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PENNSYLVANIA PATIENT SAFETY ADVISORY

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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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Robotic-Assisted Surgery: Focus on Training and Credentialing

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ABSTRACT

Since 2005, healthcare facilities have reported 722 safety events involving robotic-assisted surgery (RAS) to the Pennsylvania Patient Safety Authority. Five hundred forty-five (75.5%) were categorized as Incidents that did not result in patient harm. Of the 545 Incidents reported, 344 (63.1%) of the events were categorized as complications of a procedure/treatment/test or errors related to a procedure/treatment/test. One hundred seventy-seven (24.5%) were reported as Serious Events that resulted in patient injury, including 10 events that resulted in patient fatality. Complications of a procedure/treatment/test (n = 131) and errors related to a procedure/treatment/test (n = 44) comprised 98.9% of the Serious Events. Further review of these cases showed that the event type subcategories of unintended laceration/puncture, bleeding/hemorrhage, other events related to patient positioning complications, retained foreign body, and infection made up 75.1% of the Serious Events. The rapid growth of RAS has presented new challenges as this technology has emerged as an alternative treatment option to many laparoscopic and open procedures. Current literature supports that a steep learning curve exists as surgeons develop skills to perform robotic procedures. As professional organizations discuss developing and defining standards for training and credentialing, the responsibility falls on the individual hospital to develop programs to ensure that both the physician and the entire surgical team are proficient and competent to safely perform robotic procedures and that patient outcomes are monitored to ensure ongoing staff competency. (Pa Patient Saf Advis 2014 Sep;11[3]:93-101.)

INTRODUCTION

The use of robotic technology has escalated over the past four years, and the number of robotic-assisted surgeries (RASs) performed worldwide nearly tripled between 2007 and 2010, from 80,000 to 205,000.[1] Originally developed by the US Department of Defense for use in the battlefield in the 1990s, robotic surgical technology has rapidly changed the practice of minimally invasive surgery.[2,3] In 2000, the US Food and Drug Administration (FDA) cleared the da Vinci® Surgical System by Intuitive Surgical, Inc. for laparoscopic surgery, and as of this writing, it remains the only commercially available system. This system is currently FDA-cleared for many procedures, including general surgery, cardiac, colorectal, noncardiac thoracic, head and neck, urologic, and gynecologic procedures.[4,5] The benefits of robotic technology include three-dimensional magnified vision, enhanced ergonomics and tremor filtration, motion scaling, and improved manual dexterity.[3,6-8] Patient-centered potential advantages include reduced length of hospital stay, improved postoperative recovery time, decreased postoperative pain, and decreased blood loss.[9] The manufacturer reports the major benefits experienced by surgeons include greater surgical precision, increased range of motion, improved dexterity, enhanced visualization, and improved access.[7]

Limited valid data is currently available on complication rates or adverse events related to robotic surgery. FDA's Manufacturer and User Facility Device Experience (MAUDE) database collects medical device adverse event data, but this system has its limitations and states that information collected cannot be used to evaluate adverse outcome rates.[10,11]

The cost of implementing a robotic surgery program requires a substantial financial commitment from the hospital, as the cost of a robotic system runs in the range of $1.5 million to $2 million, with additional costs for maintenance of the system and purchase of limited-use instruments.[12] The cost of training the surgeons and the entire surgical team is estimated to be about $10,000 per surgeon.[8] As the learning curve is steep, the hospital will also need to account for the increased operative costs during this period. The professional organizations have not reached a consensus on training or credentialing standards.[7,12,13] This leaves the individual hospital responsible to develop and implement training and credentialing processes that are medically sound, that promote patient safety, and that protect the organization from undue risk.

Implementing a robotic surgery program is challenging. The focus of this article is not to debate the efficacy of one surgical approach versus another but rather to identify organizational training and credentialing processes that may increase RAS safe patient outcomes within an organization as well as reduce organizational risk.

COMPLICATIONS AND ADVERSE EVENTS RELATED TO ROBOTIC SURGERY

Valid data on complication rates and adverse patient events is limited and can be conflicting. No studies exist to support that RAS conducted by experienced robotic surgeons has complication rates that differ from other techniques.[8] Current sources of national adverse event data include FDA's MAUDE database and procedure-specific studies. In addition, the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) contains event reports that were reviewed following a query of the reporting system database that included the terms "robot" or "da Vinci." Additional like events may have been reported through PA-PSRS but not captured in this analysis if this terminology was not included in the event report.

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MAUDE

At the national level, manufacturers, importers, and device user facilities are required to report to FDA certain device-related adverse events involving serious patient injury and/or death as well as product problems.[14] Reports made to MAUDE include information that may identify patterns or problems or a failure mode with a particular device that organizations can review as part of their ongoing robotic patient safety program. MAUDE's system limitations are widely known, and FDA has indicated that the data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices, as many reports may be missing, duplicated, or incomplete.[10]

Dr. Martin Makary, Johns Hopkins University, was noted to say that MAUDE is a "haphazard reporting system that uses immature data and only the best experiences make it into the data."[15] On November 23, 2013, Intuitive Surgical, Inc. posted an analysis of the MAUDE database by date of event from 2010 to 2013. Its analysis showed a decrease in the overall adverse event rate. Included in its rate calculation explanation, Intuitive states, "Rate computed by dividing number of adverse events by number of surgical procedures completed worldwide through 31 October 2013. Q4 2013 procedures are an estimate."[12] The actual denominator of total robotic cases was not found to be reported in the literature reviewed, but the manufacturer approximated that 1.5 million procedures have been performed worldwide as of December 2013.[7,16]

Gupta et al. performed a study of the MAUDE database for the years 2009 and 2010 for which 741 events were identified that involved robotic surgery. The authors reported that of the cases reviewed, 27.3% were urology, 32.6% gynecology, 10.8% other, and 29.2% not specified. This study found that 43.4% of the cases were associated with use of an energy instrument, 19.3% with the surgical system, and 11.7% with an instrument accessory. Gupta et al. opined that the number of adverse events was low, or about 0.1% over two years.[17]

Cooper et al. also studied the FDA MAUDE database for device-related robotic surgery complications, by specialty and procedure type, reported from January 1, 2000, to August 1, 2012. In addition, the authors searched LexisNexis and Public Access to Court Electronic Records (PACER) databases for any legal judgments to see if there was a corresponding report in MAUDE. Cooper et al. found that 245 cases had been reported, which included 71 deaths and 174 nonfatal injuries. Eight cases were found in LexisNexis and PACER in which the FDA report was inaccurate, filed late, or not filed. Of these eight, FDA did not receive a report on five, although several were in litigation and had been reported via the media. Cooper et al. recommended that a standardized mechanism be put in place to monitor device and patient safety. The authors opine that there are several reasons for underreporting of robotic surgical events, including difficulty in separating poor surgical skill from device-related injuries, little oversight regarding reporting, and little incentive to improve reporting.[14]

Reviews in Literature

Tsao et al. at the University of Pittsburgh reviewed their first 100 patients having robotic-assisted laparoscopic prostatectomy from October 2004 to August 2007 performed by three attending surgeons. The variables reviewed included estimated blood loss, operative time (trocar placement to skin closure), margin status, length of stay, postoperative prostate-specific antigen level, and continence. The authors found that 99% of the surgeries were completed robotically and only one converted to an open case. No intraoperative complications were reported, and 23% of the surgeries had positive margins. Postoperative complications included pulmonary emboli (n = 4), open conversion (n = 1), ileus (n = 5), infections (n = 4), myocardial infarction (n = 2), urine leaks (n = 7), fascial dehiscence (n = 1), extremity weakness (n = 3), abdominal bleed secondary to anticoagulation for pulmonary embolus (n = 1), death due to pulmonary embolus (n = 1), reoperation for fascial dehiscence (n = 1), readmission for pelvic abscesses (n = 2), and bladder neck contractures (n = 3). The most significant decrease in operative time was seen after the first 25 patients, and blood loss was noted to decrease after 50 patients. Their overall complication rate was 26%. Improvement of surgical outcomes and patient safety was present with ongoing surgical experience.[18]

Smith et al. at the University of North Carolina conducted a study of 250 robotic-assisted radical cystectomy cases. This study showed no definitive proof that the robotic approach decreased complications or improved patient outcomes as compared with open procedures. The authors found that patient selection was key when a surgeon was new to robotics and suggested that simple cases be done until the surgeon was past his or her learning curve. The authors found that use of perioperative care pathways, intraoperative techniques learned from increasing experience, and careful instrument selection helped avoid complications.[19]

Davis et al. performed a study utilizing a large database to assess the learning curve effect for robotic-assisted radical prostatectomies (RARPs) and to compare the outcomes of RARP with open radical prostatectomy (ORP). The database consisted of 71,312 reports of radical prostatectomies performed at more than 300 hospitals by more than 3,739 surgeons utilizing an open or robotic approach from 2004 to 2010. The key variables reviewed were conversion to open, surgical time, inpatient length of stay, and complications. The RARP results by surgeon experience showed

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improvements in conversion rates (1.13% to 0.31%), surgery time (5.0 hours to 4.1 hours), hospital stay (2.4 days to 2.0 days), and complication rates (11.75% to 8.93%) within the initial 100 cases performed by the surgeon. The study also noted that there was continued improvement in conversion rates, surgery time, and hospital stay beyond the initial 100 cases. In comparing the two surgical approaches, the length of surgical time was greater for RARP than for ORP, but the length of the hospital stay and overall complication rate was lower for the robotic approach.[20]

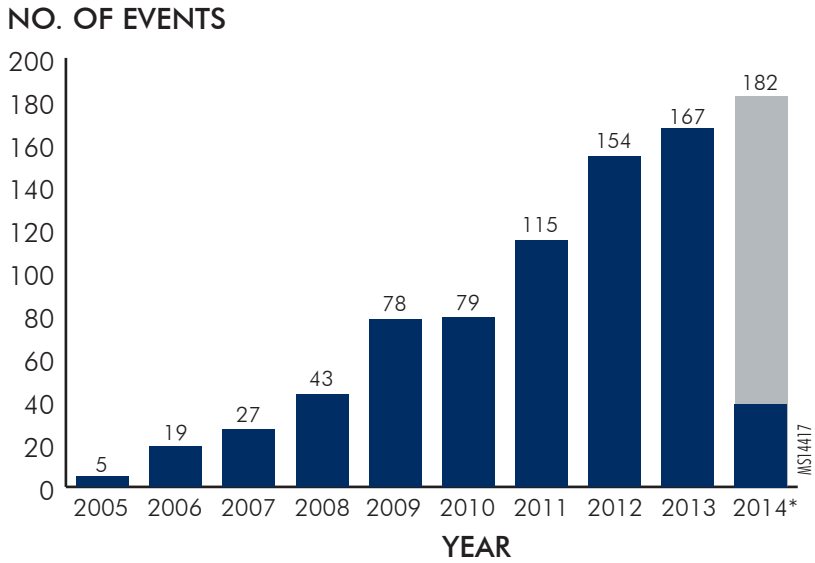
PA-PSRS Reports

A query of PA-PSRS reports using the terms "robot" and "da Vinci" from June 2004 through March 2014 found 913 events. Of these reports, 722 events directly involved RAS. Figure 1 shows the distribution of reports by calendar year. It was noted that the Authority did not receive any reports involving RAS occurring in 2004.

Analyzing the event date by event type shows that complications of procedure/treatment/test, errors related to procedure/treatment/test, and equipment/supplies/devices events comprised 90.2% of all RAS events (see Figure 2). Five hundred forty-five reports (75.5%) were categorized as Incidents that may or may not have reached the patient and did not result in patient harm. Of the 545 Incidents reported, 131 (24.0%) were attributed to equipment/supplies/devices.

One hundred and seventy-seven (24.5%) of the PA-PSRS reports were reported as Serious Events that resulted in patient injury, including 10 events that resulted in a patient death. Ninety-nine percent of Serious Events were attributed to complications of procedure/treatment/test and errors related to procedure/treatment/test, with only one event attributed to equipment/supplies/devices. Five of the 10 patient events resulting in death involved perforation or laceration of a vessel or bowel.

Figure 1. Robotic-Assisted Surgery Events by Calendar Year 2005 to 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 722 reports through March 2014)



*** The number of events for 2014 is a forecasted value. Forecast was calculated using formula a+bx, where a = $\bar{y}$-b$\bar{x}$, b = $\sum(x-\bar{x})(y-\bar{y})/\sum(x-\bar{x})^2$ and where x and y are the sample means of known calendar years and of known events reported for full calendar years, respectively. The forecast section of the stacked bar for 2014 represents the forecast total less the known number of events through first quarter 2014 (n = 35).**

Further review was performed on the subcategories and narrative details of the Serious Events to gain a better understanding of the reports that resulted in patient harm. It was noted that errors related to procedure/treatment/test and complications of procedure/treatment/test totaled 98.9% of all Serious Events (see Figure 2).

In reviewing the reported complications and narrative details of the PA-PSRS RAS Serious Events, the most frequently occurring complications were unintended laceration/puncture (43.5%) and bleeding/hemorrhage (17.5%). Retained foreign body and infection each accounted for 4.0% of complications. Other complications were reported in 31.1% of the Serious Event reports, of which 20.0% were related to positioning complications. See Figure 3.

Hospitals also provide information describing contributing factors and remedies to reduce reoccurrences. It was noted that two of the Serious Events identified inexperienced staff or issues of staff proficiency as a contributing factor. Fourteen Serious Events documented that further education and training of the staff and referral of these events to medical leadership, administration, and quality/risk management for further review were recommended to prevent reoccurrence.

The following are samples of events reported to the Authority.

Unintended Laceration/Puncture

During robotic-assisted lobectomy, the patient's pulmonary artery was nicked. The procedure was converted

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to an open thoracotomy, resuscitation was not successful, and the patient died. Training and education of the staff was recommended as a remedial measure to prevent recurrence.

Bleeding/Hemorrhage

Patient underwent robotic-assisted laparoscopic partial left nephrectomy without incident. H/H [hemoglobin and hematocrit] dropped, and increased bleeding around the JP [Jackson-Pratt] drain was noted. Patient was taken back to the OR [operating room] for exploratory laparoscopy; evacuation of hematoma and cauterization of various bleeding points was performed. Patient was returned to unit stable; later, the patient was observed with increased blood in JP drain. The decision was made to take the patient back to the OR for open exploration. Nephrectomy was performed and adrenal gland found to be actively bleeding and also removed. Patient returned to unit in stable condition.

After a robotic TATA [transanal abdominal transanal proctosigmoidectomy with descending coloanal anastomosis] and diverting loop ileostomy procedure, the patient developed hypotension, tachycardia, and a drop in hemoglobin. The patient was returned to the OR for laparoscopic washout of intra-abdominal hematoma and vascular control of the inferior mesenteric artery.

Positioning

A patient underwent an elective nephrectomy via laparoscopic robotic procedure. Noted small bowel perforation in two separate areas. Severe adhesions noted from previous abdominal surgery. Surgery consulted. Repair performed. Proceeded with open nephrectomy. Time patient positioned on side in OR exceeded expected surgical time. Patient went to the ICU [intensive care unit] postoperatively. [More than five hours later,] patient complained of flank pain on same side as positioned in OR. Symptoms of compartment syndrome noted. Return to OR for fasciotomy. Return to ICU. Condition deteriorated. Renal failure, comfort measures per family request/decision. Patient expired. Education and training of staff along with review/revision of policies and procedures and referral to medical and administrative leadership for further quality review were recommended.

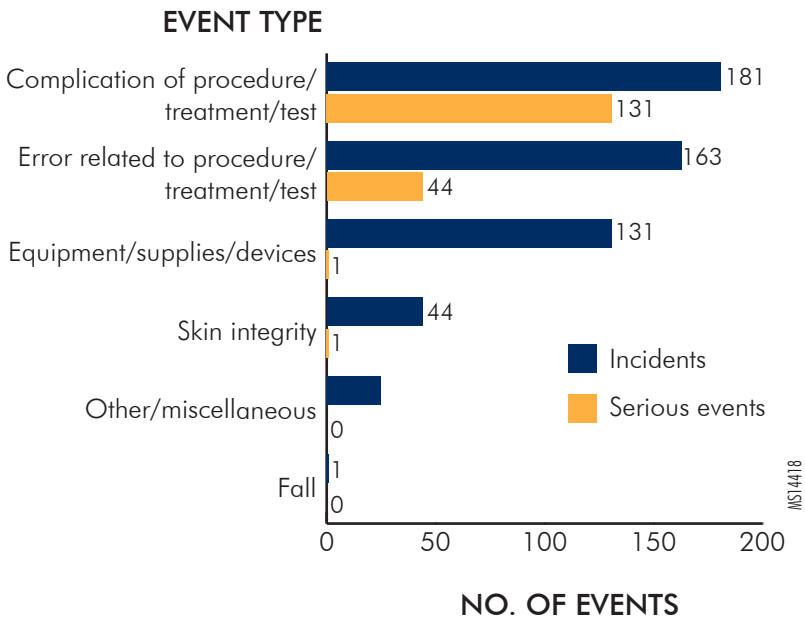
Retained Foreign Body

A patient underwent a robotic transaxillary thyroid lobotomy. Midway through the robotic dissection, the electrical power was lost [on] three separate occasions [not exceeding 30 seconds]. The case was converted to open. During the robotic procedure, metallic clips were used and the instruments were entangled in a gauze sponge. The counts were correct and the wound was closed. The staff was informed that this patient presented to another hospital for removal of a retained foreign body. Case referred to surgical and ENT [ear, nose, and throat] departments for further quality review.

Infection

Debris left on robotic instrument and was introduced into the patient's abdominal cavity upon insertion of instrument through port. Area irrigated and patient received antibiotics postoperatively. Lack of staff proficiency noted as a contributing factor to the event.

Figure 2. Robotic-Assisted Surgery by Event Report Types, 2005 through March 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 722)



KEY STRATEGIES FOR IMPLEMENTING A ROBOTIC SURGERY PROGRAM

Training and Education

As noted in several of the included event narratives, training and education, credentialing, and continuous quality

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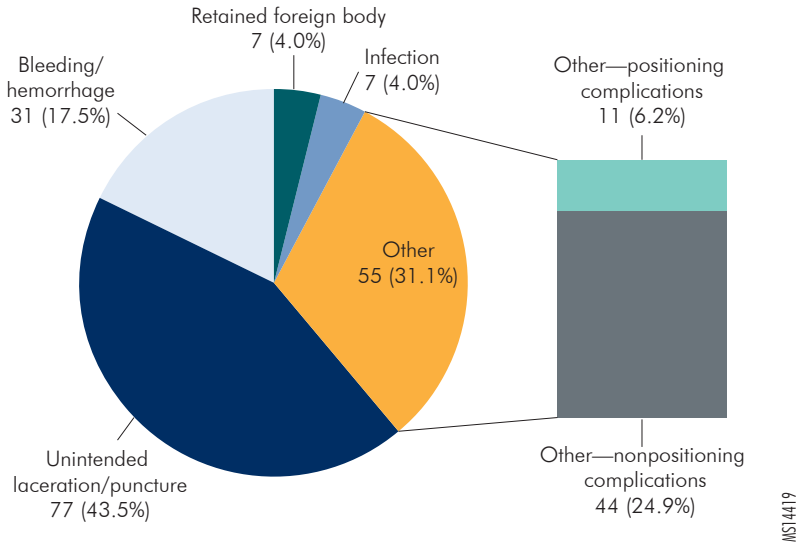
Figure 3. Robotic-Assisted Surgery Serious Events by Reported Complications, 2005 through March 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 177)



Note: **Sum of percentages does not equal 100 due to rounding.**

reviews are necessary to ensure that a robotic surgery program functions safely and efficiently. Attention to the following issues will assist the hospital in ensuring optimal patient outcomes while mitigating RAS risks and complications.

Robotic surgical training provided by the manufacturer provides basic training but does not ensure that the surgeon is competent to perform RAS. Larson et al. reported that the learning curve for a physician starting robotic surgery is steep, and the credentialing plan must address the individual learning needs.[21] Steinberg et al. devised a theoretical model to determine the operative costs during the learning curve for robotic-assisted prostatectomy and compared the costs with an actual series of robotic-assisted prostatectomies. The most expensive learning curve involved 360 cases with operative and anesthesia costs totaling $1.3 million, and the least expensive learning curve involved 24 cases and totaled $95,000.[8,22]

In general, RASs performed by inexperienced surgeons result in longer OR times and increased complications. When the necessary training time, increased procedure times, and increased risks are taken into account, overall RAS results increased costs to the medical system during the learning curve period.

