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Patient Safety Primer Last Updated: June 2017

Adverse Events, Near Misses, and Errors

Background

The concept of medical harm has existed since antiquity, famously discussed by Hippocrates and passed on in the word *iatrogenesis*, from the Greek for *originating from a physician.* The topic has received attention from notable physicians in the centuries since. A paper in the *New England Journal of Medicine* in 1956 discussed the topic of diseases of medical progress, and this paper evolved into a book that used the phrase "iatrogenic disease" in its title.

One of the first studies that sought to quantify the incidence of iatrogenic harm was the Medical Insurance Feasibility Study, funded by the California Medical Association and the California Hospital Association. This study, published in 1978, served as the model for the subsequent landmark Harvard Medical Practice Study. The California study had as its immediate goal "to obtain adequate information about patient disabilities resulting from health care management." This study did not use the term adverse event, but had as its focus the same idea, specifically "adverse outcomes to patients in the course of health care management," especially the subset of such outcomes consisting of potentially compensable events, namely disabilities caused by health care management. The California study reported 4.65 injuries to patients per 100 hospitalizations. Subsequent studies have consistently found that 10%–12% of patients experience harm while hospitalized, with approximately half of these events being considered preventable.

Definitions and Types of Patient Harm

Investigators in the Harvard Medical Practice Study defined an adverse event as "an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both." The

Institute for Healthcare Improvement uses a similar definition: "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment, or hospitalization, or that results in death."

Adverse events may be preventable or nonpreventable. One definition refers to preventable adverse events as "avoidable by any means currently available unless that means was not considered standard care." Preventable adverse events are defined as "care that fell below the standard expected of physicians in their community." These adverse events were the focus of both the Medical Insurance Feasibility Study and the Harvard Medical Practice Study. Examples of nonpreventable adverse events and preventable adverse events from the Harvard Medical Practice Study are provided in the Box.

Box. Example Adverse Event Cases From the Harvard Medical Practice Study

"Case 1: During angiography to evaluate coronary artery disease, a patient had an embolic cerebrovascular accident. The angiography was indicated and was performed in standard fashion, and the patient was not at high risk for a stroke. Although there was no substandard care, the stroke was probably the result of medical management. The event was considered adverse but not due to negligence."

"Case 4: A middle-aged man had rectal bleeding. The patient's physician completed only a limited sigmoidoscopy, which was negative. The patient had continued rectal bleeding but was reassured by the physician. Twenty-two months later, after a 14-kg (30 lb) weight loss, he was admitted to a hospital for evaluation. He was found to have colon cancer with metastases to the liver. The physicians who reviewed his medical record judged that proper diagnostic management might have discovered the cancer when it was still curable. They attributed the advanced disease to substandard medical care. The event was considered adverse and due to negligence."

In addition to preventable adverse events, two other terms appear commonly in the literature. Errors are defined as "an act of commission (doing something wrong) or omission (failing to do the right thing) leading to an undesirable outcome or significant potential for such an outcome." The related Systems Approach Patient Safety Primer discusses the relationship between errors and adverse events, summarized in the Swiss Cheese Model of accident causation. A near miss is defined as "any event that could have had adverse consequences but did not and was indistinguishable from fully fledged adverse events in all but outcome." (Some studies use the related terms "potential adverse event" and "close call.") In a near miss, an error was committed, but the patient did not experience clinical harm, either through early detection or sheer luck. For example, consider a patient who is admitted to the hospital and

placed in a shared room. A nurse comes to administer his medications, but inadvertently gives his pills to the other patient in the room. The other patient recognizes that these are not his medications, does not take them, and alerts the nurse so that the medications can be given to the correct patient. This situation involved a high potential for harm, as a cognitively impaired or less aware patient may have taken the incorrect medications.

A final subcategory of adverse event is the ameliorable adverse event, a term first coined in a study of postdischarge of adverse events. Ameliorable adverse events are those that are not preventable, but the severity of the injury "could have been substantially reduced if different actions or procedures had been performed or followed." For instance, a patient with a new diagnosis of heart failure is discharged on furosemide (a diuretic) with a follow-up visit with a cardiologist in 4 weeks but no instructions for earlier follow-up or laboratory tests. Ten days later, the patient presents to the emergency department with acute kidney injury and critically low potassium. These adverse effects of diuresis are not preventable in themselves, but the severity could have been reduced by planning to have the patient come in for lab testing within a week of discharge.

Controversies

Studies of the epidemiology of adverse events, such as a recent series of reports by the Office of the Inspector General, use a two-stage record review process in which patient charts are independently reviewed by two clinically experienced reviewers in order to determine whether an adverse event occurred and if so, whether it was preventable. It is important to note that even with highly trained reviewers, the level of agreement between reviewers with regard to the presence of an adverse event is usually only moderate. When an adverse event occurred, reviewers also may disagree about whether the event was preventable.

Designating an adverse event as preventable requires some judgment about the degree to which the evidence supports specific prevention strategies and the feasibility of implementing these strategies. As the science of patient safety advances, these judgments can change over time, such that more adverse events become regarded as preventable. For instance, after publication of the seminal paper on the central line bundle to prevent catheter-associated bloodstream infections, reviewers participating in adverse event studies might have begun to judge all central line–associated bloodstream infections as preventable.

Current Context

In summary, adverse events refer to harm from medical care rather than an underlying disease. Important subcategories of adverse events include:

- Preventable adverse events: those that occurred due to error or failure to apply an accepted strategy for prevention;
- Ameliorable adverse events: events that, while not preventable, could have been less harmful if care had been different;
- Adverse events due to negligence: those that occurred due to care that falls below the standards expected of clinicians in the community.

Two other terms define hazards to patients that do not result in harm:

- Near miss: an unsafe situation that is indistinguishable from a preventable adverse event except for the outcome. A patient is exposed to a hazardous situation, but does not experience harm either through luck or early detection.
- Error: a broader term referring to any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes patients to a potentially hazardous situation.

Editor's Picks

BOOK/REPORT

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries.

Levinson DR. Washington, DC: US Department of Health and Human Services, Office of the Inspector General; November 2010. Report No. OEI-06-09-00090.

PERSPECTIVE

In Conversation with...Lucian Leape, MD

JOURNAL ARTICLE › STUDY

Incidence and types of preventable adverse events in elderly patients: population based review of medical records.

Thomas EJ, Brennan TA. BMJ. 2000;320:741-744.

JOURNAL ARTICLE › COMMENTARY

Error in medicine.

Leape LL. JAMA. 1994;272:1851-1857.

JOURNAL ARTICLE › STUDY

Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I.

Brennan TA, Leape LL, Laird NM, et al. N Engl J Med. 1991;324:370-376.

JOURNAL ARTICLE › REVIEW

Diseases of medical progress.

Moser RH. N Engl J Med. 1956;255:606-614.

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Alert Fatigue

Background

The rapidly increasing computerization of health care has produced benefits for clinicians and patients. Yet the integration of technology into medicine has been anything but smooth, and as newer and more sophisticated devices have been added to the clinical environment, clinicians' workflows have been affected in unanticipated ways. These fundamental shifts have resulted in new threats to patient safety—a cruel irony given that technological solutions have been promoted for many years as the most promising solution to medical errors.

Most health care technologies—be they computerized provider order entry systems (CPOE), smart intravenous infusion pumps, or cardiac monitoring devices—provide auditory or visual warnings to clinicians to prevent or act on unsafe situations. These warnings are well intended and in isolation may be helpful. However, in the current highly computerized clinical environment, an individual clinician interacts with many different alert-generating devices—meaning that every day, clinicians are on the receiving end of a staggering number of alerts. A 2014 study found that the physiologic monitors in an academic hospital's 66 adult intensive care unit beds generated more than 2 million alerts in one month, translating to 187 warnings per patient per day. According to another study, CPOE systems generate warnings for 3%–6% of all orders that are entered, meaning that a physician could easily receive dozens of warnings each day.

The term alert fatigue describes how busy workers (in the case of health care, clinicians) become desensitized to safety alerts, and as a result ignore or fail to respond appropriately to such warnings. This phenomenon occurs because of the sheer number of alerts, and it is compounded by the fact that the vast majority of alerts generated by CPOE systems (and other health care technologies) are clinically inconsequential—meaning that in most cases,

clinicians *should* ignore them. The problem is that clinicians then ignore both the bothersome, clinically meaningless alarms *and* the critical alerts that warn of impending serious patient harm. In essence, a proliferation of alerts that are intended to improve safety actually results in a paradoxical increase in the chance patients will be harmed. Although little discussed prior to the widespread use of electronic medical records, alert fatigue is now recognized as a major unintended consequence of the computerization of health care and a significant patient safety hazard.

Effect of alert fatigue on patient safety

Much of the literature on alert fatigue derives from studies of CPOE and clinical decision support systems, in which alerts are provided to warn of potentially harmful drug–drug interactions or incorrect medication doses. These studies consistently show three main findings:

- Alerts are only modestly effective at best. A systematic review of computerized reminders found only minor improvements in targeted processes of care, and, while CPOE systems have been shown to markedly decrease prescribing errors, this can largely be ascribed to their ability to standardize drug doses, provide decision support, and eliminate errors from poor handwriting or incorrect transcriptions.
- Alert fatigue is common. Clinicians generally override the vast majority of CPOE warnings, even "critical" alerts that warn of potentially severe harm. There is less literature on other types of warnings, but it is likely that rates of overriding or ignoring warnings in other settings are also high.
- Alert fatigue increases with growing exposure to alerts and heavier use of CPOE systems. This finding is intuitive, but also raises the important implication that without system redesign, the safety consequences of alert fatigue will likely become more serious over time.

Although there are few studies that quantify adverse events related to alert fatigue, this phenomenon has been implicated as a significant cause in several high-profile errors. A 2011 Boston Globe investigation identified more than 200 deaths over a 5-year period attributable to failure to appropriately heed alarms from physiologic monitoring systems. A recent book

by a prominent patient safety leader details how a hospitalized teenager received a 38-fold overdose of an antibiotic, in large part because the ordering physician had been advised by colleagues to "just ignore the alerts."

Current context

Although only recently recognized, alert fatigue (and the unintended consequences of the computerization of health care) has become a high profile patient safety issue. The Joint Commission released a sentinel event alert in April 2015 calling for health care organizations to pay close attention to information technology as a safety issue. In order to mitigate these consequences—including alert fatigue—The Joint Commission recommended improving the culture of safety by creating a shared sense of responsibility between users and developers, paying careful attention to safe IT implementation, and engaging leadership to provide oversight of health IT planning, implementation, and evaluation.

There is intense interest in developing specific methods to combat alert fatigue, but as yet, there is no consensus on the optimal approaches. Solving alert fatigue will require use of the principles of human factors engineering as well as those of informatics, as the problem fundamentally arises from both the technology itself and how busy human beings interact with the technology. An AHRQ WebM&M commentary provided several suggestions on how to minimize alert fatigue in CPOE systems:

- Increase alert specificity by reducing or eliminating clinically inconsequential alerts.
- Tailor alerts to patient characteristics and critical integrated clusters of physiologic indicators. For example, incorporate renal function test results into the alert system so that alerts for nephrotoxic medications are triggered only for patients at high risk.
- Tier alerts according to severity. Warnings could be presented in different ways, in order to key clinicians to alerts that are more clinically consequential.
- Make only high-level (severe) alerts interruptive.
- Apply human factors principles when designing alerts (e.g., format, content, legibility, and color of alerts).

One limitation to addressing alert fatigue pertains to the legal consequences of removing alerts. A recent commentary pointed out that system developers have thus far been reluctant to remove alerts for fear of being held liable if patients were harmed in the absence of a warning. There has been progress toward developing guidelines for high-severity alerts (which warn of significant risk of harm and should be retained) and low-severity alerts (less clinically consequential warnings, which could be made non-interruptive or removed entirely).

In solving the problem of alert fatigue, health care will need to look to examples from other industries. The aviation industry offers a sharp contrast to health care, because cockpit technology is rigorously designed to provide only highly consequential alerts to pilots, minimizing minor alerts in order to allow pilots to maintain situational awareness. This use of human factors engineering and deep attention to the experience of the end-user has thus far been lacking in health care technology design.

Editor's Picks

PERSPECTIVE

Reducing the Safety Hazards of Monitor Alert and Alarm Fatigue

PERSPECTIVE

In Conversation With... Barbara Drew, RN, PhD

JOURNAL ARTICLE › STUDY

A cross-sectional observational study of high override rates of drug allergy alerts in inpatient and outpatient settings, and opportunities for improvement.

Slight SP, Beeler PE, Seger DL, et al. BMJ Qual Saf. BMJ Qual Saf 2017;26:217-225.

JOURNAL ARTICLE › STUDY

Rising drug allergy alert overrides in electronic health records: an observational retrospective study of a decade of experience.

Topaz M, Seger DL, Slight SP, et al. J Am Med Inform Assoc. 2016;23:601-608.

BOOK/REPORT

The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age.

Wachter R. New York, NY: McGraw-Hill; 2015. ISBN: 9780071849463.

JOURNAL ARTICLE › STUDY

Computerised physician order entry-related medication errors: analysis of reported errors and vulnerability testing of current systems.

Schiff GD, Amato MG, Eguale T, et al. BMJ Qual Saf. 2015;24:264-271.

JOURNAL ARTICLE › STUDY

Insights into the problem of alarm fatigue with physiologic monitor devices: a comprehensive observational study of consecutive intensive care unit patients.

Drew BJ, Harris P, Zègre-Hemsey JK, et al. PLoS One. 2014;9:e110274.

JOURNAL ARTICLE › STUDY

Are we heeding the warning signs? Examining providers' overrides of computerized drug–drug interaction alerts in primary care.

Slight SP, Seger DL, Nanji KC, et al. PLoS One. 2013;8:e85071.

CASE

Finding Fault With the Default Alert

JOURNAL ARTICLE › STUDY

Drug–drug interactions that should be non-interruptive in order to reduce alert fatigue in electronic health records.

Phansalkar S, van der Sijs H, Tucker AD, et al. J Am Med Inform Assoc. 2013;20:489-493.

JOURNAL ARTICLE › STUDY

Evaluating alert fatigue over time to EHR-based clinical trial alerts: findings from a randomized controlled study.

Embi PJ, Leonard AC. J Am Med Inform Assoc. 2012;19:e145-e148.

JOURNAL ARTICLE › COMMENTARY

Clinical decision support systems could be modified to reduce 'alert fatigue' while still minimizing the risk of litigation.

Kesselheim AS, Cresswell K, Phansalkar S, Bates DW, Sheikh A. Health Aff (Millwood). 2011;30:2310-2317.

CASE

Situational (Un)Awareness

NEWSPAPER/MAGAZINE ARTICLE

Patient alarms often unheard, unheeded.

Kowalczyk L. Boston Globe. February 13–14, 2011.

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Ambulatory Care Safety

Background

Despite the fact that the vast majority of health care takes place in the outpatient, or ambulatory care, setting, efforts to improve safety have mostly focused on the inpatient setting. However, a body of research dedicated to patient safety in ambulatory care has emerged over the past few years. These efforts have identified and characterized factors that influence safety in office practice, the types of errors commonly encountered in ambulatory care, and potential strategies for improving ambulatory safety.

Factors Influencing Safety in Ambulatory Care

Ensuring patient safety outside of the hospital setting poses unique challenges for both providers and patients. A recent article proposed a model for patient safety in chronic disease management, modified from the original Chronic Care Model. This model broadly encompasses three concepts that influence safety in ambulatory care:

- The role of patient and caregiver behaviors
- The role of provider–patient interactions
- The role of the community and health system

Specific types of errors can be linked to each of these three concepts.

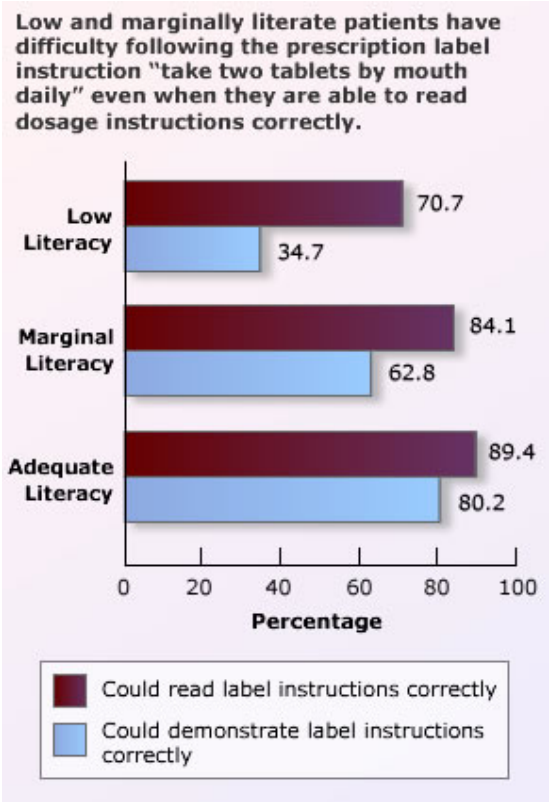
Types of Safety Events in Ambulatory Care

Since face-to-face interactions between providers and patients in the ambulatory setting are limited and occur weeks to months apart, patients must assume a much greater role in and responsibility for managing their own health. This elevates the importance of including the patient as a partner and ensuring that patients understand their illnesses and treatments. The

need for outpatients to self-manage their own chronic diseases requires that they monitor their symptoms and, in some cases, adjust their own lifestyle or medications. For example, a patient with diabetes must measure her own blood sugars and perhaps adjust her insulin dose based on blood sugar values and dietary intake. A patient's inability or failure to perform such activities may compromise safety in the short term and clinical outcomes in the long term. Patients must also understand how and when to contact their caregivers outside of routine appointments, and they must often play a role in ensuring their own care coordination (e.g., by keeping an updated list of medications).

The nature of interactions between patients and providers—and between different providers—may also be a source of adverse events. Patients consistently voice concerns about coordination of care, particularly when one patient sees multiple physicians, and indeed communication between physicians in the outpatient setting is often suboptimal. Poorly handled care transitions (e.g., when a patient is discharged from the hospital or when care is transferred from one physician to another) also place patients at high risk for preventable adverse events. When a clinician is not immediately available—for example, after hours—patients may have to rely on telephone advice for acute illnesses, an everyday practice that has its own inherent risks.

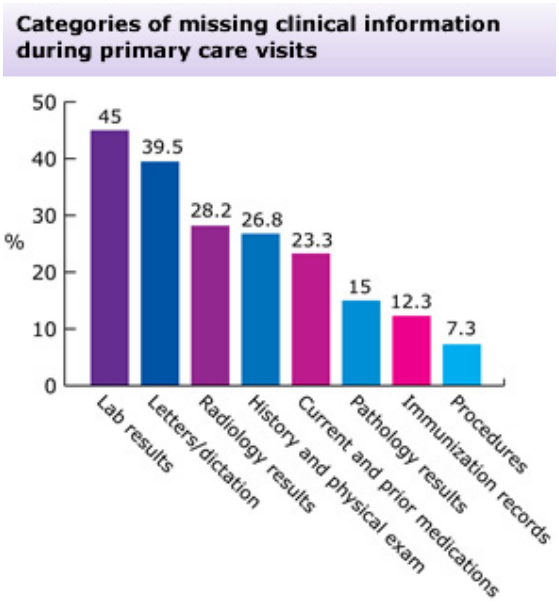
Underlying health system flaws have been documented to increase the risk for medical errors, particularly medication errors and diagnostic errors, issues that are certainly germane to ambulatory safety. Medication errors are very common in ambulatory care, with one landmark study finding that more than 4.5 million ambulatory care visits occur every year due to adverse drug events. Likewise, prescribing errors are startlingly common in ambulatory practice. Because the likelihood of a medication error is linked to a patient's understanding of the indication, dosage schedule, proper administration, and potential adverse effects, low health literacy and poor patient education contribute to elevated error risk.



Source: Wolf MS, Davis TC, Shrank W, et al. To err is human: Patient misinterpretations of prescription drug label instructions. Patient Educ Couns. 2007;67:293-300. [go to PubMed]

The fragmentation of ambulatory care in outpatient settings increases the challenge of making a timely and accurate diagnosis. Indeed, a recent study estimated that 5% of adults in the United States experience a missed or delayed diagnosis each year. Recent data suggests that timely information availability and managing test results contribute to delayed and missed diagnoses in outpatient care. Although use of electronic health records in the ambulatory setting is growing, many practices still lack reliable systems for following up on test results—a problem that has been implicated in missed and delayed diagnoses.

Finally, while an increasing amount of attention has been devoted to measuring and improving the culture of safety in acute care settings, less is known about safety culture in office practice. Burnout and work dissatisfaction, particularly among primary care physicians, may adversely affect the quality of care. The AHRQ Medical Office Survey on Patient Safety Culture is designed to assess safety culture in ambulatory care, and its comparative database (which includes data from more than 900 participating practices) is freely available from AHRQ.



Source: Smith PC, Araya-Guerra R, Bublitz C, et al. Missing clinical information during primary care visits. JAMA. 2005;293:565-571. [go to PubMed]

Improving Safety in Ambulatory Care

Improving outpatient safety will require both structural reform of office practice functions as well as engagement of patients in their own safety. While EHRs hold great promise for reducing medication errors and tracking test results, these systems have yet to reach their full potential. Coordinating care between different physicians remains a significant challenge, especially if the doctors do not work in the same office or share the same medical record system. Efforts are being made to increase use of EHRs in ambulatory care, and physicians believe that use of EHRs leads to higher quality and improved safety.

Patient engagement in outpatient safety involves two related concepts: first, *educating* patients about their illnesses and medications, using methods that require patients to demonstrate understanding (such as "teach-back"); and second, *empowering* patients and caregivers to act as a safety "double-check" by providing access to advice and test results and encouraging patients to ask questions about their care. Success has been achieved in this area for patients taking high-risk medications, even in patients with low health literacy at baseline.

Current Context

Although efforts to improve safety have largely focused on hospital care, The Joint Commission now publishes National Patient Safety Goals focused on ambulatory care. The

Agency for Healthcare Research and Quality is also leading efforts to improve ambulatory quality and safety through programs and research funding. A 2016 systematic review commissioned by the World Health Organization identified missed and delayed diagnoses and medication errors as the chief safety priorities in ambulatory care, and it highlighted the need to develop clear and consistent definitions for patient safety incidents in primary care.

Editor's Picks

WEB RESOURCE › MULTI-USE WEBSITE

National Patient Safety Goals.

Oakbrook Terrace, IL: The Joint Commission; 2018.

CASE

Continuity Errors in Resident Clinic

CASE

New Patient Mistakenly Checked in as Another

JOURNAL ARTICLE › REVIEW

How safe is primary care? A systematic review.

Panesar SS, deSilva D, Carson-Stevens A, et al. BMJ Qual Saf. 2016;25:544-553.

BOOK/REPORT

Medical Office Survey on Patient Safety Culture: 2014 User Comparative Database Report.

Sorra J, Famolaro T, Yount ND, et al. Rockville, MD: Agency for Healthcare Research and Quality; June 2014. Report No. 14-0032-EF.

CASE

A "Reflexive" Diagnosis in Primary Care

CASE

No News May Not Be Good News

JOURNAL ARTICLE › REVIEW

Failure to follow-up test results for ambulatory patients: a systematic review.

Callen JL, Westbrook JI, Georgiou A, Li J. J Gen Intern Med. 2012;27:1334-1348.

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Adverse drug events in U.S. adult ambulatory medical care.

Sarkar U, López A, Maselli JH, Gonzales R. Health Serv Res. 2011;46:1517-1533.

JOURNAL ARTICLE › STUDY

Timely follow-up of abnormal diagnostic imaging test results in an outpatient setting: are electronic medical records achieving their potential?

Singh H, Thomas EJ, Mani S, et al. Arch Intern Med. 2009;169:1578-1586.

JOURNAL ARTICLE › COMMENTARY

Refocusing the lens: patient safety in ambulatory chronic disease care.

Sarkar U, Wachter RM, Schroeder SA, Schillinger D. Jt Comm J Qual Patient Saf. 2009;35:377-383.

PERSPECTIVE

Patient Safety: A Perspective from Office Practice

TOOLS/TOOLKIT › MEASUREMENT TOOL/INDICATOR

Medical Office Survey on Patient Safety Culture.

Rockville, MD: Agency for Healthcare Research and Quality; March 2018.

PERSPECTIVE

The Role of Health Literacy in Patient Safety

PERSPECTIVE

In Conversation with...Dean Schillinger, MD

JOURNAL ARTICLE › STUDY

Information exchange among physicians caring for the same patient in the community.

van Walraven C, Taljaard M, Bell CM, et al. CMAJ. 2008;179:1013-1018.

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Measuring safety culture in the ambulatory setting: The Safety Attitudes Questionnaire—Ambulatory Version.

Modak I, Sexton JB, Lux TR, Helmreich RL, Thomas EJ. J Gen Intern Med. 2007;22:1-5.

JOURNAL ARTICLE › STUDY

Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims.

Gandhi TK, Kachalia A, Thomas EJ, et al. Ann Intern Med. 2006;145:488-496.

PERSPECTIVE

Patient Safety in the Physician Office Setting

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Adverse drug events in ambulatory care.

Gandhi TK, Weingart SN, Borus J, et al. N Engl J Med. 2003;348:1556-1564.

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Checklists

Background

A checklist is an algorithmic listing of actions to be performed in a given clinical setting, the goal being to ensure that no step will be forgotten. Although a seemingly simple intervention, checklists have a sound theoretical basis in principles of human factors engineering and have played a major role in some of the most significant successes achieved in the patient safety movement.

The field of cognitive psychology classifies most tasks as involving either schematic behavior, tasks performed reflexively or "on autopilot," or attentional behavior, which requires active planning and problem-solving. The types of error associated with each behavior are also different: failures of schematic behavior are called *slips* and occur due to lapses in concentration, distractions, or fatigue, whereas failures of attentional behavior are termed *mistakes* and often are caused by lack of experience or insufficient training. In health care, as in other industries, most errors are caused by slips rather than mistakes, and checklists represent a simple, elegant method to reduce the risk of slips. Flight preparation in aviation is a well-known example, as pilots and air-traffic controllers follow pre-takeoff checklists regardless of how many times they have carried out the tasks involved. By standardizing the list of steps to be followed, and formalizing the expectation that every step will be followed for every patient, checklists have the potential to greatly reduce errors due to slips.

Current Use of Checklists

Checklists garnered well-deserved publicity as a result of their use in the Keystone ICU project, a multicenter study in which a checklist of evidence-based infection control interventions was implemented to reduce the risk of central line-associated bloodstream infections in intensive care unit patients. This intervention achieved a stunning reduction in

line infections, with many ICUs completely eliminating line infections for months at a time. An AHRQ-funded initiative subsequently replicated this success in a wide range of hospitals nationwide. A similar level of success was achieved through implementation of a surgical safety checklist, which included specific steps during induction of anesthesia, surgical timeout, and transfer of the patient out of the operating room. Initial studies achieved reductions in surgical mortality and morbidity across a wide range of clinical settings. Further research has investigated the use of checklists to improve safety at the time of hospital discharge, augment transfer of information during in-hospital handoffs, and enhance the care of intensive care unit and trauma patients.

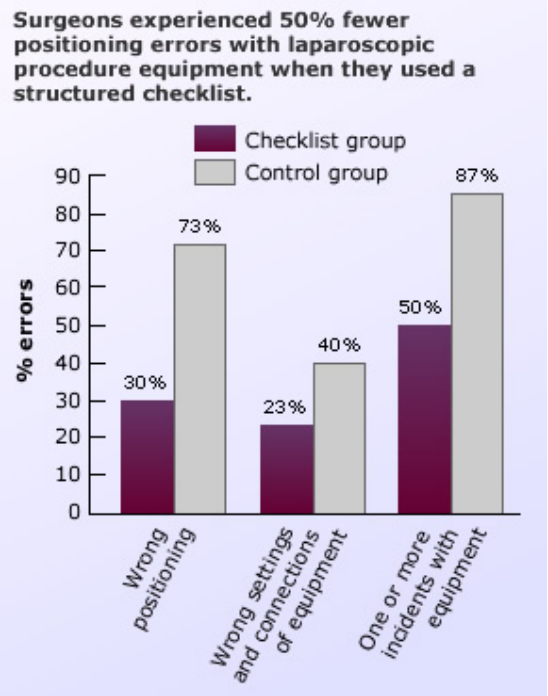
Controversies

Checklists are a remarkably useful tool in improving safety, but they are not a panacea. As checklists have been more widely implemented, it has become clear that their success depends on appropriately targeting the intervention and utilizing a careful implementation strategy.

Errors in clinical tasks that involve primarily attentional behavior—such as diagnostic errors or handoff errors—may require solutions focused on training, supervision, and decision support rather than standardizing behavior, and thus may not be an appropriate subject for a checklist. An effective checklist also requires consensus regarding required safety behaviors. The success of checklists in preventing central line infections and improving surgical safety resulted from the strong evidence base supporting each of the individual items in the checklist, and therefore checklists may not be successful in areas where the "gold standard" safety practices have yet to be determined.

When a checklist is appropriate, safety professionals must be aware that implementing a checklist is a complex sociotechnical endeavor, requiring frontline providers to not only change their approach to a specific task but to engage in cultural changes to enhance safety. Successful implementation of a checklist requires extensive preparatory work to maximize safety culture in the unit where checklists are to be used, engage leadership in rolling out and emphasizing the importance of the checklist, and rigorously analyze data to assess use of the checklist and associated clinical outcomes. Failure to engage in appropriate preparatory and monitoring before and after checklist implementation may explain why checklist use in

real-world settings is often poor, contributing to disappointing results. Ethnographic studies of successful and unsuccessful checklist implementation have been instrumental in enhancing understanding of the barriers that can limit checklist utility.



Source: Verdaasdonk EG, Stassen LP, Hoffman WF, van der Elst M, Dankelman J. Can a structured checklist prevent problems with laparoscopic equipment? Surg Endosc. 2008. Available at: http://dx.doi.org/10.1007/s00464-008-0029-3

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Editor's Picks

JOURNAL ARTICLE › REVIEW

Postoperative adverse events inconsistently improved by the World Health Organization surgical safety checklist: a systematic literature review of 25 studies.

de Jager E, McKenna C, Bartlett L, Gunnarsson R, Ho YH. World J Surg. 2016;40:1842-1858.

JOURNAL ARTICLE › STUDY

Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial.

Haugen AS, Søfteland E, Almeland SK, et al. Ann Surg. 2015;261:821-828.

JOURNAL ARTICLE › STUDY

A checklist-based intervention to improve surgical outcomes in Michigan: evaluation of the Keystone Surgery program.

Reames BN, Krell RW, Campbell DA Jr, Dimick JB. JAMA Surg. 2015;150:208-215.

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The limits of checklists: handoff and narrative thinking.

Hilligoss B, Moffatt-Bruce SD. BMJ Qual Saf. 2014;23:528-533.

JOURNAL ARTICLE › STUDY

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Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. N Engl J Med. 2014;370:1029-1038.

JOURNAL ARTICLE › REVIEW

Surgical checklists: a systematic review of impacts and implementation.

Treadwell JR, Lucas S, Tsou AY. BMJ Qual Saf. 2014;23:299-318.

JOURNAL ARTICLE › REVIEW

Systematic review of safety checklists for use by medical care teams in acute hospital settings—limited evidence of effectiveness.

Ko HCH, Turner TJ, Finnigan MA. BMC Health Serv Res. 2011;11:211.

PERSPECTIVE

What Makes a Good Checklist

JOURNAL ARTICLE › STUDY

Effect of a 19-item surgical safety checklist during urgent operations in a global patient population.

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BOOK/REPORT

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PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Communication Between Clinicians

Background

The dynamic environment in which health care is delivered requires clinicians to maintain situational awareness. The concept of situational awareness refers to the ability to access and track data relevant to the task at hand, comprehend the data, forecast what may happen based on the data, and formulate an appropriate plan in response. In a clinical context, maintaining situational awareness requires information sharing and open dialogue among clinicians in order to achieve a shared mental model—the "big picture" of the patient's condition and immediate priorities for care.

Situational awareness cannot be achieved without clear and high-quality communication between all of the providers who are caring for a patient. For example, if a patient on a medical ward begins to deteriorate, the bedside nurse will need to communicate information about the patient's known diagnoses, symptoms, vital signs, and acuity in a clear and timely fashion to the responding clinician who, in turn, will need to respond respectfully, process and comprehend the new information, and devise a plan. Any breakdown in this chain of communication will lead to impaired situational awareness, and patients may be harmed as a result. An AHRQ WebM&M case details the death of an infant shortly after repair of a congenital heart defect. Both the intensive care unit team and the cardiac surgery team were aware of the patient's deteriorating condition, but each assumed the other was primarily managing the problem. Poor communication between the two teams meant the severity of the patient's condition was not appreciated until it was too late.

Unfortunately, problems with communication between clinicians are pervasive and clearly result in preventable patient harm. Seminal studies have shown that poor levels of communication exist between clinicians at all levels of the health care system. The Joint

Commission has found that communication issues are the most common root cause of sentinel events (serious and preventable patient harm incidents). In the operating room, poor communication has been directly linked to surgical complications and has also been implicated in malpractice lawsuits in multiple clinical settings.

This Patient Safety Primer will discuss methods of improving communication between clinicians in the context of routine patient care and emergency situations. Issues involving communication between clinicians at times of transitions in care are discussed in the Handoffs and Signouts, Adverse Events after Hospital Discharge, and Checklists Patient Safety Primers.

Methods of Improving Communication Between Providers

The factors that impair effective communication between providers often relate to cultural norms and expectations within the health care environment. Rigid hierarchies, in which authority gradients discourage frontline workers from raising concerns with leadership, are persistent within health care and a known contributor to preventable harm. Overtly disruptive and unprofessional behavior is less common, but has a chilling effect on communication and teamwork. More subtle issues, such as nonverbal cues, interpersonal relations, and group dynamics, can affect communication in ways that may not be readily apparent, even to the parties involved. In many ways, these factors contribute to the overall culture of safety within an organization.

Approaches to improving communication between clinicians share common goals, but differ depending on the context. Efforts to enhance communication in the course of routine patient care have focused on developing standardized communication protocols for transmission of important information. For example, read-back protocols are now standard practice for communication of critical test results in order to reduce errors of omission. The Situation-Background-Assessment-Recommendation (SBAR) approach is widely used to facilitate communication between nurses and physicians by offering a standardized way of communicating the clinical assessment of a patient requiring acute attention. Used correctly, SBAR can be an effective tool to minimize authority gradients.

At the health care system level, formal teamwork training programs explicitly focus on enhancing communication behaviors within teams, and a growing body of literature

demonstrates that improved team behaviors lead to better patient outcomes. The unit-based safety team model, which emphasizes teamwork training approaches within a geographic unit, has also been effective in improving safety culture. Organizations are also taking a more proactive stance in addressing disruptive and unprofessional behavior by clinicians at all levels.

Current Context

The Joint Commission includes "improving staff communication" as one of its National Patient Safety Goals, emphasizing the importance of communicating test results accurately. The National Quality Forum also includes multiple approaches to enhancing communication as part of the Safe Practices for Better Healthcare.

Editor's Picks

CASE

Communication Error in a Closed ICU

TOOLS/TOOLKIT › TOOLKIT

TeamSTEPPS: Strategies and Tools to Enhance Performance and Patient Safety.

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CASE

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JOURNAL ARTICLE › STUDY

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CASE

Intubation Mishap

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Patient Safety Primer Last Updated: June 2017

Computerized Provider Order Entry

Background

The digital transformation of medicine is perhaps best exemplified by computerized provider order entry (CPOE), which refers to any system in which clinicians directly place orders electronically, with the orders transmitted directly to the recipient. As recently as 10 years ago, most clinician orders were handwritten. Spurred by the 2009 federal HITECH Act and the accompanying Meaningful Use program, CPOE usage rapidly increased in inpatient and outpatient settings. The vast majority of hospitals and most outpatient practices now use some form of CPOE. CPOE systems were originally developed to improve the safety of medication orders, but modern systems now allow electronic ordering of tests, procedures, and consultations as well. The widespread implementation of CPOE has benefited clinicians and patients, but it also vividly illustrates the risks and unintended consequences of digitizing a fundamental health care process.

The process of prescribing and administering a medication involves several steps, each of which has vulnerabilities that are addressed—to greater or lesser degrees—by CPOE:

- Ordering: the clinician must select the appropriate medication and the dose and frequency at which it is to be administered.
- Transcribing: if handwritten, the prescription must be read and understood by the recipient (usually a pharmacy technician or pharmacist).
- Dispensing: the pharmacist must check for drug–drug interactions and allergies, then release the appropriate quantity of the medication in the correct form.
- Administration: the medication must be received by the correct person and supplied to the correct patient at the right time in the right dosage. In hospitalized patients,

nurses are generally responsible for this step, but in the outpatient setting, this step is the patient's or caregiver's responsibility.

