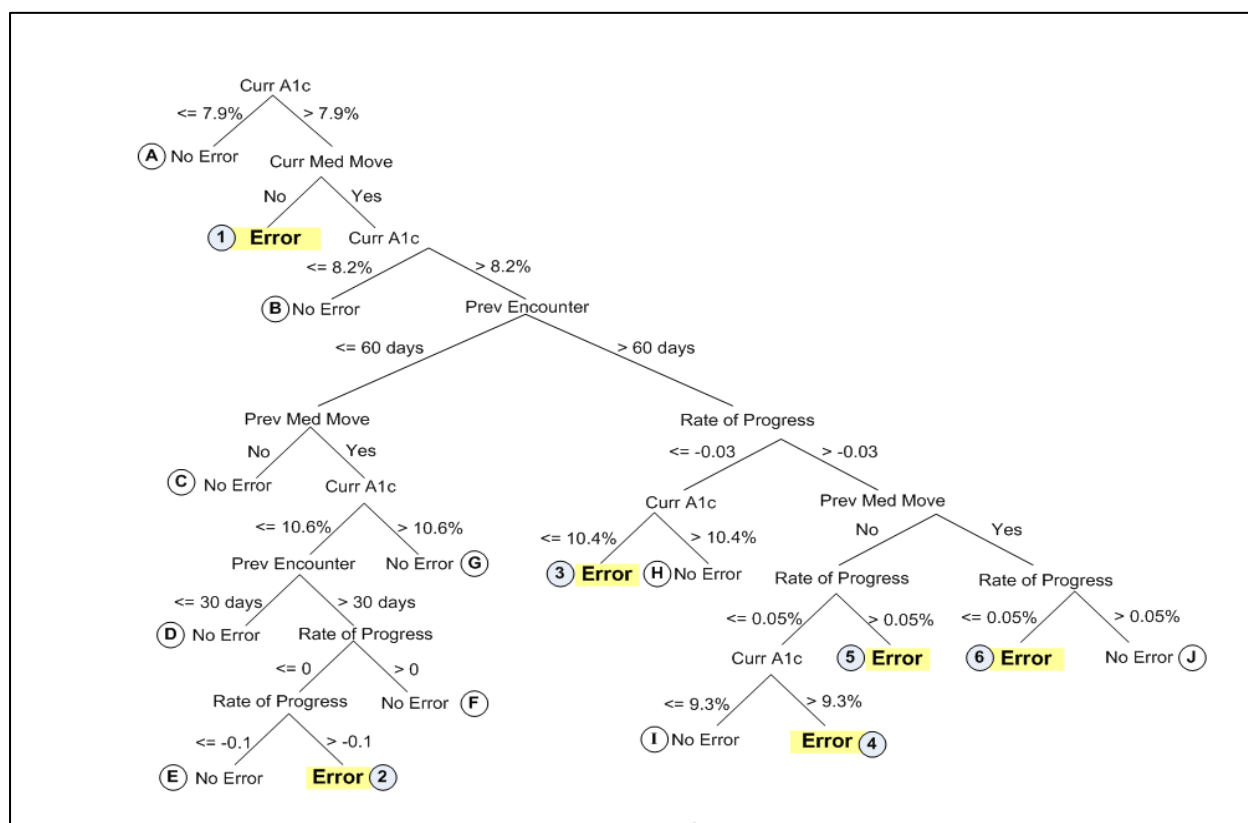


Figure 2. Decision tree generated using encounter data from combined outcomes of all models. Circled numbers identify leaf nodes where errors are predicted to occur on the next visit. Similarly, circled letters identify leaf nodes where next visits are predicted to result in no errors being committed.

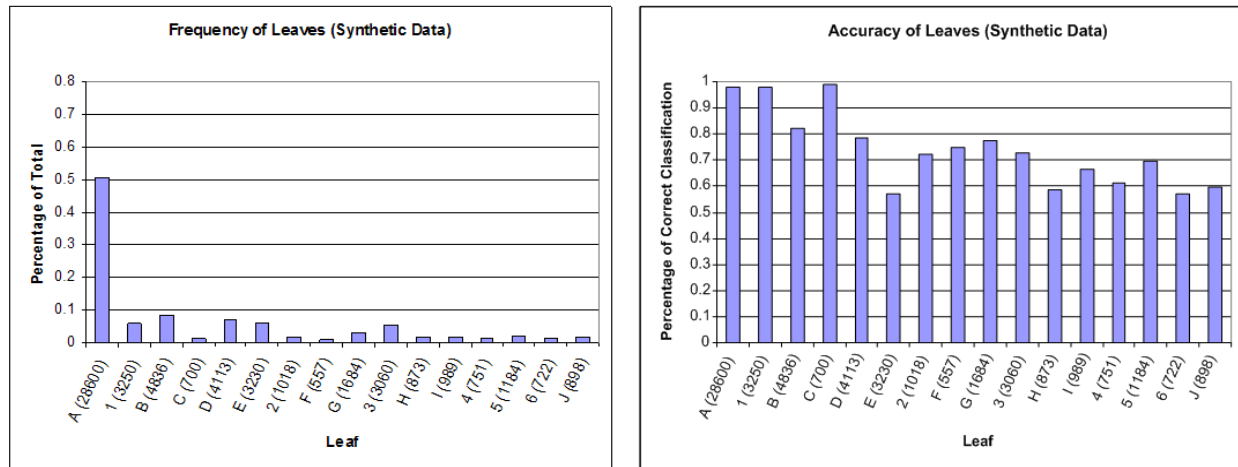


Figure 3. Histograms show the way synthetic data coursed through the decision tree during the cross-validation process and the accuracy with which each leaf node predicted “error” or “no error.” The 16 leaf nodes from the tree in Figure 2 are laid flat across the x-axis in a left-to-right organization, with letters denoting a prediction of “no error” and numbers denoting “error.” The total number of data points held in each leaf node is in parentheses.

the prediction the decision tree makes for that encounter. Circled numbers identify leaf nodes where errors of omission are predicted to occur on the next visit. Circled letters identify leaf nodes where next visits are predicted to result in no errors being committed.

The branch paths from each decision tree can be stated as logical rules to classify encounters. For example, tracing a path in Figure 2 from the root node right and then left at the next node creates the following rule: “If a patient’s current A1c is >7.9 and no medication move is made at a current encounter, then an error is likely to occur in the next encounter with this patient.” Each path can be similarly restated.

A given leaf node does not indicate that an actual error did occur at the next encounter for each corresponding input vector. Rather, it predicts that an error is likely to occur at the next encounter. Sometimes this prediction is accurate; sometimes it is not. Each leaf node is not necessarily used the same number of times throughout the dataset.

The left histogram in Figure 3 indicates the number of data records that end up in each of the 16 leaf nodes of the decision tree in Figure 2. The decision tree, when tested on the synthetic data, predicts the occurrence of “error” and “no error” as the positive and negative prediction, respectively. A total of 56,465 physician-patient encounters were used to predict errors on next visits. The tree in Figure 2 correctly predicted error 8,042 times (true positives) and incorrectly 5,093 times (false positives). No error was correctly predicted 40,814 times (true negatives) and incorrectly predicted 2,516 times (false negatives).

Classification results are summarized in Table 2. Data mining literature offers a number of different metrics to evaluate the predictive performance of decision trees.^{18,20} The traditional way to measure predictive accuracy is to calculate the percentage of correctly predicted class labels (both error and no error), i.e., $\text{accuracy} = (\text{TP} + \text{TN}) / (\text{TP} + \text{TN} + \text{FP} + \text{FN})$.

As shown in Table 2, the recall measure of the predictive performance is the percentage of errors correctly predicted out of all the errors that actually occurred; i.e., $\text{recall} = \text{TP} / (\text{TP} + \text{FN})$. Precision is the percentage of the actual errors among all the encounters that were classified as errors by the decision tree; i.e., $\text{precision} = \text{TP} / (\text{TP} + \text{FP})$. The F-measure metric is the harmonic mean of the recall and precision metrics and is computed as:

$$F\text{-measure} = 2 \times (\text{recall} \times \text{precision}) / (\text{recall} + \text{precision})$$

The F-measure, which quantifies the overall reliability of the decision tree, represents a tradeoff between correctly predicting errors and overpredicting errors. It is in the range of 0 to 1 and is commonly used in data mining literature to evaluate classifiers.

Table 2. Summarized results of training and testing decision trees on synthetic data

Number of attributes in tree	Attributes used to predict errors	Counts [N (%)]	Performance metrics
6	Current A1c		Accuracy = 87%
	Days since last encounter	TP = 8042 (14)	Recall = 0.61
	Days to next encounter	FP = 2516 (5)	Precision = 0.76
	Med adjustment – current visit	FN = 5093 (9)	F-measure = 0.68
	Med adjustment – previous visit	TN = 40,814 (72)	Kappa statistic = 0.59
	Monthly rate of change in A1c		
8	Current A1c		Accuracy = 89%
	Days since last encounter		Recall = 0.71
	Days to next encounter	TP = 9382 (17)	Precision = 0.78
	Oral adjustment – current visit	FP = 2665 (5)	F-measure = 0.75
	Oral adjustment – previous visit	FN = 3753 (7)	Kappa statistic = 0.67
	Insulin adjustment – current visit	TN = 40,665 (72)	
	Insulin adjustment – previous visit		
11	Monthly rate of change in A1c		
	Current A1c		Accuracy = 91%
	Days since last encounter		Recall = 0.78
	Days to next encounter		Precision = 0.84
	Metformin adjustment – current visit	TP = 10,248 (18)	F-measure = 0.81
	Metformin adjustment – previous visit	FP = 1967 (3)	Kappa statistic = 0.75
	Other oral adjustment – current visit	FN = 2887 (5)	
	Other oral adjustment – previous visit	TN = 41,363 (73)	
	Current creatinine level		
	Insulin adjustment – current visit		
	Insulin adjustment – previous visit		
	Monthly rate of change in A1c		

TP = true positives; FP = false positives; FN = false negatives; TN = true negatives

The Kappa statistic in Table 2 measures the similarity between the trained classifier and a random classifier. A value of 0 indicates that a random classifier predicts as well as the trained classifier, whereas a value of 1 indicates no agreement between a random classifier (i.e., chance prediction) and the trained classifier (i.e., a Kappa value of 1 is a strong indication of an accurate classifier).

The predictive accuracy (in terms of F-measure) of the decision tree in Figure 2 is 0.68. Attempts were next made to improve this rate by providing additional information to the data mining model. The model shown in Figure 2 was constructed using information present in the database of real patient encounter records available for this study. However, the synthetic models (described in the previous section) used to simulate physician/patient clinical encounters maintain a larger set of information, including the actual amounts of different types of insulin administered to each patient and the estimates of the patients' adherence to treatment. To determine whether training predictive tools using such information could increase the accuracy of error predictions, additional information was incrementally provided.

Two alternate decision trees were evaluated. In the first case, attributes for medication adjustments were further divided into oral medication adjustments and insulin adjustments. Adding these attributes increased the decision tree predictive ability (in terms of F-measure) from 0.68 to 0.75. In the second case, a decision tree was created to reflect the fact that PPMs are able to stop the use of contraindicated medications. For the formulary used in the simulation study, the PPMs use creatinine levels to determine whether metformin is contraindicated. In the second alternate tree, attributes for oral medication adjustments were subdivided into metformin adjustments vs. non-metformin adjustments, and an attribute was added for creatinine levels. These additional attributes improved the error prediction ability to 0.81.

Table 2 shows that errors can be predicted more accurately by tracking additional patient data. However, since the present research tests whether predictive tools developed in a synthetic database of patient records can be transferred to an available database of real patient records, the decision trees tested on the real (administrative) data were restricted to currently available attributes.

Predicting Errors in Clinical Patient Data

The decision tree developed with synthetic data (Figure 2) was tested on an administrative database of clinical treatment records. The test was designed to predict errors in real encounter data using a decision tree constructed from synthetic models. A database of deidentified data for 129 real primary care physicians treating 12,708 real diabetes patients over the course of 1 year served as the test bed. Data records contained date of encounter, last reported A1c value, and types and doses of prescribed oral medications (metformin, sulfonylurea, TZD). Although records indicated the use of insulin, titrations of insulin were not available. In cases where A1c values were not reported on a given encounter, the last measured A1c was used to fill in the missing value.

The clinical data were prepared using a process similar to that used in preparing synthetic treatment data. All encounters not coded as diabetes-related encounters using available ICD-9

codes and any duplicate entries were removed. Patients with initial A1c ≥ 8 percent were extracted and scored with the error definition.

In the real clinical data set, the first encounter for a patient was used to establish a baseline for that patient. The first usable medication move was in the second encounter, which is analogous in the synthetic database to the first encounter. Due to this difference, the first, second, and final encounters listed for each physician/patient treatment path were used to collect information, but could not be used as inputs for error prediction.

The initial clinical database contained 77,514 encounter records, spanning 129 physicians and 12,708 patients. Usable encounter data included 3,389 records spanning 101 physicians and 799 patients. For patients with initial A1c ≥ 10 , 83 physicians saw an average of 2.5 patients for 4.5 usable encounters per year. For patients with initial A1c ≥ 8 percent but < 10 percent, 97 physicians each saw 6.1 patients 4.2 times. Patients treated by physicians were excluded from these averages if they had fewer than four diabetes-related encounters within the year of clinical data examined.

Figure 4 shows two histograms resulting from testing the decision tree with real clinical data. A total of 3,389 physician-patient instances were used to predict errors. The tree in Figure 2 correctly predicted error 1,844 times (true positives) and incorrectly predicted error 923 times (false positives). No error was correctly predicted 122 times (true negatives) and incorrectly predicted 500 times (false negatives). The recall for errors was 67 percent (compared to 61 percent in synthetic data); the F-measure was 0.72 (compared to 0.68 for the synthetic data). As shown by the histogram on the right, most of the data are classified by the first two leaf nodes. Comparison with the histogram on the right in Figure 3 shows that, in the real database, fewer patients fell below 7.9 percent over the course of the year, and physicians made fewer medical moves, compared with simulated data.

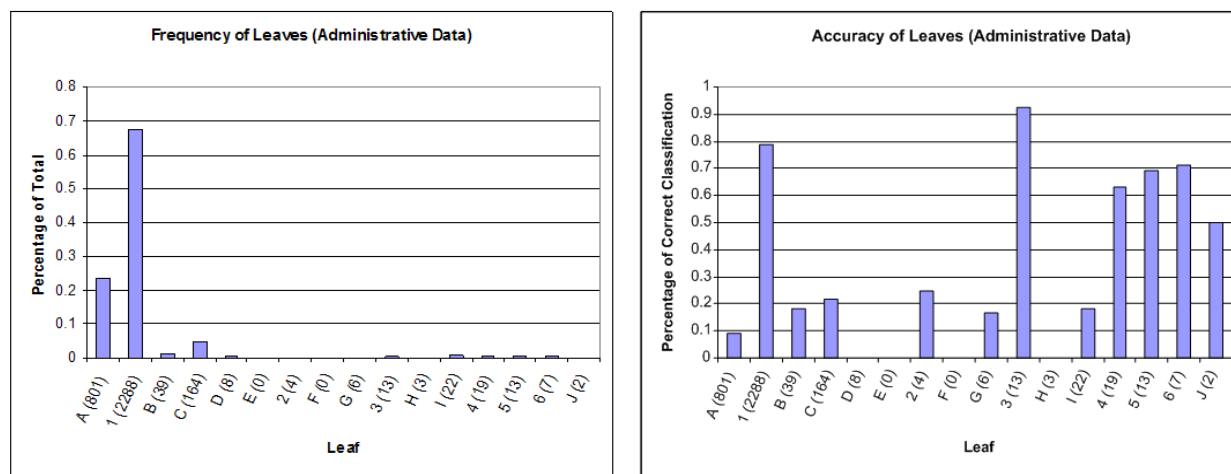


Figure 4. Histograms show the way real clinical data coursed through the decision tree (learned using synthetic data) and the accuracy with which each leaf node predicted “error” or “no error.” The 16 leaf nodes from the tree in Figure 2 are laid flat across the x-axis in a left-to-right organization with letters denoting a prediction of “no error” and numbers denoting “error.” Total number of data points held in each leaf is in parentheses.

The classification accuracy of individual leaf nodes in the decision tree varies, due in part to the small number of examples. Focusing on the first two leaf nodes (the most common nodes) it is clear that in the real (clinical) administrative data, having a patient's A1c ≤ 7.9 percent does not prevent an error from occurring on the next encounter. Not making a medical move when a patient's A1c is > 7.9 percent is highly predictive of errors of omission for next encounter. It is noteworthy that the decision tree developed in a synthetic environment was able to accurately predict errors that were detected in some of the more complex branches of the tree.

Conclusion

Simulation of four physician process models (PPMs) treating populations of individual synthetic patients with type 2 diabetes over the course of 1 year showed heterogeneity in outcome effects for different patient subgroups in terms of average resulting A1c, percent of patients reaching goal, costs of treatment, and proportion of encounters with errors of omission. From this subgroup analysis, tradeoffs in reaching evidence-based goals at the lowest possible costs were made in each subgroup. Low A1c patients were driven to goal easily by all the PPMs but at lowest cost by the feedback-weak model. Medium A1c patients were treated most effectively by the feedforward-strong model. Significant per patient cost savings were achieved by using a feedback-strong model rather than a feedforward-weak model, without a large dropoff in performance. In the high A1c cell, only the feedforward-strong model was effective at bringing a significant percentage of patients to evidence-based goals.

A specific data mining model (a decision tree) was developed to predict errors of omission that occurred throughout the patient population by virtue of different treatment strategies. Analysis of the prediction results and the specific branch paths used by the decision tree indicated where particular patterns of physician decisionmaking led to errors. The decision tree used to predict errors was formed by restricting the leaf node size to no less than 500 physician/patient encounters. This restriction resulted in a relatively small tree that could be used to interpret predictions generated by the model. The ability to interpret how an error is predicted has implications for the formation of policies based on these predictions.

An important aspect of the work presented here is the fact that physician and patient models were used to generate simulated encounter data from which data mining tools could be developed. The ability to use these tools to predict errors of omission in real (and synthetic) patient data suggests that future developments in this kind of work have the potential to enable identification and correction of physician decisionmaking strategies that lead to encounter-specific treatment errors.²¹ Application of this work to the improvement of care for patients with type 2 diabetes, as well as chronic diseases more generally, is promising.

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Venous Thromboembolism Safety Toolkit: A Systems Approach to Patient Safety

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Abstract

The current culture in health care is focused on patient safety and on delivering quality health care across the continuum of care. However, a culture of safety by itself cannot create change within an organization. Venous thromboembolism (VTE) requires coordination of care across multiple providers supported by a system that assists in the process of delivering and tracking outcomes of care. In this paper, we describe the implementation and use of safe practice interventions for patients who have been diagnosed with VTE or are at risk for VTE. In particular, we describe the use of the evidence-based, system-supported, interactive *VTE Safety Toolkit*—which includes diagnostic, preventive, and therapeutic algorithms—and the *On-line Provider Training Module on VTE Prophylaxis*, which is a mandatory Web-based VTE educational intervention for all providers. We describe how organizations and providers can use the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis* to identify business process that can be changed and create a mechanism to track provider and system performance and thereby improve patient safety and accountability around VTE.

Introduction

Venous thromboembolism (VTE) encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE is one of the most common clinical disorders among both inpatients and outpatients, and PE is the most common preventable cause of death among hospitalized patients in the United States.¹ Approximately 2.5 million cases of DVT and 600,000 cases of PE are diagnosed per year in the United States. About 30 percent to 40 percent of postoperative patients will develop some form of DVT, and VTE is associated with more than 300,000 hospitalizations annually.^{2, 3, 4} Approximately two-thirds of patients with symptomatic VTE manifest DVT alone, whereas one-third of patients manifest PE.

Appropriate prophylactic regimens for many different patient groups have been determined by randomized clinical trials, as has the appropriate treatment of established DVT.^{5, 6} Errors from omission of prophylaxis or objective diagnostic testing, or inadequate treatment are estimated to result in significant harm to hospitalized patients. A fundamental understanding of prophylaxis, diagnosis, and treatment is necessary for providers throughout the continuum of patient care. Given the magnitude of the problem, it is not surprising that the diagnosis and management have been better defined for VTE than for other common diseases.

Patient safety has been a major focus of the Agency for Healthcare Research and Quality (AHRQ). Several clinical guidelines for patient safety have been developed and implemented in health care organizations.^{7, 8, 9, 10, 11} Diverse approaches to organizational change have also been introduced.^{7, 8, 9, 10, 11} However, patient safety remains a challenge because of the difficulty in sustaining organizational change to support new initiatives. Patient safety issues associated with the prevention and management of VTE continue to pose a challenge in most U.S. hospitals.

The purpose of this project was to increase the implementation of safe practice interventions for patients at risk for or diagnosed with VTE using the evidenced-based and system-supported interactive *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis*. Multidisciplinary clinical and research teams in partnerships among the University of Washington Medical Center (UWMC), UW School of Nursing, and the Center for Health Sciences Interprofessional Education and Research have developed and implemented the *VTE Safety Toolkit* locally through a public Web site (<http://vte.washington.edu/>) for providers and patients.

This project was intended to inform providers, patients, payers, policymakers, and the public about how these safe practice interventions can be implemented successfully in diverse health care settings, leading to safer and better health care for all Americans. In this paper, we discuss the development of evidence-based tools and educational interventions around the clinical diagnosis of VTE. The processes for implementation and the plans for local, regional, and national dissemination are also discussed. The dissemination of results for the pre-implementation data collection period of the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis* will be reported in peer review journals.

VTE Safety Toolkit: What Is It?

The *VTE Safety Toolkit* consists of diagnostic, preventive, and therapeutic algorithms; a mandatory Web-based VTE educational intervention for all providers; patient educational materials; and provider communication strategies to promote continuity of care. The toolkit is divided into provider, patient, and system sections. The provider component includes educational tools for increasing knowledge on the assessment of risk for developing VTE, using VTE prophylaxis strategies, understanding diagnostic strategies for VTE, treating acute VTE in inpatients and outpatients, and managing patients after treatment. The patient component consists of educational tools for improving knowledge about the prevention of VTE and about outpatient treatment options. Systems components include clinical tools, infrastructure support, and expert consultants for improving communication between providers and patients and for improving the coordination of care throughout the continuum. Although they are not “tools” *per se*, the infrastructure support consists of an integrated clinical database, standardized reporting strategies, quality improvement tools, and computerized logbooks. Each element of the *VTE Safety Toolkit* was designed to address a specific safety issue related to VTE diagnosis, prevention, and management.

The *VTE Safety Toolkit* contains 10 components that are evidence-based guidelines for preventing, diagnosing, treating, and educating patients and providers about VTE. The components are as follows:

- VTE prophylaxis guidelines.
- VTE risk assessment tool.
- DVT diagnostic algorithm.
- PE diagnostic algorithm.
- HIT (heparin-induced thrombocytopenia) assessment.
- VTE treatment pathway.
- DVT outpatient treatment order set.
- Vascular laboratory requisition.
- Neural-axial anesthesia guidelines.
- Patient education (prevention and treatment) pamphlets.

Due to space constraints, a brief description of 4 of the 10 tools—including the VTE prophylaxis guidelines, VTE risk assessment tool, DVT and PE diagnostic algorithms, and the VTE treatment pathway—are presented here. The remaining guidelines and information about the toolkit can be found at <http://vte.washington.edu/>.

The VTE Prophylaxis Guidelines are used to assess every patient upon admission and discharge for their risk of developing VTE and for recommending the type, dose, timing, and duration of anticoagulants. If a patient presents with contraindications to pharmacologic prophylaxis (e.g., heparin, warfarin), mechanical prophylaxis—such as sequential compression devices or graduated compression stockings—is recommended. If a patient presents with signs and symptoms of DVT, the DVT diagnostic algorithm can be utilized. Before objective diagnostic studies are ordered, providers must complete a history and physical examination and a DVT risk assessment, and they must rate the clinical probability of DVT using the Wells scoring system.¹²

The PE diagnostic algorithm is very similar to the acute DVT algorithm. The provider first obtains the patient's history and physical examination, a chest x-ray, and arterial blood gases; completes the PE risk factor assessment; and rates the clinical probability of PE using the Wells PE scoring algorithm.¹³ If a patient suspected of PE presents with leg symptoms, then a venous duplex ultrasound is ordered. If no leg symptoms are present, a spiral computed tomography (CT) scan is recommended as the first diagnostic test. For patients who cannot receive contrast dye, a ventilation and perfusion scan can replace the spiral CT scan.

The VTE treatment pathway is utilized when a patient has been diagnosed with acute DVT or PE. After the initial diagnosis is made, baseline blood tests—including prothrombin time (PT) with international normalized ratio (INR), partial thromboplastin time (PTT), and complete blood count (CBC)—are obtained to ensure correct dosage of anticoagulation. If a patient is eligible for outpatient treatment, low molecular-weight heparin is recommended; inpatients are typically treated with unfractionated heparin, intravenously or via subcutaneous injections, and transitioned to warfarin following discharge. Warfarin is subsequently used for several months after the initial diagnosis of DVT or PE to prevent recurrent VTE.¹⁴ In addition to pharmacologic

treatment, compression stockings with a pressure of 30 to 40 mm Hg at the ankle are used for 2 years to prevent post-thrombotic syndrome.

