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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Contact Information

333 Market Street, Lobby Level
Harrisburg, PA 17120
Telephone: 717-346-0469
Fax: 717-346-1090
Website: http://www.patientsafetyauthority.org
E-mail: patientsafetyauthority@pa.gov

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Contact Information

Mailing address: PO Box 706
Plymouth Meeting, PA 19462-0706
Telephone: 866-316-1070
Fax: 610-567-1114
E-mail: support_papsrs@pa.gov

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These individuals reviewed articles for Vol. 13, No. 3:

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Prescribing Errors that Cause Harm

Briana B. Rider, PharmD
Patient Safety Analyst
Michael J. Gaunt, PharmD
Sr. Medication Safety Analyst
Matthew Grissinger, RPh, FISMP, FASCP
Manager, Medication Safety Analysis
Pennsylvania Patient Safety Authority

ABSTRACT

Errors that occur in the prescribing phase of the medication use process are less likely to reach the patient and cause harm because of the opportunity to intercept the error in the phases of transcribing, dispensing, administering, and monitoring. However, some prescribing errors make their way through the entire medication use process, reach the patient, and cause harm. A query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database revealed 811 Serious Events (harm score E through I) associated with reported prescribing errors that occurred from July 2004 through June 2016. Nearly 5% (4.7%, n = 38) of these errors required intervention to sustain life or contributed to or resulted in the patient's death. The most common types of events reported were wrong dose/overdosage (32.2%, n = 261), monitoring error/documented allergy (14.5%, n = 118), dose omission (14.3%, n = 116), and wrong patient (4.4%, n = 36). Recommended system-based risk reduction strategies include optimizing computerized prescriber order entry with clinical decision support to facilitate screening for drug-related problems; and developing well-designed standard order sets; (Pa Patient Saf Advis 2016 Sep;13[3]:81-91.)

Corresponding Author
Matthew Grissinger

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INTRODUCTION

Studies have found that a large number of medication errors originate in the prescribing phase of the medication use process.[1,2] Bates et al. found that 56% of preventable events originated in the prescribing stage,[1] while Leape and colleagues found that drug-drug interactions, failure to act on a test, wrong choice, and wrong dose errors occurred most frequently in the prescribing stage.[2] Reported rates of prescribing errors range from 3.13 to 62.4 errors per 1,000 medication orders.[3-5] However, a prescribing error is less likely to reach the patient and cause harm than errors that occur in subsequent phases of the medication use process, because there are more opportunities to intercept the error in the transcribing, dispensing, administering, and monitoring phases. Despite this, some prescribing errors make their way through the entire medication use process, reach the patient, and cause harm.

Historically, many medication prescribing errors have been associated with illegible handwriting, the use of error-prone abbreviations, incomplete orders, and incorrectly transcribed verbal orders. A 2004 study by Bobb et al. found that the most common medication error types for clinically significant prescribing errors were wrong dose (39.2%), wrong frequency (20.2%), nomenclature (9.4%), drug allergy (6.4%), wrong medication (6.4%), medication duplication (5.5%), and omission (4.7%). The most common drug classes for these prescribing errors were anti-infectives, cardiovascular agents, and opioids; and nearly two-thirds of the errors occurred upon hospital admission.[3]

Pennsylvania Patient Safety Authority analysts conducted an analysis of Serious Events associated with reported medication prescribing errors; that is, those that reached the patient and caused harm. Analysts sought to characterize contributing factors and identify appropriate system-based risk reduction strategies.

METHODS

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for Serious Events resulting from medication errors, harm score E through I as adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP),[6] associated with the prescribing phase, that occurred from July 2004 through June 2016. This query yielded 837 event reports. Twenty-six reports (3.1%) were excluded from final analysis because the error likely did not originate with the prescribing phase (e.g., an error occurred because the infusion pump for an appropriately prescribed medication was programmed incorrectly at the point of administration). A total of 811 event reports remained for final analysis.

The medication name, patient care area, event type, event description, phase(s) of the medication use process, and harm score, adapted from the NCC MERP harm index,[6] were provided by the reporting facility. In reports in which a medication name data field was left blank or incomplete but the name was provided in the event description, an analyst adjusted the medication name field appropriately. Reports were categorized into type of prescribing error, drug class(es) involved, and order type (e.g., handwritten, verbal, computerized prescriber order entry [CPOE]). Reports of unsafe orders that were given verbally and then transcribed into an electronic order entry system by another practitioner were coded as verbal orders, when that distinction was possible.

Error reports were further evaluated to identify contributing factors and were assessed for the likelihood that the error could be intercepted by CPOE and clinical decision support (CDS) with basic functionality. Classification of the likelihood that errors

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could be intercepted by CPOE and CDS and possibly prevented was adapted from previously published categories.[3,7] Prescribing errors related to illegible handwriting, incomplete orders, drug-allergy interactions, and wrong dose formulation were categorized as *likely* to be intercepted by CPOE and CDS, as described by Bobb et al.[3]

RESULTS

Results were categorized by harm score; the majority (67.7%, n = 549 of 811) of the Serious Events were reported as an error that occurred that may have contributed to or resulted in temporary harm to the patient and required intervention (harm score = E). Nearly 5% (n = 38) either required intervention necessary to sustain life (e.g., cardiovascular and respiratory support [harm score= H]) or contributed to or resulted in the patient's death (harm score = I; see Figure 1).

Nearly 40% (n = 319) of the events involved opioids, anticoagulants, and insulin—high-alert medications that pose an increased risk of patient harm when involved in medication errors.[8] Figure 2 shows the five most common drug classes involved in the reported events.

Four event types accounted for 65.5% (n = 531) of submitted prescribing error reports (see Figure 3).

Nearly one-quarter (21.5%, n = 174) of the serious prescribing errors in the present analysis were judged as *likely* to be intercepted and therefore possibly preventable if CPOE with CDS were used. Errors associated with the following event types and contributing factors were judged as *likely* to be intercepted: drug/allergy interactions (14.5%, n = 118), illegible handwriting (3.8%, n = 31), incomplete orders (2.2%, n = 18), and wrong dose formulation (0.9%, n = 7). See Table for examples of prescribing errors rated as *likely*, *possibly*, or *unlikely* to be intercepted by CPOE with CDS.

Figure 1. Harm Scores for Serious Events Associated with Prescribing Errors, as Reported to the Pennsylvania Patient Safety Authority, July 2004 through June 2016 (N = 811)

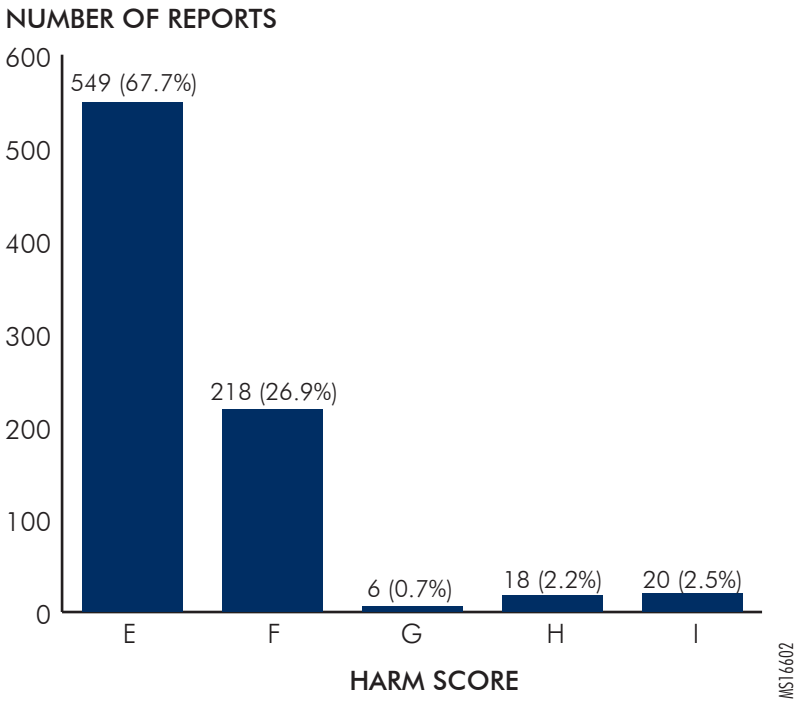
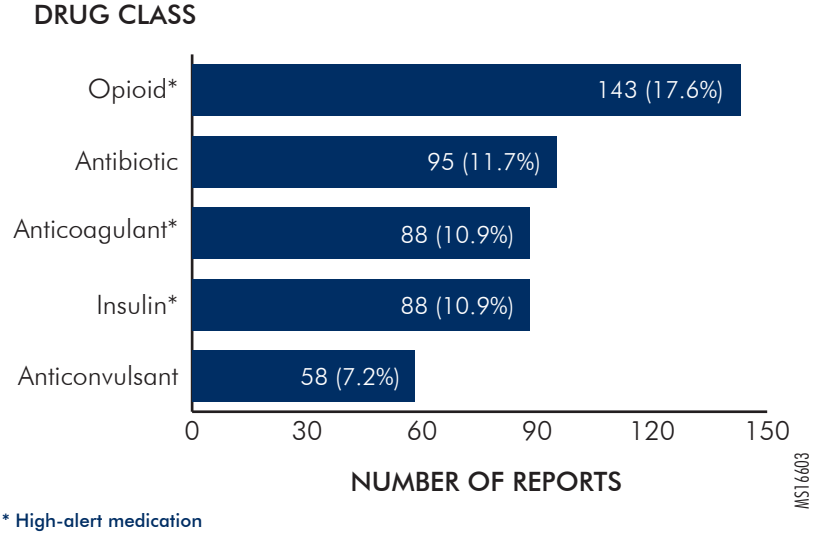


Figure 2. Most Common Drug Classes Involved in Serious Events Associated with Prescribing Errors, as Reported to the Pennsylvania Patient Safety Authority, July 2004 through June 2016 (N = 811)



* High-alert medication

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Figure 3. Event Types Involving Serious Events Associated with Prescribing Errors, as Reported to the Pennsylvania Patient Safety Authority, July 2004 through June 2016 (N = 811)

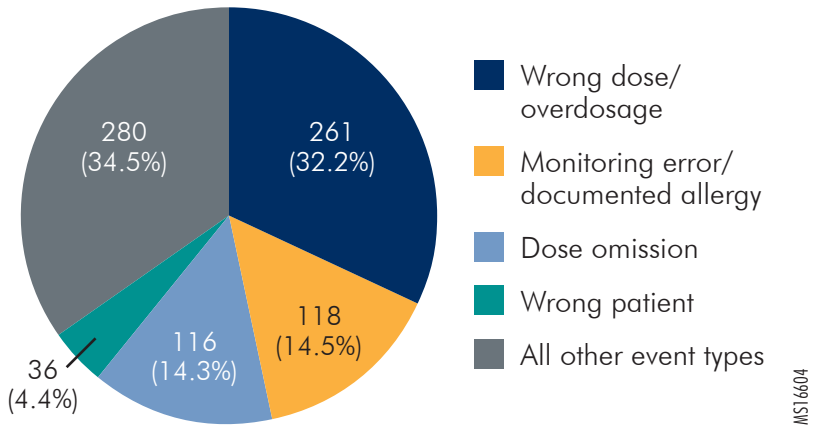
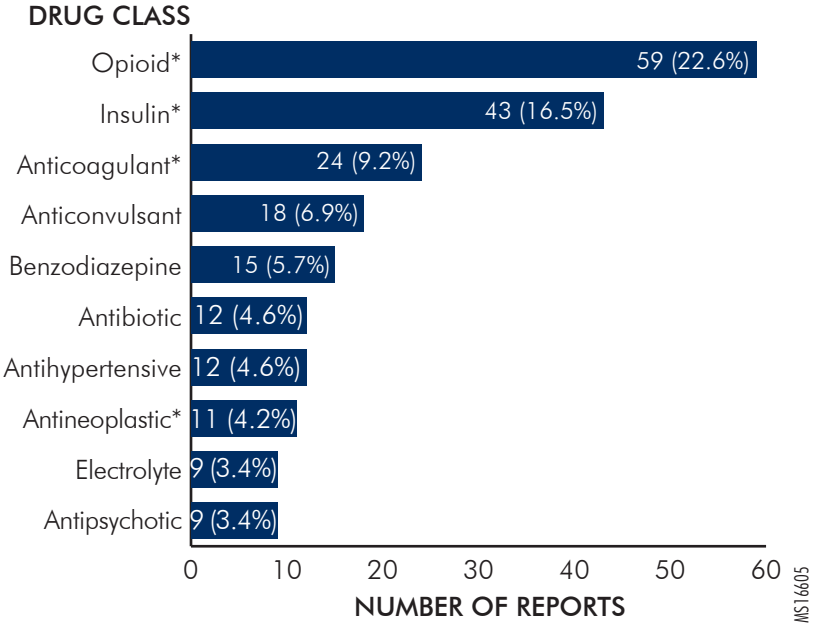


Figure 4. Most Common Drug Classes Involved in Serious Wrong Dose/ Overdosage Events Associated with Prescribing Errors, as Reported to the Pennsylvania Patient Safety Authority, July 2004 through June 2016 (n = 261)



* High-alert medication

Wrong Dose/Overdosage Errors

Nearly one-third (32.2%, n = 261 of 811) of the Serious Events were categorized by facilities as wrong dose/overdosage events. Of these reports, 22.6% (n = 59 of 261) involved opioids, 16.5% (n = 43) involved insulin, and 9.2% (n = 24) involved anticoagulants (see Figure 4).

Naloxone, a reversal agent for opioids, was administered in 71.2% (n = 42 of 59) of the reported wrong dose/ overdosage errors involving opioids. HYDROmorphone was the medication most frequently involved (52.5%; n = 31 of 59) in reported opioid wrong dose/ overdosage errors, and of these, 61.3% (n = 19 of 31) involved an intravenous (IV) HYDROmorphone dose of 1 mg or more and 41.9% (n = 13 of 31) involved an IV HYDROmorphone dose of 2 mg or more. An IV HYDROmorphone dose of 1 mg is equivalent to approximately 7.5 mg of IV morphine and is the current maximum starting dose for an opioid-naïve patient.

Similarly, rescue agents used to treat hypoglycemia (e.g., dextrose, glucagon) were administered in 72.1% (n = 31 of 43) of the wrong dose/overdosage errors involving insulin. Nearly one-fourth (23.3%, n = 10 of 43) of the reported wrong dose/overdosage errors involving insulin resulted in a 10-fold overdose. Illegible handwriting, the use of error-prone abbreviations (e.g., "u" for units) and trailing zeros, and confusing the product concentration (i.e., 100 units/mL) with the dose were identified as contributing factors linked to insulin overdosage errors.

Half (50.0%, n = 12 of 24) of the wrong dose/overdosage events involving anticoagulants mentioned the use of a reversal or rescue agent (e.g., vitamin K, protamine). Notable factors that contributed to anticoagulant overdosages included prescribing the treatment dose instead of the prophylaxis dose, wrong patient weight

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Table. Examples of Prescribing Errors and Likelihood of Being Intercepted by Current Versions of Computerized Prescriber Order Entry (CPOE) Systems with Clinical Decision Support (CDS)

CLASSIFICATION	EXAMPLE*	TYPE OF EVENT	POSSIBLE CONTRIBUTING FACTOR(S)
Likely to be intercepted with CPOE and CDS	ED [emergency department] physician wrote for .5 mg Dilaudid® [HYDROmorphone] IV. Handwriting looked like 5 mg. Due to patient's size and severity of pain, ED nurse did not question order which she read as 5 mg. The patient arrested and was resuscitated and placed on a ventilator. The patient did not regain consciousness and expired.	Wrong dose/ overdosage	Illegible handwriting
	Physician ordered Imitrex® [sumatriptan] 6 mg. No route or frequency documented. New graduate nurse gave Imitrex 6 mg IV. Patient experienced feeling of "being on fire," elevated heart rate and diaphoresis.	Wrong route	Incomplete order
	Patient with atrial fibrillation was ordered verapamil 360 mg po. It was given as immediate release. Patient became hypotensive necessitating transfer to the ICU [intensive care unit].	Wrong dosage form	Nomenclature issue—drug name suffix/modifier
Possibly intercepted with CPOE and CDS	Patient taking Effient® [prasugrel]. Post-catheterization orders started Plavix® [clopidogrel]. Both medications given and patient developed thrombocytopenia.	Duplicate therapy	Breakdown in medication reconciliation No active screening for duplicate therapy
	Female patient seen in the ED for cellulitis of the wrist and was prescribed Bactrim™ DS [sulfamethoxazole and trimethoprim] with a SCr [serum creatinine] of 4.2 mg/dL. The drug should have been contraindicated based on the patient's renal insufficiency.	Contraindicated drug	No active screening of drug order against laboratory values
	Patient admitted on Lexapro® [escitalopram] for depression. During hospitalization, physician ordered Zyvox® [linezolid] 600 mg every 12 hours. The drug interaction was not identified and the patient developed signs of serotonin syndrome.	Drug-drug interaction	No active screening for drug-drug interactions Ability to bypass alert level of major/highest severity
Unlikely to be intercepted with CPOE and CDS	Physician was computer charting on one patient and switched to print-on-demand order sheet which pulled the wrong patient name to order sheet. Methadone 50 mg was ordered on the wrong patient. Cardiac catheterization was delayed 24 hours.	Wrong patient	Multiple patient electronic records open at the same time Technology malfunction
	Patient's medication list from home states she takes HumaLOG® 75/25 Mix™ [insulin lispro protamine and insulin lispro (rDNA origin)], 60 units in the evening and 75 units in the morning. Physician inadvertently ordered HumaLOG [insulin lispro (rDNA origin)]—not 75/25 mix resulting in symptomatic hypoglycemic requiring D50 [dextrose 50%] IV.	Wrong drug	Breakdown in medication reconciliation Nomenclature issue—drug name modifier
	Patient admitted for I&D [incision and drainage] of shoulder joint. Patient was not written for pre-op or post-op antibiotics.	Dose omission	Slip or memory lapse

* The details of the Pennsylvania Patient Safety Reporting System event narratives in this article have been modified to preserve confidentiality.