A classic study of inpatient medication errors found that approximately 90% occurred at either the ordering or transcribing stage. These errors had a variety of causes, including poor handwriting, ambiguous abbreviations, or simple lack of knowledge on the part of the ordering clinician. A CPOE system can prevent errors at the ordering and transcribing stages by (at a minimum) ensuring standardized, legible, and complete orders.

CPOE systems are generally paired with some form of clinical decision support system (CDSS), which can help prevent errors at the medication ordering and dispensing stages and can improve safety of other types of orders as well. A typical CDSS suggests default values for drug doses, routes of administration, and frequency and may offer more sophisticated drug safety features, such as checking for drug allergies or drug–drug or even drug–laboratory (e.g., warning a clinician before ordering a nephrotoxic medication in a patient with elevated creatinine) interactions. The most sophisticated CDSSs prevent not only errors of commission (e.g., ordering a drug in excessive doses or a drug to which the patient has a known allergy), but also of omission (e.g., failing to order prophylaxis against deep venous thrombosis in a patient who underwent joint replacement surgery). CDSSs are also increasingly being deployed to address overuse—for example, a systematic review of CPOE for radiologic studies found that CDSS can improve adherence to guidelines for diagnostic imaging and reduce overall test usage.

Evidence of Effectiveness

CPOE offers numerous advantages over traditional paper-based order-writing systems. Examples of these advantages include: averting problems with handwriting, similar drug names, drug interactions, and specification errors; integration with electronic medical records, clinical decision support systems, and adverse drug event reporting systems; faster transmission to the laboratory, pharmacy, or radiology department; ability to recommend alternative tests or treatments that may be safer or lower cost; and potential economic savings. Supported by early evidence, the proposed benefits of CPOE served as a core part of the argument for federal funding to support the widespread implementation of CPOE.

These proposed benefits have been borne out to some extent, principally with regard to improving medication safety. Specifically, CPOE appears to be effective at preventing medication prescribing errors. A 2013 meta-analysis found that the likelihood of a prescribing error was reduced by 48% when using CPOE compared with paper-based orders, which translates into more than 17 million medication errors prevented yearly in United States hospitals. Studies of e-prescribing systems—CPOE systems used primarily in outpatient practices that allow direct transmittal of prescriptions to pharmacies—have also found similar effectiveness at preventing outpatient prescribing errors.

The effect of CPOE on clinical adverse drug event rates is less clear. Other reviews have found that CPOE does not reliably prevent patient harm, and high rates of adverse drug events persist in some hospitals with entirely computerized order entry systems. One interpretation of these results is that clinical decision support is the key intervention in reducing errors, and that, in the absence of CDSS, CPOE may prevent mostly clinically inconsequential errors. However, usability testing has demonstrated that CPOE systems with clinical decision support still allow unsafe orders to be entered and processed, and that clinicians can bypass safety steps with little difficulty. Another interpretation is that a significant proportion of medication errors occur at the dispensing and administration stages, and CPOE may not prevent these errors. Promising error reduction strategies in the setting of dispensing and administration include involving unit-based pharmacists and using barcode medication administration systems. Yet even as CPOE improves some aspects of patient safety, there is growing recognition that it can also lead to new safety concerns—particularly if the system is poorly designed.

New Safety Concerns: Implementation Issues and Workflow Impact of CPOE

The implementation of CPOE has proven to be a complex process, and early users experienced high-profile failures or safety hazards that in some cases led to abandonment of the system. A great deal of research has characterized the types of unintended consequences and disruptions to clinician workflow that result from CPOE implementation. With data from institutions with several years' experience with CPOE, these studies provide important lessons for organizations implementing not only CPOE but also a variety of technologies as part of the growing digital transformation of medicine.

Unintended consequences of CPOE

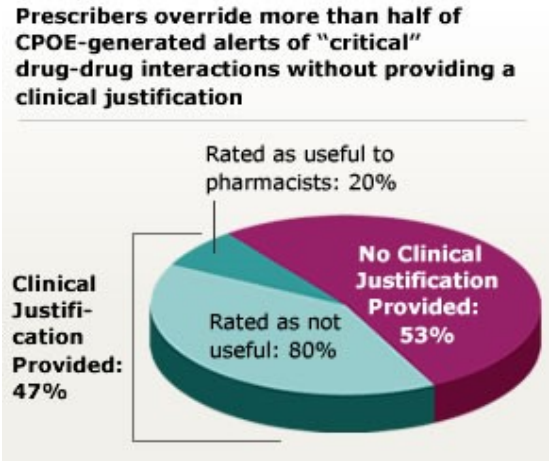
Various unintended consequences of CPOE implementation have been characterized (Table). One study conducted after implementation of a commercial CPOE system found that the system required clinicians to perform many new tasks, increasing cognitive load and decreasing efficiency, and therefore raising the potential for error. In that study, although overall prescribing errors decreased, problems related to the CPOE system itself accounted for almost half of prescribing errors after implementation. Other studies have shown that users often use workarounds to bypass safety features. In many cases, these workarounds represent reasonable adaptations due to problems with the design and usability of CPOE systems. As detailed in a 2015 Food and Drug Administration white paper (summarized here), current CPOE systems have fundamental problems such as confusing displays, use of nonstandard terminology, and lack of standards for alerts and warnings. The authors call for integration of human factors engineering principles, including real-world usability and vulnerability testing, in order to achieve the safety potential of CPOE.

Table. Types of Unintended Consequences of Computerized Provider Order Entry Systems
More or new work for clinicians
Unfavorable workflow issues
Never-ending system demands
Problems related to persistence of paper orders
Unfavorable changes in communication patterns and practices
Negative feelings toward the new technology
Generation of new types of errors
Unexpected changes in an institution's power structure, organizational culture, or professional roles
Overdependence on the technology

(Reprinted with permission from Elsevier. In: Campbell EM, Sittig DF, Ash JS, Guappone KP, Dykstra RH. Types of unintended consequences related to computerized provider order entry. J Am Med Inform Assoc. 2006;13:547-556.)

The integration of clinical decision support into CPOE systems also requires careful planning. Decision support alerts can prevent harmful drug–drug interactions and promote use of evidence-based tests and treatments. However, excessive and nonspecific warnings can lead

to alert fatigue—whereby users ignore even critical warnings. Alert fatigue is now a recognized safety threat in itself and is discussed in detail in a related Patient Safety Primer. Alert fatigue likely explains why CDSSs appear to result in only modest improvements in adherence to recommended care and may fail to prevent errors. Recent research has focused on tailoring alerts to maximize safety while avoiding alert fatigue, but the informatics field has not yet developed standard approaches to achieve this balance.



Source: Grizzle AJ, Mahmood MH, Ko Y, et al. Reasons provided by prescribers when overriding drug-drug interaction alerts. Am J Manag Care. 2007;13:573-578. [go to PubMed]

As institutions gain more experience with CPOE implementation, greater awareness of these issues may help avert problems associated with the new technology. Careful planning of the implementation process to minimize workflow disruptions and maximize the system's ease of use has been shown to avert adverse events relating to CPOE. Effective CPOE implementation requires considerable investment of time and resources as well as commitment from both CPOE vendors and organizational leadership to ensuring safe integration of the technology with existing workflows.

Current Context

CPOE is recommended by the National Quality Forum as one of the 30 "Safe Practices for Better Healthcare" and by the Leapfrog Group as one of first three recommended "leaps" for improving patient safety. The pace of CPOE adoption in both hospitals and clinics rapidly increased after passage of the HITECH Act in 2009. Recent data indicates that 84% of federal acute care hospitals had implemented CPOE by the end of 2015, although only 40% had implemented a system that included integrated CDSS. Adoption in the outpatient setting is

also rapidly increasing, and as of the end of 2015, more than half of office practices had adopted electronic prescribing (the major form of CPOE in the outpatient setting).

Editor's Picks

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CASE

Unexpected Drawbacks of Electronic Order Sets

CASE

Unintended Consequences of CPOE

JOURNAL ARTICLE › STUDY

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PERSPECTIVE

Computerized Provider Order Entry and Patient Safety

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Slight SP, Eguale T, Amato MG, et al. J Am Med Inform Assoc. 2016;23:311-316.

BOOK/REPORT

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JOURNAL ARTICLE › STUDY

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CASE

Finding Fault With the Default Alert

JOURNAL ARTICLE › STUDY

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CASE

Situational (Un)Awareness

WEB RESOURCE › MULTI-USE WEBSITE

The Leapfrog Group.

c/o Academy Health, 1801 K Street, NW, Suite 701-L, Washington, DC 20006.

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JOURNAL ARTICLE › STUDY

Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction: a randomized controlled trial.

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CASE

Bad Writing, Wrong Medication

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JOURNAL ARTICLE › STUDY

Electronic prescribing improves medication safety in community-based office practices.

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PERSPECTIVE

Integrating Multiple Medication Decision Support Systems: How Will We Make It All Work?

JOURNAL ARTICLE › STUDY

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CASE

A Troubling Amine

BOOK/REPORT

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CASE

The Forgotten Med

JOURNAL ARTICLE › STUDY

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WEB RESOURCE › MULTI-USE WEBSITE

National Quality Forum.

1030 15th Street NW, Suite 800, Washington DC 20005.

CASE

Overriding Considerations

PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Culture of Safety

Background

The concept of safety culture originated outside health care, in studies of high reliability organizations, organizations that consistently minimize adverse events despite carrying out intrinsically complex and hazardous work. High reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives. This commitment establishes a "culture of safety" that encompasses these key features:

- acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations
- a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- organizational commitment of resources to address safety concerns

Improving the culture of safety within health care is an essential component of preventing or reducing errors and improving overall health care quality. Studies have documented considerable variation in perceptions of safety culture across organizations and job descriptions. In prior surveys, nurses have consistently complained of the lack of a blame-free environment, and providers at all levels have noted problems with organizational commitment to establishing a culture of safety. The underlying reasons for the underdeveloped health care safety culture are complex, with poor teamwork and communication, a "culture of low expectations," and authority gradients all playing a role.

Measuring and Achieving a Culture of Safety

Safety culture is generally measured by surveys of providers at all levels. Available validated surveys include AHRQ's Patient Safety Culture Surveys and the Safety Attitudes Questionnaire. These surveys ask providers to rate the safety culture in their unit and in the organization as a whole, specifically with regard to the key features listed above. Versions of the AHRQ Patient Safety Culture survey are available for hospitals and nursing homes, and AHRQ provides yearly updated benchmarking data from the hospital survey.

Safety culture has been defined and can be measured, and poor perceived safety culture has been linked to increased error rates. However, achieving sustained improvements in safety culture can be difficult. Specific measures, such as teamwork training, executive walk rounds, and establishing unit-based safety teams, have been associated with improvements in safety culture measurements and have been linked to lower error rates in some studies. Other methods, such as rapid response teams and structured communication methods such as SBAR, are being widely implemented to help address cultural issues such as rigid hierarchies and communication problems, but their effect on overall safety culture and error rates remains unproven.

The culture of individual blame still dominant and traditional in health care undoubtedly impairs the advancement of a safety culture. One issue is that, while "no blame" is the appropriate stance for many errors, certain errors do seem blameworthy and demand accountability. In an effort to reconcile the twin needs for no-blame and appropriate accountability, the concept of just culture is now widely used. A just culture focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability by establishing zero tolerance for reckless behavior. It distinguishes between human error (eg, slips), at-risk behavior (eg, taking shortcuts), and reckless behavior (eg, ignoring required safety steps), in contrast to an overarching "no-blame" approach still favored by some. In a just culture, the response to an error or near miss is predicated on the type of behavior associated with the error, and not the severity of the event. For example, reckless behavior such as refusing to perform a "time-out" prior to surgery would merit punitive action, even if patients were not harmed.

Safety culture is fundamentally a local problem, in that wide variations in the perception of safety culture can exist within a single organization. The perception of safety culture might be high in one unit within a hospital and low in another unit, or high among management and low among frontline workers. Research also shows that individual provider burnout negatively affects safety culture perception. These variations likely contribute to the mixed record of interventions intended to improve safety climate and reduce errors. Therefore, organizational leadership must be deeply involved with and attentive to the issues frontline workers face, and they must understand the established norms and "hidden culture" that often guide behavior. Many determinants of safety culture are dependent on interprofessional relationships and other local circumstances, and thus changing safety culture occurs at a microsystem level. As a result, safety culture improvement often needs to emphasize incremental changes to providers' everyday behaviors.

Current Context

The National Quality Forum's Safe Practices for Healthcare and the Leapfrog Group both mandate safety culture assessment. The Agency for Healthcare Research and Quality also recommends yearly measurement of safety culture as one of its "10 patient safety tips for hospitals." Baseline data on safety culture in a variety of hospital settings, derived from the Hospital Survey on Patient Safety Culture, are available from AHRQ.

Editor's Picks

PERSPECTIVE

Our Maturing Understanding of Safety Culture: How to Change It and How It Changes Safety

PERSPECTIVE

In Conversation With… Mary Dixon-Woods, DPhil

BOOK/REPORT

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Dekker S. Boca Raton, FL: CRC Press; 2016. ISBN: 9781472475787.

BOOK/REPORT

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JOURNAL ARTICLE › STUDY

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JOURNAL ARTICLE › STUDY

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PERSPECTIVE

What We've Learned About Leveraging Leadership and Culture to Affect Change and Improve Patient Safety

PERSPECTIVE

In Conversation With… Sidney Dekker, MA, MSc, PhD

PERSPECTIVE

Update on Safety Culture

PERSPECTIVE

In Conversation With… J. Bryan Sexton, PhD, MA

JOURNAL ARTICLE › REVIEW

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Morello RT, Lowthian JA, Barker AL, McGinnes R, Dunt D, Brand C. BMJ Qual Saf. 2013;22:11-18.

WEB RESOURCE › DATABASE/DIRECTORY

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Rockville, MD: Agency for Healthcare Research and Quality.

PERSPECTIVE

Making Just Culture a Reality: One Organization's Approach

PERSPECTIVE

In Conversation with...David Marx, JD

TOOLS/TOOLKIT › MEASUREMENT TOOL/INDICATOR

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PERSPECTIVE

Establishing a Safety Culture: Thinking Small

PERSPECTIVE

In Conversation with...J. Bryan Sexton, PhD, MA

JOURNAL ARTICLE › STUDY

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BOOK/REPORT

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Patient Safety Primer Last Updated: November 2017

Debriefing for Clinical Learning

Background

Debriefing is an important strategy for learning from defects and for improving performance. It is one of the central learning tools in simulation and is also recommended after a real-life emergency response.

Debriefing is defined as a dialogue between two or more people; its goals are to discuss the actions and thought processes involved in a particular patient care situation, encourage reflection on those actions and thought processes, and incorporate improvement into future performance. The function of debriefing is to identify aspects of team performance that went well, and those that did not. The discussion then focuses on determining opportunities for improvement at the individual, team, and system level.

Debriefings can follow an actual or simulated clinical event, or they may be embedded in simulated events. Debriefing in health care was first developed and most extensively used as part of formal medical simulation programs. Debriefing remains a central learning activity in simulation, and much of the literature focuses on debriefing in the context of postsimulation exercises. Recent work has also described new forms of debriefing during a simulated event ("within-event microdebriefing"), which is followed by repeated simulation practice opportunities to enhance mastery of clinical and teamwork skills. In addition, AHRQ has long incorporated clinical event debriefing into the TeamSTEPPS team training program. Research specific to clinical events debriefing is beginning to provide support for such debriefing to improve team performance, resuscitation, and other emergency response outcomes. Although real-time or near real-time clinical event debriefing can be challenging to implement, it has been identified as an important aspect of effective clinical education, quality improvement, and systems learning. It is important to note that debriefing can be a useful

learning tool in cases where things go well, with near misses, and in cases that involve adverse events.

Components of Debriefing

All forms of debriefing have a shared structure that involves setting the stage followed by three phases including description or reactions, analysis, and application.

Setting the stage: To be effective, a debriefing must be conducted in a manner that supports learning. Thus, the purpose is not to identify error and assign blame, but to understand why actions and decisions made sense to clinicians in the moment. Such a focus increases the probability that positive performance can be reinforced and new options can be generated for changing performance that was incorrect or otherwise below the desired standard. This requires establishment of psychological safety for participants regardless of the type of debriefing conducted. Whether engaged in a clinical debriefing lasting 3 minutes or a simulation debriefing lasting 30 minutes, the tone set by the leader and the leader's management of the discussion are both critical to maintaining psychological safety.

Description or reactions: During this phase, the leader generally elicits perspectives from team members about how events unfolded in the clinical situation or simulation scenario and asks them to describe their reactions. Participants should be requested to identify the important issues to address, and the sequence of events should be clarified.

Analysis: In this phase, the leader should codevelop the priorities for discussion with the participants, balancing participant priorities with any other critical safety concerns that were noted during the event. The goal of this phase is to explore clinicians' rationales for observed behaviors, identify and close performance gaps by discussing pros and cons of chosen actions, and determine any modifiable systems issues that may have interfered with performance. Team members must be able to be direct with each other during this phase, and leaders may need to actively facilitate team members sharing what they were thinking and how they were affected by the actions of others.

Application: This phase of debriefing is designed to identify and summarize the main learning points and consider how they can be incorporated into future practice. Explicitly summarizing

lessons learned from the scenario or clinical event may help team members recall and apply these lessons in the future.

Tools

Multiple debriefing frameworks, scripts, and tools are available to assist leaders with planning and implementing debriefings. When used with simulation, the planning includes advance decisions about scenario learning objectives, and debriefing often involves expert facilitators with significant experience in reflective inquiry strategies or a synthesis of leader and learner inquiry strategies. Best practices for effective debriefing in medical simulation include preparation that involves subject expertise, facilitation skills, and selection of evaluation measures; supportive engagement of learners during the debriefing; attention to differences of perspective, conflict, and emotion management during debriefing; maintaining an emphasis on teamwork processes; and ensuring group development of solutions to performance problems. For within-event debriefings, opportunities for practicing skills to mastery are offered as well.

Special Considerations for Clinical Events Debriefing

Clinical event debriefing can be challenging to implement due to the uncertainty about when it will occur and the nature of the events to be debriefed; the time pressures of the clinical environment; and team members' variable facilitation skills and experience. Although the clinical time pressures are very real, experts agree that clinical event debriefing can be done quickly and still be effective.

A common and relatively simple approach to clinical debriefing is referred to as "plus-delta." It consists of three questions: (i) What went well? (ii) What did not go well? (iii) What can we do differently or what needs to change to improve care? The simplicity of this format works well for clinical event debriefing, especially when combined with a checklist or structure that helps the team ensure they address important teamwork principles (Box).

Box. Framework for Clinical Event Debriefing

The team should evaluate whether or not they:

- Had clear communication
- Demonstrated understanding of roles and responsibilities

- Maintained situation awareness
- Distributed workload effectively
- Engaged in cross-monitoring; asked for and offered help when needed
- Made, mitigated, or corrected errors

Adapted from the debriefing checklist in TeamSTEPPS 2.0 module *Leading Teams*.

TeamSTEPPS includes instruction on clinical events debriefing, and Kessler and colleagues provide comprehensive guidance for developing a clinical debriefing program.

Current Context

Much of debriefing in health care occurs as part of simulation activities. Debriefing is a core learning activity for simulation, and much of the research on debriefing in health care has occurred in that context. Educational research strongly supports debriefing as an effective mechanism for promoting adult learning and enhancing skills and team performance. The literature on clinical events debriefing is less robust. Small studies with historical controls have shown improvement in some resuscitation outcomes with clinical event debriefing in emergency rooms and intensive care units. The American Heart Association and the American Academy of Pediatrics recommend clinical event debriefing after cardiac arrest and neonatal resuscitations respectively based on this evidence. Further implementation research and quality improvement work is needed to determine how real-time clinical event debriefing can be more effectively evaluated and more widely disseminated.

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Patient Safety Primer Last Updated: June 2017

Detection of Safety Hazards

Background and definitions

An unacceptably large proportion of patients experience preventable harm at the hands of the health care system, and even more patients experience errors in their care that (through early detection or sheer chance) do not result in clinical consequences. Considerable effort has been devoted to optimizing methods of detecting errors and safety hazards, with the goal of prospectively identifying hazards before patients are harmed and analyzing events that have already occurred to identify and address underlying systems flaws. Despite much effort, health care institutions are still searching for optimal methods to identify underlying system defects before patients are harmed and, when errors do occur, methods to recognize them as rapidly as possible to prevent further harm. This Primer reviews both prospective and retrospective methods to identify safety hazards that can lead to errors and adverse events. (Definitions of *error, adverse events,* and foundational patient safety concepts can be found in the Systems Approach Patient Safety Primer.)

Methods of prospectively identifying safety hazards

Failure mode and effect analysis (FMEA) is a common approach to prospectively determine error risk within a particular process. FMEA begins by identifying all the steps that must be taken for a given process to occur ("process mapping") and then how each step can go wrong (i.e., failure modes), the probability that each error will be detected before causing harm, and the impact of the error if it actually occurs. The estimated likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a criticality index, which provides a rough estimate of the magnitude of hazard posed by each step in a high-risk process. Steps ranked at the top (those with the highest criticality indices) should be prioritized for error proofing.

FMEA (or similar techniques) has been used in other high-risk industries and offers a reasonable framework for prospective safety analysis. However, this technique's reliability has been called into question, as studies have shown that independent groups can reach widely differing opinions about the failure modes and criticality index of a given process. Another, more qualitative approach termed SWIFT ("structured what-if technique") can be used either as an adjunct to FMEA or as a stand-alone technique.

The field of human factors engineering attempts to identify and address safety problems that arise due to the interaction between people, technology, and work environments. Human factors engineers often lead safety efforts in other high-risk industries, and recent commentaries have called for greater integration of human factors principles into health care and patient safety.

Other methods to prospectively uncover safety hazards rely on qualitative approaches that emphasize the views of frontline providers. Establishing a culture of safety entails obtaining information on perceived safety problems from staff at all levels, through formal safety culture surveys or more informal methods such as executive walk rounds. Ethnographic approaches, which rely on direct field observations of health care personnel by researchers attuned to the cultural aspects of how care is provided, can determine distinct classes of safety problems and have also been used to identify unintended consequences of safety policies.

Retrospective error detection methods

Techniques to retrospectively identify safety hazards can be loosely classified into two groups: those used to screen larger datasets for evidence of preventable adverse events that merit further investigation and those that analyze individual cases of adverse events (or where an adverse event is strongly suspected). The former include trigger tools and methods of screening administrative datasets, while the latter include root cause analysis, mortality reviews, and related methods of in-depth investigation into specific patients.

Trigger tools alert patient safety personnel to probable adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred. For instance, a hospitalized patient receiving naloxone (a drug used to reverse the effects of narcotics) may have previously received an excessive dose of morphine or some other opiate.

In this case, the administration of naloxone would be a "trigger" to investigate possible adverse drug events. (In the emergency department, naloxone use would more likely represent treatment of a self-inflected opiate overdose, so the trigger would have little value in that setting.) In cases in which the trigger correctly identifies an adverse event, causative factors can be determined and interventions developed to reduce the frequency of common causes of adverse events. The traditional use of triggers has been to efficiently identify adverse events through chart review or review of other data sources (such as pharmacy databases), and triggers can also be used to track rates of safety events over time. Though many trigger tools exist, the Institute for Healthcare Improvement's Global Trigger Tool has been widely used and validated in different patient populations.

As with any alert system, the threshold for generating triggers needs to balance true and false positives. The system will lose its value if too many triggers prove to be false alarms. (This concern is less relevant when triggers are used as chart review tools, since the "cost" of a false positive is relatively low—mostly sufficient resources for medical record review.)

Administrative datasets, typically generated for billing purposes, contain information on clinical diagnoses and treatments for large patient populations. Several methods have been evaluated for screening these datasets for evidence of adverse events. Among these, the AHRQ Patient Safety Indicators (PSIs), which use administrative data to screen for complications of hospital care, have been widely studied and shown to be associated with increased length of stay, mortality, and hospital costs. The PSIs and similar tools are best used as screening techniques to identify potential hazards that should be investigated further. For example, if a hospital notes an elevated incidence of the postoperative sepsis PSI, it may have a systematic problem with failure to rescue in postoperative patients. The PSIs should not be used to compare patient safety between hospitals, or to estimate the overall incidence of adverse events at an institution.

Voluntary error reporting systems are ubiquitous in health care institutions and are an integral piece of organizational safety efforts. Although voluntary reporting systems are most often used to report errors that have already occurred, near-miss reporting can help prospectively identify system flaws as well. At the national level, regulations for implementing the Patient Safety and Quality Improvement Act became effective on January 19, 2009. The legislation provides confidentiality and privilege protections for patient safety information when health

care providers work with new expert entities known as Patient Safety Organizations (PSOs). Health care providers may choose to work with a PSO and specify the scope and volume of patient safety information to share with a PSO. AHRQ has also developed common definitions and reporting formats (Common Formats) for patient safety events, in order to facilitate aggregation and use of patient safety information.

Hospitals also routinely conduct root cause analyses and mortality reviews when patients experience bad outcomes suspected to be related to an adverse event. Root cause analysis is a formal multidisciplinary process that has the explicit goal of identifying systematic problems in care. Standardized mortality reviews may be used to analyze specific cases for systematic harm or to estimate the proportion of deaths related to adverse events. Similarly, autopsies have traditionally been used to identify diagnostic errors, and traditional morbidity and mortality conferences are increasingly being adapted to help uncover underlying system flaws.

Many organizations are seeking to engage patients in safety efforts, and some studies have shown that patients can identify problems in care that were not revealed through more traditional methods. Reviews of closed malpractice claims and risk management databases have also yielded useful information regarding the types of adverse events that frequently occur in specific practice settings.

Novel approaches to adverse event detection have focused on ways in which errors may be detected in real time. Innovative studies that take advantage of electronic medical records have used natural language processing and real-time triggers to identify errors contemporaneously, allowing for immediate targeting of safety solutions. As electronic medical records continue to evolve, these approaches are likely to make real-time identification of errors and near misses more accurate and efficient. Comprehensive data warehouses, which combine administrative data with other sources (such as laboratory results and pharmacy databases) and can be searched with specialized algorithms, also have promise as a means of reliably and efficiently identifying patient-level harm.

Current context

The Joint Commission currently requires all hospitals to conduct one prospective risk assessment every 18 months (typically through performing an FMEA) and also requires

performance of a root cause analysis under certain circumstances (such as when a sentinel event occurs). All hospitals are also mandated to maintain a voluntary error reporting system. Beyond these requirements, however, there are no consensus standards on how hospitals or clinics should assess their safety hazards, either prospectively or retrospectively. What is clear, however, is that no single method is comprehensive enough to provide a full picture of patient safety at an institution. A seminal study that compared safety data from five separate sources (voluntary error reports, malpractice claims, patient complaints, executive walk rounds, and a risk management database) found that each source identified different types of errors. For example, diagnostic errors were almost never identified through voluntary reports but were a relatively common source of malpractice claims. This led one commentator to compare safety hazard detection methods with an Indian fable in which five blind men describe an elephant in widely varying terms (as a wall, fan, spear, snake, or tree), depending on which part of the animal they touched. Similarly, an institution's picture of patient safety will hinge on which method they emphasize for error detection, and a comprehensive picture can only be obtained by integrating multiple methods.

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Patient Safety Primer Last Updated: June 2017

Diagnostic Errors

Background

The past decade's quest to improve patient safety has chiefly addressed quantifiable problems such as medication errors, health care–associated infections, and postsurgical complications. Diagnostic error has received comparatively less attention, despite the fact that landmark patient safety studies have consistently found that diagnostic error is common. In the Harvard Medical Practice Study, diagnostic error accounted for 17% of preventable errors in hospitalized patients, and a systematic review of autopsy studies covering four decades found that approximately 9% of patients experienced a major diagnostic error that went undetected while the patient was alive. Taken together, these studies imply that thousands of hospitalized patients die every year due to diagnostic errors.

An extensive body of research has examined the causes of diagnostic error at the individual clinician level. This work has been informed by the field of cognitive psychology, which studies how individuals process information and subsequently develop plans. As applied to health care, we have learned that clinicians frequently use heuristics (shortcuts or "rules of thumb") to come up with a provisional diagnosis, especially when faced with a patient with common symptoms. While heuristics are ubiquitous and useful, researchers have used categories developed in cognitive psychology to classify several types of errors that clinicians commonly make due to incorrect applications of heuristics:

Cognitive Bias	Definition	Example
Availability heuristic	Diagnosis of current patient biased by experience with past cases	A patient with crushing chest pain was incorrectly treated for a myocardial infarction, despite indications that an aortic dissection was present.
Anchoring heuristic (premature closure)	Relying on initial diagnostic impression, despite	Repeated positive blood cultures with *Corynebacterium* were dismissed as contaminants; the patient was eventually diagnosed with *Corynebacterium* endocarditis.

	subsequent information to the contrary	
Framing effects	Diagnostic decision-making unduly biased by subtle cues and collateral information	A heroin-addicted patient with abdominal pain was treated for opiate withdrawal, but proved to have a bowel perforation.
Blind obedience	Placing undue reliance on test results or "expert" opinion	A false-negative rapid test for *Streptococcus* pharyngitis resulted in a delay in diagnosis.

While cognitive biases on the part of individual clinicians play a role in many diagnostic errors, underlying health care system problems also contribute to missed and delayed diagnoses. Missed or delayed diagnoses (particularly cancer diagnoses) are a prominent reason for malpractice claims, and much of the research into systems causes of diagnostic error arises from studies of closed malpractice claims in primary care, pediatrics, emergency medicine, and surgery. Poor teamwork and communication between clinicians have been identified as predisposing factors for diagnostic error in emergency medicine and surgery. Lack of reliable systems for common outpatient clinical situations, such as triaging acutely ill patients by telephone and following up on test results, also increases the likelihood of diagnostic error.

Preventing Diagnostic Errors

Given that many diagnostic errors are caused by subtle biases in clinicians' thought processes, some diagnostic errors may be prevented by systems to mitigate the effect of these biases and provide physicians with objective information to assist with decision-making. Clinicians are frequently unaware of diagnostic errors that they have committed, particularly if they do not have an opportunity to see how their diagnoses turned out over time. Therefore, regular feedback to clinicians on their diagnostic performance is essential.

Unfortunately, reliable decision support or feedback systems do not yet exist. One of the earliest uses of information technology in medicine was decision support for clinical diagnosis, particularly for notoriously high-risk and difficult diagnoses such as acute myocardial infarction. However, computerized diagnostic decision support has not yet been proven to improve overall diagnostic accuracy, although active research continues in this area.

The autopsy has been the "gold standard" for diagnosis since medicine became a profession, but autopsy rates have progressively declined over the past few decades, to the point where a recent editorial raised concern over the "vanishing nonforensic autopsy." It is recommended that teaching institutions perform autopsies on 25% of inpatient deaths, but few academic hospitals reach this benchmark. The result: not only are clinicians not receiving feedback on their diagnoses, but pathologists are performing fewer and fewer autopsies during their training.

More progress has been made in addressing systems causes of diagnostic error. Information technology has improved clinicians' ability to follow up on diagnostic tests in a timely fashion, which should reduce the incidence of delayed diagnoses. Structured protocols for telephone triage, teamwork and communication training, and increased supervision of trainees may also lead to improved diagnostic performance. However, studies evaluating the effect of these interventions on diagnostic error rates are lacking.

Finally, there are aggressive efforts to teach clinicians and trainees about the relevant parts of cognitive psychology. The principal goal is to engage clinicians in "meta-cognition" (reflecting on their own thinking), with the hope that they will catch some of their own misuse of heuristics before they cause harm. A 2016 systematic review found evidence that these strategies can improve clinicians' diagnostic reasoning in simulated settings. Recent systematic reviews have assessed the evidence base of interventions to prevent cognitive errors and systems problems that can lead to diagnostic error.

Current Context

The National Academy of Medicine (formerly the Institute of Medicine) released a report in 2015 describing diagnostic error as a blind spot in the safety field. The committee made several recommendations to improve diagnosis, including promoting teamwork among interdisciplinary health care teams, enhancing patient engagement in the diagnostic process, implementing large-scale error reporting systems with feedback and corrective action, and improving health information technology. The report also recommended health care system reforms, including establishing a work system and safety culture that foster timely and accurate diagnosis, improving the medical liability system to foster learning from missed or delayed diagnoses, reforming the payment system to support better diagnosis, and

increasing funding for research in diagnostic safety. Another challenge for addressing diagnostic error is the lack of measures of diagnostic accuracy. In fact, current quality measurements do not take diagnostic accuracy into account at all, meaning that organizations could score well on quality measures even if patients receive the correct treatment for an incorrect diagnosis.

Editor's Picks

CASE

Diagnostic Delay in the Emergency Department

CASE

Diagnosing a Missed Diagnosis

CASE

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CASE

A "Weak" Response

CASE

Crushing Chest Pain: A Missed Opportunity

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Disclosure of Errors

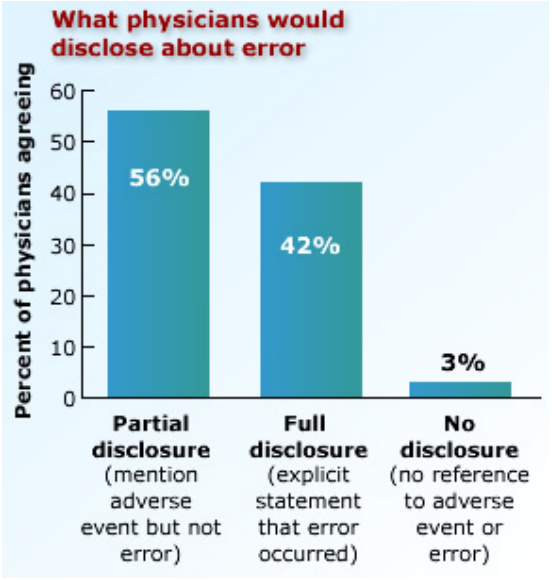
Background

Many patients harmed by a medical error never learn of the error. Physicians have traditionally shied away from discussing errors with patients, in part due to fear of precipitating a malpractice lawsuit, but also due to embarrassment and discomfort with the disclosure process. However, attitudes have changed in recent years–most physicians in a 2006 survey had disclosed a serious error to a patient and agreed that such disclosure was warranted.

Surveys have helped to define the components of disclosure that matter most to patients. These include:

- Disclosure of all harmful errors
- An explanation as to why the error occurred
- How the error's effects will be minimized
- Steps the physician (and organization) will take to prevent recurrences

"Full disclosure" of an error incorporates these components as well as acknowledgement of responsibility and an apology by the physician. However, there may be a disconnect between physicians' views of ideal practice and what actually happens. For example, most physicians agree that errors should be fully disclosed to patients, but in practice many "choose their words carefully" by failing to clearly explain the error and its effects on the patient's health.



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Accomplishing Full Disclosure

Increasing the amount and quality of error disclosure will require addressing physician discomfort with disclosure and fear of lawsuits. This may also require changes in how organizations approach error disclosure. Clinicians' fear regarding legal repercussions of error disclosure is not entirely unfounded, as a clinician's disclosure of an error may be admissible in a malpractice lawsuit. According to a 2008 survey, only eight states in the US explicitly prohibited "admissions of fault" from being used as evidence at trial (although the majority of states exclude "expressions of sympathy" from being admissible evidence). However, data does indicate that patients are less likely to consider filing suit if physicians apologize and fully disclose errors. Low disclosure rates also persist because few physicians have received formal training in how to discuss errors with patients, and given that the circumstances surrounding an error are invariably complex, physicians may be unclear about the amount of information that should be disclosed and how to explain the error to the patient. There is some evidence that formal training in error disclosure can improve physicians' comfort with the process.

When a patient is a victim of an error, hospitals have traditionally followed a "deny-and-defend" strategy, providing limited information to the patient and family and avoiding admissions of fault. This response has been criticized for its lack of patient-centeredness, and in response, some institutions have begun to implement "communication-and-response"

strategies that emphasize early disclosure of adverse events and a more proactive approach to achieving an amicable resolution. The University of Michigan model—which includes full disclosure of adverse events, appropriate investigations, implementation of systems to avoid recurrences, and rapid apology and financial compensation when care is deemed unreasonable—has resulted in fewer malpractice lawsuits and lower litigation costs since implementation. A growing body of literature describes the regulatory, legal, and practical considerations with implementing these programs. Although communication and resolution programs are being more widely adopted, implementing such a process is quite complex, and several studies indicate that the error disclosure process must be handled thoughtfully and sensitively to avoid alienating patients and families. The Agency for Healthcare Research and Quality has developed the Communication and Optimal Resolution (CANDOR) toolkit to help organizations implement communication-and-response programs.

Current Context

Disclosure of errors and adverse events is now endorsed by a broad array of organizations. Since 2001, the Joint Commission has required disclosure of unanticipated outcomes of care. In 2006, the National Quality Forum endorsed full disclosure of "serious unanticipated outcomes" as one of its 30 "safe practices" for health care. The disclosure safe practice includes standards for practitioners regarding the key components of disclosure. It also calls for health care organizations to create an environment conducive to disclosure by integrating risk management and patient safety activities and providing training and support for physicians.

