PENNSYLVANIA PATIENT SAFETY ADVISORY

Produced by ECRI Institute and ISMP under contract to the Pennsylvania Patient Safety Authority

Vol. 11, No. 2

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OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and problems in which urgent communication of information could have a significant impact on patient outcomes.

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Distractions in the Operating Room

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ABSTRACT

Distraction is a threat to patient safety in the operating room (OR). Analysis of events reported through the Pennsylvania Patient Safety Reporting System from January 2010 through May 2013 revealed 304 reports of events occurring in the OR in which distractions and/or interruptions were indicated as contributing factors. Attention is warranted to all events impacted by distraction in the OR regardless of frequency, due to their high potential to result in serious patient harm. Distraction is particularly detrimental to performance of complex tasks that require higher levels of cognitive processing, such as those frequently encountered in the OR. Studies examining the impact of distraction in the OR setting, along with guidelines and tools developed by perioperative professional associations and patient safety agencies to limit and/or ameliorate the negative impact of distraction are discussed (e.g., application of the "sterile cockpit" concept from aviation, reducing distractions from technology and noise, use of surgical safety checklists and briefings, teamwork training). Engagement of surgeons and multidisciplinary teams is necessary to address the problem of distractions in the OR. (Pa Patient Saf Advis 2014 Jun;11[2]:45-52.)

INTRODUCTION

Distraction is defined as having one's attention drawn or directed "to a different object or in different directions at the same time."[1] The impact of distraction is influenced by multiple variables, including the characteristics of the primary task, the distractions themselves, and the environment.[2] In fact, distraction is to be expected in an environment, such as healthcare, that requires constant communication and coordination. Rivera-Rodriguez and Karsh concluded that distraction due to interruptions that are purposeful and share important information may actually improve care by appropriately refocusing attention and improving problem identification, collaboration, and communication[3] (e.g., clinical alarms, a request to "stop the line" when a member of the staff identifies a patient safety concern). Of greater concern is distraction due to nonpurposeful interruptions or operational failures that impair performance and contribute to error.

Distraction is particularly detrimental to performance of complex tasks that require high levels of cognitive processing.[4] Such tasks are encountered often in the operating room (OR) due to the complex nature of each work system factor: the physical environment, teamwork and communication, tools and technology, tasks and workload, and organizational processes.[5] Even minor distractions in the OR can have a cascade effect that ultimately results in major events and patient harm.[6] Healthcare facilities can reduce both the occurrence of distractions in the OR and their potential negative impact on patient safety by identifying the sources of distraction currently present and addressing them through application of strategies and tools such as those developed by perioperative professional associations and patient safety agencies.

BACKGROUND

Distractions occur frequently in the OR setting, both due to intrinsic sources (e.g., surgical equipment alarms, surgical team communication relevant to the procedure) and extrinsic sources (e.g., beepers, phone calls, communication from staff outside the OR).[7] Distractions can affect all members of the surgical team: anesthesiologists and nurse anesthetists, nurses, perfusionists, surgeons, surgical technicians, and other team members. Cognitive workloads are demanding for each of these professionals, with high levels of cognitive processing required of different members of the team at different times, resulting in multiple high-risk points in the course of an operative procedure.[8]

OR team members can serve as both the source and the recipient of distracting communication. An observational study of distracting communications in the OR by Sevdalis, Healey, and Vincent identified many case-irrelevant communications (CICs), defined as communication not relevant to the surgical procedure in progress. Half of all CICs consisted of "small talk." Although surgeons initiated and received the greatest number of CICs, visitors to the OR (defined as external staff not belonging to the OR team involved in the current surgical procedure) initiated CICs with the highest levels of observable distraction (i.e., causing team members to pause, disrupting workflow).* Communications directed to nurses and anesthesia providers resulted in higher levels of distraction than communications directed to surgeons.[9]

*At the time of this writing, new research was published by Sevdalis et al. that identified communication from external visitors directed to the surgeon or the entire OR team as statistically the most distracting ($p < 0.05$). Lack of coordination between hospital departments was identified as the most disruptive problem. A statistically significant correlation ($p < 0.05$) was found between more frequent and/or severe communication distractions and failure to complete intraoperative patient safety checks, even with experienced teams. (Sevdalis N, Undre S, McDermott J, et. al. Impact of intraoperative distractions on patient safety: a prospective descriptive study using validated instruments. *World J Surg* 2014 Apr;38[4]:751-8.)

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Distraction from computers and personal electronic devices (PEDs) is also a growing concern for OR teams. The widespread use of computers in clinical settings, along with the recent rapid growth in the use of cell phones and smartphones, has contributed to a heightened focus on the potential for error and harm caused by distractions that result from the use of these devices, particularly within the OR environment. "Distracted doctoring" is a term coined by the media to describe this phenomenon.[10-12] Furthermore, distraction from smartphones and other mobile devices was identified for the first time as one of the top 10 health technology hazards for 2013 by ECRI Institute.[13]

In a 2011 study of perioperative nurses' perceptions of near-miss patient safety events (defined as deviations in care with clearly significant potential consequences), distractions and interruptions were listed as one of the most common causal factors, second only to communication between team members.[14] Also in 2011, the Association of periOperative Registered Nurses (AORN) surveyed its members to determine what they considered the highest-priority patient safety issues.[15] As a follow-up, in 2013, AORN published a set of recommendations that highlighted preventing distractions and interruptions as key strategies to address 3 of the top 10 patient safety issues identified in the survey: wrong-site surgery, retained surgical items, and specimen mismanagement errors.[16] These three event types are supported as priority focus areas in analysis of reports to the Pennsylvania Patient Safety Authority for events occurring in the OR related to distractions.

OR DISTRACTIONS IN PENNSYLVANIA

Analysis of events reported through the Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) from January 2010 through May 2013 revealed 304 reports of events occurring in the OR in which distractions and/or interruptions were indicated as contributing factors. The majority of these events were reported as errors related to procedures, treatments, or tests (73.7%, n = 224). Within this event type, surgery or invasive procedure problems were reported most frequently (75.4%, n = 169), followed by laboratory test problems (19.2%, n = 43).

Table 1. Surgery or Invasive Procedure Problems Attributed to Distractions in the Operating Room, as Reported to the Pennsylvania Patient Safety Authority, January 2010 through May 2013

EVENT SUBTYPE	NO. OF REPORTS	%
Count incorrect—equipment	39	23.1
Count incorrect—needles	27	16.0
Preparation inadequate/wrong	19	11.3
Break in sterile technique	12	7.1
Count incomplete/not performed	11	6.5
Other (specify)	11	6.5
Procedure delayed	10	5.9
Foreign body in patient	9	5.3
Wrong side (left versus right)	9	5.3
Count incorrect—sponges	7	4.1
Wrong procedure	4	2.4
Wrong patient	3	1.8
Identification missing/incorrect	2	1.2
Procedure canceled/not performed	2	1.2
Wrong site	2	1.2
Procedure not completed	1	0.6
Unintended laceration/puncture	1	0.6
Total	**169**	**100.1***

* Total percentage is greater than 100 due to rounding.

Of the surgery or invasive procedure problems (see Table 1), the subtypes reported with greatest frequency were incorrect counts of equipment (n = 39) and incorrect needle counts (n = 27). Of note, within the subtype labeled "Other," three events involved specimen mishandling during the procedure and three events involved the use of expired products or implanted materials that were discovered after having been used as part of the procedures.

Of the 43 laboratory test problems (see Table 2), the event subtypes most frequently reported were mislabeled specimens (n = 10), incomplete or missing specimen labels (n = 10), specimen quality problems (n = 7), and specimen delivery problems (n = 7).

Attention is warranted to all events impacted by distraction in the OR regardless of the frequency with which they are reported, due to their high potential to result in serious harm. The following are examples of Serious Events (i.e., events involving patient harm) reported through PA-PSRS associated with distraction in the OR:

- Wrong-side surgery
- Wrong-site surgery
- Transfusion of the wrong blood to the wrong patient
- Failure to remove a piece of resected bowel, requiring a return to the OR
- Injection of a patient using an unlabeled syringe and needle previously used on another patient

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Table 2. Laboratory Test Problems Attributed to Distractions in the Operating Room, as Reported to the Pennsylvania Patient Safety Authority, January 2010 through May 2013

EVENT SUBTYPE	NO. OF REPORTS	%
Mislabeled specimen	10	23.3
Specimen label incomplete/missing	10	23.3
Specimen quality problem	7	16.3
Specimen delivery problem	7	16.3
Result missing or delayed	4	9.3
Other (specify)	2	4.7
Test ordered, not performed	2	4.7
Wrong test performed	1	2.3
Total	**43**	**100.2***

* Total percentage is greater than 100 due to rounding.

- Failure to notice a significant loss of evoked potential from a patient's arm during spinal surgery
- Inflation of a tourniquet applied to a patient's leg for longer than intended, resulting in neurovascular changes

DISCUSSION

The Authority has published previously on the topic of distraction, noting that hospitals can consider steps to reduce the impact of distraction by recognizing common sources of distraction and situations that are distraction-prone, identifying clinical tasks or procedures that are most likely to result in medical error and patient harm as a result of distraction, and applying specific risk reduction strategies.[17] To support hospitals in these endeavors, the Authority sought to find examples of best practices and specific tools currently in clinical use that could be shared with hospitals in Pennsylvania. The perioperative area was identified as the healthcare setting in which the most concrete work has been done to identify such practices and develop tools to address the problem of distraction.

Limiting Distraction in the OR

One approach to managing the problem of distractions in the OR is to employ primary prevention strategies to decrease the incidence of distractions. Specific strategies supported in the literature include implementing the "sterile cockpit" rule and reducing distractions from technology and noise.

"Sterile cockpit." The concept of the "sterile cockpit" comes from aviation. It describes a protocol that applies during critical periods of high mental workload and high risk, when all communication in the cockpit is restricted to information necessary for handling the plane (i.e., during taxi, takeoff, landing, and any flight operations below 10,000 feet). This rule not only prohibits nonessential conversation but also eating, reading materials not relevant to operating the plane, and any activity that "could distract any flight crewmember from the performance of his or her duties or which could interfere in any way with the proper conduct of those duties."[18]

In order to apply the "sterile cockpit" rule in the OR, it is necessary to first define the critical phases of operative procedures during which the rule would apply. Critical phases for the OR team have been defined as briefing, time-out, and debriefing.[16,19] Difficulty lies in further identifying critical phases common to the entire team, as the tasks and their associated cognitive loads vary over the course of the procedure, with different roles experiencing higher or lower levels of mental workload at different times.[8] For instance, anesthesiologists have designated induction and emergence as critical phases in the administration of anesthesia that are analogous to takeoff and landing.[20]

But for surgeons, critical phases of an operative procedure may occur at various points during the procedure depending on the steps involved[8] (e.g., creation of an anastomosis, nerve dissection). And for nurses, surgical counts and specimen labeling are examples of critical phases.[16]

Identification of critical phases may also vary depending on the type of procedure. For example, in a study examining the feasibility of applying the "sterile cockpit" concept to cardiopulmonary bypass surgery, researchers found it was more beneficial to define critical phases according to procedure-specific events (e.g., establishment of activated clotting time, initiation of cardiopulmonary bypass, administration of cardioplegia) rather than specific time intervals. A structured communication protocol was implemented during these critical events, and miscommunications during those times were reduced by half.[8] In a similar study evaluating the use of an intraoperative pathway for deep inferior epigastric perforator flap breast reconstruction surgery, nine critical stages were identified (e.g., induction, perforator dissection/flap harvest, recipient vessel harvest). The activities for each staff member were defined for each stage, and checklists and interphase transition briefings were used to standardize processes, resulting in improved interdisciplinary communication and statistically significant reductions in OR time and costs.[21]

Reducing distractions from technology. Beyond distraction from cell phones and pagers, distraction from the use of newer technologies, such as smartphones and other PEDs, is a growing concern in healthcare.[10-12,22,23] In addition to phone calls and text messages, these devices

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introduce distractions from social media, e-mail, and other forms of electronic communication. The compulsion to constantly check PEDs is being recognized as an addiction that is impacting users of these devices, not least among them healthcare providers.[24] As of this writing, AORN is updating its position statement on noise in the perioperative setting to include new suggestions for preventing distractions from PEDs during critical phases of perioperative care.[25]

Information on hospital cell phone policies is limited. Anecdotal information gathered from administrators and OR staff suggests that in hospitals that have established such policies specific to the OR setting, cell phone use is typically banned, though these policies are not strictly enforced, nor do they apply to surgeons. In general, hospitals that have established institution-wide policies regarding cell phone use tend to restrict the personal use of cell phones to non-work time in nonpatient areas.[26]

In 2008, the American College of Surgeons (ACS) issued an official statement on the use of cell phones in the operating room in which it recognized that "the undisciplined use of cellular devices in the OR—whether for telephone, e-mail, or data communication, and whether by the surgeon or by other members of the surgical team—may pose a distraction and may compromise patient care." ACS did not propose a ban on cell phone use; rather, it listed 10 considerations to guide appropriate use, including avoiding personal calls, silencing ringtones, forwarding calls, and setting a distinct alert for emergency calls.[27]

AORN has similarly recommended that OR staff leave cell phones and pagers with someone outside the procedural environment whenever possible, properly identify cell phones and pagers that must be answered, place any nonessential communication devices on mute or standby during surgery, and limit external communication to urgent or emergent conversations.[28]

While cell phones, pagers, and smartphones have introduced new distractions in the healthcare setting, these technologies may also hold the key to better handling interruptions to workflow. Clinicians prefer synchronous communication (e.g., face-to-face or telephone conversations) and engage in more of this type of communication over asynchronous communication (e.g., numeric or alphanumeric paging, text messages, voicemail). Both types of communication produce frequent interruptions, with synchronous communication being the most disruptive.[29] Asynchronous communication using newer technologies provides a way for the sender to communicate information to the receiver while allowing the receiver to review the information and respond at a later time, if appropriate, thereby decreasing interruptions to their workflow.[30,31]

Reducing distractions from noise. In addition to the types of OR noises already discussed (from verbal communication, cell phones, pagers, and PEDs), other sources of noise in the OR include music, surgical equipment, and clinical alarms. Noise has been linked to miscommunication and impaired performance, even when the noise level falls within the range of normal conversation and ambient background noise. Performance has been found to further deteriorate with higher noise levels, most notably noise from music.[32] Music is of particular concern, as more than 60% of personnel report listening to music in the OR and more than 50% prefer to listen to music at medium to high volumes.[33]

Well-designed and properly managed clinical alarms may be considered distractions or interruptions that are purposeful and share important information. Clinical alarms are intended to improve problem identification and appropriately refocus the attention of clinicians.[2] False alarms, also called nuisance alarms, are sources of noise and distraction that disrupt patient care and impair clinician performance. Aside from this direct effect, frequent false alarms can distract clinicians, causing them to fail to recognize "real" events.[34] In a review of the literature, Konkani et al. concluded that individualizing alarm settings for each patient's condition is the most direct method for decreasing false alarms. Promoting a hospital culture that emphasizes the importance of alarm customization and using smart alarms, when available, are also suggested.[35]

Reducing harm associated with clinical alarm systems has been identified as a new 2014 National Patient Safety Goal by the Joint Commission.[36] ECRI Institute has identified hazards from clinical alarms as number one on its list of the top 10 health technology hazards for 2014 and offers a free Alarm Safety Resource Site, available at https://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx, that contains guidance and tools to help healthcare facilities improve alarm safety.[37]

Tools to Ameliorate the Impact of Distraction in the OR

In recognition of the fact that distractions will continue to occur in the OR environment despite implementation of strategies to limit their occurrence, secondary prevention strategies to ameliorate the impact of distractions are necessary. Surgical checklists and preoperative briefings are two tools that can help the OR team achieve and maintain situational awareness and avoid and/or recover from the negative effects of distraction.

Surgical checklists. When distraction diverts attention from a primary task, the likelihood of committing an error upon return to the primary task is increased.[4] Checklists are a tool to focus the attention of the surgical team on the primary task (i.e., the operative procedure) and to aid the team in quickly regaining that focus after encountering a distraction. Checklists make explicit the minimum expected steps that comprise a complex

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process and aid memory recall, particularly in situations that are distraction-prone and require high cognitive workload.[38] When used during an operative procedure, a checklist serves as an event-based cue that aids memory recall by providing information about what steps in a procedure have been completed and what steps remain to be performed.[39]

Surgical checklists have been developed by the Joint Commission,[40] the World Health Organization (WHO),[41] and AORN.[42] The Authority has also developed a preoperative checklist, which is available as part of an extensive collection of tools and resources designed to help hospitals prevent wrong-site surgeries.[43] This collection is available on the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx and includes a tool titled Actions to Satisfy Universal Protocol and WHO Surgical Safety Checklist that presents expanded advice from the Authority alongside recommendations from the Joint Commission and WHO.

Preoperative briefings. A checklist, in and of itself, does not communicate the complexity of a surgical case to all the members of the OR team. This is the purpose of a preoperative briefing. A briefing conveys "precise instructions or essential information"[44] about the primary task (i.e., the operative procedure) to all members of the surgical team. The beneficial impact of briefing on reducing distractions is illustrated in a study by Henrickson et al., which found a statistically significant ($p < 0.05$) decrease in surgical flow disruptions after implementing a cardiovascular-surgery-specific, multidisciplinary briefing protocol designed with input from all members of the OR team. The authors proposed that this is because a briefing promotes mindful engagement, open communication, and a shared mental model for the team. Without active participation in the briefing by all members of the team, staff can become disengaged and "miss subtle migrations toward error during a procedure."[45] AORN specifically includes time for a briefing, time-out, and debriefing as part of the Comprehensive Surgical Checklist.[16]

Empowering the Surgical Team

It is only within a culture of patient safety, with effective teamwork, skilled leaders, and clear communication, that OR team members may feel empowered to take action to promote an environment with reduced distractions and to speak up when distraction is recognized to be impairing performance.

Teamwork training. Crew resource management (CRM) was developed by the aviation industry in 1979 in response to the devastating crash of United Airlines flight 173 that occurred as a result of distraction (the plane ran out of fuel while the flight crew was distracted by troubleshooting a problem with the landing gear).[46] CRM was later adapted to healthcare following the 1999 Institute of Medicine report *To Err Is Human: Building a Safer Health System*, in which a recommendation was made to apply aviation safety concepts to healthcare systems. CRM is a team-based training model that teaches cognitive and social skills that empower all team members to promote safety and improve performance. The training focuses on communication, decision making, interpersonal relations, team coordination, and leadership.[47]

Similar to CRM, Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) is a team-based training program that teaches skills in four domains: leadership, mutual support, situation monitoring, and communication.[48] Situation monitoring is "the process of actively scanning and assessing elements of the situation to gain information or maintain an accurate understanding of the situation in which the team functions."[49] The skills and tools taught as part of this domain apply most directly to the challenge of managing distractions.[49]

Both CRM and TeamSTEPPS training include tools already mentioned, such as checklists and briefings. But beyond the use of these standardized processes and tools, both programs stress the importance of cross-monitoring and advocacy and assertion.[47,48]

- Cross-monitoring (i.e., "watching each other's back") is the action of "monitoring other team members by keeping track of their behavior and providing feedback [to ensure] that procedures are being followed appropriately."[49] This skill allows team members to help each other maintain focus on the primary task in the face of distraction.
- Advocacy and assertion involves speaking up about patient safety concerns, especially when the leader or other members of the team have failed to recognize the concern or do not believe the concern to be valid.[49] This skill empowers all team members, including surgeons, to speak up when they recognize a distraction or interruption is impairing performance or when they have identified the need for an intraoperative briefing because a critical phase in the procedure has been reached.

For more information on TeamSTEPPS, see "TeamSTEPPS Training."

Surgeon engagement and leadership. Lack of engagement from surgeons has been cited as a barrier to promoting a culture of patient safety in the OR. Guidelines, checklists, and protocols alone will not be effective without the input and ongoing support of surgeons.[47,50] In surveys of perioperative professionals, between 29%[51] and 43%[52] of respondents report being encouraged to speak up and report concerns during procedures. As OR team leaders, surgeons are expected to demonstrate leadership skills that are

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TeamSTEPPS TRAINING

Pennsylvania healthcare reporting facilities that would like more information about Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) train-the-trainer programs can contact the Pennsylvania Patient Safety Authority at (717) 346-0469 or by e-mail at patientsafetyauthority@pa.gov.

If an organization wishes to explore this program, TeamSTEPPS master trainers recommend first completing the TeamSTEPPS Organizational Readiness Assessment Checklist, which can be found at http://teamstepps.ahrq.gov/readiness.

foundational to establishing a culture of patient safety, as emphasized in CRM and TeamSTEPPS training. TeamSTEPPS training specifically notes that leaders should be able to effectively empower team members to speak up and openly challenge when appropriate and that effective leaders are responsible for ensuring that team members are sharing information, monitoring situational cues, resolving conflicts, and helping each other when needed[49]—all skills essential to both avoiding distraction and handling distraction in the OR.

