

PENNSYLVANIA PATIENT SAFETY ADVISORY



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OBJECTIVE

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

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The Value of Improving Patient Safety in Pennsylvania

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INTRODUCTION

Progress in patient safety has been made since the Institute of Medicine's two landmark reports were published: *To Err is Human: Building a Safer Health Care System*¹ in 1999 and *Crossing the Quality Chasm: A New Health System for the 21st Century*² in 2001.^{3,4} The Pennsylvania Patient Safety Authority, established under the Pennsylvania Medical Care Availability and Reduction of Error (MCARE) Act of 2002, is charged with reducing and eliminating harm from medical errors by collecting and aggregating data, identifying problems, and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities.⁵ The Authority was charged subsequently with also reducing healthcare-associated infections (HAIs), under Act 52.^{5,6}

Those engaged in patient safety and quality improvement initiatives must continually question whether safety is improving and whether the industry's efforts are yielding meaningful results. Current literature supports the contention that measuring patient safety is not an easy task.⁷⁻¹³ Randomness and rarity of certain events, differing event definitions, and the paucity of standardized, meaningful metrics are among the barriers to successfully implementing a measurement strategy. Determining the value of patient safety improvements is equally challenging. The Authority found it necessary to use estimates and projections when attempting to quantify the value of improvement related to specific measures. One estimate of lethal harms originating from suboptimal care during hospitalization posits that 400,000 Americans have their lives significantly shortened each year by preventable adverse events.¹⁴ Broad estimates of lethal harms originating from suboptimal care during hospitalization have ranged from 250,000 to 400,000 annually.^{14,15} Although these estimates are extrapolations that likely vary from reality, even if they are overestimated, the number of preventable harms is still large. The five measures the Authority chose are a small subset of the manifold ways in which hospitalized patients can be harmed.

Over the years, the Authority has shown reductions of several types of patient-harm events associated with patient safety initiatives, including falls with harm, wrong-site surgery, and HAIs. Likewise, the number of high harm events has decreased statewide. In a commentary on the national progress of patient safety, Drs. Pronovost and Wachter stipulate that evidence exists to support the contention that safety and quality are improving, and they cite a number of successes, such as bar coding implementation and decreased numbers of central line-associated bloodstream infections.¹⁶ They acknowledge that although safety efforts are "...encouraging and display significant improvements in certain aspects of patient safety, the absence of a valid global measure to evaluate whether safety is broadly improving makes it difficult to support a claim that safety is improving overall—just as this absence makes it difficult to say that it is not."¹⁶ In light of this dilemma, can the Authority assert that the combined efforts of healthcare facilities and the Authority have been effective in reducing and eliminating harm from medical errors in Pennsylvania? Although limitations exist, the Authority describes its methods and estimates for the value of the many improvements made by healthcare provider organizations.

The Authority is neither the sole impetus nor the only contributor to improvement efforts in Pennsylvania. Other motivations include the federal government's non-reimbursement policy for "never events," the Centers for Medicare and Medicaid Services (CMS) Value-Based Purchasing program, facility-specific publically reported data (e.g., Joint Commission's quality check, the Leapfrog Group's hospital safety scores), and providers' own natural incentives to improve quality and reduce claims.¹⁷⁻²⁰

ABSTRACT

The Pennsylvania Patient Safety Authority estimated the value of data aggregation, analysis, dissemination, and statewide collaborative learning to reduce healthcare-associated patient harm in the state. Improvements in patient safety have occurred with concentrated efforts directed at discrete issues. Measuring and appropriately attributing these improvements has been difficult. A select set of patient safety measures was chosen to demonstrate the results of the combined efforts of Pennsylvania healthcare facilities, statewide quality improvement entities, and the Authority. Using data submitted to the Pennsylvania Patient Safety Reporting System and the National Healthcare Safety Network, the Authority computed event trends and used evidence-based mortality and economic estimates to calculate theoretical lives and dollars saved over reporting periods of 11 to 12 years. The Authority estimates that through 2015 more than 2,600 lives and more than \$147 million dollars were saved. Using a standardized methodology, the value of safety improvements can be estimated to stimulate a conversation about the program's effectiveness. Fostering an environment that encourages and supports effective patient safety programs is inherent to the Authority's mission. (Pa Patient Saf Advis 2016 Dec; 13[4]: 125-136.)

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To coordinate these other motivators, various organizations, including the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and CMS, along with public-private collaborations such as the Partnership for Patients (P4P) espoused comparable goals to address quality and patient-safety improvement opportunities.^{9,10} The P4P is a large, national, quality improvement learning collaborative with two aims: to improve safety in acute care hospitals through the reduction of hospital-acquired conditions and to improve coordination of care at discharge to prevent readmissions.^{21,22} CMS invested in 26 hospital engagement network (HEN) contractors* nationally, including The Hospital and Healthsystem Association of Pennsylvania, which collectively enrolled about 3,700 acute care hospitals.^{9,10,21} In Pennsylvania, 109 acute care hospitals joined a HEN 1.0 project (December 2011 to December 2014).²³

Other quality improvement entities, including Quality Insights of Pennsylvania, the Health Care Improvement Foundation (HCIF), and the Healthcare Council of Western Pennsylvania, have also been active in statewide and regional improvement efforts. By aligning themselves with these programs, individual Pennsylvania hospitals were prompted to use their performance improvement strategies to focus on preventing patient harm and improving patient safety for the communities they serve. They benefited from collaborative learning. All of these activities, as well as additional programs based on needs and aspirations perceived by individual institutions, contributed to patient safety improvement efforts in Pennsylvania.

The Authority sought to provide information about the success and value of

statewide improvement efforts in reducing and eliminating harm from medical events in Pennsylvania by exploring outcome and economic estimates for a select set of patient safety measures.

METHODS

Measures and Sources of Data

The following patient safety measures were chosen to evaluate improvements in patient safety in Pennsylvania (Table 1):

- Falls with harm
- Central line-associated bloodstream infection (CLABSI)
- Catheter-associated urinary tract infection (CAUTI)
- Wrong-site surgery
- High harm events

These measures, with the exception of high harm events, were selected because the Authority had established focused collaboratives on these topics, standardized definitions and monitoring methods, and engaged providers in making improvements in these areas. High harm events were selected as a potential global measure of safety. The falls with harm, wrong-site surgery, and high harm measures data were reported by acute care facility type (i.e., hospitals, ambulatory surgical facilities, abortion clinics, birthing centers). They were reported according to requirements stipulated under the MCARE Act and submitted through the Authority's event reporting system, the Pennsylvania Patient Safety Reporting System (PA-PSRS).²⁴ The measures data for CLABSI and CAUTI were reported by hospitals in accordance with requirements outlined under an amendment of MCARE, Act 52 of 2007, pertaining to reporting HAIs to the National Healthcare Safety Network (NHSN).⁶

Harm

PA-PSRS uses an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention harm

index to distinguish between harm and no-harm events.²⁵ The harm score measures the extent to which the event "reached" the patient and the degree of patient harm that resulted, including death.²⁶ Events that do not reach the patient, because of chance or active recovery, and unsafe conditions are also reported.

The Pennsylvania Patient Safety Authority Harm Score Taxonomy is available at [http://patientsafetyauthority.org/advisories/advisorylibrary/2015/mar;12\(1\)/publishingimages/taxonomy.pdf](http://patientsafetyauthority.org/advisories/advisorylibrary/2015/mar;12(1)/publishingimages/taxonomy.pdf).

As can be seen from the taxonomy, high harm events are those that result in permanent injury or death or require life-saving measures.

Estimations

Analysts estimated the theoretical value of avoided events based on costs of claims and/or additional cost of treatment for associated injuries reported in the published literature.

Cost data from the literature has been adjusted for inflation, using the Bureau of Labor Statistics' publically available "consumer price index—all urban consumers for medical care databases."²⁷ Cost and mortality estimates for falls with harm, CLABSI, and CAUTI were obtained from AHRQ's 2013 Annual Hospital-Acquired Condition Rate and Estimates of Cost Savings and Deaths Averted from 2010 to 2013, AHRQ's 2015 interim update of the 2103 report, and Saving Lives and Saving Money: Hospital-Acquired Conditions Update Interim Data From National Efforts To Make Care Safer, 2010-2014.^{9,11} These costs are reported as an excess cost (i.e., a measure of the estimated additional cost per hospital-acquired condition due to the incremental cost of the hospital-acquired condition).

Cost estimates for wrong-site surgery were obtained via a special data request provided by the Physician Insurers Association of America Data Sharing

* The Hospital and Healthsystem Association of Pennsylvania has a contract with CMS for the HEN, of which the Pennsylvania Patient Safety Authority is a subcontractor.

Project Closed Claims database and reported average indemnity payments for wrong-site surgery.²⁸⁻³⁰ The Authority did not estimate wrong-site surgery mortality because there are scant metrics available that are generalizable to all surgery types.

Cost and mortality estimates for high harm events were obtained from the research by Adler and coauthors describing the impact of patient harm on clinical outcomes and hospital finances.³¹ Analysts calculated PA-PSRS high-harm mortality rate, expressed as harm score I (death) divided by harm scores G,H, and I (requiring life-saving measures, associated with permanent injury, or contributing to or resulting in death, respectively). The Authority likens this mortality estimate to the “failure to rescue” metric for complications (i.e., high-harm mortality rates are a metric for the failure to rescue harmful medical errors).^{32,33}

Some data estimation was necessary. For example, all Pennsylvania facilities began reporting infections into NHSN in July 2008; therefore, only six months of data were available for CLABSI and CAUTI for that year. The number of infections during 2008 was computed by doubling the available data to represent a full year of events. Seasonality of actual infection events was considered and an analysis of the CLABSI and CAUTI data for the first and second six months of 2009 yielded a near 50/50 split in number of reported infections, rendering this doubling method sound. The rate was assumed to be consistent throughout the year and used to justify this estimate. Likewise, July 2004 was the first full month in which PA-PSRS reporting occurred therefore, the number of high harm events during 2004 was imputed by doubling the available data. Whole calendar years were used to maintain consistency.

Value Formula

Decreases in deaths and the cost of events avoided can be used to estimate statewide improvements. The Authority used a

standardized approach to estimate the value of improvements for the patient safety measures selected (see Figure).