The University of California, Irvine (UC Irvine) developed a successful robotic training program utilizing a three-phase approach to learning and the guidance of an experienced mentor.[23] In 2003, McDougall et al. presented a five-day comprehensive mini-residency program at UC Irvine to 21 urologists from four countries that included dry lab, animal/cadaver lab, and live demonstration in the OR.[8,24] Within 14 months of the course, 95% of the participants were safely performing RARP. All participants recommended this program to their colleagues. Follow-up studies showed that these participants were able to keep up safe practice in both the short and the long term. This program was funded by a grant, but UC Irvine estimates that the cost of providing this type of training would be approximately $10,000 per surgeon.

Another example of an organization's RAS training program (at Tacoma General Hospital in Tacoma, Washington) is discussed by Lenihan.[2] The military and aviation industries have a long history of requiring flight simulation training and strict regulations on licensing and maintenance of skills.[25] Lenihan likens operating a robotic surgical system, such as the da Vinci, to flying an airplane and believes that aviation safety standards can be employed. As part of a hospital's training program, the hospital can develop a system whereby the surgeons, like pilots, train and test to become credentialed, then must perform a certain number of procedures, get additional training, and take annual examinations to prove continued competency.[2]

Lenihan reports that Tacoma General Hospital's robotic surgical training and credentialing system is based on the aviation model, and other hospitals may consider this program as a template for establishing a robotic surgery program. The program identified training candidates as those surgeons who perform frequent major surgery, are comfortable with complex surgical procedures, and have laparoscopic experience. Consistent training was given to all, including didactic training, dry lab on a robotic platform or simulator, case observation, live animal model lab training, and proctored cases. More steps could be added for residency or fellowship programs. Each surgeon had a minimum of two cases proctored and mentoring by a skilled robotic surgeon when the surgeon started performing more complex cases or new procedures. A proctor was defined as a surgeon who has performed 40 RASs internally or externally, has done the procedure they are proctoring, and has a standardized

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evaluation process to report back to both the surgeon and executive team at the hospital.[2]

Tacoma General Hospital required that 12 to 15 simple cases be done first before attempting complex cases. For the surgeon's first advanced case, a physician first assistant is utilized. If it is a new case, the physician is proctored. After completing training, the surgeon starts doing cases right away and no later than 60 days after completion of training. Tacoma General Hospital's Robotics Peer Review Committee does a focused review of the first five basic cases and first three advanced cases. The established minimum number of cases for a surgeon to maintain skills and privileges is set at 20 to 24 cases per year and at least one every eight weeks. If a surgeon does not meet their currency requirements, they can try to increase their volume of surgical procedures or they can retrain in the dry lab using a simulator and then have the next three cases proctored by a fully qualified robotic surgeon and reviewed.[2]

Although professional organizations have not reached consensus on a consistent training program, nor have they come to agreement on the definition of competency to perform the procedures, several have published recommendations.[7,12,13] In 2007, a consensus document prepared by the Society of American Gastrointestinal and Endoscopic Surgeons along with the Minimally Invasive Robotic Association presented guidelines for the level of training needed to perform robotic surgery and for granting privileges as part of the credentialing process. The guidelines include didactic training, live case observation of an experienced robotic surgical team, and simulation training in preparation for a mentored clinical experience at the hospital.[26] The Fundamentals of Robotic Surgery consensus conference brought together over 19 professional organizations and developed a list of 25 outcome measures to be mastered by a surgeon seeking privileges in robotics: 8 preoperative, 15 intraoperative, and 2 postoperative tasks.[27]

Team Training

Proper training of the entire team is critical to maintain patient safety. Staff need experience with the robotic system, cadaver training, observation of an experienced team, and simulation training. Simulation training studies show that it takes surgeons eight attempts to achieve proficiency in each step of a RAS process.[28] The entire team needs to practice together on the equipment prior to using it on patients.[29] The University of Iowa Hospitals and Clinics has developed staff competency forms and robotic suite setup diagrams for prostatectomy as good visual teaching aides for the clinical staff.[30]

Team training includes drills for any type of failure that might occur during robotic surgery—for example, drills addressing equipment failure, conversion to an open procedure, and removal of equipment from the surgical cavity.[31]

Because robotic equipment, particularly the robotic arm, necessitates unobstructed movement, patient positioning is more complex. And once the robot is docked, it is difficult to access positioning. Patients can experience position-related complications such as peripheral nerve injury and rhabdomyolysis. The deep Trendelenburg position, in which the patient is inclined at 45 degrees with the pelvis higher than the head, used in gynecologic and urologic surgeries, can increase intraocular pressure. If the patient's position is changed during the procedure, it may not be noticed, as the large robot obscures the patient. Elevating the patient's head or arm to make room for the robotic arm may lead to hyperabduction of the elevated arm and a potential neurologic injury.[32]

The team will need to adapt to the size of the robot in the operative suite and ensure that there is adequate space for proper placement of the instruments and supplies needed for RAS, along with other instruments if the case converts to an open procedure. Rehearsed practice will allow the surgical team to refine their practice and evaluate what changes they will need to incorporate into their practice and communication patterns.[33] A second time-out occurs three to four hours after the start of RAS. This additional time-out is designed to assess patient safety and promote communication between the surgical, anesthesia, and nursing staff while addressing specialty concerns, such as proper patient positioning, that affect patients during robotic surgery.[34] In addition, use of a robotic surgical safety checklist may help reduce the risk of intraoperative complications.[35]

Credentialing

The Society of Urologic Robotic Surgeons has published suggested recommendations for the safe implementation and credentialing of RARP at an institution. It stresses the need for a centralized certification authority that would not be the robotic industry. This authority would be responsible for identifying and promoting expert robotic surgeons who would be permitted to function as proctors for other physicians learning robotic skills. Among the other recommendations presented was the need to ensure that the novice urologist would have three to five cases proctored for review by the healthcare organization's credentialing committee. The credentialing committee would develop written guidelines to reduce liability exposure for the proctor as well as address informed consent. This process would include notifying the patient regarding the role of the proctor during the surgery. The organization further recommended that evaluation of the robotic surgeon be an ongoing process and that failure to perform at a satisfactory level would require a recommendation for further education or preceptoring.[8]

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Lenihan describes competency-based credentialing for robotic surgery at Tacoma General Hospital. Outcome standards were developed that include review of total operative time, estimated blood loss, and major robotic complications such as injury or conversion to an open case. If the surgeon's performance does not meet the organization's established outcome standards, the Robotics Peer Review Committee reviews the surgeon's performance. Options to improve skills can be offered, such as working with a proctor on each case, obtaining advanced training, practicing on the simulator, continuing to do only basic cases, or referring cases to a more experienced surgeon. Use of simulators can be factored into competency evaluation or annual review of skills to document proficiency. If a case falls out due to a competency issue, the committee can recommend focused reviews, additional training, having an experienced robotic surgeon review all the cases, having a proctor in on every case, or limiting privileges.[2]

A robust credentialing process requires that an ongoing quality outcomes process be in place. Literature supports the need to study patient outcomes and the cost-effectiveness of using a robotic technique versus another modality. For radical prostatectomies, most of which are done robotically, oncologic outcomes and improved complication rates have not been proved.[36] Outcomes to be measured may include blood loss, complication rates, hospital lengths of stay, operating times, postoperative pain, and time to return to activities of daily living.[30]

Brown University Women and Infants' Hospital's Robotics Surgery Peer Review Committee consists of robotic surgeons and quality, risk management, and infection control professionals. This committee reviews the following cases: any conversion to open surgery, any patient seen in the emergency department within two weeks of surgery, any case referred for review by risk management or any member of the surgical or clinical team, and all 20 cases of a surgeon in provisional status seeking advancement to full privileges.[37]

Martino et al. at Lehigh Valley Health Network studied 2,554 patients who underwent a hysterectomy between January 2008 and December 2012. Women undergoing robotic-assisted hysterectomy to treat benign disease had fewer readmissions within 30 days, less estimated blood loss, shorter lengths of stay, and a cost savings related to those readmissions when compared with laparoscopic, abdominal, and vaginal approaches. More prospective studies are recommended for all the surgical modalities so that surgeons can evaluate the outcome of robotic surgery and the benefit, or lack thereof, to the patient.[38]

Patient Disclosure

Specific informed consent considerations will need to be addressed with an RAS program. Patients need to know more than just the general risks, benefits, and alternatives that are associated with the procedure. The risk of robot malfunction and the readiness to implement a contingency plan, such as converting to an open procedure, can also be addressed in the informed consent discussion. Surgeons will need to spend time with the patient explaining the pros and cons of selecting robotic surgery over other modalities.[13,34]

Plaintiff's attorneys are alleging insufficient training and credentialing against the hospitals in medical malpractice litigation. Surgeons may be charged with failing to obtain proper informed consent even if they have disclosed surgical risk but have not disclosed the surgeon's robotic training and where they are on the learning curve. The argument presented is that had the patient known that the surgeon lacked experience in robotic surgery, the patient would not have elected to have the procedure or would have selected a more experienced surgeon.[39]

A PENNSYLVANIA HOSPITAL'S EXPERIENCE

Francine Miranda, director of OB/GYN quality and performance improvement at Lehigh Valley Hospital (LVH) and Authority editorial board member, shared in a telephone interview on May 22, 2014, the highlights of her organization's robotics program.[40] LVH implemented a robotics program in 2008 and currently has three robotic surgical systems. LVH performs between 800 and 900 RASs per year and has performed over 3,000 procedures since 2008.

Miranda stated that LVH adheres to a team approach and that training is a key component of the program. All members of the robotics team receive coordinated and intense training. The team recently attended the Fundamentals of Robotic Gynecologic Surgery Consensus Committee meeting. She reported that what is clear is that there is much discussion among the various surgical disciplines and that this group is working on coming to a consensus on generalized training and credentialing standards for all organizations to follow. LVH currently utilizes RAS in general surgery, urology, benign gynecology, gynecologic oncology, urogynecology, thoracic, colorectal, and surgical oncology procedures. Simulator training at LVH is part of the curriculum. The team also performs drills for all types of emergency situations, including converting to an open procedure. LVH utilized taped vignettes that show the correct and incorrect ways to handle emergency situations.

In regard to credentialing and privileging, every surgeon has to perform at least 25 cases—of which at least three to five are proctored by an experienced robotic privileged surgeon—before advancing to full privileges. Each physician has a scorecard that the quality/performance improvement department prepares. Indicators such as number of surgeries performed and complications are reviewed. In

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addition, 100% of benign gynecologic, gynecologic oncology, and urogynecologic robotic cases are reviewed by Miranda's quality/performance improvement staff. She stated that not all organizations are able to do this, but she feels that by doing this, her organization knows exactly what issues need to be changed in order to improve practice. Miranda noted that the more proficient a surgeon becomes, the better outcomes he or she sees.

Miranda stated that the team also does an additional time-out at four hours, as they know that a prolonged operative time along with the position of the patient can lead to complications. During this second time-out, the surgeon, anesthesiologist, and entire OR staff review patient safety issues, including patient positioning and the need for additional antibiotics.

LVH has updated its gynecology/urogynecology and gynecology oncology hysterectomy/other procedures consent forms to address potential risks specifically related to robotic surgery, such as nerve damage, lymphedema, facial swelling, and ear problems (LVH's gynecology oncology hysterectomy/other procedures form is available in the online version of this article). In addition, LVH educates the community on robotic surgery. Every year, the organization sponsors the Robotic Olympics, at which time it takes its robotic simulator out into the community and lets the general public get a chance to operate the robotic simulator.

CONCLUSION

RAS is rapidly being deployed in hospitals throughout the United States and abroad. The growth of robotics programs has outpaced the industry's ability to develop and implement clear, consistent standards for training and credentialing. Research is needed that evaluates outcomes, patient benefits, the ergonomics for the surgeon, and the costs related to RAS. The need for standardized training, consistent patient education, and outcome registries with accurate data that surgeons can use to compare RAS with other surgical modalities is necessary.

Until clear, consistent standards have been established by the professional organizations, the responsibility rests with the hospital to develop training programs that adequately prepare the physician and the entire surgical team to safely perform robotic procedures. A documented steep learning curve for surgeons as they master the use of robotic systems may challenge hospitals to ensure that training and credentialing are done in a fashion that is both medically sound and consistent. Staff may utilize various forms of training, which may include simulation training, so that they are prepared to handle any emergency situation that may occur during a robotic procedure. In addition, the hospital can ensure optimum outcomes for patients and that appropriate policies and procedures are in place for training, privileging and credentialing, proctoring, informed consent, and equipment maintenance.

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Balancing Family Bonding with Newborn Safety

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ABSTRACT

An accidental injury of a newborn in the care of family members soon after a hospital birth can cause emotional stress and guilt. The challenge for hospitals is to support bonding of newborns with their families by encouraging breastfeeding, cuddling, holding, and touching while ensuring newborn safety. Analysis of reports submitted to the Pennsylvania Patient Safety Authority from July 2004 to 2013 showed there were almost 300 newborn events reported to the Authority, including family members dropping their newborns after falling asleep, newborns slipping out of family members' arms to the floor, and newborns receiving bumps to their heads while being cared for by their families. More than 9% of the events contributed to serious patient harm. Literature shows that healthcare facilities can make a difference in newborn events by incorporating prevention methods such as family awareness, staff monitoring, and education for both staff and families. (Pa Patient Saf Advis 2014 Sep;11[3]:102-8.)

INTRODUCTION

Maternity units in healthcare facilities promote close interaction between families and their newborns to encourage the bonding process. However, newborns may be unintentionally injured while in the care of their families soon after birth. Exhausted family members may not contemplate the possibility of a fall, bump to the head, or other injury occurring while their newborn is placed in their care.

The challenge for maternity units is to promote a close interaction between families and their newborns while ensuring safety.[1] Reports submitted by Pennsylvania hospitals to the Pennsylvania Patient Safety Authority through its Pennsylvania Patient Safety Reporting System (PA-PSRS) over a nine-and-a-half year period were analyzed for events that occurred while newborns were in the care of their families.

Falls were the most common events affecting newborn safety. The study and reporting of newborn falls is a relatively new topic of concern; therefore, limited publications are available. Two published statistics of in-hospital newborn falls rates estimate nationally that 600 to 1,600 newborn falls occur annually.[1,2] Many of these falls can result in emotional stress to the family as well as harm to the newborn. Literature shows that healthcare facilities can make a difference in newborn events by incorporating prevention methods such as family awareness, staff monitoring, and education for both staff and families.

METHODS

Authority analysts identified 288 newborn events from PA-PSRS using terms associated with newborn safety (e.g., "fall," "drop," "bump," "asleep," "unresponsive"). The PA-PSRS database was queried for events reported from July 2004 through December 2013 involving newborns ≤30 days old. Analysis of events focused on newborns who were in the care of their families.

Analysis revealed that newborn events included falls, bumps to the head while being held or transferred, and events in which the newborn was found unresponsive. Newborn falls were further analyzed and categorized into six types based on the event description (see Figure 1). Rates and times of falls were also analyzed and compared with the rates and times noted in literature studies.

RESULTS

Types of Newborn Injuries

Of the reported occurrences, newborns fell in 272 events, the head was bumped or struck by an object in 14 events, and the newborn was found unresponsive in 2 events. Of these 288 events, 9.4% (n = 27) were reported as Serious Events resulting in harm to the newborn.

Fall event types. Of the 272 newborn fall events reported, 55.1% (n = 150) of the falls occurred after a family member fell asleep in a bed or chair. Examples are as follows:

> *Upon entering the mom's room, the nurse found a man crying and holding a crying infant. Mom stated she was sitting in the chair feeding the newborn when she fell asleep. The infant slid to the floor off of [the mom's] lap. Mom stated the newborn's head was hit on the right side.*
>
> *Infant was sleeping on father's chest in chair at side of bed; father fell asleep, and infant rolled to the floor facedown. Infant found crying in father's arms. [Infant] returned to nursery for assessment by pediatrician. No apparent injury.*

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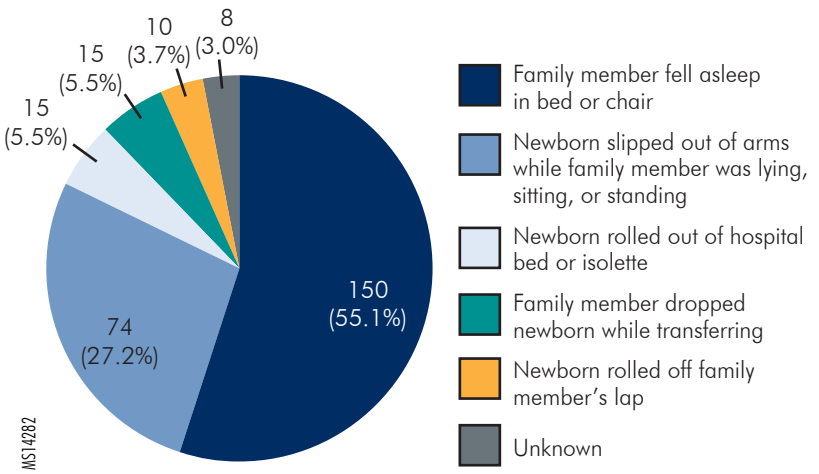
Figure 1. Reasons Newborns Fell While under Family Care, July 2004 through December 2013, as Reported to the Pennsylvania Patient Safety Authority (N = 272)



The following examples illustrate the second most common fall type, classified as "Newborn slipped out of arms while family member was lying, sitting, or standing":

> *Infant fell from mother's arms when mother bent over to pick something up from the floor.*
>
> *Mom brought baby to the nursery [in the morning]. Mom stated that she dropped the baby onto the floor while changing breastfeeding position. Mom was sitting in her bed. Baby fell and hit back of head.*

Other examples of newborn fall events are as follows:

– Newborn rolled off family member's lap:

> *Mother reports that she was holding infant in her lap and the baby slipped from her lap onto floor. Nurse assessed infant. Physician notified and assessed infant. No injury visible.*

– Newborn rolled out of hospital bed or isolette:

> *Mother rang call bell to report infant had rolled off bed onto floor. Mother fed infant and placed [newborn] on her bed instead of in crib. No injury noted.*

– Family member dropped newborn while transferring:

> *Mother rang call bell and stated that she wanted nursing to come check the baby, as she dropped the baby on the floor. Mother had been feeding baby while in bed. Mother stated she was trying to get out of bed and the baby fell from her left arm.*
>
> *Mom called via call light to nurse and asked nurse to come into her room. Nurse entered room with mom standing holding her baby next to chair, and [mom] stated to nurse, "I was getting up from the chair holding the baby, and I dropped [the newborn] on the floor".*

Of the 272 newborn falls, 8.5% (n = 23) were classified as Serious Events that resulted in harm to the newborn. Injuries reported to the Authority included various types of skull fractures (e.g., parietal bone fracture), subdural hematoma, and subarachnoid bleed. Examples of reported Serious Events are as follows:

> *Mother of [newborn] reported that her baby had fallen out of her arms and onto the floor during the night, stating that she was holding her baby and fell asleep. X-ray revealed a skull fracture.*
>
> *Infant fell from mother's arms, landing on right side of head and body. Infant taken to NICU [neonatal intensive care unit]. Infant sustained bone skull fracture and small subdural hematoma.*

Bumps to the newborn's head. In 14 reported events, the newborn's head was bumped while being held by a family member. Circumstances in which the newborn's head was bumped included the family member dropping or reaching for a telephone or cell phone; bumping the newborn's head on a door, bed, or other object; and bumping the newborn's head on an object overhead. Two events were reported as Serious Events. Examples of these kinds of events with and without harm, respectively, are as follows:

> *Mother was going to give the baby a bath in the bathroom. The telephone rang. Mother went to answer the telephone and bumped the parietal area of the baby's head on the door frame while carrying the baby to answer the telephone. CT [computed tomography] scan of the head revealed nondepressed fractures of the right and left parietal bones.*
>
> *Dad reported that he accidently bumped baby's head on plastic portion of bassinet. Baby cried briefly. No open areas or bumps noted.*

Newborn found unresponsive. Two Serious Events were reported in which the newborn was found unresponsive by the hospital staff and in which a fall or bump to the head did not occur.