Methods

VTE Diagnostic and Treatment Standards

Even though strong direct evidence is available to guide the management and prevention of VTE, morbidity and mortality remain high.^{15, 16, 17} A considerable body of literature informs practice about VTE risk assessment, prophylaxis, diagnosis, and treatment.^{14, 18, 19, 20, 21, 22, 23, 24} Evidence-based guidelines, graded by strength of evidence and methodologic quality of evidence, have been established by the American College of Chest Physicians (ACCP) Conference on Antithrombotic and Thrombolytic Therapy.^{14, 19} These guidelines, in their seventh edition in 2004, served as the basis for the development of the *VTE Safety Toolkit* and the *On-line Provider Training Module on VTE Prophylaxis*.^{14, 19, 25}

The ACCP guidelines summarize the full body of evidence regarding the risk of VTE associated with various medical illnesses and surgical procedures and have established a clear set of risk factors that can be used for stratifying VTE risk in individual patients.¹⁹ Strategies for prophylaxis in various clinical settings are defined, including mechanical and pharmacologic methods, with appropriate dose and duration of therapy. Treatment standards have also been clearly defined for both inpatients and outpatients, based on a complete review of all available evidence.^{14, 19, 25}

Development of the VTE Safety Toolkit

Despite substantial literature concerning appropriate management, VTE has been identified as an area of concern by several national groups involved with patient safety or quality improvement (i.e., Surgical Care Improvement Projects, National Quality Forum, The Leapfrog Group for Patient Safety, and The Joint Commission). When the UWMC found an increased incidence of postoperative VTE, addressing this clinical problem became a major priority. Data from previous VTE studies at UWMC, including a 15-year natural history of DVT study, demonstrated multiple problems with the diagnosis, management, and prevention of VTE at the level of the provider, patient, and system.

VTE is not a new clinical problem, but it is a unique clinical problem that requires coordination of care across multiple locations (in hospitals, in outpatient clinics, at home) by multiple providers (nursing, medicine, pharmacy, and surgery) and is supported by a system that assists in the process of delivering care. A group of interprofessional providers and researchers were responsible for the development of the pathways, order sets, guidelines, and patient handouts that make up the *VTE Safety Toolkit*. Local experts in thrombosis, vascular diagnostics, and anticoagulation were called upon in this process. The *VTE Safety Toolkit* was developed based on clinical evidence and established guidelines.

Results

Issues and Challenges of the *VTE Safety Toolkit*

The *VTE Safety Toolkit* has faced and will continue to face various issues and challenges during the development and implementation stages. In prior studies of VTE management led by our lead author, Dr. Zierler, the most common challenges were related to changing individual provider behavior, rather than changing business practices within organizations. Integrated pathways for DVT management, which were developed prior to the development of the *VTE Safety Toolkit*, were disseminated to multiple groups of providers without a plan to provide infrastructure support for use of the pathways. Although providers were given physician order sets, there was no efficient way to determine utilization of the order set, except to physically review paper records. The original pathways did not include risk assessment or prophylaxis pathways for preventing acute VTE because they focused on the outpatient treatment of acute DVT.

The risk for VTE rises during illness and during treatment for illness. Prevention, diagnosis, and treatment of VTE should occur not only during acute hospital care, but also before and after hospitalization. Patients are often referred to the UWMC and Harborview Medical Center (HMC) for only a portion of their care, and they return to their communities for further treatment. Thus, plans to reduce VTE risk should also involve external community providers. This issue has been addressed. Plans for implementation of the *VTE Safety Toolkit* include providing access to external community providers and patients. Patients need to be recruited to participate in their care, and they can be taught to identify risks, signs, and symptoms of VTE; adhere to the appropriate dose of anticoagulation; and seek medical care in a timely fashion.

In order to achieve the goal of increasing the implementation of safe practice interventions for VTE in the clinical setting, the *VTE Safety Toolkit* was developed with these significant changes from the preliminary studies. However, the *VTE Safety Toolkit* has proceeded with some expected challenges that simply cannot be addressed without institutional changes. The lack of an integrated clinical information system to view a patient's complete medical record needs to be addressed. The documentation of care and clinical outcomes are located in several different computer-based programs, one for providers, one for nurses, one for pharmacists, etc. The lack of integration of the existing information systems requires multiple steps to abstract comprehensive patient data and makes it difficult to track changes related to care in an efficient manner. A new integrated clinical information system is being programmed and piloted within small groups of providers at UWMC and HMC, but neither system has a fully integrated information component.

A goal to improve the standards of care for hospitalized patients at risk for VTE has been to create one admissions assessment form. Currently, each discipline creates an intake assessment form specific to their unit. The VTE clinical and research team has suggested the development of one form that could be standardized for use across the organization. Currently, not every unit requires that a patient be assessed for VTE risk. This is because the form that they use does not include the question of VTE risk, and changing the form incurs a substantial cost. As the organization moves toward adopting an integrated information system, it should be possible to include a standard form that requires a response to whether a patient has been assessed for VTE risk. This will be necessary because assessing each patient for VTE risk and prescribing

appropriate pharmacologic prophylaxis for VTE are now incorporated into the Center for Medicare & Medicaid's (CMS) pay-for-performance initiative (as of July 1, 2007), giving providers and health care organizations a financial incentive to document these procedures.

Online Provider Training Module on VTE Prophylaxis

As part of the patient safety movement, the UWMC and HMC administration decided that all resident and attending physicians needed training relative to VTE, since VTE was the single most preventable condition in U.S. hospitals. Moreover, less than 30 percent of eligible UWMC patients were actually receiving VTE prophylaxis.

This training has been designed as a randomized trial comparing the addition of interactive VTE case studies with an online standard didactic training module on VTE prophylaxis. All UW providers—residents and attending physicians—will participate in this quality improvement intervention and education evaluation study. Providers will receive an e-mail from the office of the Center for Clinical Excellence with instructions and the rationale for completing the online VTE prophylaxis training. Providers will log in to a protected Web site using their personal hospital username and password. A brief statement on the log in site (front page) explains that the VTE prophylaxis training module involves a research component (survey) and that we will be testing two different methods of online educational training that will affect future training module designs. All participants in this study will be aware of how collected data will be used; they will be able to opt out of having their data included in the research database; but they will not be permitted to opt out of the training.

Randomization will occur at the time of log in, and the provider will be assigned to either the control (passive didactic training only) group or the intervention (passive didactic training and interactive case studies) group. After logging in, all providers will be asked to complete a brief demographic questionnaire and pretest to measure their knowledge about VTE prophylaxis and prevention.

The pretest comprises 10 questions relating to the content of the passive and interactive “training slides” on VTE prophylaxis. All providers in the control and intervention groups will be shown nine (tutorial) passive, didactic slides with information on VTE prevention [similar to Health Insurance Portability Accountability Act (HIPAA) training—information with no immediate feedback]. Providers who are randomized to the intervention group will then review interactive case studies followed by the postassessment test. The total number of interactive cases depends on the number they answer correctly. There are four content areas and four cases for each content area, for a total of 16 interactive slides. The providers need to pass one from each content area correctly; the pass rate is a score of 80 percent or higher. Providers in the control group will complete the postassessment test following the tutorial slides.

The Director of the Center for Clinical Excellence will ask for resident (champion) physician volunteers to begin piloting the *On-line Provider Training Module on VTE Prophylaxis*, and it became mandatory in spring 2008, with post-implementation data collection planned to begin in September 2008. The goal of this research is to increase the percentage of hospitalized patients without contraindications who receive anticoagulation prophylaxis by increasing provider knowledge about VTE prophylaxis. After the evaluation, the training module will be added to the

VTE Safety Toolkit and will be available to other academic medical centers for provider training on VTE prophylaxis.

The implementation of the *On-line Provider Training Module on VTE Prophylaxis* demonstrates a change in business practices at UWMC and HMC. The VTE training module is the first mandatory education module (similar to HIPAA training) to be implemented for providers using a new Web-based learning management tool. Both medical centers are planning three mandatory educational provider training modules to address concerns about standardized training and patient safety; the VTE prophylaxis module is the first of these. Researchers with training in educational psychology and evaluation assisted with the development of the training module, including the pre- and post-assessment questions.

Implementation and Dissemination of Interventions

Implementation Plan

Provider education is a key component of the “preadoption stage” as outlined by Greenhalgh, et al.²⁶ In order for individuals involved in a system-level adoption to fully participate, they must be aware of the innovation, have adequate information to see how it affects their practice and how they would use it, and have access to support systems to help them use it. The clinical experts who finalized the *VTE Safety Toolkit* elements provided the didactic content and references for educational modules about each aspect of risk, diagnosis, management, and prophylaxis (see “About Us” on *VTE Safety Toolkit* Web site: <http://vte.washington.edu/>).

The educational component of the toolkit will be introduced through special grand rounds presentations by opinion leaders/champions for each of the clinical services that will become end-users. Because all of the medical services grand rounds include providers from the community and other UW teaching hospitals, these will also serve as initial dissemination vehicles to providers outside of UW Medicine. Nursing, pharmacy, and other relevant provider professions also have grand rounds or monthly meetings that will be accessed for the “kick-off” presentations.

UWMC and HMC providers receive continuing education credit for the grand rounds attendance, and we are currently investigating whether providers can receive additional continuing education credits for completing the *On-line Provider Training Module on VTE Prophylaxis*. These modules will be organized around illustrative cases so they actively apply evidence-based practices and engage in higher level learning activities, rather than simply reviewing the content. These modules also will be tied to appropriate UWMC intranet sites to assist providers when they are faced with retrieving appropriate evidenced-based practice guidelines in the course of patient care. In addition, a quarterly newsletter produced by the UWMC Pharmacy will provide up-to-date information on the implementation process.

Individual providers will be asked to provide feedback to the UW Center for Clinical Excellence’s reporting mechanism throughout the process to assess the effectiveness of dissemination and implementation. UWMC will continue to benchmark the incidence of VTE

quarterly, and research assistants will continue to monitor data on the incidence of VTE and the adequacy of prophylaxis and management of VTE.

External providers will have access to the *VTE Safety Toolkit* through the use of a Web-based program sponsored by the UWMC called ULINK, a referral program called MEDCON, and from the discharge summary that will have a URL linking the referring physician to a UWMC Web page that will house the *VTE Safety Toolkit*. The ULINK program gives referring providers instant access to patient information and updated records from the UWMC, HMC, and the Seattle Cancer Care Alliance, as long as their patients give permission. MEDCON is a toll free consultation and referral service of the UW School of Medicine and its primary teaching hospital. As a major resource for medical education, research, and patient care, the UW School of Medicine places particular importance on its communication with the practicing physicians in the Pacific Northwest and the WWAMI (Washington, Wyoming, Alaska, Montana, and Idaho) region. We will link the *VTE Safety Toolkit* to the UWMC patient care Web page under “Refer a Patient” so that external providers can have access to the educational tools.

Dissemination Plan

Internal dissemination target audiences are inpatient and clinic providers. The dissemination plan has been developed using the planning tool developed by the AHRQ Patient Safety Research Coordinating Committee.²⁷ The AHRQ Dissemination Planning Tool is an integral part of dissemination for the *VTE Safety Toolkit* within UWMC; it will be utilized for regional and national dissemination in the years following the end of the funded project. The AHRQ Dissemination Planning Tool is grounded in research regarding effective dissemination of innovations discussed in the background of this proposal. The AHRQ Dissemination Planning Tool helps researchers consider six elements of effective dissemination: packaging of results, identifying endusers, engaging connector organizations, identifying and overcoming barriers to implementation, developing success measures, and allocating resources to implement the plan.

The plan also has two phases. Phase I involves dissemination of the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis*, which is an integral part of implementation to internal users. Phase II involves dissemination to more distant external users. These phases are iterative in that the initial implementation strategies and tools will be revised based on initial Phase I findings. The dissemination plan was developed within the framework proposed by Greenhalgh, et al.,²⁶ and is positioned between the “help it happen” and the “make it happen” ends of the continuum.

The six key components of the Dissemination Planning Tool can be briefly described as follows:

1. **Research findings and products:** What is going to be disseminated? The products to be disseminated are the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis*. As described earlier, these Phase I products are based on research findings.^{14, 19} The Phase II products will be accomplished following the analysis of the post-implementation period and will be disseminated at national meetings, on the AHRQ Patient Safety Research Coordinating Center site, and through publications. Phase II products will consist of implementation strategies (based on lessons learned) and the two interventions *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis*.

2. **End-users:** Who will apply the findings and products in practice? For the implementation in Phase I, the clinical providers and their patients in the UWMC and HMC inpatient and ambulatory care sectors are the endusers. The providers come from the full range of clinical services and specialties where patients are at risk for or develop VTE as described earlier in the application. Providers are health care professionals involved in directly or indirectly providing care to these patients at any phase: prevention through management. They include physicians, nurses, and pharmacists. Patients include any recipients of assessment, treatment, or preventive measures for VTE from either UWMC or HMC providers.

End-users for Phase II expand to AHRQ, to providers nationally, and to actual and potential patients nationally. AHRQ is committed to national dissemination, and we will provide the materials in forms that can be disseminated widely, in a variety of technical formats, and using a variety of technologic means.

3. **Dissemination partners:** Dissemination partners include individuals and organizations through which endusers can be reached. Phase I partners are the UWMC, HMC, Center for Clinical Excellence, UW Center for Health Science Education & Research, and the providers and patients involved in the implementation. During Phase II, AHRQ will be added as a dissemination partner. Other national organizations through which we might reach endusers include the National Patient Safety Organization, AHRQ-funded dissemination centers, National Quality Forum, and the network of patient safety researchers.
4. **Communication strategies:** What is the best ways to convey the research findings and products to end users? For Phase I, these involve a variety of in-person and online means to reach individual patients and providers, who ultimately are the adopters of this innovation in terms of choosing to use the recommendations or not. Research has shown that a variety of strategies are needed to link this systematic change with individual users and their perceived needs for information and tools. As noted in the Methods section, we will have formal didactic sessions in the form of grand rounds within and among the professional provider groups; written newsletters and e-mail notices; provider supports, reminders and forms within the electronic medical record; champions and dedicated support to the users; Web sites with factual and case-based material. Printed summaries of recommendations or prescriptions will also be available, along with Web-based materials, informative posters and buttons, and other visual displays. Phase II will add a package of implementation strategies based on our lessons learned and the evaluation of Phase I implementation strategies.
5. **Dissemination Plan.** As described earlier, we used the evidence-based planning tool developed by the AHRQ Patient Safety Research Coordinating Committee²⁷ to develop our dissemination plan. According to our plan, Phase 1 will reach internal users, and Phase II will target external, distant users. The AHRQ Dissemination Planning Tool will be used to guide regional and national dissemination in future years.
6. **Evaluation:** The evaluation will determine what did and did not work with respect to dissemination. The outcomes described in the specific aims are the primary method of evaluating actual usage and the effect of the Phase I dissemination. These outcomes include: (1) an increased percentage of hospitalized patients whose VTE risk factors are assessed and documented upon admission and on discharge; (2) an increased percentage of hospitalized patients without contraindications who receive prophylaxis for VTE; (3) a decreased volume of inappropriately ordered venous duplex scans, along with an increased rate of duplex scans

ordered for patients for whom it is appropriate; (4) an increased percentage of patients with a diagnosed VTE who receive appropriate therapy in the hospital and are discharged with appropriate outpatient therapy; and (5) improved provider knowledge about VTE prophylaxis and improved satisfaction with mandatory educational interventions through the use of interactive case studies. All of these evaluations can be extracted from the computerized record, quality improvement data (results of provider educational intervention), and provider surveys.

Discussion

Translation of Science Into Practice (Diffusion and Dissemination)

Although the evidence that should inform multidisciplinary practice in prophylaxis, diagnosis, and treatment of VTE is abundant, the adoption of relevant evidence-based guidelines into practice is limited. Why then do we think that implementation of the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis* will result in a higher rate of adoption than that achieved with prior efforts?

The strong commitment of the UWMC and HMC to improving patient safety provides a context in which multiple determinants of successful adoption exist.²⁶ Namely, these organizations see the goals of this project as compatible with their organizational goals of reducing VTE and of improving safe practice interventions with this patient population.

Observable and achievable outcomes directly related to the clinical work of the multiple disciplines involved in the care of this patient population will be measured. The *VTE Safety Toolkit* will be integrated into the normal working tools of the providers and will be “augmented” with customization, training, and the clinical equivalent of a “help desk.” The implementation of the *On-line Provider Training Module on VTE Prophylaxis* is an innovative method to change the business practices for providers at UWMC and HMC. The fact that senior administrators at both medical centers have agreed to implement the *On-line Provider Training Module on VTE Prophylaxis* as the first mandatory educational intervention (similar to HIPAA training) for an identified patient safety problem signals to providers that VTE prevention is a problem that has been recognized as an organizational one and, therefore, requires an organizational solution. Withholding patient care privileges for providers pending the successful completion of the *On-line Provider Training Module on VTE Prophylaxis* is evidence that the organization is looking for measurable changes and accountability.

The patient safety movement has, in large part, promised changes in the delivery of care based on an organization adopting a “culture of safety.” In 2007, at the National Patient Safety Foundation’s annual meeting in Washington, DC, a panel of experts commented on the fact that change will occur only when the business practices of an organization change, and only then, perhaps, a change in the culture will follow.

These leaders also said that the patient safety movement will not be successful unless providers are held accountable for knowing the latest standards of care and for monitoring the outcomes of the care they provide. The development of a mandatory provider educational intervention for

VTE prophylaxis represents a change in business practices for both UWMC and HMC. Whether this change has an effect on patient safety will be measured in the post-implementation data collection period.

Greenhalgh and colleagues' recent systematic review of the diffusion of innovation literature emphasized that adoption is a process, not a one-time event, and that it is an interaction among the innovation, the intended adopter(s), and the context.²⁶ Furthermore, they emphasized that adoption is "an organic and often rather messy model of assimilation in which the organization moves back and forth between initiation, development, and implementation, variously punctuated by shocks, setbacks, and surprises."

The VTE interventions were officially implemented on March 12, 2008, during a ceremony on VTE prevention. Guest speakers from the VTE Safety Toolkit team, along with national spokesperson Melanie Bloom (coalition to Prevent DVT) also presented at the ceremony. Proclamations to support March as VTE prevention month in the State of Washington were signed by the Governor and the King County Council chair. Post-implementation data collection will begin in September 2008. The conceptual model put forth by Greenhalgh and colleagues²⁶ guides the implementation content and processes for this study.

Network Structures

Various influences are involved in the spread of innovation, such as social network structures,^{28, 29, 30} similarities in backgrounds between potential and current users of the innovation,^{28, 30, 31} opinion leaders,^{31, 32} organizational champions (e.g., physician champions, nurse champions),³³ boundary spanners (i.e., individuals with ties both inside and outside the organization in relation to the innovation),³⁴ and formal dissemination programs within organizations.³⁴ The structure and quality of social networks greatly influence the adoption of innovation by individuals, and these social networks vary by different groups of individuals and by the types of influence used within the groups.²⁶ These groups may be formal or informal, and the social networks can be described as horizontal or vertical. Physicians typically operate in formal, horizontal networks, which are considered more effective for supporting the construction and meaning and for spreading peer influence (peer to peer).³⁴ On the other hand, nurses operate more commonly in informal, vertical networks, which are considered more effective for passing on authoritative decisions and for organizing codified information.^{30, 34}

The UWMC and HMC are academic medical centers with hierarchies within services. The network structures might be described as a combination of informal and formal and horizontal and vertical structures. Multiple providers—including nurses, physicians, and pharmacists—will be involved in the care of VTE patients, and understanding the network structures and cultures within these groups will aid in the successful dissemination and diffusion of the innovation. Physician, pharmacy, and nurse champions, expert opinion leaders, boundary spanners, and a formal dissemination program supported by UWMC and HMC will provide the context in which the innovation will be disseminated and diffused. After successful dissemination and evaluation of the post-implementation data, the interventions (*VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis*) will be made available nationally.

The *VTE Safety Toolkit* and *On-line Provider Training Module for VTE Prophylaxis* were not customized to be institution-specific, so that they would be applicable elsewhere after their effectiveness is tested at UWMC and HMC. Also, the processes and models for implementing the interventions and the dissemination strategies for translating the tools into practice will be shared.

Conclusion

VTE continues to be a national patient safety issue, and we have developed two educational interventions and recommendations for system changes that support the prevention and management of this clinical problem. The support of the administrations at both medical centers and the changes in the way training will be carried out for high-risk patient safety issues (VTE prophylaxis) is a change in business practices that hopefully will change the culture of safety. The organizational changes that support the *VTE Safety Toolkit* and *On-line Provider Training Module on VTE Prophylaxis* will improve patient safety and accountability around VTE.

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Using Process Measures to Improve Patient Safety Practices to Prevent Pulmonary Embolism

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Abstract

Pulmonary embolism (PE), or venous thromboembolism (VTE), is one of the most common and potentially preventable causes of hospital death. PE reduction is a key strategy to improving patient safety in hospitals. A pilot study involving six hospitals in New York State was conducted to implement targeted methods to improve physician compliance with known prophylaxis strategies and increase awareness of whether PE events were associated with proper prophylaxis or not. While the specific processes varied among participating hospitals, key components included: support of administration, physician champions, training on available tools, followup on patient risk assessment and guideline adherence, utilization of the process measures data collection tool, use of audit and feedback data, and a plan to address barriers to acceptance/adoption. Findings show a significant increase in prophylaxis utilization. Thus, for patients suffering adverse events, the increased use of process measures improves patient safety and outcomes in hospitals.

Introduction

In recent years, there has been an increasing amount of national attention paid to patient safety, especially in response to the two landmark reports by the Institute of Medicine: *To Err is Human: Building a Safer Health System* (1999)¹ and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).²

The Agency for Healthcare Research and Quality, in their published report *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* (2001),³ ranked patient safety interventions on the strength of the evidence supporting more widespread implementation. One of the highest ranked patient safety practices was appropriate use of prophylaxis to prevent venous thromboembolism (VTE) in patients at risk. Similarly, the Surgical Care Improvement Project, a national quality partnership that aims to improve surgical care through the reduction of postoperative complications,⁴ listed the prevention of VTE for surgical patients as one of four targeted areas.

The rationale for thromboprophylaxis in hospitalized patients is based on solid principles and scientific evidence. First, the incidence of VTE is significant because most adult patients admitted to the hospital have risk factors for VTE. Second, the adverse consequences of unprevented VTE include:

- Symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE).
- Fatal PE.
- Costs of investigating symptomatic patients.
- Costs of treatment.
- Risks of treatment, especially bleeding.
- Increased future costs of treating recurrent VTE.
- Chronic post-thrombotic syndrome.

Third, thromboprophylaxis is highly effective at reducing the frequency of symptomatic VTE and mortality from PE; and the cost-effectiveness of prophylaxis has been repeatedly demonstrated.⁵

PE is a common, potentially preventable cause of hospital deaths, and reducing mortality from PE is one of the most important objectives to improve patient safety in hospitals.⁶ However, despite national attention to VTE prophylaxis, it continues to be underutilized in hospitalized patients at risk, with lower compliance in medical patients.^{7, 8, 9}

The New York State Department of Health (NYSDOH) undertook a pilot project in 2004 to address utilization of PE prophylaxis in acute care hospitals located within New York State. The pilot project took the form of an evaluation of the impact of intensive training of hospital personnel on the importance of prophylaxis among those at risk for PE, linked to review of unprevented PE at each hospital to assess whether prophylaxis had been given. The goals of the study were to enhance professional knowledge and modify practice patterns in risk assessment and the use of prophylaxis for acute PE, thereby enhancing the quality of care for patients and reducing the incidence of future events.

Methods

Data for the study were collected through the New York Patient Occurrence Reporting and Tracking System (NYPORTS).¹⁰ NYPORTS is maintained by the New York State Department of Health as a mandatory patient event reporting system intended primarily for acute care hospitals. The system was implemented statewide in 1998 and requires hospitals to provide detailed information to the Department on serious adverse events, including PE, among acute care hospital patients.

Hospitals throughout the State were invited to participate in the study. Positive responses were received from numerous hospitals, and seven were selected for inclusion in the project. (One hospital ended its participation prior to the conclusion of the baseline study period.) The participating institutions were selected to ensure inclusion of hospitals from different geographic areas of the State, teaching and nonteaching institutions, and large- and medium-sized providers. Hospitals that were known to be timely submitters of the standard administrative inpatient data needed for the project were also favored. The final set of 6 hospitals included two very large hospitals (>700 beds), two large facilities (400 - 600 beds), and two medium-sized facilities (150 - 399 beds). Four different regions of the State were represented, with two hospitals located

on Long Island, one in New York City, two in the Western part of the State, and one in the Central New York region. All but one of the six hospitals are classified as “teaching” by the NYSDOH.

The study intervention at each of the six participating hospitals included staff training on PE risk assessment and prophylaxis protocol. This intervention was facilitated by a toolkit for VTE safety practices that was also developed and disseminated to all hospitals participating in the project.

Each hospital adapted the prophylaxis protocol presented in the hospital training toolkit to fit its facility’s care process. The tool kit contained the following items: consensus guidelines developed by the Rochester Regional Thromboembolism Collaborative¹¹; a Microsoft PowerPoint® slide deck used in education sessions by Strong Memorial Hospital (Rochester, New York); the study supplemental data collection tool and its associated data dictionary; a poster; a pocket card; other decision-support tools; and a bibliography with reference articles.

Although the final prophylaxis processes varied among participating hospitals, each included a number of key components: support of hospital administration identification of a physician champion, an educational program (i.e., written curriculum, didactic/interactive sessions, reference tools and materials), a plan for patient risk assessment and guideline adherence, the use of audit and feedback techniques, and a plan to address and correct barriers to acceptance/adoption. Table 1 outlines the methods used to implement the risk assessment and prophylaxis protocol for VTE, methods of compliance monitoring and feedback to physicians, and barriers identified or lessons learned.

In addition to the standard NYPORTS reporting requirements, hospitals were asked to submit detailed information on all adult PE patients. For each identified hospital-associated PE, hospital staff provided detailed descriptive data, including information on the type of prophylaxis given, timing of the administration, the admission service (e.g., cardiology, gynecology, medicine, orthopedics, general surgery), the method of PE diagnosis, and both major and minor risk factors. Patients were classified as either medical or surgical using information available in the supplemental information provided. A case was defined as surgical if either the admission service variable indicated “surgery” or operating room time was reported. The supplemental data collected also contained information on the treatment outcomes of patients. Included were indications of transfer to a higher level of care, major bleeding, extended length of stay, and in-hospital death. Hospitals made the determination as to whether cases met the criteria for required reporting to the Department of Health.