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used to calculate dose, and inappropriate dose based on patients' laboratory studies.

Following are examples of reported errors that resulted in wrong dose/overdosage:*

> *Patient transferred to another facility for shortness of breath. Patient was on Lantus® [insulin glargine] insulin. When physician was reviewing the [previous] medication orders, the Lantus order read Lantus 100 units/mL vial inject 16 units subcutaneously at bedtime. Physician misinterpreted this order to mean Lantus 100 units subcutaneously at bedtime and ordered it as such. The patient's blood sugar was 83 at 2100 on [day 1], so this dose was not given and it was subsequently decreased to 80 units. The patient did receive the 80 units on [day] 2 and the blood sugar dropped to 55 on [day 3]. The Lantus dose was decreased again to 40 units on [day 4] and was administered at bedtime. At 0600 on [day 5] the patient had a respiratory arrest and patient's blood sugar was 9. The patient was intubated, transferred to ICU [intensive care unit], and placed on a ventilator.*

> *The patient was admitted to the ICU with sepsis and UTI [urinary tract infection]. The patient was on methotrexate as an outpatient [but] the methotrexate was held during the ICU stay. The patient was later transferred to the telemetry unit. [On the eighth day of the admission], the physician wrote for methotrexate 10 mg daily. The pharmacist entered the dose and the patient received 7-days worth of the drug before the error was caught. The records from the rehabilitation facility where the patient came from were scanned over and they showed that the patient was taking 5 mg on Sundays and 5 mg on Mondays (a total of 10 mg weekly). The patient experienced stomatitis, pancytopenia, was intubated and transferred to the ICU. The patient coded and expired.*

Monitoring Error/Documented Allergy

Errors related to documented allergies accounted for 14.5% (n = 118 of 811) of reports. The medication classes most commonly involved in documented allergy events included antibiotics (40.7%, n = 48 of 118), opioids (22.0%, n = 26), and nonsteroidal anti-inflammatory drugs (NSAIDs; 8.5%, n = 10). Similar to findings published in a 2008 *Pennsylvania Patient Safety Advisory*[9], morphine topped the list of medications involved in documented allergy events (9.3%, n = 11). Other commonly involved medications include ketorolac (6.8%, n = 8), levoFLOXacin (5.9%, n = 7), vancomycin (5.1%, n = 6), and ceFAZolin (4.2%, n = 5). The emergency department (ED) was the care area most frequently cited (26.3%, n = 31) in documented allergy events. Following are examples of reported prescribing errors that resulted in patients receiving a medication for which they had a documented allergy:

> *Patient listed allergy [reaction] to vitamin K as paralysis. The physician felt this was not a true allergy and ordered vitamin K to be administered prior to a surgical procedure (INR [international normalized ratio] 2.1). Patient suffered anaphylactic reaction, required intubation, pressor support, and was transferred to ICU.*

> *A patient [admitted] to the ED for worsening cellulitis was evaluated by the ED physician and given IV vancomycin. The patient was admitted for IV antibiotic treatment by teaching service and ordered cefepime 1 g IV, first dose now. An ED nurse initiated this order prior to transfer to the inpatient unit. Cefepime started. [Five minutes later], the patient [developed] respiratory distress, wheezing, and difficulty swallowing. IV [infusion] stopped. ED physician [came] to the room and initiated treatment for anaphylaxis including IV Solu-Medrol® [methylPREDNISolone sodium succinate], IV Pepcid® [famotidine], and subcutaneous EPINEPHrine. The patient was placed on BiPap [bilevel positive airway pressure] and symptoms/respiratory status improved. The ED physician called the teaching service residents and made them aware of the reaction. The patient was admitted to the ICU for close monitoring of airway secondary to anaphylaxis. Home medication list provided to the ED by the patient includes allergy to Ceftin® [cefuroxime].*

Dose Omission Errors

The third most common event type reported was dose omissions (14.3%, n = 116 of 811), which occurred when a medication was not ordered or reordered despite being appropriate for the patient's underlying condition. Harm related to dose omission was most commonly reported with anticoagulants (18.1%, n = 21 of 116), anticonvulsants (17.2%, n = 20), antibiotics (12.9%, n = 15), and insulin (10.3%, n = 12). Dose omissions can occur at any high-risk transition point in the patient's admission (e.g., new admission, transfer). Nearly 30% (27.6%, n = 32) of the dose omissions occurred when the patient's maintenance medication was omitted upon admission, 14.7% (n = 17) occurred when a medication was omitted upon discharge, and 10.3% (n = 12) occurred postoperatively. Nearly 13% (12.9%, n = 15) of the dose omissions were caused when the provider failed to reorder a medication that had automatically stopped. Following are examples of reported dose omission errors:

> *The patient had cardiac cath [catheterization] with insertion of drug eluting stents. On day one post-procedure, the attending physician*

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

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told the physician assistant that the patient was ready to go home and to resume home medications. The physician assistant entered DCI [discharge instructions]/medication reconciliation and indicated that all home medications were to be resumed but deleted all in-house medications. Patient was discharged without orders or prescriptions for aspirin or Plavix® [clopidogrel]. The patient was seen in physician's office [about a week later] with complaints of not feeling well and having feelings of warmth and cold. EKG [electrocardiogram] indicated a myocardial infarction with ST elevation. Repeat cardiac cath [catheterization] identified occlusion of LAD [left anterior descending coronary artery].

A patient post CABG [coronary artery bypass grafting] with sternal wound infection underwent sternectomy and placed on long term ceFAZolin. The patient developed recurrent MSSA [methicillin-susceptible Staphylococcus aureus*] bacteremia/sepsis, and it was discovered that antibiotics expired without knowledge of the physician. The patient missed 3 doses/day for 10 days. Pharmacy policy automatically discontinues antibiotics after 10 days unless order specifies otherwise.*

Wrong Patient Errors

The fourth most common (4.4%, n = 36 of 811) type of reported prescribing errors were wrong patient errors. The majority (55.6%, n = 20 of 36) of these reports did not provide enough information to ascertain the type of order (e.g., verbal, handwritten, CPOE). Of the remaining reports, 75% (n = 12 of 16) of the orders were placed via CPOE, 18.8% (n = 3) were handwritten, and 6.3% (n = 1) were communicated verbally. Following are examples of reported wrong patient errors:

The patient became somnolent. Narcan® [naloxone] administered twice. The patient was intubated to protect airway. Admitted to the ICU which was initial plan for the patient anyway. The physician placed an order for HYDROmorphone via CPOE on wrong patient's record. This medication was to be entered for another patient.

Resident entered order into order entry system on wrong patient. The medication [rocuronium bromide] was prepared, dispensed, and given to the patient.

DISCUSSION

The use of technology to prevent and detect medication errors has been increasing over the past decade. CPOE systems with CDS designed to assist prescribers with therapeutic decisions have been promoted for their ability to reduce serious medication errors by more than 50%.[10,11] A 2013 survey showed that nearly 80% of US hospitals used a CPOE system, a 58.6% increase from 2007.[12,13] Of the hospitals with CPOE, 61.4% reported concurrent CDS use.[12] CPOE could avert many of the contributing factors that lead to prescribing errors, including poorly handwritten prescriptions, improper terminology, ambiguous orders, and omitted information. A study conducted by Bobb and colleagues assessed the potential impact of CPOE and found that 64.4% of prescribing errors were likely to be prevented with CPOE, including 43% of the potentially harmful errors.[3] In the present analysis, CPOE with properly implemented and optimized CDS would *likely* be able to intercept and possibly prevent the drug-allergy interaction errors and *possibly* intercept and prevent the wrong dose/overdosage errors.

CPOE and electronic health record (EHR) systems currently in place in healthcare facilities are probably unable to catch and prevent errors of omission occurring during the prescribing phase. Automated stopping (auto-stop) values, which are used to help safeguard patients against unnecessary and prolonged drug therapy, can also lead to unintended discontinuation and dose omissions if the prescriber fails to modify the default duration of therapy within the electronic order.[14,15] The risk of placing orders in the wrong patient record exists in electronic systems as it does in paper-based systems. In fact, an increased risk of placing orders on the wrong patient may be one unintended consequence of CPOE. A 2013 analysis of PA-PSRS data found that the predominant type of wrong-patient prescribing errors involved a prescriber ordering a medication on the wrong chart.[16] According to a study conducted by Adelman et al., about 14 wrong patient electronic orders were placed every day in a large hospital system. These errors are sometimes due to juxtaposition, whereby the wrong patient may be selected from a list of names, but are more often caused by interruptions and having more than one patient's electronic record open.[17] Wrong drug or strength selection from a dropdown menu or picklist is another failure mode that may be introduced with CPOE. An analysis of electronic prescribing systems in two hospitals found that incorrect selection errors from a drop-down menu were the most frequent mechanism of CPOE system-related medication errors.[18]

CDS systems provide various forms and levels of alerts to indicate possible issues with medication orders. However, when these alerts are not analyzed and prioritized, the excessive number of alerts displayed may lead to alert fatigue or may prompt hospitals to turn off alerts, or a subset of alerts, altogether. Alert fatigue may cause prescribers to override many of the safety features afforded by CPOE and CDS, including alerts of high severity when they are buried among irrelevant or less significant alerts. A 2015 study of PA-PSRS data found that CPOE was the second most common technology involved in medication error event reports related to overrides.[19]

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Understanding vulnerabilities in CPOE and CDS systems is key to developing effective preventive measures. A 2010 analysis of 62 US hospitals' CPOE systems found that nearly 50% of prescribing errors that would result in patient fatality were unable to be detected.[20] More recently, researchers tested the vulnerability of thirteen CPOE systems to erroneous medication orders and found that nearly 80% of the unsafe orders could be placed. Over half of the orders were easily entered or entered with minor workarounds and only 26.6% of the unsafe orders generated warnings.[21] Evidence of high rates of adverse drug events in a highly computerized hospital further illustrates the need to ensure that electronic systems are operating efficiently before replacing manual safety checks.[22] To ensure CPOE systems are performing well and as expected, it is important for organizations to regularly monitor, test, and enhance these systems. The *Computerized Prescriber Order Entry (CPOE) System Evaluation Toolkit* was developed as a supplement to this *Advisory* to help organizations test their CPOE and CDS systems, to better understand their ability to detect unsafe orders and their management of high severity alerts. The Toolkit is available http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

Limitations

In-depth analysis by the Authority of Serious Events resulting from medication prescribing errors is limited by the information reported through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete. Information about underlying patient conditions, which may have impacted dose calculations for individual patients, such as opioid tolerance, was not consistently available. Information regarding the adoption and use of CPOE and CDS by the reporting facilities was also not available.

RISK REDUCTION STRATEGIES

While prescribing errors may be intercepted during subsequent phases of the medication use process, these errors can reach patients and cause serious harm, including death. It is important that stakeholders, including healthcare organizations and health information technology vendors, continue to develop, implement, and refine CPOE and CDS systems to better support prescribers and make it easier to select the correct action. Consider the strategies described below, which are based on a review of current literature, events reported to the Authority, and observations from the Institute for Safe Medication Practices (ISMP).

Patient Information

- Ensure that current and complete allergy information, including descriptions of the reactions, is readily available to all prescribers when they are ordering medications.[9]
- Establish a forcing function to make the allergy, as well as a description of the reaction to the allergen, mandatory entries into the organization's CPOE system.[9]
- Encourage prescribers to verify the patient's identity using two identifiers when prescribing drug therapy.[23]
- Standardize the baseline patient information, including weight in kilograms and laboratory values (e.g., serum creatinine), needed to order medications that require adjustment based upon patient characteristics (e.g., anticoagulants), and have a standard process in place to update this information in the EHR.[24]
- Implement functionality to improve the capture and accuracy of all comorbid conditions in a structured diagnosis/problem list field in the patient's EHR, and to link this information to the order entry system, to promote appropriate screening when new drugs are prescribed.[25]

Drug Information

- Develop an expedited admission reconciliation process for specific high-alert medications such as insulin, anti-arrhythmic agents, and other medications that may need to be given to a patient before the generally-accepted, 24-hour medication reconciliation time limit.[26]
- Each time a patient moves from one care setting to another, review previous medication orders alongside new orders and plans for care, and resolve any discrepancies.[27]
- Establish and enforce institutional, therapy-specific dose limits. Such limits could include the maximum amount for a single dose, cumulative dose for a 24-hour period, and for each component of a combination product.[28]
- If your organization has an automatic stop policy, evaluate your organization's list of drugs and the associated indications governed by this policy to determine whether a valid need exists for the drugs to remain on the list. [14]

Communication of Drug Information

- Limit the use of verbal orders to emergency situations.[16]
- Encourage prescribers to avoid using error-prone abbreviations (e.g., "u" for units) in all written and electronic communication.[29]

Standardization

- Use carefully developed standard order sets to minimize incorrect or incomplete prescribing, standardize patient care, and ensure clarity when communicating medication orders.[30]
- In order sets that include opioid drugs, guide prescribers to an appropriate opioid dose based on patient age and opioid tolerance by providing default doses for three types

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of patients: (1) most patients, (2) patients older than 64 years or with sleep apnea, and (3) opioid-tolerant patients.[31]

Environmental Factors

- Consider designing CPOE systems to allow prescribers to select the patient name from a list of patients assigned to him/her instead of a much larger list of patients.[23]
- Limit distractions during critical tasks such as medication selection.[32]
- Enhance the font size and readability of patient names on EHR screens.[23]

Staff Competency and Education

- Provide prescribers with education on medication allergies. Educational efforts need to focus on screening patients for potential allergic or other adverse reactions, recognizing an allergic reaction, and treating serious reactions.[9]
- After CPOE and CDS implementation, prioritize the most critical elements to plan for annual or semi-annual retraining and competency verification.[33]
- Assess staff competency related to the safe use of CPOE, CDS, and overrides, and provide education when indicated.[19]

Quality Processes and Risk Management

- Consider using the *Computerized Prescriber Order Entry (CPOE) System Evaluation Toolkit*, available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx, to test the facility's CPOE system to see whether potentially fatal errors—such as an order for daily oral methotrexate—are detected.
- Encourage prescribers to report CPOE-related errors including incorrect or incomplete CDS information and develop a standard process to make timely safety and quality enhancements.
- Measure the use of trigger drugs used to reverse the effects of medication overdoses (e.g., naloxone, vitamin K, glucagon, dextrose 50%) to increase detection of preventable adverse drug events (ADEs) that may have been caused by medication errors.[34] (Visit the Authority's website at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/opioids/Pages/ADEWorksheet.aspx to view or download a sample tool that can be used to identify and monitor actual or potential problems with the use of insulin, opioids, and anticoagulants.)
- Measure the use of trigger drugs used to treat allergic reactions (e.g., diphenhyDRAMINE, methylPREDNISolone, EPINEPHrine) to increase detection of preventable ADEs and determine whether there are other instances of patients with documented allergies erroneously receiving medications.[9]
- Improve the positive predictive value of alerts (e.g., the number of true positive alerts compared with all positive alerts), and adjust the presentation of the alerts (e.g., interruptive versus noninterruptive) according to the level of severity.[19]
- Develop a mechanism to identify and remove alerts that provide little or no clinical value, which may contribute to alert fatigue.[19]
- Examine the systems in place for notifying prescribers about automatic stop orders, the timing of the notification, and the process for review.[14]

CONCLUSION

Of the serious prescribing errors reported to the Authority since the inception of the program in 2004, the most common error types reported were: wrong dose/overdosage, prescribing a medication to which a patient has a documented allergy, dose omission, and prescribing a medication for the wrong patient. Well designed and implemented CPOE and CDS systems are *likely* to intercept and possibly prevent nearly one-quarter of these errors; however, evidence shows that poorly designed and implemented CPOE and CDS systems may introduce other types of errors. Opportunities exist for increasing the benefits that can be realized by CPOE with CDS. However, prescribing is just one phase of the medication use process. Implementing layers of risk-reduction strategies across all phases of the medication use process may help prevent prescribing errors from reaching the patient.

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LEARNING OBJECTIVES

- Identify the most common prescribing error event types associated with Serious Events, as reported to the Pennsylvania Patient Safety Authority.
- Predict what types of prescribing errors are likely, possible, and unlikely to be intercepted by computerized prescriber order entry (CPOE) with clinical decision support (CDS).
- Identify and assess risk reduction strategies that can be implemented to help prevent prescribing errors.