In one event, the mother was breastfeeding while sitting in a chair. The nurse checked on the mother 10 minutes later and found the baby blue and unresponsive. The mother was asleep. The newborn's face was described as being completely covered by the mother's breast.

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The newborn was placed on a ventilator and transferred to another hospital.

In the second event, the newborn was brought to the mother for breastfeeding. The mother fell asleep with the newborn in the bed. Sometime later, the mother called the nurse, who found the baby blue and unresponsive. Resuscitation efforts were unsuccessful.

Pennsylvania Rate of Newborn Falls by Year

The average length of stay in days for women who have given birth in all United States hospitals is 2.7 days.[3] Of the 272 falls, 85.3% (n = 232) occurred when the newborn was younger than four days old. Of these 232 newborn falls, 42.7% (n = 99) occurred on day one and 32.8% (n = 76) occurred on day two. See the Table for the rates per year.

By taking the total number of falls reported through PA-PSRS that occurred while a newborn (≤30 days old) was in the care of family members and using a calculation of the total births reported to the Pennsylvania Health Care Cost Containment Council,* a rate of newborn falls was estimated per 10,000 live births. Rate calculations ranged from 0.4 to 3.8 newborn falls per 10,000 live births.

Table. Pennsylvania Rate of Falls While under Family Care for Newborns ≤30 Days Old

YEAR	NO. OF NEWBORN FALLS*	NO. OF LIVE BIRTHS IN PENNSYLVANIA†	RATE OF NEWBORN FALLS PER 10,000 LIVE BIRTHS
2005	6	140,817	0.4
2006	19	144,406	1.3
2007	28	144,717	1.9
2008	21	141,345	1.5
2009	42	140,609	3.0
2010	34	136,726	2.5
2011	26	136,646	1.9
2012	35	135,811	2.6
2013	51	133,653	3.8

* Newborn falls reported to the Pennsylvania Patient Safety Authority

† Data obtained from the Pennsylvania Health Care Cost Containment Council

Time of Newborn Falls

The time of newborn falls was analyzed from PA-PSRS event reports. Time is a required field in PA-PSRS; however, the time was reported as unknown in 15 of the 272 newborn fall events. Of the 257 time-reported events, analysis showed that 58.0% (n = 149) of newborn falls occurred between midnight and 7 a.m., with 19.5% (n = 29 of 149) of these falls occurring between 5 and 6 a.m. (see Figure 2).

DISCUSSION

Newborn Injuries

Improving the safety of patients is recognized as a priority in healthcare.[4] Although falls and other injuries are primary concerns for hospitalized adults, there is a lack of newborn studies in the literature addressing newborn falls and other injuries that occur while the newborn is in the care of their families.

Even determining the true incidence of newborn events is challenging since families may be reluctant to report a newborn injury because of guilt or shame.[5] Some events submitted to the Authority describe how a fall was reported by a roommate of the patient, a staff member, or the mother several hours after the fall occurred only after noticing a change in the newborn's behavior or physical condition. One case narrative in the literature quoted a mother as saying she was not going to tell anyone about the fall because she thought the newborn would be "just fine."[1]

Fall definition. In the second quarter of 2013, the American Nurses Association's National Database of Nursing Quality Indicators (NDNQI) launched a revised fall indicator as a clarification to its definition to include a baby or child drop. A 46% increase was observed in the PA-PSRS newborn falls data from 2013, after the new definition was published, compared with 2012.

The NDNQI definition includes the following: "A fall in which a newborn, infant, or child being held or carried by a healthcare professional, parent, family member, or visitor falls or slips from that person's hands, arms, lap, etc. This can occur when a child is being transferred from one person to another. The fall is counted regardless of the surface on which the child lands (e.g. bed, chair, or floor) and regardless of whether or not

* The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens regardless of ability to pay. PHC4 has provided data to this entity in an effort to further PHC4's mission of educating the public and containing health care costs in Pennsylvania.

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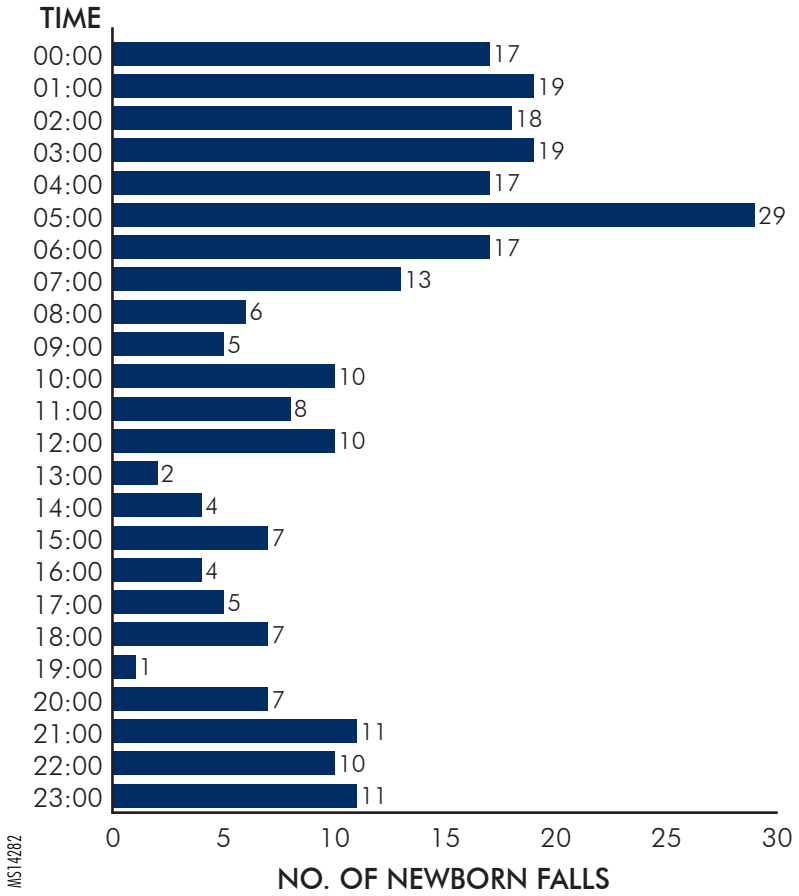
Figure 2. Time of Newborn Falls (Military Time), July 2004 through December 2013, as Reported to the Pennsylvania Patient Safety Authority (n = 257)



Note: **Times reported were rounded to the nearest hour. No times were reported in 15 of the 272 total newborn falls events.**

the fall results in an injury. Falls in which a child rolls off a bed, crib, chair, table, etc. count as falls but are not classified as drops."[6]

The Authority launched a new falls reporting program in 2012 to standardize essential program components, including standardization of the definition for falls to ensure that all participating hospitals identify, measure, and report falls in the same manner.[7]

Newborn fall studies. A literature search revealed studies in Utah and Oregon providing statistics about newborn falls in a hospital setting. Extrapolating data from the two studies suggests that the number of in-hospital newborn falls in the United States per year ranges from 600 to 1,600. This is at a rate of 1.6 to 4.14 newborn falls per 10,000 live births.[1,2]

Both the Utah and Oregon studies stated that the majority of newborn falls occurred in the early morning hours between 2 and 9 a.m.[1,2] Another study monitoring near misses stated that 78% of newborn falls might have occurred on the night shift between 11 p.m. and 7 a.m., when nurses found mothers either falling asleep or asleep while holding their newborns.[8]

Bumps and unresponsive newborn events. Events related to bumping the newborn's head or finding the newborn unresponsive were not addressed in the literature. Similar to newborn falls, exhaustion may cause inattentiveness to safety when transferring or holding a newborn.[1,2,9]

Both fatigue-related events reported to the Authority had similar maternal characteristics associated with newborn falls, including both mothers having fallen asleep while breastfeeding.

RISK REDUCTION STRATEGIES

A literature review revealed that healthcare facilities have begun to recognize newborn falls as a concern for potential harm and have implemented initiatives and adopted strategies to help reduce or prevent newborn falls.

Newborn Falls Initiative

One hospital in Alabama was able to bring their newborn fall rate to zero after adopting a comprehensive falls prevention program.[9] After seven newborn falls occurred in the postpartum unit of Huntsville Hospital for Women and Children, Huntsville, Alabama, from December 2011 to July 2012, a committee was formed to examine each fall event, review the literature on newborn falls, and talk to other hospitals about their experiences.

The hospital implemented a comprehensive falls prevention strategy in July 2012. The interventions addressed protocols for parent education, transport of newborns, placement of newborns for sleeping, review of maternal medications, assessment of environment and mother's level of consciousness, and prevention of falls during newborn feedings.

Staff attended a required class on newborn falls and started charting with two

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new tools to assess a newborn's risk of falling and perform a postfall debriefing. The staff educated parents on falls at admission, at the beginning of each shift, or as needed and instructed parents to call before and after infant feedings so that bedside rails could be raised and/or lowered as an added precaution. Newborn falls information was also added to the safety information sheet and was read to the parents and signed at admission. During the year following program implementation, no newborn falls occurred.

Rooming-In without Bed-Sharing

In an expansion of recommendations for a safe infant sleeping environment, the American Academy of Pediatrics stated that rooming-in (i.e., sharing the same room) without bed-sharing (i.e., sharing the same bed) is most likely to prevent suffocation, strangulation, and entrapments that might occur when the newborn is sleeping in an adult bed.[10] Other safe infant sleeping recommendations included placing the bassinet close to the parent's bed for feeding, comforting, and monitoring of their newborn. Newborns may be brought into the bed for feeding or comforting but should be returned to their own bassinet when the parent is ready to return to sleep. The American Academy of Pediatrics does not recommend any specific bed-sharing situation as safe.

Helsley et al. described a "no co-sleeping" policy that was incorporated into nursing practice to ensure that the newborn was moved back to the bassinet by the parents and staff when the mother was preparing for sleep, became drowsy, or had fallen asleep.[1] Hospitals may find it a challenge to balance the mother's need for rest while promoting bonding and breastfeeding success.[1,10]

Hourly rounding was incorporated into a hospital's falls prevention practice, with nurses intervening when finding a sleepy mother with a newborn in her arms. If this occurred, nurses were to thoughtfully remove the newborn from the mother's arms and place the newborn into the bassinet.[10] The author concluded that the effect of regular rounding on maternal rest and newborn falls prevention is an area requiring further research.

In order to provide an environment conducive for rooming-in, maternal characteristics have been studied. One study found several common maternal factors present when a newborn fall occurred. Another study gathered maternal information on 64 near misses when a newborn fall had the potential to occur (see "Maternal Characteristics").

Newborn Safety Information for Families

Fatigue from the labor and delivery process may lead to a newborn falling from the arms of a caregiver.[1] At this exciting time, families may not be aware that they may fall asleep while holding their newborn while lying in bed or sitting in a hospital chair.

An infant falls task force was formed from staff members of the Couplet Care Unit (postpartum unit) at Lancaster General Health's Women and Babies Hospital, Lancaster, Pennsylvania. After researching the literature, the task force developed an informational sheet that outlines security and safety risk factors for the parents and their newborn during the hospital stay.

"We have always had a safety form that we used for our parents upon delivery of their infant," said Alyssa Livengood Waite, MSN, MHA, RN, nurse manager, Couplet Care/Women's Inpatient Unit. "However, after researching this topic extensively, we felt compelled to change the format and add content regarding risk of falls and drops of newborns."

The staff reviews the informational sheet with the mother and other family members within the first two hours of transfer to the Couplet Care Unit, and then the mother signs the form. "At the time we ask for the signature, we have educated the mother and any family in the room with her as we provide our nursing care to the family," said Waite. "We find that

MATERNAL CHARACTERISTICS

According to the reviewed literature, common maternal characteristic assessed after a newborn fall included the following:

- High level of fatigue[1]
- Breastfeeding or breast/bottle feeding[2]
- Cesarean birth[2]
- Second or third postoperative night[1,2]
- Pain medication in the last two to four hours[1,2]
- Age 18 to 28 years[2]
- Prior near miss (e.g., nurses found mother either falling asleep or asleep while holding newborn)[1]
- History of narcotic substance use and/or methadone treatment program[1]

Notes

1. Slogar A, Gargiulo D, Bodrock J. Tracking 'near misses' to keep newborns safe from falls. *Nurs Womens Health* 2013 Jun-Jul;17(3):219-23.
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this education must continue to reoccur frequently throughout the family's stay."

The unit also posts an *ABC Blocks* visual reminder on each newborn's bassinet at eye level for mothers to see while they are in bed. It outlines safe sleeping habits for newborns, including sleeping alone. Other "safe sleep" education includes videos, pamphlets, and single sheets picturing correct newborn placement in the crib.

Hospital staff in seven Oregon hospitals, part of Providence Health and Services, also adopted an informational sheet titled *Newborn Safety Information for Parents* that outlines the factors that appear to increase the risk of newborn falls during the postpartum period.[1]

Challenges staff faced when using the informational sheet included receiving a parent's signature at an emotional time when not all the information may be processed or understood and when other admission paperwork is being obtained.[1] Other literature suggests providing parents with written material prenatally and scheduling meetings with childbirth educators, who can help disseminate information about newborn safety in a message that is consistent, clear, and standardized.[8] Lancaster General Health's information sheet and *ABC Blocks* and Providence Health and Services' *Newborn Safety Information for Parents* is available on the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

Safer Bed Design

Hospital beds utilized in the maternity suite were examined to determine if equipment could aid in newborn falls prevention. It was discovered that in other countries, such as the United Kingdom, bassinets are often mounted to the bed frame, keeping the newborns within reach of their mothers,[11] whereas in the United States, bassinets are designed to be separate and independent units.[1]

Research of bed manufacturers found no modifications of hospital beds or bedrails that addressed designs that would prevent newborn falls, head entrapment, or suffocation. Siderails on hospital beds may have openings large enough for a newborn to fall to the floor when the mother is lying flat or when the head of the bed is elevated by 45 degrees.[1]

Helsley et al. reported working with bed manufacturers to develop safer mother/baby beds. A picture that demonstrates how a newborn can fall out of a hospital bed is available on the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

Postfall Huddle

Evaluation by staff of why a newborn fall occurred is key to examining the incident and capturing ways to prevent future falls. This has been essential in evaluating adult falls. Providence Health and Services uses an online version of the Newborn Fall Unusual Occurrence Report/Debrief Form Post Event to capture additional details for continued evaluation of factors involved in the event.[1] This form is available on the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

CONCLUSION

The birth of a baby can be one of the most joyous experiences for families. Dropping a baby after falling asleep or caring for an infant when an accidental injury occurs can be an emotional and life-changing experience for families, especially if serious injury occurs. Literature shows that healthcare facilities can make a difference in newborn events by incorporating prevention methods such as family awareness, staff monitoring, and education for both staff and families.

NOTES

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2. Monson SA, Henry E, Lambert DK, et al. In-hospital falls of newborn infants: data from a multihospital health care system. *Pediatrics* 2008 Aug;122(2):e277-80.
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LEARNING OBJECTIVES

- Identify the types of events reported to the Pennsylvania Patient Safety Authority in which newborns were injured while in the care of their families.
- Recognize the national rate of newborn falls.
- Recognize the types of newborn fall events.
- Recall the most frequent time of day a newborn fall event occurs.
- Identify common maternal characteristics assessed after a newborn fall.

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. According to events reported to the Authority, which of the following types of events occurred while newborns were in the care of their families?
   a. Falls, bumps to the head, and unresponsiveness
   b. Falls, wrong treatment, and bumps to the head
   c. Wrong treatment, bumps to the head, and wrong expressed breast milk
   d. Unresponsiveness, wrong medication, and no newborn identification band
   e. Falls, no newborn identification band, and unresponsiveness
2. What is the estimated national rate of newborn falls per 10,000 live births?
   a. 2.5 to 6.54
   b. 1.5 to 7.03
   c. 1.6 to 4.14
   d. 3.2 to 6.53
   e. 1.2 to 3.24
3. Which of the statements below describes a situation that did *not* contribute to a newborn fall reported to the Authority?
   a. Falls occurred due to fatigue after a family member fell asleep in a bed or chair holding the newborn.
   b. Family members dropped newborns while transferring.
   c. Newborns slipped out the arms of a family member who was lying, sitting, or standing.
   d. Family members dropped newborns while walking in the hospital hallway.
   e. Newborns rolled off of a family member's lap.
4. Which time was most frequently reported to the Authority as the time of newborn falls?
   a. 10:00
   b. 14:00
   c. 19:00
   d. 05:00
   e. 01:00
5. Which of the following is *not* a maternal characteristic that may contribute to a newborn fall?
   a. High level of fatigue
   b. Age 18 to 28
   c. Pain medication in the last two to four hours
   d. Natural childbirth
   e. Breastfeeding or breast/bottle feeding

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Tracking Ambulatory Surgical Facility Cancellations and Transfers: Lessons Learned from an 18-Month Collaboration

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ABSTRACT

In 2012, 11 ambulatory surgical facilities (ASFs) in the northeast region of Pennsylvania worked in collaboration with the Pennsylvania Patient Safety Authority to address the nurse-driven preoperative screening and assessment process in an effort to reduce day-of-surgery (DOS) cancellations and transfers. The ASFs tracked the time when the nurse-driven preoperative screening and assessment process was completed (e.g., 24 hours prior to the DOS). A statistically significant difference was noted between no-show DOS cancellation rates in patients with and patients without a preoperative screening and assessment. Reasons for DOS cancellations and transfers and types of surgeries or procedures were also tracked. To continue the identification of DOS cancellations and transfers, the ASF Cancellation and Transfer Tracking tool was developed to identify trends regarding when a nurse-driven preoperative screening and assessment process has been completed, reasons for DOS cancellations or transfers, types of surgeries or procedures in patients who cancelled or were transferred, and patient characteristics associated with patient transfers. Identifying reasons for patient cancellations and transfers to an acute care hospital provides context about patient circumstances or situations that can assist healthcare staff in developing appropriate solutions to reduce their occurrence and improve patient care. (Pa Patient Saf Advis 2014 Sep;11[3]:109-14.)

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

INTRODUCTION

Cancellations and transfers are ongoing problems that ambulatory surgical facilities (ASFs) have identified, and when examined, these problems have revealed patient safety concerns.[1] Starting in 2012, the Pennsylvania Patient Safety Authority worked in collaboration with 11 ASFs in the northeast region of Pennsylvania to standardize the nurse-driven preoperative screening and assessment process in an effort to reduce day-of-surgery (DOS) cancellations and transfers. DOS cancellations represent opportunities to identify and address patient safety concerns and improve patient care by identifying medical conditions or situations (e.g., patients failing to meet screening criteria, patients not following preoperative instructions) that place patients at risk for harm if they have surgery or a procedure.

When DOS cancellations occur, communication is necessary between the surgeon and surgical team, often while in the midst of other procedures, to rearrange the surgical schedule for the rest of the day.[2] This type of disruption, referred to as a case-irrelevant communication, has the potential to distract the team and lead to adverse events.[2,3] Reducing DOS cancellations reduces distractions and preserves schedule continuity and staff attention toward patients currently receiving care, thereby improving patient safety.

During the 18-month ASF Preoperative Screening Collaboration, the implementation of three interventions resulted in reductions in DOS cancellations and transfers. The three interventions involved use of a standardized preoperative screening tool to standardize the nurse-driven preoperative screening and assessment process, institution of health literacy strategies into written materials and oral conversations with patients, and completion of an additional preoperative phone call to supplement the initial preoperative screening contact. The majority of the nurse-driven preoperative screenings and assessments were conducted over the phone, and the remainder in person.

