Running Head: CULTURAL CHANGE

Measuring Cultural Change—A Management Focused Approach To Improving The Safety Culture

Capt Brad Weast

U.S. Army-Baylor University

Graduate Management Project

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Abstract

The purpose of this applied research project was to determine if implementing an eight-step comprehensive patient safety program could positively impact staff's perception of safety culture. One 14-bed, surgical oncology intensive care unit was chosen as the focus of this effort. All eight steps of the program were completed on this unit. The first step was to obtain a baseline of staff's perception of safety culture using a ten-question survey tool. This was accomplished August 2001, n = 66. The survey tool was determined to be reliable, using the statistical package for the social sciences (SPSS), version 10.1, which measured the internal consistency of the tool (Chronbach's alpha = .7907) for all ten survey questions when analyzing response data collected from outside the test unit, n = 329. Steps two, staff education on the sciences related to safety, three, identifying staff's safety concerns, four, event analysis, five, implementation of identified opportunities, six, documentation of results and seven, the sharing of results, were then administered. Step eight; re-surveying staff's perception of safety culture was completed February 2002, n = 64. Using SPSS, a one-way analysis of variance test was conducted to determine if there was statistical significance in the pair-wise difference between means from time one to time two. There was positive movement for all ten questions, with five identified as having statistical significance ($\underline{p} < .05$). The results of this effort have been shared with the Organization's Performance Improvement, Patient Safety, Management and Board of Trustees Performance Improvement committees.

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Introduction

Conditions which prompted the study

Error in any industry exists to some degree. Error in aviation is evidenced when a plane crashes or performs an emergency landing. In the nuclear industry it is evidenced by a melt down. In medicine it may be an adverse event or death. Both aviation and the nuclear industry have studied errors extensively. Since 1975, aviation has used an error reporting system, the Aviation Safety Reporting System (ASRS), to learn from mistakes and improve systems. In medicine error rates are beginning to receive similar attention. In the Institute of Medicine (IOM) report "To Err is Human," it was estimated that between 44,000 and 98,000 Americans die each year from preventable adverse events, defined as injuries caused by medical management (Kohn, Corrigan, and Donaldson, 2000). This report used as its basis two large samples of hospital admissions from New York (using 1984 data) and from Colorado and Utah (using 1992 data). From this data it was found that 3.7% and 2.9%, respectively, of adverse events were due to medical management and that 58% and 53%, respectively, of adverse events related to errors were preventable. The lack of improvement over that time span has been cause for political and public outcry. Even when using the lower of the two estimates, 44,000, error in medicine is the eighth leading cause of death, exceeding rates for motor vehicle accidents, breast cancer and AIDS (Kohn, Corrigan, and Donaldson, 2000).

Reduction in medical error is advantageous for society. From a physician's perspective one-reason stems from the Hippocratic oath, which includes the statement, "I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone (Graham, 2000)." This guiding principle in medicine cannot be ignored when the

opportunity to remove preventable harm from patient care delivery exists. Others include the unnecessary use of limited resources and poor perceptions in quality of care (HealthCast 2010, 1999). Exceeding constraints of limited resources eat away at the bottom line, increase staff turnover and lead to other system failure. Medication error, just one type of preventable error, increases costs by as much as $5,000 per occurrence (Classen, Pestotnik, Evans, Lloyd and Burke, 1997). Preventable medical errors also cause poor perceptions in quality, which in turn leads to fewer customers. HealthCast 2010 (1999) stated that in the managed care era, "the likelihood that the patient will see the same physician when they return next year for their annual physical is low. Thus, it behooves healthcare organizations to brand at the parent or institutional level, rather than at the sub-brand or clinician level. Consider the parallel in the airline industry. The brand equity is with the airline carrier, not the individual pilot." An example is Valujet. In 1996, all 110 people aboard Valujet Flight 592 died (CNN Interactive, 1996a). Just prior to the crash the Federal Aviation Administration (FAA) had completed a safety study on low-cost airlines. The findings revealed that Valujet had more accidents than nearly all of its competition in that category (CNN Interactive, 1996b). One customer, the Department of Defense, ordered a temporary halt to using the airline. Even after the airline returned to "safety first," it could not escape the past. In 1997, the FAA denied permission for Valujet to resume all of its routes (CNN Money, 1996). Valujet could not regain the cliental lost from 1996. Even when merging with another airline the stigma of Valujet's attention to safety could not be escaped. The FAA gave the merger a clean bill of health, but only after finding no evidence of unsafe conditions or systematic failures at AirTran, the carrier who lent its logo to Valujet (CNN Money, 1998). As society becomes more empowered through education and has to pay for more of its own care vice other payers, the demand for quality will be high.

In the past error in medicine was not widely publicized. Brand loyalty before, to a hospital or health system, stemmed from name recognition or knowledge of that institution's involvement in cutting edge technology. Now that reporting medical error in general is more common, brand loyalty will stem from not only outcomes, but by how often they are compromised by preventable medical error. As reporting and the public's knowledge of preventable medical error mature educated choices will be made based on results, not names.

The heightened awareness of preventable medical error caused many to call for change. The IOM report recommended a nationwide mandatory reporting system, and suggested voluntary reporting should be encouraged (Kohn, Corrigan, and Donaldson, 2000). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) established new patient safety standards, effective 1 July 2001, which include patient safety programs to provide clear systems for internal and external reporting of information relating to medical and healthcare errors (JCAHO, 2001a). In March of 2000, then President Clinton outlined the development of a safer medical system, which included mandatory reporting of errors resulting in death or serious injury and voluntary reporting for less serious medical errors and near-misses (Prager, 2000). In 2000, State legislatures introduced bills related to medical error reduction, with eight new laws passed as a result. In 2001, five states have introduced bills to deal with the same issue (Adams, 2001). But for any of these measures to be effective, participation is key. A reporting culture must be created. This culture would ideally expose medical error in order to learn from mistakes, and to change from an industry that blames front-line operators for error to one that learns from error. That is not to say that responsibility for action should be totally absolved, but that the focus should be on the system and not the individual. An example of how to determine employee culpability is summarized in Figure 1. This decision tree is employed in the aviation industry and

may serve as a guide for others. This tool enables the organization to separate blameworthy from blameless actions. Although useful, the focus of this tool still rests with the individual perspective. This may be appropriate if the error was determined to have stemmed from an unsafe act, but should not be the starting point. The system the front-line operator inhabits should be the starting point.

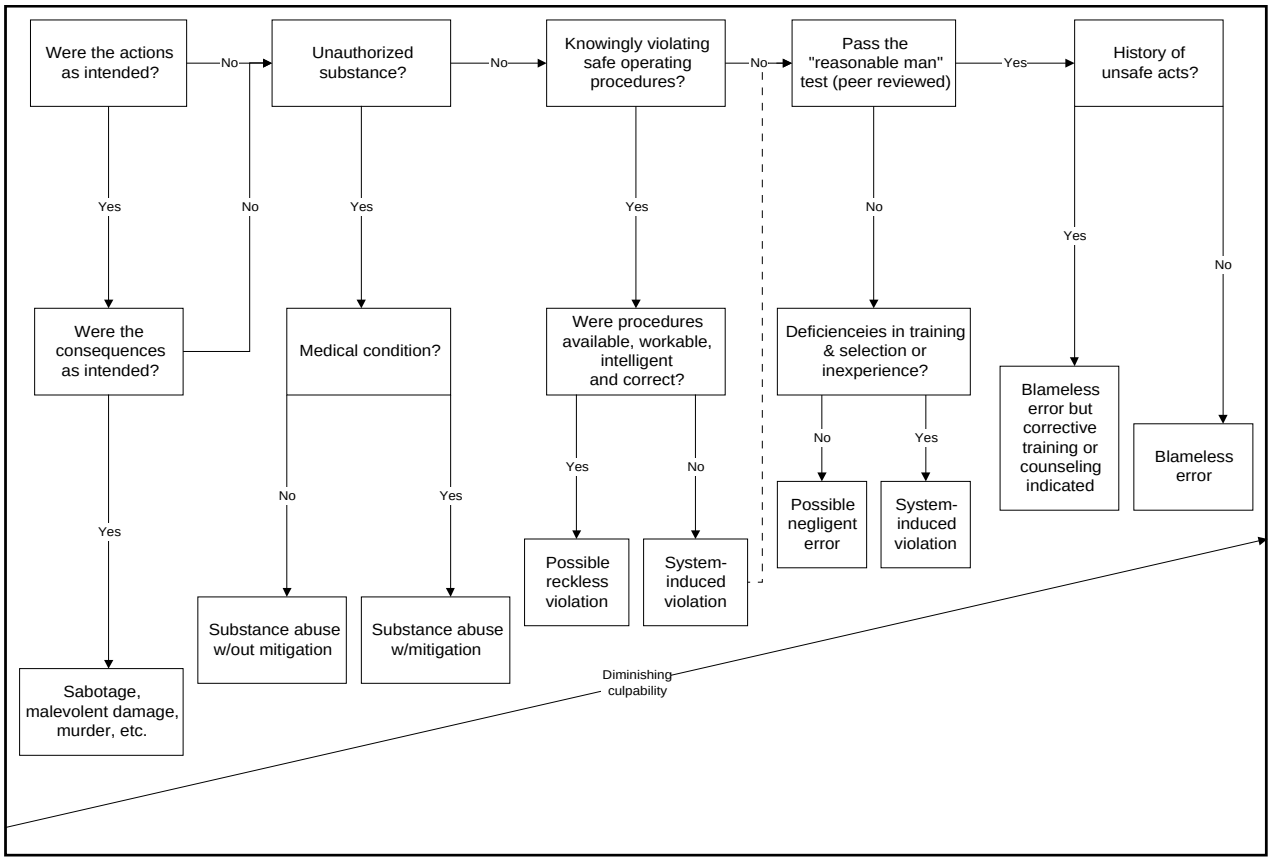

Figure 1. Decision tree for determining the culpability of unsafe acts. Reason, J., (2000a). Managing the Risks of Organizational Accidents. Burlington, VT: Ashgate Publishing Company. Reproduced with permission of the author.

To create this ideal situation, understanding why medical errors happen is important. Taken further, cognitive psychology and human factors research is being applied to understand medical errors in the context in which they happen (Leape, 1994). In aviation, training focused on perceptions of fatigue, stress, etc. continue to be targets for improvement. In medicine, the

focus is on uncovering mistakes and capitalizing opportunities to identify areas for improvement (Sexton, Thomas, and Helmreich, 2000). The current culture of medicine precludes the reporting of error. Barach and Small estimate that between 50% and 96% of adverse events are not reported annually (2000). Reasons for this are summarized in Table 1 on the next page.

Table 1.

Barriers and incentives to reporting.

	Individual	Organizational	Society
Legal			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, costs, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality and multi-institutional databases
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, enforce reporting statutes
Cultural (values, attitudes, beliefs)			
Barrier	Dependent on profession, code of silence, fear of colleagues in trouble, skepticism, extra work	Dependent on organization, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicized medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values: philanthropic, integrity, educational, cathartic	Become a leader in safety and quality; good for business	Enhanced community relations, build trust, improve healthcare, transparency
Regulatory			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, license suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intense
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
Financial			
Barrier	Loss of reputation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in healthcare system

Note. From "Reporting and Preventing Medical Mishaps: Lesson from Non-Medical Near Miss Reporting Systems," by P. Barach and S. Small, 2000, British Medical Journal, 320, p. 761.

For some time the focus on why medical errors occur stemmed from the person approach, not a system approach (Reason, 2000b). Complex systems, including healthcare, must be evaluated to identify interfaces where error can occur. Once systems interfaces are identified, the potential for human error can be removed. Identification of potential error comes from reporting, and reporting is stimulated through established trust. In all, an organization must know the "how," "why," "what" and the "who."

One organization that understood this took a management focused approach to improve patient safety. Recently, this large, world-renowned academic medical center began to change. In May of 2001, the creation of an official Patient Safety Committee (PSC), co-chaired by the Vice President for Medical Affairs and an internationally known critical care physician was established. This committee is charged with establishing a safety culture and employing best practices. Participation in rapid-fire initiatives through the Institute for Healthcare Improvement (IHI) began in July 2001. These initiatives have identified opportunities to improve work processes, affect culture and spread gains from one department to another. The development, and its component testing, of a comprehensive patient safety program (CPSP) began in August. And in October, passage of a non-punitive medical error disclosure policy was passed. Developed by the PSC, this policy sets the stage for a non-punitive system that encourages reporting, establishes a systems approach to increase safety and prescribes how to communicate error to the patient, family and the organization. All point to a systematic approach to improving the safety infrastructure and establishing trust between the systems and the people.