RISK REDUCTION STRATEGIES

In addition to the risk reduction strategies outlined in the March 2013 *Pennsylvania Patient Safety Advisory* article "Distractions and Their Impact on Patient Safety,"[17] the following strategies are suggested for reducing distractions in the OR setting:

- Assemble multidisciplinary teams to identify critical phases in operative procedures, specific to individual teams and procedure types as necessary, that should not be interrupted.[8]
- Implement a "sterile cockpit" or "no interruption zone" protocol during critical phases of operative procedures.[8,16,19]
- Use preoperative and procedural checklists.[16,38,40,41,43]
- Design and implement a multidisciplinary briefing tool.[45]
- Use a structured communication tool, such as SBAR (Situation, Background, Assessment, Recommendation), especially during critical phases of a procedure.[45,47,48]
- Minimize communication by members of the OR team that is irrelevant to the current procedure, and limit interruptions from outside staff and other visitors to the OR.[9]
- Establish guidelines and expectations, applicable to all members of the surgical team, for the appropriate use of cell phones, pagers, smartphones, and other PEDs in the OR, and monitor for compliance.[24,26-28]
- Educate staff about electronic distraction and its potential detrimental effect on patient safety.[10-13,22-25]
- Raise awareness of the addictive component of PEDs and other technologies.[24]
- Reduce noise level in the OR whenever possible, especially during critical phases in the procedure[32,33] (e.g., limit conversation not relevant to the current procedure; lower the volume of background music; adjust surgical equipment settings to reduce excess noise, as able).
- Customize alarm settings for individual patients, and use smart alarms, when available, to reduce distraction from false or nuisance alarms.[35]
- Provide teamwork training, such as CRM or TeamSTEPPS, using case study scenarios specific to the OR.[47,48]
- Engage surgeons in patient safety teamwork training and quality improvement projects targeted to reducing distraction.[47,48,50]
- Ensure that surgeons and other OR team leaders promote a culture of patient safety, encouraging all team members to practice skills necessary for situation monitoring and to voice concerns at any point during a procedure.[47-50]

LIMITATIONS

In-depth analysis by the Authority for events occurring in the OR associated with distraction is limited by the information provided in PA-PSRS event report narratives. Much of what is known about distractions in the OR has been gained from observational studies in real or simulated OR environments. Given the complexity of the OR work environment and the ubiquity of distraction, the events reported through PA-PSRS may represent a small number of all events occurring in the OR as a result of distraction.

Additionally, distraction in the OR may contribute to procedural errors not recognized until the postoperative period (e.g., a leaking anastomosis on post-op day five), at which point the event may be reported as occurring on the postsurgical unit rather than the OR and may be attributed to other causes. At this point, the distraction that may have contributed to the procedural error may not be recognized.

CONCLUSION

Distraction is a threat to patient safety that is present in all healthcare settings. Distraction can be especially dangerous during performance of highly complex procedures that require higher levels of cognitive processing, such as those performed in the OR setting. There is a growing body of research examining the impact of distractions in the OR setting. Substantial work has been done by perioperative professional associations and patient safety agencies to create guidelines and tools that can be used in hospital

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ORs to limit distraction and/or ameliorate the negative impact of distraction.

The Authority encourages hospitals to engage surgeons and form multidisciplinary teams charged with addressing the issue of distraction in the OR setting by identifying sources of distraction that may be unique to individual hospitals, surgical teams, or procedures and designing process improvements based on existing guidelines and tools. An approach that includes primary prevention (i.e., implementing strategies that decrease the occurrence of distraction in the OR environment), secondary prevention (i.e., use of tools and processes that help OR teams maintain situational awareness and avoid distraction or recover from the negative effects of distraction), and team-based training is suggested.

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Reviewer Commentary

I firmly believe that situational awareness is an essential characteristic for operating room personnel and is key to recognizing behaviors and actions that may be appropriate at one time and distracting at a different time. I also offer the following additional thoughts and questions for the reader to consider. One, other distractions worthy of attention are those introduced by exceedingly complex, detailed, and time-consuming computer data entry required of the circulating nurse and extremes in room temperature preferred by surgeons that may be too hot or cold for other OR team members. Two, while useful, the checklist and briefing may need to be fractionated into shorter, more frequent, focused episodes utilized throughout the course of complex procedures, rather than be treated as a single obligatory task to be accomplished at the beginning of a case, then forgotten. Three, does the act of identifying critical periods mean that it is okay to engage in distracting behaviors at other noncritical periods?

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Healthcare Worker Fatigue: Current Strategies for Prevention

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ABSTRACT

Since 2004, Pennsylvania healthcare facilities have reported to the Pennsylvania Patient Safety Authority 1,601 events in which healthcare worker fatigue has been cited as a contributing factor. Medication errors (62.1%, n = 995) and errors related to a procedure, treatment, or test (26.4%, n = 422) comprised 88.5% of all events reported with healthcare worker fatigue as a contributing factor. In addition, 37 events (2.3%) were reported as Serious Events in which patient injury occurred, and 4 of the Serious Events resulted in patient death. The current literature shows that primary efforts to implement regulations and guidelines addressing healthcare worker fatigue has targeted limiting hours worked, but further scientific study suggests a more comprehensive approach is needed, as simply reducing hours does not address fatigue that is caused by disruption in circadian sleep and extended work hours. Healthcare organizations are employing some mitigating practices. Much can be learned from other industries and countries that are using more developed fatigue risk management systems (FRMSs) as a method of reducing this risk. The emergence of FRMSs may point to the solution of reducing the incidence of patient injury due to healthcare worker fatigue through both proactive and reactive assessments and interventions at the staff and administrative levels. (Pa Patient Saf Advis 2014 Jun;11[2]:53-60.)

INTRODUCTION

Fatigue can be described as an overwhelming sense of tiredness, lack of energy, and feeling of exhaustion associated with impaired physical and/or cognitive functioning.[1] For industries that perform 24-hour operations, fatigue has been recognized as a safety issue for many years. The media has reported catastrophic accidents in the aviation, transportation, and nuclear power arenas in which fatigue has been noted as a major causative factor.[2]

In a highly publicized healthcare case, fatigue was noted as one of the causes of a fatal medication error. In 2006, a Wisconsin registered nurse (RN) was charged with a class H felony (neglect of a patient, causing great bodily harm) after she mistakenly gave an epidural medication through the patient's peripheral intravenous (IV) line instead of the prescribed antibiotic. Records from the Wisconsin Department of Regulation and Licensing state that this nurse had worked two consecutive eight-hour shifts ending at midnight and then planned to work the next morning at 7 a.m. for another eight-hour shift.[3]

The primary focus for addressing fatigue in the work setting has been through the implementation of hours-of-service programs whereby employee work hours are restricted to include specific rest periods between shifts.[2] Research has shown that restriction of work hours alone has not been successful in reducing the risk of fatigue-related mistakes.[2,4,5] In the case noted above, the nurse's license was suspended for nine months and she was ordered to no longer work more than 12 hours in any 24 consecutive hours and no more than 60 hours in any seven consecutive days.[3]

An analysis of fatigue-related events that have been reported through the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) provides insight into this patient safety issue. Also provided are fatigue risk mitigation practices currently in place in healthcare and other industries, including more comprehensive fatigue risk management programs.

HEALTHCARE WORKER FATIGUE AND ERRORS

Taking a page from other industries that staff around the clock, healthcare has been studying the effects of healthcare worker fatigue as it presents as both a patient safety and employee health issue. There is an increase in awareness that fatigue impairs performance, and studies have shown that 17 hours of sustained wakefulness is equivalent to a blood alcohol level of 0.05% and that after 24 hours, it is equivalent to 0.10%.[6,7] Regardless of fatigue, healthcare workers are required to maintain an astute level of alertness and vigilance to ensure that safe, quality healthcare is delivered.

Fatigue is described by Dr. A. E. Rogers as an overwhelming sense of tiredness, lack of energy, and feeling of exhaustion associated with impaired physical and/or cognitive functioning.[1] Healthcare workers experience fatigue for a variety of reasons, but the two major causes of fatigue are disruption of circadian rhythm sleep and sleep deprivation.[1,8-10] The nature of healthcare work is such that staff will work during the night and for extended shifts, such as 12-hour shifts and overtime.[11-13] These conditions go against the body's need for rest and may result in the worker being fatigued on the job.[8,14]

The Joint Commission, through a Sentinel Event Alert, reports that fatigued workers can exhibit the following conditions:[9]

- Lapses in attention and inability to stay focused
- Reduced motivation

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- Compromised problem solving
- Confusion
- Irritability
- Memory lapses
- Impaired communication
- Slowed or faulty information processing and judgment
- Diminished reaction time
- Indifference and loss of empathy

In studies conducted with nurses, it was shown that working a 12-hour work shift or working overtime is associated with difficulties staying awake while on duty, reduced sleep times, and nearly triple the risk of making an error, with the most significant elevations in the risk of making an error occurring when nurses worked 12.5 hours or longer.[1] In addition, fatigue-related cognitive impairment has been linked to adverse events and errors in care, as have working more than 40 hours per week or working voluntary paid overtime.[11] Feelings of fatigue, tiredness, sleep deprivation, sickness, and general discomfort among staff were reported as contributory factors to errors. In addition to long work hours, physical exhaustion can also be caused by lack of breaks to eat and/or drink.[15,16]

Data on the effects of extended work hours as a patient safety risk was not available when hospitals began using 12-hour shifts. Many hospitals have adopted 12-hour shifts as the norm, and it is a similar choice with nursing staff who choose to limit the number of days they work within a week. Although nursing executives may feel that using 12-hour shifts results in nursing satisfaction and retention, the research on risk of error and patient safety begs for further review.[17] Nursing has relied on the loyalty of staff to come in voluntarily when called to address acute staffing needs. This practice may be silently encouraged by supervisors and other leaders.[6] Research has shown the practice of self-regulation is not a reliable mitigator of fatigue[1,17] and the result may be a tired nurse showing up to work. Moving away from the 12-hour shift would be a major shift in practice, and clear evidence-based data would be necessary to support such a change.[17]

Table 1. Medication Errors Reported to the Pennsylvania Patient Safety Authority with Fatigue as a Contributing Factor, June 2004 through August 2013

MEDICATION ERROR	NO. OF REPORTS
Wrong dose	427
Dose omission	271
Extra dose	94
Medication list incorrect	64
Prescription refill delay	43
Monitoring error	30
Unauthorized drug	15
Inadequate pain control	4
Other	47
Total	**995**

There is much discussion regarding whether fatigue contributes to the human errors associated with adverse patient events.[2] The Joint Commission, in a Sentinel Event Alert, has stated that a fatigued worker tends to make more mistakes.[8,9] Sentinel event data released in September 2013 lists "human factors," including fatigue, as the most frequently identified root cause of a sentinel event, and the Joint Commission now recommends that fatigue be considered and evaluated as a contributing factor in the root-cause analysis process.[9,18]

Pasupathy and Barker stated that current research has not clearly identified thresholds for fatigue levels that will lead to meaningful changes in objective performances in nurses. It is unknown how much fatigue is too much or at what level of fatigue a healthcare worker is safe to work.[19] Other studies have shown that duty hour restrictions or hours-of-service regulations alone will not address the cause of fatigue, because they do not address circadian time of work (night shift), the opportunity to sleep, and the total number of hours of sustained wakefulness.[2]

PA-PSRS EVENT REPORTS

PA-PSRS allows facility reporters to select fatigue as a contributing factor to an event report. In reviewing this topic, two queries of the PA-PSRS database were performed. The first query searched for events in which healthcare worker fatigue was noted as a contributing factor. This query found 1,601 events identified between June 2004 and August 2013; 1,564 events (97.7%) were reported as Incidents and did not result in any harm to the patient, and 37 events (2.3%) were reported as Serious Events (harm score E to I) that resulted in patient injury. Four of the Serious Events had a harm score of I, meaning they involved patient fatality. The top five locations in which events occurred were the medical-surgical unit, emergency department, pharmacy, general medical ward, and the laboratory. For context associated with harm scores, in 2013, acute healthcare facilities reported 246,606 events in total, of which 239,063 events (96.9%) were reported as Incidents and 7,543 (3.1%) were reported as Serious Events.[20]

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Table 2. Errors in Procedure, Treatment, or Test Reported to the Pennsylvania Patient Safety Authority with Fatigue as a Contributing Factor, June 2004 through August 2013

ERRORS IN PROCEDURE, TREATMENT, OR TEST	NO. OF REPORTS
Lab test error	216
Radiology or imaging problem	58
Surgery or invasive procedure problem	53
Referral consult problem	18
Respiratory care	12
Dietary	5
Other	60
Total	**422**

Table 3. Serious Events with Fatigue as a Contributing Factor Reported to the Pennsylvania Patient Safety Authority, by Category, June 2004 through August 2013

EVENT CATEGORY	NO. OF REPORTS
Error in procedure, treatment, or test	17*
Medication error	9*
Fall	4
Skin integrity	2
Complication of procedure, treatment, or test	2*
Other/miscellaneous	3*
Total	**37**

* Including one Serious Event with a harm score of I (event resulting in patient death)

Medication errors (62.1%, n = 995) and errors related to a procedure, treatment, or test (26.4%, n = 422) comprised the majority (88.5%) of all events that listed healthcare worker fatigue as a contributing factor. For context associated with event types, in 2012, medication errors (18.2%, n = 42,898) and errors related to a procedure, treatment, or test (21.9%, n = 51,443) comprised the predominant event types reported by acute healthcare facilities.[20] The most common medication errors made involving healthcare worker fatigue were wrong dose given, dose omission, and extra dose given (see Table 1). Medication errors occurred more frequently in the medical-surgical unit, pharmacy, general medical ward, and emergency department than in other locations.

The most common errors related to a procedure, treatment, or test were laboratory errors, other miscellaneous errors, radiology or imaging problems, and surgical invasive procedure problems (see Table 2). These events were reported most frequently in the medical-surgical unit, laboratory, emergency department, and the operating room.

It was also noted that medication errors and errors related to a procedure, treatment, or test comprised 70% of all events categorized as Serious Events (see Table 3). Serious Events attributed to healthcare worker fatigue occurred most frequently in the operating room, intensive care unit (ICU), psychiatric unit, medical-surgical unit, and the imaging department.

The second query of the PA-PSRS database searched for events in which fatigue was mentioned in the recommendations field. Five additional reports were identified in which the staff described fatigue as a contributing factor to the event in a narrative comment. The following are examples from event reports to PA-PSRS in which staff reported that being fatigued or tired contributed to the event (emphasis added in bold).

Medication Errors

RN hung NSS [normal saline solution] bolus. Due to only having one infusion pump, the bolus was primed through new tubing, but when RN hooked up tubing to patient's central venous line, she thought she put it in the pump but didn't. Patient's main IV fluid of D51/2 NSS had been running at 30 mL/hr and [more than 80 mL] infused before the error was caught. The NSS bolus was then correctly hooked up, and the patient received the remaining ordered volume. Two physicians from neurosurgery were notified and stated this was not a problem for the patient. The RN had gone without a meal on a very intensely busy shift. Fatigue and hunger were definitely factors. If the RN could have had a chance to eat and take a break in that time, perhaps this may not have occurred.

Patient found with 3.375 Zosyn hanging, which was not prescribed to the patient. Patient had PCN [penicillin] allergy. Zosyn was due [in the morning] for Patient A. Patient A had Zosyn hanging in room. Patient B also had Zosyn hanging in room, and this bag was labeled with Patient A's name. Patient B has a documented PCN allergy. Physician aware. Patient monitored for any adverse reaction. None noted. RN manager reviewed with staff involved. ***Staff member stated they made the mistake***

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due to being fatigued and not double-checking prior to hanging bag. Staff had worked four 12-hour night shifts.

Laboratory Errors

Clerical error in cerebral spinal fluid gram stain result. Need to type "cyto" for cytospin slide instead of "cylo" and typed twice "enter" so it became cyclospora species. Work was very busy so ***I was hungry and tired****.*

Lab tech had difficult time with blood draw; procedure took longer than normal; tech was experiencing back pain/fatigue, which contributed to distraction from normal procedures, and inadvertently left tourniquet on patient. Lab techs to keep florescent orange tourniquet in view during draw attempts, and ***techs encouraged to take a break if back pain or fatigue begins to cause distraction.***

Radiology Errors

After finishing the lung scan, proceeding to send the images, and [quality-checking] the images, I realized that I would have to utilize remote radiology. Transport called and said they were tied up in ICU, so I decided to take the patient back to the unit by myself. When I arrived back in the department to finish up, I believe it had slipped my mind to fill out the form and send images to remote radiology. Later that morning while walking back to work, I realized that I might not have finished the paperwork. I immediately contacted the reading room to alert the radiologist reading. ***Tired, that would be the number one factor. Had been working for over 16 hours.*** *I got easily sidetracked in trying to get the patient situated. Next time, finish all paperwork before moving on to the next situation.*

REDUCING THE RISK OF FATIGUE-RELATED ERRORS PAST, PRESENT, AND FUTURE

In response to the current research and information on healthcare worker fatigue, healthcare organizations and professional associations have implemented programs to address the effects of fatigue in hopes of reducing the incidence of subsequent errors and patient injuries. As previously stated, the initial efforts in addressing fatigue have been through implementation of hours-of-service standards, such as those implemented for residents in training. These alone have not been successful, as they do not address the two major causes of fatigue, which are disruption of circadian rhythm sleep and sleep deprivation.[1] Hours-of-service programs address how much work is performed but may not take into effect what time of day the work is done and for how many consecutive days.[21]

In 2003, the Accreditation Council for Graduate Medical Education (ACGME) implemented duty hour standards for physicians in training. The standards were put forth with the intent of promoting safe patient care and increasing the quality of the educational experience for the resident physician. The standards included regulations on the maximum number of hours of work per week (80 hours averaged over a four-week period, inclusive of all in-house call), maximum duty period length (24 consecutive hours, inclusive of in-house call), and mandatory time that the resident would be free from duty (one day in seven free from clinical and educational responsibilities averaged over a four-week period and inclusive of call).[22-24]

These standards have been under much scrutiny and discussion since their inception, as there was concern that the limitations put forth with these standards alone did not achieve the prescribed purpose of relieving the level of fatigue or necessarily reducing medical error.[22,25,26] Concern has been voiced that adherence to the standards has not resulted in a positive impact to patient care or medical education. It was cited that the standards have resulted in an increase in the number of patient handoffs and that the patient may be cared for by a resident less familiar with the patient's case.[22,27-30] In addition, the resident may still be required to do the same amount of work in less time, which may produce more errors.[27]

In a 2009 report, the Institute of Medicine (IOM) recommended that ACGME include guidelines to increase residents' opportunities for sleep so that acute and chronic sleep deprivation could be minimized and fatigue-related errors reduced. IOM further recommended that residents be allowed 5 hours of protected sleep during any work shift that exceeded 16 hours and that this time be counted toward the weekly maximum of duty hours (80 hours averaged over four weeks). In addition, it recommended that resident supervision and handover procedures be enhanced to identify potential errors before they reach the patient.[31]

In 2011, the ACGME standards were revised. The maximum number of hours worked per week stayed at 80 hours averaged over a four-week period but now included a caveat that this was inclusive of all in-house call activity and all moonlighting.[24] Maximum duty hours for the first-year resident were reduced from 24 hours to 16 hours. For higher-level residents scheduled to a maximum of 24 hours, the program must encourage residents to use fatigue mitigating strategies, such as napping after 16 hours of continuous duty and between the hours of 10 p.m. and 8 a.m., to maintain a safe level of alertness.[22,24,25] The standards stipulate that one day free of duty must be scheduled every week (averaged over four weeks) and that at-home call cannot be assigned during the residents' free day.[24] The standards further provide a detailed approach as to program requirements for the education of faculty and staff on fatigue mitigation strategies.[22,24,25]

In regard to nurses, Trinkoff et al. state that there are only voluntary recommendations

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that nurses limit their work hours to no more than 60-hour weeks or 16 hours in a 24-hour period.[32] IOM in 2004 recommended that state regulatory agencies should prohibit nurses from providing care in excess of 12 hours in any given 24 hours and over 60 hours in a seven-day period. These recommendations apply to any combination of scheduled shifts and mandatory or voluntary overtime.[33]

Several states have prohibited the use of mandatory overtime as a means whereby hospitals can demand that nurses work extra shifts to fill known staffing needs.[8,23] In Pennsylvania, Act 102 was enacted in July 2009 and prohibits healthcare facilities from using this practice for nurses and other caregivers.[30] The American Nurses Association (ANA) has stated in its discussion of mandatory overtime that the individual RN has the ethical duty to decide if he or she is too fatigued to work additional hours or an additional shift.[23] This may be problematic, as research has shown that the fatigued worker may not be able to make this judgment regarding his or her ability to work safely and as self-regulation is not a reliable mitigator of fatigue.[1,17]

In addition, a study done by Pasupathy and Barker discussed the ranges of levels of fatigue and perceived performance. They stated that current research does not clearly identify thresholds for fatigue levels that will lead to meaningful changes in objective performances in nurses and therefore cannot predict what level of fatigue is too much to allow staff to practice safely.[19] ANA has convened a nurse fatigue professional issues panel that is charged with revising the 2006 position paper on fatigue. The position paper is expected to be released in April 2014.