Analysis of collaboration data identified a statistically significant difference between DOS no-show cancellation rates in patients who had and patients who did not have a nurse-driven preoperative screening and assessment. The initiation of health literacy strategies and completion of an additional phone call also led to reductions in DOS cancellations.[1] An important lesson learned from this collaboration was that tracking DOS cancellations and transfers helps identify opportunities to improve an ASF nurse-driven preoperative screening and assessment process. The introduction of a new ASF tracking tool that monitors the nurse-driven preoperative screening processes, DOS cancellation and transfer event information and rates, and DOS cancellation costs in real-time provides ASFs a timely way to identify trends. Collecting and trending detailed information about DOS cancellations and transfers provides opportunities to learn about the circumstances surrounding these events and to gain new insights to increase the likelihood of averting similar events in the future.

METHODS

Tracking Tool

The Authority developed the ASF Cancellation and Transfer Tracking tool to assist ASFs with tracking and trending DOS cancellation and transfer rates, as well as event information and costs associated with DOS cancellations. The tracking tool provides structured data entry that links to automated, real-time reports along with free-text fields for individualized notes. This tool collects data for a 12-month period that is determined by the ASF. When developing the tracking tool, consideration was given to the facilities' scopes of care: general surgical or specialty services. Rather than

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developing one tracking tool with a broad range of surgical and procedural choices that might not be applicable to a specialty ASF, three separate tracking tools were developed: one for general surgical ASFs, one for endoscopic ASFs, and one for ophthalmologic ASFs.

DOS Cancellations

A DOS cancellation is defined as a cancellation of a scheduled surgery or procedure for any reason that occurred after 12:01 a.m. on the DOS, whether the cancellation occurred prior to admission, after admission, or after anesthesia. Cancellation rates for three time periods were tracked during the collaboration and are tracked in the ASF tracking tool using the same time frames: DOS cancellations, 24-hour cancellations,* and 48-hour cancellations.† Cancellation rates in the tracking tool are calculated and tracked monthly and are reported as the number of cancellations per 1,000 completed procedures.

Two pieces of data are required for the tool to calculate a cancellation rate: (1) the number of cancellations for each time period (i.e., DOS, 24 hours, or 48 hours) in which the cancellation occurred during a given month and (2) the number of completed procedures for the same given month. The ASF tracking tool calculates cancellation rates in real time and presents these rates as a trend line.

DOS cancellations are identified and grouped according to the underlying reason prompting the cancellation. There were 13 reasons for DOS cancellations identified during the collaboration (see Table 1). Not all 13 cancellation reasons were amenable to the nurse-driven preoperative screening and assessment processes. For example, surgeon illness, severe weather conditions, and family emergencies are situations that are unpredictable and at times arise without ample notice to reschedule patients. Completing a nurse-driven preoperative screening and assessment had limited impact in reducing DOS cancellations due to these reasons.

Cancellation reasons deemed amenable to the nurse-driven preoperative screening and assessment processes are included in the tracking tool. The seven DOS cancellation reasons selected for inclusion in the tracking tool are based on whether the nursing-based interventions implemented in the collaboration had the potential to influence reductions in DOS cancellations. See Table 2 for descriptions of the seven reasons for cancellation included in the tracking tool.

The tracking tool also includes data fields for the time when the preoperative screening and assessment is completed and the type of surgery or procedure that is cancelled. It is important to track the time that the preoperative screening process is completed, especially given the finding of a statistically significant difference in no-show cancellations noted for patients with versus patients without a preoperative screening and assessment.[1] There are six different choices to indicate the time when a nurse-driven preoperative screening and assessment is completed:

1. DOS
2. 24 hours prior to the DOS
3. 48 hours prior to the DOS
4. Greater than 48 hours prior to the DOS
5. Screening not completed
6. ASF unable to contact the patient—consequently, no nurse-driven preoperative screening and assessment was completed

Tracking the types of surgeries and procedures cancelled during the collaboration

Table 1. Reasons for Ambulatory Surgical Facility Day-of-Surgery Cancellations from December 2012 through June 2013 (N= 824), as Reported by Collaboration Participants

REASON FOR CANCELLATION	NO. OF CANCELLATIONS	% OF CANCELLATIONS
Change in medical status*	237	28.8
No-shows	156	18.9
Preoperative instructions not followed	103	12.5
Procedure not rescheduled	77	9.3
Rescheduled procedure	52	6.3
Protocol issues	51	6.2
Weather related*	43	5.2
Financial issues	30	3.6
Transportation	20	2.4
Family issues/emergencies*	19	2.3
Surgeon illness*	19	2.3
Work related	4	0.5
Language barrier	2	0.2

* These cancellation reasons collected during the collaboration are rarely amenable to a nurse-driven preoperative screening and assessment.

* A 24-hour cancellation is defined as a cancellation that occurred 24 hours prior to 12:01 a.m. on the DOS. The collaboration 24-hour cancellation rate was 27.0 cancellations per 1,000 completed procedures.

† A 48-hour cancellation is defined as a cancellation that occurred 48 hours prior to 12:01 a.m. on the DOS. The collaboration 48-hour cancellation rate was 11.5 cancellations per 1,000 complete procedures.

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was important to the ASFs to determine if patterns existed in the cancellations. For example, diagnostic colonoscopies were the most frequently cancelled type of endoscopic procedure identified during the collaboration. The list of surgeries and procedures generated for the tracking tool is based on surgeries and procedures cancelled during the collaboration (e.g., cataracts surgery, plastic surgery, pain management).

Table 2. Ambulatory Surgical Facility Tracking Tool Reasons for Cancellations and Descriptions*

REASON	DESCRIPTIONS†
Protocol issues (i.e., failure to adhere to facility protocol)	Patient did not meet screening criteria Medical issues missed during preoperative screening Miscommunication and lack of communication between providers Equipment issues (e.g., implant not available, power outages) Incomplete or missing history and physical Scheduling delay
Preoperative instructions not followed	Nothing-by-mouth or dietary requirements not adhered to Prep issues (e.g., sick from prep, did not complete prep) Medication instructions not followed Misunderstanding day or time of procedure
Procedure not rescheduled	No explanation Patient changed his or her mind Mental health or anxiety Scheduling conflict Patient overslept
Rescheduled procedure	No explanation Scheduling conflict Communication issues with patient
Financial	Insurance and payment-related issues
Transportation	No ride to or from the ambulatory surgical facility Car troubles the day of surgery (e.g., stuck in traffic, dead battery)‡
No-shows§	No explanation Patient forgot Miscommunication and lack of communication with patient Patient wanted second opinion

* Cancellation reasons not included in the tracking tool are changes in medical status (i.e., patients with new medical conditions, exacerbation of existing conditions, colds, infections, hospitalization, death, or condition improved and no longer required treatment), surgeon illness, weather related, work related, and language barrier.

† The cancellation descriptions are based on interpretations from the ASF Preoperative Screening Collaboration.

‡ These cancellation reasons may not be affected by the preoperative screening process.

§ No-show explanations best reflected by another defined category (e.g., financial-related issues, protocol issues) are assigned to those categories to provide a clearer understanding for the reason for no-show day-of-surgery cancellations.

Transfers

A transfer is defined as an ASF admission requiring an unexpected hospital transfer or admission directly following discharge from the ASF. ASF transfers are a patient safety measure that the Centers for Medicare and Medicaid Services will use for public reporting and payment determination for 2014.[4,5] Transfer rates are calculated in the same manner as cancellation rates: monthly and reported as the number of transfers per 1,000 admissions. Two pieces of data are required, the number of transfers per month and the number of admissions per month. The ASF tracking tool calculates the transfer rate in real time and presents these rates as a trend line.

Patient transfer event information collected in this tracking tool focuses on a broader scope of data than the DOS cancellation event information. The basic data requirements for transfer event information are the same as the DOS cancellation event data collection: the event date, the time the preoperative screening and assessment is completed, and the surgery or procedure the transferred patient is scheduled to undergo or has undergone. Additional transfer data requirements comprise three patient characteristics: (1) the patient's age, physical status according to the American Society of Anesthesiologists' classification system,[6] and body mass index;[7] (2) time of the transfer (preoperative and postoperative); and (3) reasons for the transfer (selected from a 13-item list).

Cost Calculator

The ASFs participating in the collaboration requested assistance with building a business case to examine the impact of cancellations on an ASF by identifying the scope of the problem and the associated financial costs. To address this request, a

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cancellation cost calculator was developed during the collaboration and is included in the ASF tracking tool.

RESULTS

The tracking tool consists of the cost calculator, cancellation and transfer rate reports, and DOS cancellation and transfer event information reports. The *ASF Cancellation and Transfer Tracking Tool Reference User Guide* explains the different facets of the tool.

The DOS cancellation rates calculated by the tracking tool do not provide benchmarking data. For comparison purposes, the collaboration postintervention DOS cancellation rate was 26.8 cancellations per 1,000 completed procedures. During the collaboration, two reasons for DOS cancellations, changes in the patient's medical condition and no-show cancellations, accounted for almost half (47.7%, n = 393 of 824) of the DOS cancellations. Even though both reasons for DOS cancellations account for such a large portion of the cancellations, no-show cancellations are the only reason included in the tracking tool, given its amenability to the nurse-driven preoperative screening processes.[1]

The transfer rates calculated by the tracking tool do not provide benchmarking data. For purposes of comparison, the collaboration postintervention transfer rate was 1.03 transfers per 1,000 admissions. Table 3 lists the reasons for transferring patients to an acute care hospital, identified by the patient's operative status (i.e., preoperative and postoperative).

There is no benchmarking data for the cancellation cost calculator. Each ASF will determine the lost reimbursements and potential gains according to its own experience.

Table 3. Ambulatory Surgical Facility (ASF) Collaboration Reasons for Transfers, as Reported by Participating ASFs from July 1, 2012, through June 30, 2013

PREOPERATIVE TRANSFERS	POSTOPERATIVE TRANSFERS
Cardiac arrhythmias*,†	Cardiac arrhythmias*,†
Hypertension*,†	Anesthesia complications, aspirations, or respiratory monitoring*,†
Automatic implantable cardioverter defibrillator (AICD) dead battery*	Postoperative diagnostic findings*,†
Syncope†	Nausea or vomiting*
	Bleeding or hemorrhage*
	AICD battery not detecting*
	Longer monitoring of the patient†
	Pneumothorax†
	Arm weakness†
	Perforation†
	Pain†
	Urinary retention†
	Abscess†
	Seizures†

* Transfers that occurred during the preintervention time period from July 2012 through November 2012
† Transfers that occurred during the postintervention time period from December 2012 through June 2013

DISCUSSION

Tracking Tool

During the collaboration, the events the ASFs experienced were shared with them via monthly reports that included aggregated (deidentified) and individual facility data. The reports synthesized and communicated trends about cancellation rates, transfer rates, and preoperative screening processes and outcomes data. Tracking and evaluating DOS cancellations and transfers during the collaboration was instrumental in helping ASFs identify areas of a nurse-driven preoperative screening and assessment process requiring improvement.[1]

As the ASFs implemented the interventions for the collaboration, they had opportunities to evaluate changes in their processes and any changes in the number of DOS cancellations and transfers. For example, some of the ASFs were able to implement a second preoperative phone call that provided additional opportunities for the nursing staff to explore with their patients how well the patients understood their upcoming surgery or procedure and their preoperative instructions.[1] As noted in the March 2014 *Pennsylvania Patient Safety Advisory* article, many other lessons were learned as the three nursing-based interventions were implemented.[1] The ASF tracking tool provides opportunities for facilities to initiate or continue tracking DOS cancellations and transfers monthly and identify patterns and solutions to reduce these events.

DOS Cancellations

Interpreting the data and identifying the different motivations behind patient cancellations helped to clearly elucidate the underlying reasons for these events. DOS cancellation reasons included in the tracking tool were selected on the basis of how amenable they were to a nurse-driven preoperative screening and assessment process. As noted earlier, cancellations due to a change in the patient's medical status, the most frequently reported reason for a DOS cancellation, were rarely amenable to a nurse-driven preoperative screening and assessment process. This reason for cancellation comprised patients who presented to the ASF on the DOS with new undiagnosed medical conditions, exacerbation of existing medical

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conditions, cold symptoms, or infections; patients who were hospitalized or died prior to the DOS; and patients who had improvements in their medical condition that no longer required treatment.

A nurse-driven preoperative screening and assessment can have an indirect influence rather than a direct influence on this reason for cancellation because surgeons and anesthesiologists evaluate a patient's physical condition and determine eligibility for surgery or a procedure on the DOS. One way nursing staff can influence reductions in this reason for cancellation is to stress to patients the importance of calling to cancel as soon as they feel ill or notice a change in their medical condition (e.g., hyperglycemia). However, in many cases experienced during the collaboration, patients who felt ill or noticed changes in their health tended to identify them on the morning of their surgery or procedure.

There were other instances when issues occurred such as the history and physical forms being incomplete or not available at the time of preoperative screening. These types of problems (i.e., protocol issues) are much more amenable to a nurse-driven preoperative screening and assessment process. As discoveries about the underlying reasons for DOS cancellations became salient, approaches to address these issues emerged.

Nine of the 13 reasons for cancelling (i.e., transportation issues, protocol issues, no-shows, financial issues, preoperative instructions not followed, procedures not rescheduled, rescheduled procedures, work issues, and language barriers) were judged to be amenable to the interventions introduced during this collaboration. Two of the reasons, work issues and language barriers, were not included in the tracking tool, since these were rare events. Decreases in DOS cancellation rates were observed between the preintervention and postintervention period in five of these nine cancellation groups (i.e., transportation issues, protocol issues, no-shows, work issues, and language barriers), while increases in DOS cancellation rates were observed in the remaining four cancellation groups (i.e., preoperative instructions not followed, financial issues, procedures not rescheduled, and rescheduled procedures).

Pattern identification can extend beyond the list of surgeries or procedures. For example, if the majority of patients scheduled for a diagnostic colonoscopy cancelled the procedure due to getting sick from using a particular prep, the staff might alert the physician about the trend and have the physician or physician practice consider prescribing a different prep.

Transfers

ASF transfers were a rare event during the collaboration. For example, two of the ASFs had no transfers during both the preintervention and postintervention phases of the collaboration. Another ASF had two transfers during the preintervention phase and no transfers during the postintervention phase. When transfers did occur, differences between the reasons for preoperative and postoperative transfers became apparent early in the collaboration. The majority of preoperative transfers in the collaboration resulted from newly discovered medical conditions not detected during the patient's preoperative physical exam (e.g., atrial fibrillation on an electrocardiogram) or exacerbation of a preexisting medical condition (e.g., hypertension).[1]

Eighty percent of the patients transferred due to a cardiac arrhythmia preoperatively in the postintervention time period were patients 75 to 85 years old; the remaining 20% of patients were 65 to 75 years old. Dehydration and being ill on the DOS were additional conditions that may have supported the need for a patient transfer.[1] Cardiac arrhythmia was the only medical condition that occurred in both preoperative and postoperative transfers during both preintervention and postintervention time periods. While preoperative screening and assessment processes might not identify these types of problems prior to admission, these transfers represent safe patient care. The majority of transfers reflected issues arising postoperatively.

Cost Calculator

While there are no specific examples of ASF use of the cost calculator during the collaboration, it has great potential for ASFs to use as a tool to develop a business case for reducing cancellations. The tool calculates DOS cancellation rates and lost reimbursements for the facility and physicians and emphasizes opportunities to improve reimbursements associated with reductions in DOS cancellations. The cost calculator can be used to identify lost reimbursements for surgical or procedural DOS cancellations in the aggregate or in isolation.

The cost calculator requires the same data to calculate a cancellation rate and facility and physician reimbursement data. For example, if an ASF is interested in knowing the lost reimbursements for a specific type of DOS cancellation, such as diagnostic colonoscopies, the ASF would identify the total number of diagnostic colonoscopy cancellations and the expected facility and physician reimbursements for this procedure. The calculator will then calculate the cancellation rate and the total reimbursements lost for the facility and physician for cancelled diagnostic colonoscopies. It will also identify the increased reimbursements associated with reductions in diagnostic colonoscopy cancellations.

Limitations

The tracking tool collects data on 7 reasons for DOS cancellations and 13 reasons for transfers. Exclusions of cancellation reasons in the tracking tool were based on how amenable a cancellation reason was to a nurse-driven preoperative screening and assessment, use of health literacy strategies, or completion of an additional preoperative phone call.

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ASF CANCELLATION AND TRANSFER TRACKING TOOLS

The Pennsylvania Patient Safety Authority developed three ambulatory surgical facility (ASF) cancellation and transfer tracking tools, available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/asf/Pages/home.aspx, designed for three different types of ASFs:

1. The general surgery tracking tool
2. The ophthalmologic tracking tool
3. The endoscopic tracking tool

Additionally, the tool does not include how a nurse-driven preoperative screening and assessment is conducted, although they are typically conducted by phone. Phone interviews lack a visual component. Nonverbal cues from patients during the preoperative screening process afford the nurse insights to identifying patient behaviors indicative of misinterpretation or miscomprehension of preoperative instructions. The implementation of a standardized checklist that included suggested questions to ask patients, along with instituting health literacy strategies, helped to overcome some of the challenges when conducting a nurse-driven preoperative screening over the phone.

The lack of benchmarking data poses another set of challenges for ASFs. Using the cancellation and transfer rates from the collaboration provides an initial benchmark. Future transfer rate benchmarks can be obtained quarterly from the national Ambulatory Surgery Center Quality Collaboration.[8]

CONCLUSION

Reducing cancellations and transfers starts with collecting and evaluating data pertaining to the circumstances surrounding these events. Tracking components of patient cancellations and transfers in real time provides evidence of problems encountered, such as whether a nurse-driven preoperative screening and assessment process is executed.[1] Synthesizing data collected in the tracking tool provides opportunities to identify more than just problems or issues with cancellations or transfers. There are opportunities to use the data to identify and incorporate enhancements to nurse-driven preoperative screening and assessment processes, including the use of health literacy strategies and additional preoperative phone calls. As enhancements are implemented, continual tracking of these events offers facilities ongoing feedback to evaluate the value of changes made to the nurse-driven preoperative screening and assessment process. The Authority's ASF Cancellation and Transfer Tracking tool offers ASFs the opportunity to track cancellation and transfer rates, collect event information, and evaluate the costs of cancellations.

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Patient-to-Patient Aggression in the Inpatient Behavioral Health Setting

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ABSTRACT

Patient aggression in the inpatient behavioral health setting is a patient safety concern to patients and clinicians. Inpatient patient-to-patient aggression (47.2%, n = 538 of 1,139) was the behavioral health aggression–related event most frequently reported to the Pennsylvania Patient Safety Authority through the Pennsylvania Patient Safety Reporting System between January 1, 2012, and August 31, 2013. Circumstances in the inpatient setting can result in psychiatric patients responding in an aggressive manner. Use of aggression assessment scales forms the basis of a multidimensional assessment approach that incorporates patient-centered, staffing-centered, and environmental-centered considerations and is a strategy that can be used to identify factors placing patients at risk for aggressive behavior. (Pa Patient Saf Advis 2014 Sep;11[3]:115-23.)

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INTRODUCTION

Aggression and violence occur in the inpatient behavioral healthcare setting. Estimates of the percentage of patients who are aggressive during their stay on acute psychiatric wards vary widely, with figures between 8% and 44%.[1-3] Evidence indicates that between 10% and 30% of hospitalized psychiatric patients have engaged in violence prior to admission.[4,5] Aggression and violence among psychiatric patients affect the other psychiatric patients, behavioral health clinicians, and staff.[6,7] Research has focused on ways to predict and manage patients' violent behavior.[6,7]

Age plays a role in patient aggression. Behavioral symptoms such as aggression and agitation frequently coincide with psychiatric disorders in older adults.[8] Geriatric patients are often admitted with a diagnosis of dementia, and physical aggression is among the most dangerous and distressing behaviors in patients with dementia and occurs in 52% of patients with this diagnosis,[9] whereas aggressive behavior in child and adolescent psychiatric patients occurs in 29% to 40% of patients during hospitalization.[10] Historically, assessments have been patient-centric and have inadvertently left out what is now understood to be meaningful and contributory information.[11,12]

While the literature is replete with studies focusing on the individual attributes of the patient, Cutcliffe and Riahi[11,12] and Duxbury[13] applied a multidimensional approach (i.e., focusing on the environment, clinician, client, and behavioral healthcare system) to address inpatient behavioral health aggression and violence. Using a multidimensional approach when evaluating an aggressive encounter provides information beyond patient characteristics that recognizes the complexity of psychiatric patient interactions.[11-13] For example, patient characteristics and perceptions are one facet of a social interaction, yet staff characteristics and interactions also influence the psychiatric milieu.[13] In one study, patient perceptions indicated that the demeanor of staff and unit policies (e.g., patients feeling controlled by staff) were factors in the patients' aggressive responses, while nursing staff pointed to patient characteristics as the precipitating factors.[13] Additionally, an assessment strategy using a multidimensional approach addressing patient-centered considerations (including the use of aggression assessment scales), staffing-centered considerations, and environmental-centered considerations provides a proactive framework for the practitioner to identify factors that can place patients at risk for and increase the likelihood of aggressive behavior.