Literature review

The IOM report caused many healthcare administrators to question their healthcare system. Still, many thought that the report overstated its findings related to death and medical error. To investigate this possibility further the Robert Wood Johnson Foundation conducted a nation-wide survey of providers and administrators to gain their perceptions of the quality of healthcare. The survey was given to over 1,000 providers and administrators, with more than half (58%) stating that healthcare in this country is, “not very good.” As many as 95% of providers stated that they had witnessed a “serious” medical error. The most telling result was four out of five providers surveyed stated that they believe fundamental change is needed in the American healthcare system. A positive that came from the survey was that 29% of providers believe they can personally be leaders in improving the healthcare system, “as related to error (IHI, 2001).” This implies that physicians believe they can break down the barriers preventing reporting, and create a learning organization focused on improving safety systems.

Psychological and human factors research

For providers to be successful in promoting change, they too must understand why preventable errors occur in medicine. When determining causes for medical error it was found in the Harvard Medical Practice Study that 69% of errors were preventable (Leape, 1994). Error is defined as either one of omission, something neglected or undone, or commission, an act of committing something. In complex systems, such as aviation or medicine, there are many opportunities to commit both types of error. In industry, engineers and human factor experts have concerned themselves with developing human/machine interfaces that reduce the potential for human error. Cognitive psychologists too have developed models to address why people err. Through this research, a basis as to why human error occurs is applied to environments

consisting of complex systems (Leape, 1994). This knowledge will lead to developing safer systems.

Most errors result from lapses in cognitive functioning. The framework for normal cognition consists of mental functioning, most of which is automatic and repetitive. An example would be tying shoes. Once learned, the act of tying a shoe is accomplished with little or no thought, and is repeated often. This process uses “schemata,” or a system for accomplishing a task. People have many schemata to draw from on a daily basis, starting a car, driving to work along the same route, etc. This cognitive function requires essentially no conscious thought. An extension of this is known as the “attentional control mode.” This requires conscious thought and is used to solve routine problems. This type of cognition is more difficult, slower and requires effort (Leape, 1994).

A model of performance based on the concept of cognition, developed by Rasmussen and Jensen, consists of three levels (Figure 2, p. 18, summarizes the principal error types). The first is “skill-based,” which is similar in definition to schemata, and is largely unconscious. The second is “rule-based.” This is often thought of as, “if X, then Y.” The third is “knowledge-based.” This requires the application of stored knowledge and processing when confronted with an unusual circumstance. A departure from a skill-based activity requires either rule- or knowledge-based application, typically in that order (Leape, 1994). Errors that occur at the skill-based level are termed “slips.” There are four types of slips. The first is “capture,” when a common schema takes over from a similar, but less familiar one. An example is when a new step is added to improve an old sequence. The performer completes the old sequence instead of completing the new improved one. The second is “description error,” and is characterized by doing the right thing on the wrong object. Correctly spreading butter on a book is a descriptive error. The third

is “associative activation error,” and results when associations for one schema are applied to another. Answering the phone when the doorbell rings is an example. The fourth is “loss of activation errors.” This is when there is temporary memory loss while performing a task, as in the case of forgetting to drop off a child at school on the way to work (Leape, 1994).

Rule- and knowledge-based errors are characterized as mistakes. Rule-based mistakes occur most often when the right rule is applied at the wrong time, or is misapplied. Knowledge-based mistakes are more complex. Error may result due to a lack of knowledge or a misunderstanding of the problem. Pattern matching is a process preferable to calculation when confronted with a knowledge-based problem, but sometimes the wrong pattern is chosen. One such process is “biased memory,” and is typically chosen if proven effective in the past. Another is “availability heuristic,” characterized by using the first information retrieved from memory. Overconfidence is yet another example of a process that leads to a mistake (Leape, 1994).

All three, skill-, rule- and knowledge-based errors, are impacted by physiological, psychological and environmental influences (Leape, 1994). Although difficult to establish links between stress and specific accidents, errors, slips and mistakes increase under stress. Error can occur at one of two extremes, boredom or panic. Within this continuum is “coning of attention.” This is the tendency to concentrate on one single source of information when confronted with stress. Another is “revision under stress, ” characterized by behavioral patterns recently learned are replaced by older, more familiar ones, even if inappropriate (Leape, 1994). The airline industry offers an example. There are numerous prescriptive tasks airline mechanics are asked to perform. Over time these tasks are repeated often, and over time they are improved upon if warranted. Under stress, when being evaluated by a safety inspector or attempting to repair the

aircraft in time for scheduled departure, the mechanic may resort to the old “way of doing business,” ignoring any recent process improvements.

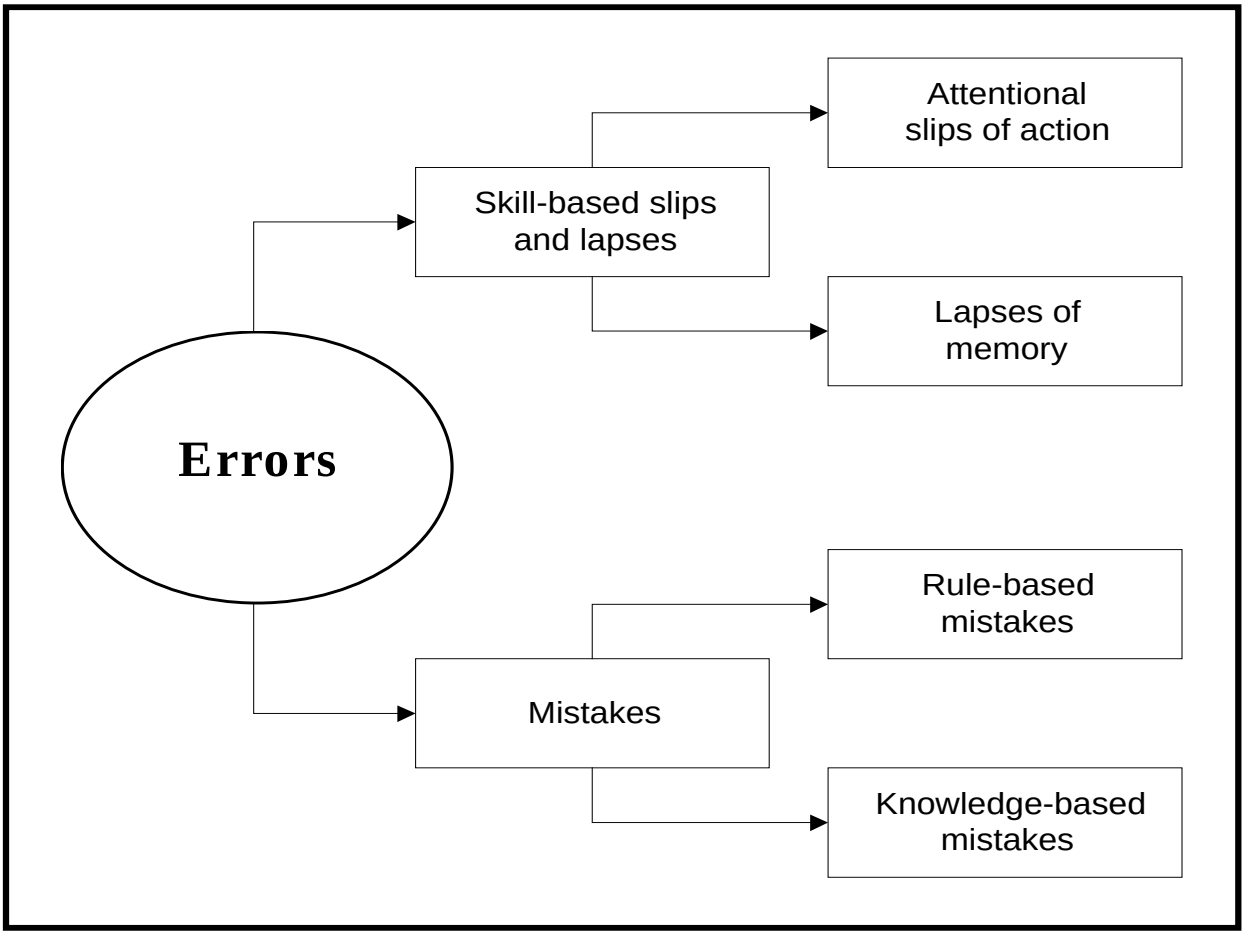

Figure 2. Summary of the principal error types. Reason, J., (2000a). Managing the Risks of Organizational Accidents. Burlington, VT: Ashgate Publishing Company. Reproduced with permission of the author.

Person approach

Management of human error can be categorized in two ways, a person approach or a system-focused approach. The person approach focuses on the act itself. Errors or procedural deviations are the fault of front-line operators, nurses, physicians, etc. These people are thought to commit the error because of laziness, inattention to detail or poor motivation. As a result, when correcting the error the focus is not on the system in which they work, but on them. Errors,

therefore, are sometimes treated as moral issues. This approach to managing error is often utilized in medicine. This mindset inhibits the development of a reporting and safety focused culture, created through education and learning from error. In aviation, approximately 90% of quality lapses were termed blameless (Reason, 2000b). This is due in part to effective risk management, but mainly it stems from experience. Aviation has created a reporting culture. Details from near misses, mishaps and the like provide the information necessary to reduce system error and minimize the impact human interface has on the system. A key element in developing a reporting culture is trust. Trust must be founded on a just culture, consisting of a line drawn between blameless and blameworthy actions. This is critical in developing a safety culture. Aviation has also shown that often the best performers make the biggest mistakes and that error tends to follow a pattern. When an approach is focused on the individual and not the system, minimizing human variability will be the focus instead of removing the error provoking properties within the system (Reason, 2000b).

System approach

The premise of this approach is that humans commit errors, even among the elite and in the best organizations. Errors are consequences and not causes of human action. The error may have developed “upstream,” and is now surfacing through this human interaction. Reducing error is not focused on changing the individual, but on the systems in which they work. Tools to assist work processes; education and creating safeguards are some examples of countermeasures to reduce error. When an event occurs it is important to determine what failed, not who (Reason, 2000b).

A model of error

Defenses, safeguards and barriers are key to the system approach in managing error. Think of them as a series of walls, one behind the other. Their function is to protect front-line operators and the patient from error. These walls are usually effective, but at times develop holes. These holes continually open and close, rarely lining up for error to stream through, but occasionally they do. These holes occur for two reasons, active failures and latent failures (Reason, 2000b). Active failures are characterized as unsafe acts committed by front-line operators. Slips and mistakes are examples. Latent conditions are inherent in the system itself. Poor design, build or procedural flaws may be the culprits. Latent conditions have two kinds of adverse effect. The first is an error provoking condition, an example of which would be understaffing because of a nursing shortage. The second is that they can create long-lasting holes in the walls meant to protect, again, the nursing shortage is an example (Reason, 2000b). Understanding how error occurs and an approach to its management will help in creating a reporting and safety culture.

How is yawning contagious? Why did crime drop precipitously in New York City? The ripple from a stone thrown into an otherwise calm pond can have a significant effect. Each ripple begets another, until the entire surface of that body of water is affected. In the book, “The tipping point,” Malcolm Gladwell (2000) attempts to explain why and how critical mass for dramatic, even epidemic change can occur. In healthcare that tipping point may lead to the reduction in accidental death, or a safety culture that reduces preventable errors to essentially zero. Three characteristics regarding “tipping points” must be understood before attempting to swing the scales in the desired direction. The first characteristic is the law of the few. A few key or influential individuals must be involved for change to spread. The second is the “stickiness

factor." Determining how to exploit opportunity, or to minimize the potential for harm must be done in a memorable way. And the third characteristic is the "power of context." Change must occur in an environment supportive of change.

