PENNSYLVANIA PATIENT SAFETY ADVISORY

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Patient Safety Authority

Vol. 9, No. 4

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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 those in which urgent communication of information could have a significant impact on patient outcomes.

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The Role of the Electronic Health Record in Patient Safety Events

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ABSTRACT

As adoption of health information technology solutions like electronic health records (EHRs) has increased across the United States, increasing attention is being paid to the safety and risk profile of these technologies. However, several groups have called out a lack of available safety data as a major challenge to assessing EHR safety, and this study was performed to inform the field about the types of EHR-related errors and problems reported to the Pennsylvania Patient Safety Authority and to serve as a basis for further study. Authority analysts queried the Pennsylvania Patient Safety Reporting System for reports related to EHR technologies and performed an exploratory analysis of 3,099 reports using a previously published classification structure specific to health information technology. The majority of EHR-related reports involved errors in human data entry, such as entry of "wrong" data or the failure to enter data, and a few reports indicated technical failures on the part of the EHR system. This may reflect the clinical mindset of frontline caregivers who report events to the Authority. (Pa Patient Saf Advis 2012 Dec;9[4]:113-21.)

INTRODUCTION

Adoption of electronic medical records (EMRs) and electronic health records (EHRs)* in US healthcare facilities is growing: HIMSS Analytics reports that, as of the second quarter of 2012, over three-quarters of US healthcare facilities have achieved at least stage 3 of their seven-stage EMR Adoption Model.[1] Stage 3 reflects a facility having the cumulative capabilities for electronic flowcharts, error checking, and picture archiving and communication systems (PACS) available outside of the radiology department.[1] However, as adoption grows, so does concern over the potential safety implications of these systems. The recently released Institute of Medicine report *Health IT and Patient Safety: Building Safer Systems for Better Care*[2] noted a lack of hazard and risk reporting data on health information technology (HIT) as a hindering factor in building safer systems. In response to this need for information on the scope and extent of EHR risks posed by today's implemented systems, Pennsylvania Patient Safety Authority analysts identified EHR events in the Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS).

METHODS

Authority analysts queried the PA-PSRS database on May 23, 2012, using the keywords "emr," "ehr," "adt," "electronic med," "electronic health," "information system," "drop-down," "default," "selection," "mouse," "no record," and "link," in conjunction with EHR supplier and system names. The query returned 8,003 reports from June 2, 2004, through May 18, 2012. Analysts noted that the search query returned some types of reports in which the term "EHR" was either incidental or EHR involvement could not be confirmed, such as the following:

— An event (e.g., a fall) that was reported in the EHR but for which no EHR systems were involved in or contributed to the event
— Manual errors that were committed outside EHR systems, such as pulling the wrong medication from a cabinet or applying the wrong label to a specimen
— Reports that indicated the use of a paper-based chart or did not specify whether an electronic system was involved

A random sample of approximately 20% of these event reports was created by assigning each of the 8,003 queried reports a random number between 0 and 1 and reviewing those reports with a randomly assigned number between 0 and 0.2. This random sample was manually reviewed by one analyst with a background in clinical and biomedical engineering to classify the events as relevant or not relevant to the topic of patient safety events involving the EHR; 933 (59.5%) of the 1,567 manually reviewed reports were identified as relevant.

With the intent of reducing manual review of irrelevant reports, the data set of manually reviewed event reports (n = 1,567) was divided into training and validation data sets for a machine-learning model. The objective of the model was to estimate the probability of relevance of unlabeled cases using an algorithm trained on manually labeled cases. The training data set contained 70% (n = 1,097) of the manually reviewed reports, while 30% (n = 470) of reports were used in 10-fold cross-validation with stratified sampling. The best-performing model, using a Naïve Bayes kernel classifier, achieved an area under the receiver operating characteristic (ROC)

* For the purposes of this article, the term "EHR" is used to denote a family of technologies that includes electronic medical records and electronic medication administration records, except in instances in which "EHR" constitutes a search or manufacturer-specific term.

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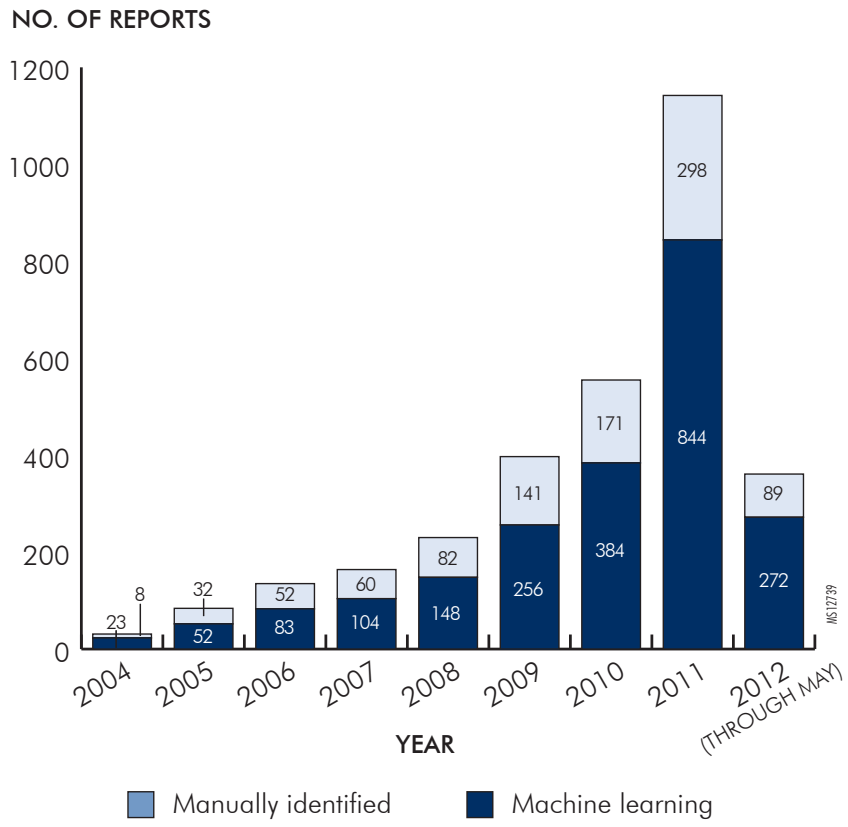
curve of 0.927±0.023 after dropping uncertain predictions (i.e., those with less than 90% confidence).

This model was then applied to the remaining 6,436 queried reports that had not been manually classified. The machine-learning tool identified 2,500 of 6,436 reports as relevant. These 2,500 reports were then manually screened to confirm relevance, and analysts deemed 2,166 of these reports (87%) as relevant to EHRs. In total, 3,099 reports were confirmed as relevant to EHRs (933 from the initial random sample and 2,166 from the machine-learning sample), and these reports were subjected to further analysis. Analysts noted that EHR-related reports are increasing over time, which was to be expected as adoption of EHRs is growing in the United States overall (see Figure 1).

Figure 1. Reports Related to Electronic Health Records (June 2004 through May 2012)



RESULTS

Classification by Harm Score

Reported events were categorized by their reporter-selected harm score (see Table 1). Of the 3,099 EHR-related events, 2,763 (89%) were reported as "event, no harm" (e.g., an error did occur but there was no adverse outcome for the patient), and 320 (10%) were reported as "unsafe conditions," which did not result in a harmful event. Fifteen reports involved temporary harm to the patient due to the following: entering wrong medication data (n = 6), administering the wrong medication (n = 3), ignoring a documented allergy (n = 2), failure to enter lab tests (n = 2), and failure to document (n = 2). Only one event report, related to a failure to properly document an allergy, involved significant harm.

> *Patient with documented allergy to penicillin received ampicillin and went into shock, possible [sic] due to anaphylaxis. Allergy written on some order sheets and "soft" coded into Meditech but never linked to pharmacy drug dictionary.*

Although the vast majority of EHR-related reports did not document actual harm to the patient, analysts believe that further study of EHR-related near misses and close calls is warranted as a proactive measure.

Classification by Event Type

EHR-related reports represented many event types in the Authority's classification system (see Table 2); however, the vast majority of reported events (81%) involved medication errors, mostly wrong-drug, -dose, -time, -patient, or -route errors (50%) or omitted dose (10%). The only other event type with a significant number of reports was complications of procedures, treatments, or tests (13%), most of which involved lab test errors (7%). Analysis attributed this distribution of event types to the wide-reaching nature of potential EHR-related problems. EHR systems are used for the ordering, validation, and administration of medications, laboratory tests, and diagnostic and therapeutic procedures. Therefore, it is not surprising that reported errors related to EHR use are associated with these event types.

Relevant cases were further classified by the same analyst according to an HIT-specific taxonomy developed by Magrabi et al.[3] This taxonomy includes classifications for problems with data input, transfer, output, general technical issues, and contributing factors (see Figure 2). Analysts considered applying the HIT taxonomy contained in the new Agency for Healthcare Research and Quality (AHRQ) Common Formats for risk reporting; however, insufficient detail was present in

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Table 1. Classification of Reports Related to Electronic Health Records, by Harm Score

HARM SCORE*	MACHINE-LEARNING REPORTS	MANUALLY IDENTIFIED REPORTS	TOTAL REPORTS	% OF TOTAL REPORTS
Incident: Unsafe Conditions (harm score A)	204	116	320	10
Incident: No Harm (harm scores B1 through D)	1,952	811	2,763	89
Serious Event: Temporary Harm (harm scores E through F)	10	5	15	0
Serious Event: Significant Harm (harm scores G through I)	0	1	1	0

* As classified in the Pennsylvania Patient Safety Reporting System database.

the narrative reports to properly apply this taxonomy.

Analysts identified four new categories, expanding the Magrabi et al. classification to include specific problems with unit errors in wrong data entry (1.2.1.1), data entered into wrong fields (1.2.1.2), misreading or misinterpreting displayed information (3.4.5), and default values in system configurations (4.4.2.1).

Some reports were tagged with more than one problem type, such as in the following example:

> *Patient was ordered albuterol 0.5 mL Q4H [every four hours] and ipratropium 2 mL Q4H nebulized breathing treatments at 8:00 a.m. into ProTouch system. The order was acknowledged by nursing, but nursing did not notify RT [the respiratory therapy department] of new orders. RT did not become aware of orders until eight hours later. Due to limitations of ProTouch, RT cannot acknowledge respiratory orders; thus, therapist on duty was unaware of the new orders until overdue order report run at end of shift (two doses of each medication missed by that time). Patient did not experience any adverse effects from delay in respiratory therapy treatment; patient's respirations were unlabored.*

— This report was tagged with:
  - 3.4.4, not alerted, because the system was not set up to alert respiratory therapists
  - 4.4.1, software issue—functionality, because the system does not allow alerting of respiratory therapists

An additional example is as follows:

> *A pharmacist entered correct day start time (9/10) for Lovenox®, but interface between pharmacy system and Bridge [administration system] caused the order to default to next day start time. The nurse signed off order without confirming correct order entry and did not "Add Dose" in Bridge to correct start time; patient missed one dose.*

— This report was tagged with:
  - 2.2, system interface issues, because the interface between the pharmacy and Bridge systems changed the order settings
  - 3.3, output/display error, because the Bridge system output an incorrect start time
  - 3.4.2, missing data (did not look at complete record), because the nurse did not confirm correct order entry
  - 4.4.2.1, software issue—system configuration—default, because the Bridge system was configured to change to a default start time

Another report read:

> *Acetate component was not ordered under the component section but was ordered in the administration instructions, which is a free-text field that does not link with the TPN [total parenteral nutrition] additives and was missed by pharmacy upon verification and transcription into the TPN program. Acetate should have been ordered as meq/kg and not acetate 50:50, which was in the administration instructions.*

— This report was tagged with:
  - 1.2.1.2, wrong input—wrong field, because the component order was placed in the wrong field
  - 3.4.2, missing data (did not look at complete record), because the pharmacist did not pull information from the administration instructions field

Overall, 96% of the reports were tagged with only one or two tags (see Table 3), and 3,946 problems were identified in the 3,099 relevant reports.

COMPARISON WITH OTHER DATA SETS

In general, narrative reports from the Authority database exhibited a very different pattern of problem types than the two sets of data tagged by Magrabi et al. (the US Food and Drug Administration's [FDA] Manufacturer and User Facility Device Experience [MAUDE] database, in which there were 712 problems from 432 reports, and Australia's Advanced Incident Management System, in which there were 117 problems). Analysts noted that the most commonly used tags for reports to the Authority were related to wrong input (applied to 47% of reports), failure to update data (18%), or default

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Table 2. Classification of Reports Related to Electronic Health Records, by Event Type

EVENT TYPE	MACHINE-LEARNING REPORTS	MANUALLY IDENTIFIED REPORTS	TOTAL REPORTS	% OF TOTAL REPORTS
A. Medication Error	**1,964**	**552**	**2,516**	**81**
1. Dose omission	257	86	343	11
2. Extra dose	125	29	154	5
3. Wrong	1,226	321	1,547	50
a. Dose/overdosage	755	181	936	30
b. Dose/underdosage	62	17	79	3
c. Drug	91	30	121	4
d. Dosage form	24	9	33	1
e. Duration	19	6	25	1
f. Rate (intravenous)	14	5	19	1
g. Route	20	6	26	1
h. Strength/concentration	17	3	20	1
i. Technique	8	3	11	0
j. Time	72	27	99	3
k. Patient	144	34	178	6
4. Prescription/refill delayed	15	9	24	1
5. Medication list incorrect	58	15	73	2
6. Monitoring error (includes contraindicated drugs)	27	13	40	1
7. Unauthorized drug	31	7	38	1
8. Inadequate pain management	0	1	1	0
9. Other (specify)	225	71	296	10
C. Equipment/Supplies/Devices	**1**	**6**	**7**	**0**
3. Equipment not available	0	1	1	0
4. Equipment malfunction	1	4	5	0
13. Other (specify)	0	1	1	0
E. Error Related to Procedure/Treatment/Test	**123**	**292**	**415**	**13**
1. Surgery/invasive procedure problem	1	2	3	0
2. Laboratory test problem	66	165	231	7
3. Radiology/imaging test problem	12	31	43	1
4. Referral/consult problem	7	16	23	1
5. Respiratory care	9	5	14	0
6. Dietary	1	5	6	0
7. Other (specify)	27	68	95	3
F. Complication of Procedure/Treatment/Test	**0**	**7**	**7**	**0**
2. Anesthesia event	0	1	1	0
10. Catheter or tube problem	0	1	1	0
13. Other (specify)	0	5	5	0
G. Transfusion	**6**	**9**	**15**	**0**
2. Event related to blood-product administration	1	4	5	0
3. Event related to blood-product dispensing or distribution	1		1	0
8. Wrong patient requested	1	1	2	0
13. Other (specify)	3	4	7	0
I. Other/Miscellaneous	**72**	**67**	**139**	**4**
1. Inappropriate discharge	0	1	1	0
5. Other (specify)	72	66	138	4
Total	**2,166**	**933**	**3,099**	**98***

* Data in this table represents 100% of the reports, but the total percentage listed is less than 100% due to rounding of individual categories.