Researchers acknowledge that difficulties still exist in defining aggression and violence.[14] For the purpose of this article, definitions of agitation, aggression, and violence are provided to establish clarity for the reader; see "Aggression-Related Definitions."

Pennsylvania Patient Safety Authority analysts examined events of aggression in behavioral health inpatient settings reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) over a 20-month period. Analysts identified patient-to-patient aggression as the predominant type (47.2%, n = 538 of 1,139 events) of aggression reported during the time period.

METHODS

Authority analysts identified aggression-related reports submitted to the Authority. The analysts then queried the PA-PSRS database using the keyword search terms "abusive," "aggressive," "agitation," "altercation," "attack," "belittle," "belligerent," "combative," "control," "hit," "ingest," "punch," "scratch," and "swallow." Results were limited to events reported by behavioral health hospitals and acute care hospital inpatient behavioral health units from January 1, 2012, through August 31, 2013.

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The analysts selected this time period to ensure an adequate sample size, given that aggression events are not an established event type within PA-PSRS.

This query identified 1,139 events. Analysts categorized the events by patient age: pediatric (i.e., age 18 or younger), adult (i.e., age 19 to 64), and geriatric (i.e., age 65 or older). Additionally, the events were categorized by type of aggression: patient to patient, patient to staff, or self-inflicted (e.g., suicide). The emphasis of the analysis was to identify patterns and trends found in the narratives to identify improvement strategies rather than to capture and analyze *all* of the aggression-related reports submitted. As noted about similar analysis in the past, "this approach has allowed the Authority to develop meaningful strategies without worrying about whether the number of events reported or the number of situations at risk for such an event is accurate."[15]

AGGRESSION ANALYSIS

Categories of Aggression

The Figure shows the percentages of the three types of behavioral health aggression events by age group. For the geriatric population, patient-to-staff aggression was the most common type of aggression reported, followed closely by patient-to-patient aggression. For the adult population, self-inflicted aggression was the most commonly reported type of aggression, followed closely by patient-to-patient aggression. For the pediatric population, patient-to-patient aggression was the most common type reported.

It was noted that the difference between the percentages of patient-to-patient aggression and the two other forms of aggression (i.e., patient-to-staff and self-inflicted aggression) in the pediatric population was large. While the difference between the percentages of patient-to-patient aggression and patient-to-staff aggression in the geriatric population was narrow, the differences between those percentages and self-inflicted aggression were very large (36.0% and 37.5%, respectively).

Patient-to-Patient Aggression

In the patient-to-patient aggression event reports, the percentages of bodily injuries, interventions implemented to keep patients safe, and the patient's role in the aggressive encounter (i.e., the aggressor or victim) had some similarities across the age groups (see Table 1).

For the majority of events reported, the reporter did not state that harm occurred or provide a description of the harm in the narrative; however, when harm was indicated, injury to the head or face occurred most frequently in all three age groups: pediatric (12.6%, n = 34 of 270), adult (13.0%, n = 31 of 238), and geriatric (33.3%, n = 10 of 30). Interventions used in managing patient aggression included seclusion, restraint use, and medication use. Seclusion was the least frequently reported intervention implemented in all age groups: pediatric (2.2%, n = 6 of 270), adult (1.7%, n = 4 of 238), and geriatric (0.0%, n = 0 of 30).

Identification of the patient as the aggressor rather than the victim had a similar pattern (i.e., nearly twice as many event reports) in the pediatric (20.0% aggressor, 13.0% victim) and adult populations (29.4% aggressor, 18.9% victim). In the geriatric population, the distribution between identification of the aggressor and victim in the event narratives was inverse to the pediatric and adult populations (36.7% aggressor, 60.0% victim). There were several events in which the aggressor and victim from the same event were both reported through PA-PSRS as separate events.

ASSESSMENT OF PATIENT-TO-PATIENT AGGRESSION

Several event reports identified circumstances external to the patient that contributed to the aggression event. Following are some examples:

> *A patient became agitated at another patient. This patient placed a hand on the other patient's hand to stop [her from] clapping her hands. When the patient did not stop, she became increasingly agitated, and the other patient [cursed] and hit the patient in the face.*

> *Patient reports she was in the hallway obtaining towels for a shower and a male patient grabbed her buttocks.*

AGGRESSION-RELATED DEFINITIONS

aggression: "A forceful behavior, action, or attitude that is expressed physically, verbally, or symbolically. It may arise from innate drives or occur as a defense mechanism, often resulting from a threatened ego. It is manifested by either constructive or destructive acts directed toward oneself or against others."

agitation: "A state of chronic restlessness and increased psychomotor activity generally observed as an expression of emotional tension and characterized by purposeless, restless activity. Pacing, talking, crying, and laughing sometimes are characteristic and may serve to release nervous tension associated with anxiety, fear, or other mental stress."

violence: "Great force, either physical or emotional, usually exerted to damage or otherwise abuse something or someone."

Source: Mosby's Medical Dictionary. 8th ed. Philadelphia: Elsevier; 2009: s.vv. "aggression," "agitation," "violence."

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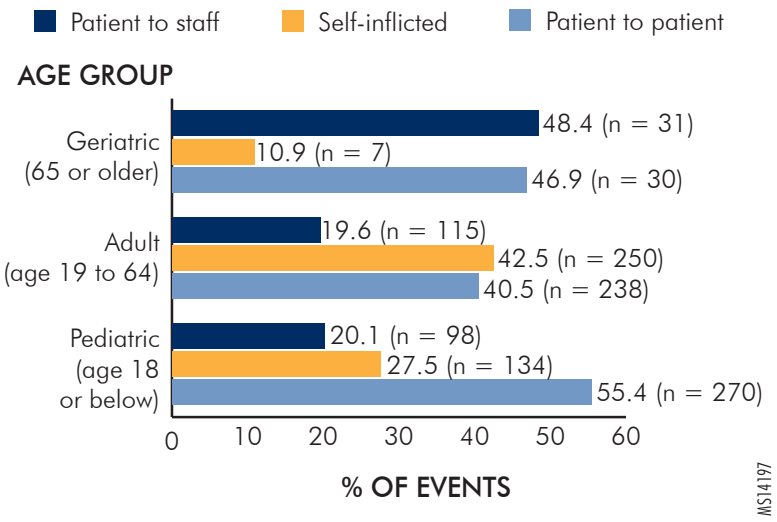
Figure. Aggression Events Reported to the Pennsylvania Patient Safety Authority from January 1, 2012, through August 31, 2013, by Age Group (N = 1,139)



Note: **Events reported for each aggression type are not mutually exclusive; therefore, the sum of the percentages for each cohort may exceed 100. There were 487 pediatric events, 588 adult events, and 64 geriatric events reported.**

> *Patient states she would have hit the other patient had he been a woman.*
>
> *Agitated patient punched [another] patient in the face several times. [The patient] was angry [after] asking for his glasses case for an hour; nothing pleased him. Several attempts were made to calm the patient, [who] started screaming, [which] escalated, and [the patient] just ran over to another patient in the hall and started punching [the other patient].*

Studies have demonstrated a proactive approach to occurrences of patient aggression and information about whether aggression can be anticipated and/or avoided. Interviews were held with Pennsylvania healthcare representatives from two different facilities, a facility leader and a manager, to identify whether proactive approaches are in use. The interviews provided a perspective on the topic of patient aggression from the viewpoint of those who are involved daily with patients and staff. While there is no one approach identified to proactively predict an aggressive situation, a multidimensional assessment strategy has shown to be successful in both the literature and in practice.

Duxbury described three models of variables and factors that contribute to aggression:[13]

1. The *internal* model is patient-focused and includes variables such as diagnosis, history of aggression or violence, and other risk factors such as substance abuse.
2. The *external* model focuses on environmental factors such as size and layout of the unit, locked versus unlocked unit, staffing considerations, and staff-patient interaction.
3. The *situational* model focuses on multiple variations in interactions between both internal model and external model factors.

Cutcliffe and Riahi describe phenomena that point to a "systematic model of aggression/violence in behavioral healthcare":[11,12]

- *Environmental-related* phenomena include structure or layout of the unit, personal space needs, noise level, and ambiance.
- *Client-related* phenomena include demographics, diagnosis, emotional state, previous responses to unmet needs, and underdeveloped or impaired self-control skills.
- *Behavioral healthcare system–related* phenomena include hospital or unit policies, unit rules, overarching behavioral health policy, and societal views or attitudes toward patients.
- *Clinician-related* phenomena include degree of communication or interpersonal skills, attitudes toward aggression, degree of de-escalation and defusion skills, and engagement in clinical supervision.

A multidimensional aggression assessment approach is a strategy that can be used to identify factors that can place patients at risk for and increase the likelihood of aggressive behavior. When performing an assessment, it is important to consider what factors to assess, when to perform the assessment, and which assessment scale to use.

Patient-Centered Considerations

Patient-centered assessments focus on what can be learned from and about the patient and include items such as a thorough medical and nursing history that incorporates the patient's social history (e.g., substance use, history of violent behavior, history of being abused, history of agitation).[6,16,17] In a number of studies, patient assessment played a role in identifying traits, characteristics, and risk factors of patients prone to exhibiting aggressive behavior.[18-22]

Assessing a patient's propensity for aggression can also include the use of an aggression risk assessment scale. Aggression

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Table 1. Patient-to-Patient Aggression Classification of Events Reported to the Pennsylvania Patient Safety Authority from January 1, 2012, through August 31, 2013

CLASSIFICATION OF EVENT REPORTS	PEDIATRIC EVENTS (n = 270), NO. (%)	ADULT EVENTS (n = 238), NO. (%)	GERIATRIC EVENTS (n = 30), NO. (%)
Injury or Treatment*,†			
Head or face	34 (12.6)	31 (13.0)	10 (33.3)
Unspecified area of bodily injuries	28 (10.4)	16 (6.7)	1 (3.3)
Other bodily injuries	26 (9.6)	19 (8.0)	9 (30.0)
Hands	12 (4.4)	8 (3.4)	0 (0.0)
Diagnostic testing	20 (7.4)	23 (9.7)	3 (10.0)
Reports without indication of injury or treatment	173 (64.1)	165 (69.3)	10 (33.3)
Intervention†			
Restraint use	39 (14.4)	17 (7.1)	2 (6.7)
Medications	22 (8.1)	27 (11.3)	2 (6.7)
Seclusion	6 (2.2)	4 (1.7)	0 (0.0)
Reports without indication of intervention	211 (78.1)	200 (84.0)	27 (90.0)
Patient's Role			
Unspecified	181 (67.0)	123 (51.7)	1 (3.3)
Aggressor	54 (20.0)	70 (29.4)	11 (36.7)
Victim	35 (13.0)	45 (18.9)	18 (60.0)

* Identification of injury was determined through analysis of the narrative, in conjunction with the harm score reported.

† The events are not mutually exclusive; therefore, the sum of the number of events may exceed the N value and the sum of the percentages may exceed 100.

scales have the benefit of evaluating patient behaviors and traits using a quantifiable system to calculate a number that is used to determine the patient's risk for aggression or document observations of actual aggression episodes. Scales that are predictive in nature are designed for use in patient assessment before the aggression episode occurs, while nonpredictive scales are designed to measure the aggressive episode.

Assessment tools and scales discussed in the literature focus on patient information and characteristics. The analysts focused on aggression scales intended for use with psychiatric inpatients. Table 2 identifies aggression scales found in the literature, which population they have been used to evaluate, and the predictive trait of the scale.

As an exemplar of a predictive trait scale, an interview was conducted with Drew Barzman, MD, who discussed his studies of the Brief Rating of Aggression by Children and Adolescents (BRACHA) scale and noted that the BRACHA scale is predictive of aggressive behavior. His study from 2011 evaluated the BRACHA version 0.8 in assessing the risk of aggressive behavior only in inpatient children and adolescents. The scale was administered by social workers in the emergency department, and the outcome of aggression was assessed on the inpatient unit. The majority of the scale items predicted inpatient aggression during the first six days of the inpatient admission; specifically, the study findings showed predictability of aggression in that "all BRACHA items relating to interpersonal violence or hostility were strong predictors of in-hospital aggression, as was a history of property destruction."[10]

The behavioral health community recognizes the need to improve assessment, identification, and treatment of aggression. In 2010, the American Association for Emergency Psychiatry embarked on Project BETA (Best practices in Evaluation and Treatment of Agitation) to address the need for quality guidelines for the treatment of agitation, a precursor to aggressive behavior.[17] While the assessment and treatment of the agitated psychiatric patient in the emergency setting is beyond the scope of this article, emergency situations may occur at any time in any setting. Symptoms of agitation may be caused by a variety of etiologies both medical and psychiatric.[23] Best practices for the assessment of the agitated patient include ruling out an underlying medical condition, performing

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Table 2. Agitation and Aggression Assessment Scales for Use in Inpatient Psychiatric Settings

SCALE	DESCRIPTION	POPULATION ADDRESSED
Staff Observation Aggression Scale[1]	An instrument used to assess the degree and frequency of violent and assaultive acts by inpatients.	The study focused on psychiatric and psychogeriatric inpatients.
Staff Observation Aggression Scale–Revised (SOAS-R)[2,3]	The SOAS-R includes revised severity scores and adds options to record autoaggressive behavior (i.e., self-destructive acts), definition of aggression, and seclusion and physical restraint as possible measures for stopping aggression.	The 1999 study focused on adult inpatients. The 2002 study focused on inpatients (age not identified).
Overt Aggression Scale[4-6]	An instrument used to assess four types of aggression: verbal, physical aggression to objects, physical aggression to self, and physical aggression to others. The instrument also measures interventions used to address aggressive acts.	The 1986 study focused on inpatient adults and children at a psychiatric hospital. The 1991 study focused on inpatients at two psychiatric centers. The 1996 study focused on inpatient children at an inpatient psychiatric unit.
Social Dysfunction and Aggression Scale[7]	Measures aggressive behavior other than obvious violence and assaults (i.e., it covers the total range of mild, moderate, and severe aggression).	The study focused on psychiatric inpatients (age not identified).
Rating Scale for Aggressive Behavior in the Elderly[8,9]	Measures aggressive behavior in the elderly, ranging from simply being uncooperative or resisting help to actual physical violence.	The 1992 study focused on psychogeriatric patients. The 1998 study focused on psychogeriatric patients.
Brøset Violence Checklist[10]	Assesses confusion, irritability, boisterousness, verbal threats, physical threats, and attacks on objects as either present or absent. A checklist resulting in a score useful in predicting violence within the next 24-hour period.	This study mainly focused on adult psychiatric inpatients, with the following acknowledgments: 2 patients were less than 20 years old, and 26 patients were greater than 50 years old.
Brief Rating of Aggression by Children and Adolescents[11]	Assesses the risk of aggressive behavior of inpatients. A predictive scale useful in predicting aggression during the first six days of admission.	This study focused on children and adolescent psychiatric inpatients; however, the location of scale administration was the emergency department.
Dynamic Appraisal of Situational Aggression[12]	Assesses the risk of imminent aggression. A predictive scale useful in predicting aggression over the subsequent 24 hours and for the next shift.	This study focused on non–forensic psychiatric inpatients (age not identified).

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(continued from page 118)

a psychiatric evaluation that includes visual observation, and paying careful attention to the patient's verbal and nonverbal interactions (i.e., watching for cues or signaling behavior such as pacing, raised voice, or threats).[17,24]

According to an interview with a manager at a Pennsylvania healthcare facility, staff are expected to do rounds and observe patients every 15 minutes to identify potential changes in any patient's behavior. The rounds conducted are formal, and the location of the patient, their behavior, and who observed them are documented every 15 minutes. Patient assessments are performed a number of times: initially on arrival to the facility (e.g., emergency crisis center, emergency department), prior to transport or upon arrival to the inpatient setting, and whenever a change in the patient's condition is warranted. A social worker meets with the patient in the crisis center to determine if they meet criteria for inpatient admission. Staff from the inpatient unit meet the patient, read them the patient's bill of rights, escort them to the unit, perform a contraband search, and obtain a nursing admission assessment, which includes medical history, family support, religion, abuse history, past violent behavior on the patient's part, sexual orientation, drug and alcohol use, contact person, and food-related issues. Nursing staff perform a suicide assessment as soon as the patient comes onto the unit to determine if the patient will require one-to-one continuous observation. A medical physician performs the medical workup and evaluation, and a psychiatrist performs the psychiatric evaluation. Based on the results of these assessments, staff identify education needs (dietary and/or physical therapy), which also includes ascertaining what works best for the patient during agitated states, such as listening to music, exercising, or crafts.

One experimental study employed an assessment approach that included the use of six different assessment scales applied routinely to each patient of an experimental group. Two scales were used daily and the rest were used weekly; they were collectively called the Crisis Monitor, defined as a structured short-term risk assessment strategy.[25] The use of multiple assessment scales together can be thought of as an assessment bundle. The study's authors predicted a reduction in aggression incidents and seclusion rates. The results showed a significant decrease in the number of aggression incidents and number of hours spent in seclusion, which suggests that a "structured short-term risk assessment incorporated into routine care planning" led to these significant reductions.[21]

Patient assessment is an integral component of providing safe behavioral healthcare, but it is only one aspect of a comprehensive assessment strategy. In a study by Griffith et al. (2013), the use of the Dynamic Appraisal of Situational Aggression–IV instrument "predicted aggression significantly better than unaided clinical risk ratings" for a limited time period in a nonforensic inpatient setting.[21]

Staffing-Centered Considerations

Patients identify staff interactions and restrictive regimens as a large factor contributing to aggression.[13] Also called "situational risk factors," the quality of the initial interaction or therapeutic alliance between the therapist and the patient has been identified as a predictor of violent behavior. One study in which the authors used the Brief Psychiatric Rating Scale and the Overt Aggression Scale as measures demonstrated that patients who had poorer therapeutic alliance at the time of admission were significantly more likely to display violent behavior during hospitalization.[26] This study suggests the importance of establishing a positive patient-therapist alliance as a strategy to limit aggression. In Cornaggia et al.'s (2011) systematic review of a decade's worth of published articles, harmony among staff (i.e., a good working climate) appears to be more useful in aggression prevention than other strategies of staffing such as more male nurses.[27] Some examples are good communication techniques, staff being available to patients, and providing patient education.

In an interview with one Pennsylvania healthcare facility manager, the manager explained how the staff "takes time to get to know the patient" and finds out from the patient what interests they have and what specifically works for them when they are becoming agitated. Specifically, this manager stated, "When you see someone starting to get agitated like walking around, pacing, or yelling, staff intervenes right away. The nurses will walk and talk to the patient, a talking technique. They ask the patient what medications have helped them in the past or for instances like this. The nurses assess what helps the patient and ask, 'What do you do to calm yourself down?' This is very specific to the patient."

The skill set and competency of staff contributes to a positive unit climate. De-escalation techniques are valuable skills to possess and are frequently used in behavioral health to prevent aggression and violence.[22,28] Specific factors to consider include having appropriate staff who possess favorable characteristics such as openness, honesty, and genuine concern for the patient; adequate training of staff; availability of staff; and space to de-escalate.

In an interview with one Pennsylvania healthcare facility manager, the manager noted that the facility's staff receive formal certified training annually in the management of the aggressive/assaultive patient and that staff have to demonstrate back to the trainer the skills they have learned.