Cases included in the study are those with a PE, defined as any “new acute PE not present on admission, unless associated with a hospitalization within previous 30 days.” The method of diagnosis (e.g., V/Q scan, spiral CT, or angiogram) was not analyzed as part of this study. Chemoprophylaxis was defined as the patient receiving any one of five anticoagulant medications: argatroban (Novastan®), heparin (SQ or IV), dalteparin (Fragmin®), enoxaparin (Lovenox®), or warfarin (Coumadin®). Administration of the drug had to occur either prior to admission or during the hospital stay but prior to the occurrence of PE. Use of any of three other

Table 1. Methods of prophylaxis implementation, monitoring and lessons learned

Methods of risk assessment and prophylaxis implementation	Compliance monitoring and feedback	Barriers/lessons learned
Standardized risk assessment tool (guideline) for use in office setting and hospital	Peer review process	Takes a lot of leg work or up front investment
Standardized history & physical	Utilizing case managers	Need to standardize process outside the hospital setting
Standard or preprinted order sets	Daily concurrent review of physicians' orders	Need to educate on effective and appropriate use of IPCs as an alternate prophylaxis intervention
CPOE	Random record reviews	No decrease in VTE rate despite compliance with protocols – may be due to increased awareness and testing
Use of teams and physician champions	Specific memos to physicians regarding a case	VTE more prevalent in certain types of patients such as cancer patients or certain procedures (CABG or Orthopedic)
Electronic charting and force functions	Weekly report cards	No national guidelines for ambulatory setting
Use of posters, charts and pocket cards	Quarterly audits	Need for education of coders
Develop new Joint Center of Excellence Program for reducing hematoma post surgery and VTE	QA Review Committees	Underutilization of VTE prophylaxis for OB patients

H&P = history and physical; IPC – intermittent pneumatic compression; CPOE = computerized physician order entry; VTE = venous thromboembolism; CABG = coronary artery bypass graft; QA = quality assessment; OB = obstetric

modalities also qualified as prophylaxis. These nonpharmacologic (mechanical) modalities included intermittent pneumatic compression (IPC), graduated compression stockings, or inferior vena cava (IVC) filter. Individual hospitals determined which type of prophylaxis was used for each patient. Patients receiving only aspirin, either pre- or post-admission, were classified as not prophylaxed. Contraindications for chemoprophylaxis were also reported through the supplemental data provided by the study hospitals. Major contraindications for anticoagulant utilization among PE patients included active uncontrolled bleeding, cerebrovascular hemorrhage, dissecting aortic aneurysm, cerebral aneurysm, bacterial endocarditis, active gastric ulcer or ulcerative GI lesion, severe uncontrolled hypertension, and severe head trauma. For such patients, mechanical prophylaxis was usually appropriate with rare exception.

To ensure that hospitals reported information for all PEs, records meeting diagnostic criteria identifying PE were selected from the NYSDOH Statewide Planning and Research Cooperative

System (SPARCS) inpatient discharge data. Potential PE cases were identified on a quarterly basis for each of the six study hospitals if they met any of three criteria:

1. PE and infarction (ICD-9-CM code of 415.1X) or obstetrical blood clot embolism (673.2X) reported in any of 14 secondary diagnosis fields as not present at the time of admission.
2. PE and infarction (415.1X) or obstetrical blood clot embolism (673.2X) as a principal diagnosis, along with a hospitalization less than 31 days prior to the admission date associated with the target discharge.
3. Any secondary diagnosis of PE and infarction (415.1X) or obstetrical blood clot embolism (673.2X) reported as present on admission, along with a hospitalization less than 31 days prior to the admission date associated with the target discharge.

Discharges meeting any of the three criteria were compiled in a hospital-specific listing of potential PEs. The lists were sent to the project staff at each hospital along with a request for further details on the status of each case. Of the 522 SPARCS-identified cases, 50 percent were determined to be nonreportable events; 51.9 percent in the baseline, and 48.4 percent in the post-intervention period. Supplemental study data were then provided for all remaining cases on the lists. For PE cases that were considered reportable but had not yet been entered into NYPORTS, hospital staff also submitted the NYPORTS-required reports.

The baseline period for the study was June 1, 2003 to May 31, 2004. The impact of the intervention on prophylaxis practice at the six participating hospitals was assessed through a comparison of the rate of PE during the baseline period to the rate during the post-intervention period of July 1, 2005 to June 30, 2006. Relationships among measures were assessed using Fisher's exact test with $P < 0.05$ denoting statistical significance.

The prophylaxis rate was expected to increase for all PE patients, with a greater increase expected among high-risk patients. As a result, one-tailed tests of statistical significance were used to assess the impact of the study intervention. Tests of statistical interaction between patient characteristics and study period were conducted to determine whether the level of change in the rate of prophylaxis between the study periods varied by the level of risk for PE. No hospital-specific analyses were conducted due to the relatively small number of observations available at each site.

Results

The baseline period comprised 117 PE patients reported through NYPORTS and/or identified through SPARCS case review; 144 PE patients were identified in the post-intervention period. There were no statistically significant differences between the two periods in terms of the patients' sex or race.

A number of risk factors appeared infrequently in the study data (Table 2). Four patient characteristics showed the presence of a higher risk condition in less than 4 percent of total cases, with six characteristics showing elevated risk in less than 7 percent of cases. The relative frequency of each risk factor was similar between periods, with 10/12 factors showing no statistically significant difference. Severe sepsis/infection did show a significant difference

between periods, increasing from 0 (0.0 percent) to 9 cases (6.3 percent) ($P = 0.01$). The number of central venous access cases increased significantly from 1 (0.9 percent) during the baseline period to 17 (11.8 percent) in the post-intervention period ($P < 0.001$).

The relationship between patient characteristics and the use of prophylaxis is summarized in Table 3. Overall, 83.1 percent of patients at risk for PE received some form of prophylaxis. Among the 12 patient characteristics signaling increased risk for PE, a statistically significant relationship with the use of prophylaxis was found for only two. Patients reported as having a prior DVT/PE received prophylaxis in 94.3 percent of cases, while those without a prior event had a prophylaxis rate of 81.4 percent. Admission service, classified as surgical or medical, showed surgical patients having an 87.4 percent prophylaxis rate compared to a rate of 77.3 percent among medical patients.

Table 4 shows that the prophylaxis rate among patients with a NYPORTS reportable PE event increased from 76.1 percent to 88.9 percent ($P < 0.01$) following the study intervention. Tests for statistical interaction (available from the authors) revealed no significant differences in the magnitude of change in the prophylaxis rate associated with the different levels of the individual patient characteristics, including prior DVT/PE and admission service type. This suggests that the increase in the use of prophylaxis following the intervention did not reflect an emphasis on selected patient characteristics or conditions, many of which are established markers of elevated PE risk. Table 4 also shows that 24 (11.1 percent) of 217 patients prophylaxed during the study period had conditions for which pharmacologic methods of prophylaxis were contraindicated according to the guideline. During the baseline period, 9/12 patients (75.0 percent) nevertheless received pharmacologic prophylaxis, either alone or in combination with a mechanical prophylaxis device. Patients having contraindications and treated during the post-intervention period received pharmacologic prophylaxis with or without mechanical prophylaxis in 7/12 cases (58.3 percent). This difference in rates between the study periods was not statistically significant.

Patient Outcomes

The supplemental data on PE cases provided by hospitals contained a number of patient care outcomes. These included transfer to a higher level of care during the hospitalization, the occurrence of major bleeding, an extended length of stay, and in-hospital death.

Table 5 shows that there was no significant change in the proportion of cases transferred to a higher level of care (12.8 percent vs. 13.2 percent) or in those developing major bleeding (2.6 percent vs. 2.1 percent). Extended lengths of stay due to PE occurred in 10.3 percent of cases during the baseline period and in 5.6 percent of patients following the intervention. Death among PE patients during the baseline period was 6.8 percent with a similar rate of 4.9 percent in the post-intervention period. None of the changes in outcome rates between the two study periods was statistically significant.

Table 2. Patient risk factor and treatment by study period

	Baseline		Post-intervention		<i>P</i> -Value
	Number of Patients	Percent	Number of Patients	Percent	
Total	117	44.8	144	55.2	
Age					
≤60	40	34.2	50	34.7	0.93
>60	77	65.8	94	65.3	
Prior DVT/PE					
No	103	88.0	123	85.4	0.58
Yes	14	12.0	21	14.6	
Malignancy					
No	80	68.4	100	69.4	0.89
Yes	37	31.6	44	30.6	
Hypercoaguable state					
No	113	96.6	141	97.9	0.70
Yes	4	3.4	3	2.1	
Prolonged immobility					
No	96	82.1	124	86.1	0.39
Yes	21	17.9	20	13.9	
Myocardial infarct					
No	110	94.0	137	95.1	0.79
Yes	7	6.0	7	4.9	
Heart failure					
No	112	95.7	141	97.9	0.47
Yes	5	4.3	3	2.1	
Severe sepsis/infection					
No	117	100.0	135	93.8	0.01
Yes	0	0.0	9	6.3	
Stroke, nonhemorrhagic					
No	111	94.9	140	97.2	0.35
Yes	6	5.1	4	2.8	
Central Venous Access					
No	116	99.1	127	88.2	<0.001
Yes	1	0.9	17	11.8	
Service					
Medical	51	43.6	59	41.0	0.71
Surgical	66	56.4	85	59.0	
Surgery >45 min ^b	66		85		
No	23	34.8	25	29.4	0.49
Yes	43	65.2	60	70.6	

a Two-tail Fisher's exact test.

b Includes all cases with operating room time ≠ 0.

DVT = deep vein thrombosis; PE = pulmonary embolism

Table 3. Prophylaxis by patient risk factor and treatment

	Total	Prophylaxis administered		<i>P-value</i> ^a
		N	%	
Total	261	217	83.1	
Age				
≤60	90	71	78.9	0.12
>60	171	146	85.4	
Prior DVT/PE				
No	226	184	81.4	0.04
Yes	35	33	94.3	
Malignancy				
No	180	147	81.7	0.22
Yes	81	70	86.4	
Hypercoaguable state				
No	254	210	82.7	0.27
Yes	7	7	100.0	
Prolonged immobility				
No	220	183	83.2	0.56
Yes	41	34	82.9	
Myocardial infarct				
No	247	206	83.4	0.43
Yes	14	11	78.6	
Heart failure				
No	253	209	82.6	0.22
Yes	8	8	100.0	
Severe sepsis/infection				
No	252	208	82.5	0.18
Yes	9	9	100.0	
Stroke, non-hemorrhagic				
No	251	208	82.9	0.47
Yes	10	9	90.0	
Central venous access				
No	243	200	82.3	0.16
Yes	18	17	94.4	
Service		85	77.3	0.02
Medical	110	132	87.4	
Surgical	151			
Surgery > 45 minutes ^b				
No	48	42	87.5	0.60
Yes	103	90	87.4	

a Two-tail Fisher's exact test.

b Includes all cases with operating room time ≠ 0.

Table 4. Prophylaxis by study period

	Totals		Baseline		Post-intervention		<i>P</i> -value ^a
	Number of patients	%	Number of patients	%	Number of patients	%	
Total number of patients	261	100	117		144		
Number of patients receiving prophylaxis	217	83.1	89	76.1	128	88.9	0.01
Number of patients with a major contraindication ^b	34	13.0	20	17.1	14	9.7	0.06
Number of patients with a major contraindication receiving prophylaxis ^c	24	70.6	12	60.0	12	85.7	0.11
Type of prophylaxis used							0.15
Anticoagulant only	9	37.5	7	58.3	2	16.7	
Prophylaxis device only	8	33.3	3	25.0	5	41.7	
Both	7	29.2	2	16.7	5	41.7	

a One-tail Fisher's exact test

b Condition for which prophylaxis via anticoagulant is contraindicated.

c Percentages based on number of patients with major contraindication for prophylaxis.

Table 5. Patient outcome by study period

	Baseline		Post-Intervention		<i>P</i> -value ^a
	Number of Patients	Percent	Number of Patients	Percent	
Total	117		144		
Transfer to higher level of care	15	12.8	19	13.2	0.54
Major bleeding	3	2.6	3	2.1	0.55
Extended length of stay	12	10.3	8	5.6	0.12
Death	8	6.8	7	4.9	0.33

A One-tailed Fisher's exact test.

Discussion

The implementation of a risk-factor assessment and prophylaxis protocol at six hospitals produced a significant, short-term increase in the use of prophylaxis among PE patients. The post-intervention prophylaxis rate of 88.9 percent was higher and statistically significant compared with the baseline rate of 76.1 percent (Table 4). In other words, the rate of prophylaxis omission declined by over 50 percent, from 23.9 percent to 11.1 percent, from baseline to post-intervention.

Both the baseline and post-intervention prophylaxis rates compare favorably to published rates. For example, one study of surgical patients with diagnosed hospital-acquired VTE showed that only 44 percent had received prophylaxis prior to the event.¹²

Despite the efforts applied at the six hospitals, a prophylaxis rate ceiling of approximately 90 percent was found. We have no information on trends in the prophylaxis rate during the post-intervention period, which may be higher or lower. One possible explanation is that the systematic use of prophylaxis takes longer to implement than allowed by the study's observation period. Another reason could be that clinicians perceived patients to be at lower risk or more fully ambulatory than our collection of risk factors—according to the prophylaxis guideline—suggested.

Yet another potential explanation is that the hospital's ability to reliably respond to the identified risk factors is difficult to maintain in the face of staff and trainee turnover. A more effective way to ensure continued compliance with thromboprophylaxis is through a forcing function, such as a mandatory pathway in computerized physician order entry systems (CPOE) or other decision support tools that provide a reminder to clinicians.¹³

In addition, the “right rate” for prophylaxis using any specific guideline may not be 100 percent. By their nature, guidelines simplify patient categorization and clinician choices. As a result, practices that deviate from the guideline might not always be incorrect (in part, one of the factors differentiating guidelines from “rules” or “protocols”). For example, the guideline assumes that virtually all hospitalized patients with risk factors are not sufficiently active for ambulation to serve as the protection from VTE. The guidelines also tend not to explicitly incorporate situations where prevention of VTE is not consistent with goals of care (e.g., end-of-life care targeting comfort and eliminating or minimizing medications).

An opportunity for improved care also exists in reducing the number of patients with a major contraindication to anticoagulants who receive prophylaxis with anticoagulants rather than mechanical devices. In both the baseline and post-intervention periods, more than half of patients with a reported major contraindication to anticoagulants received such prophylaxis. Clinicians might not have noted the presence of or appreciated the significance of the major contraindications to anticoagulant use. While no information is available on the reasons for anticoagulant protocol use among these patients, it is conceivable that some of those receiving pharmacologic prophylaxis in the face of a major contraindication were nevertheless appropriate to receive anticoagulant prophylaxis (e.g., the risk reduction of VTE with anticoagulants instead of mechanical prophylaxis might have exceeded the risk of bleeding).

This study had a number of limitations. The generalizability of our findings is limited by our sample size of only six hospitals. Although the volume of patients at high risk in hospitals is substantial, as illustrated by the number of PE events available for analysis, this small number of hospitals allows only an aggregate level assessment of the effectiveness of the PE intervention. A study population of six organizations does not support meaningful examination of hospital variation in prophylaxis improvement. There is no evidence that among the six study hospitals, a single provider was responsible for the observed improvements in PE prophylaxis. However, it was likely that the diffusion of a standardized protocol for prophylaxis would be uneven and that the impact of the intervention would attenuate at different rates among hospitals. A larger sample

of hospitals with a longer followup period would provide opportunities to examine important variations among hospitals.

The smaller number of patients at the higher level of risk for the selected individual patient characteristics limits our ability to assess the true level of improvement among subsets deriving the greatest benefit from prophylaxis (e.g., patients with hypercoagulable state or heart failure).

We chose to study those patients that experienced a PE to focus hospitals' attention on prevention efforts by analyzing undesired adverse outcomes. This would tend to include more patients at higher risk. Conversely, to the extent that prophylaxis was effective, focusing on patients with PE events could include more patients where prophylaxis was not given or failed for some reason. It is possible that a different population—e.g., all patients at high or moderate risk for thromboembolic disease at the time of admission and prior to any thromboembolic event—would provide a different result, i.e., higher or lower prophylaxis rates.

Conclusion

Venous thromboembolic disease is a life-threatening complication that is potentially preventable. For many years, efforts have been made to increase the utilization of prophylaxis and to improve documentation explaining why prophylaxis was not utilized in a given case, e.g., identify systems barriers or clinical contraindications.

In this study of six New York hospitals agreeing to participate, additional tools were utilized along with additional resources and efforts to increase attention to the occurrence of PE and the appropriate utilization of VTE prophylaxis. Mixed results were achieved. It is not surprising that the largest improvements were achieved in those areas where prophylaxis was lowest. Minimal improvements were noted in areas where prophylaxis was already higher. It is also important to note that little improvement was achieved in reducing the use of anticoagulant prophylaxis in patients with contraindications among those who nevertheless developed a PE.

CPOE was utilized in only a single institution. Although the number of patients with PE was small, this particular hospital did evidence improved rates of prophylaxis. This anecdotal evidence provides hope for further improvement based on both synchronous decision support and improvement in documentation for contraindications.

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A Tool to Assess Compliance in Anticoagulation Management

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Abstract

Compliance with any medication can be quite variable and difficult to assess. Assessment becomes particularly important in the case of a medication, such as warfarin, that has multiple interactions and requires frequent laboratory monitoring. Good compliance with medication dosage and blood test monitoring are necessary to safely manage warfarin patients. The Community Anticoagulation Therapy (CAT) Clinic, established in 2005 through a grant from the Agency for Healthcare Research and Quality (AHRQ), Partnerships in Implementing Patient Safety (PIPS), measures compliance with warfarin therapy. The Clinic developed a tool called the “Warfarin Compliance Assessment Scale,” which assigns points to categories. The assessment scale provides the CAT Clinic with an objective way to measure an individual patient’s compliance in using warfarin. It is important to note that the scores of patients enrolled to date indicate an increase in their compliance over time. This paper describes the function and benefit of the compliance tool in the management of anticoagulation therapy.

Background

In 2005, the Agency for Healthcare Research and Quality (AHRQ) awarded a 2-year grant (Award No. 5 U18 HS015830) to Kirkwood Community College and Physicians’ Clinic of Iowa (PCI). The grant supported the creation of the Community Anticoagulation Therapy (CAT) Clinic and the Cedar Rapids Healthcare Alliance (CRHA), a nonprofit corporation established to oversee the CAT Clinic. The project’s broad coalition of stakeholders included provider organizations, hospitals, payers, employers, educational institutions, and patients. Another important project partner was Rockwell Collins, a large local employer that designs and manufactures aircraft avionics systems and has extensive experience in Lean, Six Sigma®, and ISO 9000™ quality systems. These stakeholders realized that working together on a community level was a positive way to improve patient care and safety.

In writing the grant, project investigators determined that anticoagulation management was a safety issue within the community. At that time, January through December 2004, there was no dedicated anticoagulation service in the area, and adverse drug events (ADEs) related to anticoagulation accounted for 25 percent of all ADEs at each of the two 400-bed community hospitals. It was estimated that 3,000 to 4,000 patients in our community of 150,000 were taking warfarin (Coumadin®), and that approximately 60 admissions related to bleeding and clotting events occurred annually at each hospital.

At the time the grant application was submitted, the National Quality Forum listed anticoagulation management utilizing a dedicated anticoagulation service as one of the 30 National Patient Safety Practices.¹ Warfarin was also included on the Institute of Safe Medication Practices (ISMP) list of high-alert medications.² In 2004, the Joint Commission listed to “improve the safety of using medications”³ as a requirement for their National Patient Safety Goals.

The Problem

The Cedar Rapids provider community serves a growing elderly population. The Cedar Rapids Chamber of Commerce reported that in 2005 and 2006, within three area counties (Benton, Jones, and Linn), there were 15,370 adults aged 65 to 74 and an additional 15,320 over age 75. Combined, this represents 13 percent of the population of these three counties.⁴ The fastest-growing segment of the population is adults over age 80; patients in this group frequently make mistakes in taking their medications. In a 2004 Information Technology Association of America Teleconference titled *Using a Patient-Based Information Technology Approach for Solving Prescription Medication Non-Compliance*, it was reported that (1) up to 60 percent of all medications prescribed are taken incorrectly or not at all, (2) up to 90 percent of elderly patients make some medication errors, and (3) up to 35 percent of the elderly make potentially serious errors when taking their prescribed medications.⁵

Since anticoagulation therapy is particularly risky, patients need to be aware of the risks and must closely follow established treatment protocols. Health care providers must also make appropriate treatment decisions by monitoring patients regularly and following established protocols. However, because many variables can affect an individual’s anticoagulation levels and compliance is difficult to assess, it can be quite challenging for clinicians to consistently monitor outpatients on anticoagulation medication. In order to meet these challenges, many health care facilities have established outpatient anticoagulation clinics for their patients receiving warfarin.

The purposes of the CAT Clinic include:

- Provide consistent monitoring of patients taking warfarin.
- Ensure that the international normalized ratio (INR) levels are within target range.
- Decrease adverse drug events (ADEs).

Although the structure of anticoagulation clinics varies among institutions, most clinics share some of the following policies and work-related procedures:

- Identify the roles and duties of clinic staff and personnel.
- Identify which patients are viable anticoagulation clinic enrollees.
- Develop electronic systems to track patients due for lab tests, document results of lab tests, and document successful patient management.
- Develop protocols for managing patient results and for timely reporting of results to physicians and health care professionals.
- Develop and update resources for ongoing patient education.

The Solution: A Compliance-Assessment Tool

Many different factors can affect how warfarin affects patients and their INR levels, which are used to adjust the required warfarin medication dosage. Quite early in our experience, it became apparent that there was no established method to measure patient compliance with anticoagulation management. For this reason, the CAT Clinic staff designed and developed a compliance tool, the Warfarin Compliance Assessment Scale (WCAS), that assigns points to the following categories (see Table 1):

- Medication use, such as the addition/discontinuance of antibiotics.
- Amiodarone.
- Herbal supplements, aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs).
- Dietary intake of foods high in vitamin K.
- Alcohol intake.
- Missed/extra doses.

Use of the WCAS assists the CAT clinic nurses when making dosage decisions and provides a simple way to monitor the effectiveness of overall warfarin management.

The Rockwell Collins improvement specialists provided guidance in the project team's use of Lean and Six Sigma concepts in their analysis of the current anticoagulation system in two busy cardiology practices in Cedar Rapids. Their analysis produced valuable objective advice on ways to improve the warfarin management system.

Under their expert leadership, the CAT Clinic designed and developed a Web-based database to precisely document individual patient visits. Each patient is specifically identified in the database, which incorporates the WCAS compliance tool, assigning points to each item on the compliance assessment scale. After a CAT Clinic patient's blood draw is completed and the CAT Clinic nurse has received the INR level results, the nurse can contact the patient and assess the patient's compliance with each of the items on the WCAS. If the patient reports a change in any of the items, the nurse can easily update the patient's individual record by clicking on the drop-down list and choosing the most appropriate item (Figure 1).

The database then calculates a score for the individual patient based on the number of visits and the total for each item selected from the compliance assessment. For instance, if a patient reported missing two doses of warfarin since the last INR, 2 points are assigned. If the patient had two INRs that month and a score of 2.0, the compliance score is calculated as 2.0 points divided by two visits, or 1.0.

Clinic nurses can use this information to help educate patients about certain important aspects of their medication compliance. In cases where patients may be consistently missing warfarin doses, the nurse and patient can work together to plan ways to improve compliance. In addition, patients' compliance scores can be reviewed in aggregate. The patient's score is tallied each month and plotted graphically. Figure 2 documents a decrease (i.e., improvement) in average compliance score over time, as patients become more educated about their individual dosing requirements, illustrating an increase in patients' understanding and compliance with their warfarin therapy.

Table 1. Warfarin compliance-assessment scale

Compliance categories	Points	Patient score
Missed doses (not prescribed)		
Missed 1 dose in a week	1	
Missed 2 doses in a week	2	
Missed 3 or more doses	3	
Additional doses (not prescribed)		
Took 1 extra dose	1	
Took 2 extra doses	2	
Took 3 or more doses	3	
Diet: How has your diet changed over the past week?		
Ate 1-2 <u>more</u> servings than usual of vitamin K foods	1	
Ate 3-4 <u>more</u> servings than usual of vitamin K foods	2	
Ate 4 or <u>more</u> servings than usual of vitamin K foods	3	
Ate 1-2 <u>less</u> servings than usual of vitamin K foods	1	
Ate 3-4 <u>less</u> servings than usual of vitamin K foods	2	
Ate 4 or <u>less</u> servings than usual of vitamin K foods	3	
Alcohol consumption		
Drank the usual amount of alcohol in the past week	0	
Drank more than your usual amount of alcohol this past week	1	
Binged (drank excessive amounts of alcohol) 1 or more times this past week	2	
Medications		
Started or stopped an antibiotic in the past week	Yes - 1 No - 0	
Started or stopped an herbal supplement in the past week	Yes - 1 No - 0	
Started or stopped an aspirin-containing product or an NSAID in the past week	Yes - 1 No - 0	
Started or stopped amiodarone or another medication this week	Yes - 1 No - 0	
Total Score		

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The CAT Clinic has successfully implemented several interventions that might affect patients' compliance scores. Each patient referred to the clinic receives comprehensive warfarin education, and the nurse conducts a "brown-bag" review of all their current medications. During this educational session, the nurse and patient review a booklet entitled, "*My Guide to Warfarin Therapy*," which was developed by several nursing faculty members at Kirkwood Community College who were studying the issue of health literacy.⁶

If INR too high or low, patient reason :

CAT Score Visit Assessment

Any missed doses (not prescribed)? :	No missed doses since last reading (0 pts)
Any extra doses (not prescribed)? :	No extra doses since last reading (0 pts)
More <u>Vitamin K</u> in diet? :	No additional Vitamin K taken since last reading (0 pts)
Less <u>Vitamin K</u> in diet? :	No additional Vitamin K taken since last reading (0 pts)
Alcohol Consumption :	Drank the usual amount of alcohol since last reading (0 pts)
Started/Stopped an Antibiotic:	No (0 pts)
Started/Stopped an herbal supplement:	No (0 pts)
Started/Stopped an aspirin or NSAID:	No (0 pts)
Started/Stopped an Amiodarone:	No (0 pts)

Figure 1. INRPro[®] database WCAS page.