Obstacles to change

In the IOM report (Kohn, Corrigan and Donaldson, 2000) it was recommended that top leadership within the organization be involved in creating a safety culture. Specifically, the report recommended that each organization develop a patient safety program with clearly defined executive responsibility. Components within the program would include visible attention to safety by the continuum of staff, implementation of a non-punitive system for reporting, incorporating understood methods to reduce error, and taking a multidisciplinary approach. Some barriers, however, to developing and implementing a patient safety program meant to stimulate reporting and create a safety culture exist.

Mandatory reporting

To get a sense of the barriers that may prevent the implementation of an effective mandatory error reporting system, HCPro's accreditinfo.com conducted a survey to find out what fears rested with healthcare professionals (2000). The results, summarized in tables 2 and 3, illustrate the fear of reporting. 644 healthcare professionals responded, and of those 85% felt that the government could not protect the anonymity of the reporter. 90% of responders felt that it was "somewhat," or "extremely likely" that reporting is currently lacking for fear of job loss. 82% felt concerned with the potential for civil liability and 86% cited personal shame as "somewhat," or "extremely likely." Other concerns dealt with loss of market share, accreditation and a fear that the organization's reputation would be damaged (HCPro's, 2000).

Table 2.

Do you believe that medical errors go unreported within the facility because individual are:

	n	Not likely (Percentage)	Somewhat likely (Percentage)	Extremely likely (Percentage)
Concerned with civil liability?	638	17	38	44
Concerned with criminal liability?	637	37	38	25
Concerned with losing their job?	640	10	34	56
Avoiding personal shame?	635	13	41	45
Not sure how a medical error is defined?	641	35	44	21
Unaware of your organization's reporting policies or procedures?	638	48	38	13

Note. From HCPro's Accreditinfo.com, "Survey Reveals Fear Over Mandatory Medical Error Reporting," 2000, posted by Accreditation Connection. Copyright 1999-2000 MarketTools, Inc.

Table 3.

Do you believe that errors go unreported to outside authorities because health care organizations have:

	n	Not likely (Percentage)	Somewhat likely (Percentage)	Extremely likely (Percentage)
Concerns with civil liability?	642	10	28	62
Concerns with criminal liability?	641	30	33	36
Concerns with losing market share?	641	16	37	47
Concerns with losing accreditation?	638	17	40	43
Concerns with reputation?	634	6	28	65
Reporting procedures or policies that not administered?	634	30	47	21

Note. From HCPro's Accreditinfo.com, "Survey Reveals Fear Over Mandatory Medical Error Reporting," 2000, posted by Accreditation Connection. Copyright 1999-2000 MarketTools, Inc.

Even with these barriers in mind, the National Patient Safety Foundation at the American Medical Association is in support of mandatory reporting as long as protections are in place to protect the anonymity of the reporter (Prager, 2000).

Voluntary reporting

While it is felt the most effective way to encourage participation is through voluntary reporting, measures to protect the reporter must still be taken. As aviation proved, only through a trusted reporting system will valued information be made available. The ASRS collects, analyzes and responds to the information voluntarily reported by personnel. Information on error can be provided via electronic, written or telecommunication mediums. This information is invaluable to the creation of policy, planning and improvement initiatives implanted to drive out the potential for system error (ASRS, 2001).

In its revisions to the new patient safety standard JCAHO stops short of recommending a type of system (voluntary v. mandatory). It does, however, emphasize the need for the

acknowledgement of risk and leadership involvement. Leadership's responsibility is to create a reporting culture by minimizing individual blame, and instead focus on processes and systems error. Additionally, JCAHO supports these "learning organizations" sharing their knowledge of error with others in order to create a better national system of healthcare (JCAHO, 2001b).

Purpose

The purpose of this study is to measure the impact of an eight-step, CPSP on the staff's perceived safety culture in one intensive care unit (ICU) within a major academic medical center. Staff's perception of safety culture will be measured using a ten-question cultural survey. The patient safety program will use recommendations from literature on effective methods to improve patient safety and on how to change the safety culture in which medical personnel operate.

Methods and Procedures

The academic medical center will be referred to from this point on as the "Hospital." The hospital chosen for this study is consistently recognized as a national and world leader in healthcare. This reputation is based on quality in patient care, research and teaching. The entity chosen within the Hospital is a 14-bed surgical ICU that cares for oncology patients and is recognized for its outstanding clinical leadership and the willingness to participate in patient-focused safety initiatives. This unit and its supporting pharmacy personnel will be given a ten-question survey to determine their perceived safety culture.

To assess the culture of safety, a safety attitudes survey (SAS) that included 10 items, each of which was rated with a 5-point Likert scale from 1, disagree to 5, agree was used. The SAS evaluates staff's perceptions regarding their physician and nurse leaders' and senior leaders' commitment to safety, their knowledge regarding how to report adverse events, and their

understanding of systems as a cause of adverse events (Appendix A). The SAS was adapted from the cockpit management attitudes questionnaire, which has been widely used in aviation. It was developed to measure attitudes toward stress, status hierarchies, leadership, and interpersonal interaction issues (Helmreich, 1984).

The SAS employed, using the statistical package for the social sciences (SPSS), version 10.1, was found to be reliable. The internal consistency was measured using Cronbach's alpha, which was equal to .7907 for all ten survey questions when analyzing response data collected from outside the test unit, n = 329. Internal consistency measures the extent to which items on a scale or test are homogeneous, measuring all split-half combinations. Cronbach's alpha is an appropriate measure when determining the internal consistency of a survey tool that captures non-dichotomous data.

The eight-step, CPSP employed on the unit was modeled and evolved through a review of the literature, discussion with experts, trial and adaptation based on experience and feedback from involved staff. In aviation, the model that proves effective consists of designing systems that absorb human error. Human error is expected to occur. Procedures are standardized to eliminate misinterpretation and/or misapplication of steps or processes, and safety has been institutionalized. All this is possible because error reporting is encouraged and actions taken from lessons learned improve systems instead of punish people. In medicine, error is thought to stem from individuals, not systems. Human error is not expected. Standardization for any one process can vary from hospital to hospital, and even from department to department. And safety in medicine, although recognized as an essential component in healthcare delivery, has not been institutionalized (Leape, 1994). Reporting is scarce, due in part to the person focus instead of the system focus, and therefore lessons learned are few and systems improvements are sporadic.

Recognizing these limiters to an effective CPSP, management began to develop a safety infrastructure. This was accomplished with the establishment of a PSC, consisting of a multidisciplinary team responsible for developing and overseeing the CPSP and the passing of a hospital-wide, non-punitive medical error reporting policy, meant to allay fear of reporting and encourage staff's participation in the program.

Comprehensive patient safety program

What follows are the eight steps in the CPSP and their application on the unit of interest. Results from each transaction will be discussed in the Results section. To implement the program, the work unit must form an improvement team comprised of a physician, nurse, and manager; pharmacists, respiratory therapists and other staff are encouraged to participate. Through discussions with department chairs and nurse managers, there is a concerted effort to ensure that the members of the improvement team can devote at least one day a week for improvement initiatives.

A benefit of the CPSP is that it offers a framework (Figure 3, p. 60) for improvement efforts that are adaptable for problems specific to that work unit. It has the ability to affect culture, all staff including senior leaders, and gives the opportunity for staff to enhance their own environment (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

<u>Step 1: conduct cultural survey</u>

Senior leadership in any organization should embody the organization's culture. Perception of senior leadership will influence and shape behavior of staff. Leadership can affect performance and potentially, the willingness to report medical error (Pizzi, Goldfarb and Nash, 2001). To get a sense of staff's perception of safety culture the SAS was administered in August

2001. The survey was given to all staff, which included pharmacy support staff assigned to that unit. Instructions were given at the time it was handed out and staff members were encouraged to fill out the survey on their own in a setting where they could answer freely. Descriptive statistics for each question were calculated and are summarized in the Table 4 (Results section). Management desired to know what, if any, question exceeded the self-imposed goal of achieving a mean score of four or higher (out of a possible five) per question.

Step 2: Educate staff

The cultural survey completed, analyzed and reported to the PSC sets in motion the next step in the program, the education of staff on the sciences related to safety. In order to help staff understand how systems impact patient safety the focus of the presentation is based on James Reason's explanation of latent and active failure, and their impact on systems (2000a). Unit leadership and representation by either the PSC or other hospital senior leadership conduct the briefing (Figures 4-11, p. 62). Leadership involvement was identified as critical in any program's success and sustainability (JCAHO, 2001b).

Step3: Identify staff's safety concerns

Staff safety survey. At the end of the presentation staff receive a survey (Appendix B) that requests information on how the next patient will be harmed, how this can be prevented and what the PSC can do in creating organizational visibility. This information is collected and submitted to the PSC, which reviews the information, addresses any immediate issues and communicates the findings to the Management Committee, comprised of the Hospital President and all Vice Presidents.

Senior executive walk rounds. Senior leaders recognized the need for involvement. Review of the literature recommends their participation and the results of the cultural survey confirmed this finding. To capitalize on the information provided by the unit, obtained through the Staff Safety Survey, and to communicate their involvement through participation, senior executive "walk rounds" was created. Each member from the senior executive staff adopt a unit(s), with the ICUs prioritized first. This affords leadership opportunities to communicate with staff, discuss Staff Safety Survey results and to discuss any other issues staff expresses. This initiative not only affords staff time with leadership, but also provides feedback on issues impacting the unit environment, and potentially the entire organization. Providing rapid, useful, accessible and intelligible feedback was listed as a major component in developing trust and creating a reporting culture (Reason, 2000a).

After walk rounds the information about the specific issues identified by staff on the Staff Safety Survey, or new issues discussed during walk rounds, is detailed in a letter from the PSC to the unit (Appendix C). This letter is intended to serve as a quasi-contract between the PSC and the unit, provide valid and timely feedback and further support the spread of the CPSP.

Event reporting system. Yet another opportunity for staff to communicate safety issues is being developed. Funding for this initiative was obtained from the Agency for Health Care Research and Quality (AHRQ). This initiative is an attempt to reduce medical errors and improve patient safety. The reporting system is being pilot tested in 30 ICUs nationally, including the ICU of interest. This error reporting system will be web-based, and although it is currently being developed for ICUs, its applicability will extend beyond that setting (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

Step 4: Event analysis

A tool to help staff investigate adverse events that do occur is offered (Appendix D). Utilizing this tool is recommended if the source of error is not evident or understood. This tool provides staff with a structured approach to case investigation that is designed to identify the system failure(s) that leads to the adverse event (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002). The results of the investigation are communicated to the PSC.

Step 5: Implement improvements

The staff selects areas to focus improvement efforts. These areas are selected based on the strategic priorities of the Hospital, the results of the Staff Safety Survey, discussions, or prior events. The staff are instructed to prioritize improvement efforts based on the likelihood that the event will occur and the severity of harm should the event occur. Staff from the PSC help the work unit leaders prioritize improvement efforts. Originally, a structured scoring system based on the Department of Veteran's Affairs' safety program was used to prioritize improvement efforts (Bagian, Lee, Gosbee, DeRosier, Stalhandske, Eldridge, Williams, and Burkhardt, 2001). Nevertheless, staff used this form infrequently and it was eliminated from the program.

The unit is asked to select three improvement efforts that only require marginal resources and implement these immediately and to select three improvement efforts that do require resources and submit these to the PSC for funding consideration (Table 5, Results section). Staff are also asked to discuss the resources needed to implement improvement efforts with the senior leader who has adopted their ICU.

Teams are instructed to use the scientific improvement model (Appendix E) developed by Walter Shewhart. The plan-do-study-act cycle takes a plan for improvement from

implementation to actions taken based on measured results (Lighter and Fair, 2000). Another tool that provides structure is a grid that helps staff to identify a unit(s) of measure in order to monitor the improvement initiative, provide definition(s), detail the goal(s) of the changed process and suggestions for data collection (Appendix F).

The benefits in utilizing these tools are data capture, visibility, a feedback mechanism based on findings and ease of application and interpretation. For improvement efforts, the unit is encouraged to develop measures of its success and to present results, with the intent being to facilitate organizational learning (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

Step 6: Document results

In order to determine if the unit of measure is appropriate and to collect the necessary number of data points to create control limits, etc. results must be documented. The very basis of any quality improvement initiative is data and there documentation. A project cannot survive without some type of data collection and analysis. Improvement implies measurement of the effect of intervention (Lighter and Fair, 2000). Without measurement, management will be at a loss for what direction to take or how to determine the validity of any process improvements implemented.