Starting points and timeframes for the measures listed below were chosen to capture baseline performance and actual performance that resulted from specific programs being implemented for the reduction of falls with harm, CLABSIs, CAUTIs, and wrong-site surgeries in Pennsylvania. The starting points for each measure are:

- Falls with harm: 2007
- CLABSI: 2008*
- CAUTI: 2008*
- Wrong-site surgery: 2007

For high harm events, the starting point is 2004, the year reporting was initiated in Pennsylvania. Additional detail on starting points is discussed in the estimations section of this article.

The actual performance (i.e., number of events [counts] per year) was plotted. For each measure, a linear regression model was calculated to fit the data using Microsoft Excel.³⁴ The starting point of the linear regression (i.e., Y intercept) was used as the baseline value. The (negative) slope was the average yearly trend over time of the estimated measure avoidance, mortality prevented, or cost saved (Table 2). The starting point or baseline value was used to estimate what would have happened had no improvement efforts been employed (i.e., expected baseline performance). The measures’ actual performance was then subtracted from the expected performance each year and totaled. This method of estimating avoided events was selected because it is applicable to all measures and valid for use with whole numbers when rates are not available. A similar approach has been used by others to estimate the value of safety improvements in hospital-acquired conditions,

* The starting point for CLABSI and CAUTI is 2008 because mandatory reporting to NHSN began that year.

patient harm, and HAIs.^{10,22,31,35} This method assumes a constant number of opportunities, constant compliance with problem identification and reporting, no across-the-board decrease in iatrogenic errors unrelated to interventions, and that improvements are linear. Proportional improvements become more difficult over time.

The value formulas used were estimated projections. The difference between the measures’ actual and expected performance, calculated by year and totaled, (i.e., the number of years for which there is data minus one or $N - 1$) yields the cumulative estimate of the number of prevented events. To calculate estimated number of lives saved, the total estimated number of events prevented or avoided was multiplied by an evidence-based estimate of mortality per event for that specific measure. The product is the estimated number of lives saved.

Similarly, for the cost-estimate calculation, the estimated number of events prevented or avoided, ($N - 1$) was multiplied by an evidence-based estimate of cost per event for that specific measure. The sum is the estimated savings in 2015 dollars.

RESULTS

Estimates of total number of events avoided exceed 21,300 (Table 3). The highest estimate of total events avoided involve the HAIs with more than 5,100 CLABSIs and 11,500 CAUTIs avoided. Estimates exceed 960 and 1,300 overall lives saved from CLABSIs and high harm avoided, respectively. Differences in the estimated additional mortality and cost per case and the varying number of events avoided account for the variation among some of the measures’ estimates (e.g., falls with harm and CLABSI lives saved and CLABSI versus any other measure in cost savings). The estimated average annual cost savings for avoided wrong-site surgery events is more than \$636,000 and for CLABSI is more than \$14.1 million.



Table 1. Patient Safety Measures Definitions

MEASURE	EVENT DEFINITION	DATA SOURCE
Falls with harm	Any fall (see definition*) that requires more than first-aid care. Treatment beyond first-aid care includes a laceration that requires physician intervention (e.g., sutures). ¹	Pennsylvania Patient Safety Reporting System
Central line-associated blood-stream infections	Laboratory-confirmed bloodstream infection (LCBI) that is not secondary to an infection at another body site. ²	National Healthcare Safety Network and healthcare-associated infections in Pennsylvania Patient Safety Reporting System
Catheter-associated urinary tract infections (UTIs)	A UTI in a patient who has had an indwelling urinary catheter in place for >2 calendar days on the date of event, with day of device placement being day 1, AND an indwelling urinary catheter was in place on the date of event or the day before. If an indwelling urinary catheter was in place for >2 calendar days and then removed, the date of event for the UTI must be the day of discontinuation or the next day for the UTI to be catheter-associated. ³	National Healthcare Safety Network and healthcare-associated infections in Pennsylvania Patient Safety Reporting System
Wrong-site surgery	Surgery or other invasive procedure performed on the wrong site or patient or a wrong surgical or other invasive procedure performed on a patient. (See wrong-site surgery detail) ⁴	Pennsylvania Patient Safety Reporting System
High harm	A subset of all harm events assigned one of the following definitions: G – An event occurred that contributed to or resulted in permanent harm. H – An event occurred that resulted in a near-death event (e.g., required intensive care unit [ICU] care or other intervention necessary to sustain life). I – An event occurred that contributed to or resulted in death. ⁵	Pennsylvania Patient Safety Reporting System

* **Falls:** The definition of falls includes:

- Assisted falls, in which a caregiver sees a patient about to fall and intervenes, lowering them to a bed or floor.
- Therapeutic falls, in which a patient falls during a physical therapy session with a caregiver present specifically to catch the patient in case of a fall.
- Physiologic falls, in which a patient falls as a result of a seizure or syncope.

The definition of falls excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position.

† **Wrong-site surgery detail:** Surgery begins in the perioperative area at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs.

Surgery includes:

- Minimally invasive procedures involving biopsies or placement of probes or catheters requiring entry into a body cavity or orifice and through a needle or trocar.
- A range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation.
- Preoperative anesthetic blocks and postoperative pain-management blocks, if administered in the perioperative area.

Table 1. Patient Safety Measures Definitions (continued)

Surgery does *not* include:

- a. Use of instruments such as otoscopes.
- b. Phlebotomy.
- c. Preparation of the wrong site. Example: prepping and draping the wrong leg, as long as the procedure is not performed on the improperly prepped and draped body part.
- d. Insertion of incorrect implants (e.g., left/right); however, it must be the correct type of implant. Example: implantation of a left-knee prosthesis in the (correct) right knee. However, implantation of an automatic implantable cardioverter defibrillator instead of a pacemaker would be considered a wrong-site event.
- e. Incorrect interpretation of anatomical structures when verification by radiography is not tenable. An event would be included or counted as a wrong-site event if imaging for verification were the evidence-based best practice or if the incorrect anatomic structure was targeted. For instance, placing a gastrostomy feeding tube in the transverse colon would be excluded because it is not a recognized procedure; conversely, placing a feeding tube into the jejunum would be included because it is not a clinically accepted procedure.
- f. Procedures performed outside the perioperative area.

(Items d through f have been customized for the Authority's wrong-site surgery program.)

Notes

1. Pennsylvania Patient Safety Authority. Training manual and users' guide. Version 6.5 June 2015.
2. Centers for Disease Control and Prevention. Patient safety manual—CLABSI [online]. [cited 2015 Jul 27]. http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf
3. Centers for Disease Control and Prevention. Patient safety manual—CAUTI [online]. [cited 2015 Jul 27]. <http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTICurrent.pdf>
4. National Quality Forum's definition as outlined in the serious reportable events in healthcare—2011 update: a consensus report. Washington DC: National Quality Forum; 2011.
5. Pennsylvania Patient Safety Authority. Harm Score Taxonomy—High harm [online]. [cited 2015 Jul 27]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12\(1\)/PublishingImages/taxonomy.pdf](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/mar;12(1)/PublishingImages/taxonomy.pdf)

An estimated \$147.2 million was found in total cost savings over the reporting periods, with an average annual total cost savings of \$20 million.

To assess the strength of the relationship between the actual and predicted number of events per measure per year, a Pearson's product-moment correlation coefficient was calculated per measure and, as seen in Table 4, the majority of the results were statistically significant at the $P < .05$ level. CAUTI had the greatest rate of improvement per year; that is due, in part, to the statewide initiatives described below.

DISCUSSION: THE VALUE

Measuring the value of improvements in patient safety is challenging, and any estimations will be inherently imprecise. This limitation notwithstanding, the Authority believes the improvements made by

Pennsylvania healthcare providers in these focused areas are substantial and meaningful. Even if the estimated annual values of \$20 million are off more than marginally, one could argue that these improvements are meaningful on moral grounds and reduced human suffering. The general efficacy of patient safety initiatives is supported by AHRQ's research on national rates, cost savings, and deaths averted, which shows an estimated 17% decline in PFPs' hospital-acquired conditions from 2010 to 2013 and again from 2013 to 2014.^{9,11} Although AHRQ acknowledges that reasons for this progress are not fully understood, financial incentives, public reporting of hospital results, guidance and assistance from quality-improvement organizations and the Health and Human Services' PFP are cited among contributing factors.^{9,10}

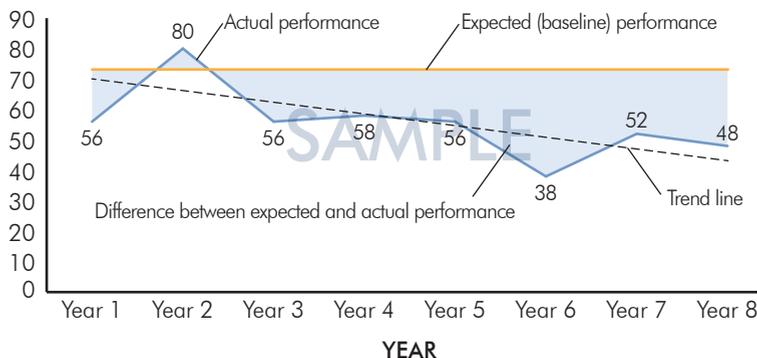
Falls with Harm

The improvement (decline in number of falls with harm) is due in part to regional and statewide learning and improvement efforts. These include the 2008–2010 joint effort between the Authority and HCIF to establish a falls reporting initiative to assist hospitals in their falls-prevention efforts and the Authority-led partnership with the Hospital and Healthsystem Association of Pennsylvania's (HAP's) Hospital Engagement Network (HEN) Falls Reduction and Prevention Collaboration, part of CMS's PFP initiative.³⁶ At its peak, 83 hospitals from across the Commonwealth participated in the collaboration. Simultaneously, the Authority has published articles and tools to help staff in Pennsylvania facilities assess