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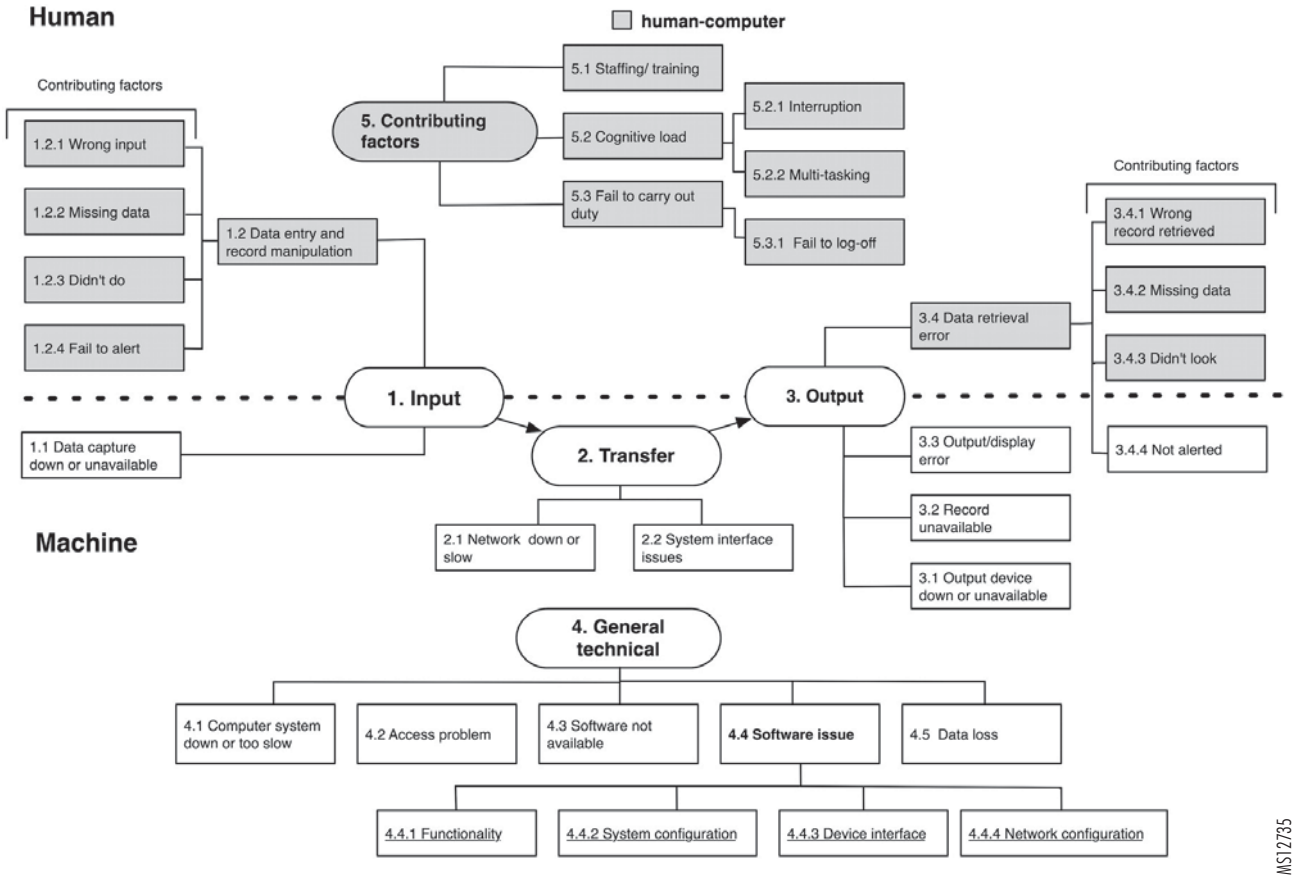
Figure 2. Magrabi et al. Classification of Reports Related to Health Information Technology



Revised classification for health information technology problems (new categories for software problems are underlined)

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(continued from page 115)

system configuration (10%).[3] Many of the classifications developed by Magrabi et al.—especially those that focused on failures of the network, hardware, or software—applied to few or no reports. (See Table 4.)

Wrong Input

Problems related to wrong input (n = 1,867) spanned a wide range of event types and outcomes: transposition or transcription errors in the entry of orders or administration information, entry of incorrect patient parameters (like weight or blood glucose) that trigger calculations of incorrect therapy, and even entry of the wrong physician name, resulting in reports being sent to the wrong recipient. Authority analysts identified two new categories to describe specific types of wrong-input problems that deserved more attention: 1.2.1.1 wrong input—units error (n = 18) and 1.2.1.2 wrong input—wrong fields (n = 65). Reports tagged with "units error" typically involved mix-ups between patient weight units (lb versus kg) or selection or entry of an incorrect dosing unit for a medication (e.g., weight-based dosing like mg/kg/hr versus non-weight-based dosing like mg/hr), and analysts noted that default values contained in EHR systems were mentioned as contributing factors in three of these reports. Reports tagged with "wrong fields" typically indicated unfamiliarity with the configuration or function of a facility's EHR system. Users were entering data in a field that was inappropriate for the intended data, as in the following example:

> *A patient received two extra doses of oral magnesium oxide 400 mg. Order originally placed by physician for [magnesium] oxide 400 mg [twice a day] for two days or four doses. Physician did not place stop date into ProTouch as per proper procedure*

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but instead wrote instructions in the free-text box of ProTouch. When the order was verified by the pharmacist, instructions in the text box [were] not acknowledged. When the nursing staff administered the medication, written instructions [were] not acknowledged. Event [was] discovered by pharmacist after the patient had received six doses of medication.

Table 3. Number of Tags Assigned per Report

NO. OF TAGS PER REPORT	MACHINE-LEARNING REPORTS	MANUALLY IDENTIFIED REPORTS	TOTAL REPORTS (N = 3,099)	% OF TOTAL REPORTS
1	1,728	616	2,344	76
2	364	250	614	20
3	59	61	120	4
4	12	5	17	1
5	3	1	4	0

Default Values

This classification was created when Authority analysts noted that a large proportion of system configuration issues mentioned errors due to default values. Like wrong-value problems, default-value problems spanned a wide range of event types and outcomes, but reports generally fell into one of two categories: (1) a user failed to modify a prepopulated default value for dose, time, route, or other parameters in an order or (2) after entry of an order, a system replaced entered information with default values, often for start times. After correspondence with Magrabi,[4] the first type of default-value reports ("user failure to modify a default," n = 70) were removed and retagged as 1.2.3 failure to update data, and the second type ("system inserts a default after human entry," n = 221) were tagged with a new code, 4.4.2.1 software issue—system configuration—default.

Failure to Update Data

Problems related to failure to update data (n = 762) largely involved four event types: (1) users failing to transcribe written or verbal orders into an electronic order or pharmacy system, (2) users failing to enter lab results into an information system, (3) users failing to modify a default value to an intended value (as described in the discussion regarding default values), or (4) users reporting that they did not properly document a clinical activity like removing a medication from stock or administering a therapy. Analysts noted that many failure-to-document events involved situations in which documentation was completed in a paper system but not an electronic system (n = 85). By attempting to use both paper and electronic systems in the course of workflow, users created confusing and conflicting situations in which patient care was compromised, such as in the following case:

> *A patient was admitted to [the emergency department] with [a urinary tract infection]. A physician prescribed ciprofloxacin 500 mg [by mouth, once]. Patient had been in the [emergency department] for a while, and the previous nurse had administered the dose without documenting it on the physician's order sheet. The next nurse also administered the dose because she did not see it documented. When she went into the EHR, she saw that the previous nurse had documented [the initial administration] in the computer. She called the nurse to double-check that the [medication] had been given. The physician was notified about the double dose.*

DISCUSSION

The pattern of reported problems present in the PA-PSRS database was different than that found by Magrabi et al. in FDA's MAUDE database. Analysts attribute this difference in problem patterns to (1) differences in both the databases themselves and the people who populate them and (2) limitations of the existing PA-PSRS data set.

PA-PSRS and MAUDE differ in scope and reporting requirements. The MAUDE database is populated by mandatory and voluntary reports of device failures and device-related errors. Currently, devices and systems like radiology information systems (RIS) and PACS are FDA-cleared medical devices with mandated reporting requirements, while EHR systems, laboratory information systems, and computerized provider order entry (CPOE) and pharmacy (PhIS) systems are not. Therefore, the MAUDE database is likely to contain more reported events related to PACS than CPOE. The query string used for this analysis also differs from the string used by Magrabi et al.; it specifically targeted EHR- and EMR-related events and did not include terms related to RIS or other more broadly defined HIT technologies.

PA-PSRS and MAUDE also differ in the background of reporting individuals. The MAUDE database is typically populated by biomedical and clinical engineers employed by facilities and manufacturers, while the PA-PSRS database is typically populated by risk management professionals who are collecting clinical narrative event reports. Both reporting systems receive reports that are framed by the reporter's experience. Frontline caregivers will likely recognize if they have failed to perform a duty or have entered incorrect information, but they will rarely have enough information to suspect a problem with device components or network

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Table 4. Application of Magrabi et al.* Taxonomy to Queried Reports

EVENT REPORT TAGS	NO. OF TAGGED REPORTS			% OF TAGGED PROBLEMS		
	Machine-Learning Reports	Random Sample of Reports	PA-PSRS† Reports	PA-PSRS Data	Magrabi et al. MAUDE‡ Data	Magrabi et al. AIMS§ Data
1.1 Data capture down or unavailable	2	1	3	0	6	2
1.2.1 Wrong input	1,348	519	1,867	47	3	17
1.2.1.1 Wrong input—units error	12	6	18	0	**	**
1.2.1.2 Wrong input—wrong fields	43	22	65	2	**	**
1.2.2 Missing data	22	16	38	1	<1 throughout	6
1.2.3 Fail to update data	490	272	762	18	<1	6
1.2.4 Fail to communicate/carry out task	9	13	22	1	0	0
2.1 Network down or slow	5	6	11	0	<1	10
2.2 System interface issues	34	55	89	2	1	9
3.1 Output device down or unavailable	107	59	166	4	<1	4
3.2 Record unavailable	15	6	21	1	<1	0
3.3 Output/display error	113	30	143	4	28	5
3.4.1 Wrong record retrieved	46	19	65	2	<1	4
3.4.2 Missing data (did not look at complete record)	22	7	29	1	0	0
3.4.3 Didn't look	15	11	26	1	<1	4
3.4.4 Not alerted	10	17	27	1	0	2
3.4.5 Misread/misinterpret	9	1	10	0	**	**
4.1 Computer system down or too slow	29	22	51	1	16	9
4.2 Software not available	1	5	6	0	0	<1
4.3 Unable to login	3	3	6	0	0	5
4.4 Software issue	**	**	**	**	**	7
4.4.1 Software issue—functionality	34	16	50	1	32	**
4.4.2 Software issue—system configuration	48	49	97	2	3	**
4.4.2.1 Software issue—system configuration—default	168	53	221	8	**	**
4.4.3 Software issue—device interface	0	0	0	0	6	**
4.4.4 Software issue—network configuration	2	0	2	0	<1	**
4.5 Data loss	33	28	61	2	2	2
5.1 Contributing factor—staffing/training	30	24	54	1	0	2
5.2.1 Contributing factor—cognitive load—interruption	1	3	4	0	0	<1
5.2.2 Contributing factor—cognitive load—multitasking	1	2	3	0	0	<1
5.3.1 Contributing factor—fail to carry out duty—fail to log off	1	3	4	0	0	3

Note: Sample sizes are as follows: machine-learning reports (2,166 reports); random sample of reports (933 reports); PA-PSRS reports (3,009 reports); PA-PSRS data (3,946 problems from 3,099 reports); Magrabi et al. MAUDE data (712 problems from 436 reports); Magrabi et al. AIMS data (117 problems).

* Magrabi F, Ong MS, Runciman W, et al. Using FDA reports to inform a classification for health information technology safety problems. *J Am Med Inform Assoc* 2012 Jan-Feb;19(1):45-53.

† Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System

‡ US Food and Drug Administration's Manufacturer and User Facility Device Experience database

§ Australia's Advanced Incident Management System

** Tag not used in analysis

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components. Therefore, most frontline caregiver reports of system availability errors may indicate that the "computer system was down" (tag 4.1), even if the underlying cause is a device interface issue, a network configuration problem, or an access problem.

Limitations

Specific limitations of this study may also shape the nature and frequency of EHR-related events present in the PA-PSRS database query.

Reporting statutes of PA-PSRS. Pennsylvania healthcare facilities are required to report Serious Events, Incidents, and Infrastructure Failures through the Authority's PA-PSRS. However, Infrastructure Failures are accessible only by the Pennsylvania Department of Health. In many facilities, a failure of a computer, information system, or network may be classified as an Infrastructure Failure and would not appear in the Authority's data set.

Awareness of EHRs as a potential contributing factor to an error. As noted previously, frontline caregivers may not suspect that an EHR system has contributed to a human error. Events in the PA-PSRS database were not picked up by the Analysts' query if they did not specifically call out a particular system or EHR in general. Therefore, if a frontline caregiver did not suspect that the configuration of an EHR somehow contributed to their choosing the wrong drug for a patient, they may have simply reported that they selected the wrong drug and not mention the EHR.

Limitations of narrative reporting affected both the types of reports queried and the tags applied. Unless a narrative report specifically included the search query terms, the report was not captured by this query. Unless specifically mentioned in a narrative report, a problem type or contributing factor could not be tagged. Perhaps because of these limitations, few of the contributing factors identified by Magrabi et al. could be applied to queried reports. Although analysts may suspect that EHR-related errors could stem from inadequate training, interruption, or multitasking, analysts could not apply these tags unless the narrative specifically identified these problems.

The limitations of using narrative review to identify EHR-related reports could be alleviated through the use of EHR- or HIT-specific event taxonomy like that used for the AHRQ Common Formats. Going forward, it may be advantageous for the Authority to include EHR- or HIT-specific options in the event type taxonomy and provide educational materials on the use of this taxonomy. This would prompt users to specify whether they believe EHR systems played a role in the reported event and would reduce the burden of manually reviewing irrelevant queried reports. As in any scientific study, adding to reporter knowledge will likely increase the quality of the reports and decrease the missed risk events, allowing the Authority a greater understanding of HIT risks.

Query design. This study's query focused on EHR system names and usage terms. Terms related to missing, lost, or corrupted data were not specifically included in the search string, although reports of this type were identified in the study. Further study on a more focused query string could identify more reports of system errors resulting in missing, lost, or corrupted data.

Further refinement of the machine-learning tool. Analysts have not manually confirmed the remaining 3,936 queried reports that were identified as "not EHR-relevant" by the machine-learning algorithm. Therefore, events that were falsely tagged by the machine-learning algorithm as "not EHR-relevant" were excluded from this analysis. Identification of false-negative machine-learning results could allow for refinement of the machine-learning algorithm.

CONCLUSIONS

Overall, 3,946 problems were identified in the 3,099 reports of EHR-related events identified through this query of the Authority's database, and several themes that may prove fruitful for further study were identified in reviewed reports, including the following:

— The types of reported human-related problems (e.g., wrong entry, wrong field, failure to update data) could have many underlying causes, which could not be captured in the current data set of narrative reports. Further study could provide more insight into the root causes of these errors, which may include issues in workflow design or policies and procedures, usability or functionality gaps in the design or configuration of an electronic system, or gaps in the training or understanding of the user population.

— Ongoing study of incident reports can help identify the common types of problems seen with EHRs. The Authority can help improve patient safety by characterizing and systematically addressing these common problem types even in the absence of root-cause data.

— EHR- and HIT-related reports that are classified by reporting facilities as Infrastructure Failures are accessible by the Pennsylvania Department of Health but not by the Authority. Because many facilities classify failures of information technology networks and systems as Infrastructure Failures, this type of report is likely to be underrepresented in the Authority's database. A query of the Infrastructure Failure reports may identify more machine- and system-related reports of EHR and HIT events.

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— Adding EHR- and HIT-specific event types and taxonomy to the Authority's reporting system may increase the number and quality of event reports related to EHRs and HIT.

— Dual workflow that uses both paper-based and electronic records seems particularly problematic and may be of interest for further study as more facilities transition between paper-based and electronic systems.