SELF-ASSESSMENT QUESTIONS

1. Which of the following prescribing error event types was most frequently reported to the Authority as a Serious Event?
   a. Wrong patient
   b. Wrong rate (IV)
   c. Wrong duration
   d. Wrong dose/overdosage
   e. Wrong dose/under dosage
2. Which of the following type of event or contributing factor is NOT likely to be prevented or intercepted by CPOE with properly implemented and optimized CDS?
   a. Incomplete orders
   b. Illegible handwriting
   c. Drug-allergy interaction
   d. Wrong dose formulation
   e. Adverse drug reaction
3. Which of the following prescribing errors is NOT likely to be intercepted by CPOE with properly implemented and optimized CDS?
   a. An emergency department physician ordered .5 mg HYDROmorphone IV; however, the handwritten order looked like 5 mg.
   b. A physician ordered sumatriptan 6 mg but did not include route or frequency. A new graduate nurse gave sumatriptan 6 mg IV.
   c. A physician was documenting care in one patient's electronic medical record. The physician then switched to print-on-demand order sheet, which pulled the wrong patient name to order sheet. Methadone 50 mg was ordered on the wrong patient.
   d. Verapamil 360 mg daily by mouth was ordered for a patient with atrial fibrillation. The pharmacy dispensed the immediate-release formulation, which was administered to the patient.
   e. A patient was taking prasugrel. The post-catheterization orders stated to administer clopidogrel. Both medications were given and the patient developed thrombocytopenia.
4. Which of the following is NOT a quality improvement strategy that can be used to optimize CDS for CPOE?
   a. Improve the positive predictive value of alerts, and adjust their presentation so interruptive alerts fire for alerts of low severity.
   b. After CPOE and CDS implementation, prioritize the most critical information about CPOE and CDS to plan for annual or semiannual retraining and competency verification.
   c. Develop a mechanism to identify and remove alerts that provide little or no clinical value.
   d. Provide a mechanism to enable prescribers to report CPOE-related errors including incorrect or incomplete CDS information, and develop a standard process to make timely safety and quality enhancements.
   e. Assess staff competency related to the safe use of CPOE, CDS, and overrides, and provide education when indicated.

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SELF-ASSESSMENT QUESTIONS (CONTINUED)

Question 5 refers to the following case:

> *The patient was admitted to the intensive care unit (ICU) with sepsis and a urinary tract infection. The patient was on methotrexate as an outpatient but the methotrexate was held during the ICU stay. The patient was later transferred to the telemetry unit. On the eighth day of the admission, the physician wrote for methotrexate 10 mg daily. The pharmacist entered the dose and the patient received 7 days' worth of the drug before the error was caught. The records from the rehabilitation facility where the patient came from were scanned over and they showed that the patient was taking methotrexate 5 mg on Sunday and methotrexate 5 mg on Monday for a total of 10 mg weekly. The patient experienced stomatitis, pancytopenia, was intubated and transferred to the ICU. The patient coded and expired.*

5. Which of the following risk-reduction strategies would NOT help prevent this prescribing error?
   a. Proactive testing of the facility's CPOE system to see whether potentially fatal errors (e.g., an order for daily oral methotrexate for non-oncologic indications) are detected.
   b. Implement functionality to improve the capture and accuracy of all comorbid conditions in a structured diagnosis/problem list field in the electronic health record, and link this information to the order entry system, to promote appropriate screening when new drugs are prescribed.
   c. Establish and enforce institutional, therapy-specific dose limits.
   d. Review previous medication orders alongside new orders and plans for care, and resolve any discrepancies each time a patient moves from one care setting to another.
   e. Measure the facility's use of trigger drugs (e.g., naloxone, vitamin K, glucagon, dextrose 50%) to reverse the effects of medication overdoses to increase detection of adverse drug events that may have been caused by preventable medication errors, and track performance over time.

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Process Assessment is Key to Prevention of Certain Ophthalmology Events

Mary C. Magee, MSN, RN, CPHQ, CPPS
Senior Patient Safety/Quality Analyst
Pennsylvania Patient Safety Authority

ABSTRACT

An estimated 24 million Americans have cataracts, making cataract removal and intraocular lens insertion one of the most common surgeries performed in the United States. Cataract surgery is safe, and serious injuries rarely occur. So when an increase in reports of Serious Events related to cataract procedures occurred in one year in Massachusetts, the Betsy Lehman Center for Patient Safety responded. The Center collaborated with a number of state and professional agencies, formed an expert panel, and consulted with the Pennsylvania Patient Safety Authority. The Authority found that from July 1, 2004, through June 30, 2015, Pennsylvania acute care facilities reported 4,307 events related to cataract procedures and 23 wrong-site anesthesia eye injections. Since July 2004, reporting of intraocular lens procedure–related events, which includes near misses and good catches, has steadily increased while the number of incorrect intraocular lens implant events has decreased. The Authority estimates the incidence of cataract-related surgical confusions in Pennsylvania at 61.8 per 1 million procedures for the July 1, 2004, through June 30, 2015, period. In response to a rising trend of intraocular lens–related reports, increased vigilance towards prevention is necessary. Active participation by engaged staff in executing the Universal Protocol—including engaging the patient—and use of an ophthalmology-specific perioperative checklist remain the recommended best practices to prevent wrong eye identification, incorrect lens implantation, and wrong-site anesthesia eye injections. (Pa Patient Saf Advis 2016 Sep;13[3]:92-99.)

INTRODUCTION

In 2015, representatives of the Betsy Lehman Center (The Center) for Patient Safety, a non-regulatory Massachusetts state agency, contacted the Pennsylvania Patient Safety Authority about cataract-surgery events in Massachusetts hospitals and ambulatory surgical facilities. The Center staff were interested in comparing Massachusetts' trends with those in Pennsylvania. Of interest were the implantation of intraocular lenses (IOL) not intended for the patient and wrong-site anesthesia eye injections; an increase in these types of errors had been reported to Massachusetts regulators the previous year.

Implantations of IOLs not intended for the patient and wrong-site anesthesia eye injection events continue to be reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS). More than 4,300 events related to cataract procedures were reported between July 2004 and June 2015. Although the overall number of IOL-related reports has been increasing since 2004, the number of incorrect lens implants has been decreasing and wrong-site eye injections have declined since 2004.

There is sparse research for comparison; however, in a study of 106 "surgical confusions"* in ophthalmology in New York state over a 23-year period, the most common confusions cited were wrong lens implant (63%) and injection of anesthesia into the incorrect eye (13%).[1] The study further analyzed claims data for a five-year period (2001–2005) and suggested an incidence of 69 surgical confusions per 1 million eye operations.[1]

Because of Pennsylvania's adverse event database and broader scope of reporting requirements, a comparison of trends of these types of events could prove useful to The Center for interpreting the Massachusetts' serious reportable events (SREs)† data.[2] The inquiry prompted the Authority to perform an analysis related to implantation of IOLs not intended for the patient and wrong-site anesthesia injections in Pennsylvania.

METHODS

Analysts queried PA-PSRS for intraocular cataract–related events and events meeting the criteria for wrong-site surgery‡ in acute care facilities (i.e., acute care hospitals, ambulatory surgical facilities) for the period July 1, 2004, through June 30, 2015. This time frame is consistent with the Authority's previously published wrong-site surgery analyses and aligns with the time frame of procedure data available from the Pennsylvania Health Care Cost Containment Council (PHC4).

Analysts individually reviewed the event report narratives and searched the cataract-related event details for the terms, "cataract," "lens," "IOL," "wrong," "incorrect," "tear," "pressure," and "IOP."

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* Surgical confusions were defined as: wrong implant, wrong-eye block, wrong patient or procedure, wrong eye, or wrong transplant.

† Massachusetts mandates the reporting of Serious Reportable Events as defined by the National Quality Forum: http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx

‡ The definition used for the Authority's wrong-site surgery program follows the National Quality Forum's definition as outlined in the Serious Reportable Events In Healthcare—2011 Update: A Consensus Report.

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Analysts requested a custom report from PHC4* using Current Procedure Terminology (CPT), Healthcare Common Procedure Code System (HCPCS), supplementary classification of factors influencing health status and contact with health services (V-codes), and the International Statistical Classification of Diseases and Related Health Problems (ICD-9) procedure codes for outpatient and inpatient eye and cataract procedures from July 2004 through June 2015. These data were analyzed and used to estimate rates and incidences for Pennsylvania.

To estimate incidences of surgical confusions in Pennsylvania commensurate with New York state claims data of Simon et al., a subset of PA-PSRS and PHC4 data was analyzed for the five-year period of 2010 to 2014. This time frame was selected because July 2004 was the first full month in which events were reported through PA-PSRS, it reflected the most recent five full years of PA-PSRS and PHC4 data available at the time of this study, and the coding adjustments were fully implemented (see Limitations).

* 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 the Authority in an effort to further PHC4's mission of educating the public and containing health care costs in Pennsylvania. PHC4, its agents, and staff have made no representation, guarantee, or warranty, express or implied, that the data – financial, patient, payor, and physician specific information – provided to this entity, are error-free, or that the use of the data will avoid differences of opinion or interpretation. This analysis was not prepared by PHC4. This analysis was done by the Pennsylvania Patient Safety Authority. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

RESULTS AND ANALYSIS

Incorrect Intraocular Lens Implants

The query resulted in 4,962 events; 4,307 met the criteria for analysis related to cataract procedures.

Of the 4,307 events

- 77 (1.8%) were associated with incorrect IOL implants (i.e., not intended for the patient)
- 32 (0.7%) were associated with elective lens exchanges
- 7 (0.2%) were associated with an expired lens being implanted
- 1 (0.02%) was surgery performed on the wrong eye

Although the number of IOL-related reports has increased since 2004, the number of incorrect lens implants has decreased (Figures 1 and 2). An analysis of wrong-site eye injection events revealed that the annual number reported has also declined since 2004. The causes of these events were not described in the event detail in sufficient quantity to make extrapolations possible.

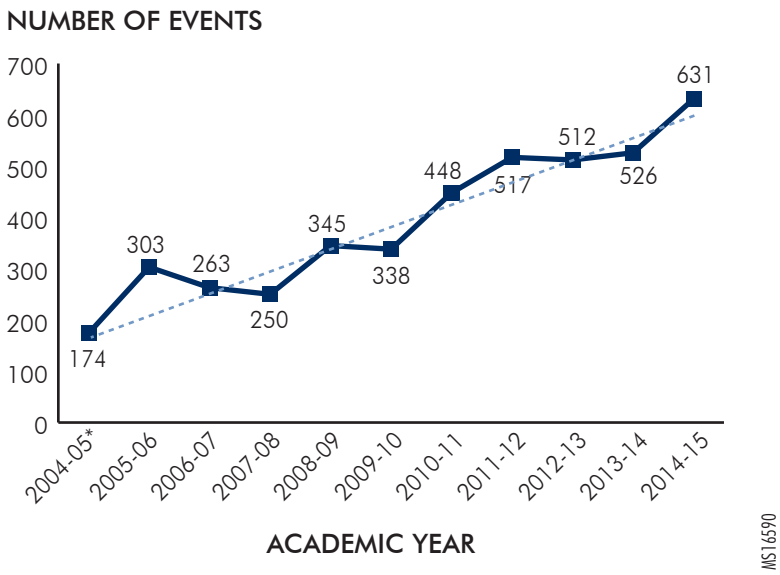
Examples of reported incorrect IOL implants include the following:†

> *During the postoperative visit, the surgeon noted that the wrong IOL power was inserted into the correct eye. When the causes were reviewed, it was discovered that the surgeon wrote the correct diopter lens on the patient's medical record; however, the incorrect lens was selected by the circulator. Additionally, the final verification had not been completed prior to start of procedure.*

> *The patient was scheduled to have a cataract removal of the left eye with an IOL implant of diopter 12.0. Instead the patient received a 23.5 diopter. The error was discovered when the nurse was preparing the*

† The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Figure 1. Number of Intraocular Lens Procedure-Related Events Reported by Academic Year* through PA-PSRS (N = 4,307)



* July 2004 was the first full month in which events were reported through PA-PSRS.

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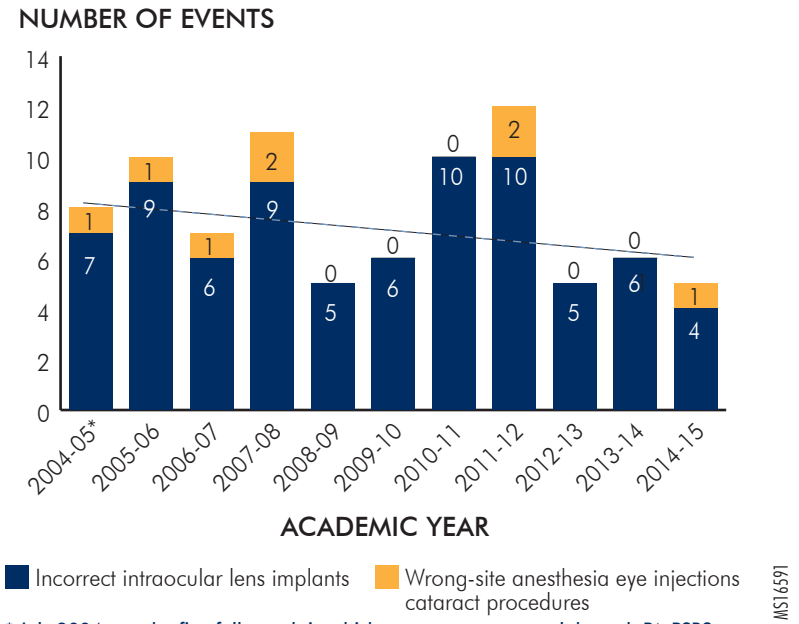
Figure 2. Incorrect Intraocular Lens Implants (N = 77) and Wrong-Site Anesthesia Eye Injections involving Cataract Procedures (n = 8) Reported through PA-PSRS by Academic Year*



* July 2004 was the first full month in which events were reported through PA-PSRS.

OR suite for the next surgery. The patient was returned to the operating room for insertion of the correct lens.

Detection

Of the 77 incorrect IOL implant events:

- 53 (68.8%) mentioned when the error was detected
  - 34 (64.2%) of the events were discovered on the day of surgery
  - 19 (35.8%) of the events were discovered after the day of surgery (e.g., post-operative visit in the physician's office)
- 48 (62.3%) reports indicated that the patient returned to the operating room or had an additional procedure performed

Lens Characteristics

Analysts reviewed the 77 events involving incorrect IOL implants. Forty-four (57.1%) of the 77 reports mentioned the lens strength, type, size, or other as being incorrect (these data are not mutually exclusive). Of the 44:

- 33 (75.0%) reports mentioned the lens power
- 9 (20.5%) reports mentioned two or more lens-related items
- 8 (18.2%) reports mentioned the lens type
- 5 (11.4%) reports mentioned the lens size
- 1 (2.3%) report mentioned lens displacement or other effect and was classified as *Other*

Harm

Analysts reviewed the 77 events by harm score.* Figure 3 shows the percentage of IOL implantation events not intended for the patient by harm score. Thirty-four (44.2%) were reported as an unsafe condition (A-D) or no harm event, and 43 (55.8%) events were reported as contributing to or resulting in temporary harm (E-F) and required either treatment or intervention or initial or prolonged hospitalization.

Facility

The majority of events, 51 (66.2%), were reported by ambulatory surgical facilities, where most lens-implant procedures are performed.

Wrong-Site Anesthesia Eye Injections

The PA-PSRS query resulted in 23 event reports that met the criteria for a wrong-site event. Nineteen (82.6%) were associated with wrong-side anesthesia injections (i.e., wrong eye identified) and 4 (17.4%) were associated with unintended anesthesia injections of the correct eye; for example, the following errors were found:

- Re-injection of an anesthetic instead of an antibiotic
- Injection of the wrong concentration and mixture of an anesthetic
- Injection of the wrong anesthetic
- Injection of the anesthetic prior to marking the pupil

Discipline and Type of Anesthesia Injection

Analysts reviewed the event detail of the reported events to determine which disciplines performed the injection and what types of anesthesia injection were involved. The majority, 17 (73.9%) of the 23, were performed by a surgeon, and 6 (26.1%) were performed by an anesthesiologist.