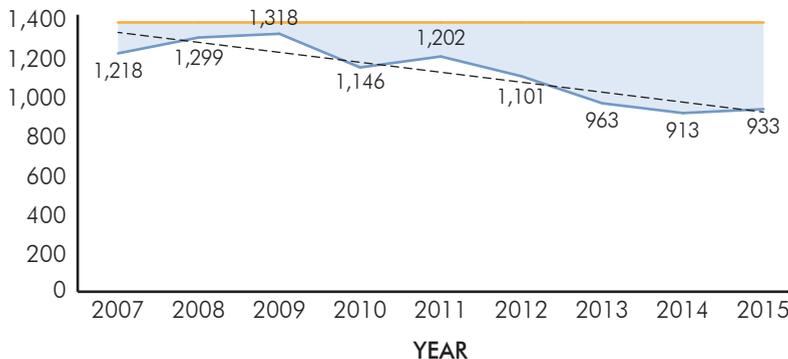
(continued on page 131)

FIGURE. PENNSYLVANIA PATIENT SAFETY EVENTS

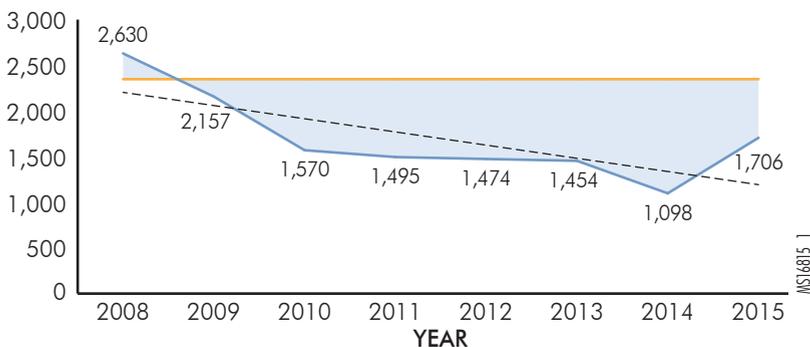
**Sample Data
NUMBER
OF EVENTS**



**Falls with Temporary or Significant Harm*
NUMBER OF EVENTS
REPORTED THROUGH PA-PSRS†**



**Central Line-Associated Bloodstream Infections
NUMBER OF EVENTS
REPORTED THROUGH NHSN‡**



* Harm: the event reached the patient, causing temporary or significant harm (Serious Event: harm scores E through I). High harm: the event reached the patient, causing significant harm (Serious Event: harm scores G through I). The Pennsylvania Patient Safety Authority's event-reporting system uses an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention harm index and the Veterans Health Administration National Center for Patient Safety severity assessment code system to distinguish between harm and no-harm events. The Authority harm score taxonomy is available exclusively online at [http://patient.safetyauthority.org/advisories/advisorylibrary/2015/mar;12\(1\)/publishingimages/taxonomy.pdf](http://patient.safetyauthority.org/advisories/advisorylibrary/2015/mar;12(1)/publishingimages/taxonomy.pdf)

† PA-PSRS, Pennsylvania Patient Safety Reporting System.

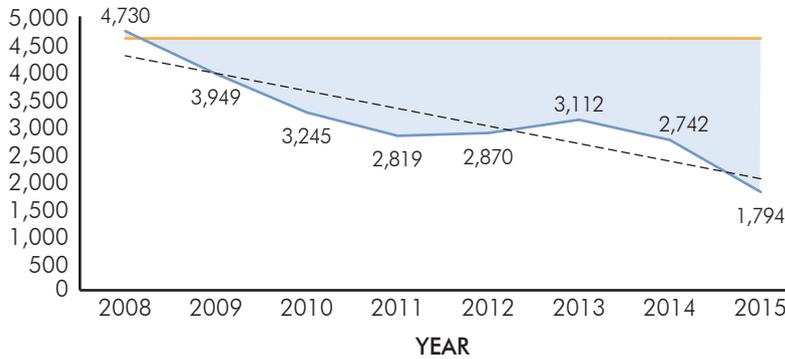
‡ NHSN, National Healthcare Safety Network; figures are from Pennsylvania reporting.

§ The number of wrong-site surgery events in this graph reflect the number of events reported through 2015 and are not consistent with the current number of events reported.

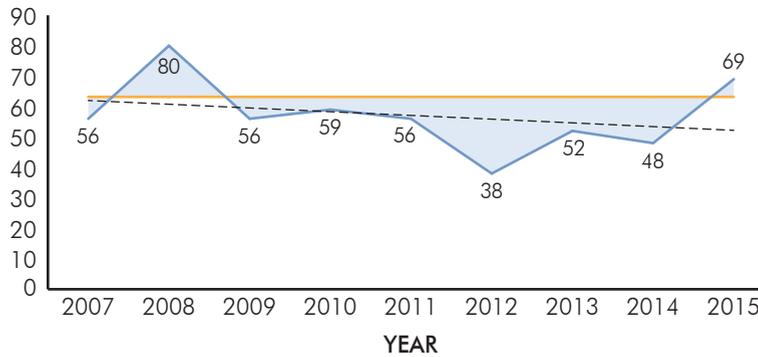
FIGURE. PENNSYLVANIA PATIENT SAFETY EVENTS (continued)

(continued from page 129)

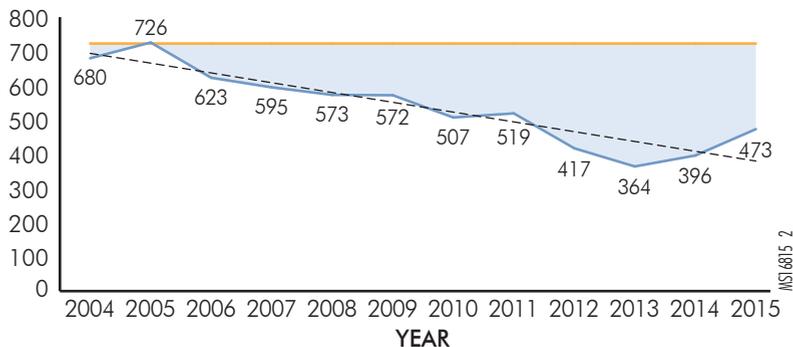
Catheter-Associated Urinary Tract Infections
NUMBER OF EVENTS
REPORTED THROUGH NHSN[‡]



Wrong-Site Surgeries[§]
NUMBER OF EVENTS
REPORTED THROUGH PA-PSRS[†]



Events with Significant Harm^{*}
NUMBER OF EVENTS
REPORTED THROUGH PA-PSRS[†]



and investigate falls and determine the appropriate event type classification for reporting through PA-PSRS.³⁶⁻⁴⁴ The facility-level performance improvement work rests solely with those staff implementing best practices in fall reduction, aided by these collaborative efforts. Before these initiatives, the number of falls with harm events were on the rise.

CLABSI and CAUTI

The number of CLABSIs is trending down despite the most recent year's increase in number of reports, and CAUTIs reported to the NHSN have been on the decline since mandatory reporting began in 2008.⁶ The Authority works closely with the Pennsylvania Department of Health, the Pennsylvania Health Care Cost Containment Council, HAP, the Association for Professionals in Infection Control and Epidemiology, HCIF, the Pennsylvania Health Care Quality Alliance, and other government and professional associations in infection-prevention improvement efforts.

Through prevention programs, articles, and toolkits, the Authority guides and educates healthcare facilities in detecting serious infection trends and in developing new strategies to prevent HAIs.⁴⁵⁻⁴⁹

To fulfill the responsibilities created by Act 52 of 2007, Pennsylvania established the Healthcare-Associated Infection Prevention (HAIP) website, which issues infection prevention newsletters and annual reports on HAIs. "The mission of HAIP is to protect patients, residents, visitors and healthcare personnel as well as promote safety, quality and value in the healthcare delivery system."⁵⁰ In 2012, Quality Insights of Pennsylvania, the Medicare quality improvement organization for the state, released a Best Practice Intervention Package: Preventing Healthcare-Associated Infections, which



Table 2. Value Formula: Estimate of the Projected XYZ Measure

EVENTS AVOIDED (SAMPLE DATA)

CALENDAR YEAR	YEAR OF DATA	EXPECTED PERFORMANCE	ACTUAL PERFORMANCE	DIFFERENCE
2007	Year 1	68	56	12
2008	Year 2	68	80	-12
2009	Year 3	68	56	12
2010	Year 4	68	59	9
2011	Year 5	68	56	12
2012	Year 6	68	38	30
2013	Year 7	68	52	16
2014	Year 8	68	48	20
2015	Year 9	68	49	19
Total estimated projected XYZ cases avoided over time				118

MORTALITY

XYZ CASES AVOIDED OVER TIME	MULTIPLY	ESTIMATED ADDITIONAL INPATIENT MORTALITY PER XYZ	EQUALS	ESTIMATED POTENTIAL LIVES SAVED
118	×	0.05	=	5.9

COST

XYZ CASES AVOIDED OVER TIME	MULTIPLY	ESTIMATED ADDITIONAL COST PER XYZ (ADJUSTED TO 2015 DOLLARS)	EQUALS	ESTIMATED POTENTIAL SAVINGS
118	×	\$2,000	=	\$236,000

Note: Fictitious data used for example only.

provided valuable prevention resources and the structure for performance improvement activities to reduce the number of CLABSIs and CAUTIs.

Before receiving the HEN contract, HAP managed two AHRQ-funded projects from 2008 to 2011 that used the Comprehensive Unit-based Safety Program to work with hospitals to reduce CLABSI and CAUTI. Additionally, the HAP-led HENs and Reduction in CLABSI and CAUTI Collaborations were instrumental in driving improvements locally and regionally.⁵¹ Before these initiatives, the number of CLABSI and CAUTI events were essentially unchanged.