— The configuration of electronic systems, especially the use of default values, seems to lead to certain types of errors in medication orders and documentation. Further study could shed some light on best practices in the use of default values in system configuration.

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NOTES

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Analysis of the Multiple Risks Involving the Use of IV FentaNYL

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ABSTRACT

FentaNYL is a synthetic opioid analgesic with potent analgesic activity and fewer side effects in comparison with morphine whose rapid onset of action has led to increasing use in postanesthesia care units (PACUs) and emergency departments (EDs). Analysts reviewed medication errors and adverse drug reactions (ADRs) involving intravenous (IV) fentaNYL that were reported to the Pennsylvania Patient Safety Authority. The predominant medication error event types associated with IV fentaNYL were wrong-dose/overdosage events and wrong-drug events. Of the reported wrong-dose/overdosage events originating in the administration node, almost 68% mention breakdowns during the pump-programming process. High-alert medications were involved in almost 70% of wrong-drug events with fentaNYL. The most common categories of care areas cited in ADR reports include procedural areas (43.2%), surgical areas (19.9%), and intensive care units (12.5%). Effective risk reduction strategies include restricting the use of patient-controlled analgesia with fentaNYL to anesthesia or pain management team members, establishing standardized protocols and order sets for pain management, and requiring an independent double check before administering IV fentaNYL doses. (Pa Patient Saf Advis 2012 Dec;9[4]:122-9.)

INTRODUCTION

FentaNYL is a lipophilic, short-acting synthetic opioid that was synthesized to produce an opioid analgesic with potent analgesic activity and potentially fewer side effects in comparison with meperidine or morphine.[1,2] Injectable forms of fentaNYL have been in clinical practice for more than 40 years as a component of anesthetic analgesic regimens and for the management of acute pain by different routes of administration.[2] The drug has strong affinity for the mu opioid receptor, binding at many sites within the central nervous system (CNS), increasing pain threshold, altering pain reception, inhibiting ascending pain pathways, and producing an analgesic effect, as well as adverse effects such as nausea, vomiting, and respiratory depression.[1,3,4]

When fentaNYL is administered intravenously (IV), it has a short onset of action (one to two minutes), making it an ideal analgesic when rapid pain relief is required. This rapid onset of action explains why fentaNYL has been used with increasing frequency in postanesthesia care units (PACUs) and emergency departments (EDs).[3,5] Within three to five minutes of administration, the drug reaches its peak effect, yet it has a relatively short duration of action of 30 to 60 minutes. The short duration of action makes fentaNYL an ideal agent when the goal is to have a short recovery time, such as in outpatient procedures. It should be noted that the elimination half-life of fentaNYL ranges between two to four hours and is influenced by the extent of storage into fatty issue.[2,3] FentaNYL is thought to be 80 to 100 times as potent as parenteral morphine for acute pain in patients who are opioid-naïve.[3,5] Some studies show that 25 mcg/hr of parenteral fentaNYL is equal to 1 mg/hr of parenteral morphine.[3]

Although medication errors with opioid analgesics are common,[6] Pennsylvania Patient Safety Authority analysts found no specific studies addressing medication errors associated solely with IV fentaNYL. An examination of medication errors in PACUs reported over a seven-year period to MEDMARX (Quantros, Milpitas, California), an Internet-accessible medication error reporting system available to subscribing hospitals and related health systems, found that the most common medications mentioned were morphine, meperidine, HYDROmorphone, and fentaNYL.[7] In a separate study of pediatric medication errors in the PACU reported over a six-year period to MEDMARX, researchers reported that 20% of the medication errors were harmful, with half of the errors involving morphine, acetaminophen, meperidine, or fentaNYL.[8]

An adverse drug event (ADE) is defined by the Joint Commission as "any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient."[9] ADEs can be divided into two categories: (1) medication errors, which are considered to be *preventable* ADEs, and (2) adverse drug reactions (ADRs), which are considered to be *unpreventable* ADEs. Despite this distinct difference in definition, ADR reports may be a source of potentially preventable events, even though reporters thought the ADE could *not* have been prevented.

The following analysis addresses medication errors *and* ADRs specifically involving IV fentaNYL reported to the Authority and the predominant types of reported events involving IV fentaNYL.

METHODOLOGY

Analysts queried the event description field of all event types in the Authority's Pennsylvania Patient Safety Reporting System database from June 2004 to March 2012 for "fentanyl." The search also included the "medication prescribed" and "medication administered" fields in medication error events and the "suspected medication" field

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in ADR events. The initial query yielded 3,857 reports. To focus on events involving only IV doses of fentaNYL, analysts excluded reports (n = 1,538) involving other dosage forms, including transdermal systems (e.g., Duragesic®) and oral formulations (e.g., Actiq®, Fentora®). The final data set included 2,319 events involving the use of IV fentaNYL.

AGGREGATE ANALYSIS OF EVENTS INVOLVING IV FENTANYL

Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index,[10] shows that 74.6% (n = 1,729) of the events reached the patient (harm score = C to I), 33.1% (n = 768) of the events reached the patient *and* required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm (harm score = D), and 3.2% (n = 74) of the events resulted in patient harm (harm score = E to I).

The care areas in which the events occurred were distributed across many units. No individually mentioned unit represented more than 8% of reports. The most often cited care areas include pediatric intensive care units (ICUs) (7.8%, n = 180), pharmacy (6.6%, n = 154), medical-surgical units (6.6%, n = 152), PACUs (4.9%, n = 114), and neonatal ICUs (4.8%, n = 112). More than 85% (n = 1,972) of reports involving IV fentaNYL were reported as medication errors, 10.4% (n = 241) were reported as ADRs, and the remaining events were submitted as other types of reportable events. Besides the event type of "medication error, other" (16.6%, n = 385), the predominant event types reported mentioning IV fentaNYL (see Table) were "medication error, wrong dose/overdosage" (15.0%, n = 347), "medication error, wrong drug" (10.5%, n = 243), and "ADR, other" (7.6%, n = 177).

FOCUSED EVENT TYPE ANALYSIS

Wrong Dose/Overdosage

Review of the descriptions of the events submitted to the Authority show that the most common nodes associated with wrong-dose/overdosage events involving IV fentaNYL were administration (58.5%, n = 203), prescribing (15.2%, n = 53), and dispensing (6.3%, n = 22). In addition, most of the wrong-dose/overdosage events (38.9%, n=135) reached the patient and required monitoring and/or required intervention to preclude harm to the patient (harm score = D). Categorization of the harm revealed that 4.6% (n = 16) of the wrong-dose/overdosage events resulted in patient harm (harm score = E to I).

When looking at care areas, the most commonly cited care areas were ICUs (30.8%, n = 107) and units caring for pediatric patients (e.g., pediatric ICU, neonatal ICU, pediatric units) (21.0%, n = 73), followed by obstetrics and gynecology (5.2%, n = 18) and surgical areas (e.g., PACU, operating rooms [ORs], anesthesia) (4.6%, n = 16).

Pump programming. Of the events originating in the administration process, almost 68% (n = 138) mention breakdowns during the pump-programming process. Further analysis of the events that occurred during the administration of IV fentaNYL by infusion pump shows that most of the reported cases involved programming the wrong rate of infusion (59.4%, n = 82) or wrong drug concentration (19.6%, n = 27).

> *The patient's epidural infusion was ordered for 8 mL/hr. The patient's level of sensation and ability to move extremities were normal for the first two hours. The patient then became nauseated, felt fatigued, and [had low] blood pressure. ePHEDrine was administered. When moving the patient's position, the patient had difficulty positioning his arms. An additional dose of ePHEDrine was administered. It was at this time that the [infusion] rate was noted to be set at 88 mL/hr. The pump was shut off and the physician was notified. . . . The patient was monitored.*

> *The patient was found lethargic with shallow respirations. A fentaNYL drip was infusing at 25 mL/hr (250 mcg/ hr) instead of 5 mL/ hr (50 mcg/hr). The infusion was immediately stopped, the patient was placed on 100% oxygen, and 0.2 mg Narcan® was given.*

> *A fentaNYL infusion was ordered to run at 20 mcg/hr. The infusion was programmed at 40 mcg/hr. Further investigation showed that the medication concentration had been changed from 10 mcg/mL to 20 mcg/mL, but the pump setting was not adjusted accordingly when the new syringe was hung.*

Table. Predominant Event Types Associated with the Use of IV FentaNYL (N = 2,319), June 2004 to March 2012

EVENT TYPE	NO. OF REPORTS	% OF TOTAL REPORTS
Medication error, wrong dose/overdosage	347	15.0
Medication error, wrong drug	243	10.5
Medication error, wrong rate	134	5.8
Medication error, wrong strength or concentration	96	4.1
Medication error, wrong patient	70	3.0
Medication error, other	385	16.6
Adverse drug reaction, other	177	7.6

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Administering. The descriptions of events that occurred during the administration node and did not involve the programming of an infusion pump (n = 78) did not provide enough detail to determine specifically what went wrong. Most reports (56.4%, n =44) simply stated that the patient received a higher or wrong dose than what was intended. However, analysts were able to determine that the package size of the vials or ampules and/or that the available concentration (50 mcg/mL) of IV fentaNYL may have contributed in these errors, especially for the pediatric population.

> *During a trauma care, the physician gave a verbal order for fentaNYL 25 mcg IV push for one dose. The first nurse drew up the entire vial of fentaNYL (5 mL = 250 mcg) into a syringe. She did not label the syringe in any way. She handed the syringe to the second nurse and instructed him to push 25 mcg without telling him how much was in the syringe. The second nurse pushed the entire syringe, which was 250 mcg, a [tenfold] overdose from what was prescribed. The error was immediately noticed by the first nurse when the second nurse returned with an empty syringe. Physician [was made] aware, and patient was closely monitored for any adverse effects.*

> *A six-month-old infant was admitted to the hospital for head trauma. In preparation for a head CAT [computerized axial tomography] scan to evaluate the status of his injury, the baby was to be given fentaNYL 5 mcg. The nurse caring for the child drew up 1 mL of fentaNYL (50 mcg) with the intention of administering 0.1 mL (5 mcg); however, a nurse orientee working with the nurse administered the entire syringe. The error was immediately noticed and the child was given Narcan 0.2 mg.*

Prescribing. Of the wrong-dose/overdosage events originating in the prescribing node, analysis shows that 35.8% (n = 19) involved orders exceeding the normal therapeutic dosing range, followed by duplicate therapy (30.2%, n = 16) and mix-ups between the dosage units of mg and mcg (17 %, n = 9).

> *An order [was] written for a two-month-old patient for fentaNYL 1 mcg/kg/dose, but the [patient's] weight was entered incorrectly as 70 kg. The patient actually weighs 3.7 kg. The dose was ordered by anesthesia as 70 mcg instead of 4 mcg. The fentaNYL was given in the OR, but the dose [was] not recorded. . . . The pharmacy saw this order in PACU and halted the order immediately.*

> *An order was received for a fentaNYL infusion for a patient who was already on a morphine infusion. Upon calling the PACU, I questioned the fact that this patient was already on morphine at 5 mg/hr. The equivalent dose of fentaNYL would be 50 mcg/hr. The order was written for fentaNYL at 200 mcg/hr. The order was corrected, and the morphine infusion was discontinued.*

Wrong Drug

Almost one-third of wrong-drug events (29.6%, n = 72) involving IV fentaNYL reached the patient and required monitoring and/or required intervention to confirm that it resulted in no harm (harm index = D). Roughly 5.3% of events (n = 13) resulted in patient harm (harm score = E to I). The care areas most often cited with IV fentaNYL wrong-drug events include ICUs (22.2%, n = 54), surgical areas (20.2%, n = 49), pediatric units (11.1%, n = 27), and procedural areas (e.g., endoscopy/gastrointestinal lab, imaging) (4.9%, n = 12).

Analysts determined that high-alert medications, drugs that bear a heightened risk of causing significant patient harm when used in error,[11,12] were involved in almost 70% (n = 170) of drug mix-ups with fentaNYL. Four medications accounted for nearly half (47.7%, n = 116) of the mix-ups with fentanyl, including HYDROmorphone (15.6%, n = 38), morphine (13.6%, n = 33), midazolam (11.1%, n = 27), and the combination fentaNYL/bupivacaine (7.4%, n = 18).

Examples of the events involving mix-ups with fentaNYL include the following:

> *Patient was admitted to the ED for multiple trauma. The ED physician was going to intubate the patient, and nursing brought the requested medications for the intubation, including midazolam, fentaNYL, and succinylcholine. The succinylcholine had been drawn up in a syringe and labeled. The physician decided not to intubate but ordered the nurse to give fentaNYL for pain. The nurse picked up the syringe and administered 0.5 mL when he realized it was succinylcholine.*

> *A physician, in the labor and delivery area, ordered ampicillin and fentaNYL at the same time. The nurse prepared the medications at the same time. The fentaNYL for the epidural was hung in place of the ampicillin; the nurse noted the error after approximately 5 mL were given.*

> *Anesthesia signs out a drug box each morning, which contains fentaNYL and ketamine. The ketamine was recently added to the drug box. The doctor stated she was not aware that ketamine was in the box. She drew up the ketamine but labeled and administered [it] as if it were fentaNYL. Patient [was] not arousing in the recovery area as anticipated, and doctor [was] informed of this. Error [was] realized when the medication box was checked back in by a staff nurse. The fentaNYL and the ketamine counts were incorrect.*

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The patient was agitated and attempting to self-extubate. A nurse grabbed a syringe at the bedside and thought it was fentaNYL. The nurse asked the respiratory therapist at the bedside to place the patient back on the vent. At that time, the patient was no longer breathing and was tachycardic. The nurse looked at the syringe in which they pulled the dose and saw it to be pancuronium.

Roughly 8.2% (n = 20) of wrong-drug events with IV fentaNYL involved retrieving the incorrect drug from the automated dispensing cabinet (ADC) or stocking the wrong drug in the drawers of those cabinets.

Went to the ADC to get a HYDROmorphone PCA [patient-controlled analgesia] syringe, pulled the medication, went to patient's room with syringe, and before loading it into the PCA pump, I checked the medication, and it was fentaNYL. I informed the charge nurse, who checked the ADC and found that the HYDROmorphone drawer had fentaNYL and that the fentaNYL drawer had HYDROmorphone.

Nearly 12% (n = 29) of wrong-drug events with IV fentaNYL involved epidural PCA therapy.

Patient was connected to an epidural infusion in the OR by anesthesia. It was discontinued at the time of transport to the PACU. In the PACU, the physician went to restart the infusion and it was determined that the medication in the bag was morphine sulfate for PCA use only and the medication was not restarted. An epidural infusion with fentaNYL was started.

Adverse Drug Reaction

Similar to the analysis of HYDROmorphone ADR reports published in the September 2010 *Pennsylvania Patient Safety Advisory*,[13] analysts reviewed ADR reports submitted to the Authority to determine if there were cases that may have been preventable (e.g., errors caused by an excess dose of IV fentaNYL, use of concomitant respiratory/CNS depression drugs). Analysts searched for "fentanyl" in the "suspected medication," "additional suspected drug medication," and event description fields to find ADR reports that may have involved IV fentaNYL alone or in combination with other medications.

There were 318 ADR reports submitted to the Authority between June 2004 and March 2012 related to the use of IV fentaNYL. Analysts excluded reports that would not have resulted from dosing-related problems that were categorized as skin reactions (24.2%, n = 77) from the analysis, resulting in 241 reports. Almost 82.2% (n = 198) of the ADR reports indicated that the patient received the medication and required monitoring and/or required intervention to confirm that it resulted in no harm (harm score = D), with nearly 8% (n = 19) of ADRs resulting in patient harm (harm score = E to I). Specific care areas most often cited in ADR reports involving fentaNYL include the endoscopy/gastroenterology lab (24.1%, n = 58), OR (7.9%, n = 19), and PACU (7.5%, n = 18). The most common categories of care areas cited include procedural areas (43.2%, n = 104), surgical areas (19.9%, n = 48), and ICUs (12.4%, n = 30).