Ten states mandate disclosure of unanticipated outcomes to patients, and more than two-thirds of states have adopted laws that preclude some or all information contained in a practitioner's apology from being used in a malpractice lawsuit.

Editor's Picks

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CASE

Medication Reconciliation Pitfalls

PERSPECTIVE

Disclosure of Medical Error

PERSPECTIVE

In Conversation with…Thomas H. Gallagher, MD

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PERSPECTIVE

Removing Insult from Injury—Disclosing Adverse Events

WEB RESOURCE › MULTI-USE WEBSITE

Being open: communicating patient safety incidents with patients and their carers.

National Patient Safety Agency.

CASE

The Wrong Shot: Error Disclosure

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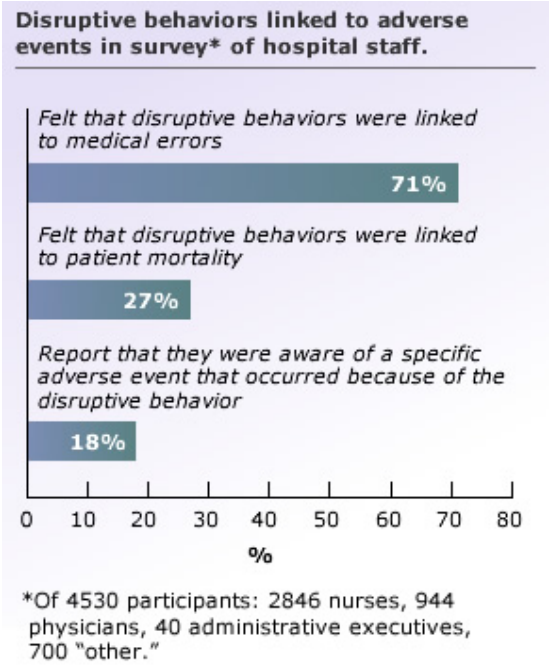
PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Disruptive and Unprofessional Behavior

Background

Although the television physician of old was sometimes depicted as grandfatherly (Marcus Welby), today's iconic TV physician is Dr. Gregory House: brilliant, irascible, and virtually impossible to work with. This stereotype, though undoubtedly dramatic and even amusing, obscures the fact that disruptive and unprofessional behavior by clinicians poses a definite threat to patient safety. Such behavior is common: in a 2008 survey of nurses and physicians at more than 100 hospitals, 77% of respondents reported witnessing physicians engage in disruptive behavior (most commonly verbal abuse of another staff member), and 65% reported witnessing disruptive behavior by nurses. Most respondents also believed that unprofessional actions increased the potential for medical errors and preventable deaths. Disruptive and disrespectful behavior by physicians has also been tied to nursing dissatisfaction and likelihood of leaving the nursing profession, and has been linked to adverse events in the operating room. Physicians in high-stress specialties such as surgery, obstetrics, and cardiology are considered to be most prone to disruptive behavior. These concerns should not obscure the fact that no more than 2%–4% of health care professionals at any level regularly engage in disruptive behavior.



Source: Rosenstein AH, O'Daniel M. A survey of the impact of disruptive behaviors and communication defects on patient safety. Jt Comm J Qual Patient Saf. 2008:34;464-471. [go to PubMed]

Although there is no standard definition of disruptive behavior, most authorities include any behavior that shows disrespect for others, or any interpersonal interaction that impedes the delivery of patient care. Fundamentally, disruptive behavior by individuals subverts the organization's ability to develop a culture of safety. Two of the central tenets of a safe culture–teamwork across disciplines and a blame-free environment for discussing safety issues–are directly threatened by disruptive behavior. An environment in which frontline caregivers are frequently demeaned or harassed reinforces a steep authority gradient and contributes to poor communication, in turn reducing the likelihood of errors being reported or addressed. Indeed, a workplace culture that tolerates demeaning or insulting behavior is likely to be one in which workers are "named, blamed and shamed" for making an error. The seriousness of this issue was underscored by a 2008 Joint Commission sentinel event alert, which called attention to this problem.

Preventing and Addressing Disruptive Behavior

As the sentinel event alert noted, "There is a history of tolerance and indifference to intimidating and disruptive behaviors in health care." This attitude is so widespread that, in some settings, disruptive behavior is considered the norm. While most patient safety problems are attributable to underlying systems issues, disruptive behaviors are primarily due to individual actions. The concept of just culture provides an appropriate foundation for

dealing with disruptive behavior, as it calls for disciplinary action for individuals who willfully engage in unsafe behaviors. The Joint Commission requires that organizations have an explicit code of conduct policy for all staff and recommends including a "zero tolerance" approach to intimidating and disruptive behaviors.

Recent studies have identified promising ways to identify clinicians at risk for disruptive behavior, remediate such clinicians, and mitigate these behaviors to avoid institutional disruption. Several studies have demonstrated that unprofessional behavior during medical school is linked to subsequent disciplinary action by licensing boards, suggesting that an early emphasis on teaching professionalism and addressing disruptive behavior during training may prevent subsequent incidents. Among practicing physicians, studies indicate that a small proportion of physicians account for a disproportionate share of both patient complaints and malpractice lawsuits. Earlier identification of such clinicians might allow for targeted interventions to address disruptive behavior and reduce patient risk. An editorial by Dr. Lucian Leape, one of the founders of the patient safety movement, proposed a systems-level approach to identifying, monitoring, and remediating poorly performing physicians, including those who regularly engage in unprofessional behavior. This approach would require a strong organizational emphasis; Vanderbilt University has achieved notable success in this area through identification of problem behaviors using a formal early detection and structured intervention approach (described in a 2009 PSNet interview). A systems-level approach would also require collaboration between hospital accreditation organizations, federal and state medical licensing boards, and individual hospitals to establish formal standards for professional conduct, monitor adherence to those standards through confidential evaluations, and provide punishment and/or remediation in response to violations.

Other interventions to prevent disruptive behavior include measures to improve safety culture. Role modeling desired behaviors, maintaining a confidential incident reporting system, and training managers in conflict resolution and collaborative practice are likely to be beneficial. Although not formally studied, other interventions designed to improve a safety culture, such as teamwork training and structured communication protocols, may have the potential to reduce disruptive behaviors, or at least promote early identification of them.

Current Context

The Joint Commission's Leadership Standard went into effect in 2009, including mandates for organizations to maintain a code of conduct that defines disruptive behaviors and a process for managing such behaviors. A subsequent sentinel event alert issued in March 2017 reinforced the importance of leadership in ensuring a culture of safety, with prevention of disruptive behavior among the key leadership attributes delineated. Adherence to the leadership standard is evaluated as part of Joint Commission accreditation surveys.

Editor's Picks

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JOURNAL ARTICLE › STUDY

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PERSPECTIVE

In Conversation with…Gerald B. Hickson, MD

PERSPECTIVE

How to Identify and Manage Problem Behaviors

CASE

Danger in Disruption

CASE

Difficult Encounters: A CMO and CNO Respond

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Behaviors that undermine a culture of safety.

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Is the "Surgical Personality" a Threat to Patient Safety?

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PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Duty Hours and Patient Safety

Background

Long and unpredictable work hours have been a staple of medical training for centuries. In fact, the term "resident" is a relic of times when physicians in postgraduate training literally lived at the hospital. Though this system faded away several decades ago, as recently as 15 years ago, resident physicians routinely worked 90–100 hours per week, for up to 36 consecutive hours without rest, for the entire duration of residency training. These grueling hours were viewed by many as a necessary "rite of passage" and were considered essential to ensure that physicians developed their clinical acumen and would be capable of independent practice once training was completed.

Little attention was paid to the potential patient safety effects of fatigue among residents until March 1984, when 18-year-old Libby Zion died at New York Hospital due to a medication-prescribing error while under the care of residents in the midst of a 36-hour shift. The subsequent investigation into her death led to the formation of the Bell Commission, which passed regulations in 1987 mandating that residents at New York hospitals should work no more than 80 hours per week and no more than 24 consecutive hours.

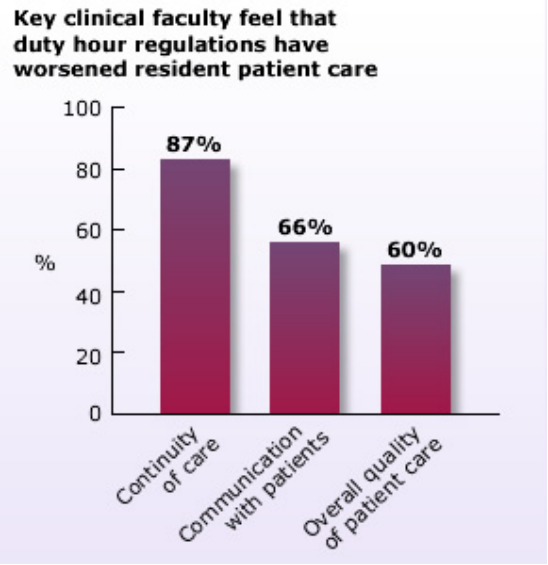
Though work hours and shift duration decreased somewhat for residents over the next decade, it was not until the goals of the patient safety movement aligned with research documenting a connection between fatigue and clinical performance that stronger regulations came into place. In 2003, the Accreditation Council for Graduate Medical Education (ACGME) implemented rules limiting work hours for all residents, with the key components being that residents should work no more than 80 hours per week or 24 consecutive hours on duty, should not be "on-call" more than every third night, and should have 1 day off per week. (Some fields, principally surgical specialties, received partial

exemption from the regulations.) The ACGME's current duty hour regulations went into effect in July 2011. These regulations maintained a maximum limit of 80 work hours per week, but eliminated extended duration shifts (which have been linked to errors in prior studies) for first-year residents, and strengthened oversight by senior physicians. (By comparison, residents in many other countries work significantly fewer hours; the European Working Time Directive currently limits residents in Europe to no more than 48 hours per week on duty.)

Effect of Resident Duty Hour Regulations

Duty hour regulations have engendered significant controversy since their implementation, and thus far, their overall effect appears to be mixed. A systematic review found that while resident well-being improved after implementation of the 2003 work hour regulations, there was no clear effect on patient safety or clinical outcomes. Reviews including data since the 2011 regulations were implemented have reached similar conclusions. The reasons for the regulation's lack of effect on safety outcomes are unclear and may be due to several factors. Residents are more closely supervised than in the past, which may mitigate the effect of trainee discontinuity. Any potential benefit of duty hour reductions may be attenuated because of the increased number of patient handoffs, which may result in more safety hazards. Finally, burnout and fatigue—known risk factors for poor job performance—remain common among residents despite reduced duty hours.

The impact of the duty hour regulations on educational variables has also been surprisingly mixed. Residents' educational experience appears to have been adversely affected by the regulations. Surveys of key clinical faculty and residents themselves have found that, although residents' quality of life has improved since 2004, their overall educational experience may have worsened, because they have less time available for teaching and to attend educational activities. A 2014 systematic review found that surgical residents had lower case volumes and scored more poorly on certification exams after implementation of duty hour restrictions.



Source: Reed DA, Levine RB, Miller RG, et al. Effect of Residency Duty-Hour Limits. Arch Intern Med. 2007;167:1487-1492. [go to PubMed]

Despite concerns about duty hour regulation's effect on education, a 2014 study found that patient outcomes for doctors who trained under reduced duty hours were similar to those who trained prior to implementation of the regulations.

Practicing Clinicians

Duty hour regulations for residents have also spurred interest in the issue of fatigue among practicing clinicians. One study found that many attending physicians, particularly surgeons, routinely work hours that would be prohibited in residency programs. Despite this fact, available data seems to indicate that physician sleep deficits do not affect the safety of surgical care. One case-control study found no increase in complications in elective procedures performed by surgeons who had operated the night before (compared to those with no overnight responsibilities), and another population-based study found no differences in mortality, complications, or readmissions between procedures performed by surgeons with sleep loss compared to those without sleep loss.

Current Context

The ACGME modified its duty hour regulations in 2017. The new regulations were based in part on randomized trials of different duty hour structures conducted in general surgery and internal medicine residency programs. The Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial, published in 2015, randomized 118 general surgery residency programs to adhere to the 2011 ACGME regulations or to abide by more flexible rules that essentially

followed the prior standard of a maximum 80-hour workweek. The study found no significant differences in patient outcomes, including death and serious complications. The iCompare trial, a similar study involving internal medicine residency programs, completed data collection in 2016. On the basis of these results, the ACGME eliminated the 16-hour shift limit for first-year residents, but kept the remainder of the 2011 regulations: an overall 80 hour per week work limit, maximum shift duration of 24 hours (plus 4 hours for transitioning care), one day off per week (averaged over a 4-week period), and on-call no more than once every 3 nights.

Editor's Picks

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Exposing physicians to reduced residency work hours did not adversely affect patient outcomes after residency.

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Ahmed N, Devitt KS, Keshet I, et al. Ann Surg. 2014;259:1041-1053.

AUDIOVISUAL

Residency Training—A Decade of Duty-Hour Regulations.

Weinstein DF, Arora V, Drolet B, Reynolds EE. N Engl J Med. 2013;369:e32.

JOURNAL ARTICLE › STUDY

Effects of the 2011 duty hour reforms on interns and their patients: a prospective longitudinal cohort study.

Sen S, Kranzler HR, Didwania AK, et al. JAMA Intern Med. 2013;173:657-662.

JOURNAL ARTICLE › REVIEW

Systematic review: association of shift length, protected sleep time, and night float with patient care, residents' health, and education.

Reed DA, Fletcher KE, Arora VM. Ann Intern Med. 2010;153:829-842.

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PERSPECTIVE

In Conversation with…Thomas J. Nasca, MD

PERSPECTIVE

The Role of Graduate Medical Education (GME) in Improving Patient Safety

JOURNAL ARTICLE › STUDY

Risks of complications by attending physicians after performing nighttime procedures.

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BOOK/REPORT

Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.

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JOURNAL ARTICLE › STUDY

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Landrigan CP, Fahrenkopf AM, Lewin D, et al. Pediatrics. 2008;122:250-258.

WEB RESOURCE › MULTI-USE WEBSITE

Common Program Requirements. The Learning and Working Environment (Duty Hours).

Accreditation Council for Graduate Medical Education.

PERSPECTIVE

In Conversation with…Christopher P. Landrigan, MD

JOURNAL ARTICLE › STUDY

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Landrigan CP, Rothschild JM, Cronin JW, et al. N Engl J Med. 2004;351:1838-1848.

JOURNAL ARTICLE › STUDY

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Gaba DM, Howard SK. N Engl J Med. 2002;347:1249-1255.

BOOK/REPORT

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PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: November 2017

Electronic Health Records

Background

Electronic health records (EHRs) have been widely adopted over the past decade in both inpatient and outpatient settings. EHR systems are made up of the electronic patient "chart" and typically include functionality for computerized provider order entry (CPOE), laboratory and imaging reporting, and medical device interfaces. Ideally, the system creates a seamless, legible, comprehensive, and enduring record of a patient's medical history and treatment. However, the transition to this new way of recording and communicating medical information has also introduced new opportunities for error and other unanticipated consequences that can present safety risks.

In a review of EHR safety and usability, investigators found that the switch from paper records to EHRs led to decreases in medication errors, improved guideline adherence, and (after initial implementation) enhanced safety attitudes and job satisfaction among physicians. However, the investigators found a number of problems as well. These included usability issues, such as poor information display, complicated screen sequences and navigation, and mismatch between user workflow in the EHR and clinical workflow. The latter problems resulted in interruptions and distraction, which can contribute to medical error. Additional safety hazards included data entry errors created by the use of copy-forward, copy-and-paste, and electronic signatures, lack of clarity in sources and date of information presented, alert fatigue, and other usability problems that can contribute to error. Similar findings were reported in a review of nurses' experiences with EHR use, which highlighted the altered workflow and communication patterns created by the implementation of EHRs.

One theme of the literature on EHR implementation is the emergence of unanticipated consequences. For example, a detailed study of types and rates of medication safety events

before and after EHR implementation in two ICUs found that, while overall medication safety improved, new vulnerabilities emerged, including increases in wrong patient, wrong medication, or wrongly timed orders. One source of technology-induced error was overspecification of functions within the CPOE module. In the ICU study, the CPOE system required physicians to select the medication schedule, a function that nurses or pharmacists may be better prepared to do (and had historically done) in inpatient settings. Similarly, in a case study of electronic prescribing for patients with diabetes in a safety net clinic, investigators found overspecification to be a source of medication errors in both insulin ordering and insulin use. Specifically, when prescribers were forced by the CPOE system to select brand name insulin from a list of similar-looking brand names, they could inadvertently choose an incorrect type of insulin. The system configuration also presented barriers to pharmacist consultation on insulin selection, reducing opportunities for preventing or correcting prescription errors. Finally, prescribers were unable to use recommended universal medication scheduling practices for instructing patients when to take their diabetes medications, creating further potential for error by patients in self-administering their medications. Universal medication scheduling improves comprehension of prescriptions among patients with low health literacy and low English proficiency, and can thereby reduce mistakes in adherence to prescribed therapy.

A review of studies of EHR issues that present patient safety risks found numerous problems with software functionality and usability (Table). A review of studies conducted in 2014–2015 found safety gains associated with EHRs and other health information technology (IT), but also determined that these systems have yet to live up to their full potential. Furthermore, confusing interfaces and security measures have disrupted workflow and communication and created incentives for clinicians to develop unsafe workarounds. Guidelines and frameworks for safe health IT implementation and use have been developed. However, several experts have observed that the present state of EHRs represents a "big miss," in that they have failed to appreciate and account for the complexity of patients and health care processes; the depth of cognitive work, communication, and collaboration required to optimally support the work of health care; and the cognitive load created by the poor usability of current systems. These experts envision a future in which user-centered design and fundamental rethinking of how EHRs can and should work will allow these systems to reach

their full potential, ultimately transforming health care to achieve higher value and a more satisfying experience for patients and clinicians.

Current Context

Health IT and EHRs are here to stay. While new approaches to EHR and health IT design are likely to emerge, health care organizations need to ensure both the safety of their current technology and the safe use of that technology today. Several resources are available to assist health care organizations in this effort. The Office of the National Coordinator for Health Information Technology has produced the SAFER guides. These nine guides provide assessment checklists and structure for teams to assess and improve their systems in the following domains: high-priority practices, organizational responsibilities, contingency planning, system configuration, system interfaces, patient identification, CPOE with decision support, test results reporting and follow-up, and clinician communication. SAFER guides are designed for use in all types of health care settings. The Joint Commission issued a sentinel event alert in 2015 on the safe use of health information technology, and the Agency for Healthcare Research and Quality produced a 2011 guideline for reducing unintended consequences of EHR implementation.

Table

Table. Problems With Software Functionality and Usability.

Software Quality Domain	Safety Risk	Potential Consequences
Functional Suitability *The degree to which software features are complete, accurate, and appropriate*	Lack of functionality to support clinical workflow	Development of potentially unsafe workarounds
	Lack of data coding, standardization, and structure	Lack of appropriate alerts
	Lack of duplicate record detection capability	Fragmentation of information; gaps in documentation
	Inaccurate, incomplete, or outdated	High load of false positive alerts; alert fatigue; automation bias resulting in decisions based on incorrect information

	decision support rules	
	Software bugs	Corruption, loss, or incorrect storage of patient data; incorrect dosage calculations; incorrect linking of orders to medications; potential to introduce new bugs through EHR maintenance and updating processes
	Problematic content import features	Copy-and-paste and other content import features can propagate incorrect, outdated, or improperly attributed information
	Default values	May not be noticed by users and therefore result in incorrect action—e.g., incorrect dosing of medication
	Problematic alerts	Excessive, irrelevant, or low-priority alerts interrupt clinical workflow and can result in distraction; alert fatigue can cause users to miss important alerts
	Simultaneous task performance	Opening multiple records simultaneously can result in documentation errors; editing the same record simultaneously by different users may result in inconsistent information
Usability *Ease of understanding, learning, and using the interface, including user attraction and accessibility*	Inadequate information displays	Incomplete information display (e.g., medication or allergy information), high information load, and buttons that look alike but have different features can result in patient misidentification or incorrect interpretation of patient data
	Unclear current state of user actions in order processing	Clinicians may not be aware of incomplete order submission process; documentation may be incomplete
	Difficult interfaces	Difficult navigation and usability of interface may result in errors in clinical decision making and contribute to errors or delays in treatment
	Error-prone interfaces	Lack of error protection in interfaces—e.g., poor grouping and selection of drop-down menu items—can promote errors, especially in medication ordering
Efficiency *Processing time, processing capacity, and resource consumption*	Delays in system response	Lack of system responsiveness can result in user inadvertently entering multiple duplicate actions, such as duplicate prescriptions, through repeated clicks
Compatibility *Degree to which 2 or more systems can exchange information*	Intersystem communication errors	Poor interoperability with other systems and failures in network infrastructure can result in delays when patient context or status is not timely or correctly communicated
Reliability *Maturity, availability, fault tolerance, recoverability*	System unavailability	Planned and unplanned EHR downtime can result in lack of access to information

Source: Virginio LA Jr, Ricarte IL. Identification of patient safety risks associated with electronic health records: a software quality perspective. Stud Health Technol Inform.

2015;216:55-59. [go to PubMed]

Editor's Picks

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Patterson ES, Sillars DM, Staggers N, et al. Jt Comm J Qual Patient Saf. 2017;8:375–385.

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Incidence of clinically relevant medication errors in the era of electronically prepopulated medication reconciliation forms: a retrospective chart review.

Stockton KR, Wickham ME, Lai S, et al. CMAJ Open. 2017;5:E345-E353.

JOURNAL ARTICLE › STUDY

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Furukawa MF, Spector WD, Limcangco MR, Encinosa WE. J Am Med Inform Assoc. 2017;24:729–736.

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A National Web Conference on Improving Health IT Safety Through the Use of Natural Language Processing to Improve Accuracy of EHR Documentation.

Agency for Healthcare Research and Quality. February 7, 2017.

CASE

The Hazards of Distraction: Ticking All the EHR Boxes

JOURNAL ARTICLE › REVIEW

Safe practices for copy and paste in the EHR. Systematic review, recommendations, and novel model for health IT collaboration.

Tsou AY, Lehmann CU, Michel J, Solomon R, Possanza L, Gandhi T. Appl Clin Inform. 2017;8:12-34.

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Chaparro JD, Classen DC, Danforth M, Stockwell DC, Longhurst CA. J Am Med Inform Assoc. 2017;24:268-274.

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How to Improve Electronic Health Record Usability and Patient Safety.

Philadelphia, PA: Pew Charitable Trusts; September 6, 2016.

TOOLS/TOOLKIT › FACT SHEET/FAQS

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BOOK/REPORT

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Sittig DF, Singh H, eds. Waretown, NJ: Apple Academic Press; 2015. ISBN: 9781771881173.

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Wachter R. New York, NY: McGraw-Hill; 2015. ISBN: 9780071849463.

WEB RESOURCE › MULTI-USE WEBSITE

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Washington, DC: Office of the National Coordinator for Health Information Technology.

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Patient Safety Primer Last Updated: November 2017

Failure to Rescue

Background

The concept of failure to rescue captures the idea that, although not every complication of medical care is preventable, health care systems should be able to rapidly identify and treat complications when they occur. As with many key concepts in patient safety, this one began with work outside of health care, including Reason's organizational accident theory, Perrow's normal accident theory, and other foundational work in human factors and complex systems. Around the same time, Karl Weick and others articulated the notion of high reliability organizations (HROs) and identified resilience as a defining characteristic of HROs.

In the late 1980s, early leaders in patient safety in anesthesiology, including Gaba and Runciman, adopted these concepts to their field. For example, Gaba described most anesthetic accidents as evolving from small errors and system failures that interact to produce more serious consequences, and he noted that there are often multiple opportunities to interrupt the "evolutionary cascade" that results in an adverse event. Throughout the 1990s, anesthesiologists led efforts to promote the capacity to detect and respond to evolving and unpredictable situations through improved crisis management strategies and sophisticated simulation training, and this work continues today.

From an HRO perspective, the capacity for organizational resilience is based on understanding that the unexpected is inevitable, and therefore no amount of planning and anticipation will prevent all complications. Indeed, Weick argues that overreliance on planning and anticipation can actually interfere with adaptive responses to unexpected events, and that resilient teams manage the inherent uncertainty in dynamic situations by maintaining awareness of the potential for things to go wrong. Resilient teams consistently update their understanding of a situation using interpersonal trust and respectful interaction to inquire

about the characteristics of the situation and consider new data to inform their situation awareness, processes known as sensemaking. Thus, resilient teams manage what they consider to be inherently uncertain conditions by continually scanning for potential problems and working quickly to mitigate those problems as they arise, often beginning this mitigation work before they fully understand the complete nature of the problem.

When applied to health care, the concept of resilience refers to the ability of the team to identify changes in a patient's condition quickly and to act on those changes in a manner that benefits the patient's health. When viewed conceptually through the lens of resilience, failure to rescue would occur in any situation where the clinical team was unable to mitigate preventable harm to patients. As a safety and quality measure, failure to rescue has been defined as the inability to prevent death after the development of a complication. For example, a woman with no known comorbid conditions who undergoes an abdominal hysterectomy and develops difficulty breathing and tachycardia on the second postoperative day. The failure to identify these symptoms and signs as being consistent with pulmonary embolism, leading to a failure to perform appropriate testing and institute treatment for an ultimately fatal complication, would be consistent with the concept of failure to rescue.

Developing Failure-to-rescue Measures

Approaches to measuring failure to rescue as a quality indicator in health care were first developed in 1992 by Silber and colleagues. These investigators hypothesized that death following complications in common surgeries would be more strongly associated with hospital characteristics than the surgical complication rate, and they confirmed this in their study. They also showed that comparing mortality in patients with complications after surgery had some advantages over comparing overall mortality rates. The idea behind this type of measurement is that high quality hospitals would be more likely to be able to prevent patient death in the face of complications, even when they serve populations of patients with significant surgical risk factors. This is because variation in complication rates can be driven by patient characteristics that are present on admission, whereas the ability to rescue patients (prevent death from complications) was thought to reflect the resources and preparedness of the hospital system, in essence, its resiliency. Multiple studies in the intervening decades have shown that hospitals can have low complication rates but high failure-to-rescue rates, and vice versa. One explanation for this phenomenon may be that

hospitals with higher complication rates have more experience recognizing and responding to complications when they develop, whereas hospitals with low complication rates have fewer opportunities to hone their rescue skills.

Needleman and Buerhaus subsequently developed a measure of failure to rescue that could be derived from readily available administrative data, included both medical and surgical populations, used outcomes thought to be sensitive to nursing care, and integrated exclusion rules aimed to eliminate cases in which the complication was present on admission or preoperatively. This measure, sometimes referred to as "failure to rescue—nursing," was later shown to be associated with nurse staffing and was ultimately adopted and modified by the National Quality Forum as a nurse-sensitive quality measure. AHRQ adopted a similar approach to measuring failure to rescue in Patient Safety Indicators (PSIs) in 2003.

The development of these failure-to-rescue measures was considered an important advance in quality and safety measurement. However, controversies about measure details continued for some time. Stakeholders had concerns about which kinds of deaths should be counted in the measure, questioning whether the approach could apply to all hospitalized patients or only specific types of surgical patients. The reliability of various approaches to identifying cases of failure to rescue was also questioned. Finally, there was strong interest in being able to better differentiate whether serious complications were hospital-acquired as opposed to being due to preexisting conditions. In 2007, the Centers for Medicare and Medicaid Services (CMS) addressed this concern by mandating that hospitals report whether or not all diagnoses were present on admission, and CMS began monitoring failure-to-rescue rates in 2010 (measure PSI 04). Since that time, the PSI 04 algorithm has been continuously updated to take advantage of changes in coding practices, including the present on admission indicator and the ICD-10 coding system.

Current Context

Software for calculating the Failure to Rescue PSI version 5 for ICD-9 and version 6 for ICD-10 is publically available (PSI 04: Death rate among surgical inpatients with serious treatable conditions). This PSI is also publically reported by CMS and an average national rate of 13.7% is presently reported on Hospital Compare. Many specialty surgical services, including pediatric and adult cardiac surgery, trauma care, gynecologic surgery, and gastrointestinal

surgery, have developed context-specific approaches to measuring failure to rescue. Higher hospital volume, communication failures, and lower nurse staffing have all been associated with higher failure-to-rescue rates. Detailed analyses of failure-to-rescue rates for specific types of surgery are yielding more granular information about the types of cases with the highest risk for death from complications, which may provide new opportunities for quality improvement. Such measures also may shed light on specific opportunities for changing clinical microsystem processes, such as lowering the number of patients per nurse; increasing nursing surveillance; and improving safety culture, communication, and teamwork to promote early identification of clinical deterioration and timely rescue.

Editor's Picks

CASE

Transfusion Thresholds in Gastrointestinal Bleeding

CASE

Despite Clues, Failed to Rescue

JOURNAL ARTICLE › STUDY

Inattentional blindness and failures to rescue the deteriorating patient in critical care, emergency and perioperative settings: four case scenarios.

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JOURNAL ARTICLE › REVIEW

How to avoid catastrophic events on the ward.

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BOOK/REPORT

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JOURNAL ARTICLE › REVIEW

Importance of teamwork, communication and culture on failure-to-rescue in the elderly.

Ghaferi AA, Dimick JB. Br J Surg. 2016;103:e47-e51.

JOURNAL ARTICLE › STUDY

Surgeon-specific mortality data disguise wider failings in delivery of safe surgical services.

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JOURNAL ARTICLE › STUDY

Escalation of care and failure to rescue: a multicenter, multiprofessional qualitative study.

Johnston M, Arora S, King D, Stroman L, Darzi A. Surgery. 2014;155:989-994.

JOURNAL ARTICLE › STUDY

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PERSPECTIVE

In Conversation with...Patrick S. Romano, MD, MPH

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PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Falls

Background

Falls are a common and devastating complication of hospital care, particularly in elderly patients. Epidemiologic studies have found that falls occur at a rate of 3–5 per 1000 bed-days, and the Agency for Healthcare Research and Quality estimates that 700,000 to 1 million hospitalized patients fall each year. Patients in long-term care facilities are also at very high risk of falls. Approximately half of the 1.6 million nursing home residents in the United States fall each year, and a 2014 report by the Office of the Inspector General found that nearly 10% of Medicare skilled nursing facility residents experienced a fall resulting in significant injury.

More than one-third of in-hospital falls result in injury, including serious injuries such as fractures and head trauma. Death or serious injury resulting from a fall while being cared for in a health care facility is considered a never event, and the Centers for Medicare and Medicaid Services do not reimburse hospitals for additional costs associated with patient falls. Falls that do not result in injury can be serious as well. As noted in a PSNet perspective, "even supposedly 'no harm' falls can cause distress and anxiety to patients, their family members, and health care staff, and may mark the beginning of a negative cycle where fear of falling leads an older person to restrict his or her activity, with consequent further losses of strength and independence."

This Primer will focus on fall prevention in health care facilities, because these are generally placed under the umbrella of health care–associated harms. Falls in community-dwelling patients are also very common and highly morbid; the Centers for Disease Control and Prevention has published guides for patients and clinicians on preventing falls in outpatients. Of course, some of these may represent patient safety issues if, for example, a sedating medication was a root cause.

Preventing Falls

Fall prevention has been the subject of intensive research and quality improvement efforts, which have helped define key elements of successful fall prevention programs. Prevention efforts begin with assessing individual patients' risk for falls. There are several existing clinical prediction rules for identifying high-risk patients, but none has been shown to be significantly more accurate than others. Most falls occur in elderly patients, especially those who are experiencing delirium, are prescribed psychoactive medications such as benzodiazepines, or have baseline difficulties with strength, mobility, or balance. However, nonelderly patients who are acutely ill are also at risk for falls.

There are two overarching considerations in planning a fall prevention program. First, fall prevention measures must be individualized—there is no "one size fits all" method to preventing falls. A successful program must include a combination of environmental measures (such as nonslip floors or ensuring patients are within nurses' line of sight), clinical interventions (such as minimizing deliriogenic medications), care process interventions (such as using a standardized risk assessment tool), cultural interventions (emphasizing that fall prevention is a multidisciplinary responsibility), and technological/logistical interventions (such as bed alarms or lowering the bed height). The program should explicitly tackle the underlying assumption held by many health care providers that falls are inevitable and not necessarily preventable. Measures to improve the overall culture of safety in a particular unit may be helpful. A 2011 PSNet perspective discussed the specific components most often used in successful fall prevention interventions. They include:

- Multidisciplinary (rather than solely nursing) responsibility for intervention.
- Staff and patient education (if provided by health professionals and structured rather than ad hoc).
- An individualized plan of care that is responsive to individuals' differing risk factors, needs, and preferences.
- Provision of safe footwear (rather than solely advice on safe footwear).
- A focus on prevention, detection, and treatment of delirium.

- Review and (where appropriate) discontinuation of "culprit" medications associated with increased risk of falls, especially psychotropic medication.
- Continence management, including routines of offering frequent assistance to use the toilet.
- Early access to advice, mobility aids, and (where appropriate) exercise from physiotherapists.
- A postfall review used as an opportunity to plan secondary prevention, including a careful history to identify potential syncope.

The other consideration is acknowledging the tension between fall prevention and other goals of a patient's hospitalization. A large body of literature documents that elderly patients lose mobility and functional status rapidly during hospitalizations, and that this loss of functional status has long-term consequences. Promoting mobility and activity has therefore become a key component of programs to improve outcomes of hospital care in elderly patients. Overzealous efforts to limit falls may therefore have the adverse consequence of limiting mobility during hospitalization, limiting patients' ability to recover from acute illness and putting them at risk of further complications.

The evidence regarding the efficacy of specific fall prevention programs has been mixed. One widely cited, high-quality randomized trial documented a significant reduction in falls among elderly patients by using an individualized fall prevention intervention drawing on many of the elements listed above. It is likely that differences among patient populations, risk factors, and hospital environmental factors may limit the generalizability of published interventions across hospitals. AHRQ has published toolkits with implementation guides for fall prevention programs in hospitalized patients and patients in long-term care settings. These toolkits emphasize the role of local safety culture and the need for committed organizational leadership in developing a successful fall prevention program.

Current Context

Fall prevention is a National Patient Safety Goal for both hospitals and long-term care facilities. The Joint Commission highlighted the importance of preventing falls in a 2009 Sentinel Event Alert. As noted above, falls with injury are a serious reportable event for The

Joint Commission and are considered a "never event" by CMS. The most recent data from AHRQ's National Scorecard on rates of Healthcare Associated Complications (HACs) indicates that fall rates at US hospitals declined by approximately 15% between 2010 and 2015.

Editor's Picks

JOURNAL ARTICLE › COMMENTARY

The tension between promoting mobility and preventing falls in the hospital.

Growdon ME, Shorr RI, Inouye SK. JAMA Intern Med. 2017;177:759-760.

BOOK/REPORT

National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data From National Efforts to Make Health Care Safer.

Rockville, MD: Agency for Healthcare Research and Quality; December 2016.

BOOK/REPORT

Preventing Patient Falls: A Systematic Approach From the Joint Commission Center for Transforming Healthcare Project.

Chicago, IL: Health Research & Educational Trust; October 2016.

CASE

Falling Through the Crack (in the Bedrails)

JOURNAL ARTICLE › STUDY

6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial.

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LEGISLATION/REGULATION › SENTINEL EVENT ALERTS

Preventing falls and fall-related injuries in health care facilities.

Sentinel Event Alert. September 28, 2015;(55):1-5.

CASE

Medical Devices in the "Wild"

PERSPECTIVE

The Physical Environment: An Often Unconsidered Patient Safety Tool

PERSPECTIVE

Implementing a Fall Prevention Program

PERSPECTIVE

In Conversation With… Ann L. Hendrich, RN, PhD

JOURNAL ARTICLE › STUDY

Fall prevention in acute care hospitals: a randomized trial.

Dykes PC, Carroll DL, Hurley A, et al. JAMA. 2010;304:1912-1918.

JOURNAL ARTICLE › COMMENTARY

Medicare nonpayment, hospital falls, and unintended consequences.

Inouye SK, Brown CJ, Tinetti ME. N Engl J Med. 2009;360:2390-2393.

JOURNAL ARTICLE › STUDY

Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports.

Healey F, Scobie S, Oliver D, Pryce A, Thomson R, Glampson B. Qual Saf Health Care. 2008;17:424-430.