* The Authority's event-reporting system uses an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention harm index and the Veterans' Administration National Center for Patient Safety severity assessment code system to distinguish between harm and no-harm events. The Pennsylvania Patient Safety Authority Harm Score Taxonomy is available exclusively online at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12(1)/PublishingImages/taxonomy.pdf

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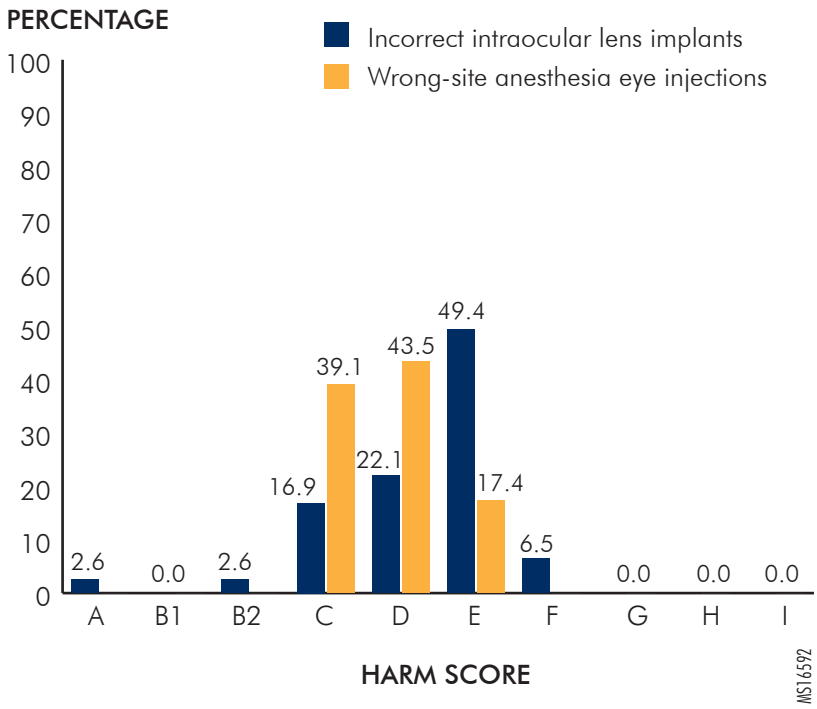
Figure 3. Incorrect Intraocular Lens Implant Events (N = 77) and Wrong-Site Anesthesia Injections (n = 23) by Harm Score Reported through PA-PSRS, July 1, 2004, through June 30, 2015



Of the 17 injections performed by a surgeon:

- 14 (82.4%) were wrong-side anesthesia blocks, of which 4 specifically mentioned the location
  - Two were retrobulbar injections
  - One was a posterior auricular injection
  - One was a peribulbar injection
- Three (17.6%) were unintended-eye injections administered in the correct eye, of which one specifically mentioned the location
  - One was an inferotemporal quadrant injection behind the limbus

Of the six injections performed by an anesthesiologist:

- Five (83.3%) were wrong-side anesthesia blocks of which four specifically mentioned the location
  - Two were retrobulbar injections
  - One was a periocular injection
  - One was a peribulbar injection
- One (16.7%) was an injection of the anesthetic before the pupil was marked for the specific lens implant (i.e., against standard procedure for this facility)

Examples of reported wrong-side anesthesia injections include the following:

> *A patient was scheduled to have a cataract removal. The surgeon performed a block to the incorrect eye after verifying the incorrect eye with the patient. The error was discovered prior to the cataract removal, and the correct eye was then anesthetized and operated on.*

> *When the patient was asked which eye he was having his cataract surgery on, he was unsure. The medical record was checked and confirmed the left eye was to be operated on. The patient suddenly became restless and began retching. It took several minutes for the patient to settle down. During this time, the non-operative eye was mistakenly marked, and the anesthesia block was given to the incorrect eye. This mistake was identified once the patient arrived in the OR. The correct eye was then anesthetized.*

Surgical Procedure

Analysts reviewed the event detail of the 23 wrong-site injections to determine the surgical procedure involved. A slight majority (n = 12, 52.2%) mentioned the surgical procedure performed and of those:

- 66.7% (n = 8) were cataracts
- 16.7% (n = 2) were vitrectomies
- 8.3% (n = 1) was an ectropion correction
- 8.3% (n = 1) was an endophthalmitis

See Figure 2 for the number of wrong-site injections of anesthesia involving cataract procedures.

Patient Harm

Analysts reviewed the 23 events by the reported harm score. Figure 3 shows the percentage of wrong-site eye injection events by harm score. The majority, 19 (82.6%), were reported as an unsafe condition or no harm event.

Facility Type

The majority of events, 12 (52.2%), were reported by hospitals.

DISCUSSION

National and State Statistics

By current estimates 20 million to 24 million Americans have cataracts.[3,4]

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The National Eye Institute projects that cataracts will affect more than 38 million Americans by 2030 and more than 50 million by 2050.[4] Annually in the United States and Pennsylvania, an average of 3 million and 149,000 cataract procedures are performed, respectively.[4,5] In a 2006 study on wrong-site surgeries, Seiden and Barach analyzed reports from four databases spanning one year and determined that "cataract procedures were the second most common wrong-site incidents."[6]

Healthgrades reports that cataract removal is the number one procedure performed in the United States.[7] Cataract surgery is safe, serious injury is rare, and most patients report an improved quality of life after the procedure.[8,9]

In Pennsylvania for the study period July 1, 2004, through June 30, 2015, for which PHC4 procedure data are available, the incidence of surgical confusions is 61.8 per 1 million cataract procedures (see Table for types of events).

It is difficult to make comparisons or benchmarks because of the lack of standardized definitions and dearth of research and statistics about intraoperative cataract procedure events. Simon et al. used the number of eye procedures, not cataract procedures, and suggested an incidence of 69 surgical confusions per 1 million *eye* operations in New York state.[1] In comparison, the Authority estimates 41.0 per 1 million *eye* procedures and 47.6 per 1 million *cataract* procedures for a comparable five-year period (2010 through 2014). Cataract procedures make up 86.1% of all eye procedures for this comparative time period.[5]

As noted, the reporting of IOL procedure–related events, including good catches such as preoperative identification of incorrect eye or lens power documentation, has steadily increased since reporting began in 2004. The overall increase in reporting may be related to a corresponding increase in eye and cataract procedures in Pennsylvania.[5] However, the trend of incorrect IOL implant events and wrong-site anesthesia eye injections has gradually decreased.

It is encouraging to note that Pennsylvania hospitals and ambulatory surgical facilities are reporting cataract-related Incidents. This reporting trend suggests that facility staff are learning from Incidents, the Authority's equivalent of good catches and near misses, which is a characteristic of high reliability organizations.

In the Authority's most recent published update on wrong-site eye surgery, 174 events were related to anesthesia blocks.[10] Of those events, 23 (13.2%) were wrong-site anesthesia eye injections. The Authority estimates an incidence of wrong-site anesthesia injections is 14.1 per 1 million cataract procedures in Pennsylvania for the period July 1, 2004, through June 30, 2015.

Table. Incidence of Cataract-Related Surgical Confusion Events as Reported through the Pennsylvania Patient Safety Reporting System in the state, July 1, 2004, through June 30, 2015 (N = 101)

TYPE OF EVENT	NUMBER	INCIDENCE PER 1 MILLION CATARACT PROCEDURES
Incorrect intraocular lens implant	77	47.2
Wrong-site anesthesia injection	23	14.1
Wrong eye surgery	1	0.6

Note: 1,633,039 = Number of cataract procedures performed in Pennsylvania, July 1, 2004, through June 30, 2015, provided by custom report from the Pennsylvania Health Care Cost Containment Council. 2016 Jun.

Interstate Agency Cooperation

The Center was established to coordinate and strengthen patient safety efforts in Massachusetts through data analysis, consumer engagement, communications, and sharing of best practices.[11]

In 2014, 11 serious reportable events (SREs) related to cataract surgeries had been reported to the Massachusetts Department of Public Health. In a review of data from the previous five years, The Center discovered that "the most frequent type of SRE associated with cataract surgery was implantation of the incorrect IOL."[8] "The panel determined that system failures appeared to be involved in incidents that resulted in either implantation of IOLs not intended for the patient or wrong-site injections of anesthesia."[12] The Center, working closely with the Massachusetts Department of Public Health, the Massachusetts Society of Eye Physicians and Surgeons, and the Massachusetts Society of Anesthesiologists, issued an advisory to hospitals and ambulatory surgery facilities informing them of what was being reported, why they were being informed, what next steps were being taken, and what the facilities could do to prevent patient harm.[12] Additionally, The Center assembled an expert panel of anesthesiologists, ophthalmologists, nurse administrators, and patient advisors to analyze the contributing factors to these events and to identify strategies to reduce risk.[12]

Similar to what was done in Massachusetts, in Pennsylvania, the Authority identified reports of wrong-site anesthesia eye injections and a wrong-site eye surgery events. In Pennsylvania the harm scores associated with these events indicated a range from unsafe conditions to temporary patient harm.

Risk Reduction Strategies

Checklist Advocated

Relying on memory alone to confirm surgical details can increase the likelihood of errors.[13,14] In a study by Pikkel et al.,

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cataract surgeons attempted to identify the correct operative side without using a preoperative verification process. "Before entering the operating room (OR) surgeons were asked to identify the correct operative side by using only the patient's name and then upon entering the OR, the surgeons were asked to identify the correct operative side by looking at the patient's face standing near the patient but not close enough to see the dilated pupil. The surgeons incorrectly identified the operative side in 27% of the cases using name only and in 17% of the cases looking at the patients' faces."[15]

The use of a surgical checklist enhances the likelihood of identifying safety hazards.[16,17,18] Simon asserts that the use of the Universal Protocol would have prevented wrong-lens implants, wrong-eye surgeries, and wrong-eye anesthesia blocks in 85% of the cases studied in New York state.[1] The American Academy of Ophthalmology (AAO) convened a wrong site task force and in 2014 revised its recommendations for preventing wrong-site ophthalmology surgery and updated its Ophthalmic Surgical Safety Checklist.[19,20] AAO specifies steps to follow prior to the day of surgery (e.g., the order for surgery and communication with surgery staff) and on the day of surgery (e.g., consent process, hard stop empowerment, marking the operative eye in the preoperative area, and the time-out).[19] AAO also issued a list of special considerations for the various types of eye surgeries that depend on preoperative calculations; for IOL surgery, recommendations include performing an independent double check of IOL powers and documenting "patient's name, eye, and IOL power on a white board or taped to the operating microscope."[19]

The Authority's resources for preventing wrong-site surgery are available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx. These resources include preoperative checklists such as the Surgeon's Office Checklist to Prevent Wrong-Site Surgery[21] and the Self-Assessment Checklist for Program Elements Associated with Preventing Wrong-Site Surgery.[22] Previous Authority publications on this topic have provided best practices to decrease the likelihood of implanting the incorrect lens or performing wrong-site surgery.[23,24] In response to concerns that staff are just "going through the motions" of the Universal Protocol, the Authority created and distributed a poster, titled *Patients and Surgical Teams Work Together to Avoid Wrong-Site Surgery* that engages the patient in the confirmation process (http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/poster_avoid%20wss.pdf).[10]

Expert Panel Strategies

The Center's expert panel key recommendations to prevent wrong-lens, wrong-eye, and wrong-patient errors and injuries related to ocular anesthesia appear below.[25]* Please refer to the panel's full report for details.

- To prevent wrong-lens, wrong-eye, and wrong-patient errors:
  - ☐ Institute a formal lens management policy that defines uniform processes for ordering, storing, selecting, and verifying IOLs
  - ☐ Adopt a uniform, facility-wide policy for marking the operative eye, and perform a separate time-out prior to a nerve block
  - ☐ Use multiple patient identifiers and engage patients using active verification
  - ☐ Perform robust time-outs before every key step in the procedure
- To prevent injuries related to anesthesia:
  - ☐ Use the least invasive form of anesthesia appropriate to the case
  - ☐ Stay current on evidence-based practices for minimizing the risk of patient harm from anesthesia
  - ☐ Engage patients in decisions about anesthesia and sedation
  - ☐ Strengthen "onboarding" of new and contracted anesthesia staff, including thorough credentialing, formalized orientations, and observed eye block assessments

Performance Improvement

Accrediting and licensing agencies require ongoing assessments of safety and quality processes.[26,27] Organization and medical staff leadership may proactively conduct periodic observational surveillance of compliance with perioperative processes including the Universal Protocol. Additionally, eligible providers can report quality-of-care compliance through the Physician Quality Reporting System.[28]

Should a wrong-site eye surgery or other adverse event or near miss occur, facility staff may benefit from studying the event and analyzing the contributing factors and root causes. Evaluating and reinforcing successful processes may also be of value.[29] Collecting and analyzing data over time allows facilities to follow trends and measure improvements. The Authority has a Wrong-Site Surgery Error Analysis Form that provides a format to capture "information about wrong-site surgery, near misses, and actual occurrences"[30] and a template for Gap Analysis and Action Plan to Prevent Wrong-Site Surgery; the template allows facilities to compare surgical observations to evidence-based principles, goals, and measurement standards.[31] Information learned from these analyses can be used to reduce safety hazards, implement risk reduction strategies, and reward successful interventions.[29]

LIMITATIONS

Relevant information is derived from the event type taxonomy and from free-text narratives; categorization and

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narrative detail are provided by the report submitter.

Every effort was made to ensure that applicable procedure codes were identified to present a comprehensive depiction of eye and cataract procedures in Pennsylvania, including recognition that coding adjustments occurred during the data collection period and impacted the calculation of the number of cataract procedures before the third quarter of 2007. As PHC4 explains, "Prior to Q3-2007, PHC4 outpatient data was reported with a primary procedure and additional five secondary procedure code fields; giving facilities the option of submitting ICD-9 [inpatient] codes, CPT codes (HCPCS LEVEL I) and HCPCS LEVEL II codes. Effective Q3-2007 facilities must report either HCPCS LEVEL I OR HCPCS LEVEL II codes. ICD-9 codes are no longer valid for outpatient data."[5] Although every effort was made to identify a comprehensive list of eye and cataract procedures, some may have been unknowingly excluded.

CONCLUSION

Events of incorrect IOL implants and wrong-site anesthesia eye injections are still reported through the Authority, even though the incidence and level of harm are low. However, events have steadily increased, indicating the opportunity to evaluate processes to prevent the potential for these events. Individual facilities will find it beneficial to trend and analyze their own data and perioperative practices. Information learned can be used to reduce safety hazards and implement risk-reduction strategies.

The Center's expert panel identified a number of procedure-specific recommendations to reduce the likelihood of error in cataract surgery. Encouraging patient and family engagement with active participation by staff in the implementation of the Universal Protocol and use of an ophthalmology-specific perioperative checklist remain the recommended best practices for preventing incorrect lens implantation, wrong-eye surgery, and wrong-site anesthesia eye injections.

The Authority welcomed the opportunity to share data trends and information with The Center in Massachusetts, a colleague organization with complementary patient safety goals. Willingness to contact resources, share knowledge, and cooperate with one another towards the common goal of improving cataract-related patient safety not only enhances interagency expertise but furthers patient safety work on a national level.

Acknowledgments

Theresa V. Arnold, DPM, Pennsylvania Patient Safety Authority, contributed to data analysis and inter-state agency collaboration for this article.

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Blood Transfusion Events—Lessons Learned from a Complex Process

Deborah Dubeck, RN, MPH
Patient Safety Analyst
Pennsylvania Patient Safety Authority

ABSTRACT

From January 1, 2010, through December 31, 2014, healthcare facilities reported 19,687 events involving a blood transfusion to the Pennsylvania Patient Safety Authority. Of these reports, 19,492 (99%) were categorized as Incidents that did not result in patient harm. A majority of the events (16,513) were reported under the category of transfusions.

The American Red Cross reports that more than 30 million transfusions of blood components are performed each year in the United States. Transfusion is not without serious risk, ranging from mild reactions to life-threatening conditions. Transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), and hemolytic transfusion reactions (HTR) represent the most common morbidity and mortality events reported nationally.

Although not all transfusion-related events are caused by errors, this complex process has many critical decision points at which errors can occur; preparing and administering a transfusion is a multistep and multidisciplinary process. Pennsylvania Patient Safety Reporting System (PA-PSRS) data show staff are identifying errors and making corrections prior to the event resulting in harm to the patient. Hemovigilance surveillance programs, emerging both internationally and in the Unites States, seek to learn from both Serious Events and Incidents, to continually improve the safety of blood transfusions. Advances in donor screening; improved testing of the blood supply; use of emerging technology, such as barcoding; and improvements in transfusion medicine practices have been found to increase the safety of blood transfusion. (Pa Patient Saf Advis 2016 Sep;13[3]:100-107.)

INTRODUCTION

The American Red Cross reports that more than 30 million transfusions of blood components are performed each year in the United States.[1] Blood transfusions are safer today than in the past because of advances in donor screening; improved testing of the blood supply; use of emerging technology, such as barcoding; and improvements in transfusion medicine practices.[2,3] However, transfusion is not without risk. Complications can range from mild reactions to life-threatening conditions, such as transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO); and hemolytic transfusion reactions (HTR).[3-5] Administering a blood transfusion is a complex process, involving multiple steps and staff from multiple locations from the time of donation through administration.[2,6-9] Studies have shown that mislabeling the blood sample and patient misidentification continue to occur, resulting in the wrong blood getting to the wrong patient.[10] Mistransfusion, giving the wrong blood to the wrong patient, remains a major cause of transfusion-related illnesses and fatalities.[6,9,11,12] The final check of the patient's identity and the product label are critical steps in preventing mistransfusion.[7,9,10]

The US Food and Drug Administration (FDA) is responsible for the regulatory oversight of the US blood supply. Since the 1950s, the American Association of Blood Banks (AABB) has published standards to improve the quality and safety of blood banks and transfusion services. Additionally, the College of American Pathologists (CAP) has established standards for laboratories, and both organizations provide accreditation programs for blood banks, laboratories, and transfusion services.

Hemovigilance programs began in France in the early 1990s. The goal of the program primarily was to improve safety of blood transfusions, but also quiet the public's fear after incidents of HIV-tainted blood were reported in France.[13] In 2010 the Centers for Disease Control and Prevention (CDC), with support from the AABB, launched the National Healthcare Safety Network biovigilance component hemovigilance module surveillance protocol (NHSN HVM).[14,15] This voluntary program implements national surveillance protocols for the entire transfusion process, from donor to product administration. CDC also analyzes adverse events and makes evidence-based public health recommendations for the transfusion community.[9,14]

Pennsylvania healthcare facilities reported transfusion-related events to the Pennsylvania Patient Safety Authority. The Pennsylvania Patient Safety Reporting System, PA-PSRS, is unique among state reporting systems and collects reports of unsafe conditions and events without harm, as well as events with harm.[16] The literature supports that, besides reviewing serious and fatal events, studying transfusion incidents that don't harm the patient can help improve safety in transfusion medicine.[6,17]

METHODS

Analysts queried the Authority's PA-PSRS database for event reports submitted from January 1, 2010, through December 31, 2014. The search to identify events included events coded as "transfusion" event type or containing "transfus" in the narrative details. Events were excluded if the transfusion was unrelated to use of blood or a blood product or if information about the transfusion was incidental. The remaining events were analyzed by calendar year, gender, harm score,* age, event type, and subcategories of transfusion events.