The teams are advised that improvement efforts should be publishable. As such, teams are encouraged to write specifications for each measure defining who will measure, what will be measured, how will it be measured, when will it be measured and where will it be measured. Teams are encouraged to present data in an annotated run chart and to try to select a common metric (events per week, for example). In the academic culture in which the ICU operates, the

ability to produce publishable results is paramount (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., (2002).

Step 7: Share success stories and disseminate results

The "Safety Tales" form (Appendix G) is a medium for the unit to facilitate feedback to the participants, and to share successes and lessons learned organizationally. Mentioned earlier, feedback is key in developing trust in the system. This is critical when any organization attempts to change its culture. To change the culture from one focused on the daily grind to "safety first" it is important to let individuals know that their behaviors make a difference.

Step 8: Re-accomplish Step 1

The cultural survey was accomplished in February 2002 and is discussed in the Results section. Also within the Results section, a statistical analysis of the results is presented.

Expected Findings and Utility of Results

This applied research project was conducted on a 14-bed, surgical oncology intensive care unit and will measure the staff's perception of safety culture. The tool used is a ten-question cultural survey, administered before and after the introduction of a CPSP. This safety program is focused on staff education and the reporting of patient safety issues to management in order to enhance and build safety systems.

The hypotheses for this research project are:

H_o: There will be no change in staff's perceived safety culture as measured by the cultural survey.

H_a: There will be a change in staff's perceived safety culture as measured by the cultural survey.

This will be measured using SPSS, version 10.1, applying the one-way analysis of variance test to determine if statistical significance in the pair-wise difference between means per question from time one to time two exists. The alpha level was set a priori at $p < .05$.

Results

Cultural Survey

The results of the cultural survey prior to and six months after implementing the CPSP in the ICU are presented in Table 4. Appendix H contains the resulting analysis of variance table. Received were completed surveys from 66 and 64 people, time one and two, respectively. Participating role types included physicians, nurses, pharmacists, both clinical and pharmacy technicians, support associates, clerical staff, other and unspecified.

Statistical significance was found in the difference in means from time one to time two for five survey questions (questions 5 and 7-10). These responses illustrate an increased understanding related to the Hospital's commitment to improving patient safety, and if an error occurs, that the staff believes most adverse events originate due to multiple system failures. At the very crux of creating a safety culture lies question five, "I am encouraged by my supervisors and co-workers to report any unsafe conditions I observe." Without reporting and unit-based support creating safer healthcare delivery systems, a learning organization and a safety culture are next to impossible.

Although improvement was realized from time one to time two for all survey questions, no statistical significance was found in questions one through four and six. This further emphasized the need for senior leadership's continued involvement and visibility in the program, and is one reason senior executives have adopted a unit(s) to serve as an advocate and to discuss patient safety issues with staff.

The results from this program component, the cultural survey, have been positive. Each question affords leadership insight on where to focus its attention. In healthcare there are finite resources, and so it is crucial to possess the ability to segment a population or areas of interest, prioritize them and then match resources appropriately. The cultural survey tool affords this flexibility and is a recognized critical component in the CPSP. To that end, one of the PSC co-chairs has been working with Brian Sexton, a colleague of Robert Helmreich, author of the survey tool adapted by the Hospital, to begin creating a more encompassing survey tool and a plan to develop a body of data that can be used for similar future research efforts nationally.

Table 4.

Intensive care unit cultural survey results by question.

	*Time One**			*Time Two*			*Overall*	
Question	n	Mean Score (SD)		n	Mean Score (SD)		Difference	Percentage change
1	65	3.52	(1.02)	62	3.55	(1.08)	.025	.72
2	26	3.54	(.91)	63	3.84	(1.02)	.303	8.56
3	64	3.55	(1.02)	64	3.75	(.89)	.203	5.73
4	64	3.61	(1.16)	63	3.76	(1.10)	.153	4.23
5	64	3.78	(1.16)	64	4.25	(.93)	.469	12.40 †
6	64	3.97	(1.00)	64	4.27	(.78)	.297	7.48
7	65	3.66	(1.14)	64	4.13	(.86)	.463	12.66 †
8	64	3.50	(1.10)	64	3.91	(.90)	.406	11.61 †
9	65	3.97	(1.05)	63	4.37	(.75)	.396	9.97 †
10	66	3.88	(1.21)	64	4.39	(.80)	.512	13.20 †

† $\underline{p} < .05$

* Original survey consisted of nine questions for ICU staff, excluding question two, but all other staff (pharmacy and other ancillary support) had all 10 questions. All other questions were the same, and question two, included in some time one surveys, is the same question, question two, in the survey administered for time two.

Staff Education

The ICU received the sciences related to safety briefing September 2001. The presenter was a co-chair of the PSC, creator of the briefing and serves as one of the unit's attending physicians. Afterward the Staff Safety Survey was administered.

Staff Safety Concerns

Table 5 contains staff's patient safety concerns communicated through the Staff Safety Survey. This information served as the basis for discussion during the senior executive walk rounds, and contains the issues followed by the ICU and its advocate, the President of the Hospital and health system. To date this unit has participated in three walk rounds, and will meet with its advocate on a routine basis.

Table 5.

Safety issues identified by staff.

Identified concern	*Staff's recommend change*
Lack of standardized concentrations of vasopressors among ICUs and operating room	Need to standardize concentration and labels for vasopressor
Removing care giver from bedside to transport patient	Use dedicated transport team
Advising and educating staff on potential medication errors in real time	Point of care pharmacist available on rounds
Potential for adverse drug event	Label meds in buritol
Poor management of patients pain	Create guideline or protocol for pain assessment and management
Poor communication among ICU providers	Create Short Term Goals Sheet
Poor communication with receiving team during ICU discharge leading to Medication errors in transfer orders	Medication Reconciliation Process at ICU discharge

Event analysis

There were no identified issues where the system error was not understood. Therefore, the event analysis tool detailed previously in Step 4 of the program was not utilized.

Implement improvements

Table 6 summarizes the staff's plans to improve patient safety. The unit was asked to select three improvement efforts that only require marginal resources and implement these immediately and to select three improvement efforts that do require resources and submit these to the PSC for funding consideration. The results of the safety survey indicated that staff perceive communication as a significant safety risk, particularly communication when patients are transferred out of the ICU.

Table 6.

Action items identified by staff.

	Identified Opportunity	*Action Taken*	*Impact*
Required Resources	Patient Transport: Dedicated team for entire hospital in order to clinical staff's capacity to provide direct patient care.	Incremental plan implemented that provided timely relief. This plan will be fully funded by July 2002.	This will allow—MD and RN roles—for more patient care to be delivered on the unit
	Point of Care Pharmacist: PharmD. assigned to unit who facilitates the flow of information and drug product between the pharmacy and the unit.	Once in place and then removed, the Pharmacy Department took note of the feedback units provided and reinstated the program.	Time previously spent coordinating ancillary support is transferred to patient care and unit safety initiatives
	Reconciliation: Reconciling pre-hospital, pre-operative and ICU prescribed medications before transfer from unit. This improved work process will reduce the potential for preventable adverse drug events.	The Performance Improvement team created a tool that performs this function.	The improved work process is being spread and is in another ICU (beta site). To also help spread use of the intranet is being utilized.
Required Marginal Resources	Goal Sheets:	Daily goal sheet developed. The plan of care for the day is written on all patients that are staying in the ICU. The goal sheet is divided into systems, and a separate goal/plan in each area of patient care need. Also discussed at this time is redundancy of lab draws, and areas of potential harm for the patient	Improved communication for the entire health care team. Cost saving with a heighten awareness of all lab drawns and clarification of the frequency of the labs to be sent.
	Labeling Buretrol:	Red medication add labels ordered and kept on patient servers in the room. When a medication is added to the buretrol, a red label is attached that states the medication infusing and the date and time	Reduced risk of medication error
	Labeling Epidural Cathether:	When a patient is admitted to WICU from the OR with a epidural cathether, the admitting nurse when initiated the PCA infusion, attaches a red label at the end of the PCA tubing next to the connection hub. Written on the label is epidural.	Reduced risk of medication error

To address the problems with communication, two initiatives were implemented. The first tool used to improve communication was the short-term goals sheet. This sheet identifies the plan for the patient that is too be carried out. The information for the plan is annotated during rounds and the sheet is then placed bedside for reference throughout the day. Any changes that occur during the day are also captured. All providers use this as a point of communication. In addition, the nurses and families use it as a communication tool (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

The second effort to improve communication was to reduce preventable potential medication errors in transfer orders (Appendix I). To define the scope of the problem, the unit's performance improvement committee created a standardized form to evaluate for the presence of a preventable potential medication error. The unit's attending and one of its nursing directors randomly selected 15 charts per week for two weeks to identify these errors. The reviewers asked three questions: 1) are medications in the transfer orders the same as the medications the patient is receiving in the ICU, 2) are allergies listed the same and 3) are home antihypertensive medications started. If the answer to any of these is "no," the nurse asked the resident if the change was intended. In addition, the nurse asked the patient if the allergies and home medications were listed correctly. The definition of a preventable potential medication error for this exercise was that as a result of this medication reconciliation process, the providers change the orders.

During the first two weeks, 31 of 33 (94%) patients had their orders changed (Figure 12, p. 66). These rates of errors were so alarming that the reviewers went to the ICU nurse manager and requested that the medication reconciliation process be part of the standard ICU transfer

process. All parties agreed with the findings and the medication reconciliation process is now a critical component of the transfer process.

In monitoring this enhanced safety system data are tracked to estimate the compliance with and effectiveness of this transfer process. Figure 13 displays the rate of compliance with medication reconciliation, and Figure 14 displays the incidence of preventable potential medication errors per week, pages 66 and 67, respectively. Also tracked are data that feed a formula crafted to estimate avoided costs related to adverse drug events. This information is summarized in Table 7 below. When using $2,182 as the cost of a medication error multiplied by the expected number of adverse drug events (17 = applied rate X projected number of medication orders changed) the medication reconciliation process is associated with approximately $37,000 in avoided costs on an annual basis for this single ICU. There are six additional ICUs in the Hospital.

Table 7.

Avoided costs: Interventions at the medication order-based level.

Interventions: Medication Order-Based Level	
Average Number Changed per Data Period	8.38
Average Number of days per Data Period	7
Projected Number of Data Periods	52
Projected Number of Medication Orders Changed	436
Applied Rate*	4%
Applied Expense*	$2,182
Expected Number of Adverse Drug Events	17
Expected Avoided Costs	$37,094

* Based on information obtained from three studies, which are listed in the References section of this paper and include an "*" for identification.

One initiative that required resources and was immediately funded was patient transport. The funding of the transport team demonstrated the power of enhanced communication through the adoption component of the CPSP. The ICU staff had submitted capital budget requests for two years to have a transport team take patients from the ICU to tests. Although two patients in ICUs suffered adverse events during transport, the funding request was never granted, likely because it was never brought to the attention of senior leaders. During the staff's meeting with senior executives, the staff discussed the need for a transport team. The senior executives heard this request; the next morning the transport team started. Besides the improvements in patient safety, the staff's discussion with senior executives demonstrates leadership's commitment to patient safety and their willingness to allocate resources to these efforts.

Documentation

During the implementation of the CPSP many data were tracked and compiled into usable information to serve as the basis for informed decision making. Some of the metrics used to chart the course for medication reconciliation includes staff's compliance with the improved work process and the intervention rate at both the patient and medication order-based levels. Staff compliance is defined as the number of transfer surveys completed divided by the total number of transfers from the unit during the data collection period—typically consisting of seven days. The patient-level intervention rate is the number of patients in whom at least one transfer

order has been changed divided by the total number of transfer surveys completed during the data collection period. And the medication order-based intervention rate is the total number of medication orders changed divided by the total number of medication orders written that correspond with the total number of transfer surveys completed during the data collection period. These metrics help communicate to staff that their efforts do make a difference. This is especially true if compliance waivers with no significant drop in interventions; increasing the likelihood that a preventable potential medication error is on the horizon. Metrics help to track progress and communicate what does and does not work. Without them effectively managing change would be next to impossible (Lighter and Fair, 2000).