CASE

Another Fall

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Patient Safety Primer Last Updated: November 2017

Fatigue, Sleep Deprivation, and Patient Safety

Background

Sleep is one of many physiologic functions that operates in a circadian rhythm, triggered by light–dark changes in the 24-hour cycle. Fatigue is the feeling of tiredness and decreased energy that results from inadequate sleep time or poor quality of sleep. Fatigue can also result from increased work intensity or long work hours. Sleep deprivation has long been known to impair various cognitive functions, including mood, motivation, response time, and initiative. The need for sleep varies individually. The absolute amount of sleep required per 24 hours is generally understood to be a minimum of 5 hours. Most healthy adults need between 7.5–8.5 hours of sleep per night and will experience deficits in cognitive performance when acutely or chronically sleep deprived.

At least two components regulate human sleep: the drive to sleep and circadian wakefulness. The physiologic drive for sleep increases with time awake and decreases during time asleep. As awake time surpasses 12–16 consecutive hours, the drive for sleep becomes increasingly powerful. Wakefulness, like sleep, also has a circadian rhythm: it is highest in the late afternoon and lowest in the early morning hours. Indeed, the strength of the circadian cycle has led researchers to argue that human beings are "biologically hard-wired to be active during the day and sleepy at night. Working at night must therefore be regarded as an inherently unnatural act." (Monk TH. Shiftwork: basic principles. In Kryger MH, Roth T, Dement WC, eds. Principles and Practice of Sleep Medicine. 4th ed. Philadelphia, PA: Elsevier; 2005:673-679.)

Given the importance of sleep and its known effect on cognitive performance, the link between sleep and patient safety has garnered considerable attention. In 2006, AHRQ funded

the National Academy of Medicine to synthesize evidence on medical resident schedules and health care safety as well as to recommend strategies to enable optimization of work schedules and patient safety. In this report, fatigue is characterized as a latent hazard and "an unsafe condition" in health care that leads to increased medical error rates. In a classic review of sleep deprivation and decision-making, investigators argued that effective performance in health care environments requires naturalistic decision-making and situation awareness. This type of thinking involves assessing and planning for rapidly changing situations, forming mental models and future status projections, evaluating risks, appreciating the consequences of actions, and rapidly revising plans in light of changing information. These cognitive activities place significant loads on prefrontal cortex functions, such as memory and tracking capacity, which are particularly sensitive to sleep deprivation and related fatigue. Both acute and chronic sleep deprivation result in cumulative deficits in executive function and mood, as well as heightened irritability—and all of these can impair communication and coordination in health care teams. Chronic sleep deprivation can also contribute to burnout, which is increasingly recognized as a threat to patient safety.

In contrast to dynamic, naturalistic decision-making, certain types of cognitive performance are less sensitive to sleep deprivation. Complex tasks that are rule-based and interesting or require critical reasoning in logical well-practiced tasks show less sleep-related degradation of performance. Thus in the context of acute sleep deprivation, individuals may be better able to compensate for cognitive impairment when tasks are complex and interesting (e.g., performing surgery). On the other hand, they may be more susceptible when tasks are rote or rely primarily on vigilance (such as reviewing laboratory tests or ordering medications). This difference may explain why evidence on the effects of acute sleep deprivation (e.g., one night of call) on physician performance has been mixed, despite robust evidence of negative impacts of sleep deprivation and extended work hours in other industries and other aspects of health care.

The effects of sleep deprivation will become increasingly important as health care moves to more shift-based physician staffing. Up to 75% of shift workers experience some degree of fatigue and sleepiness while on duty. There is good evidence of increased nursing errors when shifts last longer than 12 hours, nurses work overtime, or nurses do not receive adequate rest breaks. Similarly, in a classic study of resident work hours, Landrigan and

colleagues found medical and diagnostic error were significantly more common in residents working traditional long shifts of more than 24 hours. Studies—including research supported by AHRQ—have shown that residents make fewer errors in the setting of closely monitored, comprehensive interventions to reduce work hours and improve sleep.

Current Context

Despite ongoing controversies regarding the impact of resident work hour restrictions and physician sleep deprivation on surgical outcomes, The Joint Commission has issued several reports alerting health care providers and the public to the potential for serious adverse effects of lack of sleep. In a 2011 Sentinel Event Alert, The Joint Commission called on health care organizations to take steps to mitigate the impact of extended work hours on clinician sleep deprivation and fatigue. These steps include conducting a risk assessment; ensuring robust handoff practices; involving staff in design of work schedules; implementing a fatigue management plan including strategic use of caffeine and planned naps; educating personnel about sleep hygiene; and ensuring an adequate environment for sleep breaks. However, more evidence is needed to determine optimal practices for scheduling, planned napping, and other fatigue mitigation strategies. One challenge in addressing sleep deprivation among clinicians is that adequate sleep time requires a combination of effective organizational policies regarding work hours, shift rotation, and sleep policies, as well as personal commitment to good sleep habits. Work hour restrictions alone will be ineffective if, when working nights, clinicians do not also limit daytime activities in order to obtain adequate sleep.

Editor's Picks

JOURNAL ARTICLE › STUDY

National cluster-randomized trial of duty-hour flexibility in surgical training.

Bilimoria KY, Chung JW, Hedges LV, et al. N Engl J Med. 2016;374:713-727.

JOURNAL ARTICLE › STUDY

Hospital at night: an organizational design that provides safer care at night.

Hamilton-Fairley D, Coakley J, Moss F. BMC Med Educ. 2014;14(suppl 1):S17.

JOURNAL ARTICLE › STUDY

Association of sleep and fatigue with decision regret among critical care nurses.

Scott LD, Arslanian-Engoren C, Engoren MC. Am J Crit Care. 2014;23:13-23.

JOURNAL ARTICLE › STUDY

Sleep deprivation and error in nurses who work the night shift.

Johnson AL, Jung L, Brown KC, Weaver MT, Richards KC. J Nurs Adm. 2014;44:17-22.

JOURNAL ARTICLE › COMMENTARY

Sleep deprivation: a call for institutional rules.

McKenna L, Kodner IJ, Healy GB, Keune JD. Surgery. 2013;154:118-122.

JOURNAL ARTICLE › REVIEW

Sleep science, schedules, and safety in hospitals: challenges and solutions for pediatric providers.

Rosenbluth G, Landrigan CP. Pediatr Clin North Am. 2012;59:1317-1328.

JOURNAL ARTICLE › STUDY

Surgeon fatigue: a prospective analysis of the incidence, risk, and intervals of predicted fatigue-related impairment in residents.

McCormick F, Kadzielski J, Landrigan CP, Evans B, Herndon JH, Rubash HE. Arch Surg. 2012;147:430-435.

JOURNAL ARTICLE › STUDY

Sleep, sleepiness, fatigue, and performance of 12-hour–shift nurses.

Geiger-Brown J, Rogers VE, Trinkoff AM, Kane RL, Bausell RB, Scharf SM. Chronobiol Int. 2012;29:211-219.

JOURNAL ARTICLE › REVIEW

Sleep and circadian misalignment for the hospitalist: a review.

Schaefer EW, Williams MV, Zee PC. J Hosp Med. 2012;7:489-496.

LEGISLATION/REGULATION › SENTINEL EVENT ALERTS

Health care worker fatigue and patient safety.

Sentinel Event Alert. December 14, 2011;(48):1-4.

JOURNAL ARTICLE › STUDY

Implementing a fatigue countermeasures program for nurses: a focus group analysis.

Scott LD, Hofmeister N, Rogness N, Rogers AE. J Nurs Adm. 2010;40:233-240.

JOURNAL ARTICLE › STUDY

Sleep quality and fatigue among prehospital providers.

Patterson PD, Suffoletto BP, Kupas DF, Weaver MD, Hostler D. Prehosp Emerg Care. 2010;14:187-193.

BOOK/REPORT

Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.

Ulmer C, Wolman DM, Johns MME, eds. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety, Institute of Medicine. Washington, DC: The National Academies Press; 2008. ISBN: 9780309127721.

JOURNAL ARTICLE › STUDY

When policy meets physiology: the challenge of reducing resident work hours.

Lockley SW, Landrigan CP, Barger LK, Czeisler CA. Clin Orthop Relat Res. 2006;449:116-127.

PERSPECTIVE

In Conversation with…Christopher P. Landrigan, MD

JOURNAL ARTICLE › STUDY

Effect of reducing interns' work hours on serious medical errors in intensive care units.

Landrigan CP, Rothschild JM, Cronin JW, et al. N Engl J Med. 2004;351:1838-1848.

JOURNAL ARTICLE › STUDY

Effect of reducing interns' weekly work hours on sleep and attentional failures.

Lockley SW, Cronin JW, Evans EE, et al. N Engl J Med. 2004;351:1829-1837.

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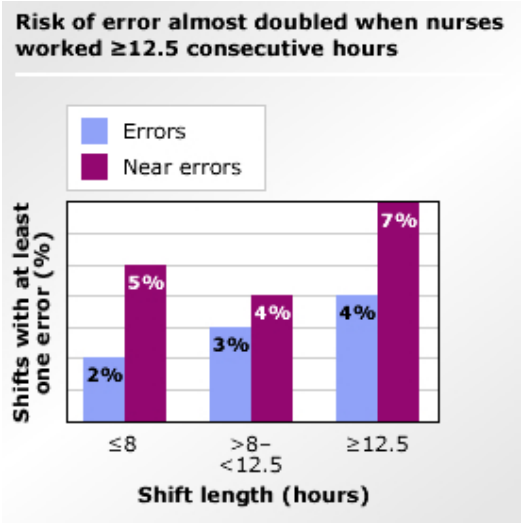
Patient Safety Primer Last Updated: June 2017

Handoffs and Signouts

Background

Discontinuity is an unfortunate but necessary reality of hospital care. No provider can stay in the hospital around the clock, so patients will inevitably be cared for by many different providers during hospitalization. Nurses change shift every 8 to 12 hours, and, particularly at teaching institutions, multiple physicians may be responsible for a patient's care at different times of the day. This discontinuity creates opportunities for error when clinical information is not accurately transferred between providers. As one author put it, "for anyone who has watched children playing 'Telephone'…the inherent potential for error in signouts is obvious." The problems posed by handoffs of care have gained more attention since the 2003 implementation of regulations limiting housestaff duty hours, which has led to greater discontinuity among resident physicians.



Source: Scott LD, Rogers AE, Hwang WT, Zhang Y. Effects of critical care nurses' work hours on vigilance and patients' safety. Am J Crit Care. 2006;15:30-37. [go to PubMed]

The process of transferring responsibility for care is referred to as the "handoff," with the term "signout" used to refer to the act of transmitting information about the patient. (This Primer

will discuss handoffs and signouts in the context of transfers of care *during* hospitalization. For information about safety issues at the time of hospital discharge, please see the related Patient Safety Primer Adverse Events after Hospital Discharge.)

Handoffs and signouts have been linked to adverse clinical events in settings ranging from the emergency department to the intensive care unit. One study found that being cared for by a covering resident was a risk factor for preventable adverse events; more recently, communication failures between providers have been found to be a leading cause of preventable error in studies of closed malpractice claims affecting emergency physicians and trainees. The seemingly straightforward act of communicating an accurate medication list is a well-recognized source of error. To avert this problem, hospitals are required to "reconcile" medications across the continuum of care. (For more information, see the related Primer "Medication Reconciliation.")

Implementing Effective Handoff and Signout Protocols

Guidelines for safe handoffs focus on standardizing the signout mechanism. Efforts to improve the quality of clinical handoffs must enhance the quality of both written and verbal signouts. In addition to accurate and complete written signouts, effective handoffs require an environment free of interruptions and distractions, allowing for the clinician receiving the signout to listen actively and engage in a discussion when necessary. The seminal I-PASS study demonstrated that in a teaching hospital setting, implementation of a standardized handoff bundle—which included a mnemonic for standardized oral and written signouts, training in handoff communication, faculty development, and efforts to ensure sustainability—markedly reduced the incidence of preventable adverse events associated with handoffs. The I-PASS mnemonic stands for:

- Illness severity: one-word summary of patient acuity ("stable," "watcher," or "unstable")
- Patient summary: brief summary of the patient's diagnoses and treatment plan
- Action list: to-do items to be completed by the clinician receiving signout
- Situation awareness and contingency plans: directions to follow in case of changes in the patient's status, often in an "if—then" format

- Synthesis by receiver: an opportunity for the receiver to ask questions and confirm the plan of care

The I-PASS signout format is now widely used in graduate medical education and is considered the gold standard for effective signout communication between physicians.

Current Context

The Joint Commission requires all health care providers to "implement a standardized approach to handoff communications including an opportunity to ask and respond to questions" (2006 National Patient Safety Goal 2E). The Joint Commission National Patient Safety Goal also contains specific guidelines for the handoff process, many drawn from other high-risk industries:

- interactive communications
- up-to-date and accurate information
- limited interruptions
- a process for verification
- an opportunity to review any relevant historical data

The Accreditation Council for Graduate Medical Education also requires that residency programs maintain formal educational programs in handoffs and care transitions.

Editor's Picks

WEB RESOURCE › MULTI-USE WEBSITE

National Patient Safety Goals.

Oakbrook Terrace, IL: The Joint Commission; 2018.

JOURNAL ARTICLE › STUDY

Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle.

Starmer AJ, Sectish TC, Simon DW, et al. JAMA. 2013;310:2262-2270.

JOURNAL ARTICLE › REVIEW

Review of computerized physician handoff tools for improving the quality of patient care.

Li P, Ali S, Tang C, Ghali WA, Stelfox HT. J Hosp Med. 2013;8:456-463.

TOOLS/TOOLKIT

Improving Transitions of Care: Hand-off Communications.

Oakbrook Terrace, IL: Joint Commission Center for Transforming Healthcare; June 2012.

PERSPECTIVE

What Have We Learned About Safe Inpatient Handovers?

CASE

Tacit Handover, Overt Mishap

CASE

All in the History

BOOK/REPORT

Improving Hand-Off Communication.

Oakbrook Terrace, IL: Joint Commission Resources; 2007. ISBN: 9781599400907.

JOURNAL ARTICLE › STUDY

Patient handover from surgery to intensive care: using Formula 1 pit-stop and aviation models to improve safety and quality.

Catchpole KR, de Leval MR, McEwan A, et al. Paediatr Anaesth. 2007;17:470-478.

TOOLS/TOOLKIT › TOOLKIT

Perioperative Patient 'Hand-Off' Tool Kit.

Association of Perioperative Registered Nurses.

JOURNAL ARTICLE › COMMENTARY

Graduate medical education and patient safety: a busy--and occasionally hazardous--intersection.

Shojania KG, Fletcher KE, Saint S. Ann Intern Med. 2006;145:592-598.

CASE

Triple Handoff

WEB RESOURCE › MULTI-USE WEBSITE

Common Program Requirements. The Learning and Working Environment (Duty Hours).

Accreditation Council for Graduate Medical Education.

JOURNAL ARTICLE › STUDY

A randomized, controlled trial evaluating the impact of a computerized rounding and sign-out system on continuity of care and resident work hours.

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JOURNAL ARTICLE › STUDY

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Patterson ES, Roth EM, Woods DD, Chow R, Gomes JO. Int J Qual Health Care. 2004;16:125-132.

CASE

Fumbled Handoff

BOOK/REPORT

Handoffs and fumbles.

Wachter RM, Shojania KG. In: Wachter RM, Shojania KG. Internal Bleeding. New York, NY: Rugged Land; 2004:159-180.

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Patient Safety Primer Last Updated: June 2017

Health Care–Associated Infections

Background

Health care–associated infections (HAIs) are among the most common complications of hospital care. According to a study by the Centers for Disease Control and Prevention (CDC), at any given time, approximately 1 of every 25 hospitalized patients in the United States has an HAI, meaning that nearly 650,000 patients contract one of these infections annually. More than one million HAIs occur across the United States health care system every year. These infections can lead to significant morbidity and mortality, with tens of thousands of lives lost each year. HAIs are estimated to cost billions of dollars annually. Such infections were long accepted by clinicians as an inevitable hazard of hospitalization. However, it is now understood that relatively straightforward approaches can prevent many common HAIs. As a result, hospitals and clinicians are prioritizing efforts to reduce the burden of these infections. Fortunately, considerable progress has been made in preventing specific HAIs through federally sponsored programs from the Agency for Healthcare Research and Quality (AHRQ), CDC, and the Centers for Medicare and Medicaid Services (CMS).

Surgical site infections (SSIs) and infections associated with indwelling devices—ventilator-associated pneumonia (VAP), central line–associated bloodstream infections (CLABSIs), and catheter-associated urinary tract infections (CAUTIs)—have historically account for a large proportion of HAIs, and recent data indicates that the epidemiology of HAIs is evolving. The CDC's 2011 data indicate that infections associated with specific indwelling devices (CLABSI, CAUTI, and VAP) and SSIs account for approximately half of all HAIs. Infections caused by the bacterium *Clostridium difficile* have rapidly become more common in hospitals, and *C. difficile* is now responsible for more than 12% of all HAIs. Preventing transmission of *C. difficile* and antibiotic-resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) is therefore an increasing focus of attention.

Prevention of HAIs

A cornerstone of HAI prevention is appropriate hand hygiene. Although the effectiveness of simple hand washing in preventing infection transmission has been known for decades, until recently hand hygiene rates among all clinicians were low. Strategies to improve hand hygiene that rely on traditional educational approaches as well as enhanced monitoring of hand hygiene, feedback on hand hygiene practice in a facility, and sociocultural approaches have resulted in improved hand hygiene at many hospitals and other health care facilities. What's more, strong evidence links higher hand hygiene rates to lower overall HAI rates.

The CDC has evidence-based guidelines that detail methods to prevent specific HAIs in the inpatient and outpatient setting. The challenge has been making it easy for clinicians and health care executives to establish and adopt the recommended methods as standard practice in health care delivery organizations. Organizations that successfully overcome this obstacle represent some of the major successes of the patient safety movement. For example, the development and implementation of the AHRQ-supported Comprehensive Unit-based Safety Program (CUSP) has brought about significant advances in HAI prevention. CUSP combines improvement in safety culture, teamwork, and communications, together with a checklist that incorporates a manageable set of evidence-based measures to prevent a particular HAI. The implementation of CUSP to prevent CLABSI has resulted in dramatic nationwide reductions in these serious infections, thanks in part to AHRQ-funded research and dissemination programs that fostered the use of CUSP in intensive care units across the country. Conceptually similar approaches have also been successful in reducing rates of SSIs, and AHRQ is currently funding a large nationwide effort to promote the use of CUSP to reduce rates of CAUTI. The combination of improvement in organizational culture and use of the checklist has powered the reductions in CLABSI that have been achieved. In-depth analysis of the project has identified other important components of the program, such as rigorous data measurement and feedback and reframing of CLABSI as a social problem in a clinical environment.

The increasing threat posed by infections such as *C. difficile* is also stimulating efforts to address this issue. Strategies to prevent *C. difficile* infections primarily involve limiting antibiotic use (a major cause of these infections), particularly through antibiotic stewardship programs, preventing patient-to-patient transmission of the bacteria through isolation

procedures and hand hygiene, and increased and improved cleaning of the environment of care including patient rooms. Toolkits to help hospitals establish antibiotic stewardship programs directed to *C. difficile* have been developed and disseminated. Prevention of transmission of antibiotic-resistant bacteria follows similar principles.

Current Context

The large burden of disease posed by HAIs has resulted in considerable regulatory attention. CMS has put limits on reimbursement for the costs of care associated with certain HAIs since 2008. Reducing the risk of HAIs is a Joint Commission National Patient Safety Goal (NPSG). The NPSG specifically requires adherence to hand hygiene practices and also considers death or serious disability due to an HAI to be a sentinel event (not primarily related to the natural course of the patient's illness or underlying condition). Appropriate hand hygiene, influenza vaccination for health care workers, and prevention of VAP, CLABSI, and SSI are among the National Quality Forum's 30 Safe Practices for Better Healthcare.

Publicly reported hospital-specific HAI rates are also being more widely utilized to monitor hospital quality of care. Currently, 27 States mandate reporting of CLABSI rates, and CMS publicly reports certain HAI rates on its Hospital Compare Web site. The effect of these policies, as well as the CMS nonpayment policy for HAIs, remains unclear. A recent study found that statewide mandatory reporting of CLABSIs did not appear to have any effect on infection rates. Another study found that the CMS "no pay for errors" policy had no measurable effect on rates of CLABSIs and CAUTIs in hospitals, and another found that few hospitals were actually denied payment due to CAUTI.

One important challenge in using public reporting and payment policies to catalyze efforts to decrease HAIs is that the definitions are complex and may be subject to interpretation by health care providers. The CDC's National Healthcare Safety Network (NHSN) has developed standard, auditable definitions for common HAIs in order to standardize reporting of infection rates and allow for more accurate comparison of infection rates between hospitals and tracking of infection rates over time.

As standardized measurement strategies and quality and safety interventions are adopted by more providers and systems, there is now evidence that shows more patients are being protected from HAIs. The most recent data from the Partnership for Patients Initiative

indicates that the overall rate of Hospital-Acquired Conditions (HACs) decreased by 17% between 2010 and 2013, representing more than 1 million adverse events prevented during that time period, including HAIs.

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PERSPECTIVE

In Conversation With… Alison Holmes, MD, MPH

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PERSPECTIVE

In Conversation with…Sanjay Saint, MD, MPH

PERSPECTIVE

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PERSPECTIVE

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CASE

Environmental Safety in the OR

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Patient Safety Primer Last Updated: June 2017

Health Literacy

Background

Health literacy is defined as an individual's ability to find, process, and comprehend the basic health information necessary to act on medical instructions and make decisions about one's health. Many studies have documented the degree to which most written health information and instructions exceed the literacy skills of the majority of Americans. Likewise, verbal communication from health care providers is frequently too complex to be understandable to patients. These discrepancies can have profound patient safety implications, as noted in a previous PSNet Perspective. Errors in care and adverse events associated with health literacy include mistakes in diabetes management; taking the wrong dose or mixing up medications; errors in dosing medications for children; incorrect use of inhalers and aerosol medications; falls; delays in receiving treatment, surgery, or tests; and wrong procedure or wrong site surgery. Moreover, the complexity of modern health information and management can be difficult for anyone to process.

In 2004, The National Academies of Science, Engineering, and Medicine (then known as the Institute of Medicine) published a landmark report calling for action to address health literacy and explicitly linking health literacy to the quality domains of patient safety, patient-centered care, and equitable treatment. AHRQ simultaneously released its first evidence report on health literacy (since updated) in a joint press conference with the Institute of Medicine report. According to the Institute of Medicine, health literacy is a function of systems within and beyond health care, and it involves interaction between the individual patient and the health care system, as well as other social, cultural, and educational factors. The report noted that many adults cannot read complex texts at all and will have serious difficulty navigating the health care environment. The only nationally representative survey of health literacy, conducted in 2003, tested adults' ability to use printed health information. It found that over a

third—77 million Americans—had basic or below basic levels of health literacy, 53% had an intermediate level, and only 12% had a proficient level of health literacy.

Reading, in and of itself, is an important health literacy skill. Low reading levels may compromise interactions with health care providers and lead to safety problems. In a compelling American Medical Association Foundation video, actual patients explain their reading difficulties, their fears of their reading limitations being discovered, and the lengths they go to in order to cover their inability to read. However, health literacy involves more than reading—it also includes the ability to write; fill out forms; listen, ask questions, and follow directions; do basic math; keep track of information over time; engage in maintaining health and managing conditions; and participate in shared decision-making. Health literacy is affected by many factors, including socioeconomic status, culture, and language.

Health literacy is not necessarily static, but can vary with a person's mental or emotional state, illness, and life stressors. Furthermore, health literacy depends on both an individual's skills and the complexity of health information and the tasks needed to manage health. Thus, anyone—regardless of background—can experience limitations in health literacy. This fact, combined with controversies regarding conducting literacy testing in health care environments, led to a Universal Precautions approach to health literacy. In this approach, clinicians and health care systems assume that all patients are at risk of not understanding medical information, and they communicate with patients in ways anyone can understand. This approach involves:

- **Creating a shame-free environment**: All patients should feel welcomed and comfortable at each stage of the health care encounter—from the telephone, to the reception area, to the finance area, and finally to the examination, procedure, or inpatient room.
- **Simplifying information**: Communicate clearly with plain language and visual cues, such as models, pictures, or videos. Limit discussion to 3–5 key points. Written materials should be at a 4th to 6th grade level, use short sentences and simple words, provide evidence-based instructions, and include pictures. The Centers for Medicare and Medicaid Services has a toolkit to support development of effective

health information material and AHRQ has a tool to assess already developed patient education materials.

- **Listening carefully**: Avoid interrupting patients when they are speaking and use words the patients use to describe their health or illness in discussion of health and medical planning.
- **Confirming comprehension**: Use a teach-back or show me method. For example, ask patients how they will take their medication tomorrow or how they will explain their treatment to their family or friends. Do not ask, "Do you understand?" as most patients will automatically say yes.
- **Improving support for navigating health care contexts**: Design signage, forms, websites, and apps from a health literacy perspective. Assist patients with accessing the care they need (e.g., making referrals easy) and with understanding health care bureaucracy and cost.
- **Supporting patients in their health management efforts**: Provide simple guides for medications and other health self-management practices. Reinforce what patients are doing well, and partner with them to develop strategies that will help them achieve goals safely.

In 2007, The Joint Commission stated, "The safety of patients cannot be assured without mitigating the negative effects of low health literacy and ineffective communications on patient care." Just as we have shifted from a focus on the individual to the function of the entire system as the locus of patient safety, experts have also long recognized that a systems approach is needed to address health literacy. Health literate health care organizations integrate health literacy into all aspects of their mission, structure, operations, planning, evaluation, measures, patient safety, and quality improvement in order to meet the needs of all while avoiding stigmatizing anyone.

Current Context

The Department of Health and Human Services has issued a National Action Plan to Improve Health Literacy, with seven goals that prioritize many of the areas discussed above. Comprehensive health literacy implementation toolkits are available from the Agency for

Healthcare Research and Quality and from Unity Point Health. A number of emerging health literacy interventions are being tested, from modified medication labels to various ways of using visual information to improve communication. However, the concept of taking a systems approach to health literacy has not yet penetrated many health care organizations or become fully integrated into safety and quality frameworks. Many experts recommend that organizations and practices should engage in health literacy self-assessment and make health literacy part of the fabric of their safety and quality programs.

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Patient Safety Primer Last Updated: November 2017

High Reliability

Background

High reliability organizations are organizations that operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures. The concept of high reliability is attractive for health care, due to the complexity of operations and the risk of significant and even potentially catastrophic consequences when failures occur in health care. Sometimes people interpret high reliability as meaning effective standardization of health care processes. However, the principles of high reliability go beyond standardization; high reliability is better described as a condition of persistent mindfulness within an organization. High reliability organizations cultivate resilience by relentlessly prioritizing safety over other performance pressures. A classic example is that of the military aircraft carrier: despite significant production pressures (aircrafts take off and land every 48–60 seconds), constantly changing conditions, and hierarchical organizational structure, all personnel consistently prioritize safety and have both the authority and the responsibility to make real-time operational adjustments to maintain safe operations as the top priority.

Characteristics of High Reliability Organizations

High reliability organizations use systems thinking to evaluate and design for safety, but they are keenly aware that safety is an emergent, rather than a static, property. New threats to safety continuously emerge, uncertainty is endemic, and no two accidents are exactly alike. Thus, high reliability organizations work to create an environment in which potential problems are anticipated, detected early, and virtually always responded to early enough to prevent catastrophic consequences. This mindset is supported by five characteristic ways of thinking: preoccupation with failure; reluctance to simplify explanations for operations, successes, and

failures; sensitivity to operations (situation awareness); deference to frontline expertise; and commitment to resilience (Table).

Table. Characteristics of High Reliability.

Characteristic	Description
Preoccupation With Failure	Everyone is aware of and thinking about the potential for failure. People understand that new threats emerge regularly from situations that no one imagined could occur, so all personnel actively think about what could go wrong and are alert to small signs of potential problems. The absence of errors or accidents leads not to complacency but to a heightened sense of vigilance for the next possible failure. Near misses are viewed as opportunities to learn about systems issues and potential improvements, rather than as evidence of safety.
Reluctance to Simplify	People resist simplifying their understanding of work processes and how and why things succeed or fail in their environment. People in HROs* understand that the work is complex and dynamic. They seek underlying rather than surface explanations. While HROs recognize the value of standardization of workflows to reduce variation, they also appreciate the complexity inherent in the number of teams, processes, and relationships involved in conducting daily operations.
Sensitivity to Operations	Based on their understanding of operational complexity, people in HROs strive to maintain a high awareness of operational conditions. This sensitivity is often referred to as "big picture understanding" or "situation awareness." It means that people cultivate an understanding of the context of the current state of their work in relation to the unit or organizational state—i.e., what is going on around them—and how the current state might support or threaten safety.
Deference to Expertise	People in HROs appreciate that the people closest to the work are the most knowledgeable about the work. Thus, people in HROs know that in a crisis or emergency the person with greatest knowledge of the situation might not be the person with the highest status and seniority. Deference to local and situation expertise results in a spirit of inquiry and de-emphasis on hierarchy in favor of learning as much as possible about potential safety threats. In an HRO, everyone is expected to share concerns with others and the organizational climate is such that all staff members are comfortable speaking up about potential safety problems.
Commitment to Resilience	Commitment to resilience is rooted in the fundamental understanding of the frequently unpredictable nature of system failures. People in HROs assume the system is at risk for failure, and they practice performing rapid assessments of and responses to challenging situations. Teams cultivate situation assessment and cross monitoring so they may identify potential safety threats quickly and either respond before safety problems cause harm or mitigate the seriousness of the safety event.
*HROs: High reliability organizations Sources: Weick et al 2007; Hines et al 2008; Chassin et al 2013; Rochlin 1999.	

Current Context

It is important to recognize that standardization is necessary but not sufficient for achieving resilient and reliable health care systems. High reliability is an ongoing process or an

organizational frame of mind, not a specific structure. AHRQ has outlined practical strategies for health care organizations aiming to become highly reliable in their report of practices employed by hospitals in the High Reliability Organization Learning Network. The Joint Commission suggests that hospitals and health care organizations work to create a strong foundation before they can begin to mature as high reliability organizations. Such foundational work includes developing a leadership commitment to zero-harm goals, establishing a positive safety culture, and instituting a robust process improvement culture. The Joint Commission also provides metrics for assessing the maturity of an organization's leadership, safety culture, and process improvement culture as preconditions to high reliability.

Editor's Picks

CASE

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Patient Safety Primer Last Updated: June 2017

Human Factors Engineering

Background

An obstetric nurse connects a bag of pain medication intended for an epidural catheter to the mother's intravenous (IV) line, resulting in a fatal cardiac arrest. Newborns in a neonatal intensive care unit are given full-dose heparin instead of low-dose flushes, leading to three deaths from intracranial bleeding. An elderly man experiences cardiac arrest while hospitalized, but when the code blue team arrives, they are unable to administer a potentially life-saving shock because the defibrillator pads and the defibrillator itself cannot be physically connected.

Busy health care workers rely on equipment to carry out life-saving interventions, with the underlying assumption that technology will improve outcomes. But as these examples illustrate, the interaction between workers, the equipment, and their environment can actually increase the risk of disastrous errors. Each of these safety hazards ultimately was attributed to a relatively simple, yet overlooked problem with equipment design. The bag of epidural anesthetic was similar in size and shape to IV medication bags, and, crucially, the same catheter could access both types of bags. Full-dose and prophylactic-dose heparin vials appear virtually identical, and both concentrations are routinely stocked in automated dispensers at the point of care. Multiple brands of defibrillators exist that differ in physical appearance as well as functionality; a typical hospital may have many different models scattered around the building, sometimes even on the same unit.

Human factors engineering is the discipline that attempts to identify and address these issues. It is the discipline that takes into account human strengths and limitations in the design of interactive systems that involve people, tools and technology, and work environments to ensure safety, effectiveness, and ease of use. A human factors engineer

examines a particular activity in terms of its component tasks, and then assesses the physical demands, skill demands, mental workload, team dynamics, aspects of the work environment (e.g., adequate lighting, limited noise, or other distractions), and device design required to complete the task optimally. In essence, human factors engineering focuses on how systems work in actual practice, with real—and fallible—human beings at the controls, and attempts to design systems that optimize safety and minimize the risk of error in complex environments.

Human factors engineering has long been used to improve safety in many industries outside of health care—it has been employed to analyze errors in aviation, automobiles, and the Three Mile Island nuclear power plant accident. Its application to health care is relatively recent; pioneering studies of human factors in anesthesia were integral to the redesign of anesthesia equipment, significantly reducing the risk of injury or death in the operating room.

Applications of Human Factors Engineering to Improving Safety

The very nature of human factors engineering precludes "one size fits all" solutions, but several tools and techniques are commonly used as human factors approaches to addressing safety issues.

Usability testing—Human factors engineers test new systems and equipment under real-world conditions as much as possible, in order to identify potential problems and unintended consequences of new technology. One prominent example of the clinical applicability of *usability testing* involves electronic medical records and computerized provider order entry (CPOE). A recent book discussed a serious medication overdose that occurred in part due to confusing displays in the institution's CPOE system—a vivid example of how failing to use human factors engineering principles in user interface design can potentially harm patients. Simulated clinical scenarios may be used to conduct *usability testing*, as was performed in a study that demonstrated that commercial CPOE systems generally did not detect potentially unsafe orders.

Usability testing is also essential for identifying workarounds—the consistent bypassing of policies or safety procedures by frontline workers. Workarounds frequently arise because of flawed or poorly designed systems that actually increase the time necessary for workers to complete a task. As a result, frontline personnel work around the system in order to get work

done efficiently. In the obstetric example above, the hospital had implemented a bar-code system designed to prevent medication administration errors. However, the system did not reliably scan IV bags. Nurses therefore developed a workaround for urgent situations, whereby they would administer the IV medication without scanning the bar code, and only later manually document its administration. This workaround was deemed to be a substantial contributor to the ultimately fatal error.

Forcing functions—An aspect of a design that prevents an unintended or undesirable action from being performed or allows its performance only if another specific action is performed first. For example, automobiles are now designed so that the driver cannot shift into reverse without first putting his or her foot on the brake pedal. Forcing functions need not involve device design. One of the first forcing functions identified in health care was the removal of concentrated potassium from general hospital wards. This action helps prevent the inadvertent addition of concentrated potassium to intravenous solutions prepared by nurses on the wards, an error that has produced small but consistent numbers of deaths for many years.

Standardization—An axiom of human factors engineering is that equipment and processes should be standardized whenever possible, in order to increase reliability, improve information flow, and minimize cross-training needs. Standardizing equipment across clinical settings (as in the defibrillator example above) is one basic example, but standardized processes are increasingly being implemented as safety measures. The widening use of checklists as a means of ensuring that safety steps are performed in the correct order has its roots in human factors engineering principles.

Resiliency efforts—Given that unexpected events are likely to occur, attention needs to be given to their detection and mitigation before they worsen. Rather than focus on error and design efforts to preclude it, resiliency approaches tap into the dynamic aspects of risk management, exploring how organizations anticipate and adapt to changing conditions and recover from system anomalies. Building on insights from high-reliability organizations, complex adaptive systems, and resourceful providers at the point of care, resilience is viewed as a critical system property, reflecting the organization's capacity to bounce back in the face of continuing pressures and challenges when the margins of safety have become thin.

Despite the above examples, it is generally agreed that human factors principles are underutilized in examination of safety problems and in designing potential solutions. The ever-lengthening list of unintended consequences of CPOE can, in part, be viewed as a failure to appropriately design such systems with human factors in mind.

Editor's Picks

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PERSPECTIVE

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CASE

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PERSPECTIVE

Human Factors Engineering Can Teach You How to Be *Surprised* Again

PERSPECTIVE

In Conversation With...Donald A. Norman, PhD

CASE

Thin Air

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PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: November 2017

Individual Clinician Performance Issues

Background

The patient safety field has emphasized the use of the systems approach to improving safety. This approach takes the stance that adverse events occur due to poorly designed systems, which allow predictable human errors to result in patient harm. The systems approach views errors made by individuals as inevitable, although it acknowledges that human error is more likely in certain circumstances (such as when clinicians are fatigued or placed in situations in which they lack adequate training or supervision to perform a task). As such, the approach intentionally deemphasizes the role of individual provider competence in contributing to errors. In health care, errors have historically been attributed to individual failings, but the current, broader understanding of patient safety recognizes the important roles of various system factors, which include individual competencies, and many other aspects of health care delivery that affect safety. There is good reason for this perspective, as analysis of adverse events in many industries has shown that isolated individual errors less commonly result in catastrophic safety failures.

The Swiss cheese model memorably summarized this concept and created a powerful metaphor: namely, that errors made by individuals result in patient harm thanks to system failings (the holes in the cheese). These holes prevent the error from being detected and mitigated, and may at times even amplify the consequences of the error. Use of the systems approach is tightly linked to the development of a culture of safety, which emphasizes a nonjudgmental approach to error reporting and analysis. As Dr. Lucian Leape, one of the leaders of the patient safety field, has said, "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes."