Environmental-Centered Considerations

When assessing for aggression, consider the factors of the environment in which the patient is being cared for, the staff who work there, and the behavioral

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health system itself. In an interview with a Pennsylvania healthcare facility leader, the leader emphasized the significance of environment and proper placement of patients on units that fit the needs of both the patient and the unit when managing aggression. Regular observation and monitoring are basic activities to start with. An environmental-centered assessment and evaluation starts with identifying patients and situations in which the milieu within a behavioral setting starts to move away from a comfortable therapeutic environment to an environment where tension becomes more noticeable.

A study by Hage et al. (2009) identified environmental risk factors specific to the adolescent population. Those factors included negative family climate, violent or antisocial peer groups or neighborhoods, negative or hostile school factors, and social disadvantages (e.g., economic status, teen pregnancy, single-parent family, low educational achievement) and were found to be linked to a likelihood of aggressive and violent behavior.[20]

Environmental-related considerations include the structure or layout of the unit, personal space needs, color and ambiance of the unit, locked doors, noise level, overstimulation, degree of privacy, and other clients.[11] Behavioral healthcare system–related considerations, such as hospital and unit policies, unit rules, societal views or attitudes toward the patient, and culture and customs of the healthcare organization, also play a role when assessing the patient's environment.[13]

Based on the studies reviewed by Cutcliffe and Riahi, there appears to be a relationship between environment-related (i.e., health system) factors and the likelihood of aggression.[12] In a Fagan-Pryor et al. study, patients who had observed patient-to-patient aggression identified some of the causes as bullying, patients not liking each other, use of abrasive words, and wanting another patient's material possessions.[29]

In an interview with the manager, the philosophy of the unit is to have a very structured program, keep patients busy, and not allow for much "downtime." Most of their inpatient rooms are private, and the manager feels this helps decrease aggression because patients do not have to be in the same room with one another and do not bother each other. Private rooms also give agitated or upset patients a private place to go to cool off.

MULTIDIMENSIONAL AGGRESSION ASSESSMENT

To identify factors that may place patients at risk for aggressive behavior, a multidimensional aggression assessment approach may be used that incorporates patient, staffing, and environmental-centered considerations, such as the following:

- Patient-centered:
  - Conduct a thorough medical and nursing history, which includes the social history.[22]
  - Incorporate aggression assessment scales.[6,7,18,21,23,25,26]
  - Rule out an underlying medical condition.[17]
  - Perform a psychiatric evaluation, including visual observation.[17]
  - Observe for cues or signaling behavior.[21]
- Staffing-centered:
  - Establish a positive initial alliance between the therapist and staff.[26]
  - Incorporate an approach by staff that is respectful, noncontrolling, unprovocative, and noncoercive.[12,13]
  - Use training, skills, and competencies that include de-escalation.[22,28]
  - Ensure that the staff is harmonious and staff members possess good interpersonal skills.[22,30]
- Environmental-centered:
  - Ensure availability of diversionary activities for the patient.[11,20,22]
  - Create a physical layout that avoids overcrowding and permits freedom to move around.[12,30]
  - Apply and communicate unit rules in a consistent manner.[13]
  - Establish an environment that minimizes aversive stimuli, such as noise.[12]
  - Maintain a smaller inpatient census and shorter length of stay.[31]
  - Create a physical layout that allows for personal space and privacy.[12]

LIMITATIONS

In Pennsylvania, facilities submit three types of reports: (1) Incidents, which are submitted only to the Authority; (2) Serious Events, which are submitted to both the Authority and to the Department of Health (DOH); and (3) Infrastructure Failures, which are submitted only to DOH.[32] Facilities may report aggression as an Infrastructure Failure; therefore, the quantity of events discussed in this article may not represent the full scope of patient aggression events in Pennsylvania. According to the Medical Care Availability and Reduction of Error Act, an Infrastructure Failure is "an undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety."[33]

Furthermore, some of the event reports have a "canned" or the same submission narrative, which limits insights into understanding circumstances that factored into the aggression event. Narrative keyword search terms such as "throw," "bite," or "spit" were considered in identifying aggression event reports but were deemed unreliable, as these words are in many instances a substring of another

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word that would lead to the identification of non-aggression-related event reports.

For example, the word "bite" is a substring of the word "exhibited,"and the word "spit" is substring of the word "despite." These keywords also can be used in a nonaggressive context (e.g., throw out a tissue, flea bites), thereby confounding the identification of aggression-related event reports.

CONCLUSION

Aggression in the inpatient behavioral health setting poses a patient safety concern to patients and behavioral health clinicians. Analysis revealed that reports of patient aggression were categorized as patient to patient, patient to staff, and self-inflicted. Inpatient patient-to-patient aggression was the behavioral health aggression–related event most frequently reported to the Authority through PA-PSRS from January 1, 2012, through August 31, 2013.

Patient assessment is the first step in understanding the complexities of a psychiatric patient's experience. Historically, assessments for aggression have been patient-centric and have inadvertently left out what is now understood to be meaningful and contributory information. While there may be no single approach to head off an aggressive situation, establishing a multidimensional assessment approach that incorporates patient-centered, staffing-centered, and environmental-centered considerations and using assessment scales are strategies that can help identify factors that can place patients at risk for aggressive behavior.

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Results of the 2013-2014 Opioid Knowledge Assessment: Progress Seen, but Room for Improvement

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ABSTRACT

In 2012, the Pennsylvania Patient Safety Authority provided hospitals participating in the Pennsylvania Hospital Engagement Network adverse drug event collaboration with an 11-question opioid knowledge assessment tool to assess practitioners' knowledge about the use of opioids. In the winter of 2013-2014, the same assessment tool was distributed to reassess any changes in knowledge in the year elapsed from the first assessment. Overall, improvement in knowledge about the use of opioids did occur from 2012 to 2013-2014. There was a small but statistically significant increase in the percentage of correct answers selected in 7 of the 11 questions. The lowest-scoring questions continue to be those that encompass topics identifying the predictors of respiratory depression in patients receiving intravenous opioids, defining what constitutes an opioid-tolerant patient, and choosing medications that could potentiate the effects of an opioid with respect to a patient's ventilation. While education is important, a mix of high-leverage strategies (e.g., fail-safes, constraints, standardization) will be needed to improve and sustain the safe and appropriate use of opioids. (Pa Patient Saf Advis 2014 Sep;11[3]:124-30.)

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INTRODUCTION*

Published studies have examined errors related to knowledge deficiencies regarding the use of opioids.[1,2] In 2012, prompted by the literature and as part of the Centers for Medicare and Medicaid Services–sponsored Pennsylvania Hospital Engagement Network (PA-HEN) adverse drug event (ADE) project, the Pennsylvania Patient Safety Authority partnered with the Pennsylvania Medical Society to develop an opioid knowledge assessment tool to assess practitioners' knowledge about the use of opioids.[3] The questions covered issues associated with the use of opioids, including differences between opioid-naïve and opioid-tolerant patients, indications for long-acting opioids, and patient-specific conditions that require a lower starting dose of opioids.

The results of the 2012 knowledge assessment identified basic knowledge gaps by practitioners, particularly in the areas of identifying the predictors of respiratory depression in patients receiving intravenous (IV) opioids, defining what constitutes an opioid-tolerant patient, and choosing medications that could potentiate the effects of an opioid with respect to a patient's ventilation. The Authority published the results of the 2012 assessment in the March 2013 issue of the *Pennsylvania Patient Safety Advisory*.[3]

METHODS

In the winter of 2013-2014, the collaboration team distributed the assessment tool developed and used in 2012 for the first round of the opioid knowledge assessment[3] to the 12 hospitals currently participating in the collaboration that also participated in the assessment in 2012. The tool was developed to assess prescribers', pharmacists', and nurses' knowledge about the use of opioids. The assessment consisted of two demographic questions—the practitioner's position and how long he or she has worked in the facility—followed by 11 multiple-choice assessment questions. The questions covered a variety of problematic issues associated with the use of opioids, including the following:

- Differences between "opioid naïve" and "opioid tolerant," and what constitutes or makes a patient "opioid tolerant"
- Indications for long-acting opioids (who and/or when they should be prescribed)
- Comparative dosing between two different opioids, particularly morphine and HYDROmorphone
- Patient-specific conditions that require a lower starting dose of opioids
- The impact of concomitant medications in combination with opioids
- Monitoring the effects of opioids

The multiple-choice assessment was built and conducted in a web-based survey tool, which was distributed by e-mail. Users were required to enter an organization-specific four-digit code to associate results with specific facilities. No practitioner identities or identifiers were collected in either assessment. A paper version was also used by organizations to capture responses from practitioners who were unable to respond online. This tool was released on September 27, 2013, and the last day of data submission was March 13, 2014. A listing of the assessment questions can be found in the Opioid Knowledge Self-Assessment, which is available for use at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/opioids/Pages/home.aspx.

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RESULTS

Participating Hospitals

In 2012, there were 29 hospitals participating in the PA-HEN ADE collaboration. Twenty-four of those hospitals participated in the 2012 opioid knowledge assessment. In 2013-2014, there were 22 hospitals, some of which were new to the collaboration beginning in 2014, participating in the PA-HEN ADE collaboration. In order to compare results between 2012 and 2013-2014, only those organizations (n = 12) that participated in the 2012 assessment were invited to participate in 2013-2014. Ten (83.3%) collaborating hospitals participated in both the 2012 and 2013-2014 opioid knowledge assessments.

Practitioner Characteristics

Practitioners, including physicians, medical residents, physician assistants, nurse practitioners, pharmacists, and nurses, from the 10 hospitals that signed up for the collaboration participated in the 2013-2014 assessment. In 2012, 2,223 practitioners started the survey, but only 1,758 (79%) completed it. In 2013-2014, 1,122 practitioners started the survey, but only 829 (74%) completed it. A chi-square test comparison of these completion rates found that this difference in completion rates, though small, is statistically significant ($p < 0.001$).

Similar to the results from 2012, more registered nurses (62%) completed the opioid knowledge assessment than any other type of practitioner (see the Table). A chi-square test for independence found statistical significance in the types of practitioners who participated in 2012 versus 2013-2014 ($p < 0.001$). Respondents in 2012 achieved slightly higher levels of prior education than respondents in 2013-2014. Thus, a comparison of overall opioid knowledge scores could be biased in favor of the 2012 respondents.

The length of time a practitioner had worked at his or her current facility was also assessed. Respondents could choose one of the following selections: fewer than 5 years, 5 to 9 years, 10 to 14 years, 15 to 19 years, or 20 or more years. More respondents had worked in their current facility for less than five years than other lengths of time. Overall, there was no statistically significant difference in the duration of time working at the current facility between 2012 and 2013-2014.

Table. Percentage of Respondents to the Opioid Knowledge Assessment by Type of Practitioner for Each Round of the Assessment

PRACTITIONER TYPE	2012 (%)	2013-2014 (%)
Attending/staff physician	18	13
Resident physician/physician in training	9	7
Physician assistant/nurse practitioner	4	3
Registered nurse	48	62
Pharmacist	16	12
Other or missing	6	3

Overall Scores

For this analysis, comparisons were made between the overall number of questions answered correctly in 2012 and 2013-2014 (see Figure 1). Only those respondents who answered all 11 questions were included. In 2012, the median correct score was 6 of 11 questions, and the average was 6.5, with a standard deviation of 1.9. In 2013-2014, the median correct score was 7 of 11 questions, and the average was 7.0, with a standard deviation of 2.1. A comparison of these overall scores found that the average score was statistically significantly higher in 2013-2014 than 2012 ($p < 0.001$). However, the improvement of 0.5 more questions answered correctly in 2013-2014, on average, is small. The percentage of people who answered all 11 questions correctly increased from 1.6% in 2012 to 8.9% in 2013-2014; this difference was statistically reliable using the chi-square test ($X^2[2] = 80.0$, $p < 0.001$).

Analysts also compared the overall scores from 2012 with those from 2013-2014 separately for each practitioner type. There was statistically significant improvement for three groups: (1) attending/staff physicians ($p < 0.001$), (2) physician assistants/nurse practitioners ($p = 0.02$), and (3) registered nurses ($p < 0.001$). The other three groups, resident physicians/physicians in training, pharmacists, and "other or missing," showed improvement from 2012 to 2013-2014, but the improvement was not statistically significant.

Individual Questions

The percentage of correct answers for each question from each round of the opioid knowledge assessment can be seen in Figure 2. There was improvement from 2012 to 2013-2014 in 10 of the 11 questions. For questions 1, 2, 4, 5, 6, 7, and 8, the improvement was statistically significant. The largest improvements were seen in questions 1, 2, 7, and 8. The percentage of correct answers for question 10, a case-based question assessing the respondents' knowledge of adjusting the pain medication regimen based upon patient response, declined in 2013-2014.

Similar to the results from 2012, the three lowest-scoring assessment items in 2013-2014 were identifying the most important predictor of respiratory depression in patients receiving IV opioids, defining what constitutes an opioid-tolerant patient, and choosing which medication could potentiate the effects of HYDROmorphone on ventilation.

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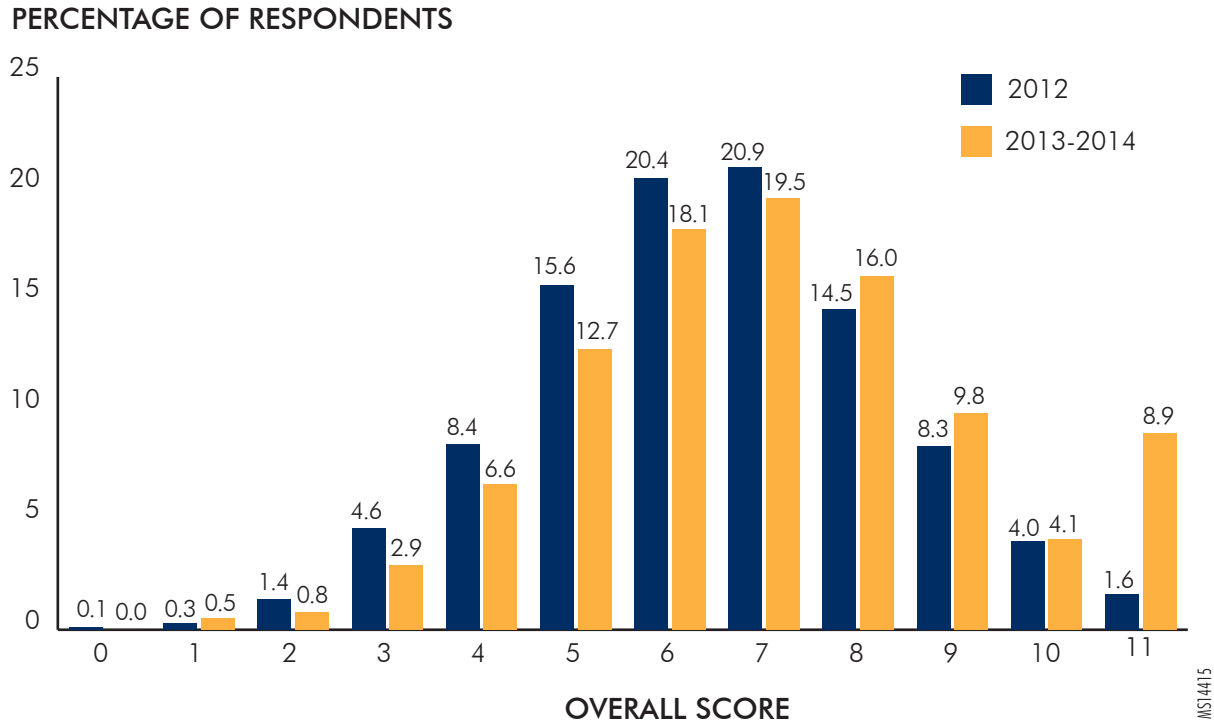
Figure 1. Percentage of Respondents by Overall Score (number of correct answers out of 11) in 2012* and 2013-2014†



*** 1,758 respondents completed the opioid knowledge assessment in 2012.**
† 829 respondents completed the opioid knowledge assessment in 2013-2014.

***Note:* A t-test comparison of the overall scores found that the average score was statistically significantly higher in 2013-2014 than 2012 (t [2,585] = 6.8, p < 0.001). A Wilcoxon test found the same thing (p < 0.001).**

Predictor of Opioid-Induced Respiratory Depression

Opioid-induced respiratory depression can be defined as a decrease in the effectiveness of an individual's ventilatory function after opioid administration.[4] Sedation generally precedes significant respiratory depression.[5,6] Opioid-induced sedation occurs on a continuum ranging from full consciousness to complete loss of consciousness and respiratory arrest. Unintended advancing of sedation occurs at increasingly higher levels along the continuum of sedation, impairing both arousal mechanisms and content processing.

Question 2 of the assessment asked respondents to select the most important predictor of respiratory depression in patients receiving IV opioids. Overall, the percentage of respondents (of those who completed the entire knowledge assessment) answering the question correctly increased from 24% in 2012 to 37% in 2013-2014 ($p < 0.001$). While an improvement from a quarter to over a third of respondents answering the question correctly is significant, it still means that 63% of the respondents were unable to accurately identify important predictors to increase the safe use of IV opioids.

Opioid Tolerance

The decision to use a potent and/or long-acting opioid and the selection of an appropriate medication is dependent upon an assessment of the patient's opioid status. This means determining if the patient is either opioid naïve (i.e., the patient has not been chronically receiving opioids on a daily basis) or opioid tolerant (i.e., the patient has been chronically receiving opioids on a daily basis for a specified amount of time[7,8]) before prescribing, dispensing, or administering an opioid.

Question 1 of the assessment asked respondents to select which treatment regimen would meet the definition of opioid tolerance. Only one of the four treatment regimens was correct. Overall, the percentage of respondents (of those who completed the entire knowledge assessment) answering the question correctly increased from 29% in 2012 to 37% in 2013-2014 ($p < 0.001$). However, this leaves 63% of respondents who selected regimens that would have indicated the patient was opioid naïve.

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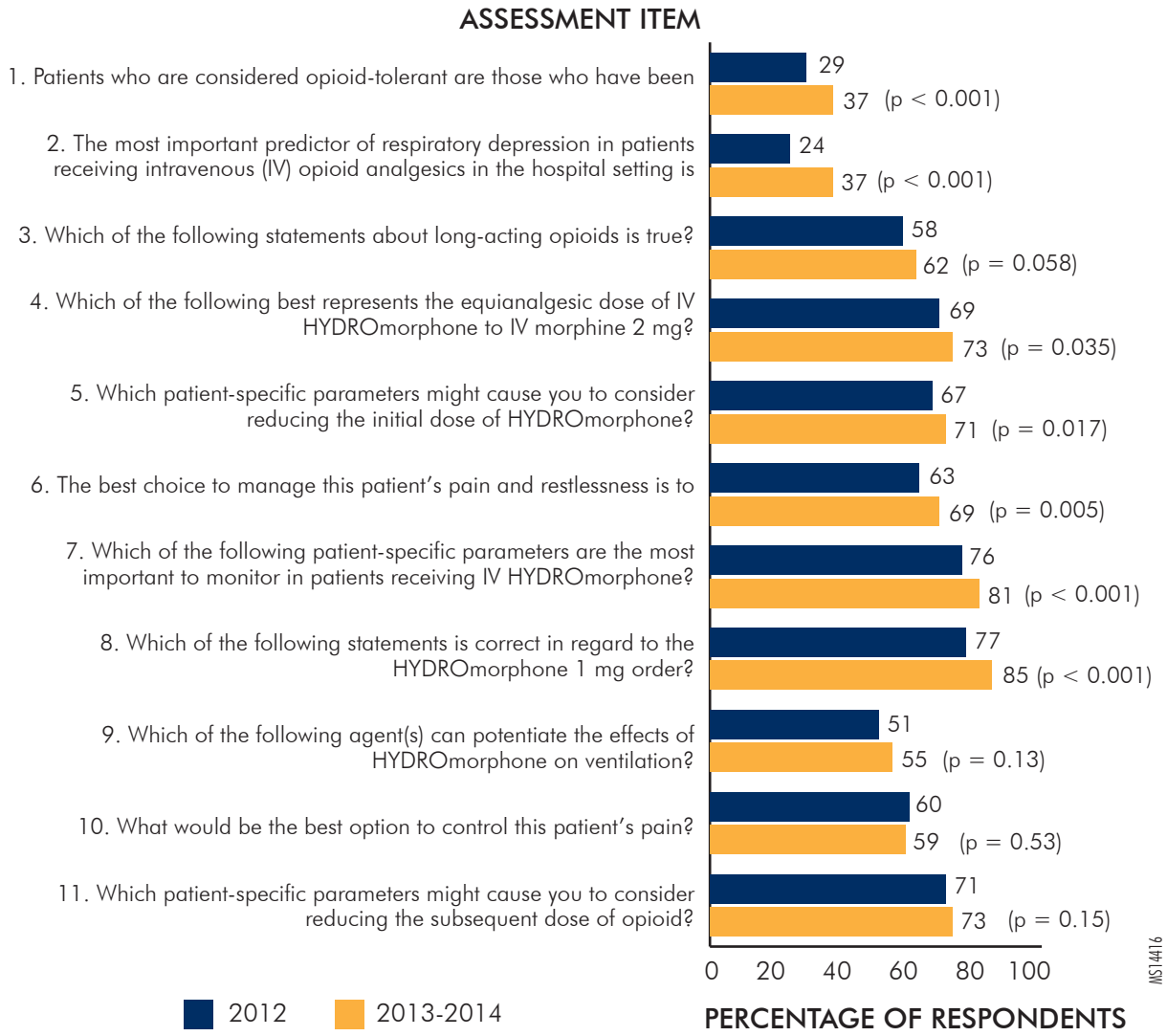
Figure 2. Percentage of Respondents Who Chose the Correct Answer for Each Assessment Item, 2012 and 2013-2014



Note: **The complete Opioid Knowledge Self-Assessment tool, including the target answers, is available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/opioids/Documents/assessment.pdf.**

Medications That Potentiate the Effects of Opioids on Ventilation

Patients with sleep apnea or those who are morbidly obese are at increased risk for experiencing adverse events from the use of opioids. Patients who are concurrently receiving other medications that are central nervous system or respiratory depressants (e.g., benzodiazepines, antihistamines, diphenhydrAMINE, sedatives) are also at higher risk of adverse events.[9,10] Question 9 of the knowledge assessment was designed to measure practitioners' ability to identify which medications (i.e., atorvastatin, FLUoxetine, ALPRAZolam, atorvastatin and ALPRAZolam, or FLUoxetine and ALPRAZolam) could potentiate the effects of HYDROmorphone on ventilation. Overall, the percentage of respondents (of those who completed the entire knowledge assessment) answering the question correctly increased from 51% in 2012 to 55% in 2013-2014. However, the improvement was not statistically significant ($p < 0.13$).