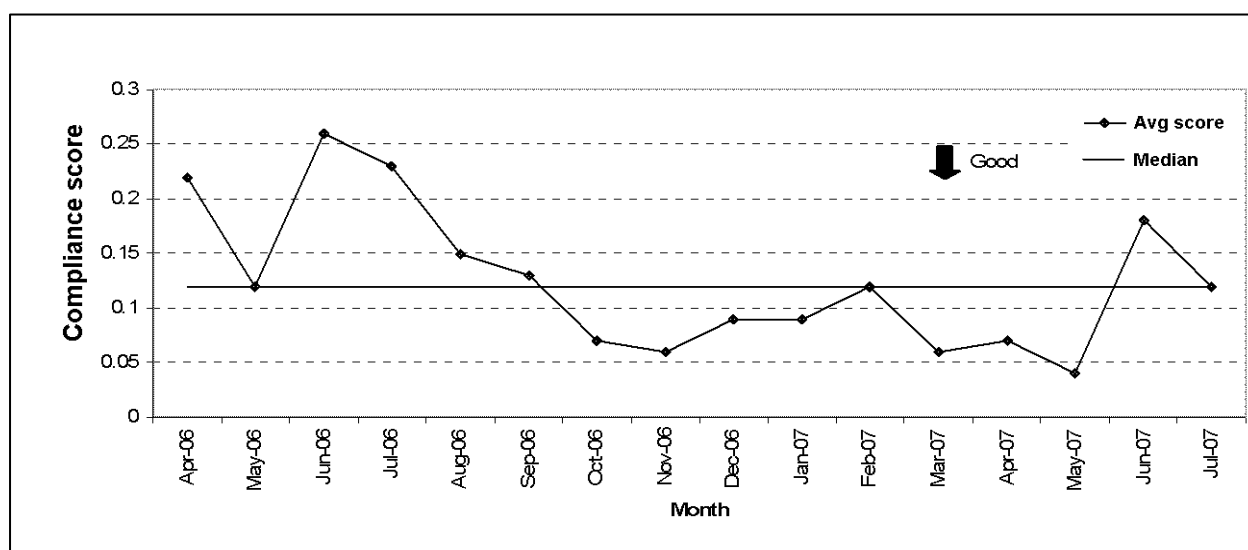


Figure 2. Average CAT compliance score, from April 2006 to July 2007.

Health literacy concerns are compounded by the high number of older adults living in the Cedar Rapids community who are taking warfarin. Many of these adults require intensive guidance in order to help them comply with their unique medication requirements. While this guide was in development, a group of participants at a local Cedar Rapids senior center reviewed the contents and provided valuable feedback that served to strengthen the guide. The nursing instructors reviewed the existing warfarin patient education materials and found that they were too difficult for patients to understand because they:

- Were written using medical language that was too technical.
- Were printed in a color other than black ink on white paper.
- Used too small a font and contained too few pictures (e.g., not enough “white space”).

The new guide is written at a fifth-to-sixth grade level and is printed in black ink on white paper using a larger size font. The guide uses numerous pictures and bullet points to explain important aspects of warfarin therapy.

During the “brown-bag” medication review, patients bring in their actual prescription pill bottles and all of their over-the-counter medications, as well as a list of medications they are currently taking. CAT Clinic nurses review each medication name, indication, dose, and frequency with the patient. If the patient has a question or does not understand something, the nurse uses this as an opportunity to educate the patient about his or her medication. If there is a discrepancy between the medication listed and the medication taken by the patient, the nurse contacts the patient’s primary care physician for clarification and confirms the correct medication and dosage with the patient.

Another intervention found to be useful in monitoring patient medication compliance and making dosage decisions is the control chart (Figure 3), which provides a statistical signal that a process might have gone awry, allowing the operator to make the necessary adjustments to bring the process back into control.⁷ The CAT Clinic utilizes the database mentioned above which displays a control chart of each patient’s historical INR values along with a histogram. This information allows the CAT Clinic nurse to make statistically based decisions on whether the patient needs a dose change, instead of basing decisions solely on the most recent readings. The compliance assessments, along with the use of the control chart, are simple techniques for making objective dosage decisions for the CAT Clinic patient.

Conclusion

Good compliance with medication and blood test monitoring are necessary for safely managing patients taking warfarin. In our community, and in most others, there usually is no established method to actually measure patient compliance with anticoagulation therapy. The AHRQ PIPS grant provided the necessary support to enable a community-wide group of health care professionals and manufacturing quality engineers to join forces to find solutions to this problem. The CAT Clinic staff and the quality engineers worked together to develop a compliance tool that assigns points to various aspects of medication use, diet, and alcohol use.

In addition to assisting clinicians in making warfarin dosage decisions, the WCAS score has become useful for assessing and updating patients' plans of care. The tool can be customized to review an individual patient's compliance, and it can be aggregated to provide accurate data on all patients in an anticoagulation clinic. The tool is easy to use, provides an objective measure of patient compliance with warfarin therapy, and has made a positive impact on patients seen in the CAT Clinic.

Acknowledgments

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Using Lean Six Sigma® Tools to Compare INR Measurements from Different Laboratories Within a Community

Brion Hurley, CSSBB; James M. Levett, MD, FACS; Carla Huber, ARNP; Tim L. Taylor, SSBB

Abstract

Whenever measurements are taken on a patient or health care process, the measurement system must be analyzed in order to verify that it is adequate for the application. A Gage Repeatability and Reproducibility (R&R) study was performed to determine if blood samples taken from a patient on warfarin have the same International Normalized Ratio (INR) results when analyzed in different labs (reproducibility) and when analyzed multiple times in the same lab (repeatability). Results showed a statistically significant difference among labs. The therapeutic range for INR is typically 2.0 to 3.0, yet the data showed a difference in INR of 0.4 among labs on a small sample of 10 warfarin patients, almost 50 percent of the range. Root cause analysis revealed that the normalizing number (mean normal prothrombin time, MNPT) utilized in one of the labs varied greatly from other area labs. The team determined a new qualification process for MNPT to keep results consistent across all the labs.

Introduction

Use of anticoagulation within the inpatient and outpatient settings has expanded greatly in recent years, particularly with the aging of the population and the growing number of indications for anticoagulation. Over 2 million patients in the United States are taking warfarin (a blood anticoagulant, also referred to as Coumadin®),¹ and it is estimated that between 3,000 and 4,000 patients in the Cedar Rapids community take warfarin on a regular basis.

Cedar Rapids is a northeastern Iowa community with a population of approximately 150,000, and a primary and secondary service area of around 300,000.² Warfarin anticoagulation accounts for approximately 25 percent of adverse drug events (ADEs)³ (i.e., any unexpected or dangerous reaction to a drug) in the two community hospitals. Cedar Rapids has a high proportion of elderly patients who are at particularly high risk for an ADE.

Several members of the physician and health care provider community believed that establishing an anticoagulation clinic within the Cedar Rapids community would allow standardization of protocols for prescribing warfarin, improved monitoring of patients on warfarin, and improved communication with patients. The features of such a clinic would also improve the culture of safety within the community, reduce errors and adverse drug reactions, and reduce readmissions for complications in patients taking warfarin.

Establishing an anticoagulation clinic specifically addresses two National Quality Forum safe practice items:⁴ Item 1. Creation of a health care culture of safety; and Item 18. Utilization of dedicated antithrombotic services that facilitate coordinated care management.⁵

In 2005, the Agency for Healthcare Research and Quality (AHRQ) awarded a 2-year grant (Award No. 5 U18 HS015830-02) to Kirkwood Community College and Physicians' Clinic of Iowa (PCI). The grant supported the creation of the Community Anticoagulation Therapy (CAT) Clinic and the Cedar Rapids Healthcare Alliance (CRHA) to oversee the CAT Clinic. The project represents a broad coalition of stakeholders including provider organizations, hospitals, payers, employers, educational institutions, and patients.

Rockwell Collins, Inc., designer and manufacturer of aircraft avionics and military systems, with several ISO certifications and extensive experience in Lean, Six Sigma^{®6} and ISO-9000⁷ quality systems, agreed to offer training in Quality, Lean, and Six Sigma concepts. To identify areas for process improvement, Rockwell Collins improvement specialists began work with community health care providers during the analysis and design phase of clinic development. The design and operation of the anticoagulation clinic involved numerous quality concepts used in the avionics industry; one specific experience is discussed in this paper.

Methods

The Rockwell Collins improvement specialists, with a background in Lean and Six Sigma, used the Define-Measure-Analyze-Improve-Control (DMAIC)⁸ approach for improving this process. Each phase of the DMAIC model is very structured with respect to both the actions completed in the phase and the improvement tools implemented.

To begin the project, the specialists spent several days evaluating the overall process of anticoagulation management currently being performed at two cardiology clinics in Cedar Rapids. These two practices manage approximately 2,000 patients on long-term warfarin therapy, representing about half of all warfarin patients in the community. The evaluation involved process and value stream mapping, combined with the application of Lean and Six Sigma concepts in the overall analysis.

One of the first steps when making improvements to any metric is to determine if the measurement system is adequate. Early in the experience, it was determined that four laboratories were being used within the community to run tests for the International Normalized Ratio (INR) values—the key measure of warfarin anticoagulation—for the patients. In this process, the question was whether the INR values were comparable among the different labs.

The labs explained that, since normalizing factors are taken into account to adjust for equipment and plasma material differences used in the testing process, INR values are indeed standardized, in contrast to the prothrombin time (PT) values previously used to manage patients. To validate this statement and the measurement system, a Gage Repeatability and Reproducibility (R&R)⁹ study was performed at two of the four labs. A Gage R&R study is a structured statistical experiment that is designed to compare the repeatability (within the same lab) and

reproducibility (between labs) and to compare measurement variations to the typical limits needed for the process. The details of the Gage R&R are described below.

To conduct this experiment, it was necessary to make a case that the experiment was needed. Thus, a small study with non-warfarin patients was established to see what preliminary results could be obtained. The patients who participated in the study were informed of the experiment ahead of time, and appropriate consent was obtained. Four volunteers involved in the project were used for the initial study, and six tubes of blood were collected from each volunteer (all from the same blood draw) at the same lab (Lab A). To remove the lab-to-lab blood draw process variation from the study, one lab was chosen as the “Host.” Three tubes were sent to a second lab (Lab B), while retaining the other 3 tubes at the first lab (Lab A). Each lab would take PT and INR results at three specific times during the day: 8 a.m., 12 pm, and 4 p.m. Thus, each volunteer would have three tubes tested at each lab, at established times of the day. The experiment would determine if testing time delays or differences between the two labs provided a greater influence on INR determinations (Table 1).

Results

After collecting the data, it was noted that there was a consistency to the repeat results within 8 hours of testing. However, there appeared to be a lab-to-lab difference. Table 1 summarizes the data, by patient, to document the observed differences. The Gage R&R calculations showed that the R&R variation accounted for 38.49 percent of the

Table 1. Summary of INR differences between Labs A and B

Patient	Average INR		INR Difference
	Lab A	Lab B	
1	0.953	1.050	0.097
2	0.890	0.963	0.073
3	1.010	1.100	0.090
4	1.000	1.097	0.097
Average	0.963	1.053	0.089

INR = International Normalized Ratio

tolerance, with most of the variation coming from the reproducibility (lab-to-lab differences). Therefore, almost 40 percent of the variation in a patient’s therapeutic range (typical therapeutic ranges for INR values are 2.0-3.0; 2.5-3.5; and, 3.0-4.0) could be coming from the measurement system. A good measurement system must be less than 30 percent, and ideally less than 10 percent. The difference between the two labs was statistically significant, even with just the four patients used in the study ($P < 0.001$), which justified using actual warfarin patients. Permission was obtained from the Institutional Review Board, which serves the two community hospitals in Cedar Rapids, to begin work on the followup Gage R&R study.

Since the 8-hour blood testing time delay study did not show any significant differences, the second experiment was revised to focus on the differences in lab results using 10 patients. The 10 patients who participated in the study were informed of the experiment ahead of time, and appropriate consent was obtained. They were selected on a “first-come, first-served” basis. Each patient had his/her blood drawn from Lab A, and the blood was then separated into six tubes.

Three tubes remained at Lab A for testing, and three tubes were immediately sent to Lab B for testing. The labs were located near one another, so after some discussion with lab personnel, it was agreed that there was minimal concern about travel and handling effects.

The initial findings with the non-warfarin patient Gage R&R study were confirmed by a significant difference between INR results from Lab A and Lab B ($P < 0.001$) (Table 2). The Gage R&R study results determined a percent of tolerance of 116 percent, which is far worse than the initial study. This variation required attention first, before trying to address the root cause of the patient's INR result variation, since the measurement system can be a significant factor in these differences.

The next step was to determine the root cause of the differences. A better understanding of the INR formula was needed. The INR value is a normalized

value to measure the coagulation time of a patient's blood. If the results are too high or too low, compared to the recommended therapeutic range, then the patient's dosage is adjusted accordingly. Since dosage changes are made based on this value, it is critical that the INR values be precise and accurate. A defect of the anticoagulation management process occurs when dosage is changed unnecessarily (Type I error) and when dosage is not changed when it should be (Type II error). Reducing the variation in the INR actual values would reduce the chances of Type I and Type II errors.

The INR value is calculated from a blood test, using the prothrombin time (often called pro time, which measures how many seconds it takes the blood to coagulate) and the International Sensitivity Index (ISI) rating of the thromboplastin (reagent) being used at the lab to test the blood. The purpose of pro time/INR ratio is to offset differences in thromboplastins and instruments being used at various labs, so a patient can get the same results, regardless of where the blood test is performed.

The third variable in the INR equation is a normalizing factor, called the mean normal prothrombin time (MNPT), which is the geometric mean of the PT of 20 or more non-warfarin

Table 2. Summary data from warfarin patient Gage R&R study

Patient	Average INR		INR difference
	Lab A	Lab B	
1	2.777	3.170	-0.393
2	2.100	2.320	-0.220
3	2.887	3.110	-0.223
4	1.693	1.830	-0.137
5	2.920	3.160	-0.240
6	1.267	1.413	-0.147
7	3.877	4.320	-0.443
8	2.090	2.240	-0.150
9	2.993	3.300	-0.307
10	3.300	3.553	-0.253
Average	2.590	2.842	-0.251 ^a

a $P < 0.001$

R&R = repeatability and reproducibility

patients, conducted annually at each lab. This is the factor used to standardize labs to one another:

$$\text{INR} = (\text{Patient pro time}/\text{MNPT})^{\text{ISI}}$$

For Lab A, MNPT = 11.4 and ISI = 1.93; for Lab B, MNPT = 11.9 and ISI = 1.97. It was initially thought that the differences in ISI values were the cause of the variations, since they were directly attributable to the manufacturer of the thromboplastin. However, looking at the INR equation, the impact on INR results seemed to be more highly affected by MNPT differences than ISI differences. To clarify this, a hypothetical simulation was conducted using patient data but keeping either the ISI or MNPT value constant for both labs.

After running the simulation with both the ISI and MNPT values held constant, the difference between labs was still significant if the ISI values were equal (Table 3). They became insignificant if the MNPT values were equal (average difference = 0.019).

This indicated that the lab differences were a result of differences in MNPT value. The next step was to determine why the MNPT values were different.

First, the process used to calculate MNPT had to be understood. Each lab used 20 non-warfarin patients, both males and females, to determine the MNPT on an annual basis. Each lab took a minimum of 20 individuals,

tested their blood with the current lot of thromboplastin, and calculated the geometric mean of the pro time determinations from those patients. To better understand how the labs came up with vastly different MNPT values, the data from those 20 patients were needed. Since there was no accepted standard for the optimal MNPT value, the data from all four labs were obtained and used to help understand which lab MNPT value was more accurate.

The normal patient pro time results from each lab are shown in Figure 1. The results from Lab A differed significantly from the other labs. The difference between the pro times of Lab A and Lab B was statistically significant ($P = 0.0003$). Compared to Lab C and D, Lab B appeared to

Table 3. Simulation results: Constant ISI value (1.97), different MNPT values

Patient	Average INR		INR difference
	Lab A	Lab B	
1	3.167	2.855	-0.313
2	2.318	2.138	-0.180
3	3.106	2.967	-0.139
4	1.832	1.719	-0.113
5	3.157	3.005	-0.152
6	1.409	1.276	-0.153
7	4.323	4.016	-0.307
8	2.240	2.130	-0.110
9	3.301	3.081	-0.220
10	3.554	3.406	-0.148
Average	2.841	2.659	-0.181 ^a

a $P < 0.001$

ISI = International Sensitivity Index; MNPT = mean normal prothrombin time; INR – International Normalized Ratio

be closer in average. Thus, there was reason to suspect that Lab A was doing something different from the other labs, which could have led to lower pro time values. This would change the MNPT value, which consequently changed patients' INR results. However, the possibility could not be excluded that Lab A had the correct MNPT value, and the other lab results were less accurate.

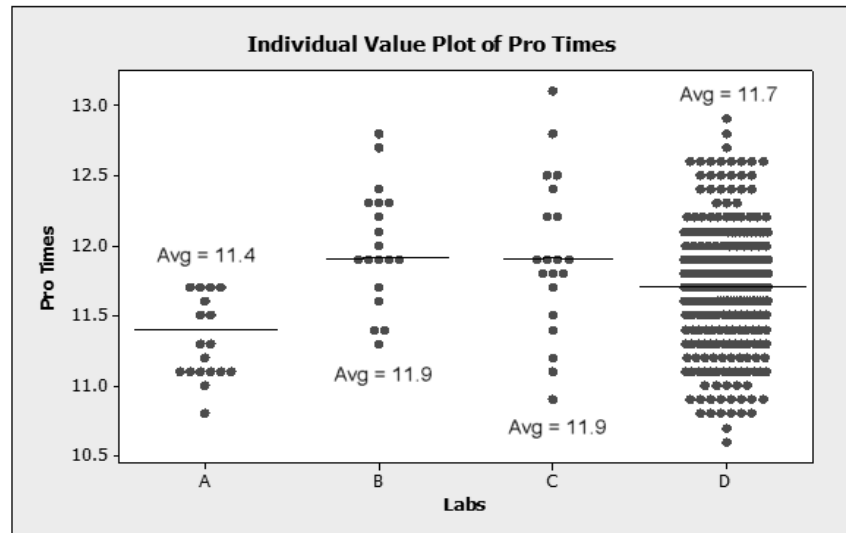


Figure 1. Individual values plot of pro time results from non-warfarin patients by lab.

To review the results and brainstorm the potential causes for the discrepancy, we convened a meeting that included representatives from the four labs and the test equipment manufacturer. All data from the study were presented and reviewed with the team. A Cause-and-Effect (Fishbone) Diagram was then created to organize the causes.⁸ The Rockwell Collins support team facilitated the session.

The group identified numerous possible causes. Under “Measurement,” some labs performed statistical analysis on the results to identify outlier MNPT values (results that would fall outside 3 standard deviations from the group mean of the sample), while other labs used all patient determinations without checking for outliers. Under “Methods,” the criteria for selecting a “non-warfarin normal” patient seemed to be rather ambiguous, where some labs used staff and personnel in the lab, and others used patients coming in for blood testing who were not on warfarin. As a result of the brainstorming session, the group came to the consensus that a new MNPT calculation process was needed, one that would be consistent among all four labs in Cedar Rapids.

Under the new MNPT process, blood samples would be collected within the same group of “normal” patients using new criteria provided by the equipment manufacturer. The samples would be divided evenly and provided to each lab to collectively set up the equipment and MNPT values at their facility. Labs with MNPT results that differed from the others could be quickly identified and corrected before test results were provided to actual patients.

The group also decided to transition over to Innovin[®], a manufactured thromboplastin that has a consistent ISI value. This change minimizes the amount of adjustment that needs to be made with every new lot of material shipped and avoids the need for coordination of thromboplastin lots within a community. Previously, all labs within a city, region, or community had to have the same thromboplastin lot number, which required a great deal of coordination from both the labs and the thromboplastin supplier. This change became official in Cedar Rapids in March 2007.

Discussion

Once the Cedar Rapids community had successfully addressed its measurement system issues, the focus could move to individual patients and how they could better control their INR results. Luckily, the groundwork had already been established on how to capture and analyze patient INR data. In practical terms, most patients in our community typically use the same lab for all their testing, so lab differences would not be likely to directly affect the variation of their results, although it could consistently offset the true result for each patient. To adjust for that lab difference, some patients might get more or less medication than they need.

On a national scale, many patients on warfarin are “snowbirds,” who travel south for the winter. Blood testing still occurs in their winter destination, so this variation in lab values might be even greater than that in their local community. If the labs are not in agreement, then some patients are getting results higher or lower than their true INR value and are unknowingly receiving a different amount of medication due to the difference in testing methods.

One of the goals for improving the process is to reduce the communication time from completion of the lab testing until the patient is notified of the INR result. Lean tools, useful for addressing process speed, are employed in this process to address the lag time. We observed that each lab had different names for these lag times, and some labs measured the lag times at different points in the process. Consequently, the time data needed from the labs had to be standardized first, before the overall cycle time could be properly managed and tracked in the system.

The new system also integrates a first in - first out (FIFO) approach, showing the order of patients needing to be called, based on how long their results have been in the system. Specific time goals can also be established within the new system to highlight specific parts of the process that take longer than expected (e.g., time to enter data into the system when sent from the labs) and to help identify areas for improvement.

Another observation is that some of the labs batch INR results and fax them to the clinic all at one time or when some predetermined number deemed sufficient are available to be faxed. This is commonly done when processes are handed off to another area because it is an efficient way to minimize the total amount of time for the labs to fax results. However, batching often extends the overall length of time that patients have to wait to receive their results. Batching might be optimal for the labs, but the customer (patient) does not get timely results with this approach. “One-piece flow” is a key teaching point of Lean methodology, since it seems counterintuitive to those working in the process. After explaining the impact on the patient, the labs have been encouraged to fax the results as soon as they are completed to reduce the overall time it takes to communicate back to the patient.

With improved INR data coming from the labs, another goal of the project was to identify the reasons why so many dosage changes had been made in the past. Since the INR value was the key indicator for dosage changes, the team agreed that having the ability to monitor and track real-time patient INR data was critical. In the process of designing the CAT Clinic processes and procedures, it became clear that a software system and database were needed. No software products available on the market fit the needs of the project, so a new software system was

designed by an outside software development company and programmed specifically for the CAT Clinic.

One of the key features needed in the new database system was Statistical Process Control (SPC).¹⁰ A control chart of each patient's historical INR values was integrated into the system, along with a histogram, enabling the nurse practitioner to make a statistically based decision as to whether a patient required a dosage change. Typically, this decision was based solely on the most recent results (last INR value compared to current INR value), background knowledge of the patient, and the experience level of the nurse in an anticoagulation clinic. If the patient's INR result was within the control limits, then the patient was deemed "under control," and the standard dosing guidelines were applied to that patient. If the patient was deemed "out of control," then a more detailed evaluation of the patient's compliance to their dosing, diet, and medication usage was necessary before making any permanent dosage changes.

With SPC in place, the patients' results were entered into the system and the chart displayed, along with any "out-of-control" conditions. The control chart helped identify these conditions through the use of trend analysis and statistical control limits. These limits helped identify the region where a high probability of INR results should fall, specific to each patient. Results outside that region were unlikely (low probability of occurring), based on that patient's historical results, and had to be investigated.

Trend analysis looks for patterns in the data, such as 6 increasing or decreasing points in a row, or 9 data points above or below the average line. These may still fall within the statistical limits, but they would be indicators that something abnormal is happening, prompting an investigation. Not all identified "out-of-control conditions" are valid or indicate a problem, but they all require evaluation.

If an out-of-control condition were deemed relevant, and an assignable or identifiable cause were determined for the out-of-control condition, then either the cause would be noted and the data point essentially ignored, or the process would be changed (dosage change or change in testing frequency) to correct the issue. An example of an out-of-control condition is a situation where a patient admits to recently ingesting a large amount of alcohol. This would explain the higher INR result, so there would be no evidence showing the dosage amounts to be incorrect. In such a case, the data point would be isolated and reviewed with the patient, who would be asked to return for another INR test at a later date after the effects of that issue have been minimized.

Repeat INR determinations would be made until the patient was back in therapeutic range. An incorrect conclusion from that situation might result in a permanent dosage change that could inappropriately lower the patient's INR, especially if the patient avoided alcohol ingestion. This dosage adjustment, to account for outliers and special causes, could lead to serious complications. This new approach requires the clinic staff to ask a lot more questions of the patient to determine whether a special cause exists. To help increase understanding of this concept, clinic and lab personnel are now provided with SPC training to explain the details behind outliers and out-of-control conditions.

Figure 2 shows an actual patient's control chart (the patient's name has been changed). The bar in the middle of the figure denotes the patient's therapeutic range; the changing line indicates the patient's actual INR results; the areas directly above and below the bar in the middle of the figure are the patient's statistical process control limits (three

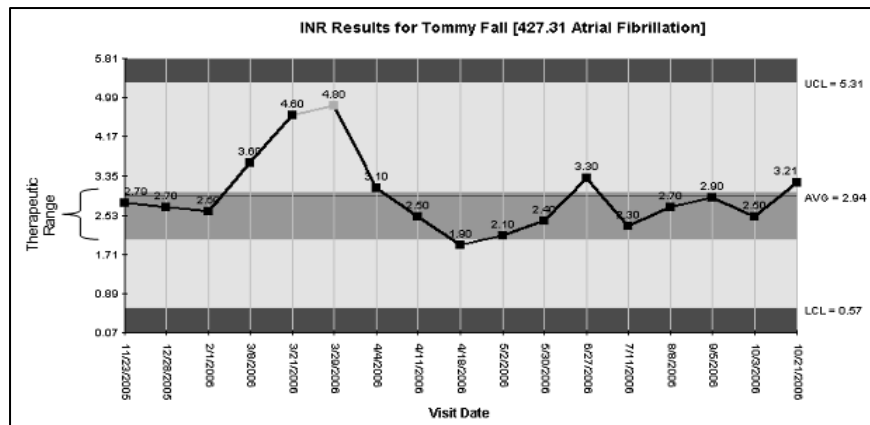


Figure 2. Warfarin patient SPC chart, from INR Pro[®] software.

standard deviations above and below the average); and the very top and bottom bars are considered an unlikely INR value for the patient that falls outside individual control limits.