Nevertheless, it is undeniable that individual clinicians vary in their skill level, and this variation may have safety consequences for patients. As one piece of evidence, studies have consistently shown that a small proportion of clinicians are responsible for a disproportionate number of patient complaints and malpractice lawsuits. For example, an Australian study found that just 3% of physicians accounted for 49% of all complaints filed by patients, and a United States study found that 1% of physicians accounted for 32% of all malpractice complaints over a 10-year period. Highly publicized cases of individual physicians who repeatedly provided substandard—and even dangerous—care have also served to highlight the problem of individual clinician performance issues. Although comparable data is not currently available for other health professions, some reports have raised the concern that similar problems may exist among nurses.

Detection of Individual Performance Issues

Individual clinician performance issues may relate to technical competence to perform specific tasks or procedures necessary to provide safe patient care. Alternatively, a clinician may be technically proficient—or even outstanding—but provide unsafe care for a variety of other reasons, including poor communication skills, lack of professionalism, or medical or mental health conditions. This broader concept of individual clinician performance that also includes how individuals engage and work with other clinicians and the system in general is supported by an expanding body of scientific evidence and practical experience. Health care organizations increasingly understand that safe, high-quality care cannot be achieved without well-designed systems of care that are supported by individuals with a full range of competencies. They also appreciate that individual awareness of systems science and how to apply it to health care can be as critical to a patient's care as effectively applying the traditional base of medical knowledge.

The health professions educational system aspires to train clinicians to achieve basic proficiency in technical and nontechnical skills in order to be able to practice independently, but variation in skill among physicians can affect patient safety. A seminal 2013 study used video recording of bariatric surgical procedures to evaluate the correlation between objectively assessed technical skill and patient care outcomes. The study found that surgeons rated in the lowest quartile of surgical skill (as assessed by peer review of videotaped operations) had rates of surgical complications nearly three times as high as

those rated in the highest quartile of surgical skill. As this study involved practicing surgeons with considerable experience with the procedure in question, the study vividly demonstrated the link between individual clinician skill and patient outcomes. Although many studies document variation in clinician practice patterns, few other studies definitively link variation in technical skills to safety outcomes.

Yet even clinicians who have the knowledge and skill to provide safe care may not always do so. Health care is a team endeavor, and clinicians who lack the ability to work productively within a team context certainly pose risks to their patients. The link between overtly disruptive and unprofessional behavior and patient safety has been well documented, and considerable efforts are underway to end a "culture of disrespect" that permeates many organizations. Even highly competent and professional clinicians can, over the course of their careers, find themselves in situations that prevent them from providing high-quality and safe care. The growing prevalence of burnout among clinicians has been linked to adverse patient outcomes and is discussed in detail in a 2015 Annual Perspective. Impaired clinicians—those unable to perform competently due to illness, mental health conditions, or substance use—also pose a threat to patient safety; studies estimate that 10%–12% of physicians develop a substance use disorder at some time during their career.

Addressing Individual Performance Issues

The first step in addressing individual performance issues requires addressing a philosophical tension: how should the patient safety field balance the systems approach with the need for individual accountability? A 2015 Annual Perspective discussed this question. There is now a general consensus that a just culture approach—which seeks to draw clear boundaries around "at-risk" behaviors that clearly endanger patient safety and define consequences for these behaviors—is a more appropriate and nuanced approach than a blanket "no blame" philosophy. There is also a consensus among clinicians and patients that clinicians should be held accountable and face disciplinary consequences for engaging in at-risk behaviors, such as refusing to perform a preprocedural timeout. As evolving evidence identifies safe practices and defines clearer safety standards, individual clinician accountability for adhering to such practices will become more important.

The studies cited above identify a subpopulation of physicians that are disproportionately prone to allegations of malpractice or complaints by physicians. These studies also found a high recidivism rate, in that a physician who was the subject of a complaint or lawsuit was likely to be the subject of further concerns about their performance. There were also variations between specialties, with surgical specialists and obstetricians at the highest risk of both lawsuits and complaints. These findings raise the question of whether clinicians with performance issues can be detected—and intervened upon—before they pose safety risks.

A classic study found that medical students who demonstrated unprofessional behavior (as students) were significantly more likely to be disciplined by state licensing boards once in practice. Analysis of malpractice and patient complaint databases have also identified some predictors of performance concerns, including male gender, procedural specialty, the number of complaints, and time since the last complaint.

However, much remains unknown about physicians who experience recurrent performance concerns. As discussed in a PSNet perspective, it remains unclear what proportion of physicians with problems lack skill in specific areas (i.e., insufficient technical competence) versus in multiple dimensions of care (i.e., poor communication skills, inability to reflect upon errors, or failure to incorporate new knowledge). We also do not know what proportion of clinicians fail to perform competently due to time-limited, potentially reversible events (such as an episode of burnout or depression) versus general lack of or deterioration in skill. Early detection of poorly performing clinicians thus remains a challenge, exacerbated by the fact that clinicians often do not report impaired colleagues even when they have first-hand knowledge of performance issues.

A variety of approaches can potentially be used to intervene in the cases of clinicians who pose safety risks to patients. Simulation has proven to be a very effective educational approach, and the combination of simulation and individualized coaching can reduce adverse events associated with specific procedures. Building upon the bariatric surgery study cited above, it is likely that video recording of procedures and other types of clinical encounters will become routinely used both for assessment and improvement purposes. Finally, physicians are required to participate in some form of Continuing Medical Education (CME) and Maintenance of Certification (MOC) to retain their professional licensure and credentials, and these programs are being revamped to ensure they achieve their goal of ensuring

professional competency. The trend to align quality improvement initiatives and individual certification requirements so that they collectively address shared goals offers the potential to increase uptake and value of these related activities and also decrease burden on clinicians.

For a small subset of clinicians, disciplinary action is needed to protect patients. State licensing boards are tasked with identifying physicians who pose a threat to patient safety and intervening as needed. Unfortunately, states vary considerably in the rate of both major and minor disciplinary actions taken against physicians, which implies that there may be a role for standardizing states' approaches to disciplining physicians who pose a safety risk.

Current Context

Professional organizations and regulatory bodies have drawn attention to safety issues related to individual clinician performance, most prominently with regard to disruptive and unprofessional behavior. Most health care organizations, and many states, mandate that health professionals formally report colleagues who they suspect of being impaired or otherwise unable to fulfill their patient care duties. It seems likely that the emergence of new approaches to health care delivery and documentation (including electronic health records, simulation, and new methods of measuring quality) will pave the way for new approaches to performance assessment and improvement.

It should be noted that most research on individual clinician performance pertains only to physicians. There are few studies on the prevalence of adverse events or errors due to performance issues among other health professionals, and little to no evidence on methods to address performance concerns. Research into the relationship between clinician performance and safety should not only seek to define clinician factors that predispose to performance issues and adverse events, but should also examine the role of skill and professional competence of other members of the health care team.

Editor's Picks

PERSPECTIVE

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Patient Safety Primer Last Updated: June 2017

Leadership Role in Improving Safety

Background

Most health care organizations are still striving to attain high reliability—the ability to minimize adverse events while consistently providing high-quality care in the context of a rapidly changing environment. Workers at the sharp end are best positioned to identify hazardous situations and address system flaws. Although the concept of leadership has traditionally been used to refer to the top rungs of an organization, frontline workers and their immediate supervisors play a crucial leadership role in acting as change agents and promoting patient-centered care. As the safety field has evolved, there is a growing recognition of the role that organizational leadership plays in prioritizing safety, through actions such as establishing a culture of safety, responding to patient and staff concerns, supporting efforts to improve safety, and monitoring progress. Research using a variety of methodologies has defined the relationship between leadership actions and patient safety and has begun to elucidate key organizational behaviors and structures that can promote (and hinder) safety efforts.

This Patient Safety Primer will discuss the role of organizational leadership in improving patient safety. The crucial roles that frontline and mid-level providers play in improving safety are discussed in the related Safety Culture and High Reliability Patient Safety Primers.

The Historical Role of Hospital Leadership in Quality and Safety Activities

All hospitals are overseen by a board of directors, whose responsibilities include (but are not limited to) formulating the organizational mission and key goals, ensuring financial viability, monitoring and evaluating the performance of high-level hospital executives, making sure the organization meets the needs of the community it serves, and ensuring the quality and safety of care provided by the organization. However, hospital boards have traditionally had relatively

little direct engagement in evaluating and improving quality and safety. As a 2010 review article explains, board members historically have been community leaders with little to no health care experience, often lacking the knowledge to interpret complex data on the quality and safety of care. Boards also had limited ability to address quality issues that lived within the domain of practicing physicians, given that most physicians are not directly employed by the hospital.

Surprising as it may seem, despite being accountable for the quality and safety of care being provided in their organizations, until recently board, executive, and medical staff leadership at most hospitals in the United States placed relatively little emphasis on identifying and addressing safety issues. A 2010 survey of more than 700 hospital board chairs found that only a minority considered improving the quality of care to be one of the board's top two priorities, and very few board chairs had any direct training in quality or safety. This situation is changing, driven by data on the influence of leadership engagement, as well as greater emphasis on quality and safety in general. Today, we are seeing a shift toward more direct oversight of quality and safety at the organizational level.

How Leadership Can Influence Patient Safety

An emerging body of data now demonstrates a clear association between board activities and hospital performance on quality and safety metrics. A 2013 review found that high-performing hospitals—defined as those ranking highly on objective measures of quality and safety—tended to have board members who were more skilled in quality and safety issues and who devoted more time to discussion of quality and safety during board meetings. Insight into how boards can positively influence quality was provided by a recent study of hospitals in the US and England, which found that boards of high-quality hospitals used more effective management practices to monitor and improve quality. These practices include structured use of data to enhance care, both by setting specific quality goals and regularly monitoring performance dashboards. They also included explicitly using quality and safety performance in the evaluation of high-level executives and focusing on improving hospital operations. Examples of organizations that have transformed their practices and organizational culture to emphasize patient safety include the Dana-Farber Cancer Institute, which responded to a serious and widely publicized preventable death by ingraining patient safety into the responsibilities of clinical and organizational leadership and emphasizing

transparency with patients and families, and PeaceHealth, which created a governance board overseeing all safety and quality activities across the system and tied executive compensation to specific quality and safety goals.

Hospital boards influence quality and safety largely through strategic initiatives, but data also shows that executives and management can improve safety through more direct interactions with frontline workers. Leadership walkrounds—visits by management to clinical units in order to engage in frank discussion around safety concerns—can positively impact safety culture. Although walkrounds are widely used and recommended as a safety intervention, recent research indicates that relatively small differences in the way walkrounds are conducted can markedly enhance or limit their effectiveness. For example, issues raised by frontline staff during walkrounds must be promptly addressed, lest staff view the rounds as simply a visibility exercise for leadership. Similarly, voluntary error reporting systems often lack credibility among frontline staff due to insufficient follow up after an error is reported. By engaging with those who take the time to report errors and devoting time and resources to structured follow through, hospital leadership can both address specific safety issues and tangibly illustrate the importance of patient safety as an organizational priority.

An important area in which hospital leadership can directly address safety concerns is through managing disruptive and unprofessional behavior by clinicians. As boards have oversight over the medical staff, they have the ability to ensure unprofessional or incompetent clinicians do not put patients at risk. Although there is limited evidence regarding specific strategies leadership can use to prevent disruptive behavior, some organizations have developed a structured approach that emphasizes early intervention by hospital leadership for clinicians who display recurrent unprofessional behavior or are the subject of multiple patient complaints.

Current Context

The Joint Commission issued a 2009 sentinel event alert highlighting the importance of leadership engagement in improving patient safety. The alert called for organizational leaders to take specific actions to enhance safety within their institutions, including improving the culture of safety and establishing a just culture for addressing errors. The Joint Commission also strongly recommended strengthening hospital boards and patient engagement in safety

efforts and making safety performance an explicit part of how leadership is evaluated. The Joint Commission evaluates adherence to the recommendations in sentinel event alerts during the accreditation process.

Editor's Picks

PERSPECTIVE

In Conversation With… Amy C. Edmondson, PhD, AM

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PERSPECTIVE

The PeaceHealth Governance Journey in Support of Quality and Safety

PERSPECTIVE

Organizational Change in the Face of Highly Public Errors—I. The Dana-Farber Cancer Institute Experience

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Patient Safety Primer Last Updated: June 2017

Long-term Care and Patient Safety

Background

The patient safety field has primarily focused on improving safety in hospital and ambulatory settings. Yet a large and growing number of Americans who do not require hospital-level care but are unable to be safely cared for at home reside in settings referred to as long-term care. These settings include skilled nursing facilities (SNFs), inpatient rehabilitation facilities, and long-term acute care hospitals. There were more than 1.6 million residents of SNFs in 2011, and long-term acute care hospitals admissions among Medicare beneficiaries have more than doubled over the past 15 years.

Patients in long-term care settings may be particularly vulnerable to safety problems in the course of their care. Patients requiring care in long-term care facilities are disproportionately older and chronically ill, and they often enter long-term care after an acute hospitalization. Health care utilization after entering long-term care is high—a study by the Office of the Inspector General (OIG) found that nearly 25% of Medicare SNF residents require hospitalization each year.

Each type of long-term care setting provides different services and is suitable for different types of patients:

- Long-term acute care hospitals care for medically complex patients expected to require care for weeks to months. These patients are often chronically critically ill, most commonly recovering from a hospitalization that included an intensive care unit stay. These facilities provide services very similar to acute care hospitals, including the ability to care for patients requiring mechanical ventilation, complex wound care, or hemodialysis. The facilities may be freestanding or attached to an

acute hospital, and they are subject to the same licensing and credentialing requirements as traditional hospitals. Patients at long-term acute care hospitals generally require daily evaluation by a physician.

- Inpatient rehabilitation facilities care for patients recovering from surgery, trauma, or an acute illness. They provide intensive rehabilitation—patients must be able to tolerate 3 hours of physical or occupational therapy daily—with the goal of restoring patients to their premorbid functional status. Care is overseen by a multidisciplinary team that includes a physician, typically a specialist in rehabilitation medicine.
- Skilled nursing facilities generally care for patients who may be chronically ill but are considered medically stable. In general, these patients do not require daily evaluation by a physician but do require services such as physical therapy or wound care.

Patients often enter long-term care after an acute hospitalization. Data from 2011 indicates that nearly 40% of Medicare beneficiaries are discharged to some form of long-term care facility—most often a SNF—after hospital discharge. Therefore, the term *postacute care* is also used to refer to the utilization of long-term care facilities to provide continuing care after hospitalization. Postacute patients represent an increasing proportion of the overall SNF patient population, and these patients—who are often medically complex and frail—may tax the ability of SNFs to provide safe care. As a result of all these factors, the safety field is starting to examine and address safety issues faced by patients in long-term care.

Safety Concerns in Long-term Care

Preventable adverse events are common in long-term care. A 2014 report by the OIG found that 22% of Medicare beneficiaries in SNFs experienced an adverse event during their stay, half of which were preventable. More than half of the patients who experienced an adverse event at a SNF required hospitalization. A separate OIG report found an even higher incidence of adverse events at rehabilitation facilities. Among these are hazards that are well documented in older patients, such as medication errors, health care–associated infections, delirium, falls, and pressure ulcers. Adverse drug events were the most common type of adverse event in the OIG study as well as in other studies of long-term care populations. While patient complexity explains some of these events, it is also worth noting that

computerized provider order entry and other medication safety strategies have not been implemented as widely in SNFs as in hospitals. Health care–associated infections—particularly catheter-associated urinary tract infections—are also common in long-term care, and efforts are underway to address this problem. A WebM&M commentary discusses the types of adverse events that occur in SNF patients in more detail and gives evidence-based recommendations for preventing these harms.

Establishing a robust culture of safety is essential for minimizing patient harm. Unfortunately, safety culture in many long-term care facilities is poorer than that found in hospitals and ambulatory clinics. A 2006 study using the AHRQ Hospital Survey on Patient Safety Culture found that nursing home administrators perceived safety culture in their facilities to be lower than hospital benchmarks across nearly all domains of the survey. AHRQ subsequently developed a safety culture survey instrument for nursing homes and has released biannual benchmarking data since 2008. The most recent (2014) data indicates overall improvement in long-term care safety culture, but respondents still raise concerns about potential patient harm due to inadequate staffing and an overly punitive culture.

Current Context

Improving safety in long-term care facilities will require research into the safety problems faced by patients, education and training of health care providers in long-term care settings, system-level interventions to enhance care coordination, and greater incentives for long-term care facilities to prioritize patient safety.

The federal government is leading many efforts to improve the safety and quality of care at long-term care facilities. The Center for Medicare and Medicaid Services (CMS) Nursing Home Compare website allows patients and providers to compare long-term care facilities on various quality metrics, including measures of patient safety (such as the proportion of patients who experience a health care–associated infection). CMS has also proposed new revisions to long-term care facilities' conditions of participation in the Medicare and Medicaid programs, which explicitly emphasize a focus on ensuring the quality of care for long-term care facility residents. AHRQ is funding research to examine the epidemiology of adverse events in long-term care settings and identify effective preventive strategies. AHRQ has also developed a number of resources to examine and address safety in long-term care, including

training programs for staff, an ongoing collaborative program to prevent catheter-associated urinary tract infections, and a guide to help nursing homes appropriately use antibiotics.

The Joint Commission offers accreditation programs for nursing care centers that provide postacute care services. These include SNFs and most inpatient rehabilitation facilities. The accreditation process emphasizes the importance of patient safety and efforts to prevent hospital admissions among long-term care patients. The Joint Commission National Patient Safety Goals for long-term care facilities were updated in 2016. These require SNFs to have measures in place to prevent specific clinical harms (such as falls, pressure ulcers, and health care–associated infections) and to conduct medication reconciliation. Long-term acute care hospitals and inpatient rehabilitation facilities are accredited in the same fashion as acute care hospitals, and they are subject to the same National Patient Safety Goals (which were also updated in 2016).

While these efforts are important (and are beginning to bear fruit), fundamental health care system issues must be addressed in order to improve safety in long-term care. As discussed in a 2015 WebM&M commentary, neither hospitals nor long-term care facilities are incentivized to improve care transitions under the current prospective payment system. CMS is developing novel care models and payment systems to encourage health care systems to prioritize safe care transitions between different types of facilities. Although the data on these new models—which include accountable care organizations, bundled payments for specific diagnoses, and financial penalties for hospitals with high readmission rates—is still preliminary, there are early indications that health care systems are shifting their orientation toward caring for patients across the continuum of care rather than in single episodes.

Editor's Picks

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SNFs: Opening the Black Box

PERSPECTIVE

In Conversation With… Nicholas G. Castle, MHA, PhD

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Measurement of Patient Safety

Background

The 1999 Institute of Medicine *To Err Is Human* report drew national attention to the problem of preventable harm in medicine and led to the creation of the modern patient safety field. Yet little of the material in *To Err Is Human* was new—the key studies on which the report (and its headline-grabbing estimate of up to 98,000 deaths every year due to preventable harm) was based were performed many years before the report was issued. The reason *To Err Is Human* had such a profound impact was largely because it was released from the IOM and estimated, for the first time, the toll of medical errors at the national level. Since the report was issued, several studies using similar retrospective chart review methodology have found that adverse events remain common and have likely decreased only slightly over time.

The impact of *To Err Is Human* demonstrates the importance of rigorously measuring the incidence and prevalence of preventable harm. However, measurement of patient safety is complex, and, while several different methods may be used, there is no single validated method for measuring the overall safety of care provided in a given health care setting. One commentator compared safety measurement to the fable in which five blind men describe an elephant in widely varying terms (as a wall, fan, spear, snake, or tree), depending on which part of the animal they touched. In this analogy, an institution's view of its safety issues inevitably depends on the method being used to measure safety, and a comprehensive picture can only be obtained by integrating multiple methods.

This primer will review methods of measuring patient safety. A related Patient Safety Primer discusses Detection of Safety Hazards.

A Framework for Measuring Patient Safety

In the 1960s, health services researcher Avedis Donabedian defined a taxonomy for measuring the quality of health care. The "Donabedian triad," which is still widely used today, defines three lenses through which quality may be viewed:

- Structures—how care is organized
- Processes—what is done to the patient
- Outcomes—what ultimately happens to the patient

A structural measure of patient safety might assess whether a hospital has key resources in place to improve safety, such as an electronic health record or a mechanism to rapidly start the work of root cause analysis teams after a serious adverse event has occurred. Process measures assess adherence to safety standards, such as the proportion of surgical patients for whom a postoperative checklist is completed or the proportion of patients in a hospital receiving appropriate prophylaxis for venous thromboembolism. Outcome metrics can measure the incidence or prevalence of adverse events—harm experienced by patients as a result of interaction with the health care system. A related Patient Safety Primer on Adverse Events, Near Misses, and Errors discusses the definition and types of adverse events in more detail.

The choice of measurement method also depends on the reason measurement is being performed. Measurement is used for a variety of purposes: to evaluate the effectiveness of safety interventions, identify new or emerging safety threats, compare safety across hospitals and clinics, or to determine whether patient safety is improving over time. There is no one-size-fits-all approach to measurement—the choice of metric varies depending on the purpose of measurement. For example, studies of missed nursing care measure processes—the frequency with which required care elements are not completed. Studies of medication reconciliation may measure processes (such as the proportion of patients for whom a best possible medication history was documented at hospital admission) or outcomes (such as the preventable adverse drug events). The Leapfrog Hospital Survey evaluates hospitals based on structural metrics—the use of specific patient safety practices, such as computerized provider order entry.

Methods for Measuring Patient Safety

Several methods that can be used for measuring patient safety events are described in the Table below.

Table. Representative Examples of Safety Measurement Strategies

Measurement Strategies	Advantages	Disadvantages
Retrospective Chart Review (by itself or after use of a trigger tool)	Considered the "gold standard," contains rich and detailed clinical information	Costly, labor-intensive, data quality variable due to incomplete clinical information, retrospective review only. Efficiency improved by focusing chart reviews on cases identified by a reliable trigger tool or software tool
Voluntary Error Reporting Systems	Useful for internal quality improvement and case-finding, highlights adverse events that providers perceive as important	Capture a nonrepresentative fraction of adverse events (in hospitals, most reports are submitted by nurses; relatively few by doctors), retrospective review only based on provider self-reports
Automated Surveillance	Can be used retrospectively or prospectively, helpful in screening patients who may be at high risk for adverse events using standardized protocols	Need electronic data to run automated surveillance, high proportion of triggered cases are false positives
Administrative/Claims Data (e.g., AHRQ Patient Safety Indicators)	Low-cost, readily available data, useful for tracking events over time across large populations, can identify potential adverse events	Lack detailed clinical data, concerns over variability and inaccuracy of ICD-9-CM and ICD-10-CM codes across and within systems, may detect high proportion of false positives and false negatives
Patient Reports	Can capture errors not easily recognized by other methods (i.e., errors related to communication between providers)	Measurement tools are still in development

(Adapted from Wachter RM. Understanding Patient Safety, Second Edition. New York, NY: McGraw-Hill Professional; 2012. ISBN: 9780071765787.)

Retrospective chart review using a two-stage process was originally developed for the pioneering Harvard Medical Practice Study to detect and measure adverse events in hospitalized patients. In the first stage, screening criteria (which may include trigger tools) are used to identify cases where harm may have occurred. These cases are reviewed in depth, ideally by two independent clinicians, to determine whether harm occurred, the severity of injury to the patient, and if the harm was preventable. In addition to the advantages listed above, chart review can be used to measure process or outcome metrics and can reliably measure the frequency of specific adverse events. It is also useful for comparing estimates of overall patient safety events between hospitals or over different time periods. This method

has been used in several influential studies of the prevalence of safety problems over time. Another seminal study by AHRQ used the Medicare Patient Safety Monitoring System to assess temporal trends in patient safety. This process also uses retrospective medical review with defined algorithms for detecting 21 measures of safety that can be reliably abstracted from medical records.

Problems and Controversies in Measuring Patient Safety

Despite the importance of accurately measuring adverse events, existing tools all have limitations, and controversy continues to plague efforts to measure safety and compare safety between organizations. Retrospective chart review using trigger tools or well-defined specific adverse events is often used in research studies, but it is so labor-intensive that most hospitals do not routinely monitor safety performance in this fashion. Other commonly used methods, such as voluntary error reporting systems and the AHRQ Patient Safety Indicators, are useful for screening purposes but cannot be reliably used for measuring incidence or prevalence of most safety problems. Certain types of errors—such as diagnostic errors—still lack standardized and reliable measurement strategies, and studies have shown that variation in how medication errors are defined can result in widely varying estimates of error prevalence. As a result, 15 years into the safety movement, evaluating the effectiveness of safety programs remains a challenge for most organizations.

Even when adverse events can be measured, an additional layer of controversy concerns determining whether the event was preventable. In the seminal studies that formed the basis of *To Err Is Human,* experienced clinicians often disagreed on whether an error was preventable. Differences in definitions of errors account for some of the wide variation in estimates of the proportion of hospitalized patients who experience preventable harm, which ranges from about 12% among Medicare patients in the 2010 Office of the Inspector General study to nearly 33% in a 2011 study.

Current Context

Progress has been made toward measuring trends in safety at the national level. The Partnership for Patients—a public-private initiative launched in 2011—uses a combination of 28 metrics to determine a national Hospital-Acquired Conditions (HAC) rate. The HACs include certain health care–associated infections, medication errors, and never events.

Analysis by AHRQ has demonstrated a consistent and sustained decline in HAC rates since the inception of the Partnership for Patients.

Nevertheless, accurate and reliable measurement of errors and adverse events remains a major challenge for the patient safety field. The 2015 *Free From Harm* report by the National Patient Safety Foundation called for the creation of a "common set of safety metrics that reflect meaningful outcomes" as one of eight recommendations for advancing patient safety. Their specific recommendations included establishing a standardized set of process and outcome measures for use on a national basis (as well as retiring outdated measures), creating measures of patient safety for settings outside the hospital, improving the quality of safety reporting systems, and developing ways of measuring safety in real time (as opposed to retrospective measurement). The AHRQ Common Formats were developed in order to "help providers uniformly report patient safety events and to improve health care providers' efforts to eliminate harm." The Common Formats represent an important step toward achieving the goal of developing a universal framework for measurement of safety processes and outcomes.

Editor's Picks

PERSPECTIVE

Measuring and Responding to Deaths From Medical Errors

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BOOK/REPORT

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PERSPECTIVE

The Emergence of the Trigger Tool as the Premier Measurement Strategy for Patient Safety

JOURNAL ARTICLE › STUDY

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PERSPECTIVE

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PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Medication Errors

Background and Definitions

Prescription medication use is widespread, complex, and increasingly risky. Clinicians have access to an armamentarium of more than 10,000 prescription medications, and nearly one-third of adults in the United States take 5 or more medications. Advances in clinical therapeutics have undoubtedly resulted in major improvements in health for patients with many diseases, but these benefits have also been accompanied by increased risks. An adverse drug event (ADE) is defined as harm experienced by a patient as a result of exposure to a medication, and ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year. Nearly 5% of hospitalized patients experience an ADE, making them one of the most common types of inpatient errors. Ambulatory patients may experience ADEs at even higher rates—the dramatic increase in deaths due to opioid medications has largely taken place outside the hospital. Transitions in care are also a well-documented source of preventable harm related to medications.

As with the more general term adverse event, the occurrence of an ADE does not necessarily indicate an error or poor quality care. A *medication error* refers to an error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication. *Preventable ADEs* result from a medication error that reaches the patient and causes any degree of harm. It is generally estimated that about half of ADEs are preventable. Medication errors that do not cause any harm—either because they are intercepted before reaching the patient, or by luck—are often called *potential ADEs.* An *ameliorable ADE* is one in which the patient experienced harm from a medication that, while not completely preventable, could have been mitigated. Finally, a certain percentage of patients will experience ADEs even when medications are prescribed

and administered appropriately; these are considered *adverse drug reactions* or *nonpreventable ADEs* (and are popularly known as *adverse effects*).

For example, the intravenous anticoagulant heparin is considered one of the highest-risk medications used in the inpatient setting. Safe use of heparin requires weight-based dosing and frequent monitoring of tests of the blood's clotting ability, in order to avoid either bleeding complications (if the dose is too high) or clotting risks (if the dose is inadequate). If a clinician prescribes an incorrect dose of heparin, that would be considered a medication error (even if a pharmacist detected the mistake before the dose was dispensed). If the incorrect dose was dispensed and administered, but the patient experienced no clinical consequences, that would be a potential ADE. If an excessively large dose was administered and was detected by abnormal laboratory results, but the patient experienced a bleeding complication due to clinicians failing to respond appropriately, it would be considered an ameliorable ADE (that is, earlier detection could have reduced the level of harm the patient experienced).

Risk Factors for Adverse Drug Events

There are patient-specific, drug-specific, and clinician-specific risk factors for ADEs. Polypharmacy—taking more medications than clinically necessary—is likely the strongest risk factor for ADEs. Elderly patients, who take more medications and are more susceptible to specific medication adverse effects, are particularly vulnerable to ADEs. Pediatric patients are also at elevated risk, particularly when hospitalized, since many medications for children must be dosed according to their weight. Other well-documented patient-specific risk factors include limited health literacy and numeracy (the ability to use arithmetic operations for daily tasks), both of which are independently associated with ADE risk. It is important to note that in ambulatory care, patient-level risk factors are probably an under-recognized source of ADEs. Studies have shown that both caregivers (including parents of sick children) and patients themselves commit medication administration errors at surprisingly high rates.

The Institute for Safe Medication Practices maintains a list of high-alert medications—medications that can cause significant patient harm if used in error. These include medications that have dangerous adverse effects, but also include look-alike and sound-alike medications, which have similar names and physical appearance but completely different pharmaceutical properties. The Beers criteria, which define certain classes of medications as

potentially inappropriate for geriatric patients, have traditionally been used to assess medication safety. However, the newer STOPP criteria (Screening Tool of Older Person's inappropriate Prescriptions) have been shown to more accurately predict ADEs than the Beers criteria, and they are therefore likely a better measure of prescribing safety in older patients.

Though there are specific types of medications for which the harm generally outweighs the benefits, such as benzodiazepine sedatives in elderly patients, it is now clear that most ADEs are caused by commonly used medications that have risks but offer significant benefits if used properly. These medications include antidiabetic agents (e.g., insulin), oral anticoagulants (e.g., warfarin), antiplatelet agents (such as aspirin and clopidogrel), and opioid pain medications. Together, these four medications account for more than 50% of emergency department visits for ADEs in Medicare patients. Focusing on improving prescribing safety for these necessary but higher-risk medications may reduce the large burden of ADEs in elderly patients to a greater extent than focusing on use of potentially inappropriate classes of medications.

The opioid epidemic has also brought to light the role of clinician-specific and health system factors in medication errors. Opioid prescribing has increased dramatically over the past 15 years, and recent research questions the benefit of this practice. For example, opioid prescribing after dental procedures and low-risk surgical procedures increased sharply between 2004 and 2012, despite lack of evidence for the benefit of opioids in these situations. Another study also found wide variation in opioid prescribing practices between physicians in the same specialty. These findings indicate widespread overprescribing of opioids by physicians. The reasons behind why physicians overprescribe opioids are complex, and they are explored in more detail in a 2016 Annual Perspective.

Prevention of Adverse Drug Events

The pathway between a clinician's decision to prescribe a medication and the patient actually receiving the medication consists of several steps:

- Ordering: the clinician must select the appropriate medication and the dose and frequency at which it is to be administered.

- Transcribing: in a paper-based system, an intermediary (a clerk in the hospital setting, or a pharmacist or pharmacy technician in the outpatient setting) must read and interpret the prescription correctly.
- Dispensing: the pharmacist must check for drug–drug interactions and allergies, then release the appropriate quantity of the medication in the correct form.
- Administration: the correct medication must be supplied to the correct patient at the correct time. In the hospital, this is generally a nurse's responsibility, but in ambulatory care this is the responsibility of patients or caregivers.

While the majority of errors likely occur at the prescribing and transcribing stages, medication administration errors are also quite common in both inpatient and outpatient settings. Preventing medication errors requires specific steps to ensure safety at each stage of the pathway (Table).

Table. Strategies to Prevent Adverse Drug Events

STAGE	SAFETY STRATEGY
Prescribing	• Avoid unnecessary medications by adhering to conservative prescribing principles • Computerized provider order entry, especially when paired with clinical decision support systems • Medication reconciliation at times of transitions in care
Transcribing	• Computerized provider order entry to eliminate handwriting errors
Dispensing	• Clinical pharmacists to oversee medication dispensing process • Use of "tall man" lettering and other strategies to minimize confusion between look-alike, sound-alike medications
Administration	• Adherence to the "Five Rights" of medication safety (administering the Right Medication, in the Right Dose, at the Right Time, by the Right Route, to the Right Patient) • Barcode medication administration to ensure medications are given to the correct patient • Minimize interruptions to allow nurses to administer medications safely • Smart infusion pumps for intravenous infusions • Patient education and revised medication labels to improve patient comprehension of administration instructions

Although each of the strategies enumerated in the Table can prevent ADEs when used individually, fundamentally, improving medication safety cannot be divorced from the overall goal of reducing preventable harm from all causes. Analysis of serious medication errors invariably reveals other underlying system flaws, such as human factors engineering issues and impaired safety culture, that allowed individual prescribing or administration errors to reach the patient and cause serious harm. Integration of information technology solutions (including computerized provider order entry and barcode medication administration) into "closed-loop" medication systems holds great promise for improving medication safety in hospitals, but the potential for error will remain unless these systems are carefully implemented and these larger issues are addressed.

Current Context

Preventing ADEs is a major priority for the United States health system. The Joint Commission has named improving medication safety as a National Patient Safety Goal for both hospitals and ambulatory clinics, and the Partnership for Patients has included ADE prevention as one of its key goals for improving patient safety. The opioid epidemic has spurred the development of multiple initiatives to reduce inappropriate opioid prescribing, including enhanced prescription drug monitoring programs and updated prescribing guidelines for clinicians, as well as initiatives to mitigate risks associated with opioid use. These programs are summarized in a 2016 Annual Perspective and a 2017 PSNet perspective.

Editor's Picks

CASE

May I Have Another?—Medication Error

CASE

Multifactorial Medication Mishap

CASE

Finding Fault With the Default Alert

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Effect of bar-code technology on the safety of medication administration.

Poon EG, Keohane CA, Yoon CS, et al. N Engl J Med. 2010;362:1698-1707.

CASE

Bad Writing, Wrong Medication

LEGISLATION/REGULATION › SENTINEL EVENT ALERTS

Preventing pediatric medication errors.

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CASE

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CASE

Medication Overdose

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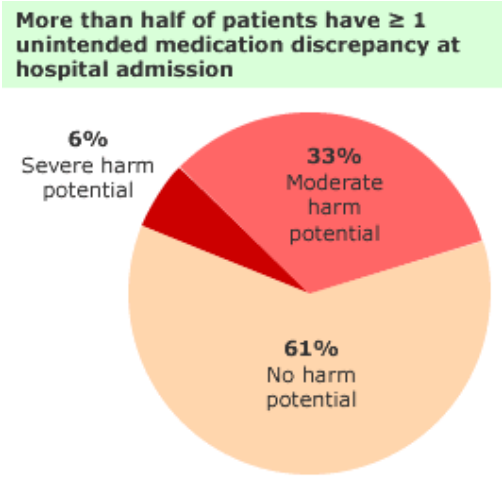
PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Medication Reconciliation

Background

Patients often receive new medications or have changes made to their existing medications at times of transitions in care—upon hospital admission, transfer from one unit to another during hospitalization, or discharge from the hospital to home or another facility. Although most of these changes are intentional, unintended changes occur frequently for a variety of reasons. For example, hospital-based clinicians might not be able to easily access patients' complete pre-admission medication lists, or may be unaware of recent medication changes. As a result, the new medication regimen prescribed at the time of discharge may inadvertently omit needed medications, unnecessarily duplicate existing therapies, or contain incorrect dosages. These discrepancies place patients at risk for adverse drug events (ADEs), which have been shown to be one of the most common types of adverse events after hospital discharge. Medication reconciliation refers to the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission, transfer, and discharge and comparing it with the regimen being considered for the new setting of care.



Source: Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med. 2005;165:424-429. [go to PubMed]

Accomplishing Medication Reconciliation

The evidence supporting patient benefits from reconciling medications is relatively scanty. Most medication reconciliation interventions have focused on attempting to prevent medication errors at hospital admission or discharge, but the most effective and generalizable strategies remain unclear. A 2016 systematic review found evidence that pharmacist-led processes could prevent medication discrepancies and potential ADEs at hospital admission, in-hospital transitions of care (such as transfer into or out of the intensive care unit), and at hospital discharge. A 2013 systematic review published as part of the AHRQ *Making Health Care Safer II* report also found that pharmacist engagement in medication reconciliation prevented discrepancies and potential ADEs after discharge. However, both the actual clinical effect of medication discrepancies after discharge appears to be small, and therefore, medication reconciliation alone does not reduce readmissions or other adverse events after discharge.