The most common categories of reactions described in the narratives include respiratory depression (50.2%, n = 121) and mental status changes (10.8%, n = 26). Roughly 22% (n = 52) of the reports did not give enough information to discern the types of reaction. Since fentaNYL is a primary drug for conscious sedation, determining preventability is difficult in these events without knowing the details of the procedure (e.g., length of the procedure), as multiple doses of fentaNYL may be needed for longer cases.

Anecdotal examples of events that appear to be preventable events include:

Patient scheduled for ERCP [endoscopic retrograde cholangiopancreatography]. Patient received initial medications consisting of midazolam 3 mg, fentaNYL 80 mcg, and diphenhydrAMINE 40 mg. The patient was still awake, so additional doses of midazolam 2 mg and fentaNYL 40 mcg were given. Within 10 minutes, the patient became somnolent and the oxygen saturation fell into the 70s. Narcan was given.

Patient was admitted for a colonoscopy and was given sedation for the procedure. Shortly after the colonoscopy began, the patient became dusky, respirations decreased, and she became unresponsive, with a pulse oximetry [reading] of 65%. She had received a total of 5 mg of midazolam and 250 mcg of fentaNYL in titrated doses. She was given Narcan 1.2 mg in divided doses and bagged with an Ambu bag. She immediately recovered a pulse oximetry [reading] of 96% and became awake and alert. The procedure was able to be completed, and the patient was monitored in the recovery area for two hours prior to discharge.

A 71-year-old patient received a total of fentaNYL 120 mcg and midazolam 4 mg for ERCP procedure. The patient became less responsive, the respiratory rate was 8 and pulse oximetry [reading] was 72% despite repositioning of head and increased oxygen. 0.3mg Narcan given.

RISK REDUCTION STRATEGIES

Healthcare facilities can strive to identify system-based causes of errors with the use of IV fentaNYL and other opioids and implement effective types of risk reduction strategies to prevent harm to patients. Risk reduction strategies such as constraints and standardization, which focus

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on system improvement, will be more effective than education alone, which relies on individual performance.[14,15] Consider the strategies described below, which are based on a review of the literature and of events submitted to the Authority, as well as observations from the Institute for Safe Medication Practices.

Constraints

- Prescribing
  - Consider restricting fentaNYL PCA use to anesthesia or pain management team members only.[16]
  - Consider requiring prescribers to undergo a privileging process to verify proficiency with PCA pain management.[17]
  - Implement standard order sets for PCA therapy, with all sections completed, and limit verbal orders to dose changes.[16]
  - Take into consideration important information about the patient that could affect the prescribing of IV fentaNYL (e.g., patient's current medication profile for drugs with additive CNS or respiratory depressant side effects, age, drug-drug interaction, total current opioid therapy).
- Storage
  - Reduce stock amounts of IV fentaNYL wherever possible, and eliminate it from floor stock entirely if usage is low.
  - Store each medication in a separate, lock-lidded bin or drawer in the ADC to help prevent drug-selection errors. In the pharmacy, segregate prefilled syringes and vials of these drugs, especially if they contain the same concentration.[18]

Standardization

- Establish and mandate the use of standardized protocols for pain management, including a standard pain scale for assessment, guidelines for the use of specific analgesics, standard order forms and screens, guidelines outlining conditions that require a dose reduction, and requirements for monitoring.[17]
- Match the sequence of information that appears on fentaNYL PCA medication labels and order sets with the sequence of information that must be entered into the PCA pump.[15]
- Establish one standard concentration for IV fentaNYL used for PCA.[16]
- Establish protocols for reversal agents that can be administered without additional physician orders when warranted.[19]
- In standard order forms, guide prescribers to an appropriate dose based on age and opioid tolerance by providing default doses for three types of patients: (1) most patients; (2) patients older than 64 years or those with sleep apnea; and (3) opioid-tolerant patients.[20]

Differentiation

- Clearly label infusion bags that contain epidural fentaNYL with "For Epidural Use Only" in a large font. Use color and design to differentiate these products from IV medications.[16]
- For epidural infusions, use pumps that look different than pumps used for IV infusions and clearly label pumps used to deliver epidural medications as "Epidural Only."[16]
- Use yellow-lined tubing without injection ports for epidural infusions to set its appearance apart from typical IV tubing. Never use yellow-lined tubing for anything other than epidural administration.[21]

Redundancies

- Where possible, require an independent double check before administering IV fentaNYL doses. Since nurses routinely obtain narcotics from floor stock, the typical pharmacist-nurse double check is not in place (as it is with specific patient doses dispensed from the pharmacy). Some ADCs can be programmed to require a witness when selected narcotics are removed or when the override feature is used to access selected narcotics. Reminders can also appear on the screen.[17]

Patient Monitoring

- Establish guidelines for appropriate monitoring of patients who are receiving fentaNYL, including frequent assessment of the quality of respirations (not just a respiratory rate), the type of equipment to be used for monitoring respirations (e.g., capnography), and specific signs of oversedation. Ensure resources—both personnel and equipment—are available to monitor patients per established guidelines.[18]
- Use standardized formats for documenting pain control and monitoring parameters.[18]
- Ensure that oxygen and naloxone are available where opioids are administered.[18]
- Establish a process to screen patients for obstructive sleep apnea before initiation of fentaNYL PCA therapy, with further assessment by a respiratory therapist if the screening reveals two or more risk factors.[19]

Education and Information

- Require annual competence assessments for all professionals who prescribe, dispense, administer, or monitor the effects of fentaNYL.[16]
- Create mandatory education programs for all practitioners potentially involved with IV fentaNYL use. Include all aspects of safe use; accepted prescribing practices,

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including those related to the management of the opioid-naïve patient; dosing norms; assessment parameters; and monitoring techniques.

— Provide staff with safety information on the use of potent narcotics via newsletters, during in-services, or through material available on their preferred form of technology (e.g., smartphones, tablets).

Monitoring of ADRs

— As demonstrated by previous analysis of ADR reports submitted to the Authority,[12] these types of reports serve as a potentially rich source of information to identify risk with the use of IV fentaNYL, as well as other opioids, in the facility. Consider reviewing ADR reports, as well as the use of "trigger" drugs (e.g., naloxone) used to reverse the effects of opioids, to obtain outcome measures to get a broader picture of the harm resulting from the misuse of IV fentaNYL.

— Consider measures other than practitioner reporting of medication errors to evaluate your organization's processes with the use of IV fentaNYL, including assessing core processes associated with IV fentaNYL.

CONCLUSION

FentaNYL is a potent, synthetic opioid analgesic with fewer side effects in comparison with morphine whose rapid onset of action has led to increasing use in many care areas including PACUs and EDs. Analysis of medication errors and ADRs involving IV fentaNYL reveal that the predominant medication error event types associated with IV fentaNYL were wrong-dose/overdosage events and wrong-drug events, which could lead to patient harm. More than two-thirds of reported overdosage events mention breakdowns during the pump-programming process, and high-alert medications were involved in almost 7 out of 10 wrong-drug events with fentaNYL. Effective risk reduction strategies to prevent patient harm could include restricting fentaNYL PCA use to anesthesia or pain management team members, establishing standardized protocols and order sets for pain management, and requiring an independent double check before administering IV fentaNYL doses.

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LEARNING OBJECTIVES

- Recognize the risks associated with the dosing of intravenous (IV) fentaNYL.
- Recognize the types of medication errors that are associated with IV fentaNYL.
- Identify common reported adverse drug reactions with the use of IV fentaNYL.
- Select appropriate strategies to promote the safe prescribing, dispensing, and administering of IV fentaNYL.

SELF-ASSESSMENT QUESTIONS

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

A physician writes an order for 500 mcg of IV fentaNYL for a 39-year-old who complains of pain after a laparoscopic procedure. After receiving this dose, the patient was found unresponsive with low oxygen saturation and respiratory rate.

1. What is the equivalent dose of morphine IV for this patient?
   a. 10 mg
   b. 20 mg
   c. 50 mg
   d. 75 mg
2. Which of the following statements *best* describes why IV fentaNYL has been considered to be an ideal analgesic agent in outpatient procedures, where the goal is to have a short recovery time?
   a. IV fentaNYL has fewer side effects compared with other analgesics.
   b. IV fentaNYL has a rapid onset of action.
   c. IV fentaNYL is safer than other analgesics.
   d. IV fentaNYL is more potent than other analgesics.
3. Which of the following is the type of medication error involving the use of IV fentaNYL most commonly reported to the Pennsylvania Patient Safety Authority?
   a. Wrong drug selection
   b. Wrong rate of infusion
   c. Wrong dose/overdosage
   d. Monitoring error/documented allergy
4. Which of the following is the area of care with medication errors involving the use of IV fentaNYL most commonly reported to the Authority?
   a. Intensive care unit
   b. Postanesthesia care unit
   c. Emergency department
   d. Medical-surgical unit
5. Which of the following is the adverse drug reaction related to IV fentaNYL most commonly reported to the Authority?
   a. Bradycardia
   b. Hypotension
   c. Central nervous system depression
   d. Respiratory depression

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SELF-ASSESSMENT QUESTIONS (CONTINUED)

A facility's pain team evaluated a patient at 10 a.m. and increased the basal rate of the fentaNYL patient-controlled analgesia (PCA) to 20 mcg/hr from 12 mcg/hr. Three hours later, the palliative care team saw the patient and increased the basal rate of the PCA to 100 mcg/hr. Early the next morning, the patient needed a dose of naloxone, and fentaNYL basal rate was decreased to 50 mcg/hr by the hospitalist.

6. Based on this scenario, which of the following is the *least* effective strategy to mitigate the risk of harm with IV fentaNYL?
   a. Provide staff with safety information on the use of IV fentaNYL via newsletters and in-services.
   b. Restrict the use of fentaNYL PCA to anesthesia or pain management team members.
   c. Establish standardized protocols and order sets for pain management.
   d. Implement processes with double checks during the administration phase of IV fentaNYL.

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Surgical Fires: Trends Associated with Prevention Efforts

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ABSTRACT

Fires on the operating field are dangerous to patients and providers. The Pennsylvania Patient Safety Authority did an analysis of the reports of surgical fires in its database. Analysts identified reports of fires submitted over seven years that occurred in the operating room on the surgical field and involved combustion resulting from a combination of heat, oxygen, and fuel. Seventy events that met the analysts' definition of fires on the operating field were reported in the seven years between July 1, 2004, and June 30, 2011. Over the past four years for which data was available, the rate of surgical fires has varied from 0.63 per 100,000 operations (1 per 157,545 operations) in the academic year 2007-2008 to 0.32 per 100,000 operations (1 per 309,305 operations) in the academic year 2010-2011. One-third of the reported events indicated harm to the patient. Risk to providers, rather than patients, was cited in 6% of reports. Surgical fires remain a significant enough risk to justify use of a Fire Risk Assessment Score and adherence to the recommendations of the American Society of Anesthesiologists Task Force on Operating Room Fires and those of the Anesthesia Patient Safety Foundation. (Pa Patient Saf Advis 2012 Dec;9[4]:130-5.)

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

INTRODUCTION

Fires on the operating field are rare events that should never happen, but do. They are dangerous not only to the patient but to the operating room (OR) team members as well. The Pennsylvania Patient Safety Authority did an analysis of reports of surgical fires in its database for the primary purpose of determining if surgical fires continue to be a problem, as identified by the Joint Commission,[1] or if facilities have responded to advisories on prevention, such as those proposed by the American Society of Anesthesiologists.[2]

METHODS

A panel of patient safety analysts identified surgical fires reported to the Authority between July 1, 2004, and June 30, 2011. Potential reports of interest were identified using the keywords "fire," "flame," "ignite," and "extinguish." A report was classified as a surgical fire if it

— occurred on the sterile surgical field or in the airway and
— caused combustion of surgical or anatomic substance.

The analysts excluded the following:

— Heat-related injuries caused by direct contact with a heat source, such as electrosurgical active electrodes (Bovie units), lasers, fiberoptic light cord, surgical lights, hot water, or hot instruments
— Normal arcing from electrosurgical active electrodes between tip and tissue without secondary ignition of a substance
— Arcing or ignition of the insulation of electrosurgical active electrodes without secondary ignition of a substance
— Reports of smoke without evidence of combustion
— Heat-related melting without evidence of combustion
— Fires off the surgical field

To calculate the rates at which fires occurred, the Authority obtained the number of trips to the OR (operations) done in Pennsylvania hospitals and ambulatory surgical facilities from the Pennsylvania Health Care Cost Containment Council (PHC4).* Robust numbers of operations were available from July 1, 2007, through June 30, 2011. Those numbers were used to calculate the rate of fires per operation (see Figure). Prior to July 1, 2007, only the number of patients having operations was reported under a uniform format, not the number of operations.

To extend observations of the rates of surgical fires to the entire period between July 1, 2004, and June 30, 2011, the number of surgical patients was used to calculate the rate

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

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.

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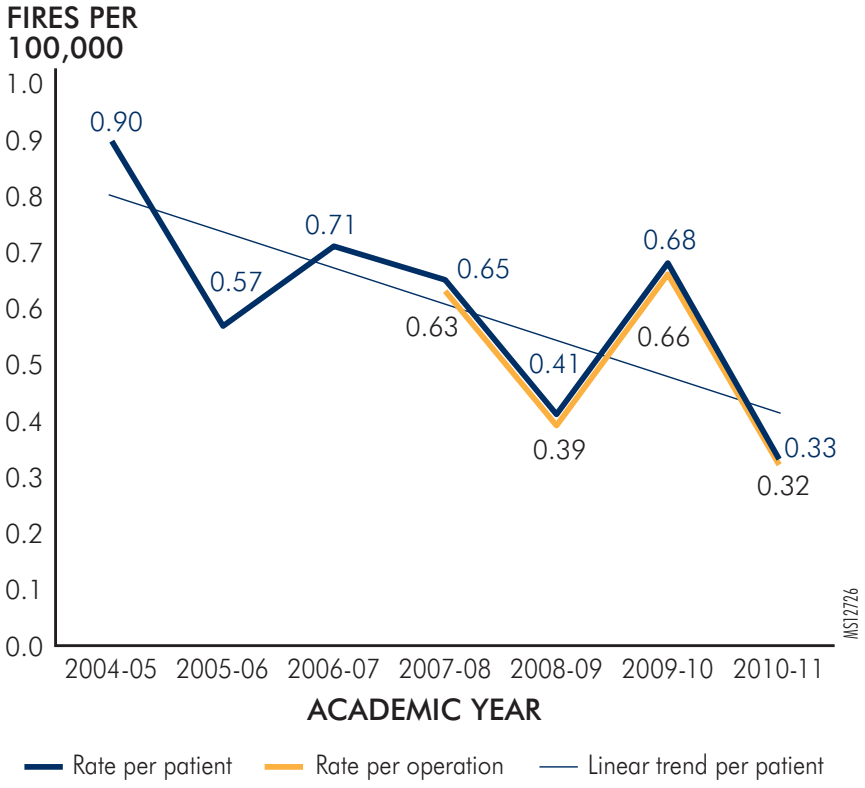
Figure. Trends in Surgical Field Fires



of fires per surgical patient (see Figure). A surgical patient was a patient who had one or more operations during an admission. If the same patient had a second admission, he or she was counted as a second surgical patient.

Some facilities did not provide the number of surgical patients or operations for some quarters. However, no fires were reported from those facilities during those quarters.