Wrong-Site Surgery

Wrong-site surgeries in Pennsylvania trended down from 2007 through 2014, with an increase seen in 2015. The noted improvement (i.e., decline in the number of wrong-site surgery events) in the eight-year period was due, in part, to the HCIF-led Partnership for Patient Care regional Wrong-site Surgery Prevention Program (2008) and the Authority-led partnership with HAP’s HEN, Wrong-Site Surgery Collaboration, which ended in 2014.⁵²⁻⁵⁴ Through on-site assessments, education, updates in the *Pennsylvania Patient Safety Advisory*, and toolkits, the Authority continues to provide guidance to healthcare facilities in preventing and reducing wrong-site surgery.^{29,30,31,55-57} Because wrong-site

anesthesia blocks administered by anesthesiologists and surgeons account for nearly 27% of all wrong-site events identified in Pennsylvania operating suites, the Authority has partnered with the Pennsylvania Society of Anesthesiologists to update Authority guidance materials and to develop evidence-based resources for dissemination statewide.⁵⁸

High Harm

High harm events, a leading indicator for Serious Events, have been decreasing annually in number and as a percentage of Serious Events.⁴⁵ The Authority has seen an increase in the number of Incident (non-harm) reports reported through PA-PSRS over this period,

Table 3. Estimates Summary Detail

MEASURE	TOTAL NUMBER OF EVENTS AVOIDED (YEARS, N – 1*)	MORTALITY PER EVENT	LIVES SAVED	COST PER EVENT*	COST SAVINGS	AVERAGE ANNUAL COST SAVINGS
Falls with harm	2,290 (8 years)	0.055 ¹⁻³	126	\$8,110 ¹⁻³	\$18,571,900	\$2,321,488
Central line-associated bloodstream infection	5,199 (7 years)	0.185 ¹⁻³	962	\$19,059 ¹⁻³	\$99,091,553	\$14,155,936
Catheter-associated urinary tract infection	11,544 (7 years)	0.023 ¹⁻³	266	\$1,121 ¹⁻³	\$12,940,600	\$1,848,657
Wrong-site surgery	57 (8 years)	N/A	N/A	\$162,063 ^{†‡}	\$5,095,449 [‡]	\$636,931
High harm events	2,230 (11 years)	0.59 [§]	1,316	\$5,174 [§]	\$11,538,020	\$1,048,911

Note: all figures are estimates, cost per event is adjusted to 2015 dollars, and lives saved have been rounded to whole numbers.

* Calculated using the number of years post baseline.

† Inflation adjusted to 2015 U.S. dollars.

‡ Estimate is based on average amount awarded per claim, multiplied by the percentage of wrong-site surgery claims paid out (0.554).

Notes

- Agency for Healthcare Research and Quality. Interim update on 2013 annual hospital-acquired condition rate and estimates of cost savings and deaths averted from 2010 to 2013 [online]. [cited 2015 Apr 8]. <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.pdf>
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- Quarterly update on the preventing wrong-site surgery project [online]. Pa Patient Saf Advis 2008 Sep;5(3):103-5 [cited 2015 Mar 17]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5\(3\)/Pages/103.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/103.aspx)
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Table 4. Average Improvement per Measure

MEASURE	IMPROVEMENT PER YEAR (N – 1)*, %	P-VALUE	MEASUREMENT PERIOD, YEARS (N)
Wrong-site surgery	2.1	0.469	9
Falls with harm	4.5	< 0.001	9
High harm	5.3	< 0.001	12
CLABSI	8.4	0.036	8
CAUTI	10.1	0.002	8

* Calculated using the number of years for which there is data minus one.

suggesting that the decreased number of Serious Event reports is not due merely to an overall decline in vigilance of surveillance or reporting.⁴⁵ Given that the number of medical interactions is increasing, a plausible hypothesis for this decline in high harm events is that as improvements are realized in patient safety, the number and severity of harmful adverse events is decreasing. The Authority

has seen an increase in the number of Incident (non-harm) events reported through PA-PSRS, and this is consistent with this hypothesis that there is a shift to earlier detection and reporting of events with fewer events reaching the patient and causing serious harm. The decrease in the number of falls with harm is one example. In addition to what has been discussed here, other quality improvement projects

and initiatives have been performed by the Authority and others throughout the Commonwealth in the past 11 years and have contributed to the reduction of harm to patients.

The Authority’s (PA-PSRS data) calculated high-harm mortality rate of 58.8% is in keeping with a recent study by Adler and coauthors, in which patients experiencing harm (consistent with PA-PSRS high harm



categories) had a 59% higher mortality probability than patients experiencing no harm or only temporary harm.³¹

LIMITATIONS

The data presented here are from databases in Pennsylvania. Despite mandatory reporting laws, the data are subject to the limitations of self-reporting, including the complexities of selecting the appropriate event type, harm level, and harm score. Over time, the Authority has collaborated with facilities, organizations, and the Pennsylvania Department of Health to clarify definitions and reporting standards, which the Authority believes has helped to standardize and facilitate reporting.

To estimate number of lives saved and cost savings per measure, the Authority chose to use whole numbers versus rates in the calculation of the value formula. This mitigates the effect of changes in practice, such as inserting central lines and urinary catheters in fewer patients, but may not align with other reporting methods. It presumes a constant baseline of opportunities for error and at least consistent (not necessarily complete) compliance with identification and reporting of problems.

The references cited to estimate mortality and cost (i.e., Adler et al., AHRQ) use *inpatient* estimates.^{9,11,31} The Authority acknowledges that some of the events for falls with harm, CLABSI, and CAUTI

may have come from outpatient settings (e.g., ambulatory surgical facilities, birthing centers, and abortion clinics) but by far the majority of these events (98.7%) were from acute care hospitals.

Inevitably, there was some measure *overlap* within the high harm measure in that high harm is an aggregate of all event types reported as harm score G, H, or I; for example, falls with harm accounted for 5.1% of high harm events during the time period. The overlap is minimal and the objective was to calculate and estimate lives saved and cost savings for individual measures as well as a representative whole such as high harm.

The number of admissions and acuity of inpatients fluctuated between 2004 and 2015. Since 2005 at Pennsylvania acute care hospitals, inpatient admissions have declined 13.5% and inpatient days per 1,000 population have decreased 16.1%.^{59,60} This decrease may impact the rate of improvement estimated. Patients admitted to acute care hospitals for the same conditions are sicker and in need of more intensive care.^{61,62} It is indeterminate which of these countervailing forces are stronger, but both could have influenced these measures.

CDC has a data validation process for CLABSI and CAUTI that includes involvement of the Pennsylvania Department of Health.⁶³ Different measures are validated to different extents and detailed validation of all measures is limited.

CONCLUSION

The Authority sought to measure its effectiveness by determining and describing the value of data aggregation, analysis, dissemination, and collaborative statewide learning efforts in reducing healthcare-associated patient harm in Pennsylvania. This analysis is based on clinical outcomes and economic estimates for a select set of patient-safety measures. Results reflect the combined efforts of the Authority, healthcare facilities, and other quality-improvement entities in Pennsylvania after the implementation of the MCARE Act and Act 52. The Authority has found that fostering collaborative initiatives across facilities and collaborating with other agencies in Pennsylvania has helped facilities make improvements in certain areas of clinical focus.⁴⁵

Although it is difficult to parse out any individual agency's contribution to a given effect, through the use of literature-based and explicit methodology, the Authority has estimated lives saved and costs avoided for selected patient safety measures. By sharing these concepts and results, the Authority hopes to enrich the conversation about improving patient safety and stimulate continued progress.

Acknowledgment

Edward Finley, BS, data analyst, Pennsylvania Patient Safety Authority, contributed to the abstraction, analysis, and preparation of data for this article.

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Analysis of Reported Drug Interactions: A Recipe for Harm to Patients

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ABSTRACT

Patients admitted to a hospital often receive many medications. Concomitant use of multiple medications can lead to drug interactions that occur prior to administration (i.e., drug incompatibility) or after ingestion or injection (i.e., drug-drug interaction). When an interaction occurs, the effects and characteristics of the drugs may be altered, leading to increased or decreased drug activity or new and unanticipated adverse effects. Analysts searched the Pennsylvania Patient Safety Reporting System database for reports submitted as “Medication error/Monitoring error/Drug-drug interaction” that occurred from April 2009 through March 2016. A total of 815 event reports were included in the final analysis. The most commonly reported type of drug interaction involved drug incompatibilities (41.8%, n = 341) and drug-drug interactions (27.9%, n = 227). Healthcare facilities can help reduce the opportunity for drug interactions reaching patients by addressing all areas of the medication-use process and not relying solely on the effectiveness of alerts when orders are entered into electronic health records. (Pa Patient Saf Advis 2016 Dec;13[4]:137-148.)

INTRODUCTION

Drug interactions may occur inside (drug-drug interaction [DDI]) or outside (drug incompatibility) the body. When an interaction occurs, the pharmacological effect and/or physical characteristics of one or both drugs is altered. As a result, the pharmacological effect of one or both drugs may be increased or decreased, or a new and unanticipated adverse effect may occur.

DDIs may result from pharmacokinetic interactions (absorption, distribution, metabolism, and excretion) or from interactions at drug receptors. Often these interactions are not benign. The risk of patient harm and the potential financial burden from DDIs is significant. For example, DDIs have been estimated to account for up to 30% of all adverse drug events (ADEs).^{1,2} Certain patient factors (e.g., age, impaired renal function, current medications) can increase the risk and potential harm from DDIs.

A drug incompatibility occurs when two or more injectable drugs are mixed and the stability or structure of the drugs is altered by physical or chemical reactions. The resulting solution is often no longer optimal or safe for the patient. For example, physical changes to the solution may lead to precipitate formation that can cause catheter occlusion and embolism and can contribute to a range of ADEs, from thrombophlebitis to multi-organ failure. Additionally, the reduction or elimination of the active drug can lead to a therapeutic failure. The consequences of drug incompatibilities can be particularly severe in neonatal and pediatric patients. Unfortunately, inappropriate Y-site combinations (used to infuse multiple medications through one venous access point) of continuously infused drugs may be common. In an observational study of 13 intensive care units (ICUs) in Canada, the prevalence of inappropriate drug combinations was 8.5% among all patients but rose to 18.7% in patients receiving at least two continuously infused drugs.³

As the number of approved drugs increases, the risk for DDIs and drug incompatibilities increases. Pennsylvania Patient Safety Authority analysts have not previously explored drug interactions reported through the Authority’s Pennsylvania Patient Safety Reporting System (PA-PSRS). With this analysis of drug interactions reported to the Authority, analysts sought to characterize contributing factors and identify appropriate system-based risk reduction strategies to help facilities identify potential risk and minimize potential patient harm.

METHODS

Analysts queried the PA-PSRS database for reports submitted as “Medication Error/Monitoring error/Drug-drug interaction” that occurred from April 2009 through March 2016. This query yielded 870 event reports. Fifty-five reports (6.3%) were excluded from final analysis because upon review of the event’s description, the error did not involve a drug interaction. A total of 815 event reports remained for final analysis.