* The Pennsylvania Patient Safety Authority Harm Score Taxonomy is available online at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12(1)/PublishingImages/taxonomy.pdf.

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RESULTS

The initial query found 21,884 reports of events involving transfusions; 2,197 were excluded, leaving 19,687 events for further review. The majority of transfusion events (99.01%, n = 19,492 of 19,687) were reported as Incidents and did not result in harm to the patient. Only 0.99% (n = 195) were reported as Serious Events, resulting in patient harm. Of the 10 events associated with severe harm or death, only 1 event was attributed to the patient receiving the wrong blood (see Figure 1). Transfusion events occurred most frequently in patients age 70 to 79 years (18.96%, n = 3,732) followed by age 60 to 69 (18.57%, n = 3,655) and age 80 to 89 (17.55%, n = 3,456; see Figure 2). The most frequently reported event type was transfusion event (83.88%, n = 16,513) followed by an error related to procedure/treatment/test (6.66%, n = 1,312) and complication related to a procedure/treatment/test (4.36%, n = 858; see Figure 3).

For those events entered as transfusion (G) events, the most common subcategories were:

- Events related to sample collection (29%)
- Events related to blood product administration (20%)
- Apparent transfusion reactions (16%)
- Events related to blood product dispensing/distribution (9%)

The following are samples of events reported to the Authority,* beginning with examples of events related to sample collection:

> *Two tubes of blood drawn by phlebotomy for type/screen on ER [emergency room] patient. The tubes arrived in blood bank with only the patient's last name. Medical record*

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Figure 1. Transfusion-Related Reports by Harm Score, 2010-2014, as Reported to the Pennsylvania Patient Safety Authority (N = 19,687)

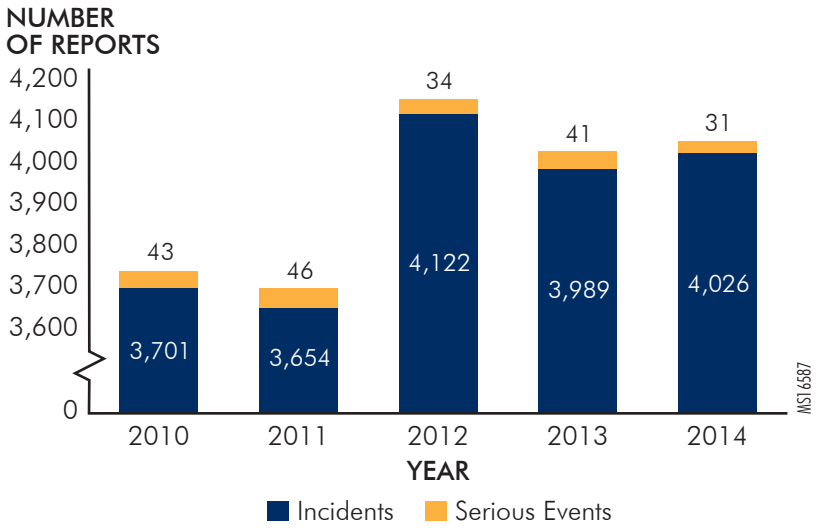

Figure 2. Transfusion-Related Reports by Age, 2010-2014, as Reported to the Pennsylvania Patient Safety Authority (N = 19,687)

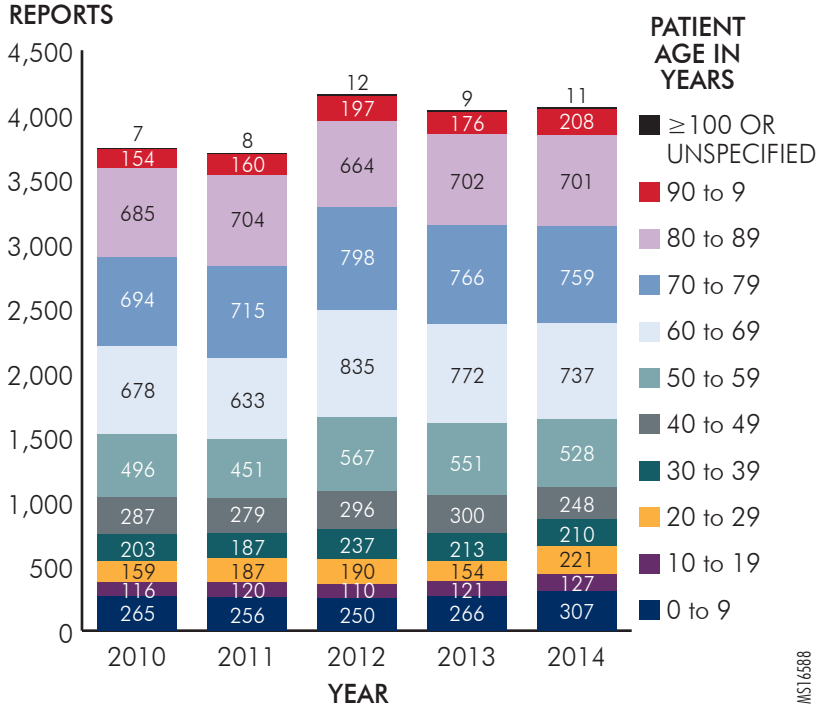

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Figure 3. Transfusion-Related Reports by Event Type, 2010-2014, as Reported to the Pennsylvania Patient Safety Authority (N = 19,687)

EVENT TYPE	2010	2011	2012	2013	2014	TOTAL
Medication error	72	71	68	56	61	328
Adverse drug reaction	10	3	9	11	11	44
Equipment/supply/device	10	9	16	10	13	58
Fall	10	11	6	18	13	58
Error related to procedure/treatment/test	262	277	241	243	289	1,312
Complication related to procedure/treatment/test	160	174	167	174	183	858
Transfusion	3,114	3,048	3,553	3,409	3,389	16,513
Skin integrity	3	3	11	8	9	34
Other	103	104	85	101	89	482
Total	3,744	3,700	4,156	4,030	4,057	19,687

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number, encounter number, date, and initials were missing. Tubes rejected by blood bank and phlebotomy notified to recollect patient. Standard operating procedures for drawing blood bank specimens were not followed.

Specimen received for type and cross that had no encounter number on it. When I spoke to the OR [operating room] staff they stated that the patient didn't even have an armband on. I alerted them that they need to armband the patient, collect, and properly label a new specimen.

The following reports are examples of events related to blood product administration:

Patient received an incorrect unit of blood during emergency transfusion. Blood was sent for another patient. Both patients had the same blood type. Patient to receive 2 units of packed red blood cells, each unit over 4 hours. Patient received 2 units within 4 hours due to misread of the order. Patient experienced shortness of breath and oxygenation desaturation.

The following reports are examples of events of an apparent transfusion reaction:

Patient with sickle cell anemia developed chest pain and chills after transfusion of 1 unit red blood cells. The patient was transferred to the emergency department. Cardiac markers were negative. Patient was given Benadryl and steroids intravenously. Patient improved and was discharged.

Patient developed fever, hypotension, and oxygen saturation of 77% following blood product transfusion. Patient was transferred to the intensive care unit and required a higher level of care. Physicians believe the patient developed transfusion related acute lung injury (TRALI), which is a risk of transfusion.

The following reports are examples of events related to blood product dispensing/distribution:

Blood dispensed by blood bank was for the next case scheduled in the OR. Staff retrieving blood did not have a patient sticker to verify whether the blood is for the correct patient. The error was discovered before the patient received the transfusion.

While checking 4 units of FFP [fresh frozen plasma], found 2 units that had expiration dates that did not match what was recorded on the paperwork. Units returned to the blood bank resulting in delay of stat FFP order by a few minutes. Per the lab, the blood bank has inventory of FFP received pre-International Society for Blood Transfusion (ISBT) barcode conversion and also post ISBT where all new received FFP product has a specific ISBT product barcode. Two of the units prepped for this patient had pre-conversion labels where the lab staff must manually change the date/time on the unit. The cross-match paperwork sent with the units was correct. Product returned to blood bank and expiration date on product corrected. Two other units had ISBT labels where the updated date and time automatically print on the label.

DISCUSSION

The American Red Cross reports that in the United States, blood transfusions occur in more than 10% of all hospital admissions that include a procedure.[1,18] Although media coverage frequently focuses on transfusion infection risks, the risk of receiving infected blood is now much lower than the risk of receiving incompatible blood.[3,5,10]

FDA has published updated rules, effective May 23, 2016, which mandate

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changes to donor screening tests, including changing the infectious disease language from "communicable disease" to "transfusion-transmitted infection." The rules also updated donor clinical parameters for minimal hemoglobin levels (minimum hemoglobin levels for males from 12.5g/dL to 13.0 g/dL; for women, remains the same), specification of blood pressure levels (minimum and maximum blood pressure levels of 90 to 180 mm Hg systolic and 50 to 100 mm Hg diastolic), and heart rate (50 to 100 beats per minute) and removes the requirement that donor specimens must be tested on the day of donation, thus allowing flexibility in test timing. The new rules address decisions that must be made by the "responsible physician" and cannot be delegated and dictate when the responsible physician must be physically present.[19,20]

Healthcare organizations and blood centers are required to report to FDA fatalities related to blood transfusions.[3] In fiscal year 2014, FDA received reports of 68 patient fatalities. Of these, 59 occurred after receiving a transfusion; 9 deaths occurred after a patient had donated blood. Of these post-donation fatalities, upon further review, 2 deaths were not directly related to blood donation and in one case the patient became lightheaded after donating, fell, and sustained fatal brain injury. For the remaining 6 deaths, donation as a contributing factor could not be ruled out, because the cause of death was unclear.[3]

The Cost of Errors

Besides causing patient harm and distress, blood-transfusion errors also impose a considerable expense for healthcare systems.[9] Since 2007, the Centers for Medicare and Medicaid Services has identified and denied additional costs related to preventable hospital errors. Mistransfusion is considered a preventable error and no costs can be passed along to the patient or reimbursed by Medicare.[9] Additionally, increases in professional liability insurance premiums and the cost of litigating or settling a lawsuit can be significant.[9,10] Other indirect costs associated with transfusion errors include discarding the blood, repeating sample collection, doing additional testing, correcting the patient record, and relabeling blood components. Additional calls and communication among staff may result in transfusion delays.[17]

Masken et al. performed a prospective study of transfusion errors at a large teaching hospital in Canada from 2005 to 2010, which showed that the cost of blood-product waste due to errors was C$593,337. The estimated cost of recollecting improperly labeled specimens was C$80,766.[21]

Mistransfusion

In a seminal study of blood transfusion events, in which the focus was shifted from infectious complications to identifying the rate of transfusion errors, Linden et al. performed a 10-year study, from 1990 to1999, which reviewed the incidences of giving a blood transfusion to the wrong patient or issuing an incorrect ABO or Rh group for transfusion. The authors showed that there was 1 incorrect administration for every 19,000 red blood cell (RBC) units given. Approximately 56% of these events were caused by a single error in a patient care area. Blood bank errors accounted for 29% of the events. The remaining 15% were compound errors that involved multiple clinical areas and staff. The identification process, whether of the patient, the specimen, or of the blood product to be transfused was the most frequently found error.[22]

In 2014, Dehnavich et al. performed a cross-sectional study of the blood transfusion process using failure mode effects and analysis, which identified 77 potential failure modes for 24 sub-processes in 8 processes of blood transfusion. Of these, 13 were identified as unacceptable risk, with the majority of failure modes in the pre-analysis stage of blood transfusion (i.e., collecting, identifying, and processing the specimen) and the majority of errors in care-processes stages (i.e., clinical judgment and task errors).[23] Irreducible risks remain, even though healthcare facilities may have appropriate policies and procedures in place to mitigate errors.[6,7]

Many errors go undetected or unreported because staff might not realize that events that are caught and corrected before they reach the patient are still errors. Some staff might decide that the incident failed to meet the criteria for submitting an event report because of a lack of harm.[7] Li et al. performed a retrospective study of pediatric patients receiving platelet transfusions from 2010 to 2011 and showed that 116 cases out of 805 transfusions met the definition of an acute transfusion reaction; 4 of the 116 cases were reported to the hospital transfusion committee.[24]

Severe Transfusion Events

The FDA reports that TRALI caused the highest number of transfusion-related deaths (41%) in the 2010 to 2014 period, followed by TACO (22%) and HTR (21%).[3] TRALI has been a known risk of blood transfusions for nearly 60 years but was not named until 1983. It is defined as a new onset of hypoxemia within 4 to 6 hours after transfusion, accompanied by new pulmonary infiltrates on chest x-ray study.[5,25-27] Treatment is supportive, with oxygen administration and, possibly, mechanical ventilation.[5,28] The majority of cases are caused by passive infusion of human leukocyte antigen (HLA) and human neutrophil antigen (HNA) in donor blood.[27] HLA and HNA are mostly found in blood from multiparous women who became sensitized during pregnancy.[26,27,29] Eliminating female donors who have been pregnant significantly reduces the risk of TRALI for FFP and platelets.[5,26,28,29] Recipient risk factors for TRALI include end-stage liver disease, sepsis, mechanical ventilation, and blood malignancies; risks are increased in patients receiving platelets or FFP. The

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risk of TRALI increases in relation to the number of units being transfused.[26]

Patients with TACO develop pulmonary edema within 6 hours of receiving a blood transfusion and exhibit dyspnea, orthopnea, cyanosis, tachycardia, jugular venous distention, and widening pulse pressure. Management includes treatment of the underlying condition, fluid restriction, diuretics, and ventilator support.[5] Patients most susceptible include the elderly, infants, and patients with a history of renal failure, anemia, heart failure, hypoalbuminemia, or plasma transfusion.

HTR occurs when the transfused RBCs are destroyed by the patient's immune system.[5] This type of reaction can be related to an ABO incompatible transfusion. Reactions can range from mild to severe and patients can experience back and flank pain, hematuria, chills, and fever. Symptomatic treatment, including intravenous fluids and antipyretics, may be appropriate for mild reactions. For patients with severe HTR, treatment is focused on preventing kidney failure and shock.[3,5]

IMPROVING TRANSFUSION PRACTICES

Blood Management Programs

Reducing the use of blood and using blood-conservation techniques during surgery help reduce the risk of adverse reactions by reducing the need for transfusions.[5] Endorsed by AABB, a blood-management program is defined as "an evidence-based multidisciplinary approach to optimizing the care of patients who need a transfusion."[29,30] The multidisciplinary goals of a blood-management program recognize that managing blood use through monitoring operative blood use and curtailing inappropriate orders for blood products may result in better patient outcomes, such as reduced complications and infections and shorter lengths of stay.[21,31,32]

The Joint Commission published patient blood management (PBM) performance measures in 2011. The seven performance measures are as follows:

- Transfusion consent
- RBC transfusion indication
- Plasma transfusion indication
- Platelet transfusion indication
- Blood administration documentation
- Preoperative anemia screening
- Preoperative blood type screening and antibody testing

These measures, although not nationally endorsed, can serve as a guideline for healthcare organizations when reviewing their internal practices.[15] In 2011, De Leon et al. used the Joint Commission's PBM-02, RBC transfusion indications, because RBC orders represented more than 70% of all blood components at the study facility. Before the study, the healthcare organization had implemented transfusion guidelines, which included a blood component order form that contained all the data points in the Joint Commission's PBM-02. An earlier study found only that 13% of orders contained a clinical indication for RBC transfusion. The study found that 96% of the orders contained the appropriate clinical indications and hemoglobin and hematocrit levels before the transfusion, representing a significant improvement.[32]

Goodnough et al. performed a retrospective study from 2008 to 2013 in which RBC transfusions were reviewed before and after implementing a clinical decision support (CDS) system. The CDS triggered at the time of computerized physician order entry (CPOE) and contained the consensus guidelines for ordering, a link to current literature, and a section for the provider to document the reason for continuing with the order if it didn't fall within ordering guidelines. The study included all inpatients whose hemoglobin was greater than 7 g/dL at discharge. The study revealed that the use of real-time CDS at the time of CPOE resulted in a decrease in RBC transfusions. They also noted that quality indications for clinical patient outcomes improved, leading them to associate decreased blood use with improved quality of care, evidenced by decreased patient exposure to RBC transfusion, fewer blood transfusions, and decreased blood-transfusion costs.[18]

In a telephone interview, Carmelita Moultrie-Savage, BSN, RN, MT, BB (ASCP), the blood bank quality manager at The Children's Hospital of Philadelphia (CHOP), shared quality issues and initiatives she is working on at her organization. Moultrie-Savage is responsible for ensuring that CHOP meets all laws and regulatory guidelines related to blood transfusion set forth by AABB, CAP, TJC, FDA, and Department of Health of both New Jersey and Pennsylvania. The hospital also follows National Security Association guidelines for security against terrorist acts, because of special type of equipment in the blood bank. CHOP is reviewing a quality initiative addressing the use of platelets, because platelets have a short half- life and inappropriate orders may result in product waste.[33]

Jennifer Hill, BSN, RN, CPN, and clinical nurse peak II on the apheresis unit at CHOP discussed in a telephone interview the highlights of risk-reduction strategies performed on her unit.[34] The apheresis unit is busy, and Hill reports that in 2015, staff performed 1,771 procedures and infused 6,417 units of RBCs. Hill reports that ensuring the patient gets the right blood is a top priority on the unit. Staff is trained to allow no distractions as they check seven patient and blood identifiers on all units of blood prior to administration. Before a procedure, two RNs check the identifiers on all of the units of blood. She believes that this commitment to following the protocol reduces the risk of errors.