FATIGUE RISK MANAGEMENT SYSTEMS

The term fatigue risk management system (FRMS) has evolved from organizational risk management and is being used in healthcare and other industries. The Federal Aviation Administration has defined a fatigue risk management program as "a data driven and scientifically based process that allows for continuous monitoring and management of safety risks associated with fatigue-related error. It is part of a repeating performance improvement process. This process leads to continuous safety enhancements by identifying and addressing fatigue factors."[4] Using its aviation maintenance FRMS,

Table 4. Mapping between Fatigue Interventions and Fatigue Risk Management Objectives

INTERVENTION	REDUCE FATIGUE	REDUCE OR CAPTURE FATIGUE-RELATED ERRORS	MINIMIZE THE HARM CAUSED BY FATIGUE
Hours-of-service limits	X		
Scientific scheduling	X		
Napping strategies	X		
Training and education for aviation maintenance technicians and inspectors	X	X	
Training and education for supervisors and planning staff	X	X	X
Excused absences		X	
Medical treatment for sleep disorders	X		
Self-assessment		X	
Fatigue detection technology	X	X	
Work breaks	X	X	
Work environment		X	
Careful use of caffeine	X	X	
Fatigue-proofing of task procedures		X	X
Task scheduling interventions		X	X
Progressive restrictions of work responsibilities		X	X

Source: Hobbs A, Avers KB, Hiles JJ. Federal Aviation Administration. Fatigue risk management in aviation maintenance: current best practices and potential future countermeasures [online]. 2011 Jun [cited 2013 Nov 19]. https://primis.phmsa.dot.gov/crm/docs/FRMS_in_MX_OAM_TR_HobbsAversHiles.pdf

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levels of risk are assessed to determine what fatigue risk mitigating strategies need to be employed. Table 4 lists the fatigue interventions used to achieve the objectives of reducing fatigue, reducing or capturing fatigue-related errors, and minimizing the harm caused by fatigue-related errors.[4] A successful program will be system-based and will limit the potential for human errors and have redundant systems that catch errors before they reach patients.[8]

The key characteristics of an FRMS are as follows:[2]

- Science-based
- Data-driven
- Cooperative
- Fully implemented
- Integrated
- Continuously improved
- Budgeted
- Owned

A good FRMS will provide the following:[8]

- Education and training on the effects of fatigue
- Strategies to increase alertness and mitigate fatigue
- Opportunities to identify and treat any medical conditions that may affect alertness or fatigue, such as sleep disorders
- Scheduling policies
- Adverse event, medical error, and occupational injury investigation

The most well-documented healthcare model of a comprehensive FRMS is that of Queensland Health in Australia. Its belief that fatigue is an occupational hazard that needs to be managed just as hospitals would manage hazardous chemicals led to the implementation of the Queensland Health Medical Fatigue Risk Management Policy in 2011. This policy was developed with the intent of minimizing the risk of patient harm caused by fatigue and keeping employees and the work environment healthy and safe.[5] At each level, the staff and leadership can gather data and determine what controls, if any, need to be implemented to alleviate fatigue (see Table 5).

Queensland Health suggests that a series of questions can be asked at each level, including the following:[5]

- What information do we have about hours of work, actual sleep, time awake, fatigue reports, and so on?
- Do we need to collect more information or data about these factors?
- What is the information telling us?
- What do we need to do differently (e.g., work practices)?
- Can we do things differently?
- What prevents or restricts us from changing things? Are these reasonable barriers?

Developing a comprehensive FRMS may appear daunting, but careful review of current organizational leadership policies, procedures, and practices may reveal that portions of an FRMS exist. Currently, the healthcare industry has provided some programs to address fatigue through duty hour restrictions and restrictions on mandatory overtime. In addition, research has shown that other efforts are being used to mitigate fatigue within hospitals and include the following:[1,8,9,25,26,34]

- Education and training on the effects of fatigue
- Alertness strategies and fatigue mitigators (e.g., snacking, exercising, eating, drinking)
- Napping
- Use of caffeine
- Use of lights, such as at nurses' stations, in laboratories, and in other areas that would not disturb patients' sleep

Table 5. Fatigue Risk Management Framework

INCIDENT TRAJECTORY	PROACTIVE OR REACTIVE?	HAZARD ASSESSMENT	CONTROL MECHANISM
Level 1	Proactive	Adequate sleep opportunity?	Hours-of-work guidelines
Level 2	Proactive	Acceptable levels of prior sleep and wake?	Individual fatigue likelihood score Prior sleep/wake assessment
Level 3	Proactive	Are there fatigue-related behaviors?	Subjective reports Individual/collegial symptom checklist
Level 4	Reactive	Fatigue-related errors?	Analysis of fatigue-related errors and near-miss reports
Level 5	Reactive	Fatigue-related incidents?	Incident analysis Address levels 1 through 4

Source: Queensland Health. Fatigue risk management system resource pack [online]. 2009 [cited 2013 Nov 13]. http://www.health.qld.gov.au/hrpolicies/other/FRMS_web.pdf

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– Appropriate scheduling policies, including use of fatigue risk management software as used in other industries to develop more healthful schedules[17,32]

HIGHLIGHT ON READING HOSPITAL

Reading Hospital in Pennsylvania is actively addressing healthcare worker fatigue. In an interview with Gayle Walsh, patient safety coordinator, she relayed that her organization has been working on this issue with more focus since the Joint Commission published the Sentinel Event Alert titled "Health Care Worker Fatigue and Patient Safety" on December 14, 2011.

Through the sponsorship of their patient safety committee made up of representatives from selected clinical departments, Reading Hospital completed a survey in which the department representatives reviewed pertinent policies and procedures, staffing, current fatigue management strategies, and staff education related to fatigue management. One immediate outcome from this assessment was the certified registered nurse anesthetists revising their scheduling process to reduce the effects of fatigue on their staffs.

A subcommittee of the patient safety committee has since been formed with the goal of reviewing current literature and developing a toolkit that can be used by the organization to educate and inform staff on the effects of fatigue and what can be done to minimize fatigue. The subcommittee, with representation from high-reliability departments and human resources, is charged with developing policies that most likely will impact current work patterns. In addition, it will continue to evaluate how handoff processes can be enhanced to mitigate the risk of fatigue and catch potential fatigue-related errors before they result in harm to the patient. Walsh envisions that the toolkit will include a self-learning module that can be loaded onto their intranet so that the information will be available 24/7 to their staff. Reading Hospital has already incorporated the evaluation of fatigue in their discussion when performing root-cause analyses. Lastly, Reading Hospital is exploring modifying their current event reporting system to gather data regarding fatigue as a contributing factor to the event.

Walsh reports that the efforts have been positive. Walsh discussed that in addition to the hospital's work on this issue, the organization has had to prioritize other major project work, such as implementation of a new electronic health record system.

CONCLUSION

Due to the nature of round-the-clock staffing, fatigue is an occupational hazard in healthcare. A fatigued healthcare worker is more likely to make an error that may result in patient injury. Initial programs to address healthcare worker fatigue have primarily been focused on reducing hours worked for resident physicians. Current research shows that work-hour restriction alone will not solve the problem, as it does not address the disruption in the circadian cycle and sleep deprivation associated working the night shift or working long, extended shifts.

Most of the events reported to PA-PSRS in which healthcare worker fatigue was cited as a contributing factor were medication errors and errors related to a procedure, treatment, or test. Reporters have indicated that working extended shifts, multiple long shifts, or without a break or meal have led to feelings of tiredness and fatigue.

FRMSs are emerging as a more scientific and comprehensive method for mitigating the causes of fatigue and reducing the impact fatigue has on patient safety. An FRMS will include education for staff and leadership on the effects of fatigue, risk mitigation strategies for monitoring and managing fatigue-related risk, and a process for monitoring and evaluating any fatigue-related events.

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An Analysis of Reported Adverse Drug Reactions

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ABSTRACT

Past research has shown that both the incidence and severity of adverse drug reactions (ADRs) are significant. The American Society of Health-System Pharmacists (ASHP) has published guidelines on ADR monitoring and reporting. As a part of these guidelines for pharmacists, ASHP states that any ADR program should include "evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescribers, other health care professionals, and patients." Over a 12-month period, Pennsylvania hospitals reported 4,875 reports through the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System describing ADRs. Nearly 30% (n = 1,365) of these reports described ADRs to contrast agents, which are considered high-alert medications by the Institute for Safe Medication Practices. Other high-alert agents that were frequently reported include opioids, taxane derivatives, platinum analogs, warfarin, and insulin. While many of the ADRs reported to the Authority could not have been prevented, there are strategies that can be utilized to reduce the incidence and severity for a portion of these ADRs. These strategies may include appropriate premedication regimens, providing clear instructions for the administration of medications with complicated infusion rate titrations, ensuring thorough patient medication and allergy histories are completed, and improving the quality of ADR reports within healthcare organizations. (Pa Patient Saf Advis 2014 Jun;11[2]:61-8.)

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INTRODUCTION

There are various published definitions for adverse drug reactions (ADRs) currently being used in practice and published in the literature. The World Health Organization defines ADRs as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."[1]

The American Society of Health-System Pharmacists (ASHP) expands upon this definition by stating that an ADR is "any unexpected, unintended, undesired, or excessive response to a drug that requires discontinuing the drug (therapeutic or diagnostic), requires changing the drug therapy, requires modifying the dose (except for minor dosage adjustments), necessitates admission to a hospital, prolongs stay in a health care facility, necessitates supportive treatment, significantly complicates diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death."[2]

There are two major types of ADRs, type A and type B. Type A reactions are related to the pharmacological action of the drug and are typically predictable. Type B reactions are not related to the pharmacological action of the drug, are typically unpredictable, and are frequently classified as either immune-mediated or idiosyncratic reactions.[3]

Past research has shown that both the incidence and severity of ADRs are significant.[3-5] A study published in 1998[4] sought to describe the overall incidence of ADRs and serious ADRs occurring in US hospitals by evaluating previously published literature. The overall incidence of ADRs for hospitalized patients was 15.1%. A 2005 study completed in the United Kingdom[5] evaluated the incidence of ADRs on medical and surgical wards. Over a six-month time period, 14.7% of hospitalized patients experienced at least one ADR. Additionally, ADRs directly increased the length of stay for 147 patients during this same six-month time period. In order to address the significant impact that ADRs may have on patients, ASHP published guidelines on ADR monitoring and reporting in 2009.[2] As a part of these guidelines for pharmacists, ASHP states that any ADR program should include "evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescribers, other health care professionals, and patients."

Analyses of ADRs reported by Pennsylvania healthcare facilities to the Pennsylvania Patient Safety Authority have identified the most common agents associated with ADRs in Pennsylvania. While many of the reported events appear to have been unpreventable, there are strategies that can be implemented to reduce the risk and severity of patient harm for several of the most common agents involved in ADRs reported to the Authority.

METHODS

Authority analysts queried the Authority's Pennsylvania Patient Safety Reporting System database for reports of ADRs submitted over a 12-month period, from November 2012 through October 2013. Pennsylvania hospitals reported 4,875 events describing ADRs during this time. Analysts manually reviewed the reported ADRs to determine the medication(s) involved in the reported event as well as other contributing factors. When the medication name field was left blank but the name of the suspected medication was provided in the event description, the medication name field was adjusted. The analysts determined, when possible, if an ADR could have been prevented. Analysts made note of ADRs involving high-alert medications, based on *ISMP's List of High-Alert Medications*.[6]

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ANALYSIS

The Table displays the medications, or medication classes, most frequently involved in the reported ADRs. Nearly 30% (n = 1,365) of the ADRs reported to the Authority were for contrast agents. A discussion of the most frequently reported ADRs, as well as those that may be preventable, follows.

Contrast

The majority of contrast-related reports (n = 851, 62.3%) described reactions that are consistent with product labeling for contrast agents. These reactions included headache, nausea, vomiting, itching, rash, and sensation of heat. More severe reactions included throat tightness, swelling, shortness of breath, and anaphylaxis. There were 484 instances (35.5%) of more severe reactions reported to the Authority. For 30 (2.2%) of the reports, the type of reaction could not be determined due to a lack of information. The Figure displays the specific products involved in the ADRs reported to the Authority by trade name.

In 130 (9.5%) of the reported contrast-related reactions, the patient had a documented history of an allergy to a contrast agent. In these cases in which an allergy was present prior to administration of contrast, the use of a premedication protocol was documented in 106 (81.5%) of these cases.

Opioids

There were a total of 416 reports (8.5%) for ADRs with opioids, including reactions to the following medications: butorphanol, codeine, fentaNYL, hydrocodone-acetaminophen, HYDROmorphone, meperidine, morphine, nalbuphine, oxyCODONE, oxyCODONE-acetaminophen, and tapentadol. The event descriptions revealed a variety of reactions, ranging from generalized itching and rash to shortness of breath, excess sedation, and respiratory depression.

Table. Predominant Medications in Adverse Drug Reaction Events Reported to the Pennsylvania Patient Safety Authority, November 2012 through October 2013 (N = 4,875)

MEDICATION OR MEDICATION CLASS	NO. OF EVENTS	% OF TOTAL EVENTS
Contrast*	1,365	28.0
Opioids*	416	8.5
Fluoroquinolones	300	6.1
Vancomycin	250	5.1
RiTUXimab*	235	4.8
Taxane derivatives*	219	4.5
Platinum analogs*	199	4.1
Cephalosporins	136	2.8
Chlorhexidine	64	1.3
Intravenous immune globulin	62	1.3
Warfarin*	62	1.3
Insulin*	58	1.2
Unknown	281	5.8

* A high-alert medication

One trend that emerged through analysis of the opioid-related ADRs was the use of naloxone. In 136 (32.7%) of the reported ADRs with the causative agent being one or more opioids, naloxone was administered to the patient due to the level of sedation. Examples of reported ADRs that involved the administration of naloxone include the following:

> *Patient on fentaNYL patch, post-op from bowel resection, was found to be less responsive than last night per [registered nurse]. The patient was giving one-word or short-sentence answers to questions when stimulated. Naloxone was given with an appropriate response.*

> *Patient was admitted for severe pain and received three doses of HYDROmorphone 2 mg [over a six-hour period]. Patient was found to be hypoxic and drowsy and received 0.04 mg of naloxone with relief.*

Fluoroquinolones

Fluoroquinolones were cited in 300 (6.1%) of the reported ADRs. Dermatologic reactions were the most frequently reported ADRs for fluoroquinolones (ciprofloxacin, levofloxacin, and moxifloxacin), accounting for 268 (89.3%) of the reports.

There were four instances of documented cardiac rhythm abnormalities as detected on electrocardiogram (prolonged QT interval or ventricular tachycardia). In these instances, no other medications known to cause these changes were included in the event description or as a suspected medication. An event reported to the Authority involving prolongation of the QT interval is as follows:

> *Patient was admitted to the medical-surgical unit with acute bronchitis and dyspnea. Patient started on moxifloxacin 400 mg IV [intravenous] daily and received one dose in the evening and a second dose the next morning. Repeat electrocardiograms on subsequent days showed a prolonged QT interval from baseline. Moxifloxacin stopped after the second dose.*

The results of a recently published case-control study indicated that there is an

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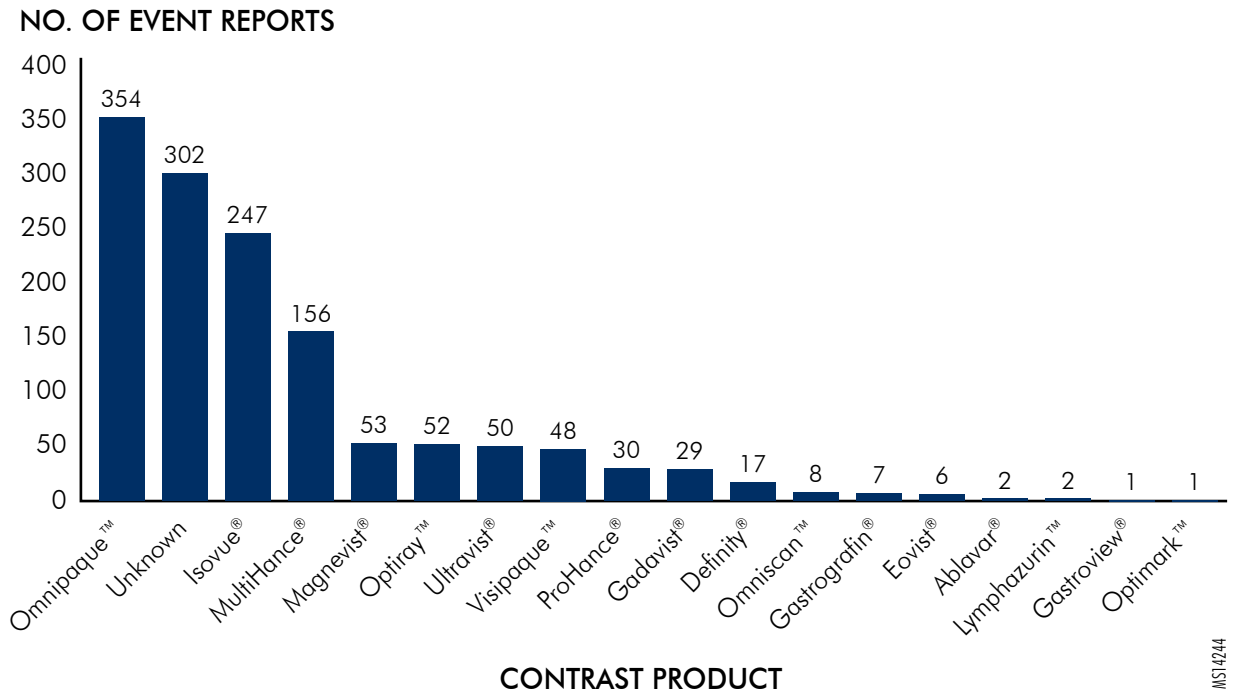
Figure. Products Involved in Contrast-Related Adverse Drug Reaction Events Reported to the Pennsylvania Patient Safety Authority, November 2012 through October 2013 (N = 1,365)



increased risk of hepatotoxicity associated with exposure to fluoroquinolones.[7] There was one possible case of hepatotoxicity due to ciprofloxacin reported to the Authority. In this report, there were no other medications listed as a possible cause of hepatotoxicity, but there were not enough details provided in the report to definitively state that ciprofloxacin was the causative agent.

Vancomycin

Overall, 250 (5.1%) of the ADR events involved vancomycin. Infusion reactions (e.g., rash, itching, redness of the skin) accounted for 208 (83.2%) of the vancomycin-related ADRs reported to the Authority. There were several reported ADRs in which the patient's renal function worsened during the course of vancomycin therapy (n = 14, 5.6%).

Examples of these event reports are as follows:

> *[There was a] likely nephrotoxic accumulation of vancomycin after following the protocol. A patient received a 2 g load then 1.5 g IV every 12 hours. The vancomycin level after four days was 100, and serum creatinine went from 0.7 to 1.8.*

> *Patient had been on vancomycin [for 10 days before a vancomycin trough was drawn]. The patient's serum creatinine began to climb and went from 0.9 to 1.4. On [the 10th day of therapy], the trough was drawn and the [vancomycin] level was 56.*

RiTUXimab

RiTUXimab is a monoclonal antibody that is approved by the US Food and Drug Administration to treat non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, microscopic polyarteritis nodosa, and Wegener granulomatosis. RiTUXimab was involved in 235 (4.8%) of the reported ADRs. The types of reactions reported for riTUXimab were consistent with those that are reported in the prescribing information for the product.[8] Infusion reactions consisted of itching, chills, rigors, hives, nausea, vomiting, and diaphoresis. The prescribing information for riTUXimab contains a boxed warning stating that severe and fatal infusion reactions may occur with riTUXimab. Serious infusion reactions reported included hypotension, chest pain, angioedema, hypoxia, and anaphylactic reactions. These reactions occurred in 94 (40.0%) of the riTUXimab-related ADR reports submitted to the Authority.