Share Stories

As mentioned earlier, the "Safety Tales" form is intended to provide a structured way to communicate successes and lessons learned with the unit and the Hospital. This is critical in developing a learning organization that is focused on improving safety systems. Without this information duplication of efforts may result, wasting valued and scare resources, not too mention the fact that they may have already been proven ineffective. A completed form for the medication reconciliation process can be found at Appendix J.

Discussion

Nationally many groups have become involved in safety. Although patient safety is thought to be inherent in the delivery systems, the healthcare industry is in its infancy in creating safety systems derived from a reporting culture. The Agency for Health Care Research and Quality (AHRQ) published steps to safer healthcare (2002). The American Hospital Association has created a framework to evaluate safety initiatives (2002). And the National Quality Forum (2002) and AHRQ (IHI, 2002) have both published safety recommendations founded on

evidence-based medicine. These collective calls for change have impacted the industry to some extent.

Groups have formed to use these and other recommendations as a foundation to demand change. The best example of this is the Leapfrog Group, which is a patient-safety advocacy coalition, consisting of 96 major employers from various industries. Xerox, IBM and General Motors, to name a few, are taking evidence-based information and calling for the health systems to incorporate these "best practices." Examples of this include computerized physician order entry systems (CPOE), thought to be critical in eliminating error from medication use processes, and closed-staff ICUs, thought to be key in providing continuity in care. Beyond the demands, Leapfrog is also taking inventory and rewarding those that meet the specified safety criteria. A survey has been created to evaluate health systems, with the results used as information on where to send the member group's employees. In New York, for example, 4% bonuses per patient are being offered to hospitals that have CPOE and closed-staff ICUs (Health Care Advisory Board, 2002). It is this type of concerted effort from significant stakeholders that will force change on the healthcare industry.

Despite the emphasis regarding patient safety in healthcare, there have been few concerted efforts to evaluate a healthcare organization's culture regarding safety and the impact that may have on outcomes. In response to the recent IOM report, "Crossing the Quality Chasm (Kohn, Donaldson, Corrigan, Pike and Maguire, 2001)," and an organizational commitment to patient safety, a systematic assessment of the culture of safety at the Hospital was conducted, and from this, used as a basis to develop a strategic plan to improve safety (Pronovost, Weast, Rosenstein, Haller, Kidwell, Feroli and Rubin, 2002). But there is little to compare these efforts to nationally or otherwise.

Limitations of Study

Several limitations are recognized. First, the CPSP has only been implemented in ICUs. There is a need to evaluate the generalizability of this program in other work units. Second, this program was implemented in an academic medical center. It is unclear how this program would work in non-academic healthcare environments. Third, the full impact of the program has yet to be determined. The Hospital does not have a broad measurement of the incidence of adverse events and has not evaluated the long-term impact of the program. Nonetheless, the improvements in safety documented are important to staff, patients and families. Fourth, the instrument used to measure the culture of safety could be improved. Brian Sexton and colleagues have developed a survey instrument that evaluates job satisfaction, perceptions of management, teamwork climate, safety climate, stress recognition, and working conditions. The use of a broader instrument such as this may provide broader insights into an organization's culture of safety and assist in the quest to develop a learning organization focused on improving safety systems (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

Future Directions

The Hospital plans to implement the CPSP throughout the organization. The program is now implemented in anesthesiology, general medicine, pediatrics, rehabilitation medicine, and orthopedics. The creation of a web site for safety efforts will help to coordinate improvement initiatives within the Hospital. The current SAS will be discontinued and a broader survey tool developed by Brian Sexton and others will be employed. In addition, plans for a safety summit where the improvement teams from each of the work units will get together to learn, share

successes and failures are underway (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

Conclusions

The Hospital has developed and fully implemented a CPSP in the ICU of interest at an academic medical center. As a result, there has been an improvement in staff's perceptions regarding patient safety as well as reduced rates of several specific adverse events. Senior leadership has accepted the program and has become intimately involved in affecting cultural change. Unit advocates include the Dean of the Medical School and CEO of the health system, the Dean of the University, the President of the Hospital and health system, the COO of the Hospital and health system and the Vice President of Human Resources for the Hospital, with many more waiting in the wings. Realizing the vision of creating a learning organization focused on improving safety systems is well underway (Pronovost, P., Weast, B., Rosenstein, B., Haller, K., Kidwell, R., Feroli, R., Poe, S., Wassilchalk, D. and Mirrow, J., 2002).

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Appendix A

CULTURAL SURVEY QUESTIONNAIRE

We are conducting a survey to evaluate the culture of safety in your unit. The survey will take approximately three minutes to complete. Please leave the completed survey in the survey mailbox or designated point of contact from your unit.

Role (circle one): Attending/Fellow Physician / Resident Physician / Nurse /

Respiratory Therapist / Support Associate / Other (please list): _____

Unit (please write in title and/or location): _____

Date: _____

Please circle one answer per question

1. The senior leaders in my hospital listen to me and care about my concerns.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
2. The physician and nurse leaders in my area listen to me and care about my concerns.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
3. My suggestions about safety would be acted upon if I expressed them to management.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
4. Management/Leadership will never compromise safety concerns for productivity.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
5. I am encouraged by my supervisors and coworkers to report any unsafe conditions I observe.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
6. I know the proper channels to report my safety concerns.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
7. I am satisfied with availability of clinical leadership (MD, RN, RPh.)	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
8. Leadership is driving us to be a safety-centered institution.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1

9. I am aware that patient safety has become a major area for improvement in my institution.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1
10. I believe that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions.	Agree 5	Somewhat Agree 4	Neutral 3	Somewhat Disagree 2	Disagree 1

Thank you for engaging in patient safety

Quantum Leaps in Patient Safety
Institute for Healthcare Improvement
Modified from Brian Sexton/Robert Helmreich Aviation Cultural Survey

Appendix B

Staff Safety Survey

Please describe how you prevented a patient from being harmed:

Please describe how the next patient in your work area will be harmed:

Please describe how we can **prevent** this harm:

Please describe how we can **make visible** the potential harm before it happens:

If the patient were to suffer this harm, how could we **reduce** the harm:

Appendix C

Date

Address

Dear Unit Physician and Nursing Directors (and any other identified staff),

The Patient Safety Committee (PSC) would like to thank you for your participation in the patient safety program. The Hospital is committed to improving patient safety. The patient safety program is but one tool, and involves the full continuum of staff—from the CEO to frontline staff actively engaged in patient care, teaching and research.

Without the feedback you provided during Senior Executive Walk Rounds, a key program component, we would not have been made aware of the many opportunities we have to improve patient safety in your area and throughout the Hospital. Capitalizing on these opportunities is paramount to the success of the patient safety program.

Specifically, during our Senior Executive Walk Rounds we discussed safety issues identified by the Staff Safety Survey completed by unit representatives. At the conclusion of our meeting a number of opportunities were listed that need to be addressed. We have listed those issues below, along with the responsible person(s).

Patient Safety Issue	*Point of Contact*
1.	
2.	
3.	
4.	
5.	
6.	

If you have any questions or if the PSC can be of further service, please do not hesitate to call. Thank you.

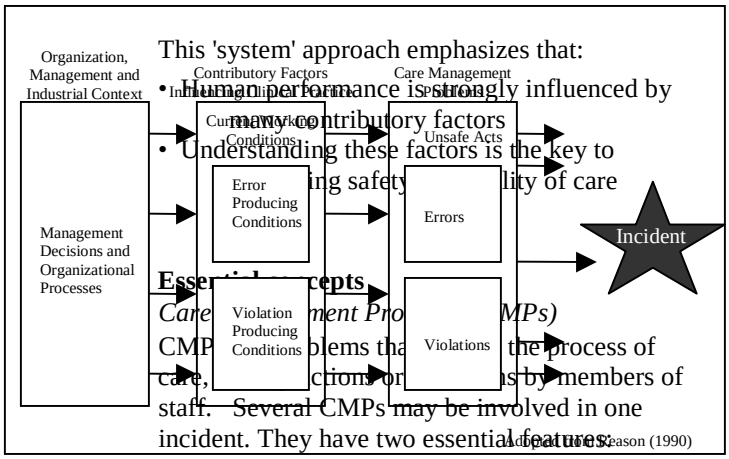
Sincerely,

Attending members of the Patient Safety Committee and unit advocate

Case Analysis - A Window onto the Healthcare System

Case analysis can be used to understand many aspects of the process of healthcare. Our approach systematically explores the wider healthcare system. It derives from Reason's model of organizational accidents.

Appendix D



This 'system' approach emphasizes that:

- Human performance is strongly influenced by many contributory factors
- Understanding these factors is the key to ing safety lity of care

Essential concepts

Care ment Pro MPs)

CMP blems tha the process of care, ctions or s by members of staff. Several CMPs may be involved in one incident. They have two essential features:

- Care deviated beyond safe limits of practice
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient.

Examples of CMPs are:

- Failure to monitor, observe or act
- Incorrect (with hindsight) decision
- **Not seeking help when** necessary
- Wrong treatment given

Clinical Context

Salient clinical events or condition of the patient at the time of the CMP (e.g. bleeding heavily, blood pressure falling; patient very distressed; unable to understand instructions). The essential background information required to understand the clinical context of the CMP.

Contributory Factors

Many factors (see Framework below) may contribute to a single CMP. For example:

- Individual factors may include lack of knowledge or experience of particular staff
- Task factors might include the non-availability of test results or protocols
- Team factors might include poor communication between staff.
- Work environment might include high workload or inadequate staffing.

Specific or General Contributory Factor?

Each contributory factor may be specific to that incident or, more importantly, may reflect more general problems on the unit. For example:

- A lack of knowledge shown may imply that a staff member requires additional training.
- An instance of poor communication may reflect more general problems within the unit.

Framework of Contributory Factors

Patient factors
- Condition (complexity & seriousness)
- Language and communication
- Personality and social factors

Task factors
- Task design and clarity of structure
- Availability and use of protocols
- Availability and accuracy of test results

Individual factors
- Knowledge, skills & competence
- Motivation & attitude
- Physical and mental health

Team factors
- Verbal & written communication
- " Supervision and seeking help
- Team structure & leadership

Working conditions

Staffing levels, skills mix and workload
Availability and maintenance of equipment
Administrative and managerial support

Organisation and management

Financial resources & organisational structure
Policy standards and goals
Safety culture and priorities

Institutional context
- Economic and regulatory context
- Health policy and political context

Full Investigation and Analysis

The purpose of the process is to implement changes that will make the system safer, which is primarily done by identifying the most important contributory factors.

Reviewing the Case Records

Make an initial summary of the principal events as recorded in the notes. List the key staff involved and decide who to interview.

Framing the Problem

Decide which section of the process of care to examine. Analysis should initially focus on the time period where problems were most apparent.

Interviews

While analyses can be conducted from statements and case records, talking to staff involved provides hugely important additional information. There are several distinct phases to the interview:

- Establishing the role of that member of staff and their view of the sequence of events
- Explain the concept of CMP. Ask them to identify CMPs in the process of care
- For each CMP ask specific questions about each level of contributory factors: patient, task, individual, team, working conditions and, if relevant, higher level factors
- For important contributory factors ask whether this is a general problem on the unit
- Ask about impact on patient, family and staff

Analysis of the case

The core of the process is to ask: What happened? How did it happen? Why did it happen? What can we leam from this and what changes should we make, if any? The analysis follows the same sequence as the interviews:

- Establish the chronology: an agreed history of events, specifying any important areas of disagreement between accounts

Authors: Charles Vincent, Sally Taylor-Adams, David Hewett, Jane Chapman, Sue Prior, Pam Strange & Anne Tizzard. Thanks to Allan Frankel and Tejal Gandhi for their on the spot ideas and to Richard Cook for the '2 sides ofA4' inspiration.

Appendix E

Project Design Template
(Plan-Do-Study-Act Cycle)

1. Plan

Objective of first test:

What did you predict?

What was the plan to conduct the test? (who, what, when, where and how)

What measure(s) did you plan to use to assess the success of the test?

2. Do

What actually happened?

3. Study

What were the results of the test, and how did they compare with your prediction?

4. Act

Based on what you learned, what will you do next?

- List the principal CMPs identified from records, statements and interviews
- For each CMP identify the principal contributing factors.
- Note those contributory factors that are thought to be general problems in the unit. These are the targets for action and implementation

Reporting and Acting on the findings

- Summarise the chronology
- Identify the care management problems and their contributory causes, giving most emphasis to general contributory factors
- Emphasise positive features of the care given
- Recommend action for each of the general factors requiring attention.