RESULTS

In the seven years between July 1, 2004, and June 30, 2011, 70 reports met the analysts' definition of fires on the operating field.

A total of 7,172,132 operations were reported to PHC4 during the four-year time period from July 1, 2007 through June 30, 2011 (see Table 1). A total of 36 fires on the operating field were reported to the Authority during the same time period. The rate of surgical fires ranged from from 0.63 per 100,000 operations (1 per 157,545 operations) from July 1, 2007, through June 30, 2008, to 0.32 per 100,000 operations (1 per 309,305 operations) from July 1, 2010, through June 30, 2011. In the same time periods, the number of operations per patient averaged 1.03 operations per patient.

A total of 11,651,199 patients were reported having operations during the seven-year time period from July 1, 2004, through June 30, 2011 (see Table 2). As noted above, a total of 70 fires on the operating field were reported to the Authority during the same time period. The rate of surgical fires ranged from 0.90 per 100,000 surgical patients (1 per 110,649 surgical patients) from July 1, 2004, through June 30, 2005, to 0.33 per 100,000 surgical patients (1 per 300,973 surgical patients) from July 1, 2010, through June 30, 2011. This noticeable downward trend is not statistically significant by linear regression ($R = -0.72$, $R^2 = 0.52$, $p < 0.10$ by two-tailed levels of significance).

The incidence of fires on the operating fields in Pennsylvania hospital ORs and ambulatory surgical facilities should be considered within the context of initiatives to prevent surgical fires. Those initiatives have been as follows:

— 2003: Joint Commission Sentinel Event Alert on preventing surgical fires[1]

— 2005 to 2009: Joint Commission National Patient Safety Goal for ambulatory surgery

— 2008 to 2009: American Society of Anesthesiologists' "Practice Advisory for the Prevention and Management of Operating Room Fires"[2]

— 2010: Anesthesia Patient Safety Foundation's fire safety video[3]

— 2011 to present: Food and Drug Administration Preventing Surgical Fires initiative[4]

An analysis of the 70 reports of fires on the operating field reinforces the information driving the existing initiatives.[1-4]

Patient harm was reported in 23 reports (33%), and no harm was reported in 46 (67%) of the 69 reports with information about harm. Three events involved fires in the surgeons' hands, and one involved a fire on the scrub technician's gown. None of these four events produced harm to the staff or patient.

Of the 65 reports with information about the ignition source, the source of ignition was an electrosurgical unit (Bovie unit) in 38 reports (58%), a fiberoptic light cord in 25 reports (38%), and a laser in 2 reports (3%).

The role of oxygen was highlighted in seven reports, with two specific mentions

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Table 1. Rates of Fires per 100,000 Surgical Operations

YEAR	NO. OF PATIENTS*	NO. OF OPERATIONS*	OPERATIONS PER PATIENT	NO. OF SURGICAL FIRES†	OPERATIONS PER FIRE	RATE OF SURGICAL FIRES PER 100,000 OPERATIONS
July 2007 to June 2008	1,683,170	1,732,996	1.03	11	157,545	0.63
July 2008 to June 2009	1,727,387	1,775,920	1.03	7	253,703	0.39
July 2009 to June 2010	1,757,928	1,807,384	1.03	12	150,615	0.66
July 2010 to June 2011	1,805,835	1,855,832	1.03	6	309,305	0.32
Total	**6,974,320**	**7,172,132**	**1.03**	**36**	**199,226**	**0.50**

* Data obtained from the Pennsylvania Health Care Cost Containment Council.
† Surgical fires reported to the Pennsylvania Patient Safety Authority.

Table 2. Rates of Fires per 100,000 Surgical Admissions

YEAR	NO. OF PATIENTS*	NO. OF SURGICAL FIRES†	PATIENTS PER FIRE	RATE OF SURGICAL FIRES PER 100,000 PATIENTS
July 2004 to June 2005	1,549,082	14	110,649	0.90
July 2005 to June 2006	1,572,611	9	174,735	0.57
July 2006 to June 2007	1,555,186	11	141,381	0.71
July 2007 to June 2008	1,683,170	11	153,015	0.65
July 2008 to June 2009	1,727,387	7	246,770	0.41
July 2009 to June 2010	1,757,928	12	146,494	0.68
July 2010 to June 2011	1,805,835	6	300,973	0.33
Total	**11,651,199**	**70**	**166,446**	**0.60**

* Data obtained from the Pennsylvania Health Care Cost Containment Council.
† Surgical fires reported to the Pennsylvania Patient Safety Authority.

of nasal cannulas, one specific mention of a "leak" in the oxygen tubing, one specific mention of an oxygen mask over a tracheostomy stoma, and one specific mention of using an electrosurgical unit to incise a trachea during a tracheostomy. Nitrous oxide was not mentioned as a source of oxidizer in any reports.

The materials that caught fire were noted in 66 reports, with multiple materials noted in some reports. They included surgical items and/or patient sources. Of the surgical items, drapes were most commonly ignited (involved in 30 reports), followed by surgical sponges (13); bone cement (3); surgical towel, gown, or gloves (1 each); and accessory cable (1). Of the patient sources of combustion, hair and tissue in the incision were most common (11 each), with individual mentions of lip, palate, soft tissue, and bowel gas.

Alcohol-based skin preparations were mentioned in three reports. Two of the reports stated the skin was dry when the electrosurgical unit was used, igniting hair. The other report noted that a sponge used to help dry the skin was left on the field and was ignited by the electrosurgical unit.

The locations of the fires were noted in 34 reports, with 3 noting more than one site. Sites on the surface of the patient's body were mentioned in 32 reports, internal sites were mentioned in 6, and fires on the surgeons' hands were mentioned in 3 (see Table 3). Of the 38 surface and internal patient sites mentioned, 25 were located in the head or neck areas.

Twenty-three reports mentioned 26 ways in which the fire was extinguished. Six ignited surgical sponges were removed from the surgical field and extinguished. One surgical drape was removed and doused with saline. One surgical sponge was moved to a basin of sterile saline. Seven reports mentioned removing, disconnecting, or turning off the light cord when it was the source of igniting surgical drapes. Including the report of the flaming surgical drape, just mentioned, and the report of a tracheal fire below, five reports mentioned dousing the fire with saline or water. Three fires were reportedly extinguished using towels, one noted to be wet. One surgeon put out a bone cement fire with his or her hand. A fire caused by using the electrosurgical unit to enter the trachea was extinguished with a combination of the surgeon's hand, followed by dousing the site with saline and discontinuing supplemental oxygen.

> *[The surgeon] was opening trachea with cautery. A flash fire occurred at site and was immediately extinguished with [the surgeon's] finger*

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followed by saline. Anesthesia also immediately turned off [the supplemental oxygen].

DISCUSSION

A coordinated approach to surgical fire prevention and response by the surgical team is important to eliminate fire hazards and to minimize the time until the fire is extinguished.[1,4] Three elements are necessary for a fire: a heat source, oxygen, and a fuel. The surgeon is usually in control of the heat source, most commonly an electrosurgical unit, and can remove it from the field. The anesthesia professional is usually in control of the supplemental oxygen source and can eliminate the oxidizer component of the fire triangle. The circulating nurse or scrub technician can help ensure meticulous application of alcohol-containing skin-prepping solutions and ensure that they are dry before the application of surgical towels and drapes; can ensure occlusive draping when indicated; can keep exposed ends of fiberoptic light cords off the surgical field; and can ensure the availability of moist sponges, towels, and aqueous solutions.

Response to a Surgical Fire

Surgical fires are preventable, but if a fire occurs, the surgeon and other surgical team members can immediately remove burning materials from the patient and can help by extinguishing the fire with an aqueous solution, their hands, or a wet sponge or towel. Ideally, a wet sponge or wet towel is always available in the sterile setup for such an emergency. The anesthesia professional should minimize the availability of oxygen. Burning materials that have been removed from the patient can then be extinguished by other team members, if needed, with an aqueous solution, or in extreme cases, with a carbon dioxide fire extinguisher.

Prevention of Surgical Fires

More prudent than a coordinated team response to the tracheal fire above would be to avoid the risk by not incising the trachea with an electrosurgical unit in the first place.[2,5]

The Christiana Care Health System in Wilmington, Delaware, has developed a simple, brief Fire Risk Assessment Score to identify operations at increased risk for surgical fires.[6] The score assesses the presence or absence of three elements. A score identifying the following three elements present indicates a high risk for a surgical fire:

— Christiana Fire Risk Assessment Score:
- ☐ Surgery above the xiphoid
- ☐ Open oxygen source
- ☐ Available ignition source (e.g., electrosurgery, laser, fiberoptic light cord)

The Fire Risk Assessment Score can easily be included in either the WHO Surgical Safety Checklist preoperative briefing or the Universal Protocol time-out.

Table 3. Location of Surgical Fires as Reported to the Pennsylvania Patient Safety Authority

LOCATION	NO.
External	**32**
Head	**18**
Scalp	2
Face	13
Face	4
Periorbital	9
Eyelid	1
Eyebrow area	3
Eyebrow	2
Eyelashes	3
Ear	3
Neck	**5**
Neck	4
Tracheal stoma	1
Shoulder	**1**
Chest	**2**
Legs	**5**
Legs	1
Leg	2
Thigh	2
Trocar site	**1**
Internal	**6**
Nasopharynx	**1**
Trachea	**1**
Chest cavity (surgical sponges)	**2**
Abdominal cavity (bowel gas)	**1**
Hip incision (bone cement)	**1**
Surgeon's Hand	**3**
Surgeon's hand	**2**
Surgeon's finger	**1**

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A score of 3 indicates a high risk for a surgical fire. A score of 2 indicates a low risk, with potential for conversion to high risk. A score of 1 indicates low risk. When an operation is assessed as being at high risk for a surgical fire, risk mitigation should be done to decrease the risk. ECRI Institute has summarized these mitigation strategies related to surgery of the head, face, neck, and upper chest and for oropharyngeal procedures, bronchoscopic surgery, and tracheostomy.[5]

The American Society of Anesthesiologists Task Force on Operating Room Fires and the Anesthesia Patient Safety Foundation have determined that the most important practice for managing the risk of a surgical fire is to determine if supplemental oxygen is needed to maintain adequate arterial oxygen saturation. This assessment is especially important when the oxygen would be administered in an "open" fashion, via a nasal cannula or face mask, thereby saturating the surgical field with high oxygen concentrations. Keeping oxygen concentrations less than 30% is desirable to prevent rapidly spreading fires. When there is a risk of fire and the patient requires supplemental oxygen to maintain an adequate arterial oxygen saturation, a controlled airway, such as an endotracheal tube or laryngeal mask, is recommended to help isolate the oxidizer from the heat source.[2,7]

There are defined exceptions in which supplemental oxygen delivery may be required via an open source on the face.[5,8] For such cases, fire risks will be reduced by starting with an administered concentration of oxygen of less than 30% and titrating the oxygen to the lowest concentration needed to maintain an adequate arterial oxygen saturation. Risks will be reduced further by using occlusive draping techniques to minimize the flow of dangerously high concentrations of oxygen from under the drapes onto the surgical field.[5,8]

Electrosurgical active electrodes (Bovie units) should not be used, if possible, in high-risk situations. If used, the power settings should be as low as possible for surgical needs.[9] Bipolar electrodes could also be used.

It should also be noted that the end of a fiberoptic light cord is about as dangerous to place on the surgical drapes as a lit cigar. Azizi notes that the temperature from a fiberoptic light cord with a new bulb in the light source can reach 670 degrees Fahrenheit.[10]

Moist sponges minimize the risk of setting a sponge on fire. A dry sponge can be ignited easily, especially in the presence of an oxygen-enriched atmosphere, whereas a moist sponge resists ignition.[8] Water or saline should also be available for dousing a fire. A five-pound carbon dioxide fire extinguisher should be available in the OR.[2,7]

The number of fires involving bone cement was the same as the number involving alcohol preps. Care should be taken with alcohol preps. Of note, two of the reports involving alcohol preps said the skin was dry, but the electrosurgical unit caused the hair to catch fire. The prep should dry for at least three minutes to allow full evaporation of the alcohol, and longer for hairy areas or areas involving body crevasses or skin folds. Avoid pooling of the alcohol-based solutions. Drape only after all alcohol has dried.[7]

The Authority offers a surgical fire toolkit at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/airway_fires/Pages/home.aspx. Additional information about surgical fire prevention is also available through ECRI Institute at https://www.ecri.org/Products/Pages/Surgical_Fires.aspx.

CONCLUSION

Surgical fires remain a significant enough risk to justify use of a Fire Risk Assessment Score, the communication that should occur with a Fire Risk Assessment Score of 2 or 3,[6] and adherence to the recommendations of both the Anesthesia Patient Safety Foundation[3] and the American Society of Anesthesiologists Task Force on Operating Room Fires.[2,5]

Acknowledgments

Edward Finley, BA, Pennsylvania Patient Safety Authority, and Art Augustine, BS, formerly of the Pennsylvania Patient Safety Authority, contributed to the data analysis.

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NOTES

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Multifaceted Differences in Implementation of Practices for Prevention of Colorectal and Bariatric Surgical Site Infections

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ABSTRACT

The Pennsylvania Patient Safety Authority and the Pennsylvania National Surgical Quality Improvement Program (PA- NSQIP) initiated a collaborative project in December of 2010 to reduce surgical site infections (SSIs) among the PA-NSQIP member hospitals and to transfer successful strategies and lessons learned to other Pennsylvania hospitals. Participating hospitals' SSI data as reported to the NSQIP was used to select colorectal and bariatric surgeries as the collaborative focus and to identify high-performing and outlier hospitals' SSI rates in these areas. An SSI prevention assessment tool was developed to conduct on-site hospital interviews to assess the level of implementation of specific preventive practices at the pre-, intra-, and post-operative levels and to determine if the high-performing hospitals' lower SSI rate could be attributed to variation in implementation of practices. The on-site interviews conducted in December of 2011 revealed that the hospitals that were more diligent with a standardized approach to implementation of practices were also the high-performing hospitals with the lowest SSI rates. This article reveals multifaceted differences in the implementation of practices and identifies specific interventions for facilities needing improvement to reduce SSIs related to bariatric and colorectal surgery. (Pa Patient Saf Advis 2012 Dec;9[4]:136-42.)

Scan this code with your mobile device's QR reader to access the Authority's surgical site infection prevention toolkit.

INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC), approximately 1 in 20 hospitalized patients acquires a healthcare-associated infection (HAI).[1] Surgical site infections (SSIs) are cited as the second most common HAI, accounting for 17% to 22% of all HAIs among hospitalized patients.[2,3] It has been estimated that SSIs may result in as many as 3.7 million additional hospitalization days and an annual overall cost of $1.6 billion in the United States.[4] The 2007 average attributable per-patient treatment costs are estimated at over $34,000.[5] SSIs are serious, life-threatening infections. The Klevens et al. report of HAIs in US hospitals in 2002 estimated the number of SSIs at 290,485, with 8,205 associated deaths, a 2.8% case fatality rate.[2] Using estimates from national reports and published studies related to HAIs, the study suggests that implementation of infection control practices in all US hospitals could reduce the number of SSIs and save 2,133 to 4,431 lives annually.