Based on the prescribing information, a premedication regimen consisting of an antihistamine and acetaminophen should be initiated prior to the infusion.[8] There were examples for which the administration

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of premedication, as recommended in the prescribing information, was documented in the event description; however, other reports lacked this information. Examples of these event reports are as follows:

> *Patient having first riTUXimab infusion. Infusion started at 50 mL/hr increments. When rate increased to 150 mL/hr, the patient started to complain of feeling cold and then developed chills. Infusion stopped. Normal saline running. Physician and pharmacist were called. MethylPREDNISolone sodium succinate 100 mg IVP [IV push], meperidine 25 mg IVP, and diphenhydrAMINE 25 mg IVP were all given. Rigors stopped after approximately 10 minutes. Infusion restarted at 50 mL/hr after approximately one hour.*

> *Patient here for first R-CHOP [riTUXimab, cyclophosphamide, DOXOrubicin, vinCRIStine, prednisONE], premedicated. RiTUXimab started. Patient complained of "itchy throat." RiTUXimab was stopped, and additional diphenhydrAMINE 25 mg and methylPREDNISolone sodium succinate 100 mg given IVP. [Patient] returned to baseline and riTUXimab restarted [two hours later]. [Infusion] completed with no further problems.*

Taxane Derivatives

Taxane derivatives are used to treat a variety of cancers. Overall, taxane derivatives were cited in 219 (4.5%) of the ADR events. The ADRs for PACLitaxel and DOCEtaxel were consistent with previously published reactions. The majority of the reports described mild reactions (e.g., rash, flushing, pruritus, fever), but several severe reactions (e.g., hypotension, angioedema, bronchospasm) were also reported.

When analyzing reactions for these medications, it is important to note that there is data to support the use of premedications to prevent and minimize hypersensitivity reactions.[9,10] There were examples of cases for which premedications were listed in the event description and cases for which there was no mention of the administration of these premedications. Reports for each of these scenarios are included as follows:

> *[The patient] had less than ¼ of his ordered PACLitaxel dose for this date when [the patient] had complaints of back pain. [The patient] was given NSS [normal saline solution] and hydrocortisone. The patient had been pretreated with dexamethasone and diphenhydrAMINE and still reacted. CARBOplatin was able to be started as planned and was completed. The patient was able to tolerate it with no issues and was discharged after it was completed.*

> *DOCEtaxel had been infusing for about an hour when the patient began feeling flush. Infusion was stopped and emergency medications provided. The physician was made aware and evaluated [the patient]. Once symptoms subsided, the infusion was resumed and tolerated without any further difficulty. No harm to patient.*

Platinum Analogs

Analysts identified that platinum analogs were implicated in 199 (4.1%) of the reported ADRs. Platinum analogs are currently used to treat a variety of types of cancer. The reactions reported to the Authority for this group of medications (CARBOplatin, CISplatin, oxaliplatin) were consistent with those reported in previous studies. These consisted of rash, itching, hives, flushing, and shortness of breath. An example of a reaction to oxaliplatin is as follows:

> *Outpatient with a diagnosis of metastatic colon adenocarcinoma with metastases to lung and reproductive organs arrived to the infusion center for chemotherapy. During oxaliplatin infusion, the patient developed facial flushing. The flushing became severe. Drug [oxaliplatin] stopped and methylPREDNISolone sodium succinate 125 mg IVP, diphenhydrAMINE 25 mg IVP, and levalbuterol treatment given. Symptoms resolved. Patient rechallenged at slower rate without any further issues.*

The majority of hypersensitivity reactions that occur with these agents develop after frequent treatment. Multiple studies have shown that the risk of hypersensitivity reactions increases with subsequent courses of therapy with these agents.[11,12]

Cephalosporins

Cephalosporins were involved in 136 (2.8%) of the ADR events. The majority of the reactions seen with cephalosporins (n = 102, 75.0%) were dermatologic in nature (e.g., rash, red skin, itching) and hives. Previous studies have shown that there is a small percentage of patients who will experience a reaction to a cephalosporin if there is a documented history of penicillin allergy.[13,14] There were eight instances in which the patient had a documented penicillin allergy. The reactions for these patients were hives (five cases), redness of the skin (one case), shortness of breath (one case), and swelling of the tongue (one case).

Chlorhexidine

Chlorhexidine is a topical product that is used as a part of infection prevention practices in many hospitals and health systems. All of the reports (n = 64) submitted to the Authority for chlorhexidine described dermatologic reactions (e.g., redness, itching, rash).

Intravenous Immune Globulin

Analysts identified 62 (1.3%) ADR events that involved intravenous immune globulin (IVIG). The events reported to the

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Authority described ADRs that consisted of itching, flushing, chills, fever, nausea, and diaphoresis. While the majority of the reports described these mild infusion reactions, there were several that described more severe reactions following infusion of an IVIG product. An example of a severe infusion reaction is as follows:

> *Patient in for immune globulin infusion. Premedications given and infusion started at 25 mL/hr, with max rate calculated at 150 mL/hr. Rate increased to 50 mL/hr per protocol [with] vital signs stable. Evaluated patient prior to next rate increase, and noted change in respiratory rate. Patient reported difficulty breathing and chest tightness. Infusion stopped and the doctor evaluated the patient. Patient nebulizer activated and emergency medications given per physician. Oxygen increased to 15 L/minute. Patient received diphenhydrAMINE 25 mg IV, hydrocortisone sodium succinate 100 mg IV, and methylPREDNISolone sodium succinate 100 mg IV. Vital signs improved, and the patient [was transferred] to hospital in stable condition.*

Warfarin

All of the ADR reports (n = 62) submitted to the Authority for warfarin revealed an elevated international normalized ratio (INR). There were not enough details (e.g., dose, duration of therapy) provided in the event descriptions to determine causality or contributing factors for these reports. An example of a reported ADR for warfarin is as follows:

> *Vitamin K administered to patient due to elevated INR levels (repeat levels drawn x1). Patient on Coumadin 1 mg to 7.5 mg.*

Insulin

All of the ADR reports (n = 58) submitted to the Authority for insulin therapy described patients with low blood glucose values. There were not enough details provided in the reports (e.g., insulin product, dose, time of dose administration) to determine causality or contributing factors for these reports. An example of this type of event report is as follows:

> *Patient on insulin drip with titration accuchecks being done every hour. [Most recent] accucheck was 60. Patient was nonverbal with no physical symptoms noted. Physician aware, patient given ½ amp of D50 [Dextrose 50%].*

Unknown

There were a total of 281 (5.8%) ADR reports in which the suspected medication, or medication class, could not be determined. In these events, multiple medications from different classes were listed as possible causative agents.

RISK REDUCTION STRATEGIES

When evaluating events involving medications, it is important for organizations to focus on those that may be prevented or minimized. There are several questions that can be used to help determine whether or not an ADR could have been prevented.[15] A listing of such questions can be found in "Criteria for Determining Preventability of an ADR."

For several of the aforementioned events, there are mitigation strategies that can be utilized to reduce the incidence and severity of patient harm. In many of the ADRs reported to the Authority, there was not enough information included to determine the specific medication involved in the ADR, the type of reaction, or if the event may have been preventable.

Potential risk reduction strategies include the following:

Contrast

- The American College of Radiology (ACR)[16] offers several elective premedication regimens to be given prior to contrast for patients with a documented allergy:
  - ☐ PredniSONE 50 mg by mouth at 13 hours, 7 hours, and 1 hour before contrast media injection, plus diphenhydrAMINE 50 mg IV, intramuscularly, or by mouth 1 hour before contrast medium.
  - ☐ MethylPREDNISolone 32 mg by mouth 12 hours and 2 hours before contrast media injection. An antihistamine (e.g., diphenhydrAMINE) may also be added to this regimen.

CRITERIA FOR DETERMINING PREVENTABILITY OF AN ADR

Answering "yes" to one or more of the following suggests that at an adverse drug reaction (ADR) is preventable:

- Was the medication involved inappropriate for the patient's clinical condition?
- Was the dose, route, or frequency of administration of the medication inappropriate for the patient's age, weight, or disease state?
- Was required therapeutic drug monitoring or another necessary laboratory test not performed?
- Was there a history of allergy or previous reactions to the medication?
- Was a drug interaction involved in the ADR?
- Was a toxic serum drug concentration (or laboratory monitoring test) documented?
- Was poor adherence involved in the ADR?

Source: Schumock GT, Thornton JP. Focusing on the preventability of adverse drug reactions. *Hosp Pharm* 1992 Jun;27(6):538.

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- When time does not allow for either of the regimens listed above, ACR offers the following for patients with a documented allergy to contrast:[16]
  - ☐ MethylPREDNISolone sodium succinate 40 mg or hydrocortisone sodium succinate 200 mg IV every 4 hours until contrast study is required, plus diphenhydrAMINE 50 mg IV 1 hour prior to contrast injection.
  - ☐ Omit steroids entirely and give diphenhydrAMINE 50 mg IV.
  - ☐ IV steroids have not been shown to be effective in preventing ADRs with contrast when administered less than 4 to 6 hours before contrast injection.
- While the ADRs reported to the Authority did not reveal any incidences of contrast-induced nephropathy (CIN), this is a concern for patients with certain risk factors.[16] See "Risk Factors for the Development of Contrast-Induced Nephropathy" for a list of risk factors identified by ACR. Developing and reviewing institutional guidelines for the identification and management of patients at risk for CIN can prevent or mitigate patient harm.

Vancomycin

- Reviewing institutional guidelines for the administration and therapeutic monitoring of vancomycin.
- Ensuring that vancomycin infusions are administered over a period of at least one hour to minimize infusion-related reactions. For larger doses (e.g., 2 g), the infusion time should be extended to 1.5 to 2 hours.[17]
- Utilizing the published report "Therapeutic Monitoring of Vancomycin in Adult Patients" to guide the dosing and monitoring of vancomycin.[17]

RiTUXimab

- Ensuring that protocols are in place for riTUXimab infusions that address premedication, management of infusion reactions, and infusion rates.
- Premedicating patients before each riTUXimab infusion with an antihistamine and acetaminophen.[8]
- For the *first* riTUXimab infusion, initiating the infusion at a rate of 50 mg/hr and then increasing the infusion rate by 50 mg/hr increments every 30 minutes (in the absence of an infusion reaction), to a maximum of 400 mg/hr.[8]
- For *subsequent* riTUXimab infusions, initiating the infusion at a rate of 100 mg/hr and then increasing the rate by 100 mg/hr increments every 30 minutes (in the absence of an infusion reaction), to a maximum of 400 mg/hr.[8]

Taxane Derivatives

- Reviewing protocols for PACLitaxel and DOCEtaxel to ensure that proper premedication regimens are included. Studies have shown that the incidence and severity of hypersensitivity reactions can be reduced by administering corticosteroids and antihistamines prior to treatment with taxane derivatives.[9,10]

Platinum Analogs

- Ensuring that appropriate treatment for hypersensitivity reactions for CARBOplatin, CISplatin, and oxaliplatin is included in protocols for these agents. Consider establishing clear guidelines for the treatment of these hypersensitivity reactions (e.g., corticosteroids, antihistamines).

Intravenous Immune Globulin

- Ensuring that instructions for the infusion rates are clearly defined for staff, as dosing and infusion rates vary among the different IVIG products currently on the market. Titration schedules also vary, many of which are product specific and included in the product-specific prescribing

RISK FACTORS FOR THE DEVELOPMENT OF CONTRAST-INDUCED NEPHROPATHY

The American College of Radiology suggests that the presence of any of the risk factors listed below may warrant preadministration serum creatinine screening in patients ordered to receive intravascular iodinated contrast agents. Developing tools to assess patients for these risk factors can help avoid or identify contrast-induced nephropathy in order to mitigate patient harm.

- Age greater than 60 years
- History of renal disease, including the following:
  - ☐ Dialysis
  - ☐ Kidney transplant
  - ☐ Single kidney
  - ☐ Renal cancer
  - ☐ Renal surgery
- History of hypertension requiring medical therapy
- History of diabetes mellitus
- Use of metFORMIN or metFORMIN-containing medications

Source: American College of Radiology. ACR manual on contrast media, version 9 [online]. 2013 [cited 2014 May 6]. http://www.acr.org/quality-safety/resources/contrast-manual

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information. It is important that these are clearly defined for nurses and other healthcare practitioners.

Medication Reconciliation

- Reviewing policies and procedures for collecting and documenting patient medications and allergy histories.
- Ensuring that medication allergies, including the type of reaction, are documented in the patient's medical record.

ADR Reporting Quality

- In order to improve the ability of hospitals and health systems to utilize reported ADRs and ensure that appropriate mitigation strategies are used, there are recommendations provided by the US Food and Drug Administration to improve the quality of reported events for pharmacovigilance practices.[18] If used, these recommendations can also improve the ability of an organization to utilize its internal ADR data.
- The characteristics of a good case report include the following:[18]
  - ☐ Description of the event, including the time to onset of signs or symptoms
  - ☐ Suspected and concomitant product therapy details, including over-the-counter medications
  - ☐ Patient characteristics (e.g., age, race, sex), baseline condition prior to the initiation of therapy, use of concomitant medications, comorbid conditions, and presence of other risk factors
  - ☐ Clinical course of the event and patient outcomes (e.g., hospitalization, death)
  - ☐ Relevant therapeutic measures and laboratory data, if appropriate
  - ☐ Information about the response to therapy dechallenge or rechallenge

CONCLUSION

Although not all ADRs can be prevented, it is still important for organizations to evaluate the medications, or medication classes, suspected to be involved with ADRs. In order for organizations to see tangible benefits from ADR reporting programs, it is important to continually review reported ADRs; educate prescribers, caregivers, and patients about suspected ADRs; identify and monitor drugs most likely to cause an ADR; and implement strategies to minimize the incidence and severity of ADRs. By continually assessing the types of ADRs being reported, reviewing the mitigation strategies utilized for medications involved in these reports, and updating protocols as necessary, practitioners can likely reduce the incidence and severity of ADRs.

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LEARNING OBJECTIVES

- Identify the medications most frequently involved in adverse drug reaction (ADR) events submitted to the Pennsylvania Patient Safety Authority.
- Recognize ADRs that may be prevented or mitigated.
- Identify risk reduction strategies that can be implemented as a part of an ADR monitoring program.

SELF-ASSESSMENT QUESTIONS

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own questions.

1. Which of the following medications, or medication classes, was most frequently reported to the Authority as an ADR?
   a. Heparin
   b. Opioids
   c. Warfarin
   d. Contrast
   e. Vancomycin
2. Which of the following is *not* a question that may help practitioners and organizations determine the preventability of ADRs?
   a. Was required therapeutic drug monitoring or another necessary laboratory test not performed?
   b. Was a drug interaction involved in the ADR?
   c. Was poor adherence involved in the ADR?
   d. Was a nonformulary medication involved in the ADR?
   e. Was the medication involved inappropriate for the patient's clinical condition?
3. For which of the following medications, or medication classes, should the infusion time be extended for larger doses to reduce the risk of adverse effects?
   a. Platinum analogs
   b. RiTUXimab
   c. Vancomycin
   d. Insulin
   e. Cephalosporins
4. Which of the following is *not* a risk factor for the development of contrast-induced nephropathy?
   a. History of diabetes mellitus
   b. History of liver disease
   c. Age greater than 60 years
   d. Use of metFORMIN or metFORMIN-containing medications
   e. History of hypertension requiring medical therapy

Questions 5 refers to the following case:

A patient presented for a planned, outpatient computed tomography scan of the abdomen, with contrast. Shortly after administration of the contrast agent, the patient began complaining of severe itching on both arms and legs. Hives were noted upon physical examination. The imaging procedure was temporarily stopped, and the patient was treated for an allergic reaction. After the reaction was noticed, a note was discovered in the patient's medical record that described a previous reaction (redness of the skin, hives) to a contrast agent.

5. Which of the following risk reduction strategies may have prevented this reaction?
   a. Conducting a thorough patient medication and allergy history
   b. Continuing with the imaging procedure as planned
   c. Administering 0.9% sodium chloride prior to the imaging procedure
   d. Considering an alternative contrast agent
   e. Administering intravenous steroids immediately prior to the imaging procedure

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Falls Reduction and Prevention Update: Pennsylvania Hospitals Increase Implementation of Best Practices

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ABSTRACT

In 2012, the Pennsylvania Patient Safety Authority provided hospitals participating in the Pennsylvania Hospital Engagement Network Falls Reduction and Prevention Collaboration with two tools to evaluate their falls prevention programs: an annual self-assessment survey and a quarterly process measures audit. Hospitals that completed the survey in 2012 and 2013 reported an increase in full implementation for 16 of 17 categories of falls prevention best practices. Comparison of 2012 survey responses to audit results revealed a gap between levels of full implementation of best practices reported on the survey and compliance with falls prevention practices observed during the audit process. Analysis of 2013 data shows a decrease in this gap and improved compliance with falls prevention practices. Rates of falls with harm decreased for hospitals that completed the self-assessment survey in 2012 and 2013 in addition to all quarterly audits. Hospitals participating in the collaboration and utilizing these tools have been able to evaluate their current falls prevention programs, identify and implement evidence-based practices missing or in need of improvement, monitor staff compliance with falls prevention practices, and decrease rates of falls with harm. (Pa Patient Saf Advis 2014 Jun;11[2]:69-77.)

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INTRODUCTION*

In December 2011, the Pennsylvania Patient Safety Authority partnered with the Hospital and Healthsystem Association of Pennsylvania to lead the Pennsylvania Hospital Engagement Network (PA-HEN) Falls Reduction and Prevention Collaboration. Beginning in January 2012, hospitals from across the commonwealth joined the collaboration and enrolled in the Pennsylvania Patient Safety Reporting System (PA-PSRS) Falls Reporting Program. A group of 80 hospitals participated through December 2013.

As part of the collaboration, the Authority developed two tools for the enrolled hospitals to use in evaluating their falls prevention programs: an annual self-assessment survey and a quarterly process measures audit (available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/falls/Pages/home.aspx). Analysis of results from the initial use of these tools in 2012, as well as hospital rates of falls with harm, was published in the December 2013 *Pennsylvania Patient Safety Advisory* article "Falls Prevention: Pennsylvania Hospitals Implementing Best Practices."[1] Highlighted findings include the following:

- Thirty-five individual falls prevention practices and/or specific program elements were identified that correlated with lower rates of falls with harm.
- Although the majority of hospitals reported full implementation for the majority of best practices in falls prevention, all hospitals reported practices that were missing or in need of improvement.
- Medication review and sitters were identified as two categories of falls prevention practices that correlated with lower rates of falls with harm, but these practices were reported to have low levels of full implementation in most hospitals.
- A "policy-practice gap" was identified (i.e., interventions prescribed by policy were not implemented in practice) when comparing best practices reported as having full implementation on the falls self-assessment survey with falls prevention practices observed during the audit process.

Hospitals participating in the collaboration that have continued to use these tools have been able to evaluate their current falls prevention programs and successfully identify and implement evidence-based practices missing or in need of improvement. They have also been able to monitor staff compliance with falls prevention practices and have seen increases in compliance, as well as reductions in rates of falls with harm.

METHODS

Falls SAT Survey

The PA-HEN Falls Reduction and Prevention Collaboration Self-Assessment Tool (SAT) survey was adapted from an existing questionnaire[2] and was designed to evaluate the current structure and content of hospital falls prevention programs compared with evidence-based best-practice guidelines. The SAT survey was intended to serve as a tool to assist hospitals in identifying best-practice elements that could be targeted for improvement in their current falls prevention programs. For each falls prevention practice listed in the SAT survey, respondents could report either full implementation, partial implementation, or no implementation. Hospitals participating in the collaboration were asked to complete the falls SAT survey in 2012 and again in 2013.

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The Authority analyzed and compared survey responses between the two years to identify changes in implementation level for falls prevention practices over the course of the collaboration. Only hospitals that completed the falls SAT survey for both time periods were included in the analysis.

Falls Prevention Process Measures Audit Tool

The Falls Prevention Process Measures Audit Tool is a point prevalence data collection tool used to assess compliance with falls prevention practices most commonly included as part of hospital falls prevention programs. Hospitals were asked to complete quarterly audits on the unit or units where they were piloting small tests of change as part of collaboration. This point prevalence audit consisted of documentation review (e.g., "Was a fall prevention plan documented?") and observation of patients and the environment (e.g., "Does the patient have risk identifiers?"). The Authority analyzed the results of audits conducted for the quarter beginning July 1, 2013, and ending September 30, 2013, to identify overall compliance with falls prevention practices. A secondary analysis of audit results was completed to evaluate compliance with specific practices in hospitals reporting full implementation of these practices on the falls SAT survey.

Falls-with-Harm Rates

Rates of falls with harm per 1,000 patient-days were calculated for January through June 2012 and for January through June 2013 using falls with harm as reported through PA-PSRS (i.e., any fall reported as a Serious Event, as defined by Pennsylvania reporting requirements) and total facility patient-days as reported to the Pennsylvania Health Care Cost Containment Council (PHC4).[3] At the time of the initial analysis in 2012, the period of January through June was selected for two reasons: (1) this was the time period for which the most complete data was available from PHC4, and (2) this time period immediately preceded completion of the falls SAT survey, therefore controlling for the influence survey completion may have had on rates. The second time period of January through June 2013 was selected for these same reasons, as well as to allow for comparison between two similar time periods.