Hemovigilance Systems

Hemovigilance programs are in place worldwide, with the first programs

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implemented in France in 1993 and in the United Kingdom in 1996. A hemovigilance program can be described as the collection and analysis of information on the complications of blood transfusion.[13]

In 2010 CDC, in partnership with AABB, launched the National Healthcare Safety Network biovigilance component, hemovigilance module surveillance protocol. [12,14] The NHSN HVM is voluntary program that healthcare facilities and blood centers can join. This program's goal is implementing national surveillance protocols of the transfusion process, from donor to product administration, and analyzing its associated adverse events to improve patient safety, minimize fatalities, and develop evidence-based public health recommendations for the transfusion community.[9,14] Because the surveillance definitions are designed to capture data in a consistent fashion, national benchmarks will be produced that can be used for quality-improvement processes. Additionally, NHSN HVM allows comparison of US data with data from other countries.[35] This system allows facilities to better identify incidents without harm.[12] In 2011, 100 hospitals were enrolled and about 2,500 adverse reactions and incidents had been reported.[9] The program published findings for the first three years of the program. By 2012, 164 facilities were enrolled in NHSN HVM and 5,136 adverse events and incidents where included for analysis.[4] During the years 2010 to 2012, 239.5 adverse reactions were reported per 100,000 transfused blood components, with 8% being identified as severe, life-threatening, or fatal.[4]

As of 2016, 247 organizations were participating in the program, but this still represents a small percentage of healthcare organizations that could participate; compare that to the United Kingdom's Serious Hazards of Transfusion (SHOT) program, which as of 2013 had 99.5% voluntary participation.[4,36] Because the NHSN HVM is new, the program has been evaluated to determine whether improvements are needed. In 2013, AuBuchon et al. performed an AABB validation study to review how healthcare facilities were assigning the HVM definitions to transfusion events. Twenty-two facilities participated, of which 11 were actively participating and another 11 were not participating but had access to the HVM definitions and training materials. The study revealed that two-thirds of the time, the group had a matching diagnosis with the HVM criteria and expert review. The authors also found that individual medical judgment allowed participants to follow the HVM criteria loosely and inconsistently, which may result in difficult data analysis.[37] It was also noted that hemovigilance systems with active surveillance had more adverse reactions reported than did passive systems.[36]

Heddle et al. performed a study from May2008 to March 2010. Nurses and physicians from five countries, including the United States, were interviewed. Five major areas of interest emerged: pre-transfusion checking process, organizational policies, staff training, opportunities for errors, and transfusion monitoring.[6] In the pre-transfusion checking process the authors found opportunities for errors that included:

- Staff being unfamiliar with organizational policy or having difficulty accessing policies
- Inadequate training, resulting in staff's unfamiliarity with the process
- Patient-identification issues, including whether the correct wristband was on the patient and whether staff was familiar with the patient
- Location where the checks were done (i.e., at the patient's bedside)
- Number of persons performing the check
- A busy environment and other distractions that caused the staff to fail to follow the process[6]

Additionally, use of technology, such as the BloodLoc™ system, increased transfusion safety because correct patient identification information must be entered before the transfusion product is released. These systems are not used consistently because they increase the cost of transfusion.[6]

Advances in technology can help prevent transfusion errors. The use of BloodLoc and wristband bar-coding technology has been found effective in preventing human-error identification errors associated with transfusions.[17,38] Nuttall et al. performed a retrospective study to determine the effect of a bar-code system for blood identification over four years before implementation and four years after implementation from 2002 to 2005 and 2007 to 2010 (2006 was excluded). The study results showed that before the bar-code system was implemented, the manual process caught only three errors. After bar coding was implemented, 113 incidents were found.[38]

CONCLUSION

Slightly less than 1% of transfusion-related event reports received by PA-PSRS involve patient harm, and nationally, the fatality rate attributed to blood transfusion is small. The relatively uncommon serious risks associated with blood transfusions can cause patient mortality and morbidity. Non-life-threatening errors can result in patient discomfort and increased cost to an organization from product waste and additional efforts by staff to correct the errors. Transfusion medicine has expanded its scope of review from studying only severe reactions to valuing opportunities for practice improvement, including the study of incidents that did not result in harm. Nationally, the safety of transfusion has been attributed to advances in transfusion medicine, including improved donor screening and testing; advances in technology, such as barcoding; increased hemovigilance surveillance protocols; and blood management programs.

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NOTES

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Early Detection of Sepsis in Pennsylvania's Long-Term Care Residents

Terri Lee Roberts, BSN, RN, CIC, FAPIC
Infection Prevention Analyst
James Davis MSN, RN, CCRN, CIC, FAPIC, HEM
Senior Infection Prevention Analyst
Pennsylvania Patient Safety Authority

ABSTRACT

Sepsis impacts between 900,000 and 3 million people in the United States each year. With a mortality rate of 15% to 30%, it is the leading cause of death from infection. Sepsis incidence increases disproportionately in older adults. Over a two-year period, 486 potential occurrences of sepsis with 17 potential sepsis-related fatalities were recorded for residents in long-term care in Pennsylvania. Recognizing early sepsis and implementing evidenced-based therapies are actions that improve outcomes and decrease mortality. Despite the prevalence of sepsis and its serious consequences, awareness remains low, and sepsis is frequently under-diagnosed early, when it is still potentially reversible. The signs of both infection and organ dysfunction may be subtle, and recognizing sepsis in older adults with multiple comorbidities may be difficult. Using a sepsis screening tool to identify sepsis early in long-term care may help to optimize safety in this population. Holding simulation sessions using the tool and acting on positive sepsis screens can lead to user proficiency in resident assessment and improved communication with medical providers. Incorporating a sepsis screening tool into the electronic health record can potentially aid with early identification of sepsis. (Pa Patient Saf Advis 2016 Sep;13[3]:108-113.)

Corresponding Author
Terri Lee Roberts

INTRODUCTION

The word sepsis, first introduced by Hippocrates (ca. 460-370 BC), is derived from the Greek word *sipsi*, meaning to make rotten.[1] One of the oldest syndromes known in medicine, sepsis remains an ongoing and significant challenge. It is a serious concern to healthcare providers, policymakers, and patients because of the large number of cases, high mortality rates, and associated costs.[2]

Sepsis impacts between 900,000 and 3 million people in the United States each year. With a mortality rate of 15% to 30%, sepsis is a leading cause of death in the United States.[3] Adults age 65 years or older are five-fold more likely to have sepsis than younger adults (6.5% vs. 1.3%) and nursing home residents are seven-fold more likely to have sepsis, compared with sepsis rates in adults not residing in a nursing home (14% vs. 1.9%).[4] The cost of care related to sepsis for older U.S. adults has been documented to be $13.8 billion annually.[5] With 486 potential occurrences of sepsis, 17 of those potential sepsis-related fatalities, affecting Pennsylvania's long-term care (LTC) residents over a 2-year period, this is a patient safety concern for the state's 702 long-term care facilities (LTCFs).

Sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection. Septic shock, a subset of sepsis, is manifested by profound circulatory, cellular, and metabolic abnormalities associated with a greater risk of mortality than sepsis alone.[6] Sepsis worsens health status and increases disability among its survivors.[7] Long-term effects include sepsis-induced inflammation, immunosuppression, functional disability, and cognitive impairment.[8] Sepsis often originates with an infection in the lungs, urinary tract, abdomen, or a surgical site.[2] Respiratory tract infections are the most common site of infection causing sepsis and are associated with the highest mortality.[9] Respiratory tract infections and urinary tract infections are the top two types of infection causing sepsis in LTC.[10]

METHODS

Analysts reviewed LTC events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) from April 1, 2014, through March 31, 2016, to determine the number of residents with a healthcare-acquired infection (HAI) requiring transfer to either a higher level of care within the facility or to an acute-care facility. Analysts used data related to resident transfer in the context of an HAI as a surrogate because PA-PSRS does not include a specific field asking if the resident had a diagnosis of sepsis. Analysts interpreted the PA-PSRS transfer question as an indicator of increased acuity likely attributable to some degree as sepsis.

RESULTS

LTC Events

Pennsylvania's LTCFs reported 486 events in which residents had an HAI requiring transfer to either a higher level of care within the facility or to an acute-care facility. Of those HAIs, respiratory tract infections and urinary tract infections were the most common types of infections. Seventeen events were fatal. Figure 1 shows the breakdown of sepsis-related infection types reported to PA-PSRS. When the PA-PSRS data are stratified by infection type, there is external validity especially notable in the respiratory tract infection and urinary tract infection types, also found by Mylotte et al., which strengthens the authors' use of surrogate data to identify sepsis within PA-PSRS.[10]

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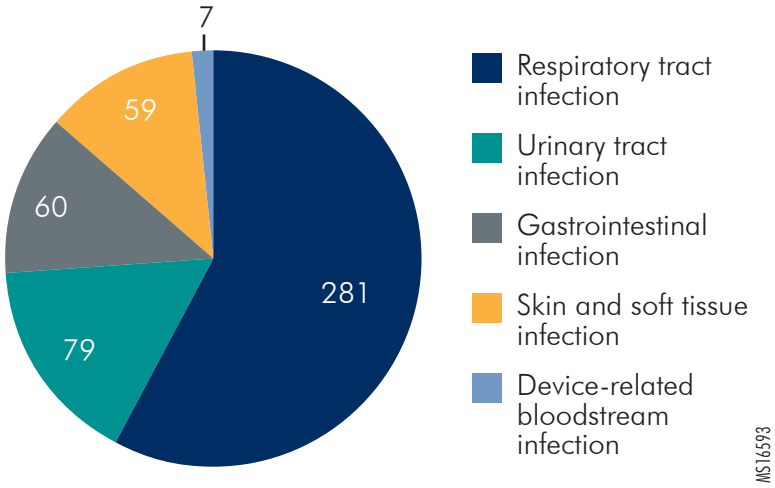
Figure 1. Hospital-Acquired Infections Reported from April 1, 2014, through March 31, 2016, in which the Resident was Transferred to a Higher Level of Care (N = 486)



Acute Care Narratives

Several narratives were found in the acute care PA-PSRS data during the time frame that reflected LTC patients transferred with systemic inflammatory response syndrome (SIRS), sepsis, or septic shock. The following are examples of sepsis-associated patient safety events reported through PA-PSRS.* In each of these acute care reports, LTC residents were admitted with sepsis:

> *Patient from skilled nursing facility transferred to emergency department with dyspnea, fever, and hypotension. Patient diagnosed with sepsis due to pneumonia.*
>
> *Patient from extended care facility transferred to hospital with lethargy and a pulse ox [oximetry] in the 80s. Patient diagnosed with sepsis.*
>
> *Nursing home patient had labored breathing, edema, and decreased level of consciousness. Patient admitted to hospital with urinary tract infection and sepsis.*
>
> *Admit from nursing home with sepsis. Nursing home called patient's PCP [primary care physician] because of temperature elevation, congested respirations, and decreased level of consciousness. Patient had been on antibiotic for several days for suspected aspiration pneumonia. Admitting physician notes coarse breath sounds. Impression was sepsis, suspect aspiration pneumonia, and lactic acidosis.*
>
> *Patient was unstable and unable to sustain a [systolic] blood pressure higher than 90 [mm Hg]. Patient arrived from a nursing home with low blood pressure and an elevated white blood cell count. Patient required two liters of fluid while in the emergency department, but hypotension persisted. The patient was admitted with primary diagnosis of septic shock.*
>
> *Patient from nursing home admitted to critical care unit with fever, nausea, and decreased oral intake. Assessment was SIRS [systemic inflammatory response syndrome] likely secondary to urinary tract infection, pneumonia is also a possibility; presume sepsis.*
>
> *Patient sent out acutely from rehab facility to hospital for a change in breath sounds with associated hypoxemia, to rule out pneumonia. Patient was admitted with septic shock.*

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

DISCUSSION: RISK REDUCTION STRATEGIES

Early Recognition and Treatment of Sepsis Saves Lives

The Surviving Sepsis Campaign (SSC) is a joint effort between the Society of Critical Care Medicine and the European Society of Intensive Care Medicine to globally reduce mortality from sepsis and septic shock. In 2004, SSC published its initial guidelines of best practices based on evidence from the literature. According to SSC's website, 30 international organizations now sponsor and support the evidence-based guidelines.[11] The 2012 International Guidelines for Management of Severe Sepsis and Septic Shock states early recognition of sepsis and implementation of evidence-based therapies improves outcomes and decreases mortality. Routine screening of potentially infected, seriously ill patients for sepsis, to improve the early identification of sepsis and allow implementation of sepsis therapy, is listed as a grade 1C recommendation†.[12] A pilot study performed by Guerra et al. showed a potential decrease in mortality when prehospital personnel used a screening tool to identify patients with sepsis.[13]

Using a sepsis screening tool to identify sepsis early is essential to optimize patient safety (see "Sepsis Screening Tools"). Sepsis screening tools that have been developed and validated generally

† The guidelines state: "A grade 1C recommendation is a strong recommendation; however, some of the key evidence supporting the recommendation is of low quality."[12]

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evaluate the patient for a known or suspected infection.

Although the key to survival is to identify sepsis early, the signs of both infection and organ dysfunction may be subtle and difficult to recognize in older adults with multiple comorbidities. Fever may be absent. There is a lower incidence of tachycardia and hypoxemia. Confusion, delirium, weakness, falls, anorexia, and incontinence may be symptoms of sepsis but can be non-specific in older adults.[12]

Similar practices among LTCFs (i.e., screening for and recognizing residents with sepsis) could promote treatment while awaiting transfer, saving precious time. The initial SSC bundle steps include measuring the lactate level and drawing blood cultures.[12] This could be accomplished in LTCFs with laboratory capabilities. Intravenous access and administration of broad spectrum antibiotics and crystalloids, the next steps in the bundle, could also be accomplished prior to transfer.[12]

SEPSIS SCREENING TOOLS

Sepsis screening tools should evaluate three areas.

1. Known or suspected infection
2. Systemic manifestations of sepsis including:
   a. Acute mental status change
   b. Hyperglycemia
   c. Hyperthermia or hypothermia
   d. Leukocytosis or leukopenia
   e. Tachycardia
   f. Tachypnea
3. Indications of new or worsened organ dysfunction including:
   g. Coagulopathy
   h. Elevated lactate, creatinine, or bilirubin level
   i. Hypotension
   j. Increasing oxygen requirements
   k. Thrombocytopenia

Source: Birriel B, Society of Critical Care Medicine. Rapid identification of sepsis – the value of screening tools [communication online]. [cited 2016 Feb 10]. Mount Prospect, IL: Society of Critical Care Medicine 2013 Apr 2. Available from Internet: http://www.sccm.org/Communications/Critical-Connections/Archives/Pages/Rapid-Identification-of-Sepsis---The-Value-of-Screening-Tools.aspx

Early Detection Screening Tools

A validated sepsis screening tool could be adopted and used routinely on all residents.[14] The certified nursing assistant (CNA), who is with the resident at the bedside, could perform the initial screening. Positive screening results should be reported to and verified immediately by the licensed nurse. The licensed nurse would then evaluate and document any acute changes and communicate the resident's status to the nurse practitioner, physician assistant, or physician. After evaluating the resident and reviewing the resident's advance directive, the clinician may direct medical management and/or transfer to a higher level of care within the facility or the hospital.[15]

Interventions to Reduce Acute Care Transfers (INTERACT), a LTC quality improvement program, provides educational and clinical tools to detect early acute changes in residents.[16] STOP and WATCH is a vertical acronym that lists conditions that identify a potential change in a resident's condition.

The "Stop and Watch Early Warning Tool" can be used by CNAs, therapists, dietary and environmental service workers, and family members to alert the licensed nurse that a resident has a potential change in condition that needs further clinical evaluation. INTERACT's Situation, Background, Appearance, and Review and Notify (SBAR) is an assessment and communication tool that guides the nurse when a resident has a change in condition. The "SBAR Communication Form and Progress Note for RNs/LPN/LVNs" directs the nurse to evaluate the resident's condition before contacting the clinician or other healthcare professional as appropriate. The nurse is then prompted to communicate this information to the primary care clinician. On the form is a space for the nurse to document the primary care clinician's recommendations. In a study by Ouslander et al., the results indicated INTERACT tools can provide for better patient assessment and communication between medical providers, improve the quality of care of LTC residents, and contribute to reducing morbidity and hospitalization costs in this population.[17]

The Minnesota Hospital Association (MHA) has coordinated the development of the LTC-specific Seeing Sepsis Tool Kit to facilitate early detection of sepsis. MHA's LTC resources include Seeing Sepsis cards and posters that alert the user to notify the nurse to screen for sepsis if the resident's temperature is higher than 100° F, heart rate is greater than 100 beats per minute, and/or systolic blood

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Stop and Watch
Early Warning Tool

INTERACT
Version 4.0 Tool

If you have identified a change while caring for or observing a resident, please **circle** the change and notify a nurse. Either give the nurse a copy of this tool or review it with her/him as soon as you can.