Reducing HAIs also saves money. The annual cost of preventable cases of SSI in the United States is estimated to be $166 million to $345 million.[6] The 2008 Society for Healthcare Epidemiology of America (SHEA) and Infectious Diseases Society of America (IDSA) practice recommendations to prevent SSIs in acute care hospitals recommends additional practices for modifiable risk factors in the areas of patient preparation, operative characteristics, and surgical suite characteristics.[7] The Joint Commission 2010 National Patient Safety Goal 07.05.01 for preventing SSIs includes elements of performance for the prevention of SSIs in the areas of education, implementation of evidence-based guidelines, risk assessment, and process and outcome measures.[8]

Effective July 1, 2011, the federal Patient Protection and Affordable Care Act prohibits Medicare and Medicaid payments for hospital-acquired conditions, including bariatric SSIs associated with laparoscopic gastric bypass, gastroenterostomy, and laparoscopic gastric restrictive surgery.[9,10] Effective January 1, 2012, hospitals that are paid under the inpatient prospective payment system are required to submit SSI data for colon procedures as part of the Hospital Inpatient Quality Reporting program in order to receive full reimbursement in Medicare's annual payment update for fiscal year 2014.[11] Hospitals not submitting the required measures will receive a 2% reduction in their annual market basket update. Beginning October 2012, Hospital Compare will include new surgical outcomes measures submitted on a voluntary basis by hospitals participating in the American College of Surgeons' (ACS) National Surgical Quality Improvement Program (NSQIP).[12,13]

As a result of the magnitude of these types of infections and the largely unchanged scope of this problem, the Pennsylvania Patient Safety Authority and the Pennsylvania NSQIP (PA-NSQIP) hospitals initiated a collaborative improvement project to reduce SSIs in bariatric and colorectal surgical cases. Participating facilities looked to successful hospitals that have complied with and extended the SSI prevention "bundle" practices for lessons about implementation and overcoming barriers to SSI prevention practices.

The proposed benefits of this collaboration for the participating PA-NSQIP hospitals include the following:

— The reduction of SSIs for a sustained period through the dedication and commitment of PA-NSQIP leadership and teams from each participating facility

— The creation of a collaborative learning network for the prevention of SSIs

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— Leveraging existing data already being collected at all hospitals through the national NSQIP
— The establishment of targeted education for facility staff on SSI prevention according to the medical literature, the Authority's *Pennsylvania Patient Safety Advisory* article and toolkit database information, and other pertinent educational resources.
— The creation of a shared, password-protected workspace on the Authority's web-based collaboration site to document all activities in this endeavor
— Guidance, assistance, and technical support provided to the participating facilities
— The collection of follow-up data and the creation of comparison reports to measure progress at the end of the program

METHODS

Participants and Data Sources

The project design used NSQIP retrospective data to determine baselines and identify high performers and outliers (hospitals with high SSI rates) within the participating PA-NSQIP consortium member hospitals. Each hospital was asked to provide their SSI data from the most recent annual report generated by ACS NSQIP (cases for calendar year 2009) and to complete a brief survey on the observed-versus-expected ratio (O/E ratio) of SSIs from the surgical categories listed in the ACS NSQIP semiannual report: (1) overall general plus vascular surgery, (2) general surgery, (3) colorectal surgery, and (4) vascular surgery. The Authority staff used this information to identify high performers and outliers within the group by analyzing aggregate and facility-level data using meta-analysis (see Tables 1 and 2). General surgery was selected as a focus area due to the high O/E ratio as compared with the other surgical categories.

Authority staff conducted on-site visits to the two outlier hospitals to analyze NSQIP monthly data and to identify which surgical procedures in the general surgery category presented opportunities for improvement. Participating hospitals' 2010 SSI data as reported to the NSQIP was used to select colorectal and bariatric surgeries as the collaborative focus. Hospitals were selected for the on-site practice interview primarily based on their overall NSQIP O/E ratio and secondarily on individual performance in the specific surgical procedure. The specific SSI rates of interest and any risk adjustment that was applied was determined based on the subspecialties in which the most infections occurred at the intervention sites. This data helped identify the general areas with the greatest potential for improvement. Once identified, the two high performers and the two outlier hospitals for colorectal and bariatric procedures were asked to do the following:

— Designate a team leader from each facility as the primary liaison for the collaborative and an interdisciplinary clinical team
— Work with Authority staff to examine the institution's NSQIP data to identify more specific targets for improvement, based on the hospital's procedure volume and the clinical services with the highest infection rates
— Convene relevant physicians and other clinical staff in the identified subspecialties for site visits from institutions doing well in those areas
— Provide adequate time for staff to complete surveys, review documents, and attend periodic conference calls and meetings

Study Design

The Authority staff provided overall coordination, project management, and logistics support for the collaborative and served as independent facilitators to collect, analyze, and report on relevant data to participating hospitals. Of the nine PA-NSQIP hospitals, eight participated in the study. The collaborative formed a steering committee consisting of NSQIP hospital surgeons, NSQIP nurse reviewers, and key Authority staff, including

Table 1. Summary Using Pooled Means: Pennsylvania National Surgical Quality Improvement Program Surgical Site Infection Summary Results, January to December 2009

SURGERY TYPE	TOTAL NO. OF CASES	NO. OF CASES OBSERVED	OBSERVED RATE (95% CI)	EXPECTED NO. OF CASES	EXPECTED RATE	OBSERVED-VERSUS-EXPECTED RATIO (95% CI)	COMMENT
Overall (general plus vascular)	11,733	588	0.050 (0.046 to 0.054)	582.06	0.0496	1.010 (0.901 to 1.133)	As expected
General surgery	10,170	542	0.053 (0.049 to 0.058)	531.98	0.0523	1.019 (0.904 to 1.149)	As expected
Colorectal surgery	1,154	154	0.133 (0.114 to 0.154)	155.61	0.1348	0.990 (0.790 to 1.239)	As expected
Vascular surgery	1,566	46	0.029 (0.022 to 0.039)	50.90	0.0325	0.904 (0.596 to 1.360)	As expected

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Table 2. Summary Using Meta-Analysis: Pennsylvania National Surgical Quality Improvement Program Surgical Site Infection Summary Results, January to December 2009

SURGERY TYPE	OBSERVED RATE (95% CI)	I^2*
Overall (general plus vascular)	0.047 (0.037 to 0.061)	90%
General surgery	0.051 (0.040 to 0.065)	88%
Colorectal surgery	0.127 (0.093 to 0.171)	74%
Vascular surgery	0.029 (0.018 to 0.048)	57%

Note: These summaries were calculated using meta-analysis, which is a statistical technique that combines data from multiple studies. For this study, data was combined from eight of the nine hospitals that are participants in the Pennsylvania National Surgical Quality Improvement Program, with weighting via inverse standard errors. The specific meta-analytic technique used for these analyses involved logit event rates and used the random-effects approach described by DerSimonian and Laird.† Comprehensive Meta-Analysis Version 2‡ software was used to perform these computations.

* I^2 "describes the percentage of total variation across studies that is due to heterogeneity rather than chance. . . . A value of 0% indicates no observed heterogeneity, and larger values show increasing heterogeneity." (Source: Higgins JP, Thompson SG, Deeks JJ, et al. Measuring inconsistency in meta-analyses. *BMJ* 2003 Sep 6;327[7414];557-60.)

† Dersimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986 Sep;7(3);177-88.

‡ Developed and available from Biostat Inc., Englewood, New Jersey.

a patient safety liaison and an infection preventionist.

The steering committee developed a unique SSI prevention assessment tool for use during on-site hospital interviews. The tool assessed the level of implementation of specific preventive practices at the pre-, intra-, and postoperative level, and it helped determine if the high-performing hospitals' lower SSI rate could be attributed to variation in implementation of practices. The tool was based on the ACS comprehensive list of practices consolidated from existing guidelines and those processes thought to be most relevant for the focus areas of bariatric and colorectal surgery. Policies and procedures from the high-performing hospitals for these focus areas were reviewed for evidence of processes and protocols that could be shared with the outlier hospitals. The steering committee developed specific interview questions to elicit detailed information on the levels of implementation of SSI prevention strategies and sorted questions into categories of whether they were related to factors specific to the patient, controlled by the systems, or controlled by the provider. Each category was grouped by provider type in order to help with the flow of the on-site interviews.

Site Visits

Cross-institutional learning was facilitated by arranging site visits and interactions between clinical teams from outlier hospitals and their colleagues from institutions that have achieved and sustained low SSI rates. The collaborative committee elected to visit two high performers and two outlier hospitals in colorectal and bariatric procedures. All four hospital teams were provided with a copy of the SSI prevention assessment tool to perform a self-assessment prior to the visit and to collect supporting documentation such as polices and protocols. Separate survey teams were formed to perform on-site visits at each of the two bariatric-procedure and the two colorectal-procedure high-performing and outlier hospitals.

The collaborative steering committee NSQIP surgeons interviewed anesthesia providers and the hospitals' surgeons from each surgical specialty. The collaborative steering committee NSQIP nurse reviewers interviewed nursing staff at the pre-, intra-, and postoperative levels. The Authority staff (a patient safety liaison and an infection preventionist) interviewed the directors of the surgical services and quality and the medical-surgical nursing staff. Interviews were conducted with each of these groups in each of the two high-performing and the two outlier hospitals using the SSI prevention assessment tool, which is available with this article on the Authority's website at http://www.patientsafetyauthority.org.

RESULTS

The assessment results were analyzed for a comparison of practice implementation. Analysis of the hospital assessment results was supported by the narrative summary completed for each facility outlining the strategies used to implement each practice. It was evident that the hospitals that were more diligent with a standardized approach to implementation of the items on the assessment tool were also the high-performing hospitals with the lowest rates of SSIs. The comparison found 8 major differences in performance between the high performers and the outliers for bariatric procedures and 16 major differences for colorectal procedures (see Tables 3 and 4).

Outliers in both the bariatric and the colorectal groups reported variation in implementing methods for bowel preparation, communication, safety briefings, and transport. While bowel preparation is a provider-specific item, communication, safety briefings, and transport are system- or hospital-controlled factors. At both high-performing hospitals, the transport was performed by registered nurses rather than by patient care technicians; safety briefings were conducted in a structured and specific manner; and communication channels were open and encouraged.

The bariatric outlier interviews identified differences with preoperative measurement of arterial blood gas and of hemoglobin A_{1c} (HbA_{1c}) indicating glycemic control, postoperative upper gastrointestinal studies, and the involvement of resident-level physicians. The colorectal

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Table 3. Comparison of Bariatric Best Practices in High-Performer and Outlier Hospitals

PRACTICES	HIGH-PERFORMER CURRENT PROCESS	OUTLIER DIFFERENCE
Pre-op arterial blood gases	Done on the day of surgery	Not done
Hemoglobin A_{1C} and fasting blood sugar	Done preoperatively	Not done
Residents	Do not perform surgery	Are involved with surgery
Post-op upper gastrointestinal series	Not done	Done on postoperative day 1
Bowel prep	Liquid diet for five days prior	Not standard
Safety briefings	Done daily or twice a day in all areas	Done weekly
Transport	By registered nurse; bedside report	By technician; report in computer
Communication	Clear team roles; everyone aware of others' responsibilities (e.g., "Anesthesia does that, and here is their process.")	Team roles defined; staff not aware of others' responsibilities (e.g., "Anesthesia does that; you will have to ask them.")

outlier interviews revealed differences in a history of steroid use, albumin checks, patient and site preps, decisions of diversion versus colostomy, wound protection and closure methods, and antibiotic timing associated with prolonged procedures, as well as OR cleaning, traffic control, and handoffs. All levels of staff interviewed at the high-performer level for both bariatric and colorectal procedures were able to identify responsibilities of all team members and policies and procedures related to OR practices, as well as protocols for the focus-area procedure. Outlier hospitals reported fewer standardized protocols, and staff were often uninformed as to the workflow of other members of the team. For example, they understood who was responsible for a task but not the specifics of how the task was done.

Each outlier facility participant took the comparison back to his or her hospital, and the hospital teams selected the following process measures for implementation.

Selected bariatric process measures included the following based on the number of bariatric procedures per month:

— Number of patients who have glycosylated HbA_{1c} drawn prior to surgery
— Number of patients with an HbA_{1c} level over 8% who had surgery
— Number of patients who received chlorhexidine gluconate wipes on the morning of the procedure
— Number of patients who received a Peridex swish on the morning of the procedure

Selected colorectal process measures included the following based on the number of colectomy procedures per month:

— Number of patients who have documentation that the surgical bundle was fully implemented
— Number of patients who have skin edge protection used during surgery

Selected colorectal process measures included the following based on those with a procedure time greater than four hours:

— Number of patients who have an antibiotic redosed

POTENTIAL BARRIERS TO IMPLEMENTATION

Bariatric and colorectal outlier hospitals in the collaborative are currently developing methods to implement the processes that will be measured. Standardization of protocols, team member roles, and communication tools were much more prevalent in the high-performing hospitals. These reflect assessment tool questions regarding factors that were identified as controlled by the systems or hospitals rather than as provider- or patient-specific. Implementation of these items will require additional resources when compared with a provider-controlled element due to the complexity of the hospitals themselves. Often, changes to protocols require buy-in from several groups and must be accepted and approved by multiple committees. It takes time, resources, and leadership support to see these types of changes through to adoption. Culture within a facility, as evidenced by communication structures and teamwork within and across units, will also play a role in the length of time and success of implementation.

LIMITATIONS

There are limitations in the study design. The PA-NSQIP consortium consists of only eight hospitals. Of those, two were identified as outliers. This is a small sample size, reflective of only the hospitals that have committed to investing resources to the NSQIP and that may already have bias toward reducing SSIs. The data is limited to NSQIP data. These are not reflective of all procedures performed within a facility. Due to the nature of SSI data collection, real-time data is nearly impossible to collect, causing several-month lag times between implementation of process changes and reflection of the changes in the data. Maintaining momentum and associating changes in process to changes in data is difficult.

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Table 4. Comparison of Colorectal Best Practices in High-Performer and Outlier Hospitals

PRACTICES	HIGH-PERFORMER CURRENT PROCESS	OUTLIER DIFFERENCE
Albumin	Standard is to assess every patient; dietary supplements are provided for low albumin; diversion performed if albumin <3.0 g/dL; Child-Pugh score calculated if alcoholic	No standard; no albumin check; no Child-Pugh score calculation
Antimicrobial timing	Standardized	No standard; staff request better communication from anesthesia for timing of next antibiotic dose
Bowel prep	At time of data analysis, used antimicrobials and citrate 1 day pre-operatively; Betadine wash used for rectal anastomosis—stopped, and trend now is back to using bowel prep	No bowel prep
Checklists and safety briefings	Policy and/or manual are on chart; attending surgeon must be present (structured process); anesthesia provides report and time for questions	No policy; pathway not on chart; any surgeon may perform safety briefings; pre-, intra-, and post-op checklists are used
Closure	Secondary closure for gross-contaminated skin opening	Secondary closure only for emergent situations
Communication and structure	Team roles are clear; everyone is aware of others' responsibilities (e.g., "Anesthesia does that, and here is their process."); communication processes are standardized and structured, with clear accountability	Team roles are defined; not everyone is aware of others' responsibilities (e.g., "Anesthesia does that; you will have to ask them."); processes are not standardized; accountability is unclear
Diversion or colostomy	Policies and standards call for diversion if post-chemo or post-radiation or if the patient is malnourished, has <3.0 g/dL albumin, or has blood loss of more than 400 cc	No policy or standard; diversion is performed in cases of radiation or sepsis
Handoff	Standardized handoff tool, protocol, policy, and procedure; postanesthesia care unit registered nurse brings patient to unit; in-person handoff performed at bedside	No protocol or policy; check-off process is verbal and not at bedside
History of steroid use	If steroid use within the last six months, then at time of operation, give stress dose steroid (regimen hydrocortisone 50 mg IV Q8 hours for 48 hours; BID for 48 hours; then once a day). If patient has active ulcerative colitis, then the steroid taper will be slowed to a longer time period. Also, any patient on steroid recently will get two-stage operation. If on steroids and infliximab, then three-stage operation.	No standard
Operating room (OR) cleaning	Process is more structured, with accountability; training, competency evaluation, and compliance monitoring performed by staff from the OR management team and by the lead anesthesia technician	Training and competency evaluation performed by staff educator
Patient prep	Surgeon does prep; standardized training is provided on patient prep	Nurse or resident does prep; process is not structured
Prolonged procedure	Standardized policy is to redose with Levaquin® or Flagyl®	Redose by anesthesia if remembered
Site prep	Written policy requires surgeon to perform site prep	Site prep by any resident or fellow; no education
Skin edge/wound protection	Use for both open and laparotomy cases	Use only for laparotomy cases
Traffic control	Structured accountability, policies, and procedures; assistant OR director or circulating nurse manages observations; observers allowed by appointment	No policy or procedure; entire team is charged with being the traffic police; staff report that this is not well managed
Transport	Policy or procedure is that OR has its own beds, which are returned to the OR after transport	No policy or procedure; beds from unit are brought to the OR

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(continued from page 139)

Several limitations exist with the tool as well. While literature- and evidence-based items were included on the assessment tool, many of the questions were identified by reviewing the high-performer hospitals' documents. These items are not necessarily better processes; they are simply identified processes that would need to be explored during the site visits. The tool also contains bias in that the more standardized a process, the more likely it was to correlate with positive outcomes. There was also no weighting of the answers, so any "yes" response was considered equal to any other "yes" response, even though not all risk factors and interventions correlate equally to SSI prevention.