Based on historical data, we have learned that this patient does not stay within the therapeutic range very often. The range is 2.0 to 3.0, yet his average result is 2.94, on the high end of the range. On March 29, 2006, “Tommy” had an INR determination of 4.80, which violated one of the out-of-control condition criteria (2 out of 3 consecutive data points beyond the 2-sigma warning limits) and therefore indicated that an investigation was needed. His INR results appeared to be steadily increasing, possibly due to the medication. Later on June 27, 2006, he had a result of 3.30, which was outside his range but well within his control limits, so an unnecessary dosage change was avoided. By now, there were enough data to support a dosage change to lower the INR result, so that the results would be closer to 2.5. The key difference in this dosing approach is that more than one data point was used to determine the need for a dosage change.

The use of SPC differs from the current method used by many providers because with SPC, the nurse practitioner and physician no longer make dosage change decisions based on “gut-feel” or intuition, which often leads to an effect called “tweaking,”¹¹ commonly referred to as a Type I error. Tweaking is intuitive to most people, since it attempts to make minor process changes to achieve a better end result. For example, if the patient had an INR of 2.65, and the appropriate range was 2.0 to 3.0, with 2.5 being the target value, it would be intuitive to want to slightly reduce the patient’s dosage in order to get closer to the ideal value of 2.5. However, the difference between 2.65 and 2.5 is most likely due to “noise,” or random variation in the process. Noise can result from a patient’s eating habits, lab variation in testing, blood draw techniques, and time of day, among many other possible factors.

In attempting to make fine adjustments to the patient’s dosage, tweaking may erroneously make things far worse for the patient. Every time the dosage is changed, the risk of hospitalization increases or a bleeding episode might occur due to excess or insufficient medication. The patient also might become confused about the new medication dosage and when it is to be taken. Warfarin patients are often elderly, which makes it harder to implement dosage changes.

Another concern is that some patients have more variability in their INR results compared to other patients. If a patient has a wider range or variation in his/her INR results, then the provider must be more cautious when making dosage changes for that patient, since historical data suggest that large changes in INR results would be expected for that patient.

Control charts must be understood in the clinical setting. Traditional control charts use an estimate of 3 standard deviations to determine the width of the control limits. Due to the lack of frequent results (lab tests taken weekly or monthly, not daily) and the fact that the random variation in INR readings has not been quantified (How much does an INR result vary throughout a given day?), modifications to the traditional control chart for application in anticoagulation management might be needed. As the use of SPC and control charting increases for managing anticoagulation patients, additional analysis must be performed to better understand whether 3 standard deviations is an appropriate calculation for control limits.

When the statistical upper control limit for a patient exceeds a value of 5.0—considered to be “high risk” for a complication—there is another concern with this new approach. If a patient has a therapeutic range of 2.5 to 3.5 and his/her INR is 4.7 (less than the upper control limit), then some intervention may be needed in order to reduce the immediate risk of a complication. This would be the case even though an INR result of 4.7 was not considered “out of control.” Additional guidelines and decision rules need to be developed to deal with these unique situations in order to avoid additional patient harm. Regardless of these concerns, it is imperative that INR results be viewed in a control chart format before making any decisions about a patient’s dosage amounts.

Conclusion

In summary, the use of statistical tools and techniques, such as Gage Repeatability and Reproducibility studies and Statistical Process Control (key tools utilized in Lean Six Sigma programs), have practical application in health care, specifically in an anticoagulation management process. The benefits expected from these improvements include reduced dosage changes (causing fewer adverse drug events), shorter response times in communicating results to the patient, better patient access to historical results (Web-based access to their data to help them take more accountability for managing their results), and less variation in INR results among the labs (causing fewer dosage changes and more time in range).

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Using Six Sigma[®] Methodology to Improve Handoff Communication in High-Risk Patients

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Abstract

Background: During the analyses of adverse events, a commonly described risk factor is the sharing of patient information. **Objective:** The objective for this project was to better understand and improve the postoperative handoff process for children with heart disease. **Methods:** The existing handoff process was evaluated and improved using Six Sigma[®] methodology and medical simulation training. Time-based metrics were compared before and after implementing performance improvement initiatives. **Results:** 29 pre- and 142 post-intervention handoff events were studied. Initiatives resulted in a reduced handoff turnaround time (15.3 min to 9.6 min; $P < 0.001$) and time to obtaining critical laboratory studies (13.0 min to 2.4 min; $P < 0.001$); an increase in chest radiographs completed (60 percent vs. 94 percent; $P < 0.01$) and percent of patients placed on cardio-respiratory monitoring (86 percent vs. 99 percent; $P < 0.01$) within unit standards. **Conclusion:** In children undergoing surgical intervention, performance improvement principles can improve the handoff process and decrease the delay of time-sensitive therapies.

Introduction

Medical errors have been recognized as a relatively common and potentially avoidable cause of patient harm. In its landmark report, *To Err is Human: Building a Safer Health System*, the Institute of Medicine (IOM) estimated that up to 98,000 deaths occur each year because of preventable medical errors. Higher rates were observed in intensive care units (ICU), operating rooms, and emergency departments.¹ In contrast to the past model of individual responsibility, the IOM report's authors concluded that errors are more frequently "caused by faulty systems, processes, and conditions that lead people to make mistakes." Although an individual clinician might be the proximal cause of an adverse event, organizational factors can create the circumstances in which a failure of judgment occurs.

This organization-based approach to improving health care delivery echoes the model utilized in other safety-critical industries, such as aviation, nuclear power, and the military. These high-reliability organizations view increasing safety as a systems-based endeavor.^{2, 3, 4, 5} To this end, attempts have been made to apply the manufacturing industry's Six Sigma[®] methodology and the automotive industry's Toyota Production System to medicine.^{6, 7, 8, 9, 10} Regardless of the specific approach, the fundamental concept is the same: a system is viewed as a set of interdependent elements acting together toward a common goal.¹¹

The focus on the process of health care delivery, in addition to the individuals who provide it, involves understanding each step used in a particular activity. By “mapping” the process, two important aspects of health care delivery have recently been brought to light: uncertainty about how a health care provider’s task should be performed and the way the activities of many individuals are coordinated.¹⁰ The frequent bedside solution is to treat the immediate problem but not to analyze the underlying obstacles that prevented optimal performance. This temporary fix is commonly referred to as a “workaround.”^{9, 10}

During the analyses of adverse events, a commonly described contributing factor is the sharing of patient information among health care providers.¹² An association between these communication failures and preventable medical errors has been suggested in all health care settings.^{12, 13} Furthermore, the transfer of patient information between health care providers—the “handoff”—has been recognized as a risk factor for adverse events.^{14, 15}

Communication among health care providers is particularly important in high-intensity, high-stress environments that demonstrate a greater incidence of medical error, such as the intensive care unit.^{1, 16} In this setting, patients may be more susceptible to human error due to the severity of their illness and the need for more frequent intervention.^{17, 18}

One such vulnerable patient population comprises children with heart disease. These patients are at increased risk for adverse events because of the complexity of their diagnosis and clinical instability, especially following a surgical intervention. Commonly, the management of such patients requires multiple disciplines—such as pediatric cardiothoracic surgery, cardiology, critical care, and anesthesiology—to coordinate decisions. Research suggests that communication failures frequently occur during the operative procedure, with “minor” events leading to serious consequences.^{19, 20} As a result, a delay in communicating critical patient information could lead to deterioration in a child’s clinical status.

Despite recognizing that communication failures can significantly affect clinical outcomes, limited data exist on how providers caring for critically ill children exchange patient information.

The overall objective of the current study was to apply performance improvement concepts to the handoff process in order to better understand and improve the way a pediatric critical care team communicates critical information for children with heart disease. We hypothesized that: (1) communication errors commonly occur during the postoperative handoff process, and (2) standardizing this process would decrease the time to obtain important diagnostic information. Specifically, standardization would reduce the time from patient arrival to completing handoff communication (turnaround time); reduce time to obtaining vital laboratory results (lab draw time); increase the percent of chest radiographs (CXR) taken within 15 minutes of patient arrival (unit standard); and increase the percent of patients placed on bedside cardiorespiratory (CR) monitoring within 3 minutes (unit standard).

Methods

Six Sigma Methodology

In order to better understand the process of handoff communication in the pediatric ICU (PICU), we utilized the Six Sigma methodology framework. This performance improvement philosophy began in the industrial sector and has gradually spread to other non-manufacturing industries. It is a data-driven approach that is focused on improving system capabilities and decreasing process variability. Often compared to the scientific method, this approach consists of the following five steps that are commonly abbreviated as “DMAIC”: Define, Measure, Analyze, Improve, and Control.^{8, 21}

The “Define” phase consists of identifying integral elements of a process, such as the individuals involved and the steps deemed “critical to quality.” For example, during the first phase of this study, a multidisciplinary focus group created a list of 18 handoff elements considered essential to providing postoperative patient care.

The “Measure” phase focuses on understanding the current process. The aim of this stage is to determine the system’s capability within the existing organizational structure. In health care, this step often involves identifying drivers of patient outcomes, such as error rates. This stage also provides a baseline performance standard against which future changes can be measured.

Once the baseline performance is defined, the “Analyze” phase pinpoints areas of high variability and identifies potential causes. In this step, process flow diagrams may demonstrate areas of greatest process inconsistency or lack of role clarity that require more immediate intervention.

Through an iterative process, the “Improvement” phase centers on creating solutions to decrease the variability of a process and to bridge critical gaps in the current system. Changes may be large in scope or limited in size. More importantly, the solution to a problem is most effective when individuals actually performing the specified tasks are engaged in creating it. In health care, this creation should involve bedside providers, such as nursing staff.

Once a more robust process is achieved, the “Control” phase emphasizes efforts that sustain these improvements. In addition to ensuring continued success, this step also involves monitoring for new problems created by system changes. In health care, for example, this may involve new methods to detect medication errors.

Study Site and Population

The methodology for the first phase of this study—the “Define,” “Measure,” and “Analyze” steps of Six Sigma methodology—has been described in detail elsewhere.²²

The second phase of this study—the “Improve” and “Control” steps of Six Sigma methodology—took place at a free-standing, tertiary care children’s hospital with a 20-bed PICU that cares for patients of all subspecialties, including those requiring extracorporeal life support. Of the approximately 1,200 children admitted per year, 25 percent of these patients have undergone surgical intervention for cardiac defects.

The study population for this second phase consisted of anesthesia, surgery, and PICU providers caring for children with heart disease following a surgical procedure.

Outcomes

Handoff process. The process of verbally communicating patient information between health care providers during the transfer of care is commonly referred to as a “handoff” and was the key process studied. Specifically, we focused on the handoff that occurs when a patient is admitted to the PICU following surgery for acquired or congenital heart disease.

The admission handoff process is critical for the following several reasons: (1) patients are often clinically unstable during the admission period and may require urgent therapies; (2) PICU staff often have limited knowledge of the patient’s medical history and, as a result, utilize this handoff process as a key source of information; (3) time to review the medical record prior to critical interventions is frequently limited; and (4) patients often require coordination of management decisions made by providers in multiple disciplines.

Data collection and outcomes. A clinically trained research assistant directly observed 29 pre-intervention and 142 post-intervention postoperative handoff events for children who had undergone surgery for congenital or acquired heart disease. Measured clinical metrics included: time from patient arrival to handoff completion (turnaround time), time to obtaining vital laboratory studies (lab draw time), the percent of chest radiographs (CXR) taken within 15 minutes of patient arrival (unit standard), and the percent of patients placed on bedside cardiorespiratory (CR) monitoring within 3 minutes (unit standard).

Statistical Analysis

The central focus of our data analysis was to determine the effect of a standardized handoff process on the aforementioned clinical metrics. A control chart was used to analyze process variation (including common cause and special cause variation) and to compare outcomes before and after intervention. All data analyses were performed with JMP[®] statistical software (SAS Institute, Cary, NC).

Approval by the Institutional Review Board at the Duke University School of Medicine was obtained prior to conducting this study.

Results

As identified in Phase 1 of this study—the “Define,” “Measure,” and “Analyze” steps of the Six Sigma framework—communication errors frequently occurred during the postoperative handoff communication process (mean 5.6; median 5.0 errors per handoff event). These most commonly involved information pertaining to a patient’s medical history or current surgical intervention (87 percent of communication errors). Furthermore, the handoff process was found to be negatively affected by the following three factors: (1) clinicians involved in a patient’s recent care did not consistently participate; (2) the handoff content and method were poorly standardized; and (3) interruptions or distractions were frequently present during handoff events.

Because of this initial evaluation, the “Improvement” step focused on a standardizing the communication process. This standardization centered on establishing a team handoff model and modifying the environment in which the handoffs occurred.

Team Handoff Model

As previously identified, clinicians involved in a patient’s recent care often do not contribute to the sharing of critical data during the handoff process. To address this communication gap, a team approach was created. This model required all relevant members of the care team—specifically, at least one representative from the pediatric cardiothoracic surgery, anesthesia, and critical care services, as well as the primary and unit charge nurses—to be present during the handoff process.

To further improve the role clarity of each provider during the handoff process, two additional process steps were outlined. First, to avoid competing clinical demands from distracting providers during the verbal report, each patient care discipline identified urgent tasks that needed to be completed prior to the verbal handoff process. For example, the patient’s primary nurse had to first review all currently infusing intravenous medications before listening to the patient report.

Second, to improve understanding of a patient’s current clinical status and expected trajectory, the verbal handoff event was divided into specialty-specific sections. For example, the cardiothoracic surgery team reviewed the patient’s history and current surgical procedure first; the anesthesiology team reviewed the anesthetic course second; and the critical care team asked clarifying questions third.

To educate the multidisciplinary health care providers caring for children’s heart disease in structured communication techniques, the staff underwent “team training” through the TeamSTEPPS™ curriculum. This program, developed by the Agency for Healthcare Research and Quality (AHRQ) in collaboration with the Department of Defense, is an evidence-based curriculum focused on improving patient outcomes by developing communication and other teamwork skills among health care professionals.²³

Work Environment

To minimize interruptions and distractions during the handoff process, we adapted a concept championed by the aviation industry—the “sterile cockpit.” In response to the increasing number of commercial airline accidents involving the cockpit crew’s attention being diverted from more critical tasks, the Federal Aviation Administration enacted regulations to prohibit crew members from performing nonessential duties or activities (including conversation) while the aircraft is involved in the phases of flight most commonly associated with error: taxi, takeoff, and landing.²⁴

Interpreting this concept for clinical medicine, the sterile cockpit was employed during the verbal transfer of patient information. Specifically, only patient-specific conversation or urgent clinical interruptions occurred during the sign-out process. As in the aviation industry, the integrity of this environment is the responsibility of all providers at the bedside, not just the reporting staff.

The aforementioned performance improvement interventions resulted in a reduction of turnaround time (15.3 min to 9.6 min; $P < 0.001$) and lab draw time (13.0 min to 2.4 min; $P < 0.001$); an increase in chest radiographs completed (60 percent vs. 94 percent; $P < 0.01$); and percent of patients placed on bedside cardiorespiratory monitoring (86 percent vs. 99 percent; $P < 0.01$) within unit standards. (Figures 1 and 2)

Discussion

To better understand and improve the handoff communication process in the critical care setting, we applied the Six Sigma methodology framework to current clinical practice.

In the “Define,” Measure,” and “Analyze” steps of the process, several important contributing factors for communication error were demonstrated:

- Clinicians involved in a patient’s recent care did not consistently participate in the communication process.
- The handoff process was poorly standardized.
- Interruptions or distractions were frequently present during handoff events.

Furthermore, our results revealed that communication errors most often involved information about the medical history and current surgical intervention.

In the “Improve” and “Control” steps, we demonstrated that standardizing the handoff process reduced the time necessary to obtain clinically important diagnostic information—specifically, handoff communication time; reduced time to obtaining critical laboratory studies; and increased the percentage of chest radiographs completed and the percentage of patients placed on bedside cardiorespiratory monitoring to within unit standards.

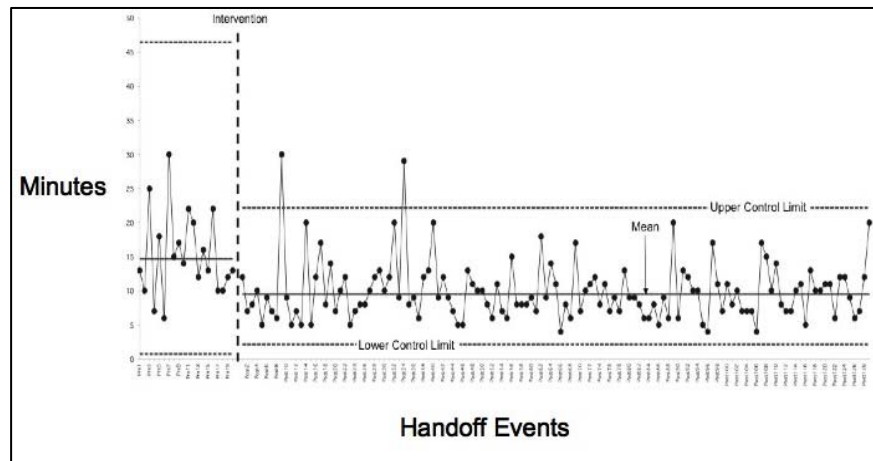


Figure 1. Handoff turnaround time.

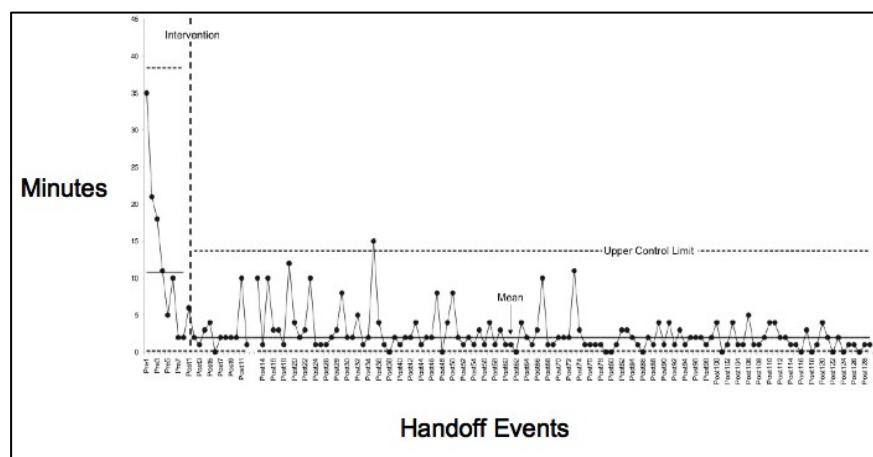


Figure 2. Time to critical lab draw.

In delivery of time-sensitive therapies, our structured team approach to communication also may have contributed to more effective team performance. As evident in other high-reliability organizations, team training concepts—such as teamwork, communication techniques, flattening of hierarchy, mutual respect within and across disciplines and situational awareness—are key components of a culture of safety. Furthermore, improving coordination of care through a structured communication process is especially important in environments in which uncertainty, interruptions, and multitasking are commonplace, such as the critical care setting. This coordination of care helps to create a “shared mental model” of a patient’s status and the expected clinical trajectory. As a result, any deviation from the anticipated postoperative course is more readily identified.

Future Directions

In addition to the two handoff communication aspects considered “critical to quality” in this study, minimizing disruption and the team handoff model, a third factor remains undefined: standardizing the sign-out content to ensure that each member of the team similarly understands the salient clinical data.

Communication checklist. Addressing the content of handoff communication involves principles of cognitive psychology. To facilitate an individual’s comprehension of what is communicated, information must be organized in a form that the recipient is prepared to mentally process. This realization has led many high-reliability organizations to utilize structured communication techniques, such as checklists and “read-back” techniques.^{5, 25, 26}

The use of a checklist as a memory aid serves two purposes: First, it ensures that critical information necessary for patient care is not overlooked; and second, it provides a consistent order in which information should be communicated. However, a checklist’s content and design must be prudent and strategic.

Although a checklist can enhance memory, longer lists may negatively influence their function. When the checklist is lengthy, there is a tendency to perform other tasks while reading the checklist in an effort to overcome a time-consuming procedure.²⁷

Furthermore, errors in the use of aviation checklists most often occurred when crews were nearing the end of the workday or rushing to make a scheduled departure time. During these latter periods, the checklist was either done from memory or was initiated but never completed.²⁸ The similarity between the cockpit setting and other high-stress clinical environments, such as the ICU, suggests a need to employ human factors engineering and crew resource management tools when implementing checklists.

Medical simulation. Although checklists may improve the consistency of handoff content, they may not directly address the question of whether all members of the health care team understand a patient’s current clinical status or expected trajectory. To this end, the use of human patient simulators has previously been employed to assess a team’s situation awareness. The concept refers to a person’s understanding of a continually changing environment, such as the ICU, and is associated with the availability of relevant information and an individual’s expertise.²⁹

Situation awareness may be divided into the following three levels: (1) perceiving elements in an environment, (2) comprehending the current situation, and (3) anticipating future status.²⁹ Furthermore, the principles of situation awareness can be applied to team environments, such as the critical care setting, and can be integral to the “Control” phase of the Six Sigma framework

Outcomes. The efficacy of system-based interventions can be assessed by process measures, outcome measures, and balancing measures.

Process measures refer to how the system components function. Composite measures assess whether each step in the process is being performed as planned, whereas “all-or-nothing” measures evaluate how often a patient receives the intended care when all process steps are completed. In our handoff communication process, for example, a composite measure may include how often the sterile cockpit environment is present. Although these measures reflect how well providers consistently perform the process, they do not provide information regarding patient-specific outcomes.

Outcome measures refer to the results of an intervention—i.e., metrics that are important to the patient. In our study of handoff communication, we used the time to obtain diagnostic information as a surrogate for outcome measures. However, it is not possible to conclude a direct cause-and-effect relationship, since many factors—such as duration of mechanical ventilation, length of stay in the PICU, and mortality rates—affect global measures.

Balancing measures refer to changes in the system, intended and unintended, following an intervention. Understanding these metrics requires individuals to avoid applying theories or models of safety to health care without first understanding the existing health care environment. Not doing so could result in the reasons for success or failure of an intervention remaining unclear. As growing evidence suggests, success in one environment does not necessarily predict success in another.³⁰ For the described structured handoff process, these measures include staff satisfaction and surrogates of productivity, such as patient flow.

Limitations

Despite the increasing complexity of patients with congenital heart disease cared for at our institution, the last several years have seen a gradual decline in mortality (Figure 3). The impetus for this decrease is most probably multifactorial, in which performance improvement efforts may have played a significant role. However, without the detection of adverse events, it is not possible to

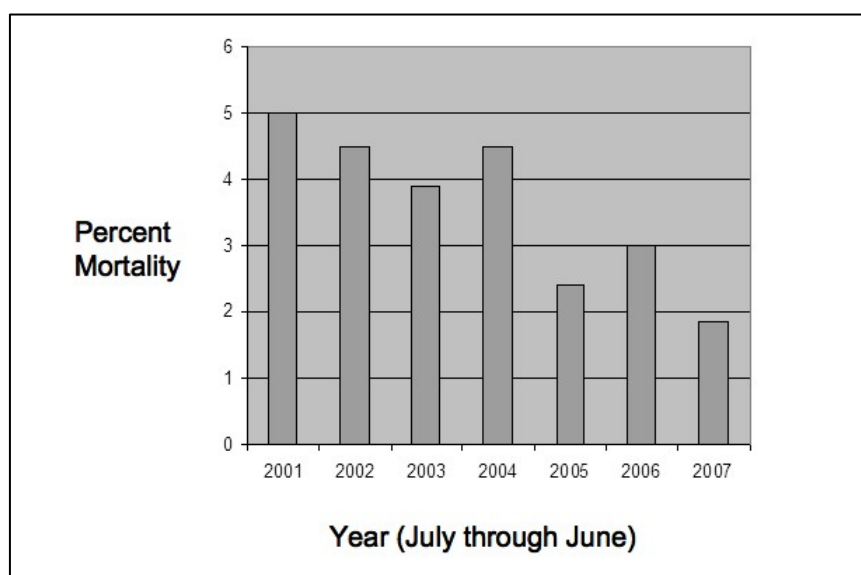


Figure 3. Congenital heart disease operative mortality.

know which handoff communication errors are clinically relevant. Since adverse events are often the result of a series of system failures, a direct causal relationship between miscommunication and an unintended outcome is often not practical.^{31, 32, 33} Communication errors, however, can be considered a gap that, when addressed, may help prevent accidents from occurring.

Conclusion

We found that communication delays commonly occurred during the handoff process of patients being transferred from the operating room to the intensive care unit. The solution to these gaps in communication was probably not based on a single approach but, rather, was due to the combination of performance improvement principles, information technology, human factors methodology, crew resource management/team training, and cognitive psychology.^{5, 34, 35, 36, 37, 38, 39}

The results of this study not only add to the growing literature demonstrating the prevalence of communication failures, but also provide insight into how process improvement concepts from other high-reliability organizations can be applied successfully to health care. Given the success of this initiative in the pediatric ICU, we have since expanded the project to focus on handoffs between other inpatient units—for example, between the PICU and noncritical care units. Furthermore, the study's findings suggest solutions to meet national health care mandates regarding communication, such as the National Quality Forum's *Safe Practices for Better Healthcare* recommendations to facilitate "information transfer and clear communication" among health care providers, and the Joint Commission's *National Patient Safety Goals* requirement to standardize an approach to handoff communication.^{40, 41}

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10-Year Experience Integrating Strategic Performance Improvement Initiatives: Can the Balanced Scorecard, Six Sigma[®], and Team Training All Thrive in a Single Hospital?