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Adjusting the Treatment Regimen in Response to the Patient's Pain

Minimizing the risk of adverse effects from the use of opioids is important. However, effectively managing and treating a patient's pain is also important. Effectively monitoring a patient's response to opioids and appropriately adjusting therapy contributes to both safe and effective pain management. Question 10 of the knowledge assessment asked practitioners to select the most appropriate treatment plan for a patient who continued to have moderate to severe pain following the administration of IV HYDROmorphone 0.2 mg. Unlike the improvement seen in the percentage of correct answers for all of the other knowledge assessment questions, the percentage of correct answers overall for question 10 declined from 2012 (60% correct) to 2013-2014 (59% correct); however, this decline was not statistically significant.

DISCUSSION

It appears that improvement in current knowledge about the use of opioids did occur from 2012 to 2013-2014. Results of the 2013-2014 opioid knowledge assessment indicate there was improvement in overall scores for all practitioner types, with statistically significant improvements for (1) attending/staff physicians, (2) physician assistants/nurse practitioners, and (3) registered nurses. There were also statistically significant increases in the percentage of correct answers for 7 of the 11 questions. However, the degree of improvement from 2012 to 2013-2014 is small. Significant percentages of practitioners, between 15% and 63% for a given question, continue to have gaps in knowledge about opioids, particularly in the following areas:

- Identifying the most important predictor of respiratory depression in patients receiving IV opioids
- Defining what constitutes an opioid-tolerant patient
- Choosing which medication could potentiate the effects of HYDROmorphone on ventilation

The highest percentage of correct answers for any one question in 2013-2014 was 85% for question 8, which asked practitioners if a starting dose of 1 mg of HYDROmorphone for an opioid-naïve 80-year-old patient was appropriate. This question also had the highest percentage of correct answers (77%) in 2012. In June 2011, the US Food and Drug Administration approved changes in the official prescribing information for HYDROmorphone. As a result, drug information compendia and databases were updated to reflect the new dosing information. It is likely that these higher-level systematic changes, beyond any educational efforts, contributed to this statistically significant improvement.

Causes of medication errors include breakdowns due to inadequate staff orientation, ongoing education, supervision, and competency validation.[11] Examples of errors in part due to deficiencies in staff education and competency are inappropriate medication doses or errors in patient assessment and monitoring due to lack of knowledge about particular patient populations; medication errors by new or reassigned ("float") staff who are required to perform unfamiliar tasks or give unfamiliar medications without proper orientation, education, or supervision; and errors with new medications given to patients without full knowledge of the preparation, dose, route, action, or effects to anticipate.[11]

Organizations often are under the belief that when errors occur, providing staff education is an effective stand-alone strategy in preventing medication errors. However, two meta-analyses of continuing medical education (CME) activities and interventions found that didactic and passive learning interventions appear to have little to no effect in changing physician performance or patient outcome.[12,13] CME activities that are interactive or use a mix of educational methods or interventions appear to effect change in physician knowledge and practice, but due to its nature, the change may wane over time.[12,13] While knowledge is necessary in the delivery of safe and effective medical care, it is not sufficient by itself to effect change in practitioner behavior or patient outcomes.[12] This is in part why strategies, such as education, that rely on individual performance will likely be ineffective when used alone in attempting to prevent errors.[14]

The intent of the opioid knowledge assessment was to assist organizations in identifying basic knowledge gaps by practitioners, which would hopefully spur organizations to address these gaps and possibly assess staff knowledge about other high-alert medications. In the course of the collaboration, each facility was responsible for providing education to address identified deficiencies, both collaboration-wide and facility-specific. Facilities indicated these educational efforts ranged from physician-specific programs to broader efforts for all staff. The ADE project team did not provide educational materials specific to the deficits identified from the assessment results to facilities, so the responsibility of developing and/or providing any educational efforts or materials was up to each separate facility. This could have led to a nonstandardized approach to the education provided within facilities (e.g., type of material, staff included in educational efforts, method of providing education, monitoring that the education was successful), which may have limited the increases in selecting the correct answers in the 2013-2014 Opioid Knowledge Self-Assessment.

Although staff education alone is an insufficient approach to error reduction, it does play an important role when combined with system-based error reduction strategies.[14] It is important that practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices,

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including new medications, nonformulary medications, high-alert medications, and error prevention.[11,14] Providing practitioners involved in medication use with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused is also important.[11] For example, organizations may consider providing staff with ongoing education about medication errors that have occurred within the organization and in other organizations, as well as strategies to prevent these errors. The use of active and interactive modalities in these educational activities, increasing the length of contact time, and continuing contact can contribute to a larger effect of the educational activities.[13]

In order to see greater improvement in practitioner knowledge of opioids, safe and appropriate use of opioids, and prevention of adverse events from opioids, the expansion (or in some cases the introduction) of extensive opioid and pain management education and training in medical, pharmacy, and nursing education programs and new-practitioner training will be necessary. However, to prevent harm with the use of opioids, a mix of high-leverage strategies (e.g., fail-safes, forcing functions, constraints, standardization), some of which are highlighted below, can be implemented in addition to education.

Fail-Safes and Forcing Functions

- Use smart infusion pumps (i.e., infusion pumps with dose error reduction software) with soft and hard stops enabled to alert the user to unsafe doses for continuous opioid infusions and patient-controlled analgesia (PCA) therapy.[15]
- Use oral syringes for administration of oral liquid products.[16] To further reduce the risk of unintended administration of oral medications via the IV route, have pharmacy dispense all oral liquids that are not commercially available as unit dose product in an oral syringe.[17,18]

Constraints

- Limit the variety of opioids, concentrations of each opioid, and formulations of each opioid included on the hospital formulary.[15]
- Prescribing
  - Consider requiring prescribers to undergo a privileging process to verify proficiency with PCA pain management.[19]
  - Consider restricting fentaNYL PCA use to anesthesia or pain management team members only.[20]
  - Implement standard order sets for PCA therapy, with all sections completed, and limit verbal orders to dose changes.[19]
  - Take into consideration important information about the patient that could affect the prescribing of opioids (e.g., patient's current medication profile for drugs with additive central nervous system or respiratory depressant side effects, age, renal function, total current opioid therapy).[21]
- Storage
  - Avoid storing concentrated oral forms of opioids in floor stock and automated dispensing cabinets (ADCs).[16]
  - Store only the smallest-size package, concentration, and dose of opioids in floor stock and ADCs.[16]
  - Store each medication in a separate, lock-lidded bin or drawer in the ADC to help prevent drug-selection errors. In the pharmacy, segregate prefilled syringes and vials of these drugs, especially if they contain the same concentration.[22]

Standardization

- Ensure current pain management protocols and guidelines for opioid use are available to guide prescribers, pharmacists, and nurses when opioids are prescribed, dispensed, administered, or monitored.[23]
- Implement a standardized pain scale(s) appropriate to the patient population to assess a patient's level of comfort/pain.[23]
- Use standardized preprinted order forms and computerized prescriber order entry (CPOE) order sets to prescribe oral and parenteral opioids.[23]
- Standardize concentrations of parenteral opioid infusions for adult patients to a single concentration per drug, and use these in at least 90% of the cases.[23]
- Standardize concentrations of parenteral opioid infusions for pediatric patients (including neonates) to a single concentration per drug, and use these in at least 90% of the cases.[23]
- Standardize preprinted order forms and CPOE order sets used for PCA.[23]
- Establish protocols for reversal agents that can be administered without additional physician orders when warranted.[24]

Redundancies

- Implement an independent double check for all parenteral opioids that are compounded in the pharmacy.[15]
- At the point of administration, implement an independent double check with each new infusion bag, bottle, or syringe, as well as with changes in the rate of infusion of parenteral opioids.[15,16]
- At the point of administration, implement an independent double check with each new PCA infusion bag, bottle, or syringe, as well as with changes in the rate of PCA administration of parenteral opioids.[15]

CONCLUSION

The results of the 2013-2014 knowledge assessment illustrate that gaps in practitioners' knowledge about opioids continue to exist. While education on statewide

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and local levels and in-facility staff training programs are necessary and can produce minor improvements in levels of knowledge, more needs to be done. Better incorporation of education about opioids in medical, pharmacy, and nursing school programs and new-practitioner training is needed. Also, the development of standardized approaches and protocols to pain management and monitoring can help institutionalize best practices regarding the use of opioids.

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Surgical Site Infection Prevention Utilizing Patient Screening and Decolonization: The PA-HEN SSI Prevention Collaboration

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ABSTRACT

Infection prevention interventions rarely engage the patient in the infection prevention process. Through the Partnership for Patients, the Hospital and Healthsystem Association of Pennsylvania (HAP) and the Pennsylvania Patient Safety Authority developed the initial surgical site infection (SSI) prevention project design, then HAP collaborated successfully with 40 participating hospitals to empower patients for the prevention of SSIs. The intervention included systematic screening and decolonization of surgical patients prior to the day of surgery. Baseline standardized infection ratio (SIR) aggregates in 2010 and 2011 were 1.274 and 1.167, respectively, while the SIR aggregates postintervention in 2012 and 2013 were 0.797 and 0.735, respectively. This work adds to the body of knowledge related to successful reduction of SSIs through screening and decolonization and also adds important information about the impact of empowering patients and institutional partners to augment prevention protocols to fit institutional culture and the needs of the patient. (Pa Patient Saf Advis 2014 Sep;11[3]:131-5.)

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

INTRODUCTION

The Hospital and Healthsystem Association of Pennsylvania (HAP) is one of only 26 Hospital Engagement Networks (HENs) as part of the federal Partnership for Patients (PfP) campaign. The PfP is a three-year initiative with two overarching goals to be achieved by the end of 2014: reduce preventable harm by 40% and reduce readmissions by 20%. These goals are to be accomplished through the partnering of HENs and acute care hospitals on improvement work across the most common preventable hospital-acquired conditions, as well as work on targeted focus areas.

HAP formed the Pennsylvania Hospital Engagement Network (PA-HEN) to provide Pennsylvania hospitals with opportunities to enhance the patient healthcare experience through participation in collaborative programs and with a portfolio of projects designed to reduce preventable harm and readmissions. HAP leads and directs the PA-HEN collaboration along with its four subcontractor partners, one of which is the Pennsylvania Patient Safety Authority. HAP partnered with the Authority for leadership on several HEN projects for which the Authority had a proven track record and, through the use of Authority experts, developed the initial SSI prevention intervention design, methodology, and preparation related to education and tool kit development.*

When it comes to making surgery safer from an infection prevention standpoint, there have been previous efforts through the National Surgical Infection Prevention Project and the Surgical Care Improvement Project.[1] However, the interventions rarely actively engage the patient in the infection prevention process. HAP and the Authority sought to design an intervention that would actively engage patients in their care. As such, HAP and the Authority focused on active screening and decolonization as the main intervention for the PA-HEN collaboration. The Authority had previous experience with the Western Pennsylvania SSI collaboration of 2011, which required patient participation as part of the decolonization protocol prior to the day of surgery. Lessons learned from the Western Pennsylvania SSI collaboration were incorporated into the SSI reduction initiative under the PA-HEN collaboration. See "Western Pennsylvania SSI Collaboration," exclusively available in the online version of this article.

METHODS

Collaborative Approach

To best inform development of the PA-HEN SSI prevention and reduction project design and interventions, Authority analysts queried the National Healthcare Safety Network (NHSN) database to determine which pathogens most commonly caused SSIs. Table 1 depicts the results of that query. *Staphylococcus aureus* had a marked effect on those procedures selected, and there were, in most instances, a greater number of incidences of methicillin-susceptible *S. aureus* (MSSA) than methicillin-resistant *S. aureus* (MRSA). Since preoperative patient participation would be required for the intervention to be successful, the Authority also assessed for the incidence of SSI related to elective, clean procedures. Baseline data for 2010 and 2011 was compared with postintervention years 2012 and 2013 by means of standardized infection ratio (SIR).

Interventions that include active screening and decolonization to control both MSSA and MRSA have been published. The majority of these interventions and results have

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been documented in the orthopedic literature.[2-9] The following *S. aureus* targeting protocol was designed by HAP, PA-HEN, and the Authority:

Overview

- Preoperative screening of the elective surgical patient is to be performed via the anterior nares for the presence of MRSA and MSSA.
- Patients are to bathe daily with 4% chlorhexidine gluconate (CHG) or 2% cloths the night before and the morning of the day of surgery.
- Patients who screened positive for MSSA or MRSA will apply mupirocin 2% nasal two times a day for five days before surgery.
- Patients are to receive a day-of-surgery cleansing of the surgical site with 4% CHG applied by a healthcare worker or 2% cloths.
- Patients are to receive prepping of the surgical site in the operating room suite with an alcohol-based product designated as a surgical skin preparation.

Office Visit

If the planned procedure is one of the procedures that is eligible for the decolonization intervention (elective/nonemergent):

- Patient education is to be provided related to screening and the intervention (verbally).
- The patient is to be screened for *S. aureus* if there is no preadmission testing policy.
- Written patient educational materials are provided to the patient.
- Preadmission (preoperative) appointment is optimally scheduled at least seven days before surgery.

Preadmission/Preoperative Visit Scheduled at Least Seven Days Prior to Surgery

- The patient is to be informed by phone of the screening result.
- Education, both written and verbal, is to be provided related to the screening result.
- The patent is then assigned to a decolonization protocol.
- Written and verbal education is provided related to the protocol, data collection, and expectations.
- Prescriptions and any other materials are then provided or called into the pharmacy for the patient.
- If MRSA-positive, ensure staff consults with infection prevention.
- The patient has the overall responsibility to comply with the protocol assigned to him or her based on the screening result.
- The patient will have access to a professional if questions arise or if there are concerns related to the decolonization process.
- The patient needs to have access to the decolonization supplies.
- Either prescriptions or supplies are provided by the facility.
- The patient should be informed of the importance of compliance and documentation of compliance using the provided forms.
- If the patient is unable to comply for any reason, staff may consult with family or other services.

Acute Care

- During patient admission, patient compliance data forms are collected and forwarded to the appropriate department by the healthcare worker.
- Application of infection control measures by staff may be considered as per facility policy (for example, contact precautions).
- Day-of-surgery preoperative CHG wipe of surgical site is done by the healthcare worker.
- Screening results are communicated to operating room staff.

Operating Room

- Application of infection control measures is to be implemented by staff as per facility policy (e.g., contact precautions).
- Operating room decolonization checklist is then completed by healthcare staff.
- Completed decolonization checklist is forwarded to the appropriate department.
- Patient's surgical site is prepped in the surgical suite with alcohol-based surgical skin prep by the operating room team.
- Immediate preoperative incision site skin prep is allowed to dry prior to procedure start.

Institutional Recruitment and Support Framework

In early 2012, Pennsylvania hospitals were invited to join the PA-HEN SSI prevention and reduction immersion project. Forty hospitals, collectively known as the immersion group, elected to participate in the project and completed a signed senior executive commitment form. In May 2012, the HAP PA-HEN project managers launched the SSI project and have conducted at least one or more activities per month throughout the duration of the project.

Core activities of the PA-HEN SSI prevention project include the provision of ongoing technical assistance; monthly education, including content calls and webinars by national expert faculty; sharing of evidence-based practices, resources, and tools; coaching calls; networking events; and the opportunity to share and spread learning and best practices for broad applicability and implementation. These activities utilize various interactive formats such as "All Teach, All Learn" and facilitate peer-led discussions, information sharing, and coaching. These activities provide updates on project results, successes, challenges, lessons learned, and action

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Table 1. Prevalence Analysis of Pennsylvania National Healthcare Safety Network 2010 Data for Selected Procedures

PROCEDURE	NO. OF INFECTIONS	NO. OF CLEAN WOUNDS*	NO. OF MRSA† (% OF TOTAL INFECTIONS)	NO. OF MSSA‡ (% OF TOTAL INFECTIONS)
Breast surgery	156	90	26 (16.7)	55 (35.3)
Hip prosthesis	321	313	83 (25.9)	88 (27.4)
Knee prosthesis	345	341	55 (15.9)	92 (26.7)
Laminectomy	193	155	31 (16.1)	86 (44.6)
Limb amputation	70	21	16 (22.9)	12 (17.1)
Open reduction of fracture	299	165	67 (22.4)	78 (26.1)
Pacemaker surgery	93	53	25 (26.9)	32 (34.4)
Spinal fusion	370	295	69 (18.6)	143 (38.6)

* Wounds classified as "clean" according to the National Healthcare Safety Network definition

† Methicillin-resistant *Staphylococcus aureus*

‡ Methicillin-susceptible *Staphylococcus aureus*

plans for implementation to close the gaps, as well as to provide tailored technical and educational assistance to hospitals.

Utilizing focus group feedback, PA-HEN project managers made modifications to the protocol and toolkit previously developed by the Authority and disseminated it to participating immersion group hospitals. The toolkit consisted of educational materials for the staff and patients, checklists, data collection tools, and protocol algorithms.

Statistical Approach

All 40 hospitals participating in the immersion group entered their infection data into the NHSN. Rights to the data were conferred to the collaboration by the participants. Authority analysts retrieved the data from the NHSN for the analysis presented herein using the facility identification numbers specific to the NHSN. The SIR formula was used for comparative purposes. SIR represents the actual number of infections divided by the predicted number of expected infections. The predicted number of infections is risk-adjusted for procedure type and is based on national baseline data collected by the NHSN. If the SIR is less than 1.0, the actual number of infections is less than predicted. SIRs were calculated by entering the data into the NHSN SIR analytic calculator. The immersion group hospitals started their SSI interventions in 2012. Results are presented in Table 2.

RESULTS

Baseline SIR aggregates in 2010 and 2011 were 1.274 and 1.167, respectively, and the SIR aggregates postintervention in 2012 and 2013 were 0.797 and 0.735, respectively. The greatest reductions in SIR from baseline to the end of 2013 were in the following procedure categories: colon, cesarean section, hip replacement, knee replacement, and laminectomy (NHSN procedure codes COLO, CSEC, HPRO, KPRO, and LAM, respectively).