CONCLUSION

The goal of the collaboration is to strengthen and improve patient safety by reducing the incidence of SSI among surgical patients in participating hospitals and demonstrating a collaborative learning approach to SSI reduction. The assessment highlights the results of on-site visits with hospitals identified as having high or low infection rates in bariatric and colorectal surgery as compared with the expected infection rates in those categories and reveals multifaceted differences in implementation of practices for the purpose of identifying specific interventions for facilities needing improvement to reduce SSIs in relevant areas. The assessment tool provided a detailed comparison of the levels and methods of implementation of SSI prevention practices of high-performing and outlier hospitals with respect to the prevention of postoperative bariatric and colorectal SSI. It also highlighted the significant role of culture and standardization in the prevention of SSIs.

In the short term, the principal outcome measures that will indicate the success of this first project of the PA-NSQIP consortium is a reduction in the SSI rates at the institutions selected for the initial intervention. Secondary measures include process metrics identified through the project and thought to have an impact on SSI reduction in bariatric and colorectal surgery (see Tables 2 and 3). Over the longer term, the consortium will demonstrate improvement by reducing the SSI O/E ratio based on risk-adjusted data published by ACS NSQIP. The consortium will track these outcomes prospectively for all participating facilities. The success of this collaboration requires a high level of commitment from PA-NSQIP leaders at each facility and from interdisciplinary clinical teams at each hospital. PA-NSQIP teams and the Authority will work to transfer knowledge gained to other hospitals throughout Pennsylvania.

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Potential Hazards of Clock Synchronization Errors

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Clinical integration is intended to reduce errors by seamlessly porting information to and from diagnostic or therapeutic devices, ancillary information systems such as for laboratory and radiology departments, and electronic medical record (EMR) systems. However, this information transfer can raise new risks if there is disagreement between the clocks of medical devices, hospital systems, and watches or devices owned by clinicians and patients. Julian Goldman, MD, of Partners Healthcare presented original research to a National Science Foundation Cyber-Physical Systems symposium at the University of Pennsylvania in January 2012[1] that showed an average clock error of 24 minutes among 1,700 surveyed medical devices. Prompted by media reports related to this research, a reporter from the *Gray Sheet* contacted the Pennsylvania Patient Safety Authority in search of further information on clock synchronization issues for a recently published article.[2]

Authority analysts queried the Authority's Pennsylvania Patient Safety Reporting System database. Analysts searched for terms in the report narratives related to "synchronization" (and derivation thereof) or "internal clock." The time scope of the query ranged from the reporting program's inception in July 2004 through May 2012 and returned six reports. Upon reviewing of the reports, analysts determined that three were relevant to clock synchronization issues:

> *An eight-minute difference [was noted] between the Epic [sic] computer and the cardiac monitor. This shows a delay in care where there is a patient issue (i.e., pain medications, blood pressure medications). (Accurate blood pressure does not correlate with time issue occurred.) Monitors and computers need to be synchronized. The patient was not harmed. System will be corrected immediately per [information technology department].*
>
> *Found out the clocks in the ICU [intensive care unit] and the lab are not synchronized, so [there were] two specimens for ionized calcium sent today that timed out before the test could be run. On the phone with lab personnel, I had them remain on the line as I drew the third specimen, marked the time on the tube that coincided with the lab clock, and received results for that specimen. This patient is critical and on ICU replacement therapy, so results are essential to provide effective treatment. We received results after third specimen was sent. [Lab staff state that] lab uses time displayed on [computers] as standard. Ionized calcium must be tested within 10 minutes of collection. Specimens received in lab after 10 minutes need to be re-collected for accurate results.*
>
> *[There was a] discrepancy [in] birth time due to unsynchronized time of clock on wall and time on fetal monitor.*

The first report, regarding a time gap between a cardiac monitor and an EMR, is especially troubling due to the resulting discrepancy between patient care as recorded by caregivers in the EMR (i.e., delivery of pain and blood pressure medication) and patient status as automatically sent to the EMR by the cardiac monitor (e.g., blood pressure). For many short-acting vasoactive medications, caregivers need to titrate the medication to result, which means that they will administer the medication and assess the patient's physiologic response. If the monitor and EMR are not synchronized, two situations could occur:

1. A caregiver may use the EMR as a source of valid information for physiologic status, receive misleading information about a patient's condition, and give inappropriate therapy. For example, a caregiver may see an alert for low blood pressure, give a vasopressor, see another reading indicating the blood pressure is still low (because the monitor clock is eight minutes behind), think the blood pressure is still low, and give more vasopressor, resulting in high blood pressure,

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which would not become apparent for another eight minutes.

2. A caregiver may notice the time discrepancy and use the cardiac monitor as the source of valid information for patient status, recording their actions in the EMR as they treat the patient. The EMR would then (incorrectly) show a delay in care between device-reported status and caregiver-reported actions, and the caregiver could face questions as to the reasons for delayed care.

Clock synchronization issues can pose hazards to both patients and staff, and the increasing integration of medical devices and information systems suggests that there may be significant growth in the frequency and severity of this issue. Authority analysts also noted that clock synchronization issues do not fit neatly into the Authority's event classification system, and narrative reports of these issues may not share the key terms used in the query. Therefore, the three relevant reports identified in this query may only represent a small portion of the actual clock synchronization events experienced in Pennsylvania hospitals.

Clock synchronization strategies may help reduce time discrepancies. As more medical devices connect to hospitals' wired or wireless networks, the use of Network Time Protocol (NTP) is an increasingly practical method of achieving clock synchronization. NTP is an Internet protocol used to synchronize computer clocks to the official standard for current time, Coordinated Universal Time (UTC).[3] Computers and servers typically set their clocks based on an incoming NTP signal from the networks to which they are connected, and networkable medical devices are increasingly able to accept an incoming NTP signal as well. If medical devices can accept the same NTP feed as the computers and information systems in a facility, time discrepancies should be minimized.

NTP is already used to provide clock synchronization of EMR systems, as noted in recent policy decisions. On August 23, 2012, the United States Department of Health and Human Services (HHS) released its meaningful use stage 2 requirements.[4] In this final rule, HHS requires that EMR and electronic health record systems use an NTP feed to stamp incoming data (whether entered manually or through integration):

> (g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC [request for comments] 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

This ruling may spur adoption of NTP capabilities in networked medical devices as facilities look to comply with meaningful use requirements.

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Quarterly Update on Wrong-Site Surgery: Facilities with Barriers to Best Practices May Experience More Wrong-Site Surgeries

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There were 11 reports of wrong-site surgery submitted to the Pennsylvania Patient Safety Authority for the third quarter of 2012, plus one late report of wrong-site surgery for the first quarter of 2012, resulting in an unenviable total of 503 since reporting began June 28, 2004. Anesthesia blocks represented 4 of the 11 wrong-site procedures in the operating room (OR) this quarter.

However, the reports this quarter matched the fourth-lowest number of reports in a quarter since statewide reporting began (see Figure). During this quarter, Pennsylvania ORs went—for the fourth time—for more than a month without any reports of wrong-site surgery; the 39-day hiatus was the second-longest period since statewide reporting began. The period was bracketed by two wrong-site anesthesia blocks. Pennsylvania surgeons went 76 days without a wrong-site procedure. The rolling two-year average (49 per year) of wrong-site surgeries set a new low (see Figure).

The Authority knows the best practices to prevent wrong-site surgery.[1] When providers follow these best practices, they can eliminate wrong-site surgery.[2] And, as will be discussed below, providers who resist following best practices may experience more wrong-site surgeries than those who implement them.

The results of following—or not following—best practices are illustrated by reports from this quarter.

Two events involving anesthesia were reported during the quarter. One was a near miss that was caught during a time-out for the block. The other was an adverse event with no preoperative verification of the documents, no reference to the surgeon's mark, and no time-out.

> *A patient [was scheduled] for right ACL [anterior cruciate ligament] surgery. The anesthesiologist was preparing to perform nerve block on left leg. . . . The time-out was initiated and the block was performed on the correct side.*
>
> *The anesthesia provider identified the patient, introduced herself, did the H&P [history and physical], then went over the anesthetic plan with the patient: a block with IV [intravenous] sedation. The provider obtained the patient's consent and asked what side was to have surgery. The patient said—and pointed to—his right shoulder. The provider then prepared to place the IV. . . . The provider asked again what side was having surgery. The patient said right. The provider then [went somewhere] to gather the ultrasound and the items needed to place the block. When she returned, the patient's left shoulder was out of the gown and his right shoulder was in the gown. The provider proceeded to prep the left shoulder while discussing how the block worked with the patient's companion. At that point, the provider's supervisor arrived. The provider put her gloves on and proceeded to block the wrong shoulder.*

The following is another example of wrong-site surgeries this quarter that were associated with providers not following known best practices,[1] in this case, not referencing a visible site marking during the time-out.

> *Patient consented for repair of right inguinal hernia. The Universal Protocol was completed for the right side. The time-out was completed for the right. . . . The patient was marked preoperatively by the surgeon, but the marking was not visible after draping was completed. The surgery proceeded as usual until the surgeon asked for a left-side mesh. At that time, it was noted they were doing a left inguinal hernia.*

Scan this code with your mobile device's QR reader to access the Authority's wrong-site surgery prevention toolkit.

However, several near-miss reports this quarter illustrate that other providers are paying attention to best practices and catching potential problems.

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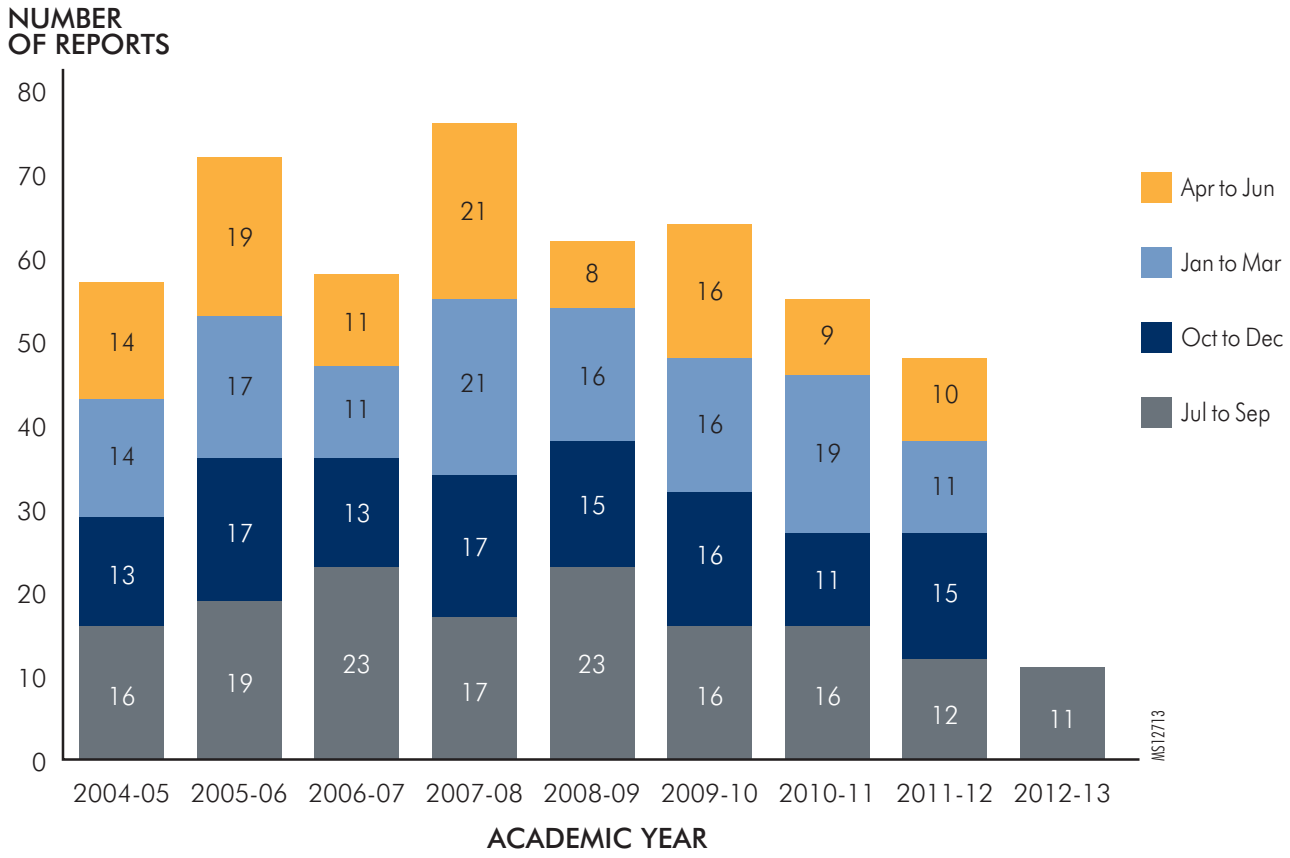
Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year



The value of preoperative verification:

> *The preoperative screening department caught that the patient's surgical reservation, OR schedule, and consent stated "RIGHT" foot surgery. [But] when the patient was called for preoperative information, he stated "LEFT" and the H&P discussed "LEFT." The surgeon's office was called and verified the correct side was LEFT. A new reservation was obtained; the OR schedule was corrected according to the reservation, and a new consent was sent by the office.*

The value of verification during the time-out:

> *When consent was read out loud for OR time-out, the consent read for posterior cervical reduction and stabilization perched facet left C5/6. Surgeon agreed with level of fusion but stated, after reviewing the MRI [magnetic resonance image], the laterality would be the right side. Initial consent was established based on . . . reading of radiological studies, which read left-sided fracture. The surgeon reviewed the MRI . . . prior to procedure and determined the right facet was fractured, not the left. . . . The procedure was carried out according to MRI review, and right side confirmed the fracture intraoperatively. After procedure, the surgeon spoke with a radiologist, who also reviewed films and confirmed a fracture to the right facet.*

A recent article surveyed all payments for surgical malpractice reported to the National Practitioners Data Bank from its inception in 1990 to 2006.[3] Operating on the wrong body part was the source of 3.21% of surgically related malpractice payments in the United States during that time. Eliminating this preventable occurrence would, in theory, single-handedly reduce surgically related malpractice payments by 3%. Evidence accumulates that implementing best practices to prevent wrong-site surgery would achieve that objective.[2,4-7] Yet, implementation has not occurred in all Pennsylvania surgical facilities.