The medication name, patient care area, event type, event description, phase(s) of the medication use process, and harm score, adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) harm index,⁴ were provided by the reporting facility. When a medication name data field was left blank or incomplete, but the name was provided in the event description, an analyst adjusted the medication name field appropriately. Reports were categorized into four categories: DDI, therapeutic duplication, contraindication, and drug incompatibility. The drug classes involved in the events also were identified. Intravenous solutions with or without electrolytes were considered to be drugs for this analysis. In the context of

this analysis, therapeutic duplications are errors when two or more medications from a similar pharmacotherapeutic class and for similar indications are prescribed and/or administered to a patient. Error reports were further evaluated to identify contributing factors and potential system-based risk reduction strategies.

RESULTS

Results were categorized by the type of drug interaction. The largest percentage of drug interaction events were drug incompatibilities (Figure 1).

Drug Incompatibilities

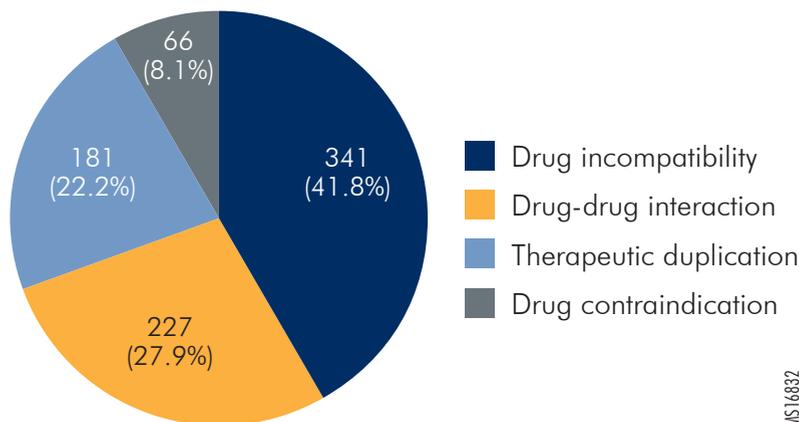
Most of the drug incompatibility events (88.3%, n = 301 of 341) reached the patient (harm score C through I). Patient harm was noted in only 0.6% (n = 2) of the drug incompatibility reports and were reported as errors that may have contributed to or resulted in temporary harm to the patient and required intervention (harm score E; Figure 2).

More drug incompatibility events involved adult patients (41.6%, n = 142 of 341) than elderly or pediatric patients (Figure 3).

Overall, 48 unique patient care areas were associated with a drug incompatibility event, with medical/surgical units involved in 13.2% (n = 45 of 341) of the events. Taken together, intensive care units (ICUs; e.g., cardiac ICU, neonatal ICU), where patients are often on multiple intravenous (IV) medications, were cited in 29.6% (n = 101) of reports.

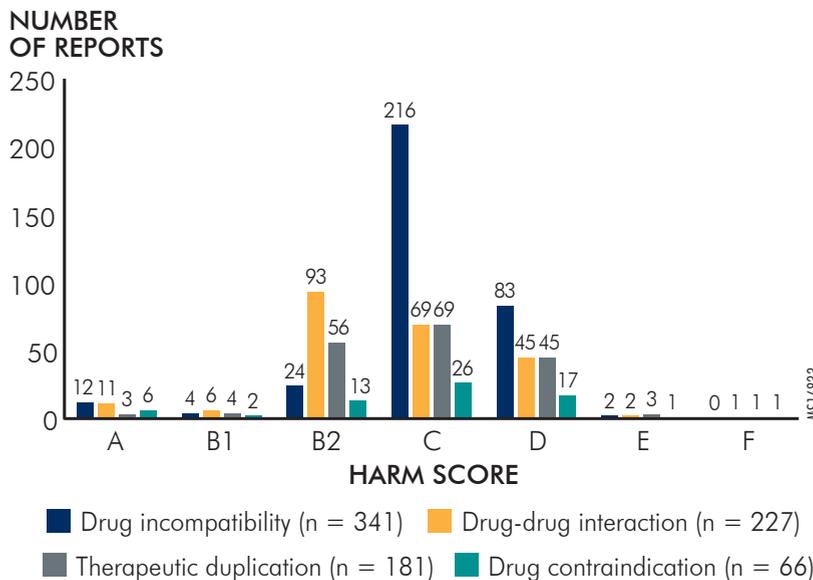
Analysts reviewed event description fields to determine whether an actual incompatibility took place or whether the reported event was a “close call” (e.g., nursing identified the potential for an incompatibility before administration to the patient). Almost one out of five drug incompatibility reports (18.8%, n = 64) mentioned the formation of a precipitate and 2.1 % (n = 7) stated an infiltration took place. The largest percentage of reported events

Figure 1. Types of Drug Interactions Identified in Events Reported to the Pennsylvania Patient Safety Authority, April 2009 through March 2016 (N = 815)



MS16832

Figure 2. Harm Scores of Drug Interaction Events as Reported to the Pennsylvania Patient Safety Authority, April 2009 through March 2016 (N = 815)*



MS16833

* There were no reported events with harm score G, H, or I.

(49.3%, n = 168) described situations in which the potential for incompatibility was identified before administration (i.e., close call) and almost 30% (28.2%, n = 96) described events where two incompatible drugs were infused, but no visible precipitate formed.

Drug incompatibility reports cited 117 unique medications. The most common medications mentioned in reports included IV fluids (e.g., dextrose 5%, sodium chloride 0.9%; 16.7%, n = 57), heparin (14.4%, n = 49), pantoprazole (8.5%, n = 29), and parenteral nutrition solutions (8.5%, n = 29). The most common pairs of medications included cefTRIAxone with lactated Ringer's solution (2.6%, n = 9) and heparin with diltiazem (2.6%, n = 9). Figure 4 shows the most common pairs of medications involved in these reported events. The most common reported pair of medications that led to actual precipitate formation was the combination of ciprofloxacin and hydration solutions with electrolytes (9.4%, n = 6 of 64).

Following are examples of reported errors involving patients receiving IV therapy and a precipitate occurred:*

Pentamidine mixed with NSS [normal saline solution]. Precipitate found in tubing. Medication stopped and tubing taken to pharmacy for discussion. Pentamidine found to have been mixed with NSS even though the label said it was mixed with D5 [dextrose 5%]. No indication that this impacted the patient or the IV site. Patient completed his medications and chemotherapy and went home as planned.

Patient had a piggyback line infusing Merrem® IV [meropenem] and a dose of ciprofloxacin was due. I flushed out the line after the Merrem was completed and hung the

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

Figure 3. Age of Patients Involved in Drug Interactions, April 2009 through March 2016 (N = 815)

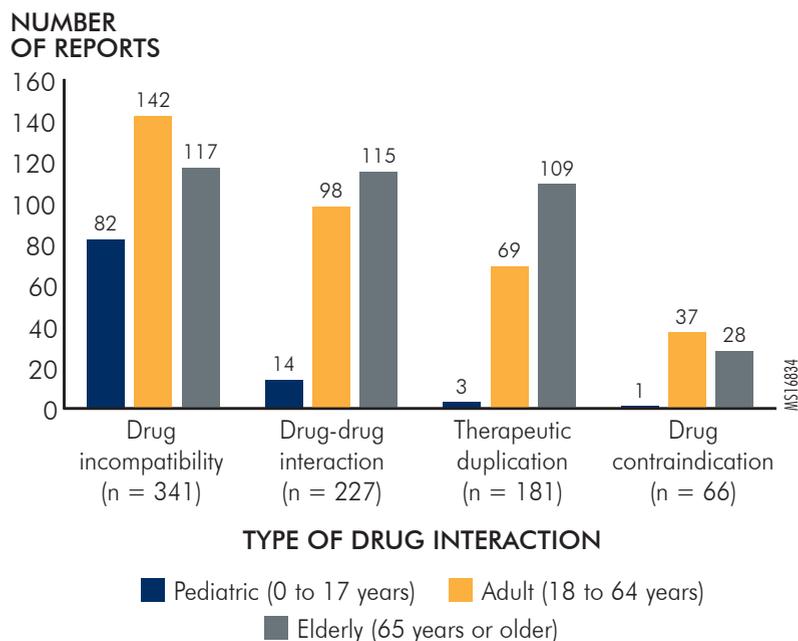
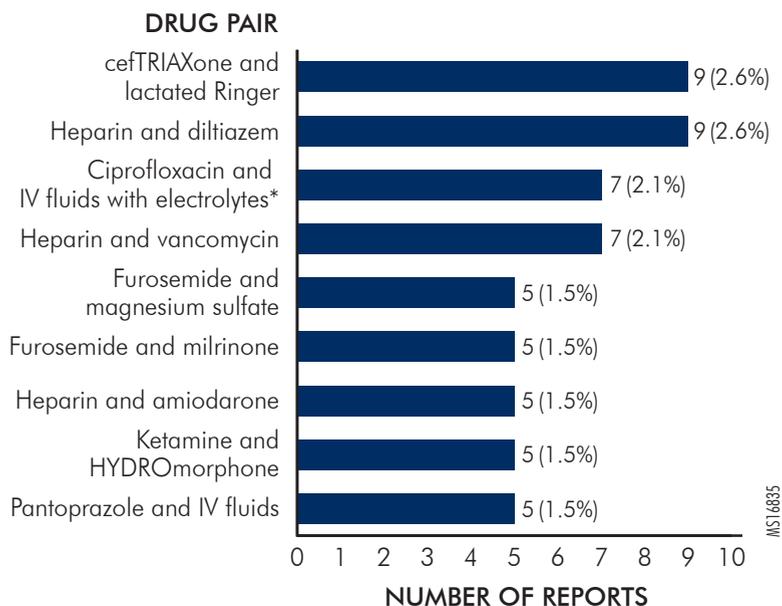


Figure 4. Most Common Pairs in Drug-Drug Interaction Reports Identified as Drug Incompatibilities, as Reported to the Pennsylvania Patient Safety Authority, April 2009 through March 2016 (n = 341)



* Accounted for more reports of precipitate formation (n = 6 of 64, 9.4%) than other drug pairs. IV, intravenous.



ciprofloxacin. Within five minutes after leaving the room, patient rang the call bell for assistance. Inside the tubing I noticed large amounts of whitish flakes. I disconnected and discarded the IV set and drew back [with a syringe] to withdraw medications from his port. I noticed very few white flakes in what I drew back. I then flushed the line with fluid and placed a new bag of ciprofloxacin on a new set of iv tubing and am completing the infusion. Physicians are to be notified, as well as Pharmacy.