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Abstract

Objective: This article demonstrates how Duke University Hospital has taken three widely diverse quality management initiatives and melded them into a comprehensive approach to achieve our strategic goals. **Methods:** The Balanced Scorecard (BSC) is a management system focused on developing a mission, strategic goals, and key metrics and linking these to specific operational initiatives. Six Sigma[®] provided a solid performance improvement framework utilizing the DMAIC approach: Define, Measure, Analyze, Improve, and Control. Team Training translated aviation's Crew Resource Management principles to a health care-specific methodology. **Results:** Utilization of the BSC has led to an increase in net margin by 236 percent. Six Sigma reduced the risk score in moderate sedation from 11.94 to 4.94 and event probability score from 3.31 to 1.34. Team Training increased awareness of safety processes by 26 percent, communication as a team by 29 percent, and independent observations of overall teamwork by 72 percent. **Conclusion:** The BSC consolidates strategic initiatives; Six Sigma facilitates focused improvement within operations; and Team Training improves communication across disciplines. Understanding these differences and building upon each approach's individual strengths is essential to success.

Introduction

A number of quality management and performance improvement (PI) methodologies are readily available for use in the hospital setting.^{1, 2, 3, 4} However, these models consist of differing frameworks and flow processes, which often compete for resources and may even have conflicting goals. Many of these methodologies have been used in business and then translated to health care.^{1, 2, 4}

One concern with this translational approach is that the goal of business is primarily to improve shareholder value, whereas the primary goal in medicine is to improve patient care. As a result, the direct translation of these business principles to health care can result in confusion as to which strategy is best for what problem. In addition, as new methodologies are introduced, the questions become:

- What exactly does this new methodology replace?
- How do these methodologies interact with each other?
- What resources are being rechanneled or added to support this approach?

Such questions are routinely asked by physicians, who often verbalize frustration at being “kept in the dark” regarding strategic planning, quality management, and PI efforts.

To eliminate these questions and other impediments to success, one needs to systematically implement clinical improvement strategies in a way that utilizes the advantages of each approach, while focusing on long-term goals. The three approaches that will be outlined in this article include the Balanced Scorecard (BSC), Six Sigma, and Team Training. They represent a small component of the quality management arsenal, but they do illustrate how one can develop a thoughtful PI platform that readily supports the overall strategic plan.

The Balanced Scorecard

Originally developed to support PI in industry, the BSC has been touted as a strategic planning framework that consolidates multiple improvement projects into a single integrated platform.¹ As such, the scorecard is an integration of multiple interventions and keeps “score” of the success or failure of the strategic goals. This approach is fundamental to success, promotes balance in the organization, and aligns all disciplines around a focused strategic agenda. The BSC at Duke Children’s Hospital has assisted in driving the success of the PI initiatives toward achieving the strategic goals.^{2, 5} However, PI at the operational level requires additional tools and techniques that bridge the gap between strategy and tactics. Two specific tools that have been introduced in our hospital to perform this function include Six Sigma[®] and Team Training.

Six Sigma[®]

Six Sigma is a data-driven approach that has been shown to excel at drilling into specific problems and reducing “defects.”³ As such, Six Sigma represents a focused look at a specific practice. This methodology has been successful in manufacturing and other industries where work processes are associated with high levels of variability and where improvement efforts have the ability to measure specific data.³ The methodology follows a very specific pattern outlined from experience in industry, consisting of 5 phases, which make up the DMAIC model: (1) Define, (2) Measure, (3) Analyze, (4) Improve, and (5) Control (Figure 1). Six Sigma projects are highly focused, “microscope-like” evaluations of specific practices. These projects require a team of individuals trained in Six Sigma methodology, data collection, and data analysis, as well as individuals who can initiate operational interventions to improve the targeted practice.

Team Training

While PI methodologies provide an important framework for improvement, these changes are not sustainable unless the improvement model also addresses the human factors that affect the process. Providing health care requires fallible human beings to work in an incredibly complex environment with little room for error. In order to achieve sustained improvement, it is essential that we minimize the risk associated with human failures. Team Training, also called “Crew

Resource Management,” is a methodology that has been used in the aviation industry to improve human performance, communication, and team work.⁴ Customizing this approach for health care provides a unique approach to PI that focuses on human behavior and helps identify ways to reduce or mitigate risk through enhanced communication and more effective teamwork.

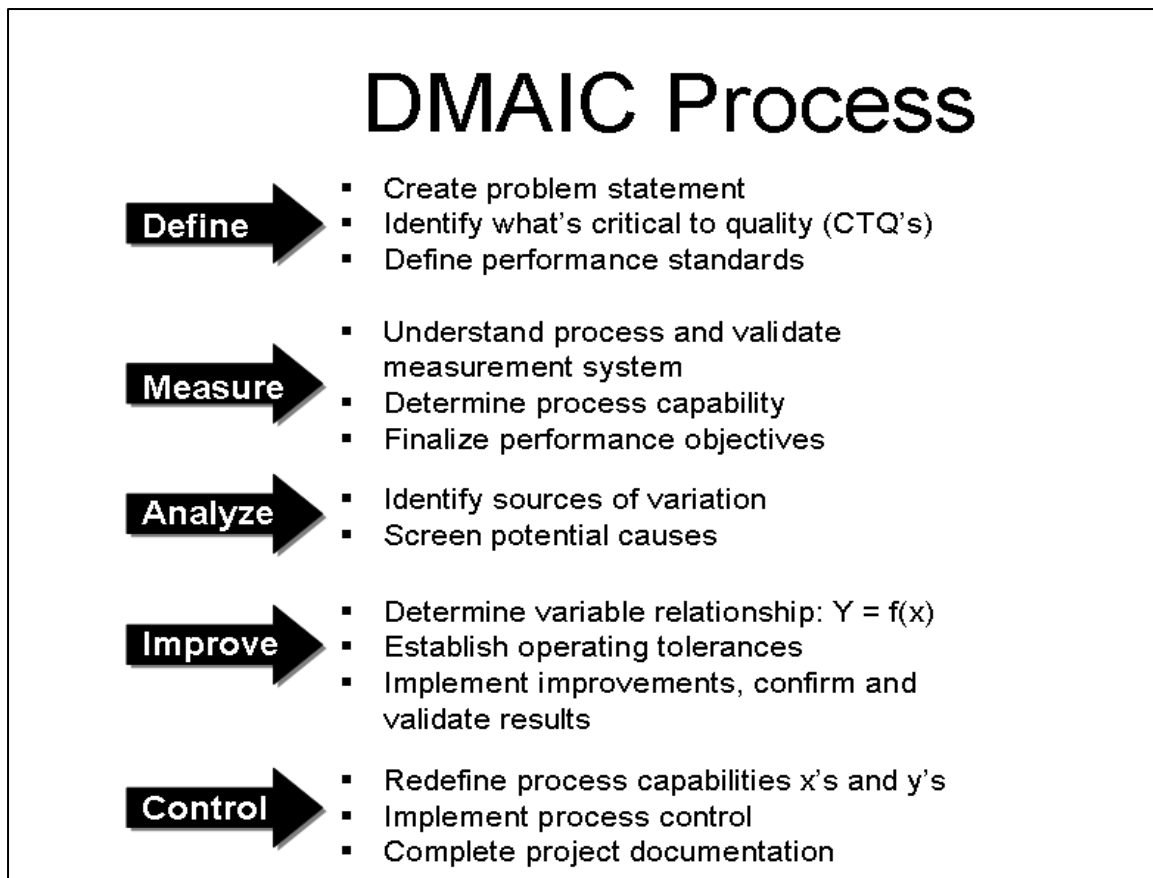


Figure 1. Six Sigma[®] methodology. Six Sigma is a data-driven methodology using the DMAIC approach.

A multitude of clinical improvement approaches can be successful in a variety of settings. The goal of this article is to demonstrate how our institution has taken three of those approaches and melded them into a comprehensive model to achieve our strategic goals.

Methods

Balanced Scorecard

Balanced scorecard methodology starts with the development of the mission and strategic plan.^{1, 2, 5} Senior management sets the strategic goals and provides support for the project. Once the senior management team has defined the strategic goals, the key metrics that measure performance are developed. Finally, initiatives are developed to improve performance and support achievement of the strategic goals. The scorecard functions as an important strategic

platform that drives the integration of key initiatives, methodologies, and processes across critical perspectives.

When translating the scorecard to health care, a significant modification of the “traditional” perspectives is required.^{2,5} The major difference in a health care BSC, as opposed to an industry BSC, is that the major focus of the health care organization’s vision and mission is on patient safety and clinical quality rather than on financial performance. To reflect this difference in focus, the scorecard is modified in the following manner:

Defining perspectives. The traditional BSC has the following perspectives: Financial, Internal Business, Customer, and Learning and Growth. The Financial perspective is typically located on the top of the card showing its importance as the key concern for the organization. Health care modifications that have been used successfully include changing the perspectives to Quality and Patient Safety, Customer, Finance and Work Culture. The Quality and Patient Safety perspective is placed at the top indicating its priority importance in health care.

Defining goals linking performance metrics. Once the strategic plan is defined, specific goals are determined by the team and linked to each strategic perspective. Limiting the goals to three or four per perspective is essential in order to maintain focus on initiatives that will drive the strategic plan. After the goals are determined, specific metrics are defined and linked to each goal. The metrics must be measurable and collected at least quarterly. Performance targets are then defined and linked to each metric. It is best to pick a modest improvement from baseline, such as 10 to 20 percent in the initial scorecard. Many of the operational metrics that populate the BSC are derived from a variety of databases that may include hospital operational and financial databases, patient safety data from internal safety reporting systems, patient satisfaction survey data, and work culture survey data.

Driving the BSC to unit levels. The performance on the scorecard rolls up to provide a single score for all goals and metrics. In this way, it provides balance to the organization because the overall score will be low if the organization performs well in one perspective (e.g., Finance) and does poorly in another (e.g., Quality). The next step is to have individual scorecards at the service unit level and, finally, at the individual operating unit level. This tiered approach encourages focused improvement efforts at the direct patient care level that are aligned with the strategic goals of the broader organization. Without this alignment, PI efforts are oftentimes reactionary and focused on local concerns that may have little impact on organizational outcomes. Aligning PI initiatives toward strategic goals provides a significant economy of scale and ensures that the entire organization benefits from collaborative efforts.

Six Sigma®

Six Sigma was chosen as our hospital’s PI methodology in 2004, replacing the FADE methodology in use at that time. Six Sigma provides a rigorous PI platform, which utilizes the scientific method to focus on specific processes with high variability, measurability, and impact on performance (Figure 1). The methodology is well defined, and consists of the DMAIC approach (Define, Measure, Analyze, Improve, and Control).³

In the define phase, specific tools are utilized to define the project's purpose and scope, and identify factors that are critical to quality. In the measure phase, the goals are to develop a reliable measurement system to track the metrics that define high quality. In the analysis phase, data are collected and evaluated to identify the root causes of process variability. The improvement phase consists of developing and implementing initiatives to improve performance and evaluating the results of those initiatives. The final phase consists of controlling the process and achieving sustainable improvement.

Our hospital's Six Sigma structure consists primarily of "Black Belts" and "Green Belts," who have received advanced training in PI techniques and rigorous statistical analysis tools. These individuals are assigned projects based on organizational priorities and identified areas for improvement. Senior administrators are designated to serve as project champions and to assist in removing obstacles to improvement. Multidisciplinary work teams are formed and, under the guidance of the Black Belt or Green Belt, conduct a DMAIC process.

The ultimate goal of these teams is to identify solutions that lead to sustainable improvement. Given the scientific rigor and sophisticated statistical analysis inherent in Six Sigma, data may be analyzed and solutions generated using various techniques. We have undertaken projects that required nothing more complex than Pareto diagrams and others that necessitated complex multivariate analyses, yet all led to substantive process improvements.

Team Training

Our initial Team Training work focused on modifying the aviation industry's Crew Resource Management process to better match health care teams' needs. In January 2006, the Pediatric Intensive Care Unit (PICU) was chosen as a pilot unit for the Health System's Team Training program, since it had a high census, strong local leadership, and a history of successful PI initiatives. Prior to the initiation of Team Training, a standardized Teamwork and Safety Climate Survey was administered to the PICU staff in order to evaluate teamwork and patient safety.⁶

A wide variety of staff and faculty members responded to the survey. Participants included physicians, nurses, administrators, respiratory therapists, pharmacists, unit clerks, and others. Survey analysis noted no differences in the background characteristics of survey respondents. In addition, evaluation of actual teamwork performance was accomplished through direct on-site observation of communication and teamwork behaviors by human factors experts. Once these baseline measurements were obtained, the health system's Chief Patient Safety Officer met with the unit's leadership team to define goals, metrics, concerns, and a training approach.

The actual Team Training consisted of a variety of didactic lectures, hands-on demonstrations, role playing, open discussions, and training internal coaches. The entire team—consisting of physicians, managers, nurses, respiratory therapists, pharmacists, social workers, ward clerks, and others—were invited to a 3-hour team training session. The improvement initiatives derived from this training were brought to the local safety and quality team meetings, revised as needed, and implemented. Reviews of the Team Training project were performed at the weekly safety meeting, monthly staff meetings, and monthly faculty meetings. A followup survey and repeat evaluation of teamwork were performed. Survey and observational data were compared using the Fisher exact test.

Results

Balanced Scorecard

In the “Quality and Patient Safety” perspective, several improvements have been noted. Compared to the previous fiscal year, there has been a reduction in morbidity, a decrease in readmits from 7 percent to 4 percent, a decrease in infection rates from 3 percent to 1 percent, and a decrease in length of stay by 0.6 days. In addition, there has been an increase in average daily census by 9 percent over the previous fiscal year. In one focus area (PICU), throughput has increased by 10 percent, as measured by hospital discharges and PICU visits.

In the “Finance” perspective, the patient flow team achieved a 26 percent improvement in discharge times and 10 percent improvement in PICU encounters. Multiple finance-based initiatives have been implemented since the BSC was first put into place. The details of these initiatives are beyond the scope of this article, but they have resulted in an increase in the variable contribution margin by 240 percent and an improvement in net margin from losing \$4.7 million per year in FY04 to a total of \$7.4 million lost over the last 2 years.

In the “Customer” perspective, patient satisfaction scores have exceeded the set targets over the last fiscal year (Press Ganey overall mean score of 84). In addition, the percentage of inpatients reporting Duke Children’s as “very good” has exceeded the target set for this fiscal year.

The majority of relevant data in the work culture perspective will be covered under team training.

Six Sigma®

A number of formalized Six Sigma projects at both Black Belt and Green Belt levels have been implemented across Duke Children’s Hospital. Areas of focus include patient safety, patient flow, and patient satisfaction. Six Sigma initiatives in these areas have resulted in a 44 percent reduction in adverse drug events, a 38 percent increase in discharge efficiency, and significant percentile ranking improvements in patient satisfaction.

In addition to focused projects, the concept of “Safe System Design” has been integrated into the Duke Children’s PI structure and is used to build overall improvement within priority areas during the DMAIC Improve phase. This concept utilizes prospective risk assessment tools, such as failure modes and effects analysis (FMEA), and combines these with system-focused error-reduction and mistake-proofing principles. By using these tools, Duke Children’s has been able to significantly reduce patient risk in specific areas of focus.

For example, a Six Sigma initiative focused on pediatric moderate sedation decreased the mean risk score from 11.94 to 4.94 (16-point scale) and the event probability from 3.31 to 1.34 (4-point scale) (Figure 2). In order to sustain such improvement and minimize the risks associated with a return to previous patterns of behavior, PI efforts are focused on “hardwired” systems solutions and attempt to build in “forcing functions” whenever possible. The intent of this approach is to offset the inherent risks associated with fallible human beings functioning in a complex clinical environment. Six Sigma provides the infrastructure for developing and

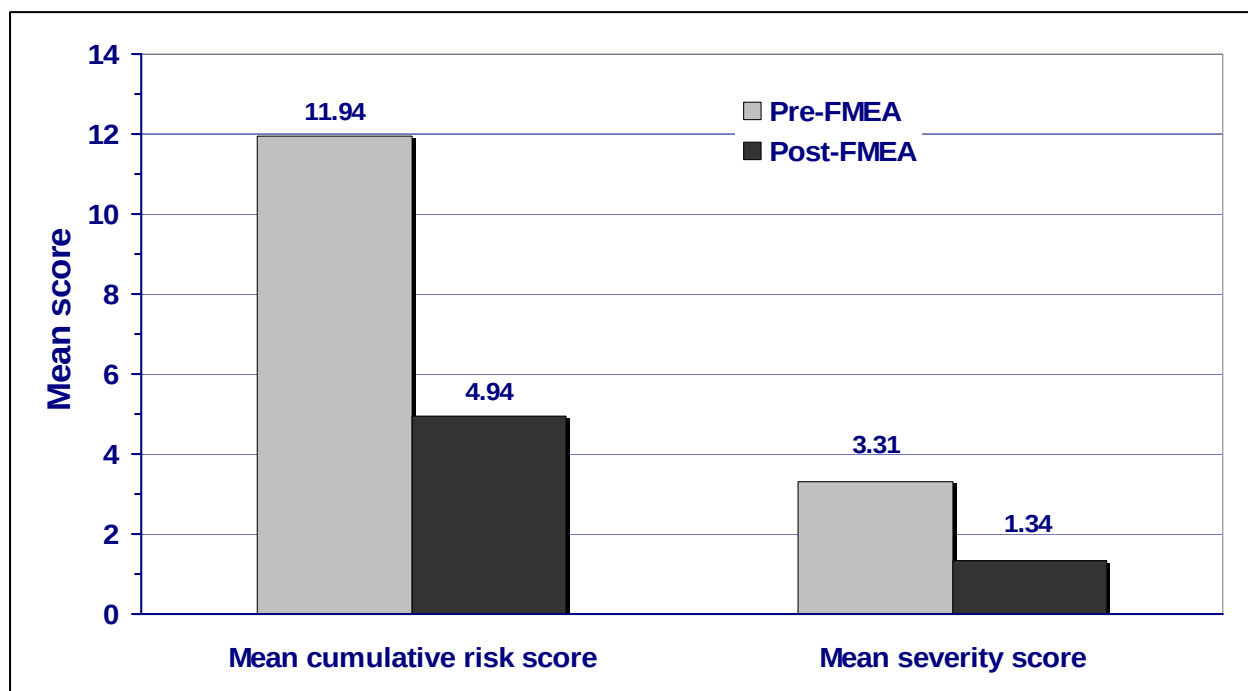


Figure 2. Comparison of pre/post-FMEA score risk and severity analysis. Sigma Six-focused initiatives resulted in a 57 percent reduction in cumulative risk and a 60 percent reduction in severity score in pediatric sedation practices.

implementing these broad-based solutions; Team Training is then utilized to further mitigate potential risks associated with human behavior.

Team Training

As a result of Team Training, a number of significant operational changes were implemented, including:

- The use of critical language to identify concerns (specifically the phrase, “I need clarity”).
- Pre- and post-round briefings and debriefings, or “huddles.”
- Situation-background-assessment-recommendation (SBAR) communication for nursing reports and telephone communications.
- Use of a “sterile cockpit” (a term borrowed from aviation’s crew resource management) limits interruptions during team rounds to criteria-driven, clinically necessary questions. This allows the team to focus on effective communication and critical issues during this vulnerable time period.
- Standardized communication process for patient handoffs.
- Utilization of an open agenda for weekly safety rounds.
- Improved distribution of safety minutes to all staff and faculty.

This focus on Team Training and the associated process improvements have resulted in significantly improved communication and an increased awareness of safety process. A repeat Teamwork and Safety Climate Survey administered 6 months after the initial training showed the

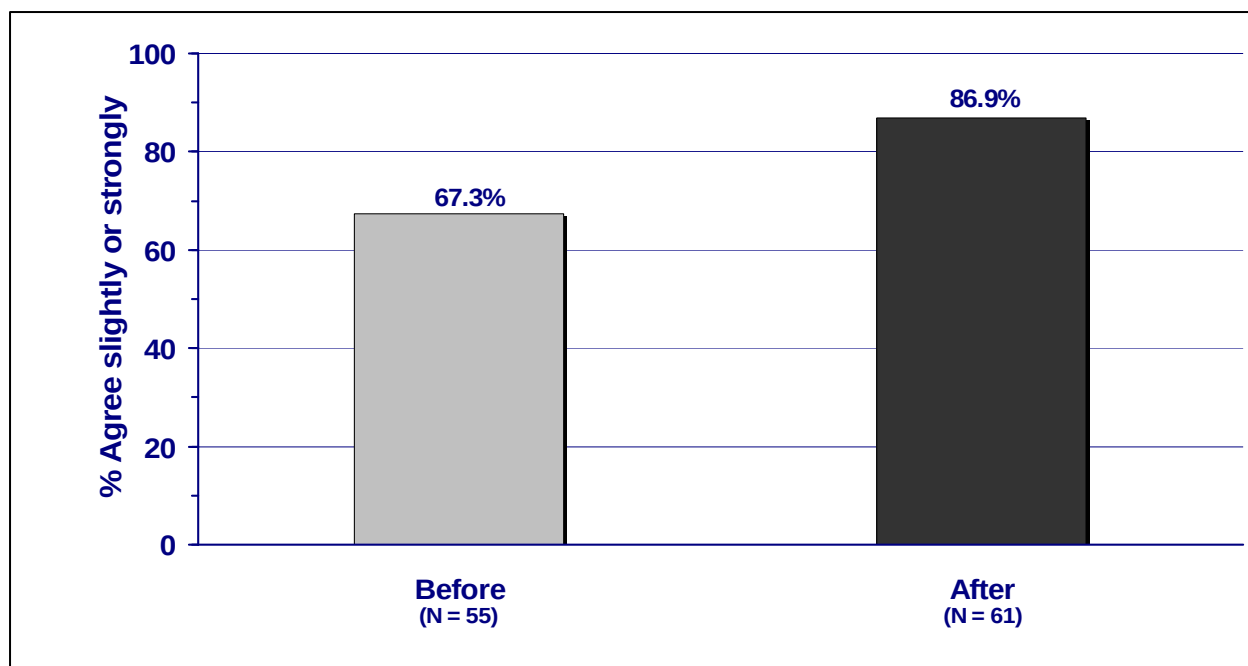


Figure 3. Results of staff surveys before and after Team Training. There was a 29 percent improvement in the staff’s perception of team work in response to the survey question: “The physicians and nurses here work together as a well-coordinated team.” $P = 0.011$ (Fisher Exact test)

following: staff’s perception of teamwork increased from 67 percent to 87 percent ($P = 0.011$) (Figure 3); use of briefings increased from 63 percent to 84 percent ($P = 0.012$); and knowing the proper channels to direct questions regarding patient safety increased from 67 percent to 87 percent ($P = 0.007$).

The independent observations of teamwork were also improved: overall teamwork increased by 72 percent ($P < 0.001$) (Figure 4), and overall perception of teamwork increased by 75 percent ($P < 0.001$). Surveys also demonstrated that 95 percent of participants believed that Team Training would improve the way they did business, and 100 percent of participants would recommend Team Training to coworkers.

Discussion

Because of the wide variety of options available and the hospital staff’s lack of experience, many health care providers find implementing clinical improvement programs in health care to be challenging.¹⁻⁴ To be successful, these programs must be supported by senior management, physicians, and caregivers. Physicians, as a group, often are difficult to engage. PI initiatives may require physicians to change their practice, yet they frequently do not include input from the physicians, resulting in a lack of physician support for improvement initiatives and placing physicians at odds with administrators.

Clinical improvement initiatives that involve a change in physician practice must engage physicians in the process. Engaging physicians is challenging, as they typically lack a background in PI and perceive that they will have difficulty contributing to the mission. This

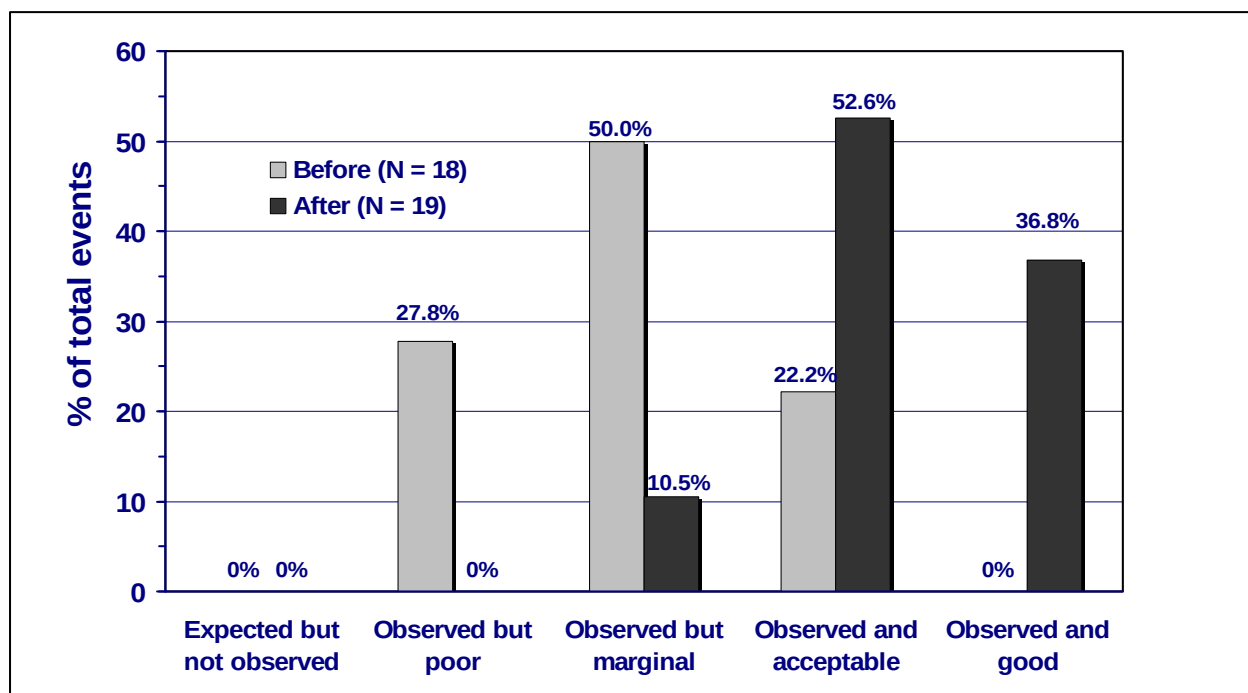


Figure 4. Results of an independent evaluation of teamwork before and after Team Training. In an independent evaluation of teamwork, overall teamwork in the PICU improved by 72 percent (Acceptable + Good scores Before vs. After). $P < 0.001$ (Fisher's Exact test).

reluctance can be overcome by developing a specific training program for physicians, identifying clear goals and areas of focus, and linking the physicians with current operational and clinical PI teams. In this way the physicians can become an integral part of the process, and the organization can leverage their considerable influence to achieve success.