RESULTS

Falls SAT Survey—Overall

Of the 80 hospitals that completed the falls SAT in 2012, 74 completed the falls SAT in 2013. Most hospitals reported full implementation for the majority of falls prevention best practices both years. As a group, these 74 hospitals reported 68.2% of all practices with full implementation in 2012, ranging from 20.5% to 92.7% for individual hospitals. In 2013, the percentage of practices reported with full implementation increased to 78.2% for the group, ranging from 52.3% to 98.6% for individual hospitals. Figure 1 shows the percentage of full implementation reported by these 74 hospitals for each category of falls prevention practices by year.

Falls SAT Survey—High Levels of Full Implementation

Event reporting, postfall assessment, and fall alarms were the top three categories of falls prevention best practices reported with full implementation in 2012 and 2013.

Event reporting. Hospitals reported an average of 85.7% of practices in the category of event reporting as fully implemented in 2012, increasing to 91.8% in 2013. Because most practices were reported as fully implemented in 2012, there was not much change reported in 2013, with a few exceptions. The largest increase was seen in the number of hospitals requiring staff to establish a new intervention plan to prevent repeat falls as part of a standardized patient safety event report (45 hospitals in 2012, 60 in 2013). More hospitals also reported full implementation for each of the following best practices in 2013:

- Communicating clear and consistent guidelines for completing patient safety event reports and follow-up or investigation forms for patients who have fallen as part of mandatory in-service educational programs (46 hospitals in 2012, 60 in 2013)
- Utilizing a follow-up or investigation form, separate from the patient safety event report form, for patients who have fallen (48 hospitals in 2012, 60 in 2013)
- Requiring staff to include a description of any equipment in use at the time of the fall in patient safety event reports (65 hospitals in 2012, 73 in 2013)

Postfall assessment. Hospitals reported an average of 80.2% of best practices in the category of postfall assessment as fully implemented in 2012, increasing to 88.7% in 2013. The two practices with the largest increase in the number of hospitals reporting full implementation were (1) postfall event interventions are reviewed and, if necessary, revised and documented in the individual's chart (49 hospitals in 2012, 64 in 2013) and (2) following a fall, the patient is reassessed for falls risk and assessment findings are communicated to staff who interact with the patient (58 hospitals in 2012, 68 in 2013).

Fall alarms. The category of fall alarms consists of three best practices. Hospitals reported an average of 79.3% of these practices as fully implemented in 2012, increasing to 86.5% in 2013. The number of hospitals reporting full implementation for each practice increased as follows:

- Holding staff accountable for a timely response to fall alarms (48 hospitals in 2012, 56 in 2013)
- Adequately training staff to use fall alarms, such as bed-exit alarms, including inspection and

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maintenance of the systems (57 hospitals in 2012, 64 in 2013)

- Using other falls prevention interventions in conjunction with fall alarms (71 hospitals in 2012, 72 in 2013)

Falls SAT Survey—Low Levels of Full Implementation

Of the falls prevention best-practice categories, medication review remained the category with the lowest percentage of full implementation, followed by sitters, with less than 50% full implementation in each category reported both years.

Medication review. Despite being reported with the lowest level of full implementation both years, some hospitals reported progress in implementing falls prevention best practices in the category of medication review. More hospitals reported including pharmacists on their falls prevention team in 2013 (n = 59) than in 2012 (n = 46), and the average percentage of medication review best practices reported as fully implemented increased from 21.6% in 2012 to 34.2% in 2013.

The following medication review best practices had the largest increases in the number of hospitals reporting full implementation:

- Instituting periodic review of formulary medications by the pharmacy and therapeutics committee to identify those that increase falls risk and make recommendations about those medications (10 hospitals in 2012, 31 in 2013)
- Providing nurses access to a list of medications that increase an individual's risk of falling that is used when assessing patients for falls risks (28 hospitals in 2012, 43 in 2013)
- Having pharmacy recommend alternative medications to reduce the patient's risk of falling if the prescribed medications increase the risk of falling (8 hospitals in 2012, 17 in 2013)

Figure 1. Reported Percentage of Falls Prevention Best Practices with Full Implementation by Category for Hospital Engagement Network Facilities Completing the Falls Self-Assessment Survey Tool in 2012 and 2013 (N = 74)

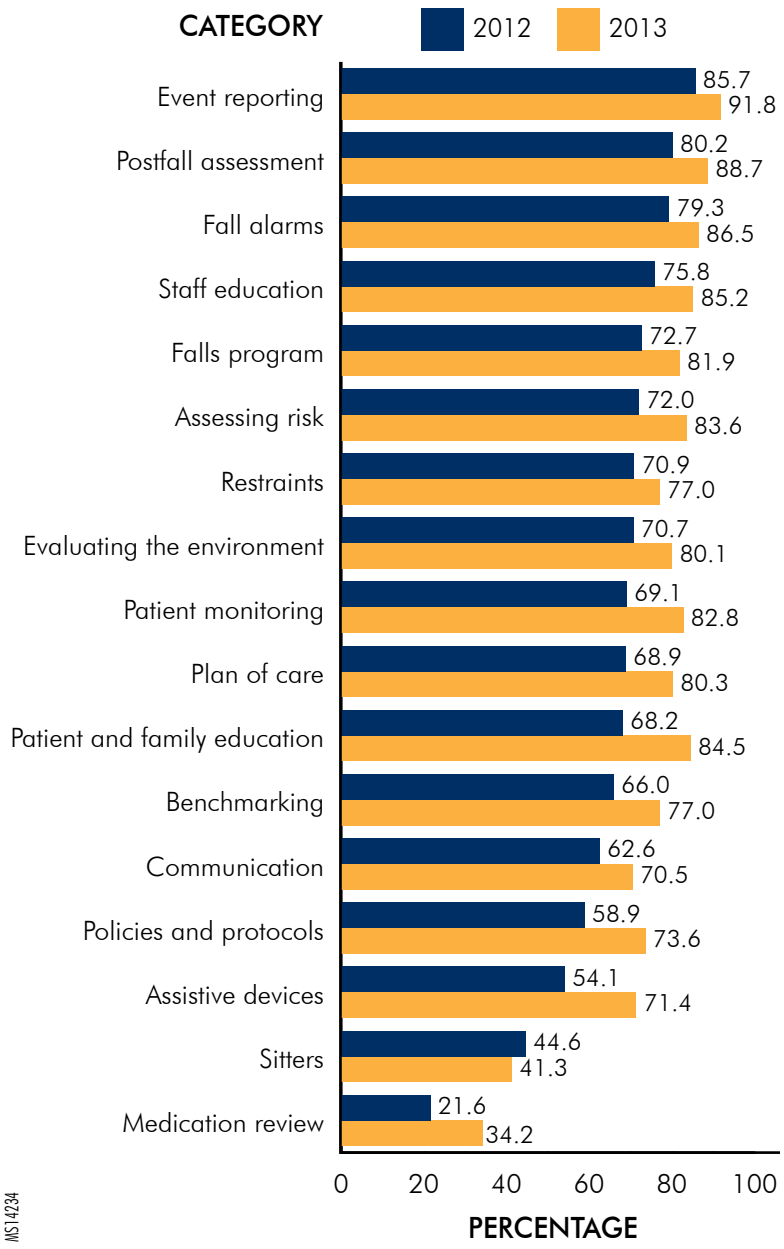

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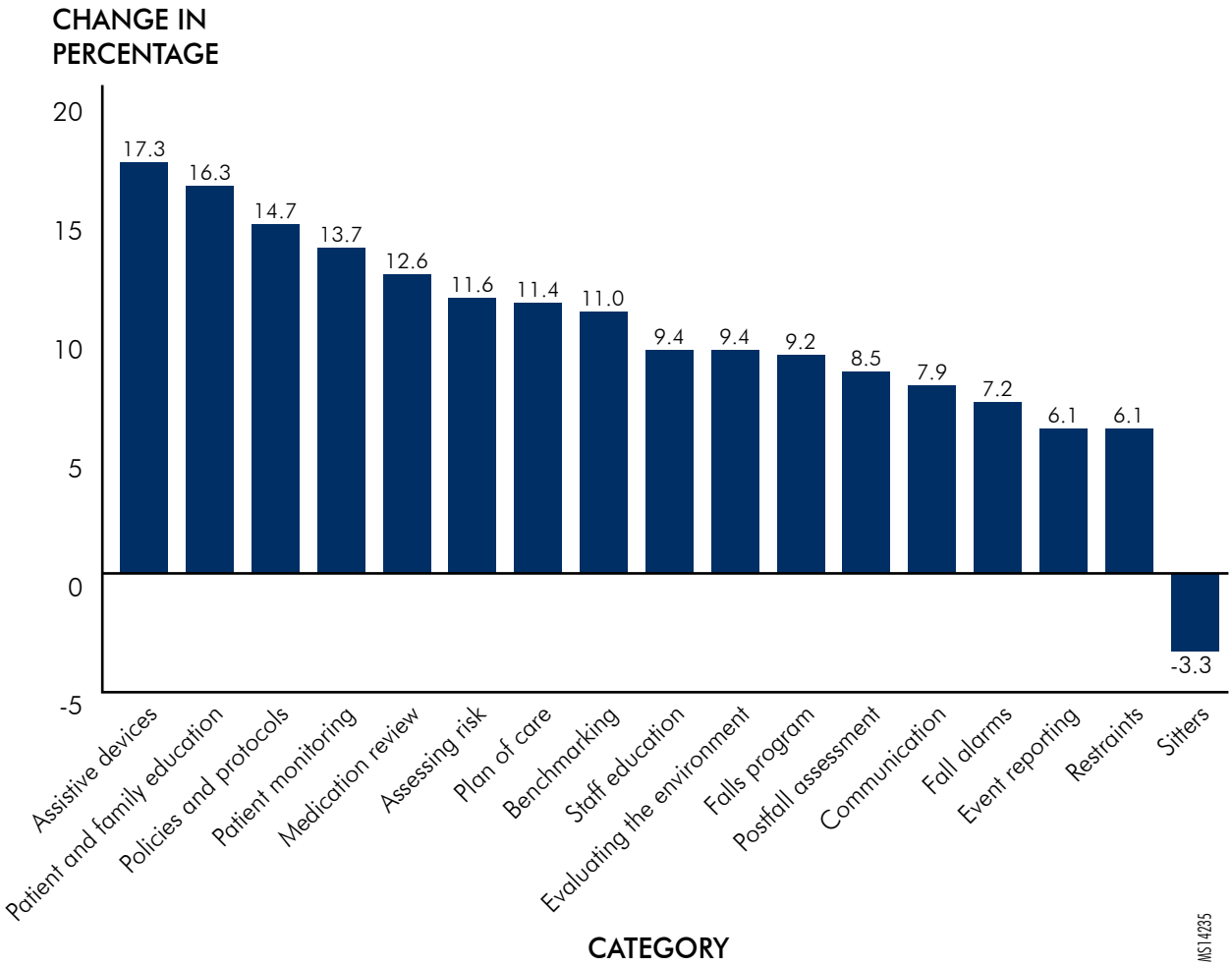
Figure 2. Absolute Change in Percentage of Falls Prevention Best Practices with Full Implementation by Category for Hospital Engagement Network Facilities Completing the Falls Self-Assessment Survey Tool in 2012 and 2013 (N = 74)



Sitters. The only category of falls prevention best practices that decreased in terms of full implementation was sitters. As a group, hospitals reported an average of 44.6% of sitter best practices as fully implemented in 2012, decreasing to 41.3% in 2013 (see Figure 1). The number of hospitals reporting full implementation of sitter programs increased from 37 to 38 between 2012 and 2013, but only 30 of those hospitals reported full implementation in both years. The other eight hospitals reporting full implementation in 2013 reported having either no sitter program (n = 5) or only a partially implemented sitter program (n = 3) in 2012. Also, of those hospitals that reported having sitter programs, fewer hospitals reported full implementation for the following best practices in sitter program design in 2013 compared with 2012:

- Having a pool of sitters (32 hospitals in 2012, 30 in 2013)
- Defining criteria for sitter qualifications (34 hospitals in 2012, 30 in 2013)
- Conducting a training program for sitters (32 hospitals in 2012, 29 in 2013)
- Creating a job description with expectations for sitter behavior and responsibilities (37 hospitals in 2012, 31 in 2013)
- Establishing a process for requesting and discontinuing sitters (33 hospitals in 2012, 28 in 2013)

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Table 1. Hospital Engagement Network Facilities' Compliance with Falls Prevention Practices* in Patients Identified as Being at Risk to Fall (N = 1,222)

FALLS PREVENTION PRACTICE	FALLS RISK PATIENTS (%)
Falls prevention plan documented	92.3
Call bell within reach	89.6
Patients have appropriate footwear: nonskid socks or slippers	79.0
Patient and family education documented	77.7
Special equipment is in use: two siderails up	76.8
Patients have risk identifiers: wristband	65.5
Hourly rounds documented	64.3
Patients have risk identifiers: sign outside room	46.9
Alarms are in use: bed alarm	39.3
Patients have risk identifiers: colored socks	36.7
Special equipment is in use: low bed	32.3
Patient have risk identifiers: sign inside room	26.2
Patients have risk identifiers: other	12.9
Alarms are in use: chair alarm	10.7
Patients have appropriate footwear: rubber-soled shoes	7.1
Special equipment is in use: floor mat	4.7
Patients have risk identifiers: colored blanket	3.8
Sitter is in place	3.1
Special equipment is in use: other	2.5
Alarms are in use: other	1.7
Special equipment is in use: hip protectors	0.7
Patients have appropriate footwear: other	0.1

* Assessed through use of the Falls Prevention Process Measures Audit Tool, July through September 2013

Falls SAT Survey—Largest Increases in Full Implementation

Overall, of 1,745 individual practices reported to have no implementation in 2012, hospitals reported moving 767 (44.0%) to full implementation in 2013. In addition, of 1,450 practices reported to have partial implementation in 2012, hospitals reported moving 921 (63.5%) to full implementation in 2013. Of 7,621 practices reported with full implementation in 2012, 6,944 (91.1%) were reported to remain at full implementation in 2013. Figure 2 shows the absolute change in the average percentage of practices reported with full implementation between 2012 and 2013 by category (i.e., the percentage of practices reported with full implementation in 2013 minus the percentage reported with full implementation in 2012). The greatest increases were reported in the categories of assistive devices, patient and family education, and policies and protocols. Increases were reported in 16 of 17 categories, with sitters identified as the only category in which the percentage of best practices with full implementation decreased.

Assistive devices. The greatest increase in the number of hospitals reporting full implementation for falls prevention best practices was seen in the category of assistive devices. The following practices had the largest increases:

- Having the falls team and/or physical therapy evaluate types of devices and aids (e.g., canes, walkers, wheelchairs, grab bars) used by the facility to prevent falls (48 hospitals in 2012, 61 in 2013)
- Providing training to staff on their use and maintenance (40 hospitals in 2012, 53 in 2013)
- Ensuring the weight-bearing capacities of these devices and aids are known to staff (25 hospitals in 2012, 41 in 2013)
- Having physical therapy evaluate patients identified as being at risk to fall and recommend appropriate assistive devices (41 hospitals in 2012, 52 in 2013)
- Providing face-to-face training in their use to patients and families (44 hospitals in 2012, 52 in 2013)

Patient and family education. The next greatest increase in the number of hospitals reporting full implementation of falls prevention best practices was seen in the category of patient and family education. Increases were reported in staff providing all patients and their family members direct education regarding the causes of falls and the interventions used to prevent falls (36 hospitals in 2012, 55 in 2013) and in documentation of education (41 hospitals in 2012, 54 in 2013). Increases were also reported for nurses educating patients specifically about the following:

- Intrinsic risk factors for falling (43 hospitals in 2012, 62 in 2013)
- How to walk and transfer in and out of bed safely (45 hospitals in 2012, 63 in 2013)
- How to use assistive devices (44 hospitals in 2012, 57 in 2013)
- What to do if he or she falls (30 hospitals in 2012, 52 in 2013)

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Policies and protocols. The category of falls prevention practices with the third greatest increase in the number of hospitals reporting full implementation was policies and protocols. The practice in this category that increased the most in terms of full implementation was including the composition, responsibilities, and goals of the falls team in the hospital's falls prevention policy (17 hospitals in 2012, 38 in 2013). Large increases in the number of hospitals reporting full implementation were also reported for the following practices:

- Establishing a frequency and process for conducting environmental rounds (29 hospitals in 2012, 46 in 2013)
- Outlining requirements to collect and review data on patient falls, including unit type, time of day, staffing ratios, interventions in place, equipment in use, toileting patterns, and medication (32 hospitals in 2012, 48 in 2013)
- Developing a process for revising assessment and intervention strategies based on data (31 hospitals in 2012, 47 in 2013)
- Defining the appropriate responses to falls, including protocols for postfall investigation (49 hospitals in 2012, 63 in 2013)
- Planning for initial and ongoing falls prevention education for staff (29 hospitals in 2012, 43 in 2013)

Falls Prevention Process Measures Audit Tool

Sixty-four hospitals submitted point prevalence audits between July 1 and September 30, 2013. A total of 1,758 patients were audited, of which 1,748 (99.4%) had completed falls risk assessments and 1,222 (69.5%) were identified as being at risk to fall. Of the patients identified as being at risk to fall, most had documentation of a falls prevention plan (92.3%), a call bell within reach (89.6%), nonskid socks or slippers (79.0%), documentation of patient and family education (77.7%), and two siderails in the up position (76.8%). Falls risk identifiers, specialty equipment, and alarms were found to have lower levels of implementation. Table 1 details the percentage of patients at risk to fall who were found to have each falls prevention practice in place.

In hospitals that completed the 2013 falls SAT, 56 were identified that completed point prevalence audits between July 1 and September 30, 2013. As in 2012, comparison of falls SAT survey responses with audit results revealed a gap between levels of full implementation of best practices reported on the falls SAT survey and compliance with falls prevention practices observed during the audit process. However, in comparing results from 2012 with 2013, an increase in compliance was observed. The category of falls risk indicators has been used to illustrate this gap and the improvement (see Figure 3). For example, in 2012, in hospitals that reported full implementation for posting of signs communicating falls risk outside patient rooms, only 52.7% of patients identified at risk to fall were found to have the signs in place during audits. This percentage increased to 75.4% in 2013.

Falls-with-Harm Rates

Complete data to calculate rates of falls with harm was available for January through June 2012 and for January through June 2013 for 68 of the 74 hospitals that responded to the falls SAT survey in 2012 and 2013. Of the 68 hospitals that completed both falls SAT surveys, 41 hospitals completed all quarterly point prevalence audits from September 2012 through September 2013. Table 2 shows the difference in rates of falls with harm during these two time periods for hospitals completing all quarterly audits compared with those that did not. Rates were lower and decreased for hospitals that completed all quarterly point prevalence audits, while hospitals missing audits had a higher rate that increased between the two time periods.

Table 2. Change in Rates of Falls with Harm in Hospitals Completing the Falls Self-Assessment Tool Survey, January through June 2012 and January through June 2013

	2012: FALLS WITH HARM PER 1,000 PATIENT-DAYS	2013: FALLS WITH HARM PER 1,000 PATIENT-DAYS	% CHANGE
Hospitals missing quarterly audits (n = 27)	0.156	0.221	+41.7
Hospitals completing all quarterly audits (n = 41)	0.125	0.119	-4.8

DISCUSSION

A major focus of the PA-HEN Falls Reduction and Prevention Collaboration has been to ensure that hospitals are implementing evidence-based practices in falls prevention. Education provided to hospitals in the collaboration has included a review of what is currently established as best practice based on individual, high-quality research studies and systematic reviews, as well as evidence-based falls prevention guidelines.[4-12] The falls SAT survey was provided as a tool for hospitals to complete an annual review of their falls prevention programs, assessing for congruence with these evidence-based best practices. Hospitals were also provided with an audit tool to be completed quarterly, assessing for compliance with use of falls prevention practices for patients identified at risk to fall.