80-year-old female patient had DOBUTamine infusion and Zosyn® [piperacillin sodium and tazobactam sodium] piggybacked via y site. The combined medications crystalized and occluded the PICC [peripherally inserted central catheter] line which had to be removed and replaced with left internal jugular central line.

Drug-Drug Interactions

DDIs accounted for 27.9% (n = 227 of 815) of reported events. Although more than half (51.5%, n = 117 of 227) of DDI events reached the patient, only 1.3% (n = 3) were reported as Serious Events (harm score E and F; see Figure 2).

Most of these events involved an elderly patient (50.7%, n = 115) while 43.2% (n = 98) involved adult patients (see Figure 3).

Forty-eight unique patient care areas were associated with a DDI event, with pharmacy cited most often (31.7%, n = 72) followed by medical/surgical units (11%, n = 25) and emergency departments (4.8%, n = 11).

There were 116 unique medications and more than 112 unique pairs of medications cited in DDI reports. The most common medications mentioned in reports included IV contrast (e.g., iohexol, iopamidol; 23.8%, n = 54), metFORMIN (23.8%, n = 54), clopidogrel (9.3%, n = 21), and simvastatin (9.3%, n = 21). The most common pairs of medications

include IV contrast and metFORMIN (23.8%, n = 54), omeprazole and clopidogrel (8.8%, n = 20), and simvastatin with amiodarone (4.0%, n = 9).

Analysts queried event descriptions to determine whether alerts were mentioned or involved in the event and found that only 5.3% (n = 12 of 227) of the reports mentioned “alert,” “flag,” or “warning.”

Following are examples of reported drug interactions that reached patients:

A patient taking metFORMIN was admitted for a cardiac catheterization with contrast. MetFORMIN was not addressed on admission or discharge and was not ordered as inpatient. Discharged the next day. Instructions given to patient had no information for the patient on whether or when to resume [the metFORMIN]. The patient presented [approximately two weeks later] with myopathy, renal failure, and serum creatinine of 2.1. (Normal results are 0.7 to 1.3 mg/dL for men and 0.6 to 1.1 mg/dL for women.) The emergency department physician did not address metFORMIN. The patient was hydrated and discharged. Discharge instructions for patient instructed patient to continue metFORMIN.

A physician identified a Tapazole® [methimazole] and Synthroid® [levothyroxine] drug interaction. The admission orders were processed the previous night which included both Synthroid and Tapazole. The interaction did not flag [in the order entry system] and was missed. Pharmacy investigated and found that the computer master inventory entry for Synthroid was missing [appropriate] codes. Thus, Synthroid was not flagging for therapeutic duplications, drug interactions, etc. The physician discontinued Tapazole. Pharmacy updated the entry for Synthroid to reflect the proper coding.

The patient was prescribed fluconazole by an orthopedic surgeon after consulting with infections disease.

The patient is s/p [status post] renal transplant and taking Prograf® [tacrolimus]. The patient was admitted and Prograf was held till creatinine and tacrolimus levels returned within normal limits.

Therapeutic Duplications

Nearly a quarter (22.2%, n = 181 of 815) of reports were identified as involving therapeutic duplications. Therapeutic duplication events reached patients in 65.2% (n = 118 of 181) of the reports. Only 2.2% (n = 4) of the events were reported as Serious Events (harm score E and F; see Figure 2).

Elderly patients were involved in most (60.2%, n = 109) of these events (see Figure 3).

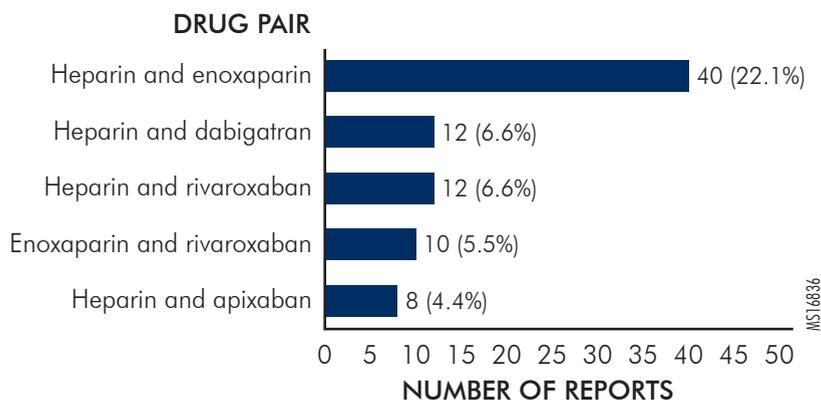
Therapeutic duplications occurred in 36 unique patient care areas with pharmacy (27.1%, n = 49 of 181) cited most often. Medical/surgical and telemetry units were involved in 13.3% (n = 24) and 11.6% (n = 21) of the events, respectively.

Overall, 78 unique medications were mentioned. The most common medications were anticoagulants, a class of high-alert medications,⁵ including heparin (47%, n = 85 of 181), enoxaparin (34.8%, n = 63), rivaroxaban (13.3%, n = 24) and dabigatran (11%, n = 20). The most common pairs of medications were combinations of anticoagulants (Figure 5). Overall, anticoagulants were mentioned 215 times (more than one anticoagulant was mentioned in some reports) in 181 reports.

Following are examples of reported therapeutic duplications that reached patients:

The patient received 3 doses of Lovenox® [enoxaparin] and 2 doses of heparin in a 24-hour period. A physician ordered Lovenox and did not discontinue heparin patient was already receiving. Pharmacy did not

Figure 5. Most Common Pairs* Involved in Drug-Drug Interaction Reports Identified as Therapeutic Duplications, as Reported to the Pennsylvania Patient Safety Authority, April 2009 through March 2016 (n = 181)



* These drug pairs consist of anticoagulants, a class of high-alert medications.

note warning when Lovenox was entered into the pharmacy computer. Nurses did not clarify order on when to give Lovenox and gave both Lovenox and heparin at the same time. Patient sent to acute care for possible GI [gastrointestinal] bleed.

Patient presented in hypertensive emergency and was started on IV furosemide, IV nitroglycerin, and IV nicardipine. The next day, the patient was being transitioned back to his home oral medication regimen. The patient was given some of his home medications while the nicardipine was still running and he became severely hypotensive requiring cardiovascular support. He was discharged home a week later with no further complications.

Upon admission to the hospital the home medication list was obtained and verified with the patient. The patient stated that he was taking captopril 50 mg TID [three times a day] and lisinopril 5 mg daily. The medication reconciliation list was printed and both orders were profiled. The pharmacist did not

catch the therapeutic duplication. Both medications were sent and both were administered. The patients experienced a rise in potassium to greater than 5.0, which sent an alert to pharmacy concerning the ACE [angiotensin-converting enzyme] inhibitors. The pharmacist called the physician and received an order to discontinue the captopril and continue the lisinopril.

Drug Contraindications

Drugs may be contraindicated when the benefit of the combination of a drug and another drug, comorbid condition, or procedure does not outweigh the risk (e.g., aspirin is relatively contraindicated for children with viral infections because it increases the risk of Reye's syndrome). Drug contraindications accounted for 8.1% (n = 66 of 815) of events. Reports involving drug contraindications were categorized by harm score with 68.2% (n = 45 of 66) of the events reaching the patient (harm score C through I). Only 3% (n = 2) were reported as Serious Events with patient harm (harm score E and F; see Figure 2).

Most (56.1%, n = 37 of 66) of these events involved an adult patient, but 42.4% (n = 28) of events involved elderly patients (see Figure 3).

Thirty-three unique patient care areas were associated with drug contraindication events with medical/surgical units (13.6%, n = 9), pharmacy (10.6%, n = 7), and telemetry (10.6%, n = 7) the top cited care areas.

Fifty-six unique medications and 21 unique pairs of medications were cited in reports. The most common medications mentioned in reports included nitroglycerin (12.1%, n = 8 of 66) and enoxaparin (9.1%, n = 6). The most common pairs of medications included nitroglycerin and sildenafil (10.6%, n = 7), methadone with nalbuphine (7.6%, n = 5), and dofetilide with sulfamethoxazole/trimethoprim (4.5%, n = 3).

There was a variety of contraindications to drug therapy, with the most common involving drug-drug contraindications (51.5%, n = 34). Contraindications due to allergies were involved in 15.2% (n = 10 of 66) and contraindications to a therapeutic intervention (e.g., administration of an anticoagulant with an epidural line in place) were involved in 12.1% (n = 8) of the reported events (see Table).

Following are examples of reported drug contraindications that reached patients:

Patient who was pregnant and on methadone for opioid addiction was admitted to rule out sepsis. Nalbuphine ordered by resident, order processed, filled and administered to patient. Directly after the dose was administered, the patient began to exhibit signs of withdrawal (i.e. tachycardia, pain, n/v [nausea and vomiting], cramps). The fetus was also tachycardic. Patient was transferred. Morphine was administered and symptoms abated. Length of stay increased by one day for monitoring.



Table 1. Most Common Drug Contraindications, as Reported to the Pennsylvania Patient Safety Authority, April 2009 through March 2016 (n = 66)

EVENT TYPE	NO. OF REPORTS	%
Drug-drug	34	51.5
Allergy	10	15.2
Therapeutic intervention	8	12.1
Laboratory values	7	10.6
Diagnosis	5	7.6
Test	1	1.5
Procedure	1	1.5

I verified an order to discontinue isosorbide mononitrate extended release 30 mg QAM [every morning]. Upon further profile review, I noticed the patient was also on sildenafil 20 mg PO [by mouth] TID. Isosorbide mononitrate and sildenafil were verified three days earlier. It is unclear whether the pharmacist verifying sildenafil spoke with physician about the contraindication between [sildenafil and] isosorbide mononitrate.

Patient was seen in urology clinic and started on ciprofloxacin and Bactrim™ [sulfamethoxazole and trimethoprim]. Unfortunately, Bactrim is contraindicated with the patient's Tikosyn® [dofetilide] therapy. Patient was doing okay on therapy but was admitted for arrhythmia evaluation which did not reveal anything. Bactrim therapy stopped after consultation with urology. Patient reeducated on drug interactions.