Some incidents may have immediate implications for action. Substantial change will usually only be implemented when a clear pattern of problems and contributory factors is seen in several incidents and the potential impact of any proposed changes is fully considered.

On the Spot Investigation

The method can be used for immediate reflection on any incident or near miss in any formal or informal group by carrying out a brief interview or structured discussion in the time available.

- Determine what happened and who was involved
- Impact on patient and staff
- Most important CMPs
- Most important contributory factors
- How those involved think future similar incidents might be prevented

Proceed to a full investigation if the incident is either very serious or has high potential for organisational learning.

Further reading

Full protocol and case examples available at www.patientsafety.ucl.ac.uk See also:

Vincent CA, Adams S, Stanhope N (1998). A framework for
the analysis of risk and safety in medicine- BMJ 3161154-7

Vincent CA, Adams S. Hewett DH et al. (2000) How to investigate and analyse clinical incidents: CRU & ALARM
protocol. BMJ320,777-781. http://www.bmj.com

Appendix F

Key Measures for Documenting Results

Measure	Definition	Goal	Suggestions for Data Collection Plan
1.			
2.			
3.			
4.			
5.			

Appendix G

Safety Tales
Feedback Form

What was the system problem identified that could cause a patient harm?

What system changes were made to prevent the harm?

What system changes were made to reduce the risk of harm?

What barriers existed, or were overcome, to reduce the risk of harm?

What resources were required for this change?

Questions that may not be answered, or that could be asked when conducting feedback

Was the system successfully changed so that patient safety was improved?

If yes, what were the lessons learned regarding successful change efforts?

If no, what were the lessons learned regarding ways to overcome barriers to change?

Where else could this system change be applied?

Appendix H

		Sum of Squares	df	Mean Square	F	Sig.
Q2	Between Groups	1.688	1	1.688	1.730	.192
	Within Groups	84.870	87	.976		
	Total	86.558	88			
Q1	Between Groups	.020	1	.020	.018	.892
	Within Groups	137.570	125	1.101		
	Total	137.591	126			
Q3	Between Groups	1.320	1	1.320	1.436	.233
	Within Groups	115.859	126	.920		
	Total	117.180	127			
Q4	Between Groups	.739	1	.739	.575	.450
	Within Groups	160.663	125	1.285		
	Total	161.402	126			
Q5	Between Groups	7.031	1	7.031	6.377	.013
	Within Groups	138.938	126	1.103		
	Total	145.969	127			
Q6	Between Groups	2.820	1	2.820	3.539	.062
	Within Groups	100.422	126	.797		
	Total	103.242	127			
Q7	Between Groups	6.927	1	6.927	6.790	.010
	Within Groups	129.554	127	1.020		
	Total	136.481	128			
Q8	Between Groups	5.281	1	5.281	5.222	.024
	Within Groups	127.438	126	1.011		
	Total	132.719	127			
Q9	Between Groups	5.013	1	5.013	6.042	.015
	Within Groups	104.542	126	.830		
	Total	109.555	127			
Q10	Between Groups	8.512	1	8.512	8.115	.005
	Within Groups	134.265	128	1.049		
	Total	142.777	129			
Q1	Between Groups	.020	1	.020	.018	.892
	Within Groups	137.570	125	1.101		
	Total	137.591	126			

Analysis of Variance (ANOVA) Table.

Appendix I

Today's Date ____/____/01Stamp with patient plate:

DISCHARGE SURVEY

Please complete on each patient before discharge from the ICU.
Place completed form in the bin located at the Reception Desk.

PART I: **Initiate** upon admission **Completed by: _____**

** Review the survey below and record pre-hospital medications in the table.

Reviewer initials	Pre-hospital medications	Last Taken	NON-compliance	Data source (See key)	If ordered in ICU: same, equivalent, or unwarranted (drug name or N/A)	If ordered on transfer: same, equivalent, or unwarranted (drug name or N/A)

PART II: Complete **before transfer** from the ICU. Completed by: _____

Prior to ICU discharge, review current ICU medications/allergies and transfer orders. Clarify preoperative medications and allergies with patient and family for accuracy.

	Yes	No	N/A
1. Are there any discrepancies between ICU orders and transfer orders that need to be corrected? **(Notify primary/ICU team before discharge if "Yes")**			
2. What are the discrepancies?			
3. Are there any discrepancies between prehospital medications and transfer orders that need correcting? **(Notify primary/ICU team before discharge if "Yes")**			
4. Are the allergies listed correctly on transfer orders?			
5. Is the patient ordered for any medications to which s/he is allergic?			
6. Have all discrepancies been resolved before transfer?			
7. Were transfer orders changed?			

Please document below any constructive feedback regarding family involvement with completing above form. Also, document below suggestions to help improve the efficiency of this form.

_____

Data Source Key: Anesthesia Record=1, Clinic Reports=2, Significant other=3, Patient=4, History form=5

Appendix J

Created by WICU PI Committee

Safety Tales Feedback Form: Medication Reconciliation Process

What was the system problem identified that could cause a patient harm?

The opportunity to reduce preventable medication errors. The system component is not isolated to the unit, but takes into consideration both pre and post drug regimens that could impact the patient.

What system changes were made to prevent the harm?
The WICU PI Committee created a reconciliation survey that would be utilized to enhance the processes employed prior to patient transfer.
What system changes were made to reduce the risk of harm?
Staff worked hard at increasing communication between nursing and physician services. This effort has created a collaborative environment and gets both role types on the same page.

What barriers existed, or were overcome, to reduce the risk of harm?
The biggest barrier was change. In addition, communication between role types and among role types needed to improve for this effort to work and be sustainable.
What resources were required for this change?
Time is key. Having a dedicated individual (both to and for the project) is a major lesson learned. Without this continuous effort progress would be slow. Without this effort staff would not have received the necessary feedback in a timely manner that validated their efforts and ultimately increased and sustained compliance.

Questions that may not be answered, or that could be asked when conducting feedback

Was the system successfully changed so that patient safety was improved?
Yes, without a doubt. We have seen marked improvement in both compliance and reduction in its variability. We have seen over time, through audits of the completed surveys, that this process is reliable, has captured potential errors and has positively impacted the communication between and among role types on the unit.
If yes, what were the lessons learned regarding successful change efforts?
The lessons are many. Identifying physician and nursing champions is key to getting the initiative off of the ground. As we discovered there was opportunity for improvement, but without leaders in each critical role type this may have not been effectively communicated to staff. Time for staff to work in the safety arena is critical. In the long run that partial FTE will save you time as reducing preventable, in this case, errors equates to less time addressing them should they come to fruition. In this case studies have shown that between 3 and 4 percent of these types of preventable errors result in an adverse drug event.
If no, what were the lessons learned regarding ways to overcome barriers to change?
N/A
Where else could this system change be applied?
This is something that could be an organizational initiative. To that end we are currently working with another ICU to implement this safety project. Additionally, we are utilizing the safety web site to disseminate our model and provide support to others. This model will eventually be offered primarily via the web or incorporated in the Eclipsis system, which is an electronic record. The Systems Department is currently exploring options to address this issue.