Analysis of falls SAT survey responses, audit results, and rates of falls with

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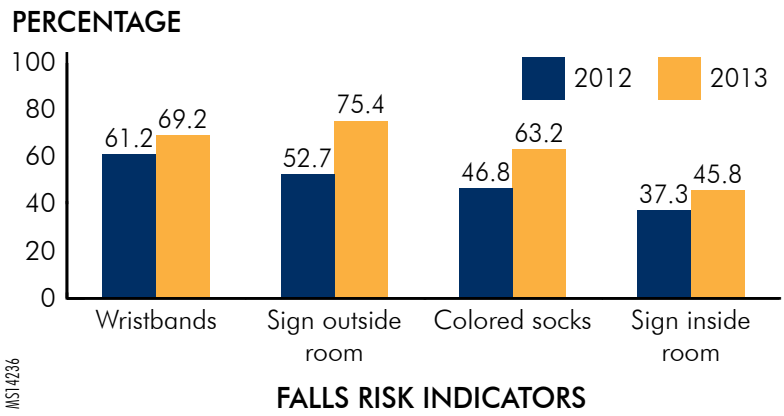
Figure 3. Compliance with Use of Falls Risk Indicators in Hospitals Reporting Full Implementation on the Falls Self-Assessment Tool Survey, July through September 2012 and July through September 2013



harm has allowed the Authority to identify the following: (1) an increase in full implementation for 16 of 17 categories of falls prevention best practices, (2) categories of falls prevention best practices in which hospitals have reported the largest increases in full implementation, (3) a decreased gap between levels of full implementation of best practices reported on the survey and compliance with falls prevention practices observed during the audit process, and (4) a lower rate of falls with harm in hospitals completing the annual falls SAT and quarterly audits.

Increased Implementation of Falls Prevention Best Practices

Overall, hospitals reported a 10% increase in the percentage of best practices reported with full implementation—from 68.2% in 2012 to 78.2% in 2013. Variability in the average percentage of practices reported with full implementation also narrowed from a range of 20.5% to 92.7% in 2012 to 52.3% to 98.6% in 2013, meaning there were fewer hospitals at the lower end of full implementation in 2013 (i.e., while some hospitals reported as few as 20.5% of all practices with full implementation in 2012, no hospital reported less than 52.3% of all practices with full implementation in 2013).

Hospitals were advised to create action plans targeted to best practices identified through completion of the falls SAT survey as missing or in need of improvement. It is therefore feasible that each hospital could have been targeting multiple and different falls prevention program elements for improvement over the course of the collaboration. Comparison of falls SAT survey responses from 2012 with 2013 suggests that this is true. As a group, these hospitals have reported making the most progress in moving best practices in the categories of assistive devices, patient and family education, and policies and protocols to full implementation.

Falls Prevention Best Practices with Low Levels of Full Implementation

Medication review and sitters continue to be the two categories of best practices in falls prevention reported with the lowest levels of full implementation. Because both categories of best practices were found to correlate with lower rates of falls with harm, and because low levels of implementation for these practices were reported on the 2012 falls SAT survey, hospitals participating in the collaboration were encouraged to carefully evaluate the need to implement these practices in their institutions.[1]

While some collaboration members were able to add pharmacists to their teams and move medication review best practices to full implementation in 2013, this continues to be an area where hospitals struggle. Likewise, even though the number of hospitals reporting full implementation of sitter programs increased by one between 2012 and 2013, six hospitals eliminated their sitter programs in that time, and the number of hospitals with sitter programs remains low. Of the hospitals with sitter programs, the number reporting full implementation of best practices in sitter program design decreased. (Additional information on the use of patient sitters to prevent falls is available on the Authority's website at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Mar;11(1)/Pages/08.aspx.)

For both of these categories of falls prevention practices, cost may be the barrier to full implementation.[13,14] In fact, cost can serve as a barrier to implementation for any number of falls prevention practices. The Authority has developed a falls-with-harm calculator (available at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Jun;9(2)/Pages/calculator.aspx) that may help hospitals make the business case for investing in practices that a falls prevention team seeks to implement. By tracking reductions in the rates of falls with harm that occur as a result of implementing new falls prevention practices, cost savings can be estimated that could justify the expense.

Policy-Practice Gap

As in 2012, comparison of responses to the 2013 falls SAT survey with the results of audits conducted on inpatient units at hospitals participating in the PA-HEN falls collaboration revealed a gap between levels of full implementation of best practices reported on the survey and compliance with falls prevention practices

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observed during the audit process. This gap has narrowed, but compliance with implementation of the specific falls prevention practices audited has failed to reach 100%, suggesting falls prevention practices are not being implemented reliably in patients identified as being at risk to fall. Of special note, this gap may be expected depending on the patient population and the hospital's fall prevention protocol (for example, spinal cord injury patients may score as being at risk to fall in a hospital that reported full implementation of nonskid socks or shoes with rubber soles; however, for this select patient population, this footwear would not be indicated).

Ongoing audits and engagement of staff in the audit process is suggested. This provides an opportunity for the falls prevention team to implement missing falls prevention practices and provide "just-in-time training"[15] to staff while in the process of conducting audits, rather than waiting for future meetings to discuss the results of the audits. Education surrounding hospital falls prevention policies and protocols can be reinforced, and solutions can be designed for barriers identified when compliance is low.

Falls-with-Harm Rates

In comparing hospitals participating in the PA-HEN falls collaboration that did and did not perform quarterly point prevalence audits, rates of falls with harm were lower initially and decreased for hospitals that completed all audits. Rates of falls with harm were higher initially and increased for hospitals that did not complete all audits. While cause and effect cannot be confirmed, this suggests that hospitals that are engaged in an ongoing audit process may achieve greater reductions in rates of falls with harm.

Limitations

The initial falls SAT survey was administered at hospitals in July and August 2012, whereas the data used to calculate falls-with-harm rates was collected for the period of January through June 2012. It is therefore possible that hospitals implemented falls prevention measures in July and August and indicated full implementation on the falls SAT survey even though the practices were not in place when the falls with harm were occurring.

Information on the implementation level for best practices in falls prevention was gathered from self-reporting hospitals completing the falls SAT survey. Designation of implementation level (i.e., full implementation, partial implementation, or no implementation) is subjective to the respondent.

Compliance with implementation of best practices in falls prevention practices was not able to be calculated for all hospitals participating in the PA-HEN falls collaboration. Of the hospitals that completed the falls SAT survey in 2012 and 2013, only 63 submitted audit data for July through September 2012 and only 56 submitted audit data for July through September 2013. It is possible that compliance with falls prevention practices may have been higher or lower across the 80 participating hospitals. In addition, while performance of all quarterly point prevalence audits of falls prevention practices appears to correlate with lower rates of falls with harm, cause and effect cannot be inferred.

Data used in calculating falls-with-harm rates is dependent on accuracy and consistency in reporting falls and identifying injury level through PA-PSRS. Hospitals included in this analysis have agreed to consensus definitions for falls and falls with harm as a condition for participation in the PA-HEN falls collaboration; therefore, this limitation should have been minimized. The consensus definitions were introduced in March 2012, which may have affected reporting in the baseline period. This data is also dependent on accurate and complete reporting of total facility patient-days to PHC4.

CONCLUSION

Hospitals participating in the PA-HEN Falls Reduction and Prevention Collaboration have been able to evaluate their current falls prevention programs and successfully identify and implement evidence-based best practices missing or in need of improvement using the Hospital Engagement Network Falls Reduction and Prevention Collaboration SAT survey. Hospitals completing the falls SAT survey and monitoring staff compliance with falls prevention practices through quarterly use of the Falls Prevention Process Measures Audit Tool have seen increases in compliance and have achieved reductions in rates of falls with harm.

Use of a self-assessment tool, such as the falls SAT survey, is suggested to identify gaps between current hospital programs and evidence-based guidelines. Conducting audits of falls prevention practices being implemented at the bedside using a tool such as the Falls Prevention Process Measures Audit Tool is also suggested to monitor for compliance with hospital falls prevention policies and protocols. Hospitals are encouraged to focus continued attention on best practices missing or in need of improvement, as identified through use of a self-assessment tool, as well as practices with which staff are found to be noncompliant during audits. Hospitals may choose to focus particular attention on best practices found to correlate with lower rates of falls with harm but reported to have low levels of implementation for hospitals participating in the PA-HEN Falls Reduction and Prevention Collaboration, namely practices in the categories of medication review and sitters.

Acknowledgments

Denise M. Barger, BA, CPHRM, CPHQ, CPPS, HEM, patient safety liaison, Delaware Valley-South, and Richard M. Kundravi, BS, patient safety liaison, Northwest Region, contributed to the design and administration of the falls SAT survey and the Falls Prevention Process Measures Audit Tool as members of the PA-HEN Falls Reduction and Prevention Collaboration project leadership team.

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Training Suggested When Changing Brands of Enteral Feeding Tubes

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ABSTRACT

A Pennsylvania healthcare facility requested guidance from the Pennsylvania Patient Safety Authority about issues arising from misplacements of small-bore nasogastric feeding tubes after switching to a different brand of an enteral feeding delivery system. The facility wanted to know if other hospitals were experiencing similar types of adverse events. Analysis of events reported to the Authority from January 2011 through October 2013 revealed 44 reports that described misplacements of small-bore nasogastric feeding tubes. It is estimated that more than 1.2 million small-bore feeding tubes are used annually in the United States. Analysis of events reported to the Authority (1) indicates an increase in reports of small-bore nasogastric feeding tube misplacements from January 2013 to October 2013 compared with the previous two years, (2) offers possible explanations for why this increase in malpositions may have occurred, and (3) suggests strategies facilities can take to reduce the risk of experiencing this adverse event, including staff training and combining placement practices. (Pa Patient Saf Advis 2014 Jun;11[2]:78-81.)

INTRODUCTION

In 2013, a Pennsylvania healthcare facility experienced misplacements of small-bore nasogastric feeding tubes, resulting in harm to their patients. The events occurred after different staff members, with a range of 10 to 15 years of experience in placing tubes, placed the nasogastric feeding tubes. The placements were then verified with radiographic confirmation, which was the established procedure at this facility.

After the second misplacement, an inquiry was made by the healthcare facility's patient safety officer (PSO) to the Pennsylvania Patient Safety Authority's regional patient safety liaison wondering if other Pennsylvania facilities were experiencing similar events. The facility had switched to a different manufacturer's enteral feeding delivery system (i.e., pumps, disposable sets, feeding tubes, kits, and related device accessories) in the first quarter of 2013 because its previous provider had withdrawn from the enteral device market.

Analysis of the events reported to the Authority indicates an increase in the reported events of misplacement. The increase in the number of reports of misplacements may be in part due to differences in the feeding tubes that were not communicated to the staff because of their familiarization with feeding tube placement. Recommendations to prevent such events include staff education and combining placement practices.

REVIEW OF REPORTS DESCRIBING MISPLACEMENTS

A database query of events reported through to the Pennsylvania Patient Safety Reporting System (PA-PSRS) from January 2011 through October 2013, using keywords such as "feed," "place," "lung," "small-bore," and "pneumothorax," returned 654 reports. Analysis revealed 44 reports that described misplacement events in the lung involving the use of small-bore nasogastric feeding tubes. More than half of the events (n = 24) were classified as Serious Events resulting in harm to patients. See Table 1 for a summary of the events by year and event type.

Examples of feeding tube misplacement events reported to the Authority are as follows:

> *A pneumothorax was noted status post [weighted feeding] tube placement. The patient was closely monitored, and a surgical consult was obtained. The patient stabilized without the need for invasive treatment.*

> *[A weighted feeding tube] was used and the correct procedure was followed. The [weighted feeding tube] has coursed to wrong destination (bronchus) instead of the intended (stomach/pylorus), as noted during confirmation by chest x-ray. Patient was on close monitor . . . without resultant complication from the [weighted feeding tube] misplacement. However, we have noted unusual events of [weighted feeding tube] misplacement since introduction of this model.*

> *The nurse inserted a small-bore feeding tube for enteral nutrition. Upon confirmation x-ray for tube placement, tube placement was noted to be in the left pleural space. Small-bore feeding tube was removed, and a repeat x-ray was taken. Repeat x-ray showed a left pneumothorax, which required an insertion of a chest tube.*

MANUFACTURER DISCONTINUES ENTERAL FEEDING DELIVERY SYSTEM

Abbott, a global healthcare company based in Illinois, announced on October 17, 2012, and again on December 10, 2012, that it would discontinue the manufacture, lease, and sale of all enteral device products in the United States, effective April 30, 2013. The announcements from the Abbott Nutrition division further explained that

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Table 1. Misplaced Small-Bore Feeding Tubes, January 2011 through October 2013, as Reported to the Pennsylvania Patient Safety Authority

YEAR	INCIDENTS	SERIOUS EVENTS	TOTAL
2011	4	9	13
2012	3	3	6
January to October 2013	13	12	25
Total	**20**	**24**	**44**

this included pumps, disposable sets, feeding tubes, kits, and related device accessories.[1,2]

The announcements and Abbott's website stated, "We encourage you to identify an alternative enteral device supplier and begin the transition to meet your ongoing pump, set and feeding tube needs."[1-3] As a result, facilities that owned or leased Abbott's enteral feeding delivery system had to identify and convert to an alternative enteral feeding tube system in a relatively short time frame.

POSSIBLE EXPLANATIONS FOR FEEDING TUBE MISPLACEMENTS

PSOs Investigate

Authority analysts interviewed PSOs of facilities that reported events in 2013 involving the misplacement of small-bore feeding tubes. The PSOs stated they noticed a trend of misplacements when reviewing incidents reported through their event reporting systems, including PA-PSRS, and investigated why this was occurring by talking to involved staff and conducting root-cause analyses. Common findings reported by the PSOs after their investigations included the following:

- Facilities had recently switched from Abbott's enteral feeding delivery system to a different manufacturer's enteral feeding delivery system.
- The events occurred within a month of switching to the different system.
- Staff members who misplaced the tubes had several years of experience in tube placement.
- The misplaced tubes were weighted, 8 French* small-bore nasogastric feeding tubes—the same size and type as the tubes used before switching to a different manufacturer.
- The facilities used "blind placement," in which placement occurs without visualization of the access route. Placement was then verified with a radiographic confirmation after the tube was placed.
- Staff were not consistently trained on the use of new feeding tubes.

One PSO stated that staff described the integral lubrication on the new small-bore feeding tubes as "slicker" than that of the previous brand of feeding tubes, which may have caused the new tubes to have less resistance than the former tubes as the tubes were advanced during placement, in their opinion. The staff also opined that the new feeding tubes appeared to be less pliable than the previous feeding tubes.

Action Plans

Several initiatives were identified by the PSOs in action plans to correct the misplacements of the small-bore feeding tubes. Actions for some, if not all, of the facilities included the following:

- Trialing and evaluating other enteral feeding device products
- Reviewing literature on feeding tube placement to determine evidence-based placement procedures
- Using a simulation laboratory to practice feeding tube placement
- Redefining which staff and what kind of training is appropriate for the insertion of feeding tubes
- Restructuring vendor communication processes and initiating steering committees to include senior leadership and clinical stakeholders

RESULTS OF LITERATURE REVIEW

A literature search of the databases from the National Quality Measures Clearinghouse, PubMed, Embase, the Cumulative Index to Nursing and Allied Health Literature, and the American Association of Critical-Care Nurses revealed no articles that specifically addressed training requirements or other safety precautions to follow when switching enteral feeding delivery system manufacturers.

Incident Rates

In the literature, it is estimated that more than 1.2 million small-bore feeding tubes are used annually in the United States.[4-8] Evidence accumulated for over 25 years of blind placement shows that 1% to 2% of small-bore feeding tubes were misplaced in the lungs and that pulmonary injury occurred in 0.3% to 1.2% of patients.[4-8] More recent studies suggest that 0.1% to 0.3% of all patients who have blindly placed small-bore feeding tubes die as a result of bronchopulmonary injury from misplaced tubes.[4-8]

Practices to Prevent Misplacements

Although the literature does not specifically address training requirements or other safety precautions when switching to a different manufacturer's enteral feeding delivery system, there is endorsement of a variety of methods to verify placement of feeding tubes.[9-12] This includes a method used at the bedside during tube placement that would allow for repositioning of a misplaced tube, followed by radiographic confirmation.

* The outer diameter of a feeding tube is measured in French units. One French unit equals 0.33 millimeters.

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While there is no consensus on a particular combination of practices to use for checking the placement, there is general agreement that a two-step method be utilized to decrease the number of misplacements.[9-12] Manufacturers of nasogastric feeding tubes, such as CORPAK MedSystems and Covidien, recommend confirming tube position per institutional protocol.

Studies in the literature show several recommended methods to check the positioning of small-bore feeding tubes during and after placement. Assessment of feeding tube position after it has been inserted to approximately 30 to 35 cm allows repositioning of misplaced tubes and can prevent pulmonary injury.[9-12] See Table 2 for a review of practice methods to determine feeding tube placement.

Although there is limited published data, preliminary results of a survey conducted by the University of Virginia Health System suggest that more than 66% of facilities routinely use blind placement and have not adopted a standard method for verification of small-bore feeding tube placement.[4]

Recommendations for placement and verification of feeding tubes have been published by the American Association of Critical-Care Nurses,[10,13] the American Society for Parenteral and Enteral Nutrition,[11] the Joanna Briggs Institute,[9] and the National Patient Safety Agency.[12] See Table 2 for an overview of selected practices.

As noted in a past *Pennsylvania Patient Safety Advisory* article[14] and in other studies,[9,13] three practices that were used for tube verification were not recommended by studies due to their lack of effectiveness and potential risk for harm:

1. Auscultation (instilling air into the feeding tube with a syringe while using a stethoscope placed over the stomach to listen for bubbling of liquid contents in the stomach)
2. Aspirate inspection (assessing the appearance of aspirate from the tube)
3. Bubbling (observing bubbles when the end of the feeding tube is placed under water)

ONE DOCTOR'S EXPERIENCES

A patient who died as a result of a feeding tube misplacement prompted Vihas Patel, MD, FACS, CNSC, director of the Metabolic Support Service and interim

Table 2. Selected Methods Used to Check the Position of Small-Bore Feeding Tubes

METHOD	TYPES OF PRACTICES
Capnography	The measurement of carbon dioxide (CO_2) in expired air directly indicates changes in the elimination of CO_2 from the lungs.[1-3]
Colorimetric capnometry	A CO_2 detector incorporates a colorimetric paper technology engineered to display a change in color from purple to yellow within seconds when the presence of CO_2 is detected.[1-3]
Measure of pH aspirate	This practice determines the pH of the fluid aspirated from the feeding tube. Gastric fluid is usually acidic, with a pH less than or equal to 5.5. Respiratory secretions are almost always alkaline, with a pH greater than or equal to 7. Measurement of pH aspirate may not be possible with a feeding tube inserted to 35 cm, because fluid may not be available to sample from that anatomic position.[4]
Electromagnetic visualization	A transmitter is used in the tip of the feeding tube stylet. An external receiver unit is placed over the xiphoid process, and a monitor shows a real-time display of the tube position in both anterior and cross-sectional view.[1]
Radiographic confirmation	The radiograph should visualize the entire course of the feeding tube in the gastrointestinal tract and should be read by a radiologist to avoid errors in interpretation.[4-7]

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director of the Intensive Care Unit, Brigham and Women's Hospital, Boston, Massachusetts (a teaching affiliate of Harvard Medical School), to research and present information to the Intensive Care Unit Leadership Committee at the hospital. The information addressed how to safely and expeditiously establish enteral access after it is determined enteral nutrition support is required.[15]

In an interview conducted by Authority analysts,[16] Dr. Patel recommended that staff use descriptions whenever possible when referring to a feeding tube instead of just using a brand name. Even though tubes are produced by a variety of companies, healthcare staff communicate brand names interchangeably, according to Dr. Patel. This can cause confusion for healthcare staff when documenting or caring for the patient, since the tubes are different in size, shape, and purpose.

Education of staff who regularly place feeding tubes is key to successfully managing misplacements. "With every new device, there is a learning curve," Dr. Patel said. "Ultimately, this is an operator issue. Training and education improves safety."

At Brigham and Women's Hospital, feeding tubes are placed during the day in a two-step radiographic process for patients who do not have a gag reflex. The tube is placed up to 30 cm, and then a portable x-ray is performed. "You have to have imaging guidance for patients who are at high risk," Dr. Patel said. The tube is then advanced, and another confirmatory x-ray is performed. See the Figure, available in the online version of this article on the Authority's website at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Jun;11(2)/Pages/home.aspx, for a flowchart used for feeding tube placement.

CONCLUSION

Even though the process of inserting small-bore nasogastric tubes may be a common practice for trained healthcare professionals, it is suggested that staff be consistently trained when changing brands of enteral feeding tubes. Training is also proposed for staff with adequate experience and expertise who are coming from another facility that used different tubes and enteral feeding delivery systems. It is suggested that incidents involving misplacement of enteral feeding tubes be thoroughly investigated to identify the factors leading to the misplacement and/or the failure to identify the misplacement in a timely manner to avoid patient harm.

Several studies indicate that blindly placing feeding tubes and performing a follow-up radiography is less effective than combining placement practices in a two-step process, especially for patients who are at high risk.[9-12] It is recommended to keep the focus on being well trained in whatever process the hospital chooses to use based on available hospital equipment and staff resources.

Acknowledgments

Bruce C. Hansel, PhD, CCE, executive director, forensic services, Accident and Forensic Investigation Group, ECRI Institute, provided expert review and consultation for this article.