S
T
O
P
Seems different than usual
Talks or communicates less
Overall needs more help
Pain – new or worsening; Participated less in activities

a
n
d
Ate less
No bowel movement in 3 days; or diarrhea
Drank less

W
A
T
C
H
Weight change
Agitated or nervous more than usual
Tired, weak, confused, or drowsy
Change in skin color or condition
Help with walking, transferring, toileting more than usual

☐ Check here if no change noted while monitoring high risk patient

Patient / Resident

Your Name

Reported to *Date and Time (am/pm)*

Nurse Response *Date and Time (am/pm)*

Nurse's Name

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Source: Ouslander JG, Shutes J. INTERACT [website]. [cited 2016 Feb 10]. Boca Raton (FL): Florida Atlantic University. Available from Internet: http://interact2.net/index.aspx

pressure is lower than 100 mmHg and the resident "doesn't look right." The Act Fast document for LTC includes the same screening alerts plus next steps for medical providers in the event of a positive sepsis screen.[18]

Simulation

Providing experiential education allows participants to develop new knowledge and skills in a controlled, supported learning environment, without direct risk to patients.[19] Guidelines released from the National Council of State Boards of Nursing cite a study by Lakin et al. that found that simulation improves critical thinking, performance skills, and knowledge of subject matter and increases clinical reasoning in certain areas.[20] The Society for Simulation in Healthcare states a core benefit of simulation training in healthcare is the measurable improvement in patient safety. Simulation training for LTC staff in recognizing early sepsis symptoms and promptly communicating those symptoms among the healthcare team may improve performance and reduce errors in patient care.[21] After the initial training of the staff on the standardized screening tool and communication algorithm for identifying sepsis, a facilitator can lead participants through realistic scenarios. These sessions may be recorded for playback during the debriefing process shortly after the simulation concludes. During debriefing the group reflects and engages in safe conversations to identify the strengths, weaknesses, and opportunities for improvement during the simulation. Participants gain confidence while discussing what went well and what could be improved. A study by Mihaljevic and Howard incorporated interdisciplinary sepsis simulations including licensed nurses, CNAs, and therapy staff, using INTERACT's Stop and Watch and SBAR tools throughout 19 LTCFs. The goal was for these healthcare providers to communicate effectively and intervene quickly on behalf of residents in sepsis. After the sepsis-simulation sessions, participants completed a survey to provide feedback on their experience. An overwhelming majority found a high level of satisfaction with the experience and looked forward to similar education and training in the future. Simulation helped implement sepsis education and reinforced interdisciplinary communication in the LTC setting, stimulating adoption of these tools in many LTC organizations.[22]

RESOURCES

Minnesota Hospital Association. Seeing sepsis: early identification saves lives [Seeing Sepsis Long Term Care Resources online]. [cited 2016 Feb 10]. Available from Internet: http://www.mnhospitals.org/patient-safety/current-safety-quality-initiatives/severe-sepsis-and-septic-shock

Ouslander JG, Shutes J. INTERACT [website]. [cited 2016 Feb 10]. Boca Raton (FL): Florida Atlantic University. Available from Internet: http://interact2.net/tools_v4.html

Electronic Health Record

The United States is moving toward implementing electronic health record (EHR) systems in all healthcare facilities.[23] Although hospitals and medical groups have implemented EHR systems at a brisk pace, LTC settings have been slower to adopt such technology.[23,24] In 2004, 1,174 nursing homes responded to the National Nursing Home Survey (NNHS) conducted by National Center for Health Statistics at the Centers for Disease Control and Prevention. NNHS reported 42% of the nursing home respondents used an electronic information system for patient medical records.[25] The EHR's automated access to information has the potential to streamline clinicians' workflow.[26] Its clinical decision tools offer the possibility of identifying patients in sepsis. A diagnosis of sepsis may be elusive to clinicians because they may not recognize the constellation of clinical, physiologic, and laboratory abnormalities that comprise the sepsis syndrome. The EHR has the strong potential to improve the detection of sepsis early by collecting and organizing the clinical data required to make the diagnosis. A study by Nguyen et al. sought to evaluate the accuracy of an automated EHR sepsis-detection system. The authors concluded that a specific EHR clinical support system identified patients presenting with sepsis and provided a viable strategy for sepsis identification.[27] Given the success of Nguyen's study, LTCFs that use EHRs could consider incorporating their chosen sepsis screening tool into their system to aid in early identification of sepsis.

CONCLUSION

Early recognition of sepsis and implementation of evidence-based therapies have the potential to save lives. Despite the prevalence and serious consequences of sepsis, its early diagnosis is challenging for LTC team members; therefore, sepsis may be under-diagnosed when it is still potentially reversible. The use of a validated sepsis screening tool by LTCFs and embedding the screening tool into the EHR, to identify sepsis early and to standardize communication among LTC team members, may decrease adverse outcomes. Simulation sessions using a sepsis screening tool have been shown to improve the user's ability to effectively recognize and communicate changes in a resident's condition that may indicate sepsis.

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Complications and Circumstances Pertaining to Intraosseous Lines

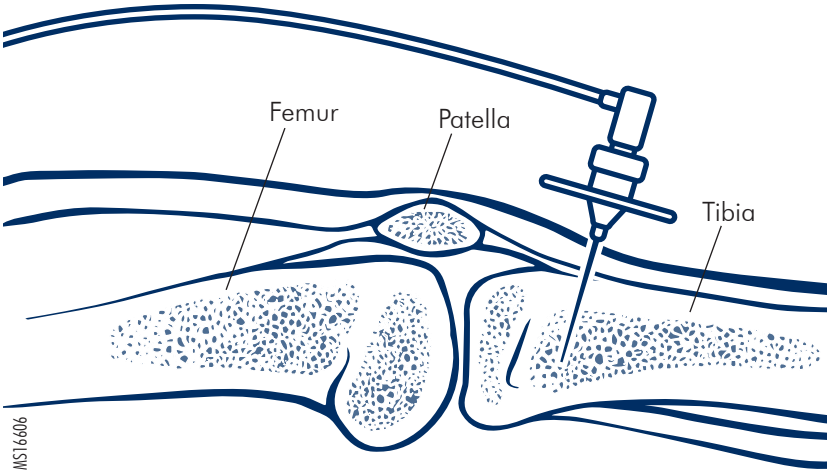
Lea Anne Gardner, PhD, RN
Senior Patient Safety Analyst
Pennsylvania Patient Safety Authority

Pennsylvania Patient Safety Authority analysts received an inquiry asking about the type of events that occurred with the use of intraosseous (IO) vascular access catheters and whether events might be related to patient age. IO line access is a method of delivering fluids when a peripheral intravenous (IV) line or central line cannot be obtained in a timely manner, and patient morbidity or mortality is possible.[1-6] IO line access was first used in animals in 1922.[7] Patient use in a clinical setting was noted in the early 1940s.[8] IO access is obtained by inserting a needle through the bone (e.g., proximal tibia, humerus; see Figure 1)[9,10] and are generally removed within 24 hours.[11,12] The bone provides a non-collapsible cavity to instill fluids and medications, which are absorbed at a similar rate to absorption via peripheral IV lines.[7,8]

A variety of guidelines generally based on age identify the appropriate circumstances for implementing this type of line access.[2-5,13] For example, the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science recommend the use of IO access in children and adults if venous access is not readily available during an emergency.[5,12] Contraindications for an IO insertion include ipsilateral (i.e., same side) fractures, previous attempts at ipsilateral IO access, local vascular injuries, cellulitis, infection or injury to the skin around the site, and burns.[14,15] Intraosseous insertion should be also avoided in patients with a high risk for fractures (e.g., severe or advanced osteoporosis, osteogenesis imperfecta).[13,14]

Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) to identify events related to IO lines during the most recent 10-year time period, January 1, 2006, through December 31, 2015, by using the keywords "IO," "i.o.," "i-o," "intraos," and "interos." The query identified 175 event reports; 85 were excluded because they were irrelevant to the scope of the query (e.g., IO as an abbreviation for intraocular) or addressed a non-IO line event (e.g., fall) during which the patient had an IO line present. The remaining 51.4% (n = 90 of 175) event reports addressed IO clinical (e.g., insertion site complications) or system matters (e.g., equipment availability or breakage).

Figure 1. Intraosseous Needle in Tibia



Source: Modified from Greene N, Bhananker S, Ramaiah R. Vascular access, fluid resuscitation, and blood transfusion in pediatric trauma. *Int J Crit Illn Inj Sci* 2012 Sep;2(3):135-42.

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The first part of the analysis examined the occurrence of harm and patient age. Five of the 90 event reports (5.6%) resulted in harm reaching the patient.* Slightly more than one third 34.4% (n = 31 of 90) event reports occurred in children younger than 10 years of age. Figure 2 provides the distribution of event reports by patient age (i.e., newborn to 23 months old and newborn through 99 years old) by harm score.

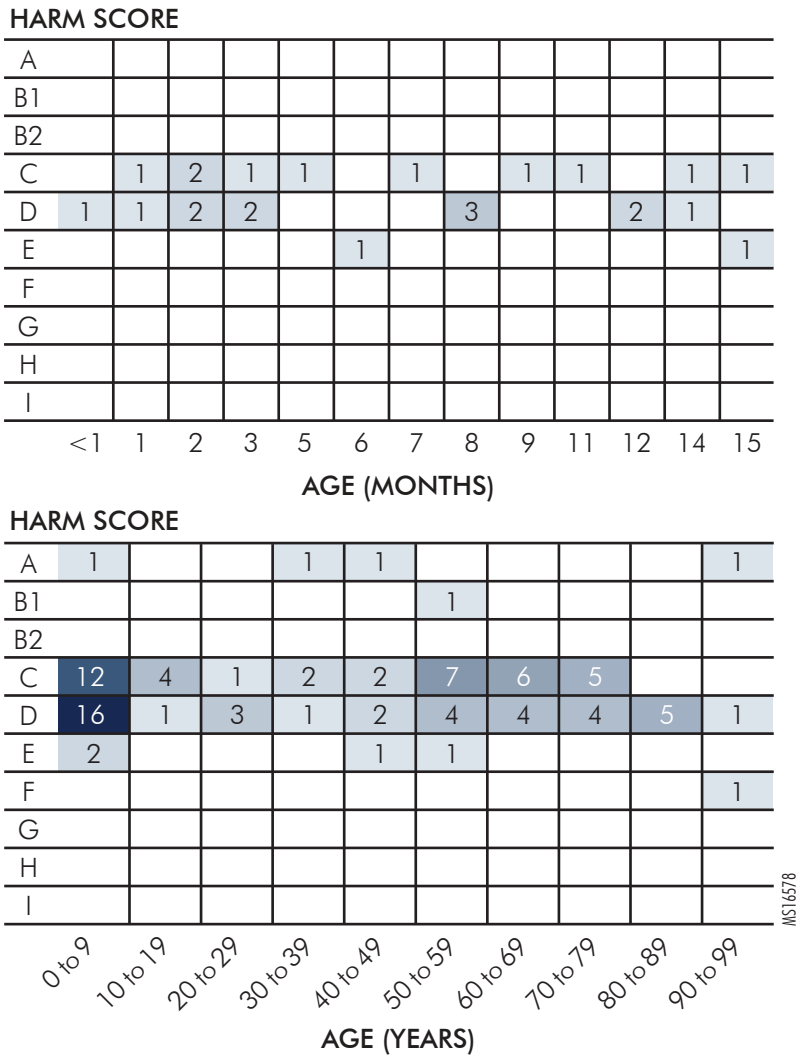
All of the IO events were reported by hospitals, and analysts grouped them according to the type of care area. The list below shows the hospital location where the events were reported.

- Intensive care units (40.0%, n = 36 of 90)
- Emergency departments (36.7%, n = 33)
- Medical, surgical, or pediatric units (13.3%, n = 12)
- Intermediate medical, surgical, or pediatric units (5.6%, n = 5)
- Unit location not identified (2.2%, n = 2)
- Imaging (2.2%, n = 2)

An analysis of the event narratives identified 15 clinical conditions or system matters involving an IO line. Of the 90 event reports, 41.1% (n = 37) described two or more circumstances in the event narrative. For example, in four events, the plastic hub disconnected from the metal IO needle during removal and in each instance, a hemostat or plier was used to remove the needle from the patient's bone. See Figure 3 for the clinical conditions and system matters and their numbers of events.

The following selected PA-PSRS event narratives provide clarity about the circumstances associated with the IO events reports:

Figure 2. PA-PSRS Intraosseous Access Event Reports by Patient Age and Harm Score Heat Map, January 2006 through December 2015 (N = 90)*



There were no event reports for children age 4, 10, 13, and 15 to 23 months.

Extravasation and Pain

Registered nurse noticed that patient's IO [site] was cold and appeared to be infiltrated. Patient complained of severe pain where IO was placed. Swelling around IO site. Warm compress applied, pain meds given.

Extremity and Extravasation

Patient's lower extremity noted to be swollen and cool. IV assessment prior to infiltration noted site ok... Infusions stopped, IO removed, extremity elevated, warmed packs applied.

** The Pennsylvania Patient Safety Authority Harm Score Taxonomy is available online at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12(1)/Publishing Images/taxonomy.pdf*

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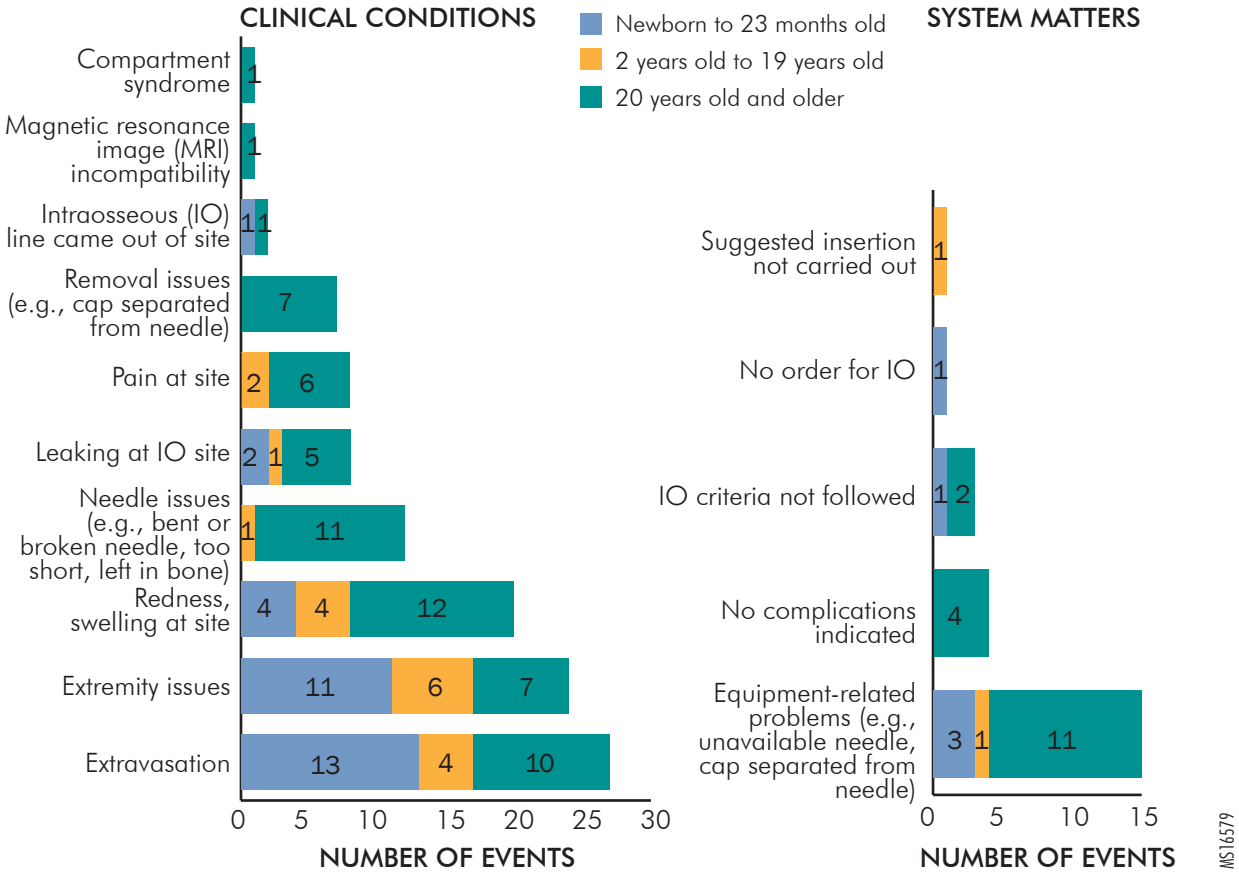
Figure 3. PA-PSRS Intraosseous Line Clinical Conditions and System Matters, January 1, 2006, through December 31, 2015 (N = 90)*



** 41.1% (37 of 90) of the event reports had two or more circumstances identified in the event narrative.*

Equipment

The patient coded and there was no IV access. There was no IO needle in the code cart so nurses had to go to another floor to obtain one.

Removal, Needle, and Equipment

Peripheral access had been obtained. Attempted removal of intraosseous (IO) line, unable to remove. During attempts to unscrew IO device, plastic attachment device came off leaving only the needle in the patient's leg. After multiple attempts the needle was removed and found to be slightly bent.

In Pennsylvania, IO needles can be inserted by physicians, advanced emergency medical technicians, and paramedics.[16] Regarding nurses, the Pennsylvania nurses' scope of practice does not prohibit the insertion of an IO line; [17] nevertheless, it is advisable for nurses to follow facility policies for inserting and accessing these lines.