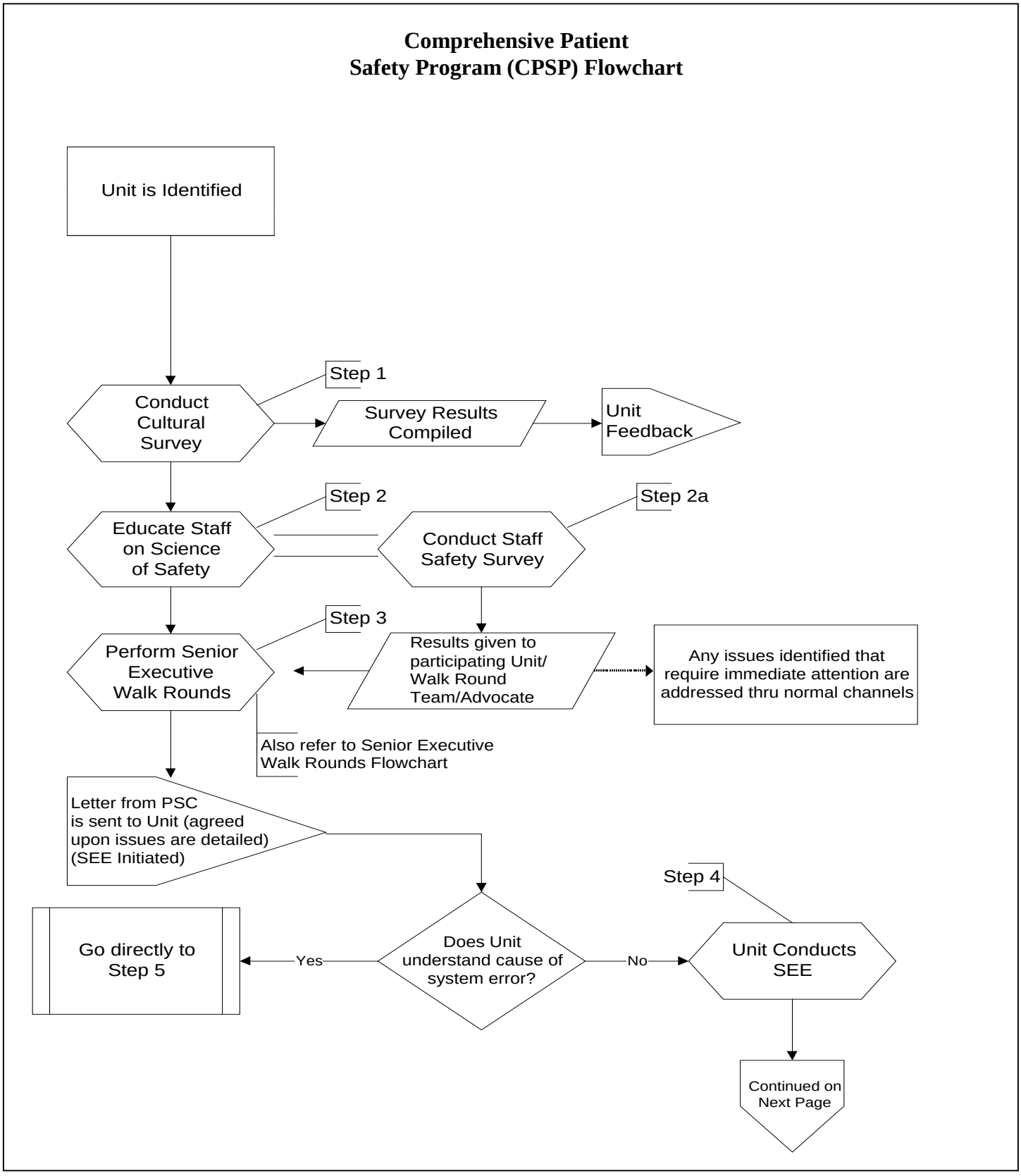


Figure 3. Page one of the comprehensive patient safety program flowchart

Continued from previous page

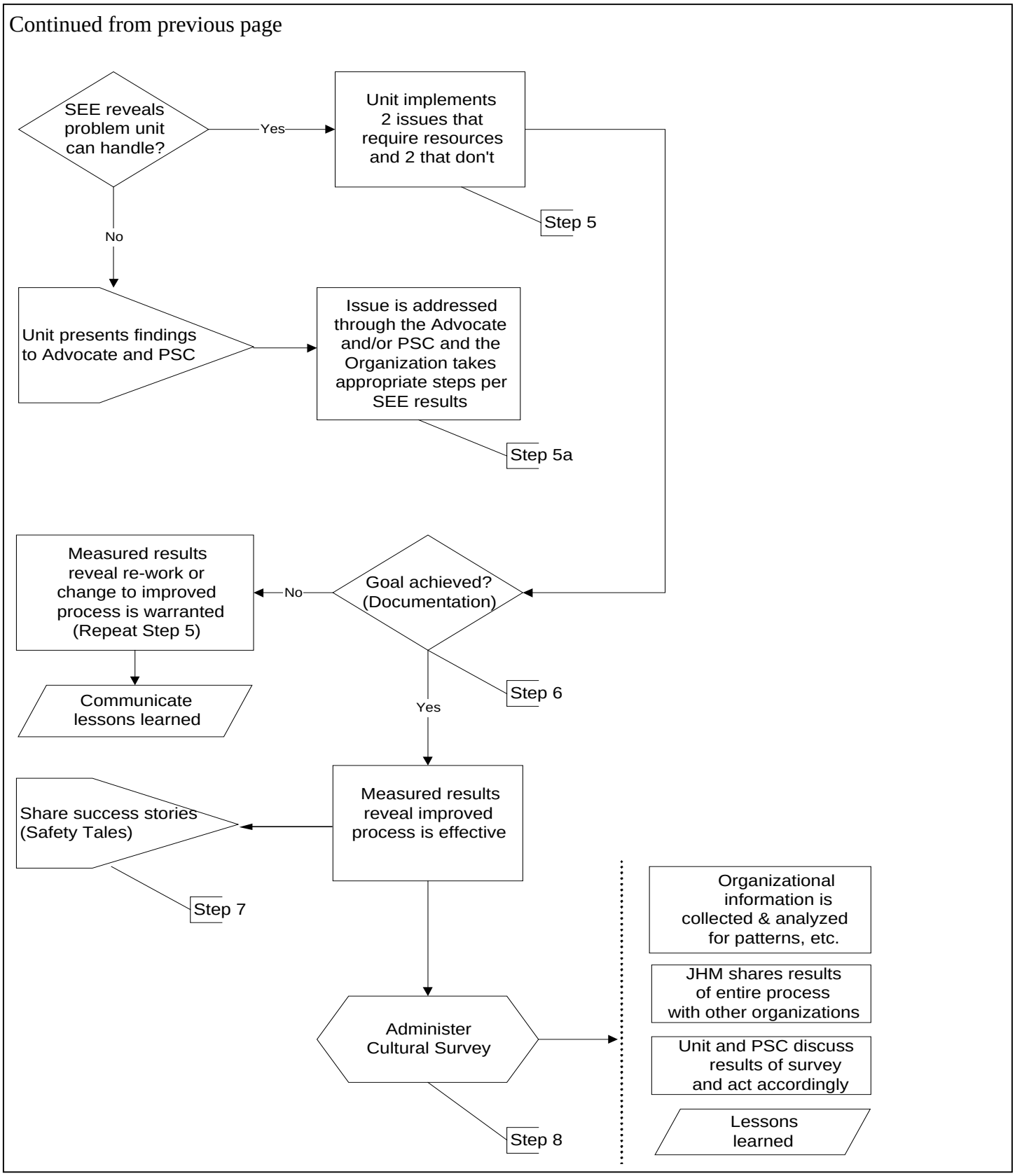


Figure 3. Page two of the comprehensive patient safety program flowchart.