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Successful Strategies for Prevention of Bariatric and Colectomy Surgical Site Infections

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ABSTRACT

The Pennsylvania Patient Safety Authority and Pennsylvania hospitals participating in the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) entered into a joint quality improvement collaboration to reduce surgical site infections (SSIs) among Pennsylvania NSQIP member hospitals and to share successful strategies and lessons learned with other Pennsylvania hospitals. Using an SSI prevention assessment tool based on the ACS best practices relevant to bariatric and colectomy surgery, analysts identified variances between implementation of best practices in hospitals with high SSI rates (outliers) and hospitals with low SSI rates. The outlier hospitals monitored and documented their process steps, barriers, successes, and outcome measures for implementation of SSI prevention practices in bariatric and colectomy procedures selected from the variance assessment. Both the colectomy and the bariatric outlier sites demonstrated substantial improvement in their SSI rates from the 2010 baseline period to March 2013. This improvement was accompanied by enhanced implementation of best-practice systems and processes. (Pa Patient Saf Advis 2014 Jun;11[2]:82-7.)

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INTRODUCTION

Healthcare-associated infections (HAIs) have a significant impact on patients and healthcare organizations. According to the Centers for Disease Control and Prevention, the socioeconomic impacts of HAIs are divided into three categories: direct medical costs, indirect costs, and intangible costs (loss of quality of life). Annual direct medical cost benefits after adjusting for infection prevention strategies are estimated at a low of $5.7 billion to a high of $31.5 billion. Annual attributable inpatient hospital costs for surgical site infections (SSIs) are estimated at $3.45 billion to $10.07 billion.[1]

In December 2010, the Pennsylvania Patient Safety Authority and the Pennsylvania National Surgical Quality Improvement Project (PA-NSQIP) initiated a collaboration targeting reduction of SSIs in the collaborative member group. By June 2013, the success of the project was demonstrated by the substantial reduction of SSIs for a sustained period, improvement in implementation of SSI evidence-based best practices, and improvement in the NSQIP decile place.

GOALS

The collaborative's short-term goal was performance improvement related to the evidence-based process measures in each of the hospitals with high SSI rates (outliers). The long-term goal was to reduce bariatric and colectomy surgery SSIs in the outlier hospitals. This would be demonstrated by a reduction in the SSI rate for each facility, as well as an improvement in the decile place on the American College of Surgeons (ACS) NSQIP national observed-versus-expected (O/E) ratio. The decile rank is a comparative rank by which individual hospital surgical outcome performance is compared with those of peer hospitals and with national averages in the ACS NSQIP national database. ACS NSQIP considers decile 1 to be "exemplary" performance, deciles 2 through 9 indicate a hospital is performing "as expected," and decile 10 is flagged as "needs improvement."

In addition to the reduction of SSIs in the outlier facilities, the lessons learned from the process and outcome successes would be shared with other Pennsylvania hospitals. Other hospitals would then be able use this information when implementing improvement plans to reduce SSIs.

METHODS

In the first phase of the project, each of the eight PA-NSQIP member hospitals provided SSI data from two ACS NSQIP sources—the 2009 ACS NSQIP annual report and a completed survey on the O/E ratio and decile ranking for the surgical categories listed in that report. Those surgical categories included general surgery, vascular surgery, and colorectal surgery. Authority analysts identified two high-performer hospitals (with SSI rates lower than expected) and two outlier hospitals (with SSI rates higher than expected) in the general surgery category. Facilities were selected based on their reported O/E ratio, decile ranking, and individual performance in the selected categories. Authority staff conducted a secondary analysis of the two outlier hospitals with the highest SSI rates in the general surgery category and established that the highest rate of SSIs was in colectomy surgery for one outlier and in bariatric surgery for the second outlier.

On-site visits were conducted at each of the two high-performer hospitals and the two outlier hospitals to determine if there were differences in implementation of surgical best practices in bariatric and colectomy surgery. On-site visits were conducted by two separate bariatric and colectomy teams consisting of key Authority and PA-NSQIP

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staff. The on-site visits were conducted using the framework of an SSI prevention assessment tool that was based on the ACS comprehensive list of existing evidence-based guidelines. The practices most relevant to bariatric and colectomy surgery were selected for the assessment tool. Interviews with nursing staff, surgeons, and anesthesia providers were conducted during the on-site visits. Authority staff analyzed the on-site assessment results and determined that the high-performing facilities (those with the low SSI rates) had stricter adherence to the best-practice guidelines.

The on-site assessment interviews identified major differences between the high-performer and the outlier hospitals for bariatric and colectomy procedures. These differences were published in a December 2012 *Pennsylvania Patient Safety Advisory* article. The *Advisory* article and assessment tool are available on the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/ssi/Pages/home.aspx.

Both provider-specific and organizational variations in practice were observed when high performers were compared with outliers in both bariatric and colectomy surgeries. Bariatric outlier interviews revealed variation in preoperative measurement of arterial blood gas and hemoglobin A1c, postoperative upper gastrointestinal studies, and the involvement of residents in the procedure. Colorectal outlier interviews revealed variation in history of steroid use, albumin checks, patient and site preparation, decisions of diversion versus colostomy, wound protection and closure methods, antibiotic timing with prolonged procedures, operating room (OR) cleaning, traffic control, and handoffs. Provider-specific variation in bowel preparation was identified in both groups. In addition, on-site interviews identified organizational variations in both the bariatric and colectomy outliers regarding communication, safety briefings, and transport.

Collaborative teams from each of the two outlier hospitals selected process measures for implementation and measurement from the on-site assessment analysis of the differences between the high performers' and the outliers' implementation of best practices.

The bariatric outlier initially selected the following process measures:

- Number of patients who have glycosylated hemoglobin A1c drawn prior to surgery
- Number of patients with a hemoglobin A1c level over 8% who had surgery
- Number of patients who received chlorhexidine gluconate (CHG) wipes on the morning of the procedure
- Number of patients who received a Peridex swish on the morning of the procedure

The colectomy outlier initially selected the following process measures:

- Number of patients who have documentation that the surgical bundle was fully implemented
- Number of patients who have skin edge protection used during surgery
- Number of patients who have antibiotic redosing for a procedure lasting more than four hours

In the second phase of the project, from July 2012 through March 2013, the two outlier hospitals monitored and documented steps, barriers, successes, and outcome measures for implementation of the selected SSI prevention practices in bariatric and colectomy procedures.

Key Authority staff provided the collaboration with overall coordination, project management, and technical support. The Authority served as an independent facilitator to analyze facility-level SSI data, to collect any additional data provided directly by the participating hospitals, and to produce reports for the collaborative. The Authority hosted monthly topic-specific coaching and content calls for collaborative leadership and team members. The Patient Safety Knowledge Exchange (PassKey), a password-protected, dedicated website created and maintained by the Authority, provided a virtual collaboration forum to post tools, bibliographies, and data analysis information.

The two outlier hospitals in bariatric and colectomy surgery SSIs developed hospital-specific implementation strategies based on their selected process measures identified from the variance assessment. The Authority developed a facility-specific, three-part data collection tool that provided the two outlier hospitals with a secure, web-based location to document, track, and measure progress. The tool included data on monthly implementation of selected process measures, SSI rates over time, a comparison of ACS NSQIP decile placement, and a monthly narrative of steps and barriers to implementation. Confidential PA-NSQIP internal hospital reports provided information on wound class and SSI category.

Outcome measures included raw numbers of SSIs, rate of SSIs per 1,000 patient-days, and the ACS NSQIP decile ranking based on the O/E ratio for SSIs data from the available national ACS NSQIP reports. Authority staff analyzed process measure implementation based on the number of processes correctly implemented for each surgical procedure during the same period. Results were further quantified by the specific type of SSI (superficial, deep incisional, or organ/space) and by wound category (clean, clean/contaminated, contaminated, or dirty/infected).

RESULTS

The baseline period for measuring SSI rates was calendar year 2010. The baseline process measurement period was July through August 2012, followed by the process implementation measurement period of September 2012 through March 2013. The SSI rate outcome period was

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July 2012 through March 2013. The ACS NSQIP national 2010 and 2012 decile reports with O/E ratios for SSIs were used to determine improvement in the O/E ratio for SSIs compared with ACS NSQIP hospitals nationwide.

Bariatric SSI Outcome Improvement

In the baseline period, the bariatric outlier hospital's SSI rate was 2.3 per 100 cases of bariatric surgery. Further baseline measures included the following:

- Superficial SSIs accounted for 66.7% (6 of 9) of the SSIs in the baseline period. Organ/space SSIs accounted for 33.3% (3 of 9) of the SSIs.
- All 9 SSIs were in the clean/contaminated wound category.
- The hospital was in the 10th decile according to the ACS NSQIP national O/E ratio for SSIs.

At the end of the implementation period, the bariatric outlier hospital's SSI rate decreased from 2.3 per 100 cases to 0.3 per 100 cases (p value = 0.036). See Figure 1. Additional findings are as follows:

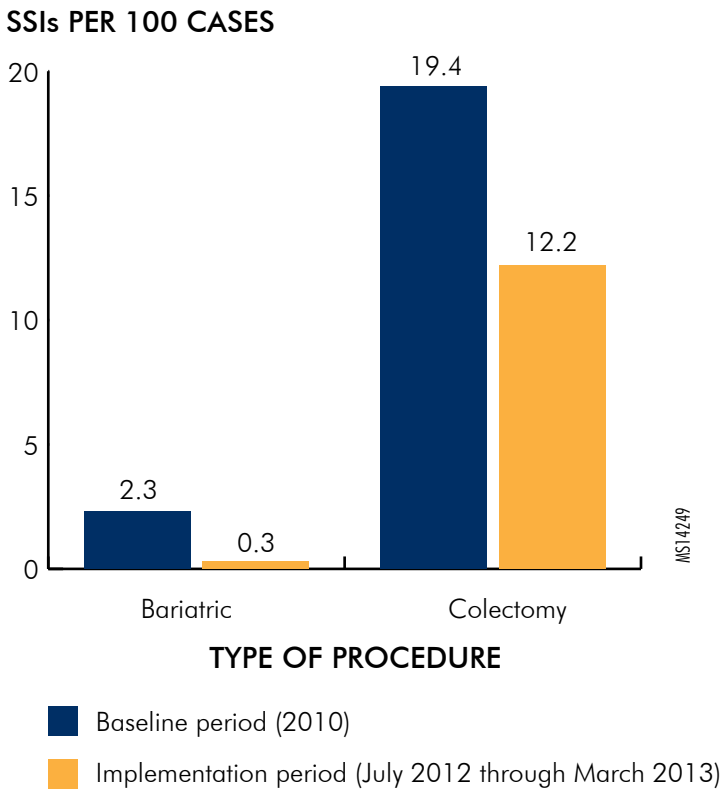
- The 1 SSI in the implementation period was a superficial SSI in the clean/contaminated wound category.
- There were no deep incisional or organ space SSIs.
- The hospital improved to the eighth decile according to the ACS NSQIP national O/E ratio for SSIs.

Bariatric Surgery Process Improvement

In the baseline period, analysis of the bariatric outlier hospital's process implementation of the selected process measures demonstrated that

- 62.5% of patients (40 of 64) took a CHG bath the night before surgery,
- 68.8% of patients (44 of 64) received a Peridex oral swish the morning of the procedure, and
- 71.9% of patients (46 of 64) received CHG wipes the morning of the procedure.

Figure 1. Bariatric and Colectomy Surgical Site Infection Outcomes



At the end of the implementation period, analysis of the bariatric outlier hospital's implementation of the selected process measures demonstrated the following (see Figure 2):

- The percentage of patients who took a CHG bath the night before surgery increased to 72.8% (166 of 228). This measure was added in response to the decision to not implement the hemoglobin A1c measure within the project time frame due to multiple system issues.
- The percentage of patients who received a Peridex oral swish the morning of the procedure increased to 90.8% (207 of 228).
- The percentage of patients who received CHG wipes the morning of the procedure increased to 81.6% (186 of 228 patients).

Colectomy SSI Outcome Improvement

In the 2010 baseline period, the colectomy outlier hospital's SSI rate was 19.4 SSIs per 100 cases of colectomy surgery. Further baseline measures included the following:

- Superficial SSIs accounted for 73.1% (19 of 26) of the SSIs in the baseline period. Of those, 78.9% (15 of 19) were clean/contaminated wounds, 5.3% (1 of 19) were contaminated

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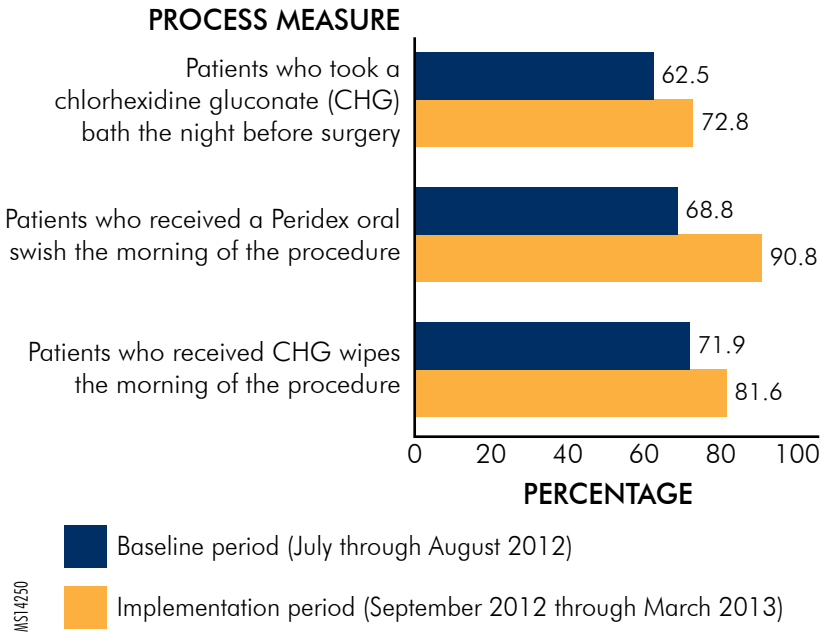
Figure 2. Bariatric Process Measure Implementation



wounds, and 15.8% (3 of 19) were dirty/infected wounds.

- Organ/space SSIs accounted for 26.9% (7 of 26) of the SSIs in the baseline period. Of those, 71.4% (5 of 7) were clean/contaminated and 28.6% (2 of 7) were dirty/infected wounds.
- The hospital was in the 10th decile according to the ACS NSQIP national O/E ratio for SSIs.

At the end of the implementation period, the colectomy outlier hospital's SSI rate decreased from 19.4 per 100 cases to 12.2 per 100 cases (p value = 0.047). See Figure 1. Additional findings are as follows:

- Superficial SSIs accounted for 63.2% (12 of 19) of the SSIs in the implementation period. Of those, 83.3% (10 of 12) were clean/contaminated wounds, 8.3% (1 of 12) were contaminated wounds, and 8.3% (1 of 12) were dirty/infected wounds.
- Organ/space SSIs accounted for 36.8% (7 of 19) of the implementation period SSIs. Of those, 100% (7 of 7) were clean/contaminated wounds.
- The hospital improved to the eighth decile according to the ACS NSQIP national O/E ratio for SSIs.

Colectomy Surgery Process Improvement

In the baseline period, analysis of the colectomy outlier hospital's process implementation of the selected process measures demonstrated that

- 33.3% of patients (2 of 6) with surgery time over four hours had an antibiotic redosed,
- 18.5% of patients (5 of 27) used CHG wipes the night before the surgery,
- 25.9% of patients (7 of 27) had skin edge protection during surgery,
- 77.8% of patients (21 of 27) were either nonsmokers or quit smoking more than two weeks prior to surgery,
- 70.4% of patients (19 of 27) had CHG wipes the morning of surgery, and
- 63.0% of patients (17 of 27) had intraoperative normothermia.

At the end of the implementation period, analysis of the colectomy outlier hospital's implementation of the selected process measures demonstrated the following (see Figures 3 and 4):

- The percentage of patients with surgery time over four hours who had an antibiotic redosed increased to 59.1% (13 of 22).
- The percentage of patients who used CHG wipes the night before the surgery increased to 26.4% (34 of 129).
- The percentage of patients who had skin edge protection during surgery increased to 27.1% (35 of 129).
- There were no improvements in the percentages of patients who were either nonsmokers or quit smoking more than two weeks prior to surgery, who had CHG wipes the morning of surgery, or who had intraoperative normothermia.

DISCUSSION

In phase 2 of the project, the bariatric and colectomy outlier hospitals documented their monthly progress toward implementation of the process measures they selected from the comparison document. Recommendations for the use of preoperative CHG wipes and Peridex mouthwash for all bariatric patients were discussed with infection control staff and with the bariatric surgery director. All bariatric surgeons agreed to order CHG wipes and Peridex oral swish preoperatively, and these were added to the standard bariatric order sets. Documentation of both process measures was discussed with the OR director of education. The surgical staging

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Figure 3. Colectomy Process Measure Implementation—Improvement

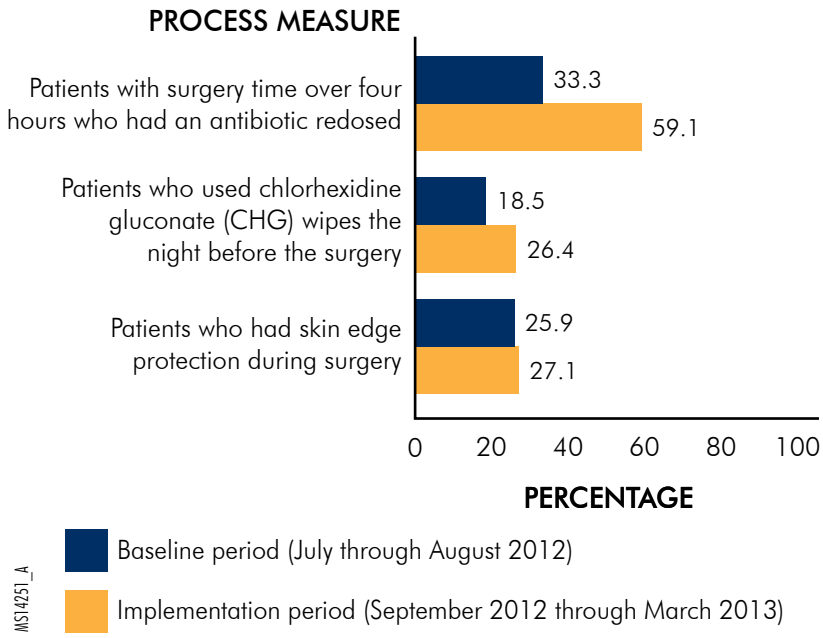
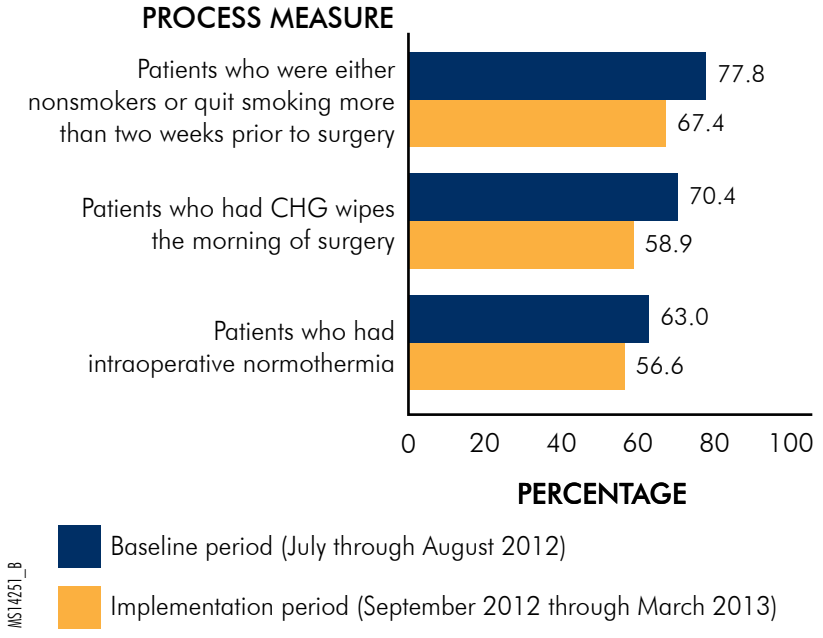


Figure 4. Colectomy Process Measure Implementation—No Improvement



area staff were instructed to document Peridex on the medication record and CHG wipes on the "ticket to the OR." All patients were given a prescription for a CHG bath at their preoperative admission testing visit. All bariatric surgeons had also implemented wound edge protection in March 2010. This strategy was not selected as a new process measure, as compliance with this practice was tracked at 100% for the entire baseline and process implementation periods.