Unfortunately, patient used two pharmacies and the insurance company did not alert the outpatient pharmacy.

DISCUSSION

Information regarding the mechanisms of drug incompatibilities is extensive, but quantitative information on the frequency of occurrence and significance in a clinical setting is limited. In one study, incompatibilities were investigated in a

pediatric intensive care ward showing that 3.4 % of drug combinations were incompatible and thus potentially dangerous.⁶ Tissot et al. found that 26% of incompatibilities in an ICU were life threatening.⁷ Another study collected 78 different medication regimens and found 15% with incompatibility reactions.⁸

It is important to understand that there are many instances when two or more medications have to be given concurrently, but that does not mean that they are compatible with each other. For example, the Institute for Safe Medication Practices (ISMP) reported that a pharmacist who was asked whether reteplase injection could be infused with heparin consulted the product package insert, which stated that heparin frequently has been given concomitantly with reteplase.⁹ Thus, the patient received both drugs through the same IV line. Unfortunately, the pharmacist missed a sentence that appeared four lines above the information he had read that indicated heparin and reteplase are incompatible when combined in solution and should not be administered together through the same IV line. (Together, the drugs react to form a mass of solid or semi-solid material, which can stop the infusion. Heparin and reteplase can be given simultaneously but never mixed within the same container.)

Kanji et al. performed a systematic review to qualify and quantify the physical and

chemical stability data published for commonly used continuously infused medications in ICU.¹⁰ The authors found 93 studies; 86 (92%) studies evaluated physical compatibility and 35 (38%) studies evaluated chemical compatibility of at least one drug combination of interest. Physical and/or chemical compatibility data existed for only 441 (54%) of the possible 820 two-drug combinations, whereas chemical compatibility data existed for only 75 (9%) of the possible combinations. Of the 441 combinations for which compatibility data were available, 67 (15%) represented incompatible combinations and 39 (9%) had conflicting information, with both compatible and incompatible data identified. The authors concluded that physical compatibility studies are lacking for commonly used medications in ICU patients and may contribute to unsafe medication practices. This is important because patients who are critically ill may require multiple IV medications administered by continuous infusion. Obtaining separate venous access sites for each drug infusion would be ideal, but in actuality, the number of drug infusions often surpasses the available access sites.

While many new drugs are approved by the U.S. Food and Drug Administration (FDA) each year, research involving incompatibilities has decreased. In 1991 and 1992, there were 245 newly published clinical pharmaceuticals research articles incorporated into the seventh edition of Trissel's *Handbook on Injectable Drugs*.¹¹ Most of the studies came from U.S. researchers in academia, pharmacy practice, and pharmacy students performing laboratory-based research. Twenty years later, Trissel noted that the 17th edition of the *Handbook on Injectable Drugs* incorporated fewer than 45 new research articles, most from foreign researchers. In other words, over a twenty-year span, new research studies of drug compatibility and stability have declined more than 80%.

The use of electronic order entry systems with clinical decision support are among the most promising strategies for detecting and possibly preventing medication errors, including drug-drug interactions. However, they have not yet been tested with respect to preventing incompatibilities.^{12,13} To render a meaningful alert, electronic decision support systems would require, in addition to the drug name, dose, and so on, input on the number of available IV lines and the drugs currently being delivered into a given lumen.¹⁴ This type of information is not routinely available in ICU patient records, much less in a structured format that would enable electronic screening.

DDIs that reach the patient can largely be considered preventable. One study reports that 9% of medication-related errors are likely due to DDIs.¹⁵ In a study that assessed the prevalence of 25 clinically important DDIs in the ambulatory care clinics of the Department of Veterans Affairs, the authors found an overall rate of 2.15% for potential DDIs.¹⁶ Case exposure rates were greatest for patients receiving selective serotonin reuptake inhibitors (SSRIs) and monoamine oxidase inhibitors (MAOIs), ganciclovir and zidovudine, anticoagulants and thyroid hormones, and warfarin and nonsteroidal anti-inflammatory drugs. With new drugs coming on the market each year, the potential for DDIs to take place will only increase. In fact, more than a decade ago, Hansten noted that more than 15,000 articles related to DDIs had been published.¹⁷

Much has been written about the use of an alerting mechanism to make prescribers and pharmacists aware of the potential for a DDI, therapeutic duplication, or contraindication while also acknowledging concerns for alert fatigue. Although alerts may be overused, relying on practitioner diligence to catch drug interactions can be unreliable, especially when there are many drugs approved by the FDA each year. Studies have shown that pharmacists and soon-to-graduate pharmacy students

identified only 66% and 68% of the potential interactions.^{18,19} Weideman et al. noted that none of the pharmacists were able to detect all potential interactions in a profile containing 8 or 16 drugs.¹⁹ This reinforces the notion that a variety of risk reduction strategies targeting system-based causes of error, rather than relying solely on human performance, is required to intercept drug interaction and other medication errors.

The most common pair of medications involved in DDIs reported to the Authority was IV contrast and metFORMIN. The most significant adverse effect of metFORMIN therapy is the potential for the development of metFORMIN-associated lactic acidosis, particularly in susceptible patients. Because metFORMIN is excreted by the kidneys, any patient with existing renal insufficiencies are more prone to these effects. Iodinated contrast agents are also eliminated by the kidneys, thus the combination of both products could be a concern. Originally, when metFORMIN was introduced to the market, the risk of acute kidney injury and metFORMIN-associated lactic acidosis led to recommendation for facilities to establish a process to “hold” metFORMIN before or after IV contrast was administered to all patients. However, both FDA and the American College of Radiology (ACR) have updated recommendations that restrict the need to discontinue metFORMIN to only certain patient populations^{20,21} (see “Concomitant Use of metFORMIN and IV Iodinated Contrast”).

Limitations

In-depth analysis by the Authority of Serious Events resulting from medication prescribing errors is limited by the information reported through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete. Information about underlying patient conditions, which may have impacted events, was not consistently

available. Information regarding the adoption and use of computerized prescriber order entry systems and clinical decision support by the reporting facilities was also unavailable.

RISK REDUCTION STRATEGIES

The occurrence and perpetuation of drug interactions involve many stages in the medication use process. This starts with identifying possible interacting drugs when obtaining a medication list during the medication reconciliation process upon patients’ admission to a facility. It includes reviewing the medication profile, prescribing medications, and pharmacy review of ordered medications. The medication use process also involves communicating to resolve clinically significant drug combinations and communicating relevant interactions to prescribers or nursing (e.g., to possibly alter the timing of administration of one of the offending drugs). It extends to monitoring patients for the possible adverse effects. Finally, it requires educating patients upon discharge.

Efforts to prevent harm from these types of drug interactions can be focused on either reducing the occurrence of potential interactions before they happen or mitigating the risk of adverse outcomes associated with interactions that reach the patient. The following strategies may be useful to healthcare facilities seeking to reduce drug interaction events.

Drug Incompatibilities

- Ensure drug information resources are available and up to date for prescribers, pharmacy, and nursing staff to assess for potential incompatibilities.
- When determining the compatibility between two drugs, it is important to also evaluate the type of tubing being used for IV administration or whether the drugs might be combined into one syringe. For



example, when a drug is incompatible with other intravenous medications, tubing used for administration sets should not have a Y connector for flushing the line or piggyback drug administration.²²

- If incompatible drugs must be given sequentially through the same line, flush the line adequately with saline or other compatible solution between the drugs.⁹
- Standardize the concentration and diluent of continuously administered IV drugs. In an attempt to minimize the risk of incompatibilities in an anesthesia ICU, the authors of one study built upon their drug standardization process and grouped the drugs according to pH, medical indication, and chemical structure.²³ The ICU staff decided to use multi-lumen central venous catheters, and each group of drugs was assigned to one lumen. Only drugs that belonged to the same group were infused simultaneously through the same lumen; therefore, intragroup incompatibilities were excluded

before establishing a new drug administration plan at the ICU. In that study, the visual compatibility of 115 clinically reasonable intragroup drug mixtures was investigated. All drug combinations were compatible for six hours except mixtures containing thiopental, which was reassigned to a single-line use.

- The use of in-line filters can reduce the risk of precipitates or particles, which result from incompatibilities, entering the body. As a consequence, the filter may become blocked if precipitation occurs. A blocked filter should signal the need to investigate the situation and check the medications ordered to eliminate any incompatibility.²⁴

Drug-Drug Interaction, Therapeutic Duplication, and Contraindication

- Avoid the combination of interacting medications when possible. However, some combinations of drug may be clinically necessary even with the

potential for unfavorable outcomes associated with their combined use.

- Explore the possibility of adjusting the dose of the object drug (i.e., the drug that is altered by the interaction) to decrease the risks from the drug interaction if concomitant use of the drugs is necessary.²⁵
- Space dosing times of drugs to avoid an interaction.²⁵ For example, some drug interactions involve drugs binding in the GI tract. These types of interactions can be avoided if the interacting drug is administered at least two hours before or four hours after the other drug. This allows the interacting drug to be absorbed before the second drug is introduced.
- Refine and improve drug-interaction alerts. When practitioners become accustomed to clinically unimportant or irrelevant warnings, they often ignore or bypass these “false alarms.”²⁶ There are strategies that can help optimize the effectiveness of alerts.

CONCOMITANT USE OF METFORMIN AND IV IODINATED CONTRAST

In the past, guidelines and drug labelling called for doses of metFORMIN to be held before patients receive any type of iodinated contrast media. The reason cited for this was an increased risk of acute kidney injury (AKI) and lactic acidosis. However, no cases of lactic acidosis have been reported after intravenous (IV) iodinated contrast medium in patients without a contraindication to metFORMIN therapy (e.g., patients with normal renal function). Upon review of recent studies and current evidence, the U.S. Food and Drug Administration (FDA) and the American College of Radiology (ACR) have updated guidelines for concurrent use of metFORMIN and iodinated contrast media. In April 2016, FDA revised the labelling requirements for metFORMIN products to include recommendations to discontinue use of metFORMIN prior to administering IV iodinated contrast to patients with estimated glomerular filtration rate (eGFR) between 30 and 60 mL/min/1.73m² or with a history of liver disease, alcoholism, or heart failure.¹ (Normal levels for eGFR are from 90 to 120 mL/min/1.73 m².) Then, in May 2016, ACR updated its guidelines, stating there is no need to discontinue metFORMIN prior to IV iodinated contrast in patients with no signs of AKI with eGFR greater than 30 mL/min/1.73m².² It is still recommended to discontinue metFORMIN if a patient is to receive intra-arterial iodinated contrast.^{1,2} Please see both the FDA and ACR updates for complete guidance and recommendations.