Pacemaker (NHSN code PACE) SIR decreased; however, due to small sample size, the SIR remains significantly greater than 1.0. The same holds true for hernia repair (NHSN code HER) in years 2010 and 2011 as far as sample size. Note, however, the sample sizes for 2012 and 2013 are greater than the baseline in 2010 and 2011; therefore, meaningful comparison is difficult especially since the SIR for HER in 2013 is greater than in 2012.

Coronary artery bypass graft with both chest and donor site incisions (NHSN code CBGB) and coronary artery bypass graft with chest incision only (NHSN code CBGC) seemed to run without much change from baseline. Preoperative prepping and decolonization has been performed in this group of surgical patients for some time.[10]

Reductions were also noted in HPRO and KPRO despite the fact that the majority of the orthopedic literature supports screening and decolonization. This intervention in most cases stretched out the decolonization process and may warrant further investigation, as it seems that (at least in this study) orthopedic replacement SIRs are able to be reduced.

Finally, the aggregate SIR shows a baseline reduction over time that falls below an SIR of 1.0 postimplementation.

DISCUSSION

Implementing an intervention to prevent *S. aureus* SSI, as described above, requires engagement and dedication of healthcare workers and patients. If the healthcare team fosters patient autonomy through empowerment in terms of active participation of patients in caring for themselves, preventing preventable infections is possible. These intervention results are repeatable by following a standardized protocol for screening and decolonization.

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Table 2. Pennsylvania Hospital Engagement Network Immersion Group SIRs by National Healthcare Safety Network Surgical Procedure Code, by Year

PROCEDURE CODE	2010			2011			2012			2013			SIR TREND LINE
	# Proc	# Inf	SIR	# Proc	# Inf	SIR	# Proc	# Inf	SIR	# Proc	# Inf	SIR	
CARD	2,610	9	1.010	2,454	9	1.081	2,740	10	1.104	2,814	6	0.640	
CBGB	1,963	21	0.887	1,789	16	0.729	1,737	20	0.960	1,713	17	0.837	
CBGC	280	2	0.559	248	2	0.639	303	2	0.525	273	2	0.577	
COLO	677	43	2.069	769	41	1.747	3,117	55	0.605	3,273	74	0.729	
CSEC	284	3	1.796	399	7	2.896	4,326	13	0.593	4,273	18	0.800	
HER	95	15	9.836	100	21	13.444	676	11	1.401	592	16	1.919	
HPRO	5,587	58	1.143	5,889	53	0.983	5,903	54	1.023	5,765	34	0.664	
HYST	3,756	24	0.828	3,365	30	1.143	3,304	20	0.731	3,047	20	0.775	
KPRO	10,169	65	1.000	10,579	45	0.677	10,972	48	0.688	10,351	28	0.432	
LAM	716	19	5.001	556	13	4.206	1,192	10	1.504	1,502	14	1.743	
PACE	76	7	46.053	110	9	40.909	80	5	31.250	86	3	17.442	
Total	**26,213**	**266**	**1.274**	**26,258**	**246**	**1.167**	**34,350**	**248**	**0.797**	**33,689**	**232**	**0.735**	

Note: # Proc = number of procedures; # Inf = number of infections; SIR = standardized infection ratio; CARD = cardiac surgery; CBGB = coronary artery bypass graft with both chest and donor site incisions; CBGC = coronary artery bypass graft with chest incision only; COLO =colon surgery; CSEC = cesarean section; HER = herniorrhaphy; HPRO = hip prosthesis; HYST = abdominal hysterectomy; KPRO = knee prosthesis; LAM = laminectomy; PACE = pacemaker surgery

It is easy to treat patient compliance like a variable, even trying to control for the variable. In an intervention as described herein, patient compliance is a variable; however, as per the results of this intervention, even the variable of limited noncompliance is minimized in the result simply because it is positive. In other words, if the intervention of CHG bathing by the patient was performed less than optimally, the patient was empowered even if they were noncompliant with the intervention; furthermore, the patient was autonomous. While providing the patient with autonomy may not lead to 100% compliance, in this example, any compliance could affect colonization. Therefore, empowering the patient and allowing for autonomy may lead to healthcare-associated infection (HAI) reduction through better compliance with the intervention as compared with zero compliance, hence decreasing SSI risk.

As noted by Sharp et al., "Empowering patients does not require disclosing all risks, regardless of magnitude and probability. However, patients should be provided with information when the risks in question are material, that is, when they could alter the decisions of reasonable persons who can respond in some beneficial way [such as compliance with decolonization protocols]. . . . HAIs often constitute a material risk, although this determination depends on a wide variety of factors, including the particular patient and the institution."[11]

A variable in this intervention is that the patient may be unable or unwilling to react to the risk in any beneficial way and engage in prevention. For example, a patient may be unable to perform activities of daily living (bathing with CHG) despite wanting to react in a beneficial way to the risk of SSI after they are informed of the risk. When patients are eligible for intervention, the team can take a holistic approach and provide solutions for limitations patients may encounter during performance of the intervention.

Similarly, institutions involved in the intervention may have the same needs for autonomy as the patients. Allowing facilities or institutions to modify protocol despite an evidence base supporting the intervention goes against a purely scientific approach. As Baudrillard observed, "It is science that masters the objects, but it is the objects that invest it with depth."[12] The authors note that within an intervention this complex—spanning from prehospital to the moment the skin is incised and beyond—if one tries to control for institutional cultural variation, the collaboration may not move past kickoff. The collaboration leaders did allow for modification of the Authority's proposed protocol if the modification was supported by the scientific literature and met the intent of the intervention, the patient being involved and empowered to react to the risk of SSI. The *objects* (institutions and patients) were able to invest depth into the science of SSI prevention rather than being constrained by a rigid protocol.

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Examples of institution-based modifications to the protocol supported by the PA-HEN collaboration are as follows:

- Povidone-iodine 5% nasal solution on the day of surgery substituted in lieu of mupirocin
- Bathing protocol shortened
- Preadmission appointments shortened or lengthened from seven days
- Modification of teaching forms, educational materials, and checklists

In addition, institutions could choose any surgical procedures they wanted to focus on as long as local epidemiological evidence pointed to *S. aureus* as having an impact on the procedure(s) selected.

CONCLUSION

This work adds to the body of knowledge related to successful reduction of SSI through screening and decolonization and also adds important information about the impact of empowering patients and institutional partners to augment prevention protocols with evidence-based modifications that fit institutional culture and the needs of the patient. Furthermore, this work begins to replicate the work done in the orthopedic and cardiac realm for other surgical types. Further research may be warranted regarding prevention of SSI through evidence-based screening and decolonization interventions and protocols that seek to empower the patient by allowing them to participate actively in the prevention of infection.

The authors do caution those who wish to prevent SSI or potentially eradicate *S. aureus* and choose not to perform routine long-term mupirocin susceptibility testing. As stated in a Society for Healthcare Epidemiology of America guideline, "Any program attempting eradication of carriage should incorporate plans for routine susceptibility testing because eradication is less likely when the drugs selected are inactive against the colonizing strain and widespread mupirocin resistance has developed due to spread in facilities using mupirocin exclusively."[13]

Tools and Resources

The collaboration toolkit can serve as a starting point for facilities to develop their own screening and decolonization programs for the prevention of SSI. The PA-HEN toolkit, along with other resources, is available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/ssi/Pages/home.aspx. The toolkit and resource materials can be modified for individual facility use.

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Quarterly Update on Wrong-Site Surgery: Marking for Regional Anesthetic Blocks

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As of July 23, 2014, there were 14 reports of wrong-site surgery in Pennsylvania operating rooms (ORs) during the second quarter of 2014 and 1 belated report from a prior quarter (see the Figure). Despite the increase in reports of wrong-site surgery this quarter over the previous three quarters, the total for the academic year 2013-2014 is the lowest to date: 45.

Of the 14 reports, 3 involved hand procedures, 2 were wrong-level spine operations, 2 involved ovarian surgery, and 1 of the other 7 was a wrong-side anesthesia block, which remains the most common wrong-site event for the academic year (n = 7 of 45) and the decade (n = 122 of 586). Two of the three incorrect-hand procedures involved starting a carpal tunnel procedure instead of the intended trigger finger release. This one type of error now represents 28% of all wrong-site hand surgery events (n = 11 of 39) and 2% of all wrong-site surgery events reported from July 1, 2004, through June 30, 2014.

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.[1,2]

Operations continue to be scheduled incorrectly, introducing errors into the verification process:

> *Procedure was booked as I&D [incision and drainage] of bilateral groin abscesses. Correct procedure was completed, which was I&D of bilateral axillary abscesses.*

> *Patient was scheduled for shoulder arthroscopy. Office schedule listed "left." OR schedule said "left." Patient to preoperative holding [area]; consent, H&P [history and physical], and patient stated "right," which is the correct side. The right side was confirmed and prepped.*

Fortunately, those receiving patient information have been checking for discrepancies and identifying them as soon as discovered for reconciliation by the surgeon based on primary sources of information:

> *Patient consented for a left craniotomy. Anesthesia noted that patient was scheduled for a right craniotomy. Neurosurgeon notified.*

> *OR schedule indicates left parietal craniotomy. Consent indicates right craniotomy. While patient was in the preoperative holding area, the surgeon was notified of the discrepancy. MRI [magnetic resonance imaging scan] was reviewed (verified right side as correct side). Surgeon, patient, and nurse verified right side as correct.*

Surgeons marking the site are not always confirming the site prior to marking with all the relevant information and with the patient, as is obvious from the following:

> *Presented for hysterectomy. Eye surgeon initialed above right eye, but this is not an eye patient. Eye surgeon was made aware and initials removed. This patient had the correct procedure completed.*

> *During preoperative assessment, the patient confirmed right-sided surgery. The surgeon marked the right side of patient. However, the consent read "left." The error was discovered during the time-out verification.*

> *This patient was [scheduled] for a bilateral ophthalmic keratopathy. The procedure was confirmed as bilateral and the surgeon marked the patient bilaterally. It was noted during the time-out that laterality was not designated on the consent. The procedure was completed bilaterally.*

The value of the mark is evident from this report:

> *Left leg was initially prepped and then staff realized that the patient was marked on the right and that the consent was also for the right side. Right leg prepped and procedure started without issue.*

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

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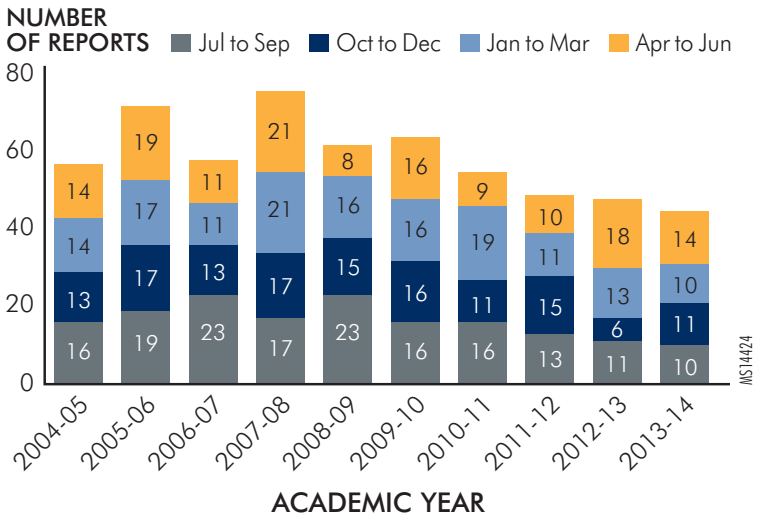
Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year



Switching ORs and running two rooms caused confusion resulting in the wrong patients being brought to these ORs:

> *A CRNA brought a patient into the OR suite not realizing that the surgeon/patient's room [had been] swapped with that of another. The outcome was that once the patient entered the room and was identified as the wrong patient, the patient had to be wheeled out. Both patients were [scheduled for] laparoscopic cholecystectomies by two different surgeons. Despite what the monitor said, the rooms were swapped and the CRNA was not aware of the circumstance.*

> *Surgeon began swinging between two operating rooms, and patients were being moved to different rooms. There was confusion on which patient was going to which room, and the patient was sent to the surgeon's other operating room. The planned procedure remained the same (right knee arthroscopy) and no equipment needed [to be] changed. However, the patient was greeted by the circulating nurse and asked his/her name, and it was discovered that they were expecting a different patient.*

IMPROVEMENT BY AREA

Analysts compared reports of wrong-site surgery for the first three years of facility reporting through the Pennsylvania Patient Safety Reporting System, before intense scrutiny with the onset of the wrong-site surgery project in July 2007, with reports for the most recent three years. Overall, there were 24% fewer reports in the most recent three years compared with the initial three-year baseline (see the Table). Comparing specific procedures to the overall experience, a statistically significant improvement was observed for thoracic procedures (5 to 0) and orthopedic procedures on the knee (11 to 2), with reductions of reports of wrong-site events for all surgical procedures on the leg.

In contrast, there was minimal reduction of reports of wrong-site events for procedures on the hand, none for procedures on the elbow, and an increase in the number of reports for procedures on the shoulder.

Another contrast was an increase in anesthetic blocks on the legs by anesthesiologists, despite a decrease in the number of wrong-site anesthetic blocks overall.

A statistically significant improvement was observed for eye blocks by ophthalmologists, although that might have been due to the shift to topical anesthetics. However, other eye procedures were also trending toward improvement.

Other commonly reported wrong-site procedures were, if anything, more common: wrong-level spinal surgery, procedures for pain management, and ureteral stenting.

The results by area indicate that focus should continue on wrong-side leg blocks by anesthesiologists, wrong-site hand surgery (especially absentmindedly starting a carpal tunnel release instead of a trigger finger release), wrong-level spine procedures, wrong-side pain management procedures, and wrong-side ureteral stenting.

MARKING THE SITE OF THE ANESTHETIC REGIONAL BLOCK MAY PREVENT WRONG-SITE REGIONAL BLOCKS

Marking the site of the surgical incision has proven to be a useful reference to the correct surgical site during the time-out before surgery.[3] The act of marking the surgical site after verification of the correct site with the documents and the patient in the preoperative holding area may refresh the surgeon's short-term memory prior to the final time-out. Pointing to the mark on the surgical site in the prepped and draped surgical field is a valuable surrogate for verbal confirmation by the patient, who is usually anesthetized and unable to otherwise participate in the final time-out process.[3]

Using the three steps of the Universal Protocol[4] when doing a regional

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Table. Reductions in Wrong-Site Operating Room Procedures by Type

PROCEDURE TYPE	2004 TO 2007 (BASELINE)	2011 TO 2014 (MOST RECENT PERIOD)	% DECREASE
All	**187**	**142**	**24.1**
Eye blocks by surgeons	8	0	100.0*
Thoracic	5	0	100.0*
Colon	4	0	100.0
Orthopedic ankle	2	0	100.0
Orthopedic knee	11	2	81.8*
Wrong device inserted	7	2	71.4
Ear, nose, and throat	6	2	66.7
Eye surgery	13	5	61.5
Knee blocks by surgeons	6	3	50.0
Graft harvest	4	2	50.0
Craniotomy	2	1	50.0
Orthopedic femur and hip	2	1	50.0
Urological procedures except ureteral	2	1	50.0
Endocrine	2	1	50.0
Wrong-side spinal surgery	5	3	40.0
Foot	9	6	33.3
Eye blocks by anesthesiologists	3	2	33.3
All pre-op anesthesia blocks	48	34	29.2
All blocks by anesthesiologists	32	26	18.8
Hand	13	12	7.7
Vascular and dialysis	3	3	0.0
Elbow	1	1	0.0
Dental and oral surgery procedures	1	1	0.0
Wrong-level spinal surgery	19	23	Increased
Pain management	19	21	Increased
Ureter	9	10	Increased
Leg blocks by anesthesiologists	6	9	Increased
Breast	4	6	Increased
Gynecological	2	4	Increased
Wrong lesion	2	4	Increased
Hernia	1	2	Increased
Shoulder	0	2	Increased
Bariatric	0	1	Increased

Note: Events total more than all cases because some were included in more than one category.

* Statistically significant differences by chi-square test ($p < 0.05$)

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(continued from page 137)

anesthetic block is recommended for this separate perioperative procedure.[1,2] The advantage or disadvantage of separately marking the site of the regional anesthetic block has been debated in theory but not tested in practice. The advantage is the value of the mark as a reference point. The disadvantage is the potential to be mistaken for the surgical mark and lead to a wrong-site operation. In the absence of evidence of the superiority of one approach over the other, the Pennsylvania Patient Safety Authority has not previously commented on whether the regional anesthetic block site should be separately marked. However, some departments of anesthesia, perhaps motivated by wrong-site blocks, have instituted policies of separately marking the site of a regional anesthetic block.

The Authority conducted a survey to determine how common the policy of separately marking the regional anesthetic block site was in Pennsylvania and if implementation of such a policy has been associated with a reduction of reports of wrong-site blocks.

At the end of the first quarter of 2014, the Authority sent a two-question survey to each acute care hospital and ambulatory surgical facility. The questions were as follows:

1. Does your medical facility have a policy or procedure that requires the anesthesia provider to mark the anesthesia site where a regional or local anesthetic block will be administered?
2. If yes, when was this policy or procedure implemented?

At the time of the survey, wrong-site anesthetic blocks were the most common wrong-site procedures in operating suites, accounting for 121 (21%) of the 571 wrong-site procedures in operating suites since the onset of reporting in July 2004. Survey responses were received from 69 facilities, of which 29 indicated that they had implemented such a policy since reporting began and 2 indicated that they had implemented such a policy prior to the onset of reporting. Among the 29 facilities that had made a change, the time of the change ranged from the first quarter of 2006 to the first quarter of 2014, with the median being the first quarter of 2012. These 29 facilities reported 25 wrong-site anesthetic blocks before implementing their policies and 5 after implementing their policies.

To balance the before and after times, only a subset of reports submitted from each facility for equal months before and after it implemented the change was considered for comparative analysis. If a facility implemented the change during the first quarter of 2012, then the nine quarters under the new policy were compared with the last nine quarters under the old policy. During these balanced periods before and after the implementation of the change, the facilities reported 12 wrong-site anesthetic blocks before the change and 3 after. Aside from 18 facilities that had no wrong-site procedures in either period and 1 that reported 1 wrong-site procedure in each period, 9 had fewer wrong-site blocks after initiating the change and 1 had more wrong-site blocks after initiating the change. This improvement after implementation of the change in policy was statistically significant by the sign test (9/10, $p < 0.05$). No facility reported wrong-site surgery as a result of erroneously referencing the site mark for the anesthetic block during the final time-out for the surgical procedure.

It is possible that the results are biased as a result of an event precipitating an immediate change in policy and increasing vigilance in the period following this change. However, several changes were implemented at system levels, meaning that multiple facilities, such as a hospital and an ambulatory surgical facility, experienced a change in policies without necessarily having an institutional experience with a wrong-site block. One of the wrong-site blocks following the implementation of the change in policy was in such a facility. However, this facility had experienced three wrong-site blocks prior to the balanced preimplementation period, so it actually experienced fewer blocks after implementation of the change in policy, albeit over a shorter total time.

As a result of the analysis based on these survey results, the Authority encourages facilities to consider developing polices within their anesthetic department to independently mark the regional block sites. Considerations for such policies include the following:

- The mark be placed after the surgeon marks the surgical site as a reference and so as to not obscure the surgeon's mark.
- The mark be placed after verification of the appropriate site for the regional block with reconciliation of all relevant information, including the schedule, the surgical consent, the history and physician examination, the patient's understanding, the surgeon's site mark, and the anesthesia consent.
- The convention for the anesthetic block mark be identifiable as a mark for an anesthetic block and be distinct from the convention for the surgical site mark.
- The anesthetic block mark be referenced in the prepped and draped field during the time-out for the anesthetic block.
- The anesthetic block mark not be visible in the prepped and draped surgical field.

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NOTES

1. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2012 [cited 2014 Jul 17]. http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/principles.pdf
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PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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