Another concern is that institutions may have several different PI approaches ongoing simultaneously. This can be very unsettling to the team and result in confusion and a lack of clear direction. To address these concerns, a systematic approach should be used that identifies a specific goal and links projects to a specific initiative that is based on the strengths and limitations of the framework being utilized.

The BSC is an excellent strategic platform that consolidates all strategic initiatives and identifies areas of opportunity.^{1, 2, 5} Once areas of opportunity have been identified, more focused approaches can be used to drill into the data. One way to describe this to the organization is to consider the BSC as the “telescope” of the organization. As such, the BSC looks widely over the landscape for any peaks or valleys and looks into the future to determine the strategic direction. If the BSC identifies a specific peak, in this analogy a mountain, then Six Sigma methodology is used to examine a specific hill on that mountain. Six Sigma is utilized as the “microscope” that looks deeply into an area that has been identified as having high variability and the need for focused process improvement.

Team training is an excellent framework for examining the effects of human factors on performance. It is ideally suited in situations where you are focusing on improving communication and education across disciplines. It reflects how interactions between individuals

affect outcomes. In the analogy above, team training would be similar to examining how the grass, plants, and trees all coexist on that mountain.

Since it is designed to increase shareholder value, the traditional BSC has limitations in health care.¹ Duke Hospital has found that by altering the scorecard to place the emphasis on quality and safety, the scorecard has been adopted by both practitioners and administration. The BSC has now become the methodology for how each operating unit reports performance to the senior management team. Unit-specific scorecards are also displayed in full view of all the staff and faculty on the individual units. The individual unit scorecards are updated on a monthly or quarterly basis, and these scorecards roll up to the service line scorecard, which then rolls up into the hospital scorecard.

The BSC requires thoughtful, considered adjustments in goals and metrics to meet the changing strategic plan. For example, if an ICU expansion is planned, the BSC might be updated with new goals and metrics tied to this project and reflected in the ICU scorecards. In this way, the BSC functions as a living record of how performance is tracking against the strategic plan.

One of the most important aspects of our program is the incorporation of Six Sigma as a key element of the overall patient safety and clinical quality structure. Six Sigma is a PI methodology that applies a rigorous, analytic approach to improving performance, and it has proven to be extremely useful in addressing safety and quality issues across Children's Services.³ The scientific rigor inherent in Six Sigma allows for highly detailed analyses of clinical concerns, and the improvement tools present in the Six Sigma "toolkit" provide numerous options for correcting and controlling problem areas.

Implementing Six Sigma in health care has many hurdles, though. First, one must train individuals in the Six Sigma methodology, which requires a significant time and capital expenditure. Once these individuals are trained, they can begin the process of defining what is critical to quality.

Second, data collection efforts—i.e., accurate measurement and analysis—in health care typically lag behind similar efforts in industry. This is a function of multiple issues including, but not limited to, lack of contemporary IT (e.g., bar coding), lack of IT investment, and conflicting priorities.

Third, after the measurement and analysis have been completed, the recommended PI initiatives frequently require clinicians and operational individuals who are not trained in Six Sigma to make changes in practice. Unlike a production line with machines, health care frequently requires changes in human behavior. This can be problematic if the individuals who must change have no knowledge of what is driving the change.

Finally, control of the process can be difficult as priorities in the organization shift. Despite these challenges, if one utilizes Six Sigma as a focused approach to achieve key specific goals of the BSC, success can be achieved. Figure 5 illustrates the Performance Improvement model used at Duke Hospital and Duke Children's. The ongoing success of our Six Sigma initiatives has led us to increase the number of Six Sigma-trained staff and faculty within Children's Services. Duke

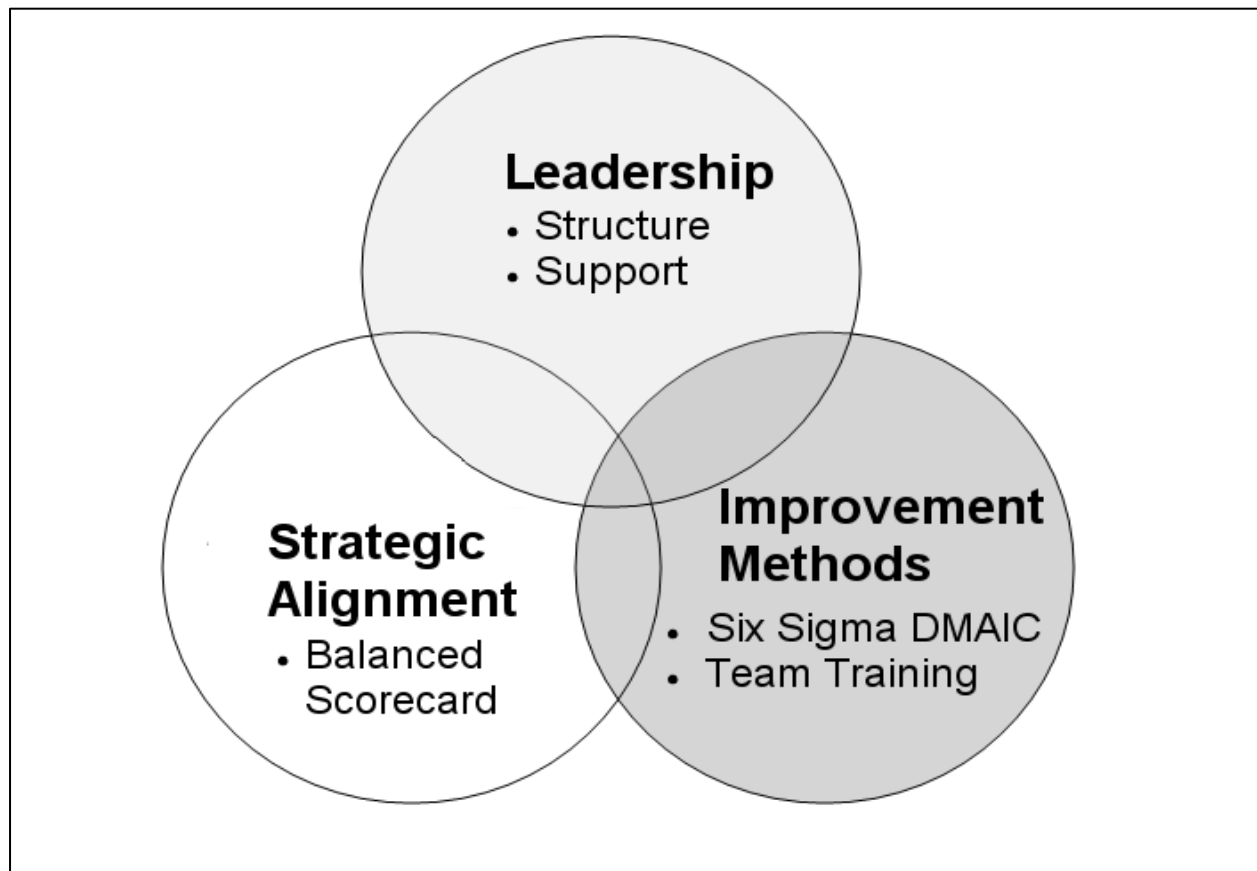


Figure 5. Performance improvement at Duke Hospital. Visual diagram of how the Balanced Scorecard (BSC), Six Sigma, and Team Training are integrated for PI at Duke. The BSC provides strategic alignment; Six Sigma provides the tools and structure to support detailed analysis; and Team Training is a tool used to improve human performance. All are supported by leadership, which provides the structure to support improvement and organizational learning.

Children’s first began intensive training in January 2004 and now has a total of four fully trained Six Sigma experts (including two physician faculty members) and five others who have received intermediate level training who are actively involved in Children’s performance initiatives.

Team Training has been utilized in other industries and is only now being translated into health care.^{4, 7} Since health care can be considered one of the highest risk service-based industries, and since human factors play a significant role in performance, one might have expected Team Training to have occurred earlier. The reason for this delay is multifactorial but may include: lack of formalized health care team training approaches; the perception that team training is “soft” and will not result in significant improvement; the lack of trained members of the team to lead the training; and the reluctance of leaders to facilitate an open discussion with a diverse staff.

Team training has the potential for dramatic effects on human performance.⁷ Staff members who have undergone team training perceived a significant increase in the amount of teamwork and

found the improved perception of leadership rewarding. These types of results have led Duke to institute Team Training in several areas throughout the institution.

While all improvement initiatives need strong champions if they are to be successful, Team Training requires it more than most, because it involves many more people from multiple disciplines and requires these leaders to stand up in front of the entire team and facilitate an open discussion. The champions must include physicians, managers, senior operational staff, and bedside staff, who are passionate, open, and willing to change.

The best area to start team training is one that has opportunity, leaders who are respected, and experience in complex PI initiatives. It is helpful for those leading the Team Training to have undergone formal training themselves, to have done a trial run, and to have a specific agenda that is both interactive and action-oriented.

The output from Team Training must be made actionable immediately. A mechanism to review the initiatives and modify the approach also must be developed. It is helpful to develop “coaches” in each area who can train new hires and reinforce what has been implemented. A standard communication methodology should also be in place so that all receive key information. It is also necessary to routinely repeat Team Training exercises to reemphasize certain aspects and to train any new personnel.

Despite all these impediments, Team Training can result in significant improvements in health care, specifically improving education and communication. Techniques used in the aviation industry are translatable to medicine but require “personalization” to each institution’s specific culture and challenges. Using the structured approach outlined here, Team Training can result in positive outcomes, not only for staff, but also for patients and their families as well. Within Duke Children’s, Team Training has become an essential part of caring for the patient and the entire team, and Duke Medicine is now beginning Team Training at the medical school level.

Limitations

Many PI initiatives are directed at unique institutional desires driven by the strategic plan. This frequently makes translating the PI approach different from institution to institution. While this is a concern, the core principles of BSC, Six Sigma, and Team Training are the same and have been translated across both the adult and children’s areas of Duke. All three approaches have been used successfully in other industries, and the uniqueness of the approach described is how to integrate these different platforms and processes in a single institution.

Another limitation is the basic concern of PI research in health care. Outcomes in health care sometimes are difficult to interpret because many confounding factors contribute to the result. It is difficult to remove all confounders, so this remains a limitation. It should be noted however, that Duke has several internal controls, such as other areas where PI initiatives were not undertaken. For example, improvement in patient flow was only demonstrated in the groups that underwent a Six Sigma project. While it is impossible to account for all potential confounders, our results are generally translatable to other institutions, and our approaches should be used as a model to drive clinical improvement.

Conclusion

Strategic management tools and PI frameworks can be integrated and used to achieve a significant improvement in performance. To achieve these results, one must employ a systematic approach that links the strengths of a specific framework with a specific problem. The BSC is an overarching management system that consolidates strategic initiatives and identifies areas of opportunity. Six Sigma is used when focused areas of improvement are needed. Team Training is an excellent framework for improving communication and education across disciplines. Understanding these differences is essential to achieve clinical success.

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Impact of Staff-Led Safety Walk Rounds

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Abstract

Objectives: The primary objectives of this study were to provide a venue for discussing safety concerns and to facilitate finding solutions for everyday safety issues. **Methods:** The multidisciplinary patient safety committee (Team Safety) at Kosair Children's Hospital began safety rounds in January 2007. Each month, several teams walked through patient care areas and talked to staff. Responses to questions and other comments mentioned during rounds were recorded. Between safety rounds, the Team Safety chairperson met with the Vice President of Clinical Operations to discuss the findings, assign priorities, and develop action plans. **Results:** From January 2007 through August 2007, Team Safety members talked with 182 staff from at least 10 disciplines and recorded 79 different concerns; 39 percent of these have been completely or partially resolved. More staff know how to report events and near misses and can describe how the information is used. **Conclusion:** Frontline caregivers can conduct effective safety walk rounds.

Introduction

Patient Safety Leadership WalkRounds™ have been shown to improve the safety culture of hospitals.¹ Safety walk rounds consisted of a core group of senior executives and/or vice presidents walking through the hospital on a weekly basis. During rounds, members of the group asked questions about near misses, adverse events, and system issues contributing to these events. The events were analyzed to determine priorities. Subsequently, executives provided quarterly reports detailing actions taken to address the events. The authors suggest that the improvement in safety culture attributed to walk rounds was related to the education that leadership provided and to the increased rate of safety-based changes.

In a subsequent study, change in safety culture was measured using the Safety Climate Survey before executive walk rounds began and again 2 months after they ended.² The authors reported that staff who had participated in walk rounds had higher safety climate scores compared to those who had not participated in walk rounds. An Internet search using "safety walk rounds" as the query yielded several articles and newspaper style stories from a number of hospitals that described the success of executive walk rounds.^{3, 4, 5}

Unit-based patient safety walk rounds represent one modification of hospital executive walk rounds. Implementation of safety walk rounds led by the emergency department director, associate director, nurse director, the clerical staff manager, and leaders of the Nurses' Quality Council in the Pediatric Emergency Department at the Children's Hospital of Philadelphia resulted in an improvement in safety culture and quality of care.⁶

In January 2007, members of the Kosair Children's Hospital Team Safety began safety walk rounds. The objectives were similar to those reported for Patient Safety Leadership WalkRounds™ and other executive walk rounds programs: to improve safety culture throughout the hospital and to facilitate resolution of safety concerns in a timely manner. An additional objective was to demonstrate that safety walk rounds led by bedside providers can achieve success that is comparable to safety walk rounds led by hospital executives and managers.

Methods

Team Safety is the hospital's multidisciplinary patient safety committee. Members include physicians (attending, trainees), staff nurses, and staff representatives from respiratory therapy, pharmacy, and the clinical laboratory. Other members include staff from risk management, clinical resource management, and education. The chief nursing officer attends the monthly meetings but does not participate in safety walk rounds. The hospital medical director is a member of the team and does participate in safety walk rounds.

Monthly safety walk rounds began in January 2007. Four teams of two to three Team Safety committee members walked through six to eight patient care areas of the hospital each month for 45 to 60 minutes and talked with staff from all disciplines. Only the Team Safety chair (author) has participated in all safety walk rounds. Other members participated as their clinical schedule allowed. Managers of the patient care areas did not participate. No advance notice was provided.

Team members carried a "toolbox" on safety walk rounds. The toolbox comprised the script, data collection forms, and giveaways (e.g., covered notepad, candy, and pocket-size hand sanitizer) that were embossed with the Team Safety's logo. Team members used a script consisting of eight questions to initiate discussion (Appendix A). All comments made by staff were recorded. Data recorded by team members included the patient care areas visited and the number and disciplines of staff who participated in safety walk rounds. Team members did not record the names of staff members who participated in walk rounds. Although staff members were not anonymous to the members when we walked, no comment was labeled with a staff member's name unless the staff member requested feedback. If a staff member requested direct feedback, the staff member's name was recorded, and a member of Team Safety provided the staff member with followup.

After each of the walk rounds, the teams met for debriefing. The chair of Team Safety took notes and collected the data sheets from the teams. Subsequent to each debriefing session, the chair collated the responses, categorized safety concerns into one of eight categories based on the focus of the concern, and identified who would resolve each of the issues. As issues were addressed and ultimately resolved, the chair updated the safety walk rounds in an Excel® worksheet to reflect the progress.

Concerns that represent immediate risk were addressed/resolved within 24 to 48 hours by actions initiated by members of the committee, the chair, or the medical director in conjunction with appropriate hospital managers and leaders. Concerns that impacted one or two care areas and required few resources for resolution were usually addressed by the chair, members of the committee, or the medical director with the appropriate managers and leaders of the care areas.

The chair met with the vice president of clinical operations on a recurring basis to discuss what was reported during safety walk rounds. These discussions resulted in the development of action plans to address the more complex, hospital-wide concerns, provided the opportunity to review successes, and served to keep hospital executives informed of the committee's actions. A summary of findings from the walk rounds, as well as the action list, were presented at the monthly Team Safety Committee meeting. In addition, the committee reported the results of safety walk rounds to other hospital committees and in various internal hospital publications.

Results

Safety walk rounds have occurred seven times between January and August 2007. Walk rounds were not held in April 2007 due to scheduling conflicts. We talked with 182 staff from at least 10 disciplines (Figure 1).

A total of 79 different safety concerns from eight categories have been identified during safety walk rounds. (Figure 2) Twenty-four percent of the concerns related to equipment, 20 percent to care delivery, 15 percent to the work environment, 10 percent to medication, 1 percent to staffing, 8 percent to communication, 8 percent to intrahospital transport, and 6 percent to security issues.

Table 1 lists examples of concerns expressed to members of Team Safety. Of 79 action items, 31 (39 percent) have been resolved or are in the process of being resolved. Issues that were reported and resolved include:

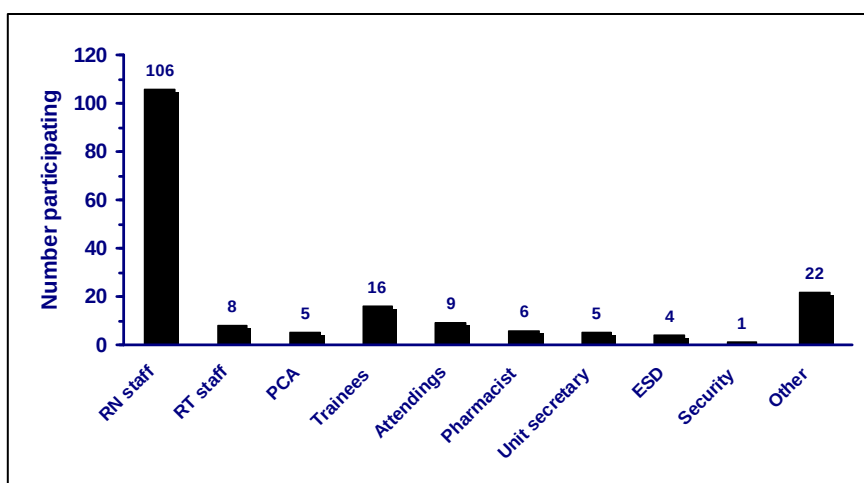


Figure 1. Number and discipline of staff participating in safety walk rounds
RN = registered nurse; RT = respiratory therapist; PCA = patient care associate; ESD = environmental services department

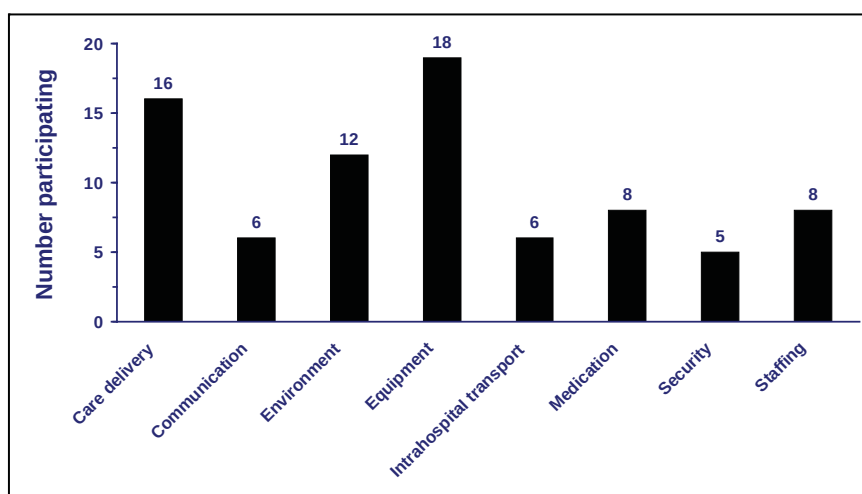


Figure 2. Classification of safety concerns identified during safety walk rounds

- Chemotherapy for different patients with the same last name dispensed to the oncology unit packaged in the same outer bag.
- Inadequate hand-off tool between staff of the cardiac catheterization laboratory, the post-anesthesia care unit, and the critical care center.
- Inaccessibility of policies and procedures stored in electronic format.
- Cumbersome event reporting system for physicians (a user-friendly format already existed for nurses).
- Inability to access the hospital's electronic medical library and drug dosing and administration references from portable computers.
- Inconsistent labeling of trimethoprim-sulfamethoxazole.
- New order sets for insulin dosing and administration.
- New forms and additional venues for reporting near misses and adverse events.
- New processes for intrahospital transport.

Table 1. Examples of comments made to Team Safety members during walk rounds

Care delivery	• Request for education and consistency regarding insulin administration. • Missed and delayed orders after new order process implemented. • Difficult to access virtual medical library and electronic drug handbook.
Communication	• Incomplete hand-off from cardiac catheterization laboratory to other areas. • Difficult to access electronic version of policies and procedures.
Environment	• Plastic bags covering clean linens pose risk to toddlers. • Nail and screw tips protruding into drawers pose risk to staff and visitors.
Equipment	• Insufficient number and remote placement of resuscitation bags and masks. • Missing pieces on ECG machines.
Intrahospital transport	• Inadequate communication between RN, transporter, and radiology department. • Lack of process for providing staff to accompany and stay with patient.
Medication	• Inconsistent naming of trimethoprim-sulfamethoxazole (generic vs. trade). • Risk of medication error involving patients with same last name.
Security	• Difficult to distinguish patients from visitors with current system. • Difficult to monitor/control visitor movement in/out of care areas.
Staffing	• Acuity/census changes faster than number of RNs increase. • Difficult to maintain appropriate skill mix when acuity rapidly changes.

An interesting observation—and hopefully, one that suggests a stronger safety culture throughout the hospital—is an increase in the number of staff who know how to report a near miss or actual event and what happens to the reported information. During the early months of safety rounds, members of Team Safety noticed that few staff members knew how to report a near miss or actual event or what was done with the information if a report was made. During the last 2

months of walk rounds, only 4 of the 52 staff members interviewed during safety walk rounds were unaware of how to make a report or how the information was used. Unfortunately, data were not collected during the early months of safety walk rounds to allow a statistical analysis of this observation.

Twenty-eight different safe habits have been reported in response to the question, “Have you developed any habits that you think help you deliver safer care?” Examples of new safe habits are listed in Table 2. Safe habits are shared with staff during safety walk rounds and through various hospital publications.

Discussion

Our results demonstrate that safety walk rounds led by frontline caregivers can lead to the identification and resolution of safety concerns important to frontline providers. Based on the number of staff who now know how to report events and understand how the information is used to improve patient care, we suggest that the enthusiasm, interest, and safety knowledge demonstrated by peers can positively influence a hospital’s safety culture. To our knowledge, we are the first to implement a safety walk rounds program that does not include unit managers and executives. Our results mirror the successes demonstrated in Patient Safety Leadership WalkRounds™ and other programs in which rounds are led by hospital leaders.¹⁻⁵

The approach to safety walk rounds described in this report varies from the process previously described for executive walk rounds in several ways. Members of Team Safety who lead safety walk rounds have no formal instruction on how to conduct walk rounds or patient safety. They are provided the script and asked to talk with their peers in a nonthreatening setting with the primary goal of identifying safety issues that are important to frontline providers. Although finding safe solutions may not be intuitive, identification and discussion of safety issues by frontline providers seems to be inherent in daily workflow. Members of Team Safety are very aware of the work environment and what is unsafe. Frontline providers talk about what works and does not work on a daily basis. However, a venue for addressing and resolving safety issues is frequently absent or lacks structure. The author believes that our format for safety walk rounds provides a structured venue for staff to express their concerns and contribute to developing a safer environment within the hospital.

Despite the differences, there are common elements between Patient Safety Leadership WalkRounds™ and Team Safety walk rounds. Members of Team Safety are dedicated to improving patient and staff safety and the safety culture of the hospital, as are executives who participate in safety walk rounds. In both approaches, participants usually use a script to guide the discussion. Others have reported that the success of safety walk rounds depends on executives, who are knowledgeable in safety principles, are firm believers in the benefits of safety walk rounds, and are vested in improving safety.¹ Our success depends on hospital leaders possessing these same qualities. Although hospital executives and managers do not participate in Team Safety walk rounds, they are essential to the success of our program. There must be a venue for sharing the information with hospital leadership. Meetings between the chair of Team Safety, the vice president of clinical operations, and other managers are key to implementing change, especially when financial resources are required to completely resolve a concern.

Feedback to the staff is essential for success of safety walk rounds, whether led by staff or executives. Feedback occurs in our program via e-mail, hospital committee meetings, a monthly hospital nursing publication, a bimonthly hospital physician publication, other means of communication as appropriate, and during safety walk rounds.

The distribution of the types of concerns expressed during staff-led safety walk rounds are similar to the findings during patient safety leadership walk rounds described by Grillo, et al.⁵ During our safety walk rounds, 24 percent of concerns related to equipment, 20 percent to care delivery, 10 percent to staffing, and 8 percent to communications. Grillo reported that 30 percent of the comments reported during their safety walk rounds related to equipment, 13 percent to communication, and 6 percent to workforce.

Conclusion

We implemented monthly safety walk rounds to identify safety concerns and improve safety awareness. Our results demonstrate that safety concerns are readily identified by frontline providers, and they can be identified and resolved utilizing safety walk rounds led by peers. Successful resolution of safety concerns depends on hospital leadership who are supportive and share the team's passion for decreasing adverse events in the hospital and providing safer patient care. Future directions for our safety walk rounds include visiting non-patient care areas such as the clinical laboratory and outpatient registration, walking during evening and weekend hours, and attending staff meetings to provide opportunities for more staff to participate in safety rounds, disseminate safety information, and report the impact that their safety concerns have had on creating a safer patient care environment.