Information technology solutions are being widely studied, but their effect on preventing medication discrepancies and improving clinical outcomes is similarly unclear. A 2016 systematic review found that electronic tools often lacked the functionality to accurately reconcile medications, perhaps explaining why medication discrepancies persist even in organizations with fully integrated electronic medical records. Several studies have also investigated the role of enhanced patient engagement in medication reconciliation in the outpatient setting and after hospital discharge. These efforts are promising but also lack evidence regarding the impact on medication error rates.

Medication reconciliation has therefore become an example of a safety intervention that has been effective in research settings but has been difficult to implement successfully in general practice. A 2016 commentary identified the major reasons for difficulty achieving safety improvements via medication reconciliation. They include the resource intensive nature of interventions such as clinical pharmacists, which disincentivizes organizations from investing in medication reconciliation; the alterations to clinical workflow that result from interventions, which creates inefficiencies and confusion regarding the best possible medication history; and conflict between medication reconciliation and other system quality improvement

priorities, such as patient flow improvement. The commentary provides recommendations for organizations, clinicians, and researchers on how to better implement and evaluate medication reconciliation interventions.

Current Context

Medication reconciliation was named as 2005 National Patient Safety Goal #8 by the Joint Commission. The Joint Commission's announcement called on organizations to "accurately and completely reconcile medications across the continuum of care." In 2006, accredited organizations were required to "implement a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient" and to communicate "a complete list of the patient's medications to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization."

The Joint Commission suspended scoring of medication reconciliation during on-site accreditation surveys between 2009 and 2011. This policy change was made in recognition of the lack of proven strategies for accomplishing medication reconciliation. As of July 2011, medication reconciliation has been incorporated into National Patient Safety Goal #3, "Improving the safety of using medications." This National Patient Safety Goal requires that organizations "maintain and communicate accurate medication information" and "compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies."

Editor's Picks

WEB RESOURCE › MULTI-USE WEBSITE

National Patient Safety Goals.

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CASE

A Pill Organizing Plight

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The problem with medication reconciliation.

Pevnick JM, Shane R, Schnipper JL. BMJ Qual Saf. 2016;25:726-730.

TOOLS/TOOLKIT › TOOLKIT

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JOURNAL ARTICLE › REVIEW

Hospital-based medication reconciliation practices: a systematic review.

Mueller SK, Sponsler KC, Kripalani S, Schnipper JL. Arch Intern Med. 2012;172:1057-1069.

JOURNAL ARTICLE › STUDY

Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases.

Bell CM, Brener SS, Gunraj N, et al. JAMA. 2011;306:840-847.

CASE

Reconciling Records

CASE

Medication Reconciliation Pitfalls

JOURNAL ARTICLE › STUDY

Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial.

Schnipper JL, Hamann C, Ndumele CD, et al. Arch Intern Med. 2009;169:771-780.

CASE

Medication Reconciliation Victory After an Avoidable Error

CASE

Hospital Admission Due to High-Dose Methotrexate Drug Interaction

PERSPECTIVE

Integrating Multiple Medication Decision Support Systems: How Will We Make It All Work?

CASE

Medication Reconciliation: Whose Job Is It?

JOURNAL ARTICLE › STUDY

Role of pharmacist counseling in preventing adverse drug events after hospitalization.

Schnipper JL, Kirwin JL, Cotugno MC, et al. Arch Intern Med. 2006;166:565-571.

CASE

Reconciling Doses

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PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: November 2017

Missed Nursing Care

Background

Nurses have a central role in patient safety, as discussed in a previous Patient Safety Primer. There is a well-established link between the adequacy of nurse staffing in hospitals and patient outcomes such as mortality and failure-to-rescue. However, the pathway that connects nurse staffing with patient outcomes is less well understood. One proposed pathway is the amount of surveillance, or ongoing assessment and reassessment of patient condition, that can be provided under a given staffing structure. A related proposed pathway is missed nursing care.

Missed nursing care is a subset of the category known as error of omission. It refers to needed nursing care that is delayed, partially completed, or not completed at all. Missed nursing care is problematic because nurses coordinate, provide, and evaluate many interventions prescribed by others to treat illness in hospitalized patients. Moreover, nurses also plan, deliver, and evaluate nurse-initiated care to manage patients' symptoms and responses to care, and to promote health and healing. Thus missed nursing care not only constitutes a form of medical error that may affect safety, but has been deemed to be a unique type of medical underuse.

Following Donabedian's structure–process–outcome framework, Kalisch and colleagues developed a conceptual model of missed nursing care (also described by others as "unfinished nursing care" and "care left undone"). The structural factors contributing to missed nursing care include: labor resources (number and types of nursing staff, competency level of nursing staff, education and experience of staff; material resources (availability of necessary medications, supplies, and equipment); and teamwork and communication (among the patient care team members, between nurses and physicians, between nurses and

support staff). When one or more of these resources is missing from an organization or during a work period, nurses need to prioritize their care activities and the stage is set for nursing care to be delayed or omitted.

In Kalisch's model, a nurse faced with restricted resources uses the nursing process to determine clinical priorities and make decisions about whether to delay or omit certain aspects of care. The decision process is influenced by four individual-level factors: the nurse's perceptions of team or group norms; the nurse's judgment about the importance of various aspects of care relative to the conditions of multiple patients the nurse may be responsible for; the nurse's values, attitudes, and beliefs; and the nurse's usual practice. The outcome of the clinical prioritization process in the face of resource or time scarcity is missed nursing care. An AHRQ WebM&M commentary highlights the potentially catastrophic consequences of the competing demands nurses may face in executing needed care.

The more routine consequences of missed nursing care can include delayed or omitted medications or treatments; complications such as atelectasis, deconditioning, pressure ulcers, falls, ventilator-associated pneumonia, or other nosocomial infections; increased length of stay; and decreased patient satisfaction. Kalisch's model also implies that organizational conditions can promote normalization of deviance—even when missed nursing care does not result in observable adverse effects. The experience of working under time and resource pressure can unconsciously reinforce the acceptability of delaying or omitting care, leading to missed care becoming routine.

Evidence

The prevalence of missed nursing care appears to be high, both in the United States and internationally. Data for missed care measures are obtained by nursing self-report and by patient report. In a systematic review of 42 studies, 55%–98% of nurse respondents reported missing one or more items of required care during the time of assessment (frequently the last shift worked). Investigators concluded the activities most frequently missed are those related to emotional and psychological needs, rather than those related to physiologic needs (however, findings vary depending on the measurement approach). For example, one measurement approach found that ambulation, turning, and mouth care were among the

most frequently missed aspects of care. Another approach found surveillance activities were most frequently missed.

Although individual nurse-level factors are included in the conceptual model for missed nursing care, these factors have not proven to be associated with missed care. The only exception is that nurses report more missed care than do nursing assistants. On the other hand, organizational factors such as patient safety climate, teamwork, and resource adequacy are associated with missed nursing care. In one large review, missed nursing care was correlated with quality of care and adverse events and had a moderate effect on patient outcomes. Statistically significant impacts were demonstrated on medication errors, patient falls, nosocomial infections, pressure ulcers, mortality, and patient satisfaction.

Units with better staffing appear to have lower rates of missed nursing care. This finding suggests that improving staffing will reduce missed nursing care, but this hypothesis has not yet been tested in an intervention study. A study of an intra-nursing teamwork training intervention showed improved short-term teamwork and less missed care at 2 months post-intervention. Though this intervention is potentially promising, there was no longer-term evaluation of sustainability and no testing of patient outcomes.

Prevention

The most consistent predictors of missed nursing care are staffing levels, work environment, and teamwork, though few interventions to address missed care have been evaluated. Thus missed nursing care can today be best understood as a common safety and quality threat for which there is not yet strong evidence regarding effective solutions. However, several conclusions can be drawn based upon the predictors of missed nursing care.

First, missed nursing care is primarily a problem of time pressure and competing demands, and adequate nurse staffing is needed to prevent it. Evaluation of organizational nurse staffing plans should include not just the average needs of nursing units, but also careful assessment of how frequently surges in demand or patient complexity affect the adequacy of staffing. Creativity and careful analysis may be required to develop mechanisms to nimbly deploy appropriately skilled nursing staff to clinical areas experiencing an influx of admissions, unexpectedly high numbers of complex patients, or unusually depleted staff.

Second, organizational and unit culture influence missed nursing care. Improvements in the work environment, unit safety climate, organizational culture, and teamwork skills should reduce the pressures that lead to missed nursing care. Qualitative research has found that adaptable teams can help mitigate missed care. In times of resource pressures and scarcity, such teams tend to orient themselves toward caring for the whole group of patients, mostly by assisting each other to complete needed care rather than focusing only on their own patient assignments. Cultivating cross-monitoring and cooperative problem-solving skills among staff may decrease the frequency of missed nursing care.

Third, the organization of nursing work and the organization of the supply chain that supports nursing work may contribute to preventing missed care. A well-organized, reliable supply chain for medications, clinical supplies, and equipment may contribute to nurses' capacity to complete all required care. Some authors suggest that moderate or radical rethinking of responsibilities may be required in nursing to meet the needs of patients and the profession. Specific to preventing missed nursing care, ambulation and turning—two aspects of care that are frequently missed—may be best addressed by reconfiguration of the medical–surgical nursing team to include full-time ambulation and turning assistants to ensure that patients are assisted to the bathroom and turned or repositioned every 2 hours. This has not been tested, but it might be an effective component of programs to eliminate missed nursing care.

Consideration of all of the above factors is likely to result in improved work environments for nurses, which may augment patient outcomes by enhancing teamwork and reducing time pressure, cognitive load, and burnout. Indeed, results from a study of Pennsylvania hospitals suggest that more than 30% of nurses had high burnout scores, and higher burnout among nursing staff may explain the relationship between poorer nurse staffing and increased nosocomial infection rates. Several investigators suggest that addressing work environment issues and burnout among providers are essential to achieving safety, quality, and value in health care.

Current Context

Missed nursing care is a common and potentially dangerous medical error that has received limited attention. Considerable organizational attention, quality improvement, and safety research are needed to develop effective interventions to address this safety hazard.

Editor's Picks

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Post-operative mortality, missed care and nurse staffing in nine countries: a cross-sectional study.

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Patient-reported missed nursing care correlated with adverse events.

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JOURNAL ARTICLE › STUDY

'Care left undone' during nursing shifts: associations with workload and perceived quality of care.

Ball JE, Murrells T, Rafferty AM, Morrow E, Griffiths P. BMJ Qual Saf. 2014;23:116-125.

JOURNAL ARTICLE › STUDY

Associations of patient safety outcomes with models of nursing care organization at unit level in hospitals.

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PERSPECTIVE

In Conversation With… Jack Needleman, PhD

PERSPECTIVE

In Conversation With… Ann L. Hendrich, RN, PhD

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Effects of nurse staffing and nurse education on patient deaths in hospitals with different nurse work environments.

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CASE

The Forgotten Turn

CASE

Nurse Staffing Ratios: The Crucible of Money, Policy, Research, and Patient Care

JOURNAL ARTICLE › COMMENTARY

Missed nursing care: a concept analysis.

Kalisch BJ, Landstrom GL, Hinshaw AS. J Adv Nurs. 2009;65:1509-1517.

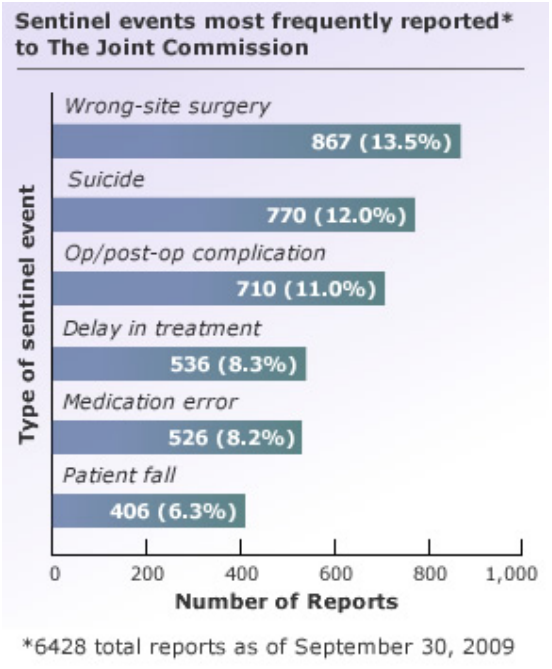
PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

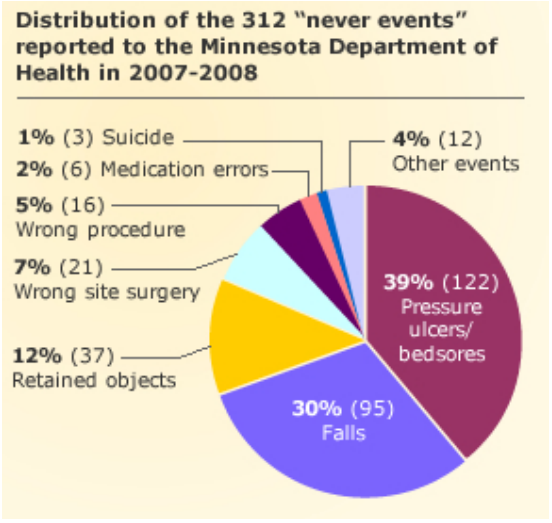
Never Events

Background

The term "Never Event" was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into 7 categories: surgical, product or device, patient protection, care management, environmental, radiologic, and criminal.



Source: Sentinel Event Statistics. September 30, 2009. The Joint Commission Web site.



Source: Adverse Health Events in Minnesota. Fifth Annual Public Report. St. Paul, MN: Minnesota Department of Health; January 2009. Available at: http://www.health.state.mn.us/patientsafety/publications/consumerguide.pdf. Accessed December 30, 2009.

Table. Never Events, 2011
The National Quality Forum's Health Care "Never Events" (2011 Revision)
Surgical events
Surgery or other invasive procedure performed on the wrong body part
Surgery or other invasive procedure performed on the wrong patient
Wrong surgical or other invasive procedure performed on a patient
Unintended retention of a foreign object in a patient after surgery or other procedure
Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists Class I patient
Product or device events
Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting
Patient protection events
Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
Patient death or serious disability associated with patient elopement (disappearance)
Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility
Care management events
Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

Patient death or serious injury associated with unsafe administration of blood products
Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
Artificial insemination with the wrong donor sperm or wrong egg
Patient death or serious injury associated with a fall while being cared for in a health care setting
Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility
Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
Environmental events
Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a health care setting
Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting
Patient death or serious injury associated with the use of restraints or bedrails while being cared for in a health care setting
Radiologic events
Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area
Criminal events
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
Abduction of a patient/resident of any age
Sexual abuse/assault on a patient within or on the grounds of a health care setting
Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

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Most Never Events are very rare. For example, a 2006 study estimated that a typical hospital might experience a case of wrong-site surgery once every 5 to 10 years. However, when Never Events occur, they are devastating to patients–71% of events reported to the Joint Commission over the past 12 years were fatal–and may indicate a fundamental safety problem within an organization. Although individual events are uncommon, on a population basis, many patients still experience these serious errors. A 2013 study estimated that more than 4000 surgical never events occur yearly in the United States.

The Joint Commission has recommended that hospitals report "sentinel events" since 1995. Sentinel events are defined as "an unexpected occurrence involving death or serious physiological or psychological injury, or the risk thereof." The NQF's Never Events are also considered sentinel events by the Joint Commission. The Joint Commission mandates performance of a root cause analysis after a sentinel event. The Leapfrog Group recommends that in addition to an RCA, organizations should disclose the error and apologize to the patient, report the event, and waive all costs associated with the event.

Current Context

Because Never Events are devastating and preventable, health care organizations are under increasing pressure to eliminate them completely. The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered Never Events. Since then, many states and private insurers have adopted similar policies. Since February 2009, CMS has not paid for any costs associated with wrong-site surgeries.

Never Events are also being publicly reported, with the goal of increasing accountability and improving the quality of care. Since the NQF disseminated its original Never Events list in 2002, 11 states have mandated reporting of these incidents whenever they occur, and an additional 16 states mandate reporting of serious adverse events (including many of the NQF Never Events). Health care facilities are accountable for correcting systematic problems that contributed to the event, with some states (such as Minnesota) mandating performance of a root cause analysis and reporting its results.

Editor's Picks

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Surgical never events and contributing human factors.

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BOOK/REPORT

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PERSPECTIVE

Advancing Patient Safety Through State Reporting Systems

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TOOLS/TOOLKIT › FACT SHEET/FAQS

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JOURNAL ARTICLE › STUDY

Incidence, patterns, and prevention of wrong-site surgery.

Kwaan MR, Studdert DM, Zinner MJ, Gawande AA. Arch Surg. 2006;141:353-358.

BOOK/REPORT

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WEB RESOURCE › MULTI-USE WEBSITE

Sentinel Event.

The Joint Commission.

CASE

The Other Side

PSNet
PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Nursing and Patient Safety

Background

Doctors are perceived—by patients and clinicians—as being the captain of the health care team, with good reason. But, physicians may spend only 30 to 45 minutes a day with even a critically ill hospitalized patient, whereas nurses are a constant presence at the bedside and regularly interact with physicians, pharmacists, families, and all other members of the health care team. Of all the members of the health care team, nurses therefore play a critically important role in ensuring patient safety by monitoring patients for clinical deterioration, detecting errors and near misses, understanding care processes and weaknesses inherent in some systems, and performing countless other tasks to ensure patients receive high-quality care.

Nurse staffing and patient safety

Nurses' vigilance at the bedside is essential to their ability to ensure patient safety. It is logical, therefore, that assigning increasing numbers of patients eventually compromises nurses' ability to provide safe care. Several seminal studies have demonstrated the link between nurse staffing ratios and patient safety, documenting an increased risk of patient safety events, morbidity, and even mortality as the number of patients per nurse increases. The strength of these data has led several states, beginning with California in 2004, to establish legislatively mandated minimum nurse-to-patient ratios; in California, acute medical–surgical inpatient units may assign no more than five patients to each registered nurse.

The nurse-to-patient ratio is only one aspect of the relationship between nursing workload and patient safety. Overall nursing workload is likely linked to patient outcomes as well. A sophisticated 2011 study showed that increased patient turnover was also associated with

increased mortality risk, even when overall nurse staffing was considered adequate. Determining adequate nurse staffing is a very complex process that changes on a shift-by-shift basis, and requires close coordination between management and nursing based on patient acuity and turnover, availability of support staff and skill mix, and many other factors. The process of establishing nurse staffing on a unit-by-unit and shift-by-shift basis is discussed in detail in an AHRQ WebM&M commentary.

Nursing skill mix and training may also be linked to patient outcomes. One classic study showed lower inpatient mortality rates for a variety of surgical patients in hospitals with more highly educated nurses. This finding has resulted in calls for all nurses to have at least a baccalaureate education. Irrespective of educational level, the quality of nurses' on-the-job training may also play a role in patient outcomes. As discussed in an AHRQ WebM&M commentary, nurses do not currently have a standardized transition to independent practice training requirement (analogous to medical residency training). Less experienced nurses may therefore lack mentorship and training in dealing with systems issues and complex clinical scenarios.

Nurses' working conditions and patient safety

The causal relationship between nurse-to-patient ratios and patient outcomes likely is accounted for by both increased workload and increased stress and risk of burnout for nurses. Missed nursing care—a type of error of omission in which required care elements are not completed—is relatively common on inpatient wards. In one British study, missed nursing care episodes were strongly associated with a higher numbers of patients per nurse. Burnout among clinicians (both nurses and physicians) has consistently been linked to patient safety risks, and some studies show that higher numbers of patients per nurse is correlated with increased risk of burnout among nurses.

The high-intensity nature of nurses' work means that nurses themselves are at risk of committing errors while providing routine care. Human factors engineering principles hold that when an individual is attempting a complex task, such as administering medications to a hospitalized patient, the work environment should be as conducive as possible for carrying out the task. However, operational failures such as interruptions or equipment failures may interfere with nurses' ability to perform such tasks; several studies have shown that

interruptions are virtually a routine part of nurses' jobs. These interruptions have been tied to an increased risk of errors, particularly medication administration errors. While some interruptions are likely important for patient care, the link between interruptions and errors is one example of how deficiencies in the day-to-day work environment for nurses is directly linked to patient safety.

Longer shifts and working overtime have also been linked to increased risk of error, including in one high-profile case where an error committed by a nurse working a double shift resulted in the nurse being criminally prosecuted. Nurses who commit errors are at risk of becoming second victims of the error, a well-documented phenomenon that is associated with an increased risk of self-reported error and leaving the nursing profession. In their daily work, nurses are also frequently exposed to disruptive or unprofessional behavior by physicians and other health care personnel, and such exposure has been demonstrated to be a key factor in nursing burnout and in nurses leaving their job or the profession entirely.

All of these factors—the high-risk nature of the work, increased stress caused by workload and interruptions, and the risk of burnout due to involvement in errors or exposure to disruptive behavior—likely combine with unsafe conditions precipitated by low nurse-to-patient ratios to increase the risk of adverse events. Using a systems analysis perspective, active errors made by individual nurses likely combine with these aligned holes in the "Swiss Cheese Model of Medical Errors" to result in preventable harm.

Current context

The National Quality Forum endorsed voluntary consensus standards for nursing-sensitive care in 2004. These included patient-centered outcomes considered to be markers of nursing care quality (such as falls and pressure ulcers) and system-related measures including nursing skill mix, nursing care hours, measures of the quality of the nursing practice environment (which includes staffing ratios), and nursing turnover. These measures are intended to illustrate both the quality of nursing care and the degree to which the working environment at an institution supports nurses in their patient safety efforts.

The Magnet Hospital Recognition Program, administered by the American Nurses Credentialing Center (a subsidiary of the American Nurses Association), seeks to recognize hospitals that deliver superior patient care and, partly on this basis, attract and retain high-

quality nurses. The program has its genesis in a 1983 study that sought to identify hospitals that retained nurses for longer than average periods of time. The study identified institutional characteristics correlated with high retention rates, an important finding in light of a major nursing shortage at the time. These findings led 10 years later to the formal Magnet Program.

As of September 2015, 14 states have enacted legislation or adopted regulations around nurse staffing ratios. Mandatory overtime for nurses is also restricted in 16 states.

Editor's Picks

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'Care left undone' during nursing shifts: associations with workload and perceived quality of care.

Ball JE, Murrells T, Rafferty AM, Morrow E, Griffiths P. BMJ Qual Saf. 2014;23:116-125.

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CASE

Are We Pushing Graduate Nurses Too Fast?

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Shaping systems for better behavioral choices: lessons learned from a fatal medication error.

Smetzer J, Baker C, Byrne FD, Cohen MR. Jt Comm J Qual Patient Saf. 2010;36:152-163, 1AP-2AP.

CASE

Difficult Encounters: A CMO and CNO Respond

WEB RESOURCE › MULTI-USE WEBSITE

Nursing Care Quality at NQF.

National Quality Forum.

CASE

Nurse Staffing Ratios: The Crucible of Money, Policy, Research, and Patient Care

JOURNAL ARTICLE › STUDY

Nurse working conditions and patient safety outcomes.

Stone PW, Mooney-Kane C, Larson EL, et al. Med Care. 2007;45:571-578.

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BOOK/REPORT

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JOURNAL ARTICLE › STUDY

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Aiken LH, Clarke SP, Cheung RB, Sloane DM, Silber JH. JAMA. 2003;290:1617-1623.

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PATIENT SAFETY NETWORK

Patient Safety Primer Last Updated: June 2017

Patient Engagement and Safety

Background

The traditional paternalistic model of medicine, in which patients have little voice in their care, has slowly but surely been evolving toward a model in which patients and clinicians work in a partnership toward the common goal of improved health. As articulated in the seminal Institute of Medicine report *Crossing the Quality Chasm*, such patient-centered care should be "respectful of and responsive to individual patient preferences, needs, and values and ensure that patient values guide all clinical decisions."

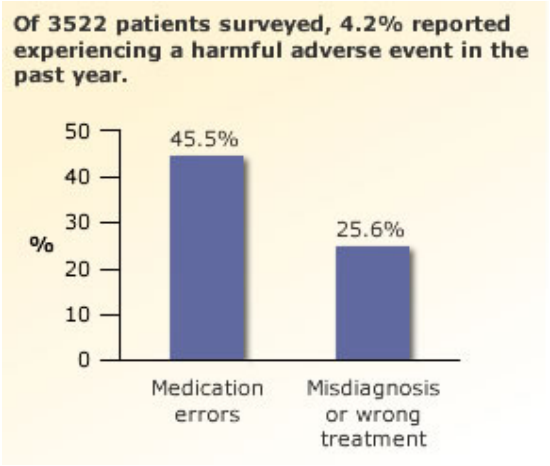
While many patient safety interventions have used traditional models of effecting change, such as changing provider behavior, encouraging interprofessional collaboration, and enhancing the culture of safety, the patient's role in safety has not been overlooked. The Joint Commission mandated that health care organizations "encourage patients' active involvement in their own care as a patient safety strategy" as a National Patient Safety Goal in 2007, catalyzing research into how patients may partner with providers to prevent errors–and how patients may themselves inadvertently precipitate errors.

Patients' Role in Preventing Errors

Efforts to engage patients in safety efforts have focused on three areas: enlisting patients in detecting adverse events, empowering patients to ensure safe care, and emphasizing patient involvement as a means of improving the culture of safety.

Hospitalized patients are routinely surveyed about their satisfaction with the care they received, and recent research has examined whether patient surveys may be used as an error detection mechanism. Studies in the inpatient setting have found that patients often report errors that were not detected through traditional mechanisms such as chart review; indeed,

patient-reported errors formed the basis of landmark studies of adverse events after hospital discharge. Concerns have been raised, however, that patient complaints may center on poor service quality rather than on clinical adverse events.



Source: Adams RJ, Tucker G, Price K, et al. Self-reported adverse events in health care that cause harm: a population-based survey. Med J Aust. 2009;190:484-488. [go to PubMed]

Patients are also being encouraged to take an active role in their own safety. The Agency for Healthcare Research and Quality's Questions Are the Answer program and 20 Tips to Help Prevent Medical Errors fact sheet, as well as The Joint Commission's Speak Up initiative, are examples of programs that educate patients about safety hazards and provide specific questions that patients (and their caregivers) can ask regarding safety. Although patients have voiced concerns about engaging in behaviors that may seem confrontational (for example, asking their clinician if she washed her hands), some preliminary studies have found that active engagement of patients can improve adherence to safety practices. The widespread availability of electronic medical records is also being used as an opportunity to engage patients in safety efforts. Early studies have leveraged information technology to incorporate patients in medication reconciliation and early identification of outpatient adverse drug events.

Finally, hospitals are increasingly recognizing the crucial role of patients' perspectives in establishing a culture of safety. Many institutions (such as the Dana-Farber Cancer Institute) have prioritized engaging patient representatives in the design and nurturing of safety efforts, and emphasize transparency in reporting errors and care problems. The active engagement of patients in safety efforts has extended to allowing patients and families to summon rapid response teams, rather than waiting for clinicians to respond. Studies in the intensive care

unit and inpatient pediatric wards have shown that interventions that explicitly include patient and family engagement can improve safety culture and may reduce adverse event rates.

Although patient engagement is a promising strategy for error reduction, there is reason for caution on several grounds. From a systems engineering viewpoint, the level of patient and family participation will always be difficult to predict, leading some to argue that a robust safety program should not depend on such engagement. Furthermore, patients and caregivers already shoulder a significant emotional burden for ensuring safety while hospitalized. An important study found that a surprising number of patients and family members feel guilty after a medical error, and another study found that most parents of hospitalized children felt personally responsible for ensuring their child's safety in the hospital. Engaging patients in error prevention therefore risks simply shifting the responsibility for safety from providers and institutions to patients themselves.

Patients' Role in Precipitating Errors

Patients themselves may be a cause of errors as well as a solution, and some early studies have sought to analyze and classify patient errors. These errors arise from the same underlying causes that contribute to clinicians' errors–while patients may engage in intentionally unsafe behavior, more commonly, patient errors are attributable to the difficulties inherent in an individual's interaction with a complex system. One study classified patient errors into *action errors*, which are errors of patient behavior such as failure to attend a scheduled appointment, and *mental errors*, which include thought process errors such as failing to take a medication as prescribed. Both of these types of error are influenced by other definable safety hazards; for example, low health literacy and poor provider–patient communication are clearly linked to medication errors. Therefore, a useful construct may be to view patient error as an undesirable outcome that clinicians should actively seek to prevent, using tools that target known risk factors for such errors. For example, lack of knowledge or fear of asking questions may cause patients to take medications incorrectly, but interventions such as pictogram-based medication labels can decrease dosing errors and improve medication adherence.

Current Context

Patient engagement in safety efforts is a strong priority of influential regulatory and governmental organizations. The Agency for Healthcare Research and Quality and the World Health Organization sponsor a variety of programs centered around patient education and encouraging patient perspectives to improve safety culture. In addition to its prioritization of patient engagement through the National Patient Safety Goal, The Joint Commission also provides educational resources for patients around safety measures in pediatric, hospital, and surgical settings.

Editor's Picks

BOOK/REPORT

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WEB RESOURCE › MULTI-USE WEBSITE

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PERSPECTIVE

Patient Engagement and Patient Safety

PERSPECTIVE

In Conversation With… Beverley H. Johnson

TOOLS/TOOLKIT › FACT SHEET/FAQS

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PERSPECTIVE

In Conversation with...Dean Schillinger, MD

PERSPECTIVE

The Role of Health Literacy in Patient Safety

JOURNAL ARTICLE › STUDY

Comparing patient-reported hospital adverse events with medical record review: do patients know something that hospitals do not?

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BOOK/REPORT

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WEB RESOURCE › MULTI-USE WEBSITE

Questions Are the Answer.

Agency for Healthcare Research and Quality.

PERSPECTIVE

In Conversation with...Sorrel King

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WEB RESOURCE › MULTI-USE WEBSITE

The Josie King Foundation.

Tony and Sorrel King.

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PERSPECTIVE

Organizational Change in the Face of Highly Public Errors—I. The Dana-Farber Cancer Institute Experience

CASE

Lethal Cap

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Patient Safety Primer Last Updated: June 2017

Patient Safety 101

The History of the Patient Safety Movement

The concept that patients could be harmed while receiving medical care has been known for thousands of years, since Hippocrates coined the phrase "first, do no harm." The term *iatrogenesis*—still used today to indicate harm experienced by patients at the hands of the medical system—stems from the Greek for "originating from a physician."

Although the idea of medical mistakes has been long known, the modern literature began with a famous 1956 *New England Journal of Medicine* paper discussing diseases of medical progress. Yet, despite research that continued to document frequent episodes of preventable harm in hospitalized patients, the safety field remained small and relatively ignored until the 1990s. The 1994 publication of the seminal commentary, "Error in Medicine," by Dr. Lucian Leape highlighted the issue and presented a framework for error analysis and prevention that is still used today. In 1999, the Institute of Medicine's *To Err Is Human* famously estimated that 44,000–98,000 Americans die each year due to preventable harm. Most consider its publication to represent the beginning of the modern patient safety movement. Since *To Err Is Human,* considerable attention has been paid to improving patient safety in hospitals, and increasingly in other settings of care as well. While much remains to be done, recent years have brought a much deeper understanding of the causes of safety issues and some progress in reducing preventable harm.

This Primer is intended to provide an overview of patient safety through defining key concepts and linking to other Primers that explore specific safety concepts in more detail.

Definitions Used in Patient Safety

The patient safety field uses the term *adverse events* to describe patient harm that arises as a result of medical care (rather than from the underlying disease). Important subcategories of adverse events include:

- Preventable adverse events: those due to error or failure to apply an accepted strategy for prevention;
- Ameliorable adverse events: events that, while not preventable, could have been less harmful if care had been different;
- Adverse events due to negligence: those due to care that falls below the standards expected of clinicians in the community.

Two other terms are used to describe hazards to patients that do not result in harm:

- Near miss: an unsafe situation that is indistinguishable from a preventable adverse event except for the outcome. A patient is exposed to a hazardous situation but does not experience harm (either through luck or early detection).
- Error: a broader term referring to any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes patients to a potentially hazardous situation.

The Adverse Events, Near Misses, and Errors Primer discusses these terms in more detail and explores controversies regarding these definitions. The Detection of Safety Hazards Primer describes how errors and adverse events are identified and analyzed, with the goal of preventing future harm.

Epidemiology of Preventable Harm

Multiple studies have found that 10%–12% of hospitalized patients experience adverse events, with approximately half of these events considered preventable. While there is general consensus about the frequency of preventable harm in hospitals, the number of deaths that directly results from these preventable adverse events is controversial, with different studies producing widely varying estimates. This controversy arises in part because measurement of specific adverse events remains a complex and evolving area, and there is no gold standard

for measuring overall safety at an institutional level. Even when an adverse event is detected, it can be difficult to determine whether the event was preventable. These concepts are discussed in more detail in the Measurement of Patient Safety Primer. Regardless, it is clear that each hospital likely has several preventable deaths per year, and a 2016 Annual Perspective explores methods by which hospitals can detect and analyze preventable deaths to try to improve overall safety.

The prevalence of preventable adverse events has not been as extensively studied in other health care settings, but a growing body of research documents that preventable harm is common in all sites of care. Most health care is delivered in the outpatient setting, and studies of outpatients have shown comparable rates of harm to those in hospitalized patients. Recent studies analyzing harm in Medicare patients in long-term care and rehabilitation hospitals have also found that more than 10% of patients in these settings experience adverse events. It has also been well documented that transitions of care are particularly risky, especially after hospital discharge. Further information on safety in these settings may be found in the Primers on Ambulatory Care Safety, Long-term Care and Patient Safety, and Readmissions and Adverse Events After Discharge.

The Systems Approach to Analyzing Patient Safety

Why are adverse events so common in medical care? Key insights from work in other fields have shaped medicine's response to analyzing why errors occur and informed more effective solutions to safety issues.

Traditionally, medicine treated errors as failings on the part of individual providers, reflecting inadequate knowledge or skill. However, pioneering work by British psychologist James Reason—who analyzed errors in fields as diverse as aviation and nuclear power—revealed that catastrophic safety failures are almost never caused by isolated errors committed by individuals. Instead, most accidents result from multiple, smaller errors in environments that have serious underlying system flaws. Reason's work led to the development of the systems approach, which takes the view that most errors reflect predictable human failings in the context of poorly designed systems. The systems approach seeks to identify situations or factors likely to give rise to human error and change the underlying systems of care in order to reduce the occurrence of errors or minimize their impact on patients.

Reason introduced the now-famous Swiss cheese model to describe this phenomenon. In this model, errors made by individuals result in disastrous consequences due to flawed systems—the holes in the cheese. This model is explored in more detail in the Systems Approach Primer.

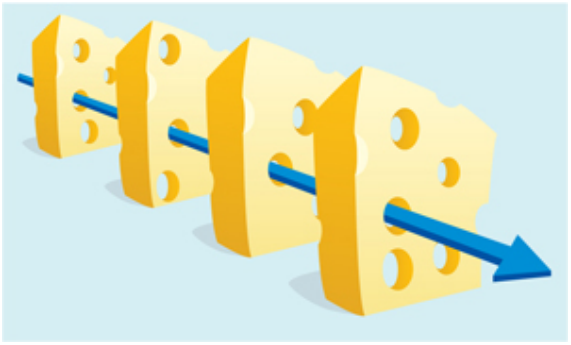

Figure. The Swiss Cheese Model of Medical Errors

It is important to note that the Swiss cheese model does not absolve individual clinicians from responsibility. Rather, it puts individual actions in the appropriate context and recognizes that the vast majority of errors are committed by well-trained, well-intentioned clinicians. As Dr. Don Berwick, the former director of the Centers for Medicare and Medicaid Services and the Institute for Healthcare Improvement, has said, "Most serious medical errors are committed by competent, caring people doing what other competent, caring people would do." Nevertheless, there is a role for individual accountability in patient safety, particularly when clinicians commit negligent acts or skirt established safety practices. The concept of just culture, now widely used in health care, emphasizes that most errors result from system flaws but also delineates where individuals should be held accountable. Further aspects of this issue are discussed in the Culture of Safety Primer and in a 2015 Annual Perspective.

Progress and Current Challenges in Patient Safety

The seminal Agency for Healthcare Research and Quality (AHRQ) *Making Health Care Safer* report, issued in 2001, was the first effort to use evidence-based medicine principles in identifying practices to improve patient safety. The report galvanized patient safety efforts at hospitals nationwide and laid the foundation for further research, resulting in some of the most prominent successes in the safety field. In the past decade, thousands of lives have been saved thanks to innovative efforts to reduce health care–associated infections, prevent surgical complications, and improve teamwork among clinicians. Progress has also been

made in efforts to build a climate of safety in health care, in which errors are routinely discussed and treated as learning opportunities and clinicians who are involved in errors receive support rather than blame. The AHRQ *Making Health Care Safer II* report, published in 2013, added to the evidence base behind patient safety interventions, and data from AHRQ indicates that rates of preventable harm have declined significantly over the past several years.