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PROVIDERS WHO RESIST FOLLOWING BEST-PRACTICE STANDARDS MAY EXPERIENCE MORE WRONG-SITE SURGERY THAN THOSE WHO IMPLEMENT THEM

The Authority has previously published the results of a survey of facilities to identify the barriers to implementation and the strategies for successful implementation of the Authority's 21 potential recommendations to prevent wrong-site surgery.[8]

The survey divided the 21 potential recommendations into six major goals (1, 2, 3A, 3B, 4, and 5), with a total of eight proposed measurement standards (1, 2A, 2B, 3A, 3B, 4A, 4B, and 5). For each of the eight measurement standards, respondents for the facilities were asked to describe barriers to implementation of the recommendations that would prevent the facilities from meeting the standard(s) for the goal. They were asked to describe any strategies they had used for successful implementation. Seventy facilities responded. Physician behavior was cited most commonly as a barrier to implementation, followed by difficulty accessing accurate information prior to the patient's arrival in the preoperative holding area. Elements of successful strategies for implementation included leadership, empowerment, improved access to information, education, and monitoring of compliance.[8]

Since the survey, the Authority has identified 24 facilities (14 hospitals and 10 ambulatory surgical facilities [ASFs]) that described only processes for successful implementation of the standards and 8 facilities (4 hospitals and 4 ASFs) that described only barriers that prevented the facilities from meeting the standards. Excluded from the analysis were respondents from facilities that listed both, single respondents responsible for multiple facilities, anonymous respondents, and respondents from facilities that only did endoscopies or infertility treatments.

The 24 facilities describing successful implementation reported 1 wrong-site surgery among the 14 hospitals (7%) and none in the 10 ASFs in the previous academic year (July 2011 to June 2012). The 8 facilities describing barriers to implementation reported 1 wrong-site surgery among the 4 hospitals (25%), and none in the 4 ASFs. The difference was not statistically significant, given the small numbers.

The sample size was expanded to the last two years, consistent with the Authority's two-year empirical cycle and rolling average. The 24 facilities describing successful implementation reported 1 wrong-site surgery among the 14 hospitals (7%) and 1 in the 10 ASFs (10%) over the prior two-year cycle (July 2010 to June 2012). Of the 8 facilities describing barriers to implementation, 1 of the 4 hospitals (25%) reported 2 wrong-site surgeries (1 each year), and 2 wrong-site surgeries were reported among the 4 ASFs (50%). The difference was statistically significant by the chi-square test ($p < 0.05$) for the group as a whole, but not for either type of facility individually, perhaps again given the small numbers.

The Authority was reluctant to take the analysis back beyond the two-year cycle. It was confident that the barriers were still existent but suspicious that the successful strategies had not yet been implemented.

The Authority suspects that the high probability of wrong-site surgery among the facilities describing barriers (3 of 8) was likely due to reporting bias. Two of the facilities describing barriers and experiencing wrong-site surgery, including one with 2 events in 2 years, described barriers preventing them from meeting 5 of the 8 standards each, suggesting a high level of frustration.

The results suggest that persistent barriers to the implementation of evidence-based best-practice standards may be associated with more wrong-site surgeries.

READINESS FOR CHANGE

From prior analysis of facilities that self-corrected, experience with the collaborations to prevent wrong-site surgery,[2,5] and review of the descriptions of the barriers and successful strategies for implementation of best practices,[8] the Authority has identified four essential elements for successful implementation of standards to prevent wrong-site surgery:

1. Leadership. The chief executive officers are willing to empower the nurses to enforce the facility's best-practice policies and provide resources to improve systems and educate providers, including physicians.
2. Manpower. Identified champions, ideally a leading surgeon, anesthesiologist, and OR nurse, have the authority, time, and resources to work with providers to change systems so that they meet best-practice goals in a way that acknowledges realistic concerns of providers.
3. Information. Near-miss events are captured and analyzed for quality improvement, policy and system changes, and education.
4. Time. Improving systems to meet the goals of evidence-based best practice without significant compromise to workflow and educating providers about making the improvements takes time, typically about six months.

The Authority can help facilities by providing information about reported events, providing checklists and other tools for improvement, and providing educational resources. (See http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx for a complete listing.)

Facility leaders can make a commitment to implement evidence-based best practices and policies and procedures to prevent wrong-site surgery, use appropriate checklists to aid compliance, achieve

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consistent compliance with those policies and procedures, and monitor for and review all wrong-site events, including, at least, critical near misses.[2,9]

COMPARISON OF THE AUTHORITY'S 21 EVIDENCE-BASED BEST PRACTICES TO PREVENT WRONG-SITE SURGERY AND THE JOINT COMMISSION'S 29 MAIN CAUSES AND SOLUTIONS FOR WRONG-SITE SURGERY

The Joint Commission Center for Transforming Healthcare Wrong-Site Surgery Project identified 29 main causes of wrong-site surgeries and their targeted solutions.[10] The Authority compared the solutions with its 21 evidence-based best practices to prevent wrong-site surgery.[1] There was overlap between the 29 main solutions identified by the Joint Commission and the 21 best practices identified by the Authority for most of the causes and best practices for prevention.

The Authority's 21 evidence-based best practices for the prevention of wrong-site surgery do not include the following specific points that were identified and tested by the Joint Commission's Robust Process Improvement methods:[10]

— Limit schedulers accepting verbal requests for surgical bookings instead of written documents by limiting "entry points for primary documentation . . . to a single fax number."

— "Confirm the presence and accuracy of primary documents critical to the verification process *prior to* the day of surgery." [italics added]

The Authority concurs with the general principle of written documentation collected and reconciled prior to the day of surgery and emphasizes that the site of the procedure is a critical piece of information that needs documentation.

The surgeon should mark the site, do it in the pre-op/holding area, and do it in an approved manner:[10]

— "Mark in the pre-op/holding area performed by the surgeon using a single-use surgical skin marker with a consistent mark type (e.g., surgeon's initials) placed as close as anatomically possible to the incision site."

— "Mark the site for every procedure; if not possible, document why a site-mark was not performed."

— "Do not move patient to the operating room before surgeon has marked the site."

— Document why site was marked in a nonapproved manner "even if a wrong site surgery event has not occurred."

The Authority has no specific evidence supporting the surgeon marking the site but agrees that the surgeon is the optimal provider for confirming that the site is marked accurately in a place that will be visible in the prepped and draped field. The Authority will further explore the sites at particular risk for wrong-site surgery.

The Authority realizes that its evidence-based best-practice principle #10 had an implicit assumption that the site would be marked before the patient enters the OR or procedure room. It has modified its principle to make that assumption explicit, as follows:

— 10. The site should be marked by a healthcare professional familiar with the facility's marking policy, with the accuracy confirmed both by all the relevant information and by an alert patient, or patient surrogate if the patient is a minor or mentally incapacitated; the site should be marked before the patient enters the OR.

As an alternate to the site mark, when needed, the Joint Commission says that facilities should "confirm identification of patient by all team members using patient armband, patient speak back, or patient caregiver if patient has been sedated."

The Authority concurs that an alert patient or caregiver participating in the time-out is a logical substitute for a site mark—since the site mark is, itself, a surrogate for the verbal participation of an alert patient in the time-out—but that the patient's response should be confirmed by all the relevant information, as it would be if the site were being marked.

Another Joint Commission solution was to "perform a pre-operative briefing in the operating room with patient involvement, if possible, to verify patient identity, procedure site, and side, along with other critical elements that need to be verified and addressed but are not part of the Time Out process."

The Authority supports the use of a preoperative briefing, such as that in the WHO Surgical Safety Checklist,[11] when the patient enters the OR, prior to the final time-out. The elements in that briefing should be those that need time to address before the incision is made, such as the availability of blood. The elements in the time-out should be those that need confirmation just as the incision is being made, such as the location of the site mark in the prepped and draped field and the administration of prophylactic antibiotics. The Authority has a suggested merger of the Joint Commission's Universal Protocol and the WHO Surgical Safety Checklist.[12] The Association of periOperative Nurses has also merged the two into a Comprehensive Surgical Checklist.[13]

The Joint Commission's targeted solutions did not address the evidence-based value of four of the Authority's evidence-based best-practice principles: supporting information from the surgeon's office (#5), doing the preoperative verification before the patient enters the OR (#6), verification by the circulating nurse upon taking the patient to the OR (#12), and the need for intraoperative verification of spinal level, rib resection level, or ureter to be stented (#21).

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NOTES

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WRONG-SITE SURGERY PROTOCOL FOLLOWED

While wrong-site surgeries receive lots of attention, there are many examples of healthcare workers preventing wrong-site surgery in Pennsylvania hospitals. The following reports illustrate the importance of multiple checks of the surgical consent, surgical markings, and communication among staff, patients, and family members.

The procedure on the operating room schedule was listed as left cataract extraction. All of the patient's paperwork, history and physical, operation consent, physician's orders, and patient preregistration form all state right cataract extraction. The incorrect side [on the schedule] was noted during verbal verification of the side during the registration process with the patient. The correct side, right, was then verified with the patient and the surgeon.

A surgical permit on [the patient's] chart . . . [was] signed by the mother of another patient. The permit should have said one eye; this [consent indicated] both eyes. The [staff] noted the wrong parental signature. Another [correct surgical] permit was obtained from the parents.

The operating room manager schedule stated a right-side hernia repair. All documentation, [including the] consent, [indicated] the left [side]. The surgeon marked the right side in error. A registered nurse handoff communication identified the error.

These reports exemplify the importance of the Universal Protocol[1] and of effective communication among staff, patients, and family members in preventing the occurrence of wrong-site surgeries.

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The Effects of Drug Shortages on Unsafe Injection Practices

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INTRODUCTION

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act of 2012. The US Food and Drug Administration (FDA) now has new authority to combat shortages of drugs in the United States and impose new requirements on manufacturers regarding early notification to FDA of potential shortages or disruptions of supplies. The legislation also requires FDA to develop a list of drug shortages, including the reason for and duration of the shortages.[1]

National drug shortages have become a factor in safe injection practices in healthcare facilities. Due to the ongoing shortages of frequently used drugs, practitioners are finding ways to help ease the burden of not having enough of these critical frequently used medications. Unsafe practices, such as reuse of single-dose vials on multiple patients, are done with the notion that they reduce costs without an appreciation of the risks involved.[2] As a patient safety liaison for the Pennsylvania Patient Safety Authority sharing information on current drug storages with my peers and facilities, some facilities have stated they are using single-dose vials for more than one patient in order to conserve resources and prevent waste. There are other rationalizations for the misuse of single-dose vials, including efficiency, time constraints, conservation of resources, avoidance of waste, and cost considerations.[3]

No matter what the rationalization is, the improper use of single-dose vials continues to result in infection outbreaks.[4] This year, two outbreaks of invasive *Staphylococcus aureus* infections in Arizona and Delaware were associated with the reuse of single-dose vials.[4] During the last five years, the Centers for Disease Control and Prevention (CDC) is aware of at least 19 outbreaks due to unsafe injection practices involving the use of single-dose or single-use medications for more than one patient.[4] National drug shortage was a documented factor in the unsafe injection practices of an outbreak involving bupivacaine this year. To conserve resources, staff used each 30 mL vial of the anesthetic, as needed, for multiple patients until the vial contents were depleted. If the 30 mL vial was not used in a single day, the vial was not discarded but saved for use the following day.[3]

Vials intended for single use are labeled "single-use" or "single-dose" because these vials contain no preservatives or antimicrobials to prevent bacterial contamination. Because such contamination is not visible to the human eye, it must be assumed that once the stopper is penetrated or the ampule is broken, contamination occurs, posing a risk of infection to the patient who next receives contents withdrawn from the vial.[3]

Frequent drug shortages complicate this problem. In most cases, there are no warnings of upcoming drug shortages or how long the shortages may last. Approximately 280 drugs, almost all manufactured in the United States, remain in short supply because of factors such as a dwindling number of drug manufacturers, deteriorating conditions in factories, and low prices for generics leading to a lack of investment to upgrade plants.[5] Propofol is another drug in particular that is on the list of drug shortages. This drug is commonly used both in hospitals and ambulatory surgical facilities. Propofol is formulated in a lipid emulsion that supports rapid bacterial growth. There have been numerous outbreaks of bacterial and viral infections as a result of reuse of single-dose vials of propofol on multiple patients.[2]

CDC and the Centers for Medicare and Medicaid Services (CMS) have recently reiterated their stance on the use of single-dose vials.[6,7] Both organizations state that the practice of using single-dose vials for more than one patient is unacceptable. There is one exception to this policy in that single-dose vials may be split into multiple doses

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when utilizing US Pharmacopeia (USP) chapter 797 guidelines. Strict adherence to these guidelines by qualified, trained personnel, and under no less than International Organization for Standardization (ISO) class 5 air quality conditions, is mandatory. Proper labeling of these medications is also required. Clinical units and operating rooms are not considered adequate for this purpose. CMS states that facilities that reuse single-dose vials for more than one patient without adhering to USP chapter 797 standards must be cited during regulatory survey.[3]

Despite the availability of guidance on best practices from CDC and other groups, there remains a lack of awareness and implementation of these recommendations by many practitioners. Guidance on the issue of safe injection practices and drug shortages can be found from various organizations, including CDC, CMS, FDA, and the Authority (in articles published in June 2008 and June 2011[8,9]). The Safe Injection Practices Coalition has joined in a partnership with healthcare organizations led by CDC in the One and Only Campaign to provide resources for safe injection practices for the healthcare community and patients. Information on this campaign can be found at http://www.OneandOnlycampaign.org.[4] Clinicians and purchasing staff should consider purchasing the smallest-size vials to prevent waste and avoid the misconception by clinical staff that there is enough medicine for more than one patient in the single-dose vials. Another alternative would be to use multidose vials when appropriate.

CONCLUSION

Outbreaks of infection resulting from unsafe injection practices are both unacceptable and preventable. Each time a healthcare professional does not adhere to safe injection practices, they endanger the very patient who they set out to help. Healthcare practitioners must not endanger patients due to these shortages and inappropriate workarounds. Single-dose vials are only meant for one patient.

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LETTER TO THE EDITOR: MALIGNANT HYPERTHERMIA

I wish to thank you and to applaud you for the efforts that you have made to improve patient safety within your state and for making your information available to all, therefore improving patient safety throughout the United States.

I am reviewing literature to review our current procedure and physician orders for the prevention, recognition, and treatment of a malignant hyperthermia crisis and reviewed your 2008 article on that subject. I wish to bring to your attention a possible misleading statement on page 92 under "Screening." Under the bullet "Obtain an anesthetic history to identify patients at risk for MH [malignant hyperthermia]: *If the patient has not had general anesthesia before* [italics added], does the patient know of a blood relative who had a bad reaction to anesthesia?" even if the patient has had general anesthesia before, the question, "Do you know of a blood relative who had a bad reaction to anesthesia?" is still appropriate, as MH-susceptible persons may have had a general anesthetic with triggering agents and may not have had a MH crisis or the reaction was not severe enough to be recognized or was misdiagnosed. Therefore, I feel the statement "If the patient has not had general anesthesia before" should be removed from that bullet point.

Rebecca Hansbrough, BSN, RN, CNOR
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Reviewer Commentary

I thank Ms. Hansbrough for her perceptive comments.

It is appropriate to modify the strategy to state that all patients requiring general anesthesia, whether they have been anesthetized previously or not, should be questioned as to a personal or family history of an unexpected adverse reaction to anesthesia, especially involving marked temperature elevation and/or muscle breakdown.

Henry Rosenberg, MD, CPE
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President, Malignant Hyperthermia Association of the United States

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PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for more than 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures, and drug technology.

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.