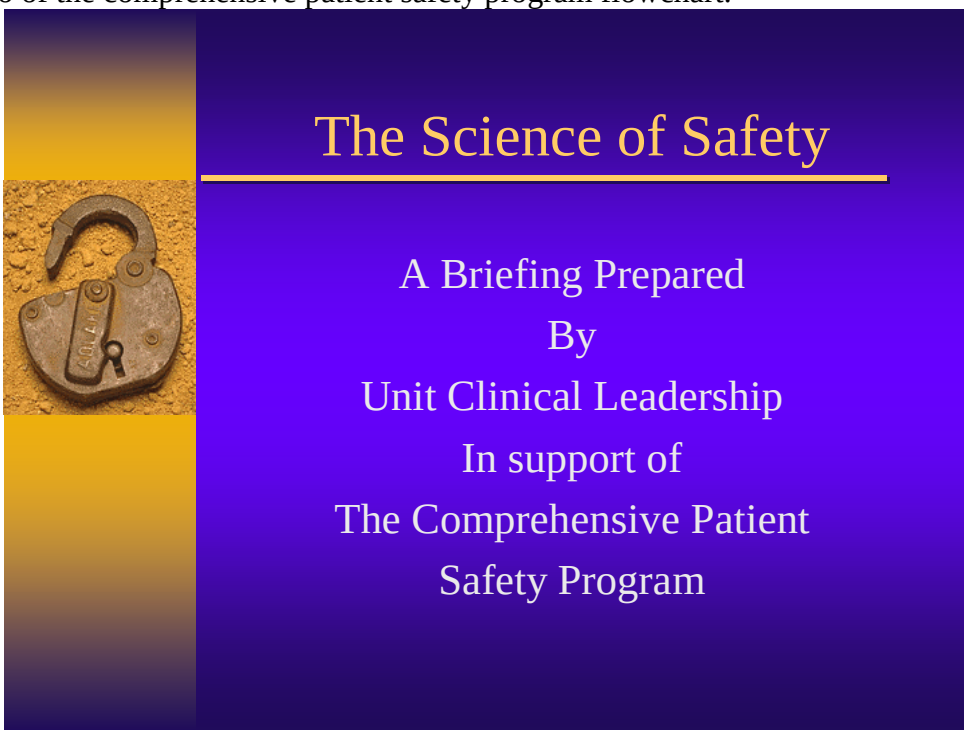


Figure 4. Science of Safety Briefing, Slide 1

Figure 5. Science of Safety Briefing, Slide 2

Figure 6. Science of Safety Briefing, Slide 3

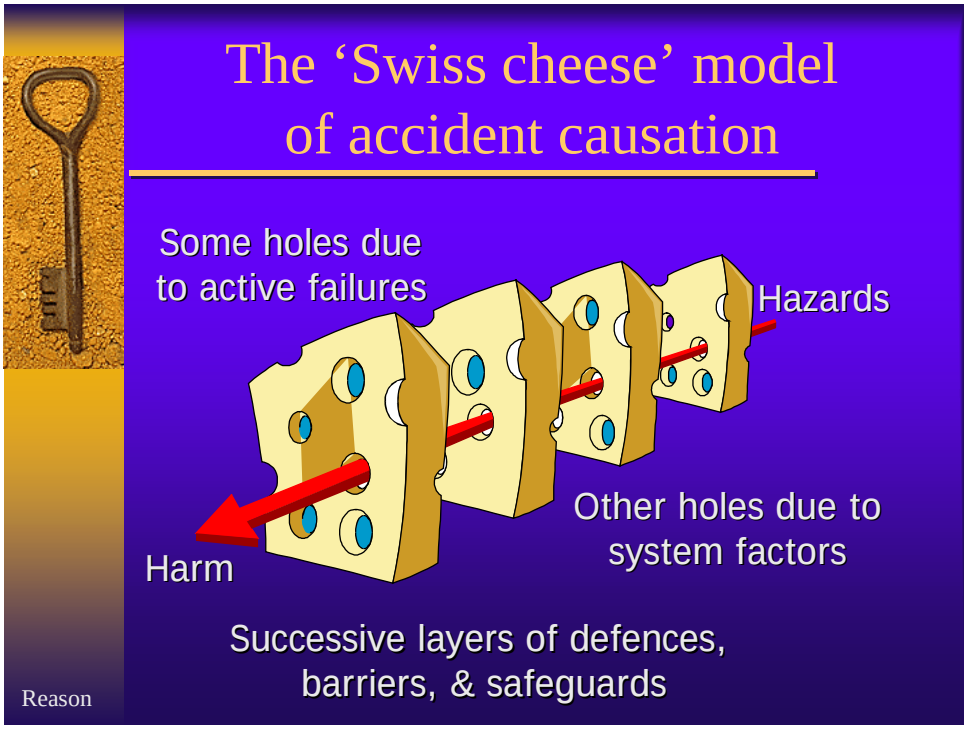


Figure 7. Science of Safety Briefing, Slide 4

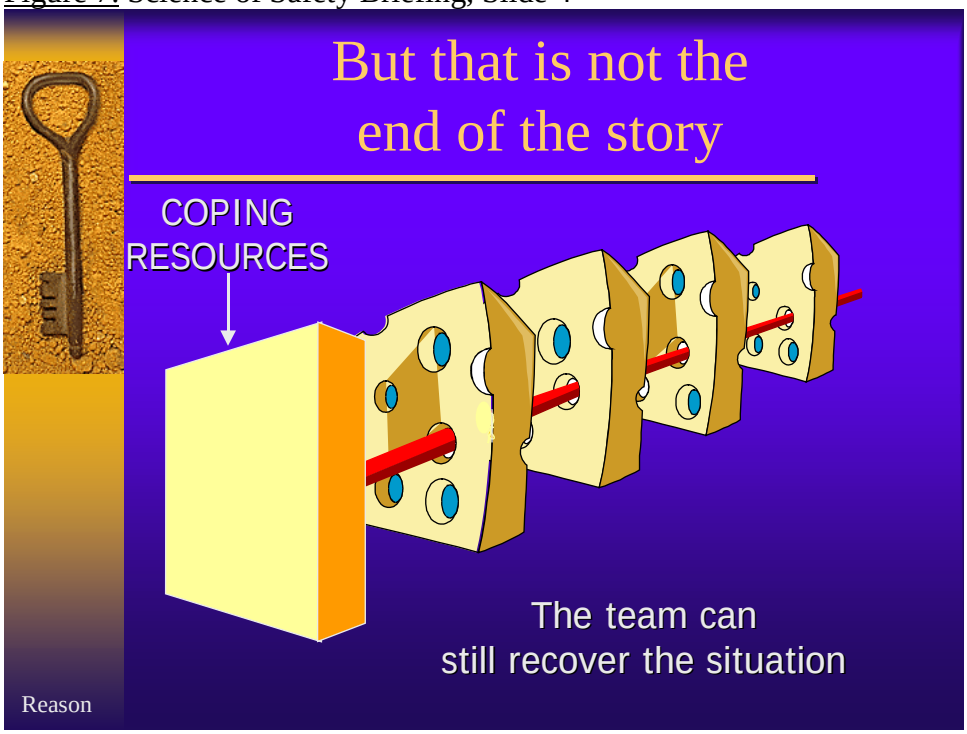


Figure 8. Science of Safety Briefing, Slide 5

Figure 9. Science of Safety Briefing, Slide 6

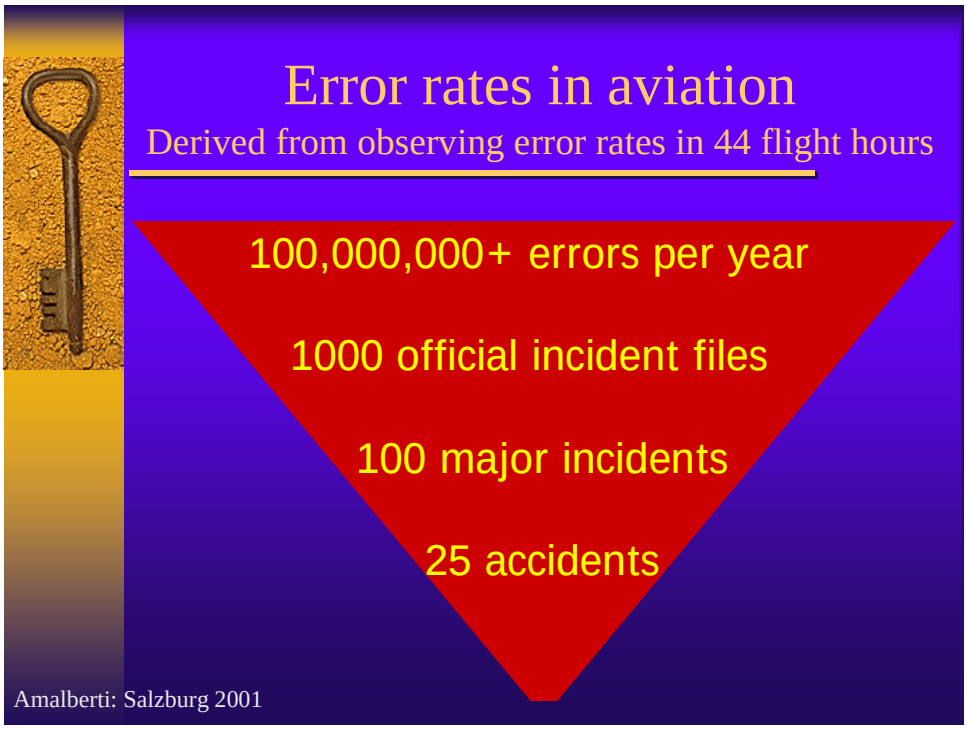


Figure 10. Science of Safety Briefing, Slide 7

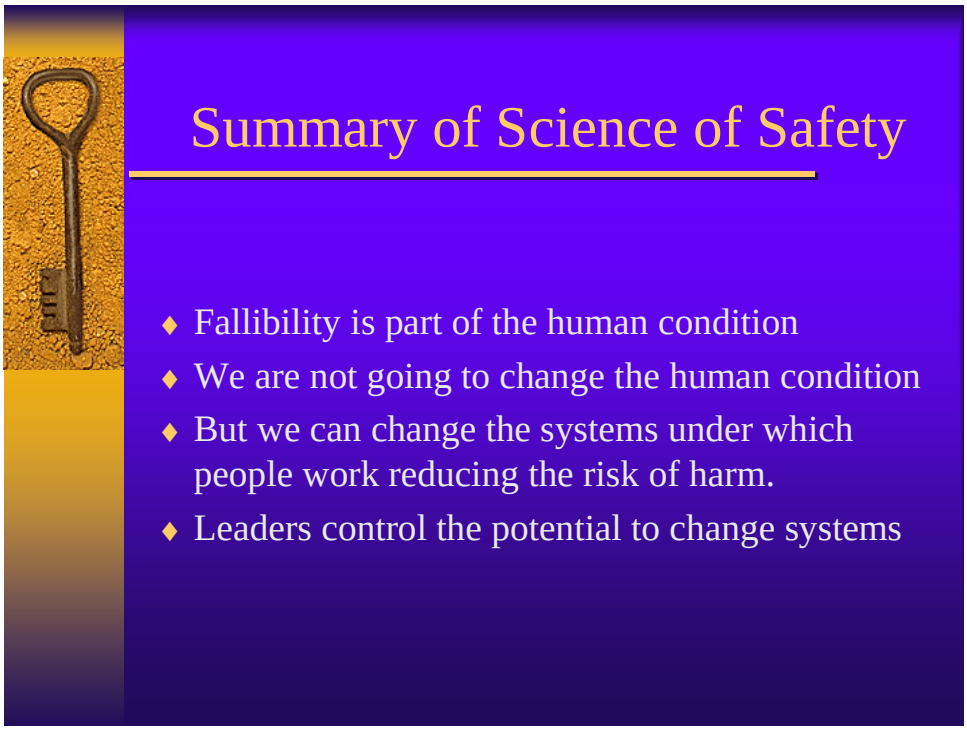


Figure 11. Science of Safety Briefing, Slide 8

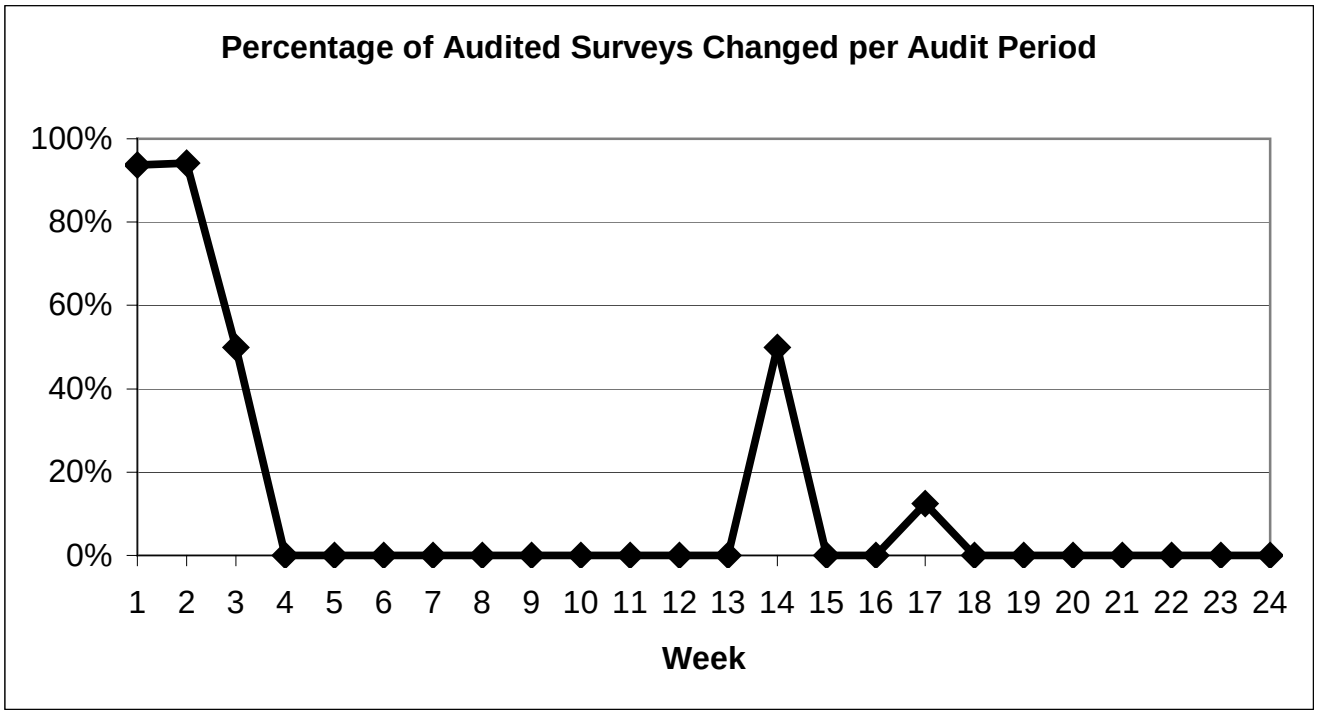


Figure 12. Accuracy Audit of Improved Work Process (Week 1 begins 1 July 2001)
Numerator: Number of audited Discharge Surveys found to have error
Denominator: Total number of Discharge Surveys audited

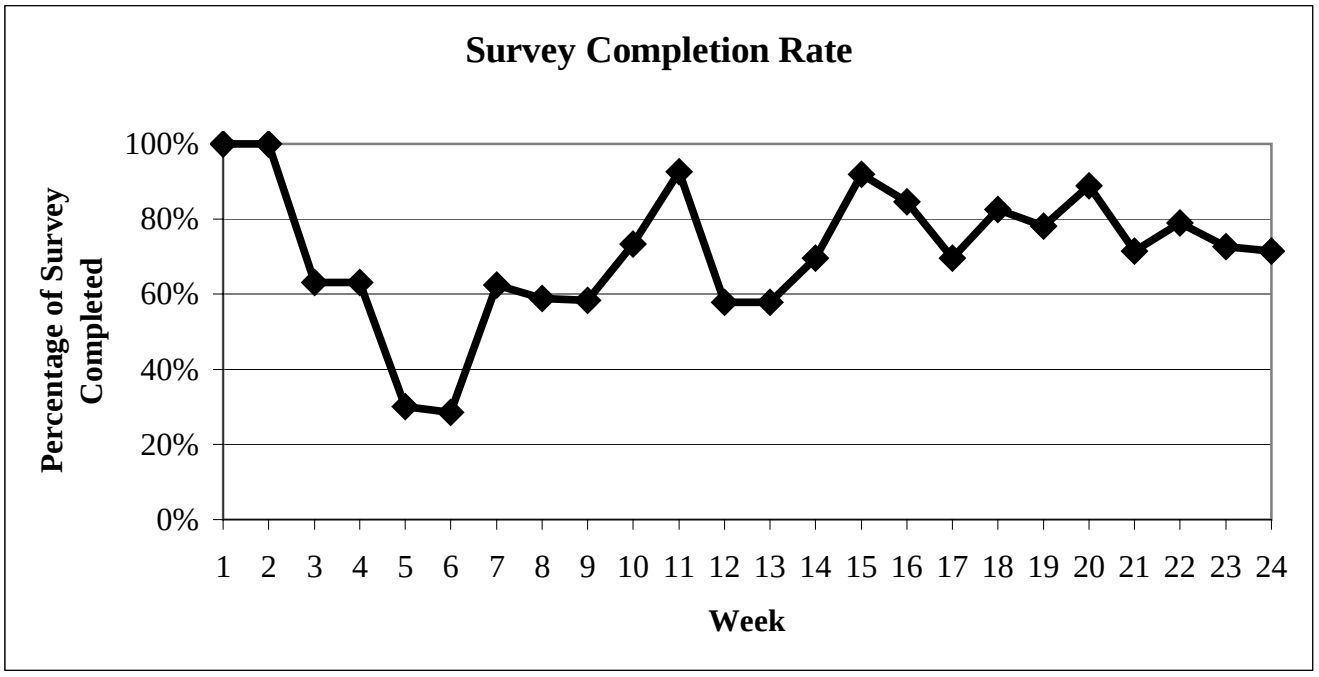


Figure 13. ICU Staff Compliance of Improved Work Process (Week 1 begins 1 July 2001)
Numerator: Number of Discharge Surveys completed by staff during the data collection period
Denominator: Total number of transfers during data collection period

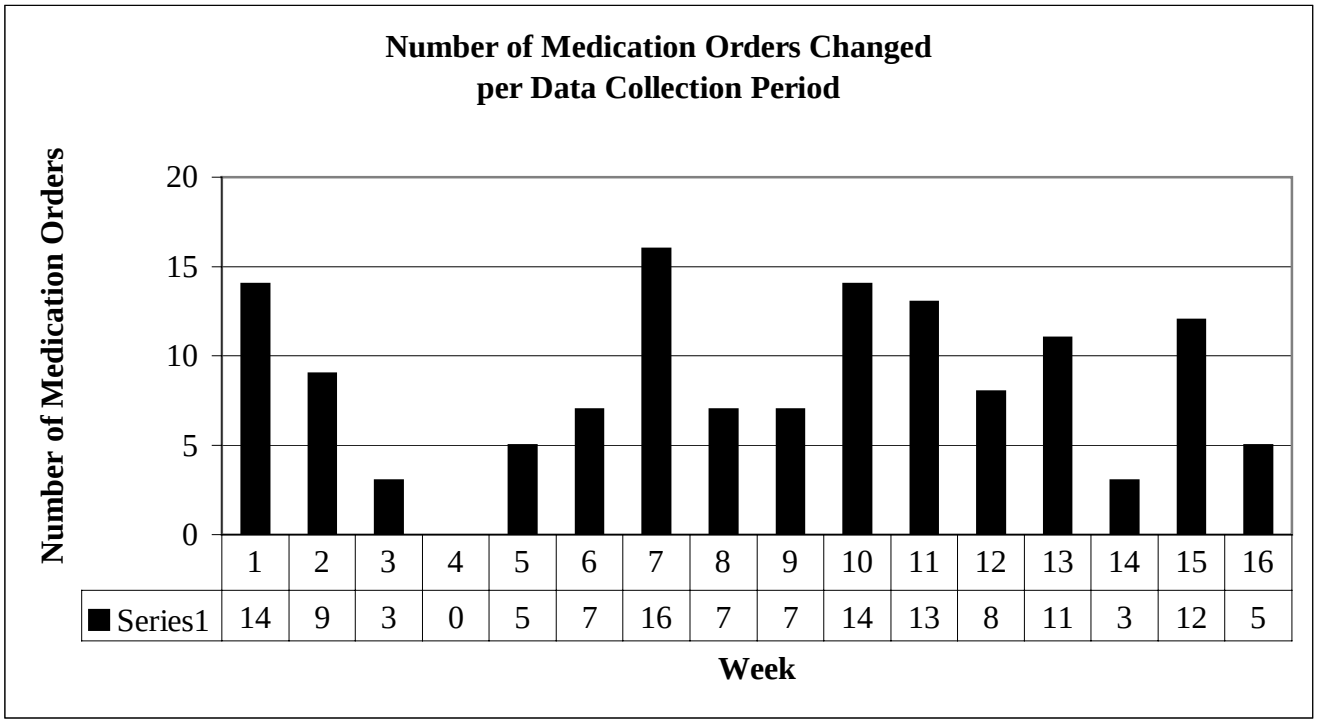


Figure 14. Number of Medication Orders Changed per Data Collection Period.
Data collection for the intervention rate at the medication order-based level began week 21. Data presented here represent weeks 21 through 36.