Despite these successes, rates of preventable harm among patients remain unacceptably high, and new challenges have emerged that have hindered efforts to improve safety. One of the main new challenges to the safety field is the information technology revolution, which has transformed the day-to-day practice of medicine but has not always resulted in safer care. Some technological innovations, such as computerized provider order entry and barcode medication administration, have clearly improved safety. On the other hand, the widespread implementation of electronic medical records has often resulted in alert fatigue—and its attendant safety risks—becoming an everyday aspect of clinician workflow. Poorly designed electronic health records are frequently cited as a cause of burnout among physicians, which in itself is associated with patient safety risks.

Another challenge for the field is the need to improve safety across the continuum of care. Research in the field of patient safety began with studies of hospitalized patients. Only recently have researchers begun to analyze safety issues in ambulatory care and long-term care, and such research is starting to fill an important knowledge gap regarding effective safety interventions in these settings. More detail on safety issues in these settings may be found in the Ambulatory Care Safety and Long-term Care and Patient Safety Primers.

A final challenge relates to measurement of safety. The safety field continues to be limited by a lack of standardized measurement criteria, especially for diagnostic errors, which have not gained as much attention as other aspects of safety despite being quite common.

The National Patient Safety Foundation issued its *Free From Harm* report in 2015. Acknowledging these and other challenges to the safety field, the report made eight key recommendations to ensure continued progress in the safety field:

- Ensure that leaders establish and sustain a safety culture

- Create centralized and coordinated oversight of patient safety
- Create a common set of safety metrics that reflect meaningful outcomes
- Increase funding for research in patient safety and implementation science
- Address safety across the entire care continuum
- Support the health care workforce
- Partner with patients and families for the safest care
- Ensure that technology is safe and optimized to improve patient safety

As the patient safety field has matured, investigators have gained a better understanding of the underlying causes of adverse events and methods to prevent errors. There is now a general consensus that the field should shift from focusing on single types of adverse events, and instead emphasize designing safer systems of care. This shift is based on the recognition that unsafe systems put patients at risk of multiple different types of adverse events simultaneously. For example, a patient in the intensive care unit at an academic hospital may be at risk for medication errors, several different types of health care–associated infections, and procedural complications, as well as errors related to poor communication between clinicians or inadequate supervision of trainees. The interrelatedness of these errors requires using insights from human factors engineering and other disciplines to design safer systems of care, rather than implementing targeted programs to prevent individual harms. This shift, accompanied by more rigorous measurement, will be necessary for patient safety to continue to improve.

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Radiation Safety

Background

Technological advances in medicine have given physicians the tools to diagnose and treat diseases much more quickly and accurately than they did a generation ago. Diagnostic imaging techniques are an area in which improved and more available technology have tremendously benefited patients. However, as the use of diagnostic imaging technologies has increased, we have also come to appreciate the risks associated with these interventions. Foremost among these risks is the potential for harm related to excess exposure to ionizing radiation.

Several commonly used diagnostic imaging techniques include computed tomographic (CT) scans, fluoroscopy CT, and nuclear medicine scans. CT scans send X-rays through the body area being studied, with each scan rotation providing a slice of an organ or body area to form a complete picture of the area. Fluoroscopy uses a steady beam of X-rays to track movement of organs within the body, to guide a needle for biopsy, or to guide other instruments in real time during invasive procedures such as cardiac catheterization. Nuclear medicine scans use a special type of camera that images gamma-radiation–emitting radioisotopes in organs or tissues that have absorbed a radioactive tracer that is injected in a vein in the patient's arm. The camera image shows the activity and function of the tissues or organs being studied. Many patients are exposed to ionizing radiation during these scans. In addition, the increasing use of imaging—CT scans in particular—has exposed many patients to large doses of radiation. Since ionizing radiation has the potential to cause cancer by damaging a person's DNA, there is considerable concern (supported by a growing body of literature) that radiation exposure from medical imaging may put patients at risk for developing cancer. Cancer risk from radiation exposure is a future statistical risk that is not known at the time of

exposure. There are also risks of adverse events such as radiation burns (more common in radiotherapy), which are evident shortly after exposure.

Approximately 40% of patients diagnosed with cancer receive radiation therapy at some point in their treatment. As the use of radiotherapy for certain types of cancer has grown, providers and researchers have raised concerns about the safety of radiation exposure. This Patient Safety Primer will discuss the safety issues associated with the use of radiation, both for diagnosis and therapy.

Radiation Risks Associated With Diagnostic Imaging

Population-based studies show that the use of diagnostic imaging has exploded over the past two decades, with one population-based study showing that the number of CT scans per 1000 adult patients nearly tripled between 1996 and 2010. More than 85 million CT scans were performed in the United States in 2011. This has led to a dramatic increase in ionizing radiation exposure to individual patients and the general population. While other imaging techniques also use radiation, CT is estimated to account for half of all medical radiation exposure, partly because more CT scans are being performed, but also because the radiation dose per scan has increased. Newer multidetector CT scanners produce much higher resolution images, which can aid in diagnosis, but also expose patients to 30%–50% more radiation than older scanners. Since ionizing radiation is a known carcinogen, it is likely that some patients who undergo CT scans with high doses of radiation, or patients who undergo many CT scans, will develop cancer as a result of the scans. Although work in this area remains controversial, one study estimated that as many as 1 in 80 young women who undergo a multiphase CT scan (repeated scanning before and after injection of a contrast dye) of the abdomen and pelvis will develop cancer later in life as a result. The expansion of interventional radiology and interventional cardiology has also increased the use of fluoroscopy, which involves significant potential radiation exposure for both patients and staff.

Variability in radiation dose also plays a role in the increasing radiation exposure attributable to medical imaging. Radiation dose varies widely for different types of examinations and is operator- and facility-dependent as well. One study showed that even for the same type of CT examination, the radiation doses varied as much as 13-fold among different institutions and

different technologists within the same institution. This variation often occurs due to failure to adjust radiation dosage based on body size. Many experts believe that adequate images can be obtained with doses at the lower end of the ranges, as seen in such studies. To the extent that this is true, observed doses at the higher end of the ranges contribute to excessive radiation exposure even when the CT scan is clinically indicated. Use of higher-than-recommended radiation dosages can also increase radiation exposure to staff, and failure to appropriately narrow the radiation beam or shield body parts that do not need to be imaged can result in unnecessary radiation exposure even when a scan is indicated.

Risks Associated With Radiotherapy

The field of radiation oncology is technologically sophisticated, and radiotherapy requires close collaboration among physicians, technologists, and medical physicists. Like any procedure that requires close coordination with a multidisciplinary team, errors that occur with radiotherapy usually arise from multiple causes and are attributable to underlying systems issues, such as communication problems. A review of 30 years of published data on safety in radiotherapy found that the overall incidence of errors was relatively low, estimated at 1500 per 1 million treatment courses. However, this number is likely an underestimate, since there is currently no mandatory reporting standard for injuries due to radiotherapy.

Errors that harm patients generally involve overexposure to radiation, which can cause direct toxicity; cases of wrong-patient and wrong-site errors have also been reported. Root cause analyses of harmful radiotherapy errors often cite poor communication among providers, particularly at the treatment planning stage, as a common source of error. These issues may be exacerbated by the use of different software programs and varying types of radiotherapy equipment. A 2010 news investigation found that many cases in which patients experienced serious harm were due to wrong dosing or incorrect configuration of equipment, often attributable to inadequate training with new equipment, poor interoperability of systems, and other human factors engineering issues. Standards for licensure and certification of technologists and treatment facilities also vary among states.

Improving Radiation Safety

The Joint Commission issued a Sentinel Event Alert in 2011 that highlighted the risks of diagnostic imaging and outlined specific strategies organizations should take to minimize the

risks of radiation. The alert emphasized the importance of educating physicians on appropriate test utilization and standardizing equipment and radiation dosage as two key interventions. These guidelines call for ordering physicians, radiologists, and technologists to establish a system that prioritizes using the *right test* and the *right dose* of radiation to achieve the desired diagnostic objective. Since implementing processes for monitoring the safety of imaging equipment, establishing standards for test ordering, and standardizing radiation dosages will require considerable leadership support, The Joint Commission also emphasized the role of an overall culture of safety in addressing radiation safety specifically.

It is worth emphasizing that eliminating unnecessary imaging, or replacing CT scans with safer studies like ultrasounds or magnetic resonance imaging, is as important for reducing the risks from unnecessary radiation exposure as lowering the dose of radiation per imaging test. Information technology can supplement clinician education in this area. For example, a systematic review of studies showed that use of computerized provider order entry (which typically provides dosage and other guidance to doctors when they enter orders in the system) increases adherence to radiology test ordering guidelines and thereby decreases overall radiology use. Many professional societies and other organizations are now conducting large-scale campaigns to reduce unnecessary radiologic imaging and to improve safety by standardizing radiation dosing. Prominent national examples include the Image Wisely campaign and the pediatric initiative, Image Gently. The Joint Commission also has promoted a public awareness campaign on medical imaging safety.

Improving the safety of radiation therapy relies in part on similar principles, including enhancing safety culture and standardizing training and equipment. Given what is known about factors that contribute to radiotherapy errors, it seems plausible that teamwork training and attention to human factors engineering principles may augment safety, but formal studies of these approaches in radiation oncology are lacking.

Current Context

Like all issues that have been the subject of Sentinel Event Alerts, radiation safety will be monitored by The Joint Commission as part of its accreditation site visits. Several regulatory steps have also been taken to improve the safety of diagnostic imaging. For example, since many imaging tests are performed in outpatients, since 2012, the Centers for Medicare and

Medicaid Services has required the accreditation of freestanding facilities that provide advanced imaging services. The state of California now requires documentation and disclosure of the radiation dose of all CT examinations and requires that all radiation dose errors be formally reported and disclosed to patients.

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Rapid Response Systems

Background

Rapid response teams represent an intuitively simple concept: When a patient demonstrates signs of imminent clinical deterioration, a team of providers is summoned to the bedside to immediately assess and treat the patient with the goal of preventing intensive care unit transfer, cardiac arrest, or death. Such teams have become a widely used patient safety intervention due in large part to their inclusion in the Institute for Healthcare Improvement's "100,000 Lives Campaign" in 2005. However, the rapid response team concept has come to exemplify the tension between those arguing for swift implementation of conceptually attractive patient safety interventions supported by anecdotal evidence of benefit and those advocating a more rigorous, evidence-based–and inevitably slower–approach.

Patients whose condition deteriorates acutely while hospitalized often exhibit warning signs (such as abnormal vital signs) in the hours before experiencing adverse clinical outcomes. In contrast to standard cardiac arrest or "code blue" teams, which are summoned only after cardiopulmonary arrest occurs, rapid response teams are designed to intervene during this critical period, usually on patients on general medical or surgical wards.

Several different models of rapid response teams exist (see Table 1), and a 2006 consensus conference advocated use of the term "rapid response system" (RRS) as a unifying term. Hospitalists are increasingly assuming RRS duties, either as the primary responder or to assist nurse-led teams.

Table 1. Rapid Response System Models

Model	Personnel	Duties
Medical Emergency Team	Physicians (critical care or hospitalist) and nurses	• Respond to emergencies

Critical Care Outreach	Critical care physicians and nurses	• Respond to emergencies • Follow up on patients discharged from ICU • Proactively evaluate high-risk ward patients • Educate ward staff
Rapid Response Team	Critical care nurse, respiratory therapist, and physician (critical care or hospitalist) backup	• Respond to emergencies • Follow up on patients discharged from ICU • Proactively evaluate high-risk ward patients • Educate and act as liaison to ward staff

A useful construct is to consider RRSs as having "afferent" (the criteria for calling) and "efferent" (responsive) arms. Despite differences in team structure, the criteria used to summon the teams are generally similar. Bedside staff are encouraged to call the team when any of a number of prespecified criteria (Table 2) are met. At certain hospitals, patients and family members are also permitted to call the team. Recent research has focused on development of more sophisticated "track-and-trigger" bedside monitoring systems that could be used to automatically trigger intervention when certain physiologic abnormalities are detected.

Table 2. Typical Rapid Response System Calling Criteria

Any staff member may call the team if one of the following criteria is met:

- Heart rate over 140/min or less than 40/min
- Respiratory rate over 28/min or less than 8/min
- Systolic blood pressure greater than 180 mmHg or less than 90 mmHg
- Oxygen saturation less than 90% despite supplementation
- Acute change in mental status
- Urine output less than 50 cc over 4 hours
- Staff member has significant concern about the patient's condition

Additional criteria used at some institutions:

- Chest pain unrelieved by nitroglycerin
- Threatened airway
- Seizure
- Uncontrolled pain

Evidence of Effectiveness

Early publications on RRSs reported significant improvements in clinical outcomes, but multiple subsequent systematic reviews have tempered the initial enthusiasm. The best available evidence indicates that RRSs slightly reduce unexpected cardiac arrests in ward patients, but they do not affect overall in-hospital mortality. The reasons for the inconsistent effects of RRSs are complex, and in some cases, may be related to local practice and cultural reasons that result in the team being underutilized. RRSs are very popular among nursing staff and can contribute to detection of underlying patient safety issues in hospitals.

Current Context

Some form of rapid response team is present in most hospitals in the United States, spurred by the 2008 Joint Commission National Patient Safety Goal, which required hospitals to implement systems to enable "healthcare staff members to directly request additional assistance from a specially trained individual(s) when the patient's condition appears to be worsening."

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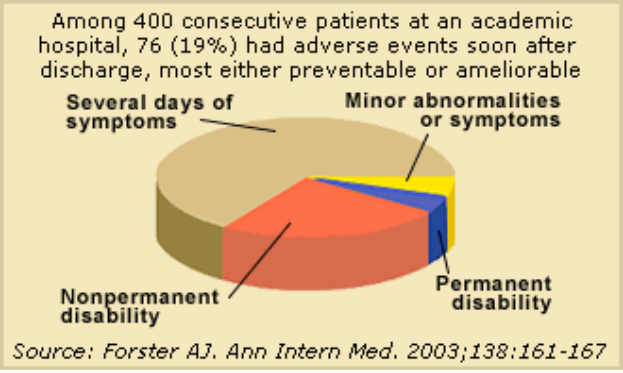
Readmissions and Adverse Events After Discharge

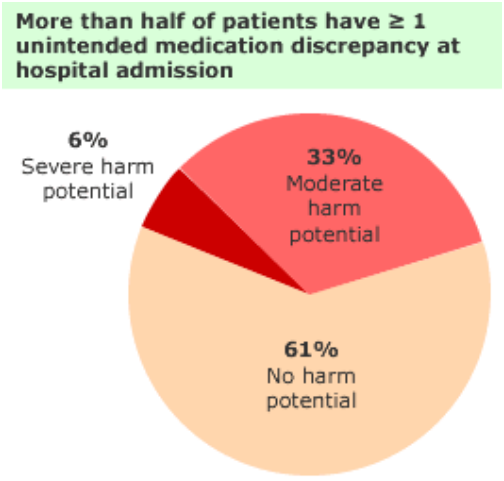
Background

Being discharged from the hospital can be dangerous. A classic study found that nearly 20% of patients experience adverse events within 3 weeks of discharge, nearly three-quarters of which could have been prevented or ameliorated. Adverse drug events are the most common postdischarge complication, with hospital-acquired infections and procedural complications also causing considerable morbidity. More subtle discharge hazards arise from the fact that nearly 40% of patients are discharged with test results pending, and a comparable proportion are discharged with a plan to complete the diagnostic workup as an outpatient, placing patients at risk unless timely and complete follow-up is ensured. As nearly 20% of Medicare patients are rehospitalized within 30 days of discharge, minimizing post-discharge adverse events has become a priority for the US health care system.



Systematic problems in care transitions are at the root of most adverse events that arise after discharge. Discontinuity between inpatient and outpatient providers is common, and studies have shown that traditional communication systems (such as the dictated discharge summary) generally fail to reach outpatient providers in a timely fashion and often lack essential information. Patients frequently receive new medications or have medications

changed during hospitalizations. Lack of medication reconciliation results in the potential for inadvertent medication discrepancies and adverse drug events—particularly for patients with low health literacy, or those prescribed high-risk medications or complex medication regimens.



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Even if communication between providers *is* timely and accurate, and appropriate steps are taken to ensure medication safety, patients and their families still assume a large burden of care after discharge. Accurately assessing patients' abilities to care for themselves after discharge can be difficult and requires a coordinated multidisciplinary effort. Failure to enlist appropriate resources to help with the transition from hospital to home (or another health care setting) may leave patients vulnerable. Finally, the fragmented nature of the health care system may limit individual hospitals' incentive to improve their discharge process, despite the benefits to patients that may result.

Preventing Adverse Events After Discharge

Ensuring safe care transitions requires a systematic approach. Three key areas must be addressed prior to discharge:

- Medication reconciliation: The patient's medications must be cross-checked to ensure that no chronic medications were stopped and to ensure the safety of new prescriptions.

- Structured discharge communication: Information on medication changes, pending tests and studies, and follow-up needs must be accurately and promptly communicated to outpatient physicians.
- Patient education: Patients (and their families) must understand their diagnosis, their follow-up needs, and whom to contact with questions or problems after discharge.

No consensus exists on how to ensure patient safety after hospital discharge, but some evidence indicates that comprehensive, multi-modal interventions may be more effective at preventing rehospitalization than targeting individual components of the discharge process. Two notable interventions used specially trained staff to meet with patients before (and sometimes after) discharge to reconcile medications, instruct patients and caregivers in self-care methods, prepare patient-centered discharge instructions, and facilitate communication with outpatient physicians. These studies, the Care Transitions trial and the Project RED study, both successfully reduced readmissions and emergency department visits after discharge. By contrast, medication reconciliation alone does not appear to reduce rehospitalization risk (but likely prevents medication errors), and other strategies such as structured postdischarge phone calls to patients and ensuring early follow-up appointments also lack supporting evidence. There is considerable interest in harnessing the power of checklists to standardize the discharge process, and electronic health records offer great potential for improving information transfer between inpatient and outpatient physicians and developing standardized discharge instructions for patients.

Evaluating the effectiveness of care transitions interventions is hindered by the fact that the standard outcome measure—30-day readmission rates—has significant limitations. Several studies have shown that only a minority of 30-day readmissions in medical patients are truly preventable, and clinicians lack tools to predict which patients are at risk of being readmitted. The reasons why patients are readmitted likely vary between hospitals and patient populations, indicating that care transitions interventions must be tailored carefully to individual patient circumstances. For example, a recent controlled study reduced readmissions through a program that included linkage to community resources and care

coordination with long-term care facilities when appropriate, as well as medication reconciliation and follow-up phone calls.

Current Context

A variety of policy initiatives have been implemented in order to encourage hospitals to address adverse events and readmissions after discharge. The Patient Protection and Affordable Care Act of 2010 contained multiple payment reforms intended to promote hospital efforts to address and prevent adverse events after discharge. Chief among these is the Hospital Readmissions Reduction Program (HRRP), which financially penalizes hospitals with above-average readmission rates for target illnesses. Since those penalties were implemented in 2012, more than 2600 hospitals had a proportion of their annual Medicare reimbursements withheld due to excess readmissions. This program appears to be effective, as readmission rates for Medicare patients have decreased since the HRRP was implemented. However, the program has drawn criticism for disproportionately penalizing hospitals that care for vulnerable patients, and CMS is implementing additional risk adjustment to readmission rates in order to mitigate this problem. Hospitals now also receive bundled payments for target illnesses that cover all costs associated with patient care for a 30-day period, providing a financial incentive to ensure continuity of care. These reforms have highlighted the importance of care transitions and resulted in improved safety for patients after hospital discharge.

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CASE

Recurrent Hypoglycemia: A Care Transition Failure?

PERSPECTIVE

Care Transitions

PERSPECTIVE

In Conversation with...Eric Coleman, MD, MPH

CASE

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Patient Safety Primer Last Updated: June 2017

Reporting Patient Safety Events

Background

Patient safety event reporting systems are ubiquitous in hospitals and are a mainstay of efforts to detect patient safety events and quality problems. *Incident reporting* is frequently used as a general term for all voluntary patient safety event reporting systems, which rely on those involved in events to provide detailed information. Initial reports often come from the frontline personnel directly involved in an event or the actions leading up to it (e.g., the nurse, pharmacist, or physician caring for a patient when a medication error occurred), rather than management or patient safety professionals. Voluntary event reporting is therefore a *passive* form of surveillance for near misses or unsafe conditions, in contrast to more *active* methods of surveillance such as direct observation of providers or chart review using trigger tools. The Patient Safety Primer Detection of Safety Hazards provides a detailed discussion of other methods of identifying errors and latent safety problems.

Characteristics of Incident Reporting Systems

An effective event reporting system should have four key attributes:

Box. Key Components of an Effective Event Reporting System

- Institution must have a supportive environment for event reporting that protects the privacy of staff who report occurrences.
- Reports should be received from a broad range of personnel.
- Summaries of reported events must be disseminated in a timely fashion.
- A structured mechanism must be in place for reviewing reports and developing action plans.

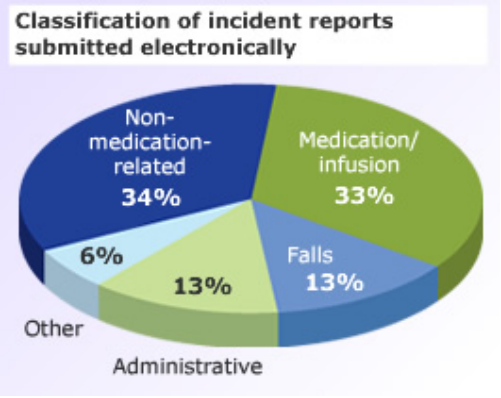
While traditional event reporting systems have been paper based, technological enhancements have allowed the development of Web-based systems and systems that can

receive information from electronic medical records. Specialized systems have also been developed for specific settings, such as the Intensive Care Unit Safety Reporting System and systems for reporting surgical and anesthesia-related errors.

Voluntary event reporting systems need not be confined to a single hospital or organization. The United Kingdom's National Patient Safety Agency maintains the National Reporting and Learning System, a nationwide voluntary event reporting system, and the MEDMARX voluntary medication error reporting system in the U.S. has led to much valuable research.

The advantages of voluntary event reporting systems include their relative acceptability and the involvement of frontline personnel in identifying safety hazards for the organization. Because event reports usually are submitted by personnel involved in the events themselves, these caregivers may have legitimate concerns about the effects reporting will have on their performance records. Voluntary event reporting systems are generally confidential, in that the identity of the reporter is known, but legal protection is provided unless professional misconduct or criminal acts took place. Some systems, such as the ICU Safety Reporting System, are entirely anonymous–neither the patient nor the reporter can be identified.

Studies of electronic hospital event reporting systems generally show that medication errors and patient falls are among the most frequently reported events.



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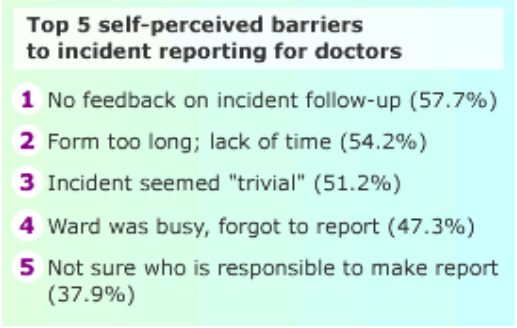
Limitations of Event Reporting

The limitations of voluntary event reporting systems have been well documented. Event reports are subject to selection bias due to their voluntary nature. Compared with medical record review and direct observation, event reports capture only a fraction of events and may

not reliably identify serious events. The spectrum of reported events is limited, in part due to the fact that physicians generally do not utilize voluntary event reporting systems.



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A 2008 study of over 1600 U.S. hospitals evaluated their event reporting systems using the criteria above (Box) and concluded that according to these standards, most hospitals do not maintain effective event reporting systems. In addition to lack of physician reporting, most hospitals surveyed did not have robust processes for analyzing and acting upon aggregated event reports. Failure to receive feedback after reporting an event is a commonly cited barrier to event reporting by both physicians and allied health professionals.

While event reports may highlight specific concerns that are worthy of attention, they do not provide insights into the epidemiology of safety problems. In a sense, event reports supply the *numerator* (the number of events of a particular type–and even here, this number only reflects a fraction of all such events) but do not supply the *denominator* (the number of patients vulnerable to such an event) or the number of "near misses." Event reports therefore provide a snapshot of safety issues, but on their own, cannot place the reported problems into the appropriate institutional context. One way to appreciate this issue is to observe that some institutions celebrate an increase in event reports as a reflection of a "reporting culture," while others celebrate a reduction in event reports, assuming that such a reduction is due to fewer events.

Using Event Reports to Improve Safety

A 2016 article contrasted event reporting in health care with event reporting in other high-risk industries (such as aviation), pointing out that event reporting systems in health care have placed too much emphasis on collecting reports instead of learning from the events that have

been reported. Event reporting systems are best used as a way of identifying issues that require further, more detailed investigation. While event reporting utilization can be a marker of a positive safety culture within an organization, organizations should resist the temptation to encourage event reporting without a concrete plan for following up on reported events. A PSNet perspective described a framework for incorporating voluntary event reports into a cohesive plan for improving safety. The framework emphasizes analysis of the events and documenting process improvements arising from event analysis, rather than encouraging event reporting for its own sake.

Current Context

At the national level, regulations implementing the Patient Safety and Quality Improvement Act became effective on January 19, 2009. The legislation provides confidentiality and privilege protections for patient safety information when health care providers work with new expert entities known as Patient Safety Organizations (PSOs). Health care providers may choose to work with a PSO and specify the scope and volume of patient safety information to share with a PSO. Because health care providers can set limits on the ability of PSOs to use and share their information, this system does not follow the pattern of traditional voluntary reporting systems. However, health care providers and PSOs may aggregate patient safety event information on a voluntary basis, and AHRQ will establish a network of patient safety databases that can receive and aggregate nonidentifiable data that are submitted voluntarily. AHRQ has also developed Common Formats—standardized definitions and reporting formats for patient safety events—in order to facilitate aggregation of patient safety information. Since their initial release in 2009, the Common Formats have been updated and expanded to cover a broad range of safety events.

As all hospitals are required to maintain a confidential event reporting system, existing voluntary reporting systems have a shared interest in developing ways to compare and benchmark safety data. AHRQ will encourage use of the initial set of Common Formats by hospitals in their internal event reporting systems and encourage other voluntary reporting systems to consider adopting the Common Formats as well. Future Common Formats will address other sites of care and other stages of the improvement process (such as forms for reporting root cause analyses).

Editor's Picks

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PERSPECTIVE

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Patient Safety Primer Last Updated: June 2017

Root Cause Analysis

Background

Root cause analysis (RCA) is a structured method used to analyze serious adverse events. Initially developed to analyze industrial accidents, RCA is now widely deployed as an error analysis tool in health care. A central tenet of RCA is to identify underlying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals. RCA thus uses the systems approach to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within health care systems that contribute to adverse events). It is one of the most widely used retrospective methods for detecting safety hazards.

RCAs should generally follow a prespecified protocol that begins with data collection and reconstruction of the event in question through record review and participant interviews. A multidisciplinary team should then analyze the sequence of events leading to the error, with the goals of identifying how the event occurred (through identification of active errors) and why the event occurred (through systematic identification and analysis of latent errors) (Table). The ultimate goal of RCA, of course, is to prevent future harm by eliminating the latent errors that so often underlie adverse events.

Table. Factors That May Lead to Latent Errors

Type of Factor	Example
Institutional/regulatory	A patient on anticoagulants received an intramuscular pneumococcal vaccination, resulting in a hematoma and prolonged hospitalization. The hospital was under regulatory pressure to improve its pneumococcal vaccination rates.
Organizational/management	A nurse detected a medication error, but the physician discouraged her from reporting it.

Work environment	Lacking the appropriate equipment to perform hysteroscopy, operating room staff improvised using equipment from other sets. During the procedure, the patient suffered an air embolism.
Team environment	A surgeon completed an operation despite being informed by a nurse and the anesthesiologist that the suction catheter tip was missing. The tip was subsequently found inside the patient, requiring reoperation.
Staffing	An overworked nurse mistakenly administered insulin instead of an antinausea medication, resulting in hypoglycemic coma.
Task-related	An intern incorrectly calculated the equivalent dose of long-acting MS Contin for a patient who had been receiving Vicodin. The patient experienced an opiate overdose and aspiration pneumonia, resulting in a prolonged ICU course.
Patient characteristics	The parents of a young boy misread the instructions on a bottle of acetaminophen, causing their child to experience liver damage.

As an example, a classic paper described a patient who underwent a cardiac procedure intended for another, similarly named patient. A traditional analysis might have focused on assigning individual blame, perhaps to the nurse who sent the patient for the procedure despite the lack of a consent form. However, the subsequent RCA revealed 17 distinct errors ranging from organizational factors (the cardiology department used a homegrown, error-prone scheduling system that identified patients by name rather than by medical record number) to work environment factors (a neurosurgery resident who suspected the mistake did not challenge the cardiologists because the procedure was at a technically delicate juncture). This led the hospital to implement a series of systematic changes to reduce the likelihood of a similar error in the future.

RCA is a widely used term, but many find it misleading. As illustrated by the Swiss cheese model, multiple errors and system flaws often must intersect for a critical incident to reach the patient. Labeling one or even several of these factors as "causes" may place undue emphasis on specific "holes in the cheese" and obscure the overall relationships between different layers and other aspects of system design. Accordingly, some have suggested replacing the term "root cause analysis" with "systems analysis."

Effectiveness of Root Cause Analysis

RCA is one of the most widely used approaches to improving patient safety, but studies have called its effectiveness into question. A 2017 commentary identified eight common reasons why root cause analyses fail to result in improved safety, including overreliance on weak solutions (such as educational interventions and enforcing existing policies), failure to aggregate data across institutions, and failure to incorporate principles of human factors engineering and safety science into error analysis and improvement efforts. The National Patient Safety Foundation has proposed renaming the process root cause analysis and action (RCA2) to ensure that efforts will result in the implementation of sustainable systems-based improvements. A 2016 Annual Perspective discusses the limitations of the current approach to RCA and how the process can be made more effective.

Current Context

The Joint Commission has mandated use of RCA to analyze sentinel events (such as wrong-site surgery) since 1997. As of 2014, 27 states and the District of Columbia have mandated reporting of serious adverse events (increasingly using the National Quality Forum's list of Never Events), and many states also require that RCA be performed and reported after any serious event. This growth of mandatory reporting systems has likely increased the use of RCA.

Editor's Picks

PERSPECTIVE

Rethinking Root Cause Analysis

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PERSPECTIVE

The Soil, Not the Seed: The Real Problem with Root Cause Analysis

PERSPECTIVE

In Conversation with...Albert Wu, MD, MPH

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PERSPECTIVE

Advancing Patient Safety Through State Reporting Systems

CASE

Getting to the Root of the Matter

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Patient Safety Primer Last Updated: November 2017

Second Victims: Support for Clinicians Involved in Errors and Adverse Events

Background

Multiple studies have shown that involvement in medical errors and adverse events can take a significant toll on clinicians. It is estimated that one in seven patients is affected by adverse events, and that as many as half of all clinicians will be involved in a serious adverse event at least once during their career. When a medical error or patient harm occurs, the first priority is to attend to the patient and family members. However, Seys and colleagues and the Institute for Healthcare Improvement have identified three levels at which damage from errors and adverse events occur: the patient, clinicians, and health care organizations. This primer addresses clinician responses to involvement in errors and adverse events, along with support that can be put in place to respond when such involvement occurs.

Common Responses to Involvement in Errors and Adverse Events

Some degree of emotional distress is likely when a clinician is involved in any error or adverse event, regardless of severity. In a survey of more than 3000 physicians in the United States and Canada, 92% reported previous involvement in events ranging from near misses to serious errors, and 81% reported some degree of job-related stress linked to the event. Responses to error and adverse events are individualized: the severity of any error(s), degree of perceived responsibility, and the outcome for the patient seem to be predictive of the degree of distress clinicians experience after an adverse event. Some clinicians are affected profoundly and with potentially lasting consequences. This distress is known as the "second victim" phenomenon, a term coined by Albert Wu in 2000.

Scott and colleagues define second victims as health care providers who are involved in an unanticipated adverse event, medical error, or patient injury and "become victimized in the sense that the provider is traumatized by the event." Across studies, clinicians involved in these events report feelings of responsibility for the patient outcome, shame, anger, failure, depression, inadequacy, and loss of confidence; some report symptoms of post-traumatic stress disorder. One systematic review found that women were more likely to experience emotional distress, feelings of guilt and inadequacy, and loss of reputation following an adverse event compared to men in similar circumstances.

A qualitative descriptive study with 31 clinicians described 6 stages of recovery after an incident (Table). The authors speculate that the intensity of the experience and the responsiveness of the organization affect how clinicians ultimately "move on."

Table. Stages of Recovery for Second Victims

Stage of Recovery	Summary
Chaos and Accident Response	Clinician experiences internal and external turmoil and may be in a state of shock in the midst of trying to both determine what happened and manage a patient who may be unstable or in crisis. Clinician is distracted and self-reflected, needs others to take over.
Intrusive Reflections	Clinician experiences feelings of inadequacy, self-doubt, and loss of confidence. Clinician engages in continuous re-evaluation of the situation through "haunted re-enactments."
Restoring Personal Integrity	Clinician seeks support from trusted persons, but may not know where to turn and may be fearful of how others will react. Unsupportive responses from colleagues can impair recovery, as they may intensify self-doubt and make it difficult for the clinician to move forward.
Enduring the Inquisition	Clinician braces for the institutional investigation, wonders about the impact on their job, licensure, and the potential for litigation. Clinician may be reluctant to disclose information for fear of violating privacy regulations.
Obtaining Emotional First Aid	Clinician feels uncertain about who is safe to confide in due to privacy concerns and not wanting to expose loved ones to pain. In the study, most clinicians felt unsupported or under-supported, partly due to ambiguity around whom to approach and what can be discussed.
Moving On	Clinicians feel internal and external pressure to "move on," and in the study had three forms of doing so: • **Dropping out:** changing their role, moving to a different practice setting, or leaving their profession • **Surviving:** "doing okay" after acknowledging mistake, but having a hard time forgiving self, finds it "impossible to let go" • **Thriving:** making something good come out of the event

Source: Scott SD, et al. Qual Saf Health Care. 2009;18:325-330.

Providing Support to Clinicians After an Error or Adverse Event

A survey of 898 clinicians at the University of Missouri found that clinicians wanted a unit- or department-based support system that could relieve them of immediate patient care duties for a brief period; provide one-on-one peer support, professional review, and collegial feedback, as well as access to patient safety experts and risk managers; and offer crisis support and external referral when needed. The University of Missouri Health Care system developed a three-tiered support program deployed by an interprofessional rapid response team.

The first tier of support consists of unit- or department-based event recognition and support by colleagues and local leaders who have received basic response training. Approximately 60% of involved clinicians will have their needs met through this tier. The second tier involves trained peer support persons embedded in high-risk clinical units to monitor colleagues for second victim responses and provide immediate intervention with one-on-one support, trigger debriefings, and access to other organizational resources such as patient safety or risk management leaders. This tier is expected to meet the needs of 30% of identified second victims. The needs of about 10% of affected clinicians are addressed at the third tier, through facilitated access to professional counseling.

Current Context

Creating an environment where clinicians feel safe disclosing their involvement in errors and adverse events is important for patients, families, clinicians, and organizations. The basics of disclosing errors to patients are covered in another Patient Safety Primer. Other important reasons to disclose involvement include enhanced clinician recovery and organizational learning, as discussed in an AHRQ commentary. A study examining provision of support for second victims in hospitals in Maryland found such services to be limited despite recognition by Patient Safety Officers of the need to support clinicians involved in errors and adverse events. The science behind interventions for second victims is in its infancy. However, several resources are available to help organizations prepare to respond. The Institute for Healthcare Improvement has a whitepaper on respectful management of serious adverse events. A group of experts developed a publicly available best practices toolkit for organizations to use in developing support programs for clinicians involved in errors and adverse events. The

toolkit includes an organizational assessment, work plan template, and downloadable list of additional resources.

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PERSPECTIVE

In Conversation with…Albert Wu, MD, MPH

PERSPECTIVE

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Patient Safety Primer Last Updated: June 2017

Simulation Training

Background

Clinical training for health care professionals has traditionally relied on learning from actual patients, even for invasive procedures and life-threatening situations. As exemplified by the medical residency maxim "see one, do one, teach one," there has been little emphasis on learning in a simulated environment prior to clinical encounters.