Acknowledgments

I would like to thank the members of Team Safety for their participation in Safety Walk Rounds. I thank the hospital executives for recognizing that progress in patient safety is key to the success of our hospital, providing ample opportunity for me to discuss the findings of safety walk rounds and working with Team Safety to develop solutions.

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Appendix A

Safety walk rounds script

- Are you aware of any “near misses” – events that almost caused patient harm but didn’t – that occurred sometime during the last several shifts that you worked?
- What are the barriers that prevent reporting of “near misses” or actual error?
- Do you know how the information from occurrence reports is used in this hospital? Do you have any ideas on how the information should be used? Have you ever received feedback?
- Were you able to care for your patients during your last three shifts as safely as possible? If not, what were the barriers/hindrances?
- What is your biggest safety concern on your unit? Is there anything that could be done to prevent the next adverse event or to address your safety concern?
- What would help improve the safety consciousness in this hospital?
- What is one thing that you think could happen today that would improve patient safety on your unit?
- Have you developed any habits that help you decrease the risk of making an error? If yes, what are they?

Source: Adapted from Frankel A, Graydon-Baker E, Nepl C, et al. Patient Safety Leadership WalkRounds™. Jt Comm J Qual Saf 2003; 29: 16-26.

Development of a Web-Based Patient Safety Resource: AHRQ Patient Safety Network (PSNet)

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Abstract

Since the Institute of Medicine released its *To Err Is Human* report, published research and other activities related to patient safety have increased substantially. Interested stakeholders now require a resource to stay abreast of the latest news and findings. Under contract with the Agency for Healthcare Research and Quality (AHRQ), we developed a comprehensive and continuously updated Web-based portal to address this need. The AHRQ Patient Safety Network (AHRQ PSNet), launched in April 2005, features weekly updates of annotated resources, a collection of patient safety “classics,” and opportunities for users to receive weekly updates and create their own “My PSNet” option. As of July 2007, the site has more than 6,500 subscribers to the weekly newsletter and receives approximately 1.5 million yearly visits. We anticipate that the AHRQ PSNet will continue to provide important and updated safety information to a diverse array of users and to leverage the reach and scalability of the Internet.

Introduction

The landmark Institute of Medicine report, *To Err Is Human*, increased public awareness about patient safety and catalyzed efforts to reduce medical errors.¹ The number of stakeholders—providers, administrators, legislators, regulators, payers, and patients—continues to grow. Advances are also evidenced by the rapid growth of published research,² the development of practical toolkits and educational curricula, the creation of safety-specific journals, and the availability of dedicated patient safety conferences.

A resulting challenge is to stay abreast of the latest patient safety literature and news. Whereas certain fields (e.g., cardiology or critical care) allow their “experts” to remain updated through a relatively narrow set of journals and conferences, patient safety experts span a variety of disparate fields. A clinician, researcher, educator, administrator, or policymaker trying to stay updated in the field might need to read a wide range of general and specialty journals in medicine, nursing, and pharmacy, as well as human factors, informatics, health policy, and law.

Recognizing the need for a comprehensive information resource for those working in patient safety, the Agency for Healthcare Research and Quality (AHRQ) issued a Request for Proposals (RFP) in July 2004 to create a “one-stop” Web-based resource for the patient safety community. Our editorial team—which comprised physicians with a strong interest and track record in patient safety and medical education, the managing editor for AHRQ Morbidity & Mortality Rounds on the Web (AHRQ WebM&M), and a library scientist and cybrarian with expertise in

patient safety—partnered with a technical contractor, Silverchair (Charlottesville, VA), and we were awarded the contract.

In particular, we aimed to leverage our experience and success with AHRQ WebM&M,³ the Web-based safety journal that first combined anonymous reporting with case-based presentations and expert commentaries.⁴ Our goal was to build a new and innovative patient safety portal that would allow delivery of timely and highly accessible information, evidence, education, and insight to improve health care systems and patient care and create a partnership and linkage with AHRQ WebM&M to permit users to benefit from both sites' resources.

Launched in April 2005, AHRQ's Patient Safety Network (AHRQ PSNet) features weekly updates of annotated resources, a collection of patient safety "classics," and opportunities for users to receive weekly e-mail updates and create their own "My PSNet" option.^{5, 6} In this article, we describe the development of AHRQ PSNet, summarize a number of key outcome measures based on site-user data, and discuss future directions. We hope our experiences provide useful lessons that can be applied by others dedicated to patient safety and those who may be considering the use of the Internet as a tool to disseminate health-related content to a widely dispersed, worldwide audience.

Site Development

The contract called for a creative and engaging patient safety portal that linked to existing resources (everything from toolkits on the AHRQ Web site to resources from the Joint Commission), could generate both passive content (i.e., posted on the site) and active alerts for new content (i.e., e-mailed to registered users), and had a fully searchable set of resources.

In addition to these requirements, our goals were to develop an intuitive and attractive user experience, ensure a seamless interface with AHRQ WebM&M, create a powerful taxonomy for organizing a large number of resources, and allow extensive customization. Next, we describe the major issues and challenges in site development, including choosing content for inclusion, refining our editorial workflow, creating specific site attributes, and developing our taxonomy.

Content Selection and Editorial Workflow

To create timely and high-quality weekly AHRQ PSNet issues, we needed a system that was fluid and dependable, could function as a content management tool, and would alert different members of the editorial team when their tasks were ready for assignment. Our technical contractor helped develop an online authoring tool that provided the necessary structure and organization to help publish our new issue every Wednesday.

Each week, our library scientist and editorial team identify potentially relevant content via systematic searches of bibliographic databases (e.g., PubMed) and also several other clinical, health care administration, business, legal, and lay press publications (e.g., newspapers and magazines). We also closely follow industry and consumer dialogue on patient safety issues via blogs, LISTSERV™ applications, and Web-facilitated news and site update alerts. Finally, our managing editor is able to anticipate inclusion of important resources in a timely manner through media access to upcoming, embargoed publications.

One of our first editorial decisions during site development focused on the number of new resources we could reliably add in a given week. We decided to choose quality over quantity, opting to provide users with editorial input into new content, rather than simply including all relevant content and potentially overwhelming users. After agreeing on a starting set of resources prior to launch (with larger input from our expert Editorial Board), we targeted inclusion of 20 to 25 new resources each week (~1,000/year) spanning journal articles, newspaper stories, conference proceedings, toolkits, and reports.

Our editorial team spotlights certain items each week by accompanying the resource with an annotated summary. These summaries (approximately 100 to 150 words) aim to highlight important information from the resource and lead users to related content, glossary items, or AHRQ WebM&M commentaries via hyperlinks. Thus, while reading an annotated summary, a user is also directed to other relevant literature elsewhere on AHRQ PSNet, a feature that enhances the user experience (Figure 1). The remaining resources receive shorter summaries with the same linking principles to create similar depth to each resource description. Evaluation of past user behavior (discussed in more detail in the Results section) has allowed us to tailor our editorial decisionmaking over time. During the last steps of our process, the “What’s New” home page is designed, with resources chosen, prioritized, and highlighted for publication.

The screenshot displays the AHRQ PSNet website interface. At the top, the header includes the United States Department of Health & Human Services logo, the AHRQ logo, and the text "Agency for Healthcare Research and Quality". A navigation menu on the right lists "Skip Navigation", "HHS Home", "Questions?", "Contact AHRQ", and "Site Map". Below the header, a sidebar on the left contains links for "Home", "What's New", "My PSNet", "Subscribe to Newsletter", "CLASSICS", "Most Popular", "Advanced Search", "Advanced Browse", "Glossary", "AHRQ WebM&M", "About", and "Contact Us". The main content area features a search bar and a "GO" button. The featured article is titled "To Err Is Human: Building a Safer Health System." by Kohn L, Corrigan J, and Donaldson M, eds. The summary text discusses the impact of the IOM report on patient safety. At the bottom of the article, there are links for "Executive summary (PDF)", "Download Adobe Acrobat (free)", and "Table of contents (free full text)".

Figure 1. AHRQ PSNet sample annotation.

One recurring challenge of our content selection process comes as we try to determine whether a resource is about “safety” (our mandated scope) or “quality” (generally, outside our scope). The distinction between “patient safety” and “health care quality” is by no means clear and is, to some extent, purely academic.⁷ Although our charge is to focus on patient safety, we do not want to inappropriately exclude quality-focused resources that are also relevant to a safety-oriented audience. For example, a study on the use of information technology (e.g., computerized provider order entry, CPOE) that improved the quality of care delivered to patients with diabetes might be excluded as quality-focused. On the other hand, a similar study demonstrating the role CPOE played in improving beta-blocker use in the perioperative setting might warrant inclusion, given that perioperative beta-blocker use was identified as an important patient safety intervention in an AHRQ technical review (e.g., that defined one aspect of safety practices as cross-cutting).⁸ The balance here remains challenging and generally defies fixed rules for inclusion and exclusion.

The broader issue involves defining the “market” for patient safety information. Does every black box warning about a medication or device require inclusion? Does an article focused on quality but relating to safety published in a marquee journal trump a safety-specific article in a lower impact journal? These sorts of discussions are resolved through consensus and with an eye toward past user feedback, while keeping in mind our overarching mission: to err on the side of high-quality resources, rather than aiming for an inclusiveness that would likely generate an overwhelming amount of content and a poor user experience.

Site Attributes

During site development, we identified the chief site attributes as:

- Timely sharing of new information.
- An attractive, usable, and intuitive user interface.
- A customized and searchable set of resources using a taxonomy that offered multiple axes.
- A balance between dynamic content (e.g., literature, meetings, and news) and resource content (e.g., toolkits, conference proceedings, and legislation).

Below, we highlight a few specific features that have been popular with our users and demonstrate the efforts to create a particular user experience on AHRQ PSNet.

What’s New and AHRQ PSNet Newsletter

We designed an interface on the site to highlight new content—i.e., “What’s New”—and an active way to alert users of the new content: the electronic newsletter. With 20 to 25 carefully chosen resources each week, we still felt the number could potentially overwhelm users on the home page. Instead, we produced a dynamic left side of the home page for “What’s New” and a static right side of the home page for existing content (Figure 2).

In “What’s New,” we select the top 10 to 12 resources each week, organized by resource type (i.e., journal article, newspaper/magazine article, Web resource), and prioritize them based on desired connection between the two sites.

United States Department of Health & Human Services

AHRQ Agency for Healthcare Research and Quality

Advancing Excellence in Health Care www.ahrq.gov

Skip Navigation

- HHS Home
- Questions?
- Contact AHRQ
- Site Map

Home ▶ A national patient safety resource

AHRQ PSNet Patient Safety Network

Search GO Advanced Search

CLASSICS

Most Popular

Advanced Search

Advanced Browse

Glossary

AHRQ WebM&M

About

Contact Us

What's New This Week 03/26/08

View more of What's New XML RSS Feed

Audiovisuals

The Wrong Medicine: Quaid on Medical Mistakes

"60 Minutes." CBS News Video. March 16, 2008.

Journal Articles

Office surgery incidents: what seven years of Florida data show us.

Coldiron BM, Healy C, Bene NI. Dermatol Surg. 2008;34:285-292.

Incidence, preventability and consequences of adverse events in older people: results of a retrospective case-note review.

Sari AB, Cracknell A, Sheldon TA. Age Ageing. 2008 Mar 10; [Epub ahead of print].

The Patient Safety and Quality Improvement Act of 2005: developing an error reporting system to improve patient safety.

Riley W, Liang BA, Rutherford W, Hamman W. J Patient Saf. 2008;4:13-17.

Browse the Collection

Browse by Resource Type

Journal articles, Books and reports, Tools and toolkits, Upcoming meetings, **More...**

Browse by Origin/Sponsor

Federal Government, Department of Health and Human Services, Agency for Healthcare Research and Quality, United Kingdom, **More...**

Browse by Subject

Safety Target

Medication errors, Diagnostic errors, Nosocomial infections, Post-operative surgical complications, **More...**

Approach to Improving Safety

Human factors engineering, Error reporting, Teamwork training, Culture of safety, Nurse staffing ratios, Regulation, **More...**

Error Types

Cognitive errors ("mistakes"), Non-cognitive errors ("slips & lapses"), Latent errors, **More...**

Clinical Area

Anesthesiology, Emergency medicine, Critical care nursing, Community pharmacy,

Figure 2. AHRQ PSNet home page.

To cue users to explore new content, we provide an opportunity to receive an AHRQ PSNet newsletter that is electronically delivered to subscribers. The email displays the “What’s New” content and allows users to link directly to the individual resources on AHRQ PSNet. We believe this feature is vital for keeping our users easily updated, a primary objective during our site development.

My PSNet

The “My PSNet” option allows users to view the latest resources available in their self-designated areas of interest. When a new resource matching their specifications is added to AHRQ PSNet, they receive e-mail alerts up to once weekly. The process begins by walking users through a series of check boxes to highlight their interests—e.g., choosing a safety target, an approach to improving safety, a setting of care, a clinical area, a target audience, and an error type. Each of these categories drills down to more specific areas, so each user can customize preferences as broadly as “All Approaches to Improving Safety,” or simply “Teamwork

Training.” We believed that by helping users define their areas of interest, matched with our custom developed taxonomy (described below), the user experience would be optimized.

Classics

Given the volume of content on AHRQ PSNet, we wanted to highlight enduring and influential resources in patient safety—i.e., our “Classics.” After agreeing on an initial list of classics at site launch (with input from our Editorial Board), our editorial team reviews resources every 6 months to designate new “Classics.” Typically, we start with a list of potential resources—all of our selected “key” articles (i.e., those with longer annotation summaries), those highlighted on the “What’s New” home page, and the most frequently viewed and cited resources. The editorial team convenes, chooses a target of approximately 50 new classics per year, and then seeks input from the Editorial Board and Advisory Panel. Once final selections are made, these resources receive the “Classic” designation, increasing its weight and importance in our searching algorithms. We believe this feature provides users, particularly those new to the field, with an easy method to identify landmark resources. A few times a year, we will also designate a particularly noteworthy new resource as an “Instant Classic.”

Glossary

Building on the success of the AHRQ WebM&M glossary, we reproduced and expanded the glossary on AHRQ PSNet. The glossary terms have grown in number and depth, as many contain links (similar to our annotations) and important references. Given the breadth of the field, a comprehensive glossary helps explain commonly used terms (e.g., “safety culture”) and activities (e.g., root cause analysis) in patient safety. Adding or modifying glossary terms is part of the editorial workflow; new terms are identified or raised by editorial members, often while writing weekly annotations for new resources. AHRQ PSNet and AHRQ WebM&M glossaries are shared, and searching for a phrase on AHRQ PSNet, such as “safety culture,” will provide both the glossary term and the available resources matching the search term.

Taxonomy

A good user experience on AHRQ PSNet requires sensitive and specific methods for visitors to locate resources. A simple text search (e.g., “culture”) across the site’s resources would be inadequately specific, whereas an unstructured keyword list would quickly become unmanageable due to size and internally redundant. Therefore, we designed a structured categorization of descriptive terms—i.e., a taxonomy—to label resources on AHRQ PSNet. The taxonomy was designed by consensus and iterative review by our editorial team. Taxonomies composed by such expert groups tend to be large; they balance high specificity when describing complex domains at the cost of complexity and decreased usability. We tried to minimize these limitations by carefully restricting the taxonomy to the minimum degree of specificity necessary to support a user experience on a Web site, rather than by attempting to exhaustively describe either the breadth of the field or the distinctions possible within it.

For example, our list of “Medical Complications” is limited to five items—nosocomial infections, pressure ulcers, delirium, venous thrombosis, and falls—rather than an enumeration of every possible medical complication. These five items were selected based on their prominence in the field and the existing literature. While we do sacrifice some specificity in the

labeling, we avoid creating the unusable user experience that would result from an attempt to list every possible medical complication.

The taxonomy is organized along 7 descriptive axes: (1) Setting of Care, (2) Target Audience, (3) Clinical Area, (4) Safety Target, (5) Error Types, (6) Approach to Improving Safety, and (7) Resource Origin. Each axis is a hierarchy of terms, ranging from the very general (e.g., Setting of Care > Hospitals) to the very specific (e.g., Safety Target > Medication Safety > Medication Errors > Transcription Errors). Each AHRQ PSNet resource is tagged by professional indexers with zero or more taxonomy terms from each of the seven axes and could be tagged with very specific “leaf” terms, or more general “trunk” terms as appropriate. The tagging drives the site’s “Browse” user experience, where users can conceptually traverse the resource collection along a descriptive axis, or define a targeted search that intersects terms from two or more of the descriptive axes.

In the initial design, the optimum level of specificity was determined subjectively by the editors, with a prejudice toward avoiding an overly complex user experience. As AHRQ PSNet has accumulated content and visitor usage data, we have used statistical methods to identify places in the taxonomy to increase specificity or add new topic areas (e.g., “medication reconciliation” and “red rules” were added after site launch). We anticipate ongoing revisions to the taxonomy, based on statistical analysis, editorial assessment of the trends in the literature, and subjective feedback from the site’s visitors.

Results

Site Usage and User Satisfaction

We have monitored the impact of AHRQ PSNet by three mechanisms:

- Site usage—measured by unique visits per month.
- User content selection—measured by analysis of user search behavior and resources accessed.
- User demographics and satisfaction—measured by voluntary survey responses.

As shown in Figure 3, the site has steadily attracted more users since its launch, with an increase from approximately 30,000 visits per month in April 2005 to more than 110,000 in July 2007. Additional data from July 2007 indicate more than 3,600 site visits daily, more than 6,500 subscribers receiving the weekly “What’s New” e-mail newsletter, and more than 3,200 subscribers with established “My PSNet” accounts. At the launch of AHRQ PSNet, the number of visits to it and to AHRQ’s WebM&M were roughly equal. By way of comparison, AHRQ PSNet now has approximately 33 percent more daily visits than AHRQ WebM&M; combined, the two sites are trending toward approximately 2.5 million unique visits per year.

Each time a user accesses the site and views a specific resource, Silverchair’s Web server logs a “hit” for the individual resource item, as well as for the taxonomy terms used to classify that item. For example, if a user viewed an annotation of a journal article on the subject of “medication reconciliation,” it would be recorded as a “hit” for the taxon “Medication Safety.” When a user searches the site, the server also logs the exact search string used. We use monthly

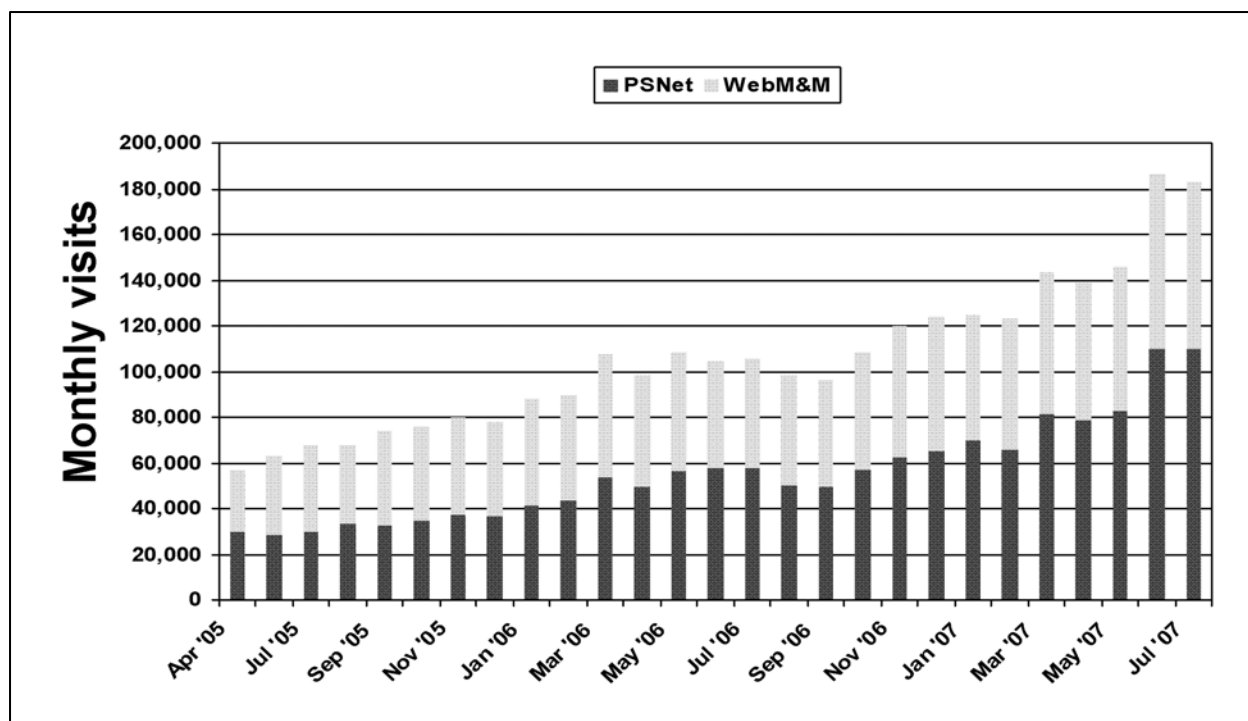


Figure 3. Visits per month to AHRQ PSNet: April 2005 to July 2007.

summary reports of these data to analyze our user’s content interests. Table 1 shows the most commonly accessed taxons over the past year; they represent the patient safety topics of greatest interest to our users. The diversity of topics, ranging from specific errors and interventions (e.g., “medication errors” and “teamwork training”) to systems and organizational issues (e.g., “nurse staffing ratios” and “culture of safety”) speaks to the varied interests of our

**Table 1. Most common search strings and taxonomy areas:
July 2006 – July 2007**

Top 10 search strings	Top 10 taxonomy areas
“SBAR” (Situation/Background/Assessment/Recommendation)	Nurse staffing ratios
“Falls”	Medication errors/preventable adverse drug events
“Medication reconciliation”	Culture of safety
“Communication”	Look-alike, sound-alike drugs
“Medication errors”	Human factors engineering
“Patient falls”	Patient falls
“CPOE” (computerized provider order entry)	Nosocomial infections
“Patient safety”	Critical care nursing
“Disclosure”	Approach to improving safety
“Culture”	Teamwork training

readers. Last summer, we conducted a voluntary user survey, gathering data on user satisfaction with the site and user demographic data. Most respondents identified their primary institutional affiliation as a hospital or health care system (60 percent) or academic institution (16 percent). The respondents came from a variety of professions and institutional roles, including nurses, physicians, and quality improvement (QI) and patient safety professionals, indicating that AHRQ PSNet is meeting our goal of providing resources for a diverse array of users (Table 2). Overall, users were very satisfied with the content, features, and ease of use of AHRQ PSNet; 92 percent of respondents stated they would recommend the site to a colleague.

Table 2. Characteristics of AHRQ PSNet users

Respondent role	Proportion of respondents (%)
Nurse/nurse practitioner	20
Quality improvement professional	19
Physician	14
Risk management professional	11
Patient safety officer	9
Administrator/manager of hospital, health plan, or medical group	6
Pharmacist	5
Others (e.g., librarians, Federal/State policymakers, students, writers/editors, and researchers)	<5

Future Directions

In May 2007, responding to the user survey, feedback, and site experiences, we launched an upgraded version of AHRQ PSNet. The improved user interface included easy-to-access navigation on the left and preserved the usability of the site. The upgrade augmented users' search capabilities using more sophisticated search algorithms. A new "Most Popular" feature highlights the most frequently viewed resources on the site.

Moving forward, we anticipate further upgrades with two specific features in the advanced planning phase: Podcasts and Patient Safety Primers. Podcasts—which are digital media files that can be automatically delivered through subscription feeds—have become a popular method for individuals to stay abreast of their favorite topics by listening at their convenience. Medical journals began offering such features recently, and the interest in developing podcasts for AHRQ WebM&M and AHRQ PSNet seemed natural and was fully supported by AHRQ. Once the technical capacity is built, we will provide podcasts for AHRQ WebM&M and AHRQ PSNet content.

With more than 3,000 content items on AHRQ PSNet, and 20 to 25 new resources added each week, novice users may find it difficult to become familiar with basic patient safety concepts.

For example, searching on “medication reconciliation” (the third most common search term as of fall 2006) yields 42 resources, displayed on three different screens. Since only 39 percent of users in the 2006 AHRQ PSNet user survey identified themselves as patient safety officers or QI/risk management professionals, it is likely that many of our users are relatively new to the field of patient safety and thus, could benefit from editorial guidance in accessing content. Therefore, in the near future we plan to introduce “Patient Safety Primers,” individual pages within AHRQ PSNet written by our editors on important patient safety topics.

The Patient Safety Primers will be organized clearly and will serve four key functions; they will:

1. Provide an introduction to the topic, including its definition, importance, and epidemiology.
2. Direct readers to the content items most relevant to the topic.
3. Improve integration of AHRQ PSNet content with AHRQ WebM&M content.
4. Improve access to both research-oriented and application-oriented content items.

In order to integrate the latest, most relevant content, the Patient Safety Primers will be continuously updated by the editorial team. Introduction of Patient Safety Primers will help move AHRQ PSNet from being a repository and library of patient safety resources toward becoming an even more comprehensive resource for the patient safety community.

Conclusion

In the past, we have described our first effort at bringing patient safety education to the Internet via AHRQ WebM&M as the “culmination of a bold AHRQ experiment.” AHRQ PSNet represents an extension of that experiment—to become the world’s premier resource for materials related to patient safety—and it appears (according to user response and visit statistics) to have been successful in this regard. In the fields of safety and quality, no comparable products, services, or Web sites provide a one-stop portal that captures important information from diverse sources, organizes the information with careful editorial input, and presents a product with a customized and attractive user interface.

AHRQ PSNet demonstrates the capacity for and value in delivering continuously updated patient safety news and literature to interested stakeholders. We hope these will aid providers, researchers, administrators, and policymakers in preventing medical errors, redesigning safer health care systems, teaching the principles of safety, and collaborating across disciplines and institutions.

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