The literature shows that use of IO lines is limited by lack of equipment and training.[18] Training in proper insertion techniques is available through Advanced Trauma Life Support and Pediatric Advanced Life Support courses.[19] The type of device used and training have been shown to increase insertion success rates.[20-22] The American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care identified multiple case studies showing that providers with different levels of training could rapidly establish IO access with minimal complications for children in cardiac arrest.[3,12]

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Although the overall number of events reported is small, the proportion involving young children is worth noting. It is unclear whether the larger number of IO event reports involving children reflects a greater risk of complications for each IO insertion or whether there may be a larger number of IO insertions in very young, ill children, in whom starting an IV may be particularly difficult. The risk of IO insertion is to be balanced against the risks of IV insertion and the risks of untimely vascular access. Training, education, and resource availability can help with successful insertion of IO lines.

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Incorrect End Colostomy Formation Using the Distal Bowel Limb: A Rare but Serious Complication

Michelle Feil, MSN, RN, CPPS
Senior Patient Safety Analyst
Pennsylvania Patient Safety Authority

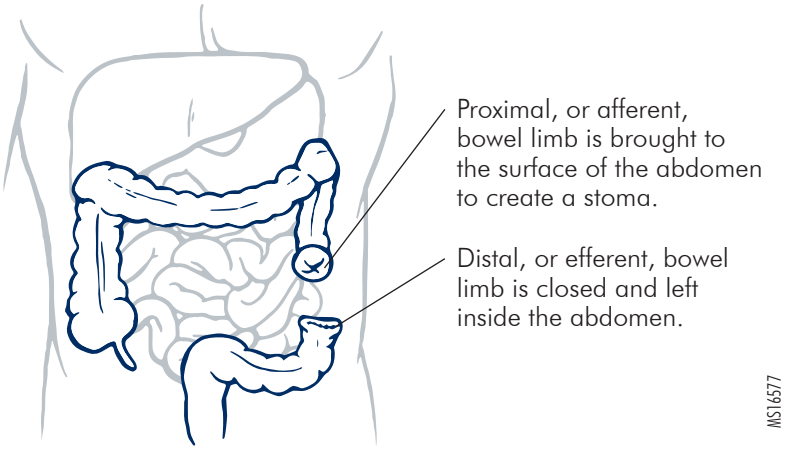
Colectomy and surgical formation of an end colostomy involves bringing the proximal, or afferent, bowel limb to the surface of the abdomen to create a stoma. The distal, or efferent bowel limb is either removed, or surgically closed and left inside the abdomen (Figure). Failure to accurately identify the correct bowel segment intraoperatively results in incorrect end colostomy formation using the distal bowel limb to create a stoma. Closing the proximal limb creates a blind pouch, which results in bowel obstruction that requires surgical correction. The frequency of this complication is not established in the literature,[1-3] but is believed to be rare.[4,5] Still, this error warrants attention because it can result in serious harm to patients, at a minimum allowing exposure to the risk of undergoing an additional surgical procedure, and at a maximum leading to bowel ischemia, perforation, sepsis, shock, and death.[6]

"This is a technical error that is very easy to make if you are not paying attention, and it is the one error that no colorectal surgeon wants to make,"[7] explained Steven Fassler, MD, Chief of Colorectal Surgery at Abington Hospital—Jefferson Health, and former president of the Pennsylvania Society of Colorectal Surgeons.

Colectomies can be performed using either an open or laparoscopic surgical approach. Laparoscopic colectomies have been steadily increasing since the 1990s, with nearly one-half of all colectomies in the United States performed using this approach.[8] While this error can occur using either surgical approach, "It is much easier to make this mistake if you are performing the surgery laparoscopically," said Fassler. "With an open case, you can visualize both ends. With a laparoscopic colectomy, it is easier to get turned around and pull up the wrong end."

Strategies exist to prevent this complication, but even when steps are taken to ensure proper end colostomy formation, this error can occur. Because of this, postoperative physical assessment of the stoma site and bowel function is key to recognizing this error, and prompt intervention is vital to ensure a viable, properly functioning colostomy. Bowel sounds should return within 24 to 72 hours of surgery, and drainage of

Figure. Anatomy of Colostomy Formation



Note: This illustration shows a descending colostomy. Colostomies may be created at other points along the length of the colon.

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ostomy effluent from a properly formed stoma should be seen within several days.[9] Prolonged postoperative ileus (>36 hours) requires further evaluation.[5]

DATA OVERVIEW

Pennsylvania healthcare facilities reported eight events involving incorrect end colostomy formation using the distal bowel limb through the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) over a 10-year period, from January 2006 through December 2015. Five of these events have been reported in the most recent four years.

All events were reported as Serious Events resulting in temporary harm, requiring treatment or intervention, and/or prolonged hospitalization.

Three of the event reports indicate that the initial surgery was performed laparoscopically. The remainder do not indicate whether the colostomies were created using an open or laparoscopic approach.

Analysis of PA-PSRS event reports reveals variation in the time intervals between the initial colectomy procedures and subsequent surgical revisions. (See Table.)

The following is an example of an event reported through PA-PSRS.* Details included in the event-report narrative illustrate the harm to patients resulting from this complication and describe the physical assessment findings that helped the healthcare team to identify that this technical error had occurred:

> *Postoperatively, the patient's bowel function failed to resume and the abdomen became progressively distended. The patient developed fevers and hypotension prompting transfer to the intensive care unit. Diagnostic testing revealed that the distal rather than the proximal end of the colon was used to create the stoma. The patient was returned to the operating room for revision of the colostomy.*

Table. Time from Initial Procedure to Surgical Revision for Colostomies Formed Using Distal Bowel, as Reported through the Pennsylvania Patient Safety Reporting System, 2006–2015

TIME INTERVAL	EVENTS
Less than 7 days	1
7 days	2
8 to 14 days	1
More than 14 days	1
Not specified	3
Total	**8**

DISCUSSION

Primary and secondary strategies exist to prevent incorrect end colostomy formation using the distal bowel limb. Primary prevention strategies are those that can be taken intraoperatively to prevent the wrong bowel limb from being used to create the stoma, and secondary strategies are those that can be taken postoperatively to recognize that the error has occurred and intervene in a timely fashion to correct the problem.

Primary Prevention

Fassler emphasizes the importance of checking multiple times throughout the procedure that the proximal and distal limbs are accurately identified. "I usually identify the proximal and distal limbs at least six times during the procedure," he said. Fassler uses several different techniques to identify the distal and proximal bowel limbs intraoperatively. One is to make a mark on the distal limb using cautery. The second involves inserting a red rubber or urinary catheter into the distal limb, infusing fluid, and checking to see whether the fluid drains from the patient's anus. And the third option, used during a laparoscopic procedure, is to leave the camera port in place, re-insufflate the abdomen, and re-insert the camera to perform a final check just prior to maturing the stoma.

Engaging other surgical team members to perform an independent double-check of the surgical site and mark is a principle encouraged by the Authority to prevent wrong-site surgery.[10] Asked whether this could be done during this procedure, Fassler said, "I always have a second person scrubbed—another surgeon, a surgical resident, or a first assistant—in addition to myself and the scrub nurse. During the procedure I verbally say, 'This is the distal limb,' and ask if they agree. It is not part of a standardized protocol, but more of a common-sense conversation with the people involved."

Secondary Prevention

Postoperative physical assessment is key to recognizing that an end colostomy has been incorrectly formed using the distal bowel limb. Delayed recognition and failure to correct the resultant bowel obstruction in a timely fashion can result in serious harm to patients, up to and including death.[6] Although no deaths were reported through PA-PSRS, it is concerning that half of the event reports describe situations in which the time that elapsed between the initial procedure and surgical revision was seven days or greater

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

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(see Table). More information is necessary to understand why these delays occurred.

Reporting to Learn

Learning from event reporting is a fundamental patient safety principle[11] and the foundation of the Authority's work. Fassler agrees, explaining that he sees the value in reporting surgical errors such as the one described in this analysis. "Everyone thinks that reporting these errors and complications is punitive, but we need to report and talk about these situations so that we can learn from them and prevent this from happening to other patients." In fact, Fassler would encourage reporters to include as many details as possible, particularly in complicated cases. "Surgeons would like to know exactly what factors contributed to the mistake. Because what we are really trying to do is say 'Hey, I may be facing a similar situation in the future, and I want to know what I could do to prevent something like this from happening for me and my patient.'"

RISK REDUCTION STRATEGIES

The following are actions colorectal surgeons, nurses, and other surgical team members can consider to prevent and/or identify and correct this technical error:

- Maintain vigilance when completing the finer technical steps involved in stoma creation, and do not delegate this task to junior or inexperienced members of the surgical team without proper supervision.[2,3]
- Ensure that novice surgeons gain proficiency in end colostomy formation through supervised direct clinical experience, including during laparoscopic training programs.[5]
- Mark the distal (or proximal) bowel limb intraoperatively using either a suture[5] or cautery.[7]
- Use the same method and mark the same bowel limb (i.e., either proximal or distal) each time the procedure is performed.[5]
- Ask surgical team members to confirm identification of the proximal and distal bowel limbs whenever possible.[7]
- Before closing the distal bowel limb, insert a red rubber or urinary catheter into the distal limb, infuse fluid, and check to see whether the fluid drains from the patient's anus.[7]
- Toward the end of a laparoscopic procedure, reinsert the camera through the camera port, re-insufflate the abdomen, and check to ensure that the proximal bowel limb is being pulled up to create the stoma.[7]
- After closing the distal bowel limb, insert a flexible sigmoidoscope or colonoscope through the rectum to visualize the staple/suture line and confirm creation of a blind pouch.[2,5]
- Once the stoma has been formed and opened at the end of the operation, instill water or air into the distal bowel limb through the rectum. If colonic contents are expressed through the stoma, the colostomy has been incorrectly formed using the distal bowel limb.[2,5]
- Monitor the patient postoperatively to confirm the return of bowel sounds within 24 to 72 hours and the production of ostomy effluent within the first several days.[9]
- Aside from absent or diminished bowel sounds and lack of ostomy effluent, assess the patient for additional signs and symptoms of bowel obstruction, including abdominal distension and pain.[6]
- In patients with postoperative ileus lasting more than 36 hours, consider instilling a contrast enema through the stoma to identify errors in colostomy formation or other causes for obstruction.[4,5]

CONCLUSION

Incorrect end colostomy formation using the distal bowel limb is a technical error that is believed to occur rarely. Events in which this error has occurred have been reported to the Authority. Though rare, this error has the potential to result in serious harm to patients, up to and including death. Colorectal surgeons, nurses, and other surgical team members can take action to prevent this error from occurring and/or recognize the error and intervene in a timely fashion to protect patients from serious harm.

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Checklists: The Good, the Bad, and the Ugly

Ellen S Deutsch, MD, MS, FACS, FAAP, CPPS
Editor, Pennsylvania Patient Safety Advisory
Medical Director, Pennsylvania Patient Safety Authority

Are checklists helpful? A colleague recently confided to me that she struggles to use a one-size-fits-all checklist, required by her organization, for her specialized procedures. The usefulness of checklists seems intuitive, and checklists have been mandated in many healthcare settings. However, these tools have both fierce advocates and determined detractors, so perhaps the devil is in the details of checklist creation and implementation. Even checklist promoters, including Atul Gawande, author of "The Checklist Manifesto,"[1] acknowledge both the potential and the limitations of checklists.

A checklist is "typically a list of action items or criteria arranged in a systematic manner."[2] But the term "checklist" can encompass a variety of formal and informal cognitive aids designed for a variety of functions: to support recall of vital information, enhance communication, activate team members, share situational awareness, and anticipate needs and hazards for individual patients.[1,3,4,5] Checklists can also be designed to document or audit processes—as lists of items requiring attention or verification, often in a sequential manner ("challenge-do-respond"), or as summations or "clean up" to confirm that the team has completed all of the requisite tasks ("do-verify").[4] Checklists in healthcare may be used to document compliance with protocols or policies and are often accompanied by the refrain that "if it's not documented, it didn't happen;" in contrast, Verdaasdonk and coauthors note that "checklist items in aviation are not marked when completed."[4]

The Good. Checklists have been used successfully and found to be effective in several high-hazard industries, including healthcare in specific settings.[2,6] Checklists can be used to reduce variability and improve performance[3,7] and may be most beneficial during urgent or emergent medical care[8] or when treating unusual conditions. They may ensure the predictability[3] and completeness of selected processes. Winters and colleagues point out that checklists democratize knowledge, thereby improving the reliable translation of information and reducing the risk of miscommunication among members of healthcare teams.[7]

The Bad. A systematic review of safety checklists for use by medical care teams in acute hospital settings revealed limited evidence of effectiveness,[9] and compliance with checklists has been only moderate.[10] Checklists targeting novices tend to be thorough but may penalize experts unfairly for being more direct or efficient.[11] Checklists may create dependence, which can interfere both with professional judgment and the objectivity of decision-making.[2] Completing checklists might also distract participants from recognizing or communicating important information about specific patients if it does not fit easily into the pre-set categories included in the checklist.

The Ugly. Checklists have the potential to create a negative impact.[12] They can be too long, hard to use, or impractical;[1] they may penalize efficiency,[11] decrease participant satisfaction,[13] create "clumsy roadblocks;"[3] and contribute to "checklist fatigue."[2,3] The greatest danger may occur when checklists are completed in a rote, perfunctory, or disengaged manner; creating a false veneer of safety without meaningful attention to potential hazards.

Creating and implementing helpful checklists involves both science and art. There is an iterative relationship between the content of the checklist and its interactions with the ambient healthcare system. The qualities of efficiency, adaptability, thoroughness, standardization, predictability, practicality, and customization for relevance may compete with each other.[3,5] The appropriate content emerges from trade-offs about the purpose, the users, and the use setting. Once the desired content is determined, whether the checklist is presented in a paper or electronic format, design principles

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can be applied to the visual layout to enhance readability. Established principles can help address the number of items included, the sequence in which items are listed, how items are grouped, text fonts, colors, bulleted lists, and other factors.[1,3,4,7,14] Adding a "not applicable option" to "yes or no" formats can improve relevance.[12] Concluding team checklists with an open-ended invitation for any team member to speak up may elicit additional information or concerns that can benefit the safe and compassionate care of a patient.

Beyond creating the checklist content and display, the context of implementation should be considered.[4] Involving users in the checklist's development can improve both relevance and buy-in, and pilot testing in situ allows refinement based on information gained in actual work circumstances. How does the checklist fit the unique characteristics of the healthcare facility? How should the checklist fit into the participants' workflow? How can ease of access be accomplished? How can we ensure sufficient, but not excessive, redundancy with other processes?[12] Can we include branching logic and decision support to make both paper and electronic checklists more intelligent and adaptable?[3]

Finally, even if a carefully crafted and thoughtfully implemented checklist approaches perfection, will it have the same relevance over time? Several authors recommend periodic review of checklists.[4,8,15] Attention to both the small details and the big picture of creating and implementing checklists can be used to optimize their helpful aspects and minimize counterproductive components. Applying both science and art to checklist creation and implementation can help resolve the devil in the details.

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Correction

Adkins J. Data Snapshot: *Clostridium difficile* infections in long-term care facilities. *Pa Patient Saf Advis* 2016 Jun [cited 2016 Sep 19]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2016/Jun;13(2)/Pages/74.aspx

This article contained statements and data representations in error on pages 74 and 75. The statements should indicate that from January 2010 through December 2015, long-term care facilities reported 13,100 Clostridium difficile infections to the Pennsylvania Patient Safety Authority. Figures and the Table should reflect this number of event reports. Corrections have been made to the online article. The editor regrets the error.

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SAVES, SYSTEM IMPROVEMENTS, AND SAFETY II

"Saves, System Improvements, and Safety II" is an occasional feature of the *Pennsylvania Patient Safety Advisory*, highlighting successes by healthcare workers in keeping patients safe. The Safety II approach assumes that everyday performance variability provides adaptations needed to respond to varying conditions and that humans are a resource for system flexibility and resilience.

Site Marking: Undoing an Error

A patient was scheduled for a right hip replacement but the surgeon marked the left (incorrect) side. Recognizing the error, the surgeon immediately drew an "X" through the incorrect mark, added the word "wrong," and marked the right (correct) hip. The nurse recognized the potential for confusion and used alcohol to remove the incorrect mark, including the word "wrong."*

This event narrative exemplifies correcting an error before harm could occur. Although members of the surgical team can do their best to prevent errors, errors may still occur. In this instance, the surgeon immediately corrected the error, before harm occurred, and the nurse reinforced the correction. There is limited information in the event report, but it's intriguing to consider the participants' possible thought processes. When the surgeon not only crossed out the incorrect mark, but wrote the word "wrong," it's possible that he or she anticipated that crossing out the mark alone might still be incorrectly interpreted as "X marks the spot" so the word "wrong" may have been added to provide additional clarification. When the nurse saw two site marks, he or she may have considered the possibility that additional team members might proceed based on the first mark they saw, which could be either the correct or incorrect mark, and not look for an additional site mark. Advisory information that may help prevent wrong-site procedures is available at http://patientsafetyauthority.org/EDUCATIONALTOOLS/PATIENTSAFETYTOOLS/PWSS/Pages/home.aspx. Part of keeping patients safe involves following evidence-based processes, and part involves being able to effectively manage uncommon or unanticipated conditions.

This is a good catch because the surgeon and nurse corrected the site-marking error before harm occurred (i.e., preventing a wrong-site event). Often protocols describe the expected course of action; it's much less common for protocols to provide guidance on how to correct errors. Kudos to the team's members for their situational awareness in an uncommon situation.

* The details of the PA-PSRS event narrative in this article have been modified to preserve confidentiality.

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The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (MCARE) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's website at http://www.patientsafetyauthority.org.

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community, including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.