Information on differences in implementation of best practices between the outlier and the high-performing colectomy hospitals identified during the site visits was shared with the colectomy surgeons. Process measures that were agreed upon to monitor actual compliance included the bundle components (i.e., the percentages of patients who used CHG wipes the night before the surgery, who quit smoking within two weeks of surgery, who had CHG wipes the morning of surgery, and who had intraoperative normothermia), antibiotic redosing in cases lasting more than four hours, and wound edge protection. The implementation team identified discrepancies in the documentation of these practices and coordinated with the OR staff to provide education and to identify and overcome barriers to accurate and complete documentation of these measures.

Surgeon champions presented the chief of colorectal surgery and members of the colorectal surgery division with their most recent hospital-specific NSQIP SSI data. They also compared their results with the ACS NSQIP national average. A review was done of the colectomy best practices, derived from the site visits, and contrasted the implementation of different processes of the high-performing and outlier hospitals in colectomy SSI prevention. The chief of colorectal surgery presented a standardized data sheet to the attending surgeons to manually collect this data to ensure compliance. The data sheets were compared with the data input

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into the "Surgical Care Bundle" screen by the OR nurses. Both outlier hospitals continue outcome and process improvement beyond the scope of this project by virtue of their continued participation in ACS NSQIP, a nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care across surgical specialties.

Limitations

The original project end point was scheduled for June 2013, at which time only the June 2012 through March 2013 cases were available for process and outcome measurement. This was due to the ACS NSQIP data abstraction process, which begins 60 to 90 days after the case is completed.

The bariatric surgical staging area documentation process was revised to begin online documentation. It was unclear if documentation was absent or was not scanned into the chart. Medical records was contacted to follow up on documentation in the paper medication records. The surgical staging area educator was contacted to remind staff to document on the paper form. Implementation of the hemoglobin A1c measure was affected by the extended time frame between the blood draw at the initial visit and the date of the procedure, which is up to 24 months from enrollment to the surgery date, as well as by inconsistent ordering and multiple physician and nurse practitioner changes in the facility's weight management center.

The outlier hospitals were encouraged to select three process measures from the phase 1 variance assessment. This strategy was suggested to ensure sufficient resource allocation to implementation activities. The colectomy outlier hospital endeavored to implement all four elements in the hospital's SSI prevention bundle, including use of CHG wipes the night before and the morning of surgery, smoking cessation, and normothermia, as well as skin edge protection and antibiotic redosing for a procedure lasting more than four hours. There was initial inconsistency in the colectomy surgeons' acceptance of the selected colectomy process measures. This cultural barrier affected the timing and progress of implementation of systems to achieve compliance with the process measures. Information technology issues were found that affected determining which cases lasting more than four hours required antibiotic redosing. This took several months to correct.

CONCLUSION

In November 2013, the project's successful outcome was shared with all PA-NSQIP consortium member hospitals and presented to the American College of Surgeons' administrative director of the Division of Research and Optimal Patient Care (Quality Programs). The project was also selected for poster presentation at the December 2013 Institute for Healthcare Improvement 25th Annual National Forum on Quality Improvement in Health Care in a poster titled "Using Cross-Institutional Learning to Reduce Surgical Site Infection Rates in Pennsylvania." These activities demonstrated the lessons learned from the process implementation and outcome successes and facilitated the goal of sharing of the successes in implementation of improvement plans to reduce SSIs with other Pennsylvania hospitals. Cross-institutional learning about bariatric and colectomy SSI prevention was facilitated by arranging site visits and interactions among clinical teams from facilities struggling with implementation and their colleagues from institutions that have achieved and sustained low SSI rates.

The dedication and commitment of PA-NSQIP leadership and teams from each participating facility and collaboration with the Authority resulted in substantial beneficial outcomes in the prevention of bariatric and colectomy SSIs. Those outcomes included the substantial reduction of bariatric and colectomy SSIs for a sustained period, the creation of a collaborative learning network for the prevention of SSIs, and the creation of comparison reports to measure progress.

Acknowledgments

The authors and the Pennsylvania Patient Safety Authority thank the PA-NSQIP collaboration project leaders, staff, and administrators at the hospitals who participated in the project and invited the Authority to review their data and observe their practices to prevent SSIs. Jonathan R. Treadwell, PhD, associate director, Evidence-based Practice Center, ECRI Institute, consulted on and contributed to statistical testing for this article.

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Quarterly Update on Wrong-Site Surgery: How to Do an Effective Time-Out in the Dark

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This update includes a quarterly update of the reports of wrong-site surgery in Pennsylvania and a failure mode and effects analysis of time-outs for laser procedures on eyes.

There were 10 reports of wrong-site surgery in Pennsylvania operating rooms (ORs) during the first quarter of 2014, the third consecutive quarter of the academic year with 10 reports (see the Figure). This is an improvement from 2009–2011, when there were five consecutive quarters with 16 reports. However, many of the reports were repetitions of problems whose prevention strategies are known and have been discussed.[1-3]

Anesthetic blocks administered at the wrong location continue to be the most common wrong-site procedure reported from Pennsylvania operating suites. Of the 10 events reported this quarter, 2 were lower-extremity blocks administered by anesthesiologists and 2 were local blocks administered by the operating surgeons. One of the latter two illustrates the importance of doing a separate formal time-out for an anesthetic block unless the surgeon is performing the anesthetic block and incision in continuity after the surgical field has been prepped and draped:[1]

> *The consent stated [surgery] on the left ankle. The left ankle was marked by the surgeon in the pre-op holding area. In the OR, the surgeon proceeded to inject Marcaine into the right ankle without asking nurses for a time-out, while the circulating nurse was on the phone. The circulating nurse [later] washed the right ankle with chlorhexidine with a scrub brush. The scrub nurse painted the right ankle with ChloraPrep, and then the surgeon requested a tourniquet. The circulating nurse obtained the tourniquet and saw the mark on the left ankle. The surgeon was informed and the consent reviewed. A prep was then performed on the left ankle and the procedure began.*

Two reports of stents placed in the wrong ureter were added to the 19 prior reports. The problem of stenting the wrong ureter was discussed in 2010, and the advice at that time remains valid: the surgeon should obtain an intraoperative imaging study to confirm proper stent placement, with the interpretation documented at the time.[1]

For the eighth time in 10 years, a report was received that a surgeon made an incision for a carpal tunnel release on a patient who was to have a trigger finger release. This problem was also discussed in 2010, and the advice at that time remains valid: the surgeon should make the mark as close as possible to the incision site, and the time-out should be done as close as possible to making the incision.[1]

Near-miss reports continue to demonstrate both areas of continued weakness and the effectiveness of the evidence-based best practices to prevent wrong-site surgery.[2,3]

The role of the surgeon's office in preventing wrong-site surgery due to errors in scheduling or consents was discussed in a recent article in the *Bulletin of the American College of Surgeons*. Incorrect or inadequate information received from the surgeon's office with respect to the OR schedule or consent accounted for 9% of all wrong-site surgical procedures—1 out every 11.[4]

Numerous patients were scheduled incorrectly, with some repercussions:

> *Patient is scheduled to have a left shoulder scope. Physician pre-op orders state left knee scope. Contacted preadmission testing department to have documents corrected. Chart corrected prior to the day of surgery.*
>
> *Incorrect paperwork [identified] in pre-op during the verification process. Pre-op physician orders state right shoulder surgery. Patient is scheduled to have right knee meniscectomy. Call placed to preadmission testing to have paperwork corrected prior to surgery.*

Scan this code with your mobile device's QR reader to access the Authority's toolkit on this topic.

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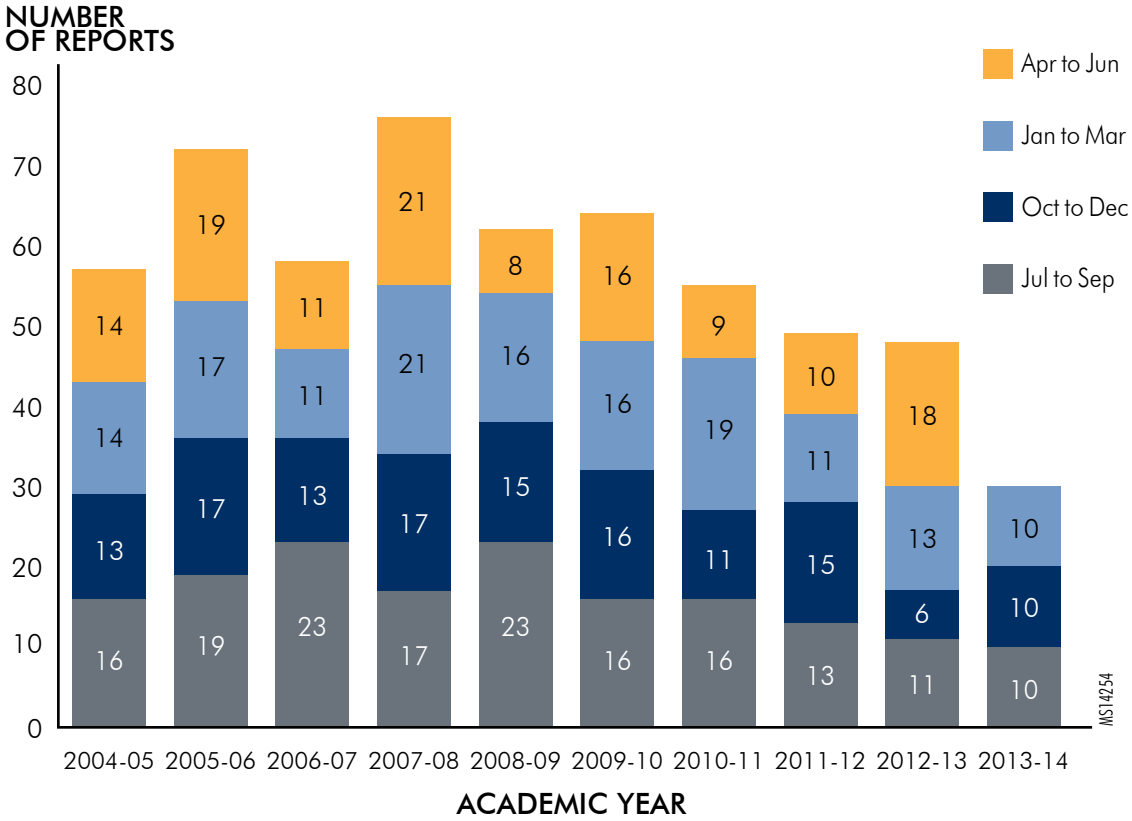
Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year



Patient on OR schedule for left ganglion block. During [the intake] interview, the patient stated right-side pain and right-sided injection. Consent signed for right ganglion block. MD confirmed right side to be performed. Reservation form from physician's office pulled and revealed incorrect side on office form sent to scheduling office (listed left side).

MD's office scheduled the patient for a right MPJ [metatarsal phalangeal joint] fusion with plate and screw fixation; patient's consent and MD's notes state left MPJ fusion with plate and screw fixation. Left side also marked by MD. Error on scheduling from MD's office.

Reservation and consent from surgeon's office stated left, but H&P [history and physical] and patient's statement explain it is the right hip joint.

Patient on OR schedule for trach [tracheostomy] and PEG [gastrostomy tube] placement. Patient did not need trach or PEG placed. [No surgical consultation] on the case. OR asked to identify medical record number and birthdate. They were correct. Husband called to check; husband unaware of any scheduled surgery. No consent signed. No orders written. Patient not sent to OR. Surgeon initially gave wrong name to [OR scheduler].

Consent for surgery, emergency room MD report, surgeon, chest x-ray, and patient state left VATS [video-assisted thorascopic surgery], and OR schedule said right VATS, and OR was set up for right-sided procedure. . . . OR notified and case delayed due to wrong setup.

Patient on OR schedule for [open] repair left inguinal hernia. Permit for laparoscopic left inguinal hernia repair. Case was scheduled incorrectly based on information from surgeon/surgeon's office. Surgery delayed for 18 minutes in order to obtain necessary instrumentation for incorrectly scheduled procedure.

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Consents continue to be obtained with incorrect or missing laterality. Other supporting patient documents have also had incorrect or missing information. Some of these errors were caught during the initial verification, but some were not caught until the patient was in the OR:

> *Staff noted that the consent was related to a right radius fracture. The left radius was the extremity with the fracture. The procedure was then planned to be performed on the correct side.*

> *Nursing noticed in pre-op that the patient was scheduled and consented for right-side surgery instead of left side. Physician notified. Patient [re-] consented for left side.*

> *Patient to have a ureteroscopy on left side. Physician's consent stated right side. Staff in holding area caught the discrepancy and investigated. . . . Error corrected before procedure.*

> *The patient was in the OR for eye surgery. The procedure was to be on the left eye, and the consent stated the right eye. The surgeon's office was called and the corrected paperwork was sent.*

> *Original H&P documented patient to have a TKR [total knee replacement] on the left knee. Correct knee for surgery was the right. Document was corrected, and the procedure was completed on the correct right knee.*

> *When checking the chart, the consent and pre-op physician orders are missing the side of surgery. Called physician assistant to obtain corrected paperwork.*

> *When checking the patient's surgical chart, the body site was missing from the scheduling sheet, consent, H&P, and pre-op physician's order. Notified PAT [preadmission testing] to correct the paperwork prior to the day of surgery.*

In one report, the surgeon was not present during the time-out when the reconciliation was done:

> *During the time-out, it was discovered that the consent did not indicate the side. History and physical [examination] did indicate the right side. Patient was prepped and draped with the right side as surgical site. Attending surgeon not present for the time-out. The assistant surgeon was present for the time-out and confirmed that the right side was the correct side. The team members present were in agreement. Verification forms [had] indicated that consents were complete.*

The wrong charts sometimes accompanied the patients, again with some repercussions:

> *Upon arrival to the pre-op area, the patient was identified. The patient's name band and all the chart information was identified to be in error. OR was postponed until the problem was rectified.*

> *Incorrect labeling of surgical chart. Two patients with the same last name are on the surgery schedule for the same day. Surgical paperwork was labeled with the wrong patient's labels and placed in the surgical folder. The charts were returned to the front desk for resolution of the problem. Labels and charts were corrected prior to the day of surgery*

> *The patient came to block room with paperwork from another patient on the chart.*

> *Upon doing the time-out, the wrong patient stamp was noted on the consent. However, the correct patient signed the consent. Her signature also matched her signature that had been obtained in the holding area prior to procedure. The consent was correct to the actual patient's procedure; it was the patient stamp that was incorrect. The patient verified to the CRNA and circulating nurse the correct procedure in the holding area prior to going to the operating room. When doing the time-out, the incorrect printed patient name was noted on consent. The surgical assistant who obtained the OR consent was notified and came into room to see the consent. The surgical assistant mixed up the patient number when printing the OR consent from the electronic form generator.*

Late changes in plans continue to result in misinformation when all possible sources of information are not uniformly updated:

> *The surgery was scheduled for the left side. The patient's consent and H&P were completed for the right side, as the patient had decided three days ago that she wanted the right side done at this time. The discrepancy was verbalized by the patient, and the MD was notified and discussed [the situation] with the patient. The right side was confirmed.*

A surgeon marked the site without prior reconciliation of the supporting documents, which were not corrected in a timely manner:

> *The time-out noted that the patient's consent was for a right leg I&D [incision and drainage], but the physician had marked the left leg and the left leg was referred to in the H&P. Upon further investigation, the physician obtaining the consent made an error. The intended leg was the right [leg]. The consent was corrected post-op and the physician informed the patient.*

The white board in the OR was a source of incorrect information according to one report:

> *Grease board read right-side surgery. Consent and patient stated left side. Confirmed side and corrections made to grease board.*

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Some surgeons still fail to appreciate that the time-out benefits them and their patients, especially in preventing the previously mentioned wrong-site blocks:

> *The surgeon started to inject the local anesthesia into the patient prior to doing the final time-out.*
>
> *The surgeon took the scalpel and made the incision without the [nurse] doing a time-out or him calling for one. The surgeon was reminded of the importance of calling and doing a time-out.*
>
> *Surgeon did not respond verbally to the procedural "time-out."*
>
> *Phase one of the time-out was completed. The surgeon was [later] asked to complete his final time-out and he would not do so.*

However, the time-out was effective in preventing wrong-site surgery:

> *Took the patient back to the operating room and did not check and confirm the side. The left leg was prepped and clipped. The surgeon applied the tourniquet to the left leg. Draped the left leg. During the surgical pause, it was discovered that the consent was for the right leg.*

HOW TO DO AN EFFECTIVE TIME-OUT IN THE DARK DURING A LASER PROCEDURE ON THE EYE

Based on a query from a nurse working in an ambulatory surgical facility, the coauthor (L.W.) took advantage of the opportunity to view a room for laser eye surgery, on a day when the ambulatory surgical facility was quieter than usual, to observe and discuss the Universal Protocol for laser procedures in this specialized room. In addition to being a unique procedure for an ambulatory surgical facility, laser eye procedures are done in a room that is dark, with only one room light. In this facility, the one light is recessed in the ceiling and is on a dimmer switch managed by the nurse and adjusted to the surgeon's preference. Another distinctive part of this procedure is the position of the patient. The patient's chin and forehead rest against the laser machine, which blocks the face and makes it impossible to see the site marking.

The observations were aided by the patient safety culture of the leaders and staff of the ambulatory surgical facility, who openly shared their descriptions of their current processes, making it possible to create a list of opportunities for improving the processes and creating a reliable, safe process for laser procedures.

The results of the observations and discussion reinforced the use of the standard Universal Protocol used for other surgical procedures, including, specifically:

- During the preoperative verification process, all documentation should be reviewed, especially the informed consent.
- The surgeon should see the patient prior to the procedure and mark the site. For a laser procedure of the eye, one could argue that the site mark is not going to be seen and therefore not needed. However, the site marking process is an important step that occurs with the patient as an active participant in establishing the correct laterality of the procedure. Acknowledging the patient and marking the site are dynamic methods to refresh the surgeon's short-term memory of the laterality of the procedure that has been agreed upon by means of the patient's informed consent. Although not mentioned by the staff of the ambulatory surgical facility, the staff of the Pennsylvania Patient Safety Authority also proposes that attaching a reflective or fluorescent wristband to the arm on the side of the procedure could be considered as an alternative to provide a lateral site mark that could be referenced during the time-out.
- The time-out in the laser procedure room should be similar to the time-out in any OR or surgical suite. Whoever is in charge of initiating the time-out should begin by asking, "Is everyone ready to do the time-out?" This alerts all the people in the room that their attention is needed.
- During the time-out, all activities in the room should stop for all participants, including the surgeon. Once all activity has stopped, the time-out should proceed. This simple step helps the participants focus their attention during the time-out.
- The leader should explicitly encourage the staff to be active participants in the time-out. A completed informed consent should be in the room during the procedure and referenced during the time-out to serve as the reference for the discussed operation, including the use of the laser.
- Prior to using the laser, the surgeon reaches around the laser machine and places a lens over the agreed upon eye. Since any mark around the eye is obscured by both the darkness and the laser machine, this step in the process is an excellent time for each person in the room to independently confirm that the surgeon has chosen the eye indicated on the consent and to stop the process if he or she has a question.

The use of laser eye procedures has resulted in atraumatic improvement of vision for patients. The safety processes used in all other areas of the OR, specifically a standard time-out, are equally important in the specialized room where laser procedures are done. A site mark around the eye is difficult to reference during the time-out because of the darkness and the laser equipment obscuring the face; therefore, alternative means of indicating laterality should be considered. The placement of a lens over the eye to be operated on by the surgeon is an extra cue that can alert staff in the room to which eye will receive the laser treatment.

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NOTES

1. Quarterly update on the preventing wrong-site surgery project: digging deeper. Pa Patient Saf Advis [online] 2010 Mar [cited 2014 Apr 28]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Mar7(1)/Pages/26.aspx
2. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2012 [cited 2014 Apr 28]. http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/principles.pdf
3. Pennsylvania Patient Safety Authority. Quarterly update: the evidence base for best practices for preventing wrong-site surgery. Pa Patient Saf Advis [online] 2010 Dec [cited 2014 Apr 28]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/dec7(4)/Pages/151.aspx
4. Clarke JR. Is your office helping you prevent wrong-site surgery? *Bull Am Coll Surg* 2014 Apr 99(4):28-31.

Reviewer Commentary

Identifying the proper eye in a patient who is undergoing a laser procedure should start in the pre-op area when the patient is being readied. Almost all patients undergoing a laser procedure will require drops in the eye prior to the procedure. The drops are usually given by the pre-op nurse. Prior to giving the drops, the nurse should check the consent and the patient should confirm the eye being operated on. The proper mark can be placed over the operative site around that time. After the drops take effect and the patient is brought into the laser room, the doctor and nurse should have a time-out to confirm the correct eye. Although the laser room is traditionally a darkened room, the lights can be raised while the patient is being prepared.

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