However, considerable evidence documents the dangers posed by inexperienced clinicians and poorly functioning clinical teams. Based in part on its success in other industries such as aviation, simulation-based training has therefore emerged as a key component of the patient safety movement and is increasingly being used to improve clinical and teamwork skills in a variety of environments. When applied properly, simulation-based training allows the opportunity to learn new skills, engage in deliberate practice, and receive focused and real-time feedback. The goal of simulation-based training is to enable the accelerated development of expertise, both in individual and team skills, by bridging the gap between classroom training and real-world clinical experiences in a relatively risk-free environment.

Methods and applications of simulation-based training

There are several approaches to simulation training, and depending on the material being emphasized, simulation curricula may employ one or more of these methods:

- Part-task trainers: These are used to train specific clinical skills through simulation. An example would be anatomically correct limb models, which are used to demonstrate phlebotomy skills or placement of intravenous catheters.
- Full-scale simulators: The most common example is a full-body manikin, which in addition to anatomic landmarks can offer realistic physiologic simulation (such as

heart sounds and respirations). These are increasingly used to teach the physical examination and other fundamental clinical skills.

- Virtual reality: In this modality, learners are immersed in a highly realistic clinical environment, such as an operating room or intensive care unit. Learners physically interact with the environment as they would in real life, using systems that are increasingly complex and technologically sophisticated.
- In situ simulation: This approach refers to simulation carried out in the actual clinical environment with the providers who work in that location. It may involve use of part-task or full-scale simulators as well.
- Standardized patients: Employing trained actors to simulate real patients has long been used to teach basic history taking and physical examination skills, and this strategy is also being applied to teach patient safety skills such as error disclosure.

These methods are not mutually exclusive, and successful curricula often use combinations of these approaches.

Simulation was initially utilized as a tool for teaching clinical skills and has been successfully applied to develop and assess foundational clinical skills as well as more advanced cognitive and technical skills, in both medical school and residency training. Simulation is also being widely integrated into teamwork training in a variety of environments, including the emergency department, operating room, and obstetrics units. Teamwork training that incorporates simulation often focuses on improving the ability of multidisciplinary teams to handle acute situations. Teamwork training with simulation has also been used with non-clinical personnel, such as one study in which non-clinician leadership and management had to respond to a simulated patient safety crisis.

The application of human factors engineering methods to patient safety represents another application of simulation. Usability testing, which refers to testing new equipment and technology under real-world conditions, can be thought of as a form of simulation designed to identify latent safety issues and workarounds.

Evidence supporting simulation-based training

Simulation training is clearly effective as an educational modality. A recent systematic review analyzed results from more than 600 studies that evaluated technology-enhanced simulation training programs and found strong positive associations between simulation training and improved outcomes of knowledge, skills, and behaviors. Another systematic review identified 38 studies—most of which used simulation to teach procedural skills—and found that simulation augments team behaviors, procedural competence, and patient care outcomes. Simulation approaches have been shown to enhance safety outcomes, such as preventing central line infections. While technology-enhanced simulation is effective, increasing technological sophistication of simulation may not always be necessary. According to another review, the key features of successful simulation education are those of successful curricula in general: individualized feedback, cognitive interactivity, deliberate practice, and longer duration of the curricula. The effect of high-fidelity technology-enhanced simulation remains controversial, and although the cost of such high-technology simulators is decreasing, their high costs may deter increasing use of this approach until more definitive evidence emerges.

The evidence supporting the use of simulation in teamwork training is more mixed. A systematic review that examined simulation training in the operating room found that most studies suffered from one of several methodological concerns, such as lack of standardization of training techniques and measurement methods. While participants generally had positive impressions of the programs, there was no clear effect on participant behaviors or clinical outcomes. Another review of multidisciplinary simulation-based team training in obstetrics did show improvement in participants' knowledge and skills, but also did not demonstrate improvement in safety or clinical outcomes. Variation in simulation approaches and curricula likely account for these disparate findings. There is increasing interest in using in situ simulation as a way of providing more realistic simulation experiences and potentially identifying latent safety hazards in the real-world clinical environment.

Current Context

All graduating medical students are required to complete a simulated patient encounter in order to pass the United States Medical Licensing Examination. The Accreditation Council for Graduate Medical Education requires that residency programs provide simulation training, although the specific requirements vary between specialties. The American Board of

Anesthesiology requires practicing anesthesiologists to complete a simulation course in order to maintain board certification, but this requirement is not present for other specialties. It is important to note that simulation has been shown to be effective as an educational tool for both practicing clinicians as well as trainees.

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PERSPECTIVE

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PERSPECTIVE

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PERSPECTIVE

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Patient Safety Primer Last Updated: June 2018

Surgical Site Infections

Background

According to data from AHRQ, more than 10 million patients undergo surgical procedures as inpatients each year, accounting for over one-fourth of all hospital stays. The most common types of inpatient surgical procedures include cesarean section, orthopedic procedures (hip and knee replacement, hip fracture repair), neurosurgical procedures (spinal fusion and laminectomy), and intraabdominal procedures (cholecystectomy and colorectal resections). Increasing numbers of patients also undergo surgery at ambulatory surgery centers (facilities specifically designed for certain types of surgery after which the patient can be discharged home directly).

Surgical site infection (SSI)—defined by the Centers for Disease Control and Prevention (CDC) as infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within 90 days if prosthetic material is implanted at surgery—is among the most common preventable complication after surgery. SSIs occur in 2% to 4% of all patients undergoing inpatient surgical procedures. Although most infections are treatable with antibiotics, SSIs remain a significant cause of morbidity and mortality after surgery. They are the leading cause of readmissions to the hospital following surgery, and approximately 3% of patients who contract an SSI will die as a consequence. Although SSIs are less common following ambulatory surgery than after inpatient procedures, they are a frequent source of morbidity in these patients as well.

Risk factors for SSI include patient factors (such as age, tobacco use, diabetes, and malnutrition) and procedure-specific risk factors (including emergency surgery and the degree of bacterial contamination of the surgical wound at the time of the procedure). While many of these risk factors are not modifiable, the majority of SSIs are considered preventable,

and recent advances have improved our insights as to how hospitals can systematically prevent these infections. This Primer will provide an overview of the prevention of SSI, with a focus on system-level interventions. Information on other types of health care–associated infections (HAIs) may be found in the Health Care–Associated Infections Primer.

Prevention of Surgical Site Infections

Accurate measurement can be a challenge in patient safety, but prevention of SSIs (and HAIs in general) has benefited from the development of standard metrics that allow for tracking of infection rates over time and comparison of infection rates between facilities. The CDC's National Healthcare Safety Network (NHSN) has developed standards for SSI measurement. These definitions are also used by the National Surgical Quality Improvement Program (NSQIP), although NSQIP uses slightly different methods of surveillance for infections. Both the NHSN and NSQIP definitions are widely used for both quality improvement and research purposes. The CDC has also developed guidelines (last updated in 2017) summarizing the evidence for clinical interventions to prevent SSI; the World Health Organization also issued SSI prevention guidelines in 2016. Adherence to these clinical standards (for example, administration of appropriate antimicrobial prophylaxis) is routinely tracked in the form of process measures that, if adhered to, should reduce the incidence of SSI.

However, as with many other quality problems, implementing the recommended methods as standard practice and sustaining the use of preventive interventions has been challenging. Many organizations have been able to achieve sustained reductions in SSIs, and AHRQ has led notable efforts to encourage dissemination and implementation of SSI prevention strategies. Key elements of organizational interventions to prevent SSIs (and HAIs in general) include improving safety culture, the use of robust data tracking and feedback mechanisms, and utilizing checklists or evidence-based bundles.

The comprehensive unit-based safety program (CUSP) has been demonstrated to be an instrumental approach to driving reductions in SSI. CUSP emphasizes improving safety culture through a continuous process of identifying and learning from errors, improving teamwork, and engaging staff at all levels in safety efforts. The AHRQ Safety Program for Surgery used the CUSP model and implementation science approaches to improve adherence to evidence-based SSI prevention practices in 197 hospitals. Participating hospitals

implemented the CUSP with mentorship from a national project team, used either the NHSN or NSQIP method to measure and feed back SSI rates to frontline personnel regularly, and participated in collaborative learning experiences. The intervention was associated with a significant reduction in SSI rates at participating hospitals, accompanied by improvement in perceived safety culture. Ethnographic analysis of the intervention found that active engagement from senior leadership and creation of a nonpunitive environment were crucial success factors. AHRQ has created toolkits for both hospitals and ambulatory surgery centers that contain guides and instructional modules for implementing CUSP principles and methods for promoting safe surgery.

Surgical safety checklists are tools to standardize safety assessment and improve teamwork and communication in surgical care, and also generally include specific steps to reduce SSI risk (for example, ensuring that preoperative antimicrobial prophylaxis has been administered at the appropriate time). The evidence base around checklists is summarized in the Checklists Primer. Although checklists are effective at preventing intraoperative and postoperative complications, real-world implementation remains a challenge, and there is no clear evidence that checklists alone can prevent SSIs. The AHRQ Safety Program for Surgery used a multicomponent intervention designed to improve safety culture in order to promote consistent use of the World Health Organization surgical safety checklist, and additionally to promote SSI prevention. The project did *not* use an explicit bundle of interventions focused on SSI, recognizing the limitations in the evidence base for SSI prevention and the fact that defects in safety systems leading to SSI may differ between hospitals. Bundled interventions may be an important part of overall institutional approaches to preventing SSIs, but the specific components of the bundle will likely vary across institutions. Another project, the AHRQ Safety Program for Improving Surgical Care and Recovery is an ongoing collaborative program to enhance the recovery of surgical patients. This project aims to address multiple types of patient harm, including SSI and other harms, in an integrated way throughout the surgical care pathway.

Current Context

SSI prevention is a high-priority goal for health care organizations. The Joint Commission includes use of guidelines to prevent SSI as one of its National Patient Safety Goals for hospitals and ambulatory surgery centers. The Centers for Medicare and Medicaid Services

require hospitals to report SSI rates, which are publicly disseminated (along with other surgical quality measures) on its Hospital Compare website.

Efforts to prevent surgical site infections have been effective. Data from AHRQ's Partnership for Patients initiative indicates that the national rate of SSI decreased by 16% between 2010 and 2015, translating into significant benefits for patients (including many lives saved), as well as significant cost savings.

Editor's Picks

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PERSPECTIVE

The Evolution of Patient Safety in Surgery

PERSPECTIVE

In Conversation With… Karl Bilimoria, MD, MS

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CASE

Environmental Safety in the OR

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Patient Safety Primer Last Updated: June 2017

Systems Approach

Background

A 65-year-old woman presented to the outpatient surgery department of one of the most respected hospitals in the United States for a relatively routine procedure, a trigger finger release on her left hand. Instead, the surgeon performs a completely different procedure—a carpal tunnel release. How could this happen?

Medicine has traditionally treated errors as failings on the part of individual providers, reflecting inadequate knowledge or skill. The systems approach, by contrast, takes the view that most errors reflect predictable human failings in the context of poorly designed systems (e.g., expected lapses in human vigilance in the face of long work hours or predictable mistakes on the part of relatively inexperienced personnel faced with cognitively complex situations). Rather than focusing corrective efforts on punishment or remediation, the systems approach seeks to identify situations or factors likely to give rise to human error, and change the underlying systems of care in order to reduce the occurrence of errors or minimize their impact on patients.

The modern field of systems analysis was pioneered by the British psychologist James Reason, whose analysis of industrial accidents led to fundamental insights about the nature of preventable adverse events. Reason's analysis of errors in fields as diverse as aviation and nuclear power revealed that catastrophic safety failures are almost never caused by isolated errors committed by individuals. Instead, most accidents result from multiple, smaller errors in environments with serious underlying system flaws. Reason introduced the Swiss Cheese model to describe this phenomenon. In this model, errors made by individuals result in disastrous consequences due to flawed systems—the holes in the cheese. This model not only has tremendous explanatory power, it also helps point the way toward solutions—

encouraging personnel to try to identify the holes and to both shrink their size and create enough overlap so that they never line up in the future.

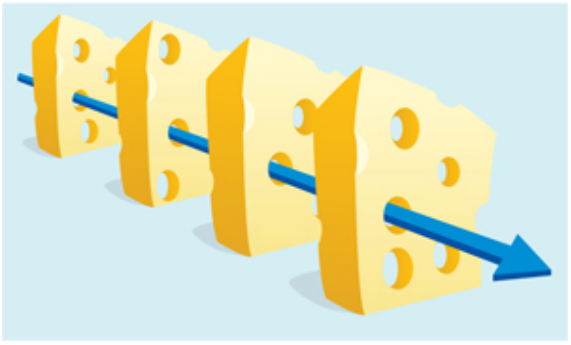

Figure. The Swiss Cheese Model of Medical Errors

Another of Reason's key insights, one that sadly remains underemphasized today, is that human error is inevitable, especially in systems as complex as health care. Simply striving for perfection—or punishing individuals who make mistakes—will not appreciably improve safety, as expecting flawless performance from human beings working in complex, high-stress environments is unrealistic. The systems approach holds that efforts to catch human errors before they occur or block them from causing harm will ultimately be more fruitful than ones that seek to somehow create flawless providers.

Reason used the terms *active errors* and *latent errors* to distinguish individual from system errors. Active errors almost always involve frontline personnel and occur at the point of contact between a human and some aspect of a larger system (e.g., a human–machine interface). By contrast, latent errors are literally accidents waiting to happen—failures of organization or design that allow the inevitable active errors to cause harm.

The terms *sharp end* and *blunt end* correspond to active error and latent error. Personnel at the sharp end may literally be holding a scalpel when the error is committed, (e.g., the surgeon who performed the incorrect procedure) or figuratively be administering any kind of treatment. The blunt end refers to the many layers of the health care system not in direct contact with patients, but which influence the personnel and equipment at the sharp end that come into contact with patients. The blunt end thus consists of those who set policy, manage health care institutions, or design medical devices, and other people and forces, which—though removed in time and space from direct patient care—nonetheless affect how care is delivered.

Errors at the sharp end can be further classified into *slips* and *mistakes,* based on the cognitive psychology of task-oriented behavior. Attentional behavior is characterized by conscious thought, analysis, and planning, as occurs in active problem solving. Schematic behavior refers to the many activities we perform reflexively, or as if acting on autopilot. In this construct, slips represent failures of schematic behaviors, or lapses in concentration, and occur in the face of competing sensory or emotional distractions, fatigue, or stress. Mistakes, by contrast, reflect incorrect choices, and more often reflect lack of experience, insufficient training, or outright negligence.

The work of James Reason and Dr. Charles Vincent, another pioneer in the field of error analysis, has established a commonly used classification scheme for latent errors that includes causes ranging from institutional factors (e.g., regulatory pressures) to work environmental factors (e.g., staffing issues) and team factors (e.g., safety culture). These are discussed in more detail in the Root Cause Analysis Primer.

In the incorrect surgery case, the active, or sharp end, error was quite literally committed by the surgeon holding the scalpel. As in most cases, the active error is better classified as a slip, despite the complexity of the procedure. The surgeon was distracted by competing patient care needs (an inpatient consultation) and an emotionally taxing incident (a previous patient suffered extreme anxiety immediately postoperatively, requiring him to console her). However, analysis of the incident also revealed many latent, or blunt end, causes. The procedure was the surgeon's last of six scheduled procedures that day, and delays in the outpatient surgery suite had led to production pressures as well as unexpected changes in the make up of the operating room team. Furthermore, the patient only spoke Spanish and no interpreter was available, meaning that the surgeon (who also spoke Spanish) was the only person to communicate directly with the patient; this resulted in no formal time-out being performed. Computer monitors in the operating room had been placed in such a way that viewing them forced nurses to turn away from the patient, limiting their ability to monitor the surgery and perhaps detect the incorrect procedure before it was completed.

Analyzing Errors Using the Systems Approach

The systems approach provides a framework for analysis of errors and efforts to improve safety. There are many specific techniques that can be used to analyze errors, including

retrospective methods such as root cause analysis (or the more generic term systems analysis) and prospective methods such as failure modes effect analysis. Root cause analysis (and similar retrospective analysis techniques) is discussed in more detail in the dedicated Primer.

Failure modes effect analysis (FMEA) attempts to prospectively identify error-prone situations, or failure modes, within a specific process of care. FMEA begins with identifying all the steps that must occur for a given process to occur. Once this process mapping is complete, the FMEA then continues by identifying the ways in which each step can go wrong, the probability that each error can be detected, and the consequences or impact of the error not being detected. The estimates of the likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a *criticality index*. This criticality index provides a rough quantitative estimate of the magnitude of hazard posed by each step in a high-risk process. Assigning a criticality index to each step allows prioritization of targets for improvement.

For instance, an FMEA analysis of the medication-dispensing process on a general hospital ward might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process would be assigned a probability of failure and an impact score, so that all steps could be ranked according to the product of these two numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing.

FMEA makes sense as a general approach, and has been used in other high-risk industries. However, the reliability of the technique and its utility in health care are not clear. Different teams charged with analyzing the same process may identify different steps in the process, assign different risks to the steps, and consequently prioritize different targets for improvement. Similar concerns have been raised about root cause analysis.

Developing Solutions for Active and Latent Errors

In attempting to prevent active errors, the differentiation between slips and mistakes is crucial, as the solutions to these two types of errors are very different. Reducing the risk of slips requires attention to the designs of protocols, devices, and work environments—using checklists so key steps will not be omitted, implementing forcing functions to minimize

workarounds, removing unnecessary variation in the design of key devices, eliminating distractions from areas where work requires intense concentration, and implementing other redesign techniques. Reducing the likelihood of mistakes, on the other hand, typically requires more training or supervision, perhaps accompanied by a change in position if the mistake is made habitually by the same worker, or disciplinary action if it is due to disruptive or unprofessional behavior. Although slips are vastly more common than mistakes, health care has typically responded to all errors as if they were mistakes, resorting to remedial education and/or added layers of supervision. Such an approach may have an impact on the behavior of an individual who committed an error, but does nothing to prevent other frontline workers from committing the same error, leaving patients at risk of continued harm unless broader, more systemic, solutions are implemented.

Addressing latent errors requires a concerted approach to revising how systems of care work, how protocols are designed, and how individuals interact with the system. Specific solutions thus vary widely depending on the type of latent error, the severity of the error, and the availability of resources (financial, time, and personnel) available to address the problem. An appropriate systems approach to improving safety requires paying attention to human factors engineering, including the design of protocols, schedules, and other factors that are routinely addressed in other high-risk industries but are only now being analyzed in medicine. Creating a culture of safety in which reporting of active errors is encouraged, analysis of errors to identify latent causes is standard, and frontline workers are not punished for committing slips, is also essential for finding and fixing systematic flaws in health care systems.

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PERSPECTIVE

In Conversation with...Albert Wu, MD, MPH

PERSPECTIVE

The Soil, Not the Seed: The Real Problem with Root Cause Analysis

CASE

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Teamwork Training

Background

Providing safe health care depends on highly trained individuals with disparate roles and responsibilities acting together in the best interests of the patient. Communication barriers across hierarchies, failure to acknowledge human fallibility, and lack of situational awareness combine to cause poor teamwork, which can lead to clinical adverse events.

The aviation industry has long recognized that safety requires crew members to receive specific training in working as a team, in addition to technical training. Several studies have documented poor levels of teamwork in medicine. A classic study that compared perceptions of teamwork between operating room personnel and flight crews found that attending surgeons were significantly less likely to acknowledge fatigue or accept suggestions from junior staff than were pilots.

Growing recognition of the need for teamwork has led to the application of teamwork training principles, originally developed in aviation, to a variety of health care settings. While there is no single standardized teamwork training program for health care, all programs stress several key concepts. Teamwork training attempts to minimize the potential for error by training each team member to respond appropriately in acute situations. Teamwork training thus focuses on developing effective communication skills and a more cohesive environment among team members, and on creating an atmosphere in which all personnel feel comfortable speaking up when they suspect a problem. Team members are trained to cross-check each other's actions, offer assistance when needed, and address errors in a nonjudgmental fashion. Debriefing and providing feedback, especially after critical incidents, are essential components of teamwork training.

Teamwork training also emphasizes the role of human factors—for example, the effects of fatigue, expected or predictable perceptual errors (such as misreading monitors or mishearing instructions), and the impact of different management styles and organizational cultures. Teamwork training may be purely classroom-based or accompanied by simulations of specific scenarios such as cardiopulmonary resuscitation, "crash" Caesarean section, or multiorgan trauma.

Teamwork training programs—implementation and effectiveness

The Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) program was developed in collaboration by the United States Department of Defense and AHRQ in order to support effective communication and teamwork in health care. TeamSTEPPS has been successfully implemented in a variety of clinical settings, including intensive care units and operating rooms. AHRQ offers a comprehensive curriculum and training program for interested organizations, which includes hands-on training through regular meetings and conferences as well as an online toolkit with an implementation guide, training materials, and measurement tools. Although originally developed for hospitals, the TeamSTEPPS program has been expanded to include long-term care and primary care. Other examples of teamwork training programs include the Veterans Affairs Medical Team Training program and crew resource management (which is based on aviation industry teamwork programs).

Teamwork training programs have been implemented in a wide variety of clinical environments, including the emergency department, operating rooms, obstetrics units, and outpatient primary care clinics. They are also being used to train hospital leadership in responding to safety events. The evidence supporting the benefits of such programs in health care is growing. A landmark study conducted in the Veterans Affairs hospital system demonstrated a significant reduction in surgical mortality associated with implementation of the Medical Team Training program. Other studies have consistently demonstrated improvements in participants' knowledge of teamwork principles, attitudes toward the importance of teamwork, and overall safety climate, although these have not necessarily translated into durable behavioral changes or enhanced skills. The effectiveness of teamwork training may depend on baseline perceptions of safety culture and readiness for change within a given unit or organization, as well as the intensity and duration of the intervention.

Current Context

All military health facilities participate in the TeamSTEPPS program, and the Medical Team Training program is being widely implemented in Veterans Affairs facilities. However, teamwork training is not required for other health care facilities. The Joint Commission's Universal Protocol for preventing wrong-site surgery mandates a preoperative "time out," based on teamwork training principles, in which all team members review the details of the surgery to take place. Many organizations are now coupling teamwork training programs with more specific efforts to structure communication, such as SBAR (situation, background, assessment, recommendation) training. Successful organizational approaches to improving safety, such as the Comprehensive Unit-Based Safety Program, also explicitly incorporate teamwork training principles.

Editor's Picks

PERSPECTIVE

New Insights About Team Training From a Decade of TeamSTEPPS

PERSPECTIVE

In Conversation With… Amy C. Edmondson, PhD, AM

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The Inside of a Time Out

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PERSPECTIVE

Team Training: Classroom Training vs. High-Fidelity Simulation

PERSPECTIVE

What Does Simulation Add to Teamwork Training?

PERSPECTIVE

Aviation Safety Methods: Quickly Adopted but Questions Remain

PERSPECTIVE

In Conversation with…Jack Barker, PhD

LEGISLATION/REGULATION › ORGANIZATIONAL POLICY/GUIDELINES

Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.

The Joint Commission.

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Patient Safety Primer Last Updated: July 2018

The Pharmacist's Role in Medication Safety

Background

As discussed in the related primer on medication error, adverse drug events occur when exposure to a medication results in harm. Correct medication use occurs when the "five rights" are followed, meaning the right dose of the right medication is administered to the right patient, at the right time, and by the right route. However, this simple phrase obscures the fact that the five rights must be individualized, as they are affected by the patient's age, medical condition, physiologic status, and other factors such as allergies. While pharmacists' contribution to medication safety has been historically focused on dispensing, pharmacists' roles have expanded as medication therapy has increased in complexity, and many patients—even those with serious illness—can now receive care in the home and in community settings.

According to the American Pharmacists Association, pharmacists in all settings have eight essential medication-related responsibilities linked to improving patient safety. These eight responsibilities and examples of how they can affect patient safety are outlined in the Table.

Safety action	What is involved	Example of impact
Ensure access to medication	Evaluate ability to pay for medication; explore alternative medications or payment means	Finding patient assistance programs or working with insurers to make medication available that patients otherwise could not afford, improving adherence and safety
Supply medication information	Educate patients and caregivers on safe and effective medication use	Reviewing proper dosing with patients or providers can prevent medication errors and adverse drug interactions
Evaluate medication appropriateness	Assess medication appropriateness, effectiveness, and safety for each individual patient	Individual consideration of "five rights" in light of patient condition, medication list, age, weight, ethnicity, diet, allergies, and kidney and liver function can result in recommendations for changes in therapy or monitoring to increase medication safety
Improve medication adherence	Help patients take medication as it is prescribed	Reviewing how patients are using medications can result in suggestions for changes in medication, dosing, or additional therapies that improve patient adherence

Provide health and wellness services	Deliver direct health and wellness service	Blood pressure screenings can reveal poorly controlled hypertension
Medication management	Comprehensive review of patient's full medication regimen to ensure medications work well together and avoid problems (e.g., interaction)	Pharmacist review may determine which of several medications is causing an adverse effect; simplify a patient's medication regimen; identify gaps in reaching treatment goals; or prevent prescription of medications that have adverse interactions
Assess health status	Determine current patient status and medication effectiveness; provide guidance regarding medication therapy	Pharmacist may detect dangerously low or high blood pressure and recommend changes in medication therapy and thereby prevent harm
Coordinating care transitions	Coordinate medication management across care transitions; assist with care coordination for transitions	Pharmacist-led medication reconciliation may identify potential interactions or omissions from medication list at transitions in care, which are prone to error.
Source: *Pharmacists' Impact on Patient Safety: A Joint Project of the American Pharmacists Association Academy of Pharmacy Practice and Management and Academy of Pharmaceutical Research and Science. Washington, DC: American Pharmacists Association;* 2016. https://www.pharmacist.com/pharmacists-impact-patient-safety.		

Pharmacists also have a crucial system-level role in planning and leading medication safety programs and improvement initiatives within health care organizations. These initiatives may include developing risk-specific protocols for high-alert medications; identifying and evaluating high-risk processes (e.g., total parenteral nutrition, compounding, pediatric dose preparation) that require special attention, protocols, and training; evaluating medication error data; evaluating and implementing new medication technologies; and fostering robust error reporting processes. Clinical trials are another area in which pharmacist leadership in designing safe protocols is critical, as there are fewer standardized safeguards in place to ensure correct medications and doses are delivered to patients.

Current Context

Pharmacists have a central role in ensuring medication safety across the continuum of care. The complexity of the medication prescribing and delivery processes can make it difficult to prove the beneficial effect of pharmacists on adverse outcomes directly, but pharmacist involvement has been shown to reduce errors, improve prescribing practices, and enhance patient monitoring across settings. For example, a cluster-randomized trial of pharmacist involvement in medication management planning on hospital admission showed a dramatic reduction in medication errors within the first 24 hours of hospitalization. A meta-analysis of

13 studies of pharmacist interventions at transitions of care estimated a 37% reduction in medication errors and a decrease in emergency department visits after hospital discharge. A recent randomized controlled trial of a pharmacist-led intervention in primary care practices in the United Kingdom tested an intervention bundle comprised of review of electronic medical records, prescriber feedback, education on error reduction, and support for improving local safety systems. This bundle of practices resulted in significant increases in appropriate prescribing and monitoring practices for specific error-prone situations, such as elderly patients taking loop diuretics or angiotensin-converting enzyme inhibitors. Despite these generally positive results, many health systems have found it difficult to hire enough qualified pharmacists, either because of a shortage in the available pharmacists or the costs of implementation. Given the latter factor, further studies that consider the return-on-investment of pharmacist-led safety programs should be considered.

Editor's Picks

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PERSPECTIVE

In Conversation with...J. Bryan Sexton, PhD, MA

PERSPECTIVE

In Conversation with…Michael Cohen, RPh, MS, ScD

PERSPECTIVE

Introducing the New AHRQ WebM&M and AHRQ Patient Safety Network (PSNet)

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Patient Safety Primer Last Updated: June 2017

Triggers and Trigger Tools

Background and definition

Health care organizations use a variety of strategies to detect safety hazards in order to prevent harm. These methods are often referred to by various names such as Targeted Injury Detection Systems and most commonly as *triggers.* Triggers have become a widely used way to retrospectively analyze medical records in order to identify errors and adverse events, measure the frequency with which such events occur, and track the progress of safety initiatives over time. Triggers alert patient safety personnel to possible adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred. The main value of triggers is efficiency, since a complete review of every medical record to find adverse events is laborious and expensive, even in the era of electronic medical records. Triggers provide a way of screening medical records for possible harm and identifying cases that merit a more detailed review.

For example, the administration of naloxone (a drug used to reverse the effect of opioid medications) to a hospitalized patient would be a reasonable trigger that could help identify instances where a patient was given a harmful dose of an opioid drug. When naloxone is administered in an inpatient ward, it may be because the patient received an excessive dose of morphine or another opioid medication. Therefore, pharmacists and patient safety personnel could use that trigger to identify cases that may represent problems with the ordering or administration of opioid medications. This method would miss many less severe cases (ones that weren't severe enough to merit naloxone administration), but the cases it did identify would very likely represent preventable adverse events. Well-defined, specific triggers like this also lend themselves to automated electronic detection, making them particularly efficient for ongoing monitoring activities. When the trigger correctly identifies an adverse event, causative factors can be determined and interventions developed to reduce the

frequency of such events. Triggers can also be used to track rates of adverse events over time.

Current use of trigger tools

The Harvard Medical Practice Study and other classic studies used fairly blunt triggers, general indications that harm may have occurred?such as death, readmission, or unexpected return to the operating room. There was no expectation that most cases would turn out to be adverse events. Refinement of this methodology has led to the development of more specific triggers.

The Institute for Healthcare Improvement Global Trigger Tool (GTT) has become one of the most widely used trigger tools for detecting harm in hospitalized patients. It combines blunt triggers (such as rapid response team activation) with more specific but relatively insensitive ones (such as an abnormally low blood glucose measurement). The GTT includes 53 different triggers, some applicable to all patients and some inappropriate for certain patient populations or settings of care. The GTT is practical for routine improvement efforts and not just research studies, and it includes detailed instructions for training reviewers and interpreting results. Conceptually, though, the method resembles that of major adverse event studies such as the Harvard Medical Practice Study. Use of the trigger tool involves screening a defined sample of medical records by two independent clinicians for presence of one or more triggers. After a trigger is identified, the entire chart is reviewed to determine whether an adverse event took place, and if so, to grade the level of harm experienced by the patient.

Various studies have assessed the reliability of judgments using the GTT and also modified it for application in different clinical settings, including pediatric patients and patients with cancer. Versions of the tool appropriate for prospective detection in real-time have also been developed.

Controversies

The IHI cautions that the GTT (or any trigger tool method) cannot identify all sources of patient harm or the cause of harm, a point emphasized in an influential commentary. Also, trigger tools are designed to detect all adverse events; reviewers are explicitly instructed to avoid making judgments about preventability of these events during the initial review process.

Nonetheless, many studies have used the GTT or other similar tools to estimate the frequency of *preventable* adverse events in a variety of clinical settings. This is not inappropriate per se, but readers of such studies should be aware that inter-rater agreement around preventability is generally only moderate. (These issues will be discussed in more detail in an upcoming Patient Safety Primer on measurement.)

Concerns have also been raised regarding the reliability of trigger tools, both for detection of adverse events and for rating the severity of harm experienced by patients. One Swedish study used 5 teams of reviewers (each of whom had at least 3 years of GTT experience) to review a random sample of hospitalizations and found that agreement between teams on the presence of an adverse event was only slightly better than chance. Another influential study of temporal trends in adverse events also found markedly different rates when the GTT was used by personnel internal or external to the hospitals being studied. It is likely that reliability of trigger tools is significantly influenced by the level of training and experience of the reviewers and their familiarity with the clinical setting being evaluated.

Finally, most existing trigger tools have been used to identify adverse events in the inpatient setting. Although some studies have sought to develop trigger tools for ambulatory care, there is relatively little data on the accuracy and reliability of these tools.

Editor's Picks

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PERSPECTIVE

The Emergence of the Trigger Tool as the Premier Measurement Strategy for Patient Safety

PERSPECTIVE

In Conversation With…David C. Classen, MD, MS

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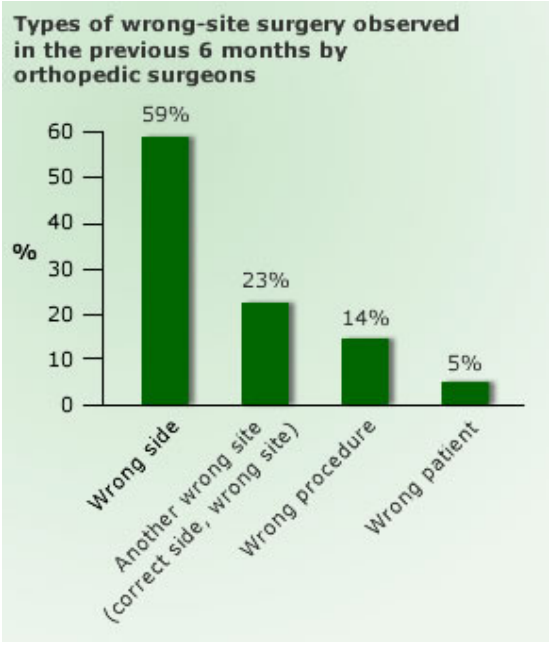
Patient Safety Primer Last Updated: June 2017

Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery

Background

Few medical errors are as vivid and terrifying as those that involve patients who have undergone surgery on the wrong body part, undergone the incorrect procedure, or had a procedure intended for another patient. These "wrong-site, wrong-procedure, wrong-patient errors" (WSPEs) are rightly termed never events—errors that should never occur and indicate serious underlying safety problems.

Wrong-site surgery may involve operating on the wrong side, as in the case of a patient who had the right side of her vulva removed when the cancerous lesion was on the left, or the incorrect body site. One example of surgery on the incorrect site is operating on the wrong level of the spine, a surprisingly common issue for neurosurgeons. A classic case of wrong-patient surgery involved a patient who underwent a cardiac procedure intended for another patient with a similar last name.



While much publicity has been given to these high-profile cases of WSPEs, these errors are in fact relatively rare. A seminal study estimated that such errors occur in approximately 1 of 112,000 surgical procedures, infrequent enough that an individual hospital would only experience one such error every 5–10 years. However, this estimate only included procedures performed in the operating room; if procedures performed in other settings (for example, ambulatory surgery or interventional radiology) are included, the rate of such errors may be significantly higher. One study using Veterans Affairs data found that fully half of WSPEs occurred during procedures outside of the operating room.

Preventing Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery

Early efforts to prevent WSPEs focused on developing redundant mechanisms for identifying the *correct* site, procedure, and patient, such as "sign your site" initiatives, that instructed surgeons to mark the operative site in an unambiguous fashion. However, it soon became clear that even this seemingly simple intervention was problematic. An analysis of the United Kingdom's efforts to prevent WSPEs found that, although dissemination of a site-marking protocol did increase use of preoperative site marking, implementation and adherence to the protocol differed significantly across surgical specialties and hospitals, and many clinicians voiced concerns about unintended consequences of the protocol. In some cases, there was even confusion over whether the marked site indicates the area to be operated on, or the area to be avoided. Site marking remains a core component of The Joint Commission's Universal Protocol to prevent WSPEs.

Root cause analyses of WSPEs consistently reveal communication issues as a prominent underlying factor. The concept of the surgical timeout—a planned pause before beginning the procedure in order to review important aspects of the procedure with all involved personnel—was developed to improve communication in the operating room and prevent WSPEs. The Universal Protocol also specifies use of a timeout prior to all procedures. Although initially designed for operating room procedures, timeouts are now required before any invasive procedure. Comprehensive efforts to improve surgical safety have incorporated timeout principles into surgical safety checklists; while these checklists have been proven to improve surgical and postoperative safety, the low baseline incidence of WSPEs makes it difficult to establish that a single intervention can reduce or eliminate WSPEs.

It is worth noting, however, that many cases of WSPEs would still occur despite full adherence to the Universal Protocol. Errors may happen well before the patient reaches the operating room, a timeout may be rushed or otherwise ineffective, and production pressures may contribute to errors during the procedure itself. Ultimately, preventing WSPEs depends on the combination of system solutions, strong teamwork and safety culture, and individual vigilance.

Current Context

Wrong-patient, wrong-site, and wrong-procedure errors are all considered never events by the National Quality Forum, and are considered sentinel events by The Joint Commission. In February 2009, the Centers for Medicare and Medicaid Services (CMS) announced that hospitals will not be reimbursed for any costs associated with WSPEs. (CMS has not reimbursed hospitals for *additional* costs associated with many preventable errors since 2007.)

Editor's Picks

CASE

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BOOK/REPORT

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WEB RESOURCE › MULTI-USE WEBSITE

Joint Commission Center for Transforming Healthcare.

The Joint Commission.

CASE

Turn the Other Cheek

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CASE

The Inside of a Time Out

CASE

Mark My Tooth

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CASE

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CASE

X-ray Flip

CASE

The Other Side

LEGISLATION/REGULATION › ORGANIZATIONAL POLICY/GUIDELINES

Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.

The Joint Commission.

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