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- Use a tiered system for interactive warnings to allow staff to view and easily bypass less serious issues if appropriate, but require staff to make a text entry to describe the rationale for overriding significant alerts.²⁶ To further enhance the effectiveness of this tiered system, work to reduce the frequency of warnings that are not clinically significant to users.²⁷ Engage frontline staff who repeatedly encounter clinical warnings in this effort, because they can help identify alerts that are not clinically significant.
- Once insignificant warnings have been reduced, organizations may want to display the highest-level alerts (e.g., contraindications, severe DDI) and lower-level alerts (e.g., warnings, precautions) for pharmacists, but display only the highest level for prescribers.²⁷
- Create and regularly update a list of significant alerts that require direct prescriber notification. The use of such a list can help guide appropriate communication of and response to a significant alert.²⁶
- Ask prescribers and pharmacists who enter orders to note warnings that they feel are not clinically significant.²⁶ Then, evaluate the severity level of these less significant warnings and adjust as necessary to minimize potential for overlooking more clinically significant warnings.
- Many systems can provide reports about all warnings that have been overridden.²⁶ Assign a clinician or manager to review the report daily to identify any problems. Consider focusing on a small number of common but critically important warnings to monitor the effectiveness of the computer's alert system.
- Work with the drug information vendor to build or modify the severity of alerts necessary to warn practitioners about possible serious or fatal adverse events, especially those for certain conditions (e.g., drugs that prolong the cardiac QT interval).²⁷ Keep in mind that the time to build custom alerts varies depending on the technology in use and expertise of staff.
- Establish a system to gather and document all comorbid conditions in a structured diagnosis or problem list field in the electronic health record (EHR).²⁷ Link this information to the prescriber and pharmacy order entry systems to promote clinical screening when new drugs are prescribed, to detect potential contraindications to those drugs.
- Monitor patients for early detection of possible interactions and adverse effects.²⁵ When it is necessary to administer a pair of drugs that interact with one another, the interaction might be managed through close laboratory or clinical monitoring. If evidence that an interaction is occurring, healthcare practitioners will be able make appropriate dosage changes or even discontinue the drug(s) if necessary.
- Use the *Computerized Prescriber Order Entry (CPOE) System Evaluation Toolkit*, available at <http://patientsafetyauthority.org/educationaltools/patientsafetytools/prescribing/Pages/home.aspx>, to test the CPOE system to see if potentially harmful drug-drug interactions or drug contraindications are detected.
- Notify prescribers and pharmacists of any changes (e.g., types of alerts not available or turned off) made to the alerting system in the order entry systems.²⁷
- Although technology can help improve patient outcomes, educate and then remind staff to avoid total reliance on any technology involved in the medication-use process and that it should be one part of a well-integrated set of safety strategies.²⁷
- Establish a process to educate staff on new and potentially serious drug interactions identified in the literature or by FDA.

CONCLUSION

Review of events submitted to the Authority shows that the medication use processes associated with the occurrence of drug interactions needs to be assessed and improved. Interactions may pose a significant risk to patients' health. Effective identification and preventive strategies need to include all stages of the medication use process to prevent harm to patients from the administration of multiple medications.

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LEARNING OBJECTIVES

- Identify the most common types of drug interactions, as reported to the Pennsylvania Patient Safety Authority.
- Identify the most common drug pairs involved in drug interactions, as reported to the Authority.
- Identify the mechanisms and potential outcomes for drug interactions.
- Assess risk reduction strategies that can be implemented to help prevent drug interactions.

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.

1. Which of the following type of drug interaction was most frequently reported to the Authority as a Serious Event?
 - a. Drug-drug interactions
 - b. Drug incompatibilities
 - c. Therapeutic duplications
 - d. Drug contraindications
 - e. Drug-food interactions
2. Which of the following drug pairs involved in drug incompatibilities was the most commonly reported?
 - a. Heparin and vancomycin
 - b. Ciprofloxacin and IV fluids with electrolytes
 - c. CefTRIAxone and lactated Ringer's solution
 - d. Heparin and amiodarone
 - e. Pantoprazole and IV fluids
3. Which of the following drug pairs involved in therapeutic duplications was the most commonly reported?
 - a. Heparin and dabigatran
 - b. Heparin and rivaroxaban
 - c. Enoxaparin and rivaroxaban
 - d. Heparin and enoxaparin
 - e. Heparin and apixaban
4. Which of the following statements about drug interactions is FALSE?
 - a. Drug interactions may occur inside (drug-drug interactions) or outside (drug incompatibilities) the body.
 - b. Drug-drug interactions may result from pharmacokinetic interactions or from interactions at drug receptors.
 - c. A drug incompatibility occurs when two or more injectable drugs are mixed and the stability or structure of the drugs is altered by physical or chemical reactions.
 - d. The pharmacological effect of a drug interaction of one or both drugs may be increased or decreased, but rarely results in an adverse effect.
 - e. Physical changes from drug incompatibilities may lead to precipitate formation that can cause catheter occlusion and embolism and can contribute to a range of adverse drug events (ADEs), from thrombophlebitis to multi-organ failure.
5. Which of the following statements about the use of metFORMIN and IV contrast is FALSE?
 - a. The most common pair of medications involved in drug-drug interactions reported to the Authority was IV contrast and metFORMIN.
 - b. The most significant adverse effect of metFORMIN therapy is the potential for developing metFORMIN-associated lactic acidosis, particularly in susceptible patients.

(continued on page 148)



(continued from page 147)

- c. Because metFORMIN is excreted by the kidneys, patients with existing renal insufficiencies are more prone to adverse effects.
- d. According to the U.S. Food and Drug Administration (FDA) and American College of Radiology (ACR), facilities should establish a process to “hold” metFORMIN before or after IV contrast is administered to all patients.

Question 6 refers to the following case:

A patient had an order for one liter of sodium chloride 0.9% to be given, as well as an order for oxaliplatin. The sodium chloride was run at a Y-site connection that was closest to the patient for the last hour of the infusion. After the infusion was completed, the patient was transferred to radiation therapy, where she developed rigors. The patient was treated with diphenhydramine and famotidine for a likely incompatibility reaction with the sodium chloride.

6. Which of the following risk reduction strategies would NOT help prevent this drug incompatibility?
 - a. Ensure drug information resources are available and up to date for prescribers, pharmacy, and nursing staff to assess for potential incompatibilities.
 - b. If incompatible drugs must be given sequentially through the same line, flush the line adequately with saline or other compatible solution after both drugs have been infused.
 - c. When determining the compatibility between two drugs, evaluate the type of tubing being used for IV administration or whether the drugs might be combined into one syringe.
 - d. Use in-line filters to reduce the risk of precipitates or particles, which result from incompatibilities, entering the body.

Question 7 refers to the following case:

An order was received in the pharmacy for a patient for amiodarone 400 mg twice a day. This patient had previously received an order for fluconazole 100 mg daily and warfarin 5 mg daily by different physicians. The computer system generated two interaction warnings involving amiodarone, one for warfarin, and a second warning for fluconazole. The orders were allowed to become active, and the pharmacist did not enter any clinical interventions indicating that the physician was questioned on either one. After discharge, the patient attempted to get prescriptions for amiodarone and fluconazole filled at a retail pharmacy and was notified of interaction.

7. Which of the following risk-reduction strategies would NOT help prevent this drug interaction?
 - a. Avoid the combination of interacting medications when possible.
 - b. Explore the possibility of adjusting the dose of the object drug (i.e., the drug that is altered by the interaction) to decrease the risks from the drug interaction if concomitant use of the drugs is necessary.
 - c. Space dosing times of drugs to avoid an interaction to allow the interacting drug to be absorbed before the second drug is introduced.
 - d. Use a system for interactive warnings to allow staff to view and easily bypass significant alerts.



Participating in a National Project, Pennsylvania Nursing Homes Reduce CAUTIs

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ABSTRACT

Urinary tract infection is one of the most common healthcare-associated infections (HAIs) in long-term care residents, and residents with indwelling urinary catheters are at increased risk. Pennsylvania facilities reported 1,079 catheter-associated urinary tract infections (CAUTIs) in 2015. CAUTI places long-term care residents at risk for sepsis and hospitalization, and the use of antibiotics to treat CAUTI can lead to the growth of drug-resistant organisms. Bacteria can enter the urinary system through external or internal surfaces of a urinary catheter. The Pennsylvania Patient Safety Authority participated in the Agency for Healthcare Research and Quality (AHRQ) Safety Program for Long-Term Care: HAIs/CAUTI project to promote safety by reducing the incidence of CAUTI. The project used evidence-based practices to prevent CAUTI and provided methods for facilities to sustain and enhance safety. Despite an insignificant reduction in catheter utilization, the use of process improvement tools and educational offerings in the project was associated with an encouraging reduction in CAUTI at participating Pennsylvania facilities. These facilities were invited to participate in a survey to assess the success of the project and the value of the process improvement tools provided. (Pa Patient Saf Advis 2016 Dec;13[4]:149-153.)

INTRODUCTION

Annually in the United States, between 1 million and 3 million healthcare-associated infections (HAIs) occur in long-term care (LTC) residents, with urinary tract infections being one of the most common.^{1,2} In 2015, Pennsylvania LTC facilities reported 1,079 catheter-associated urinary tract infections (CAUTIs) to the Pennsylvania Patient Safety Reporting System (PA-PSRS).³ Residents who develop a CAUTI are at risk of developing sepsis and requiring hospitalization.^{1,3} In addition to improving care for individual residents, reducing CAUTI in LTC also helps reduce antibiotic use that can lead to the development of drug-resistant organisms.^{1,2,4,5}

Many factors contribute to the development of a urinary tract infection (UTI), such as advanced age, female gender, or anatomic or medical conditions causing urinary obstruction.^{3,4} Healthcare-acquired UTIs are frequently associated with the use of an indwelling urinary catheter; CAUTIs are associated with indwelling urinary catheters inserted through the urethra. (Infections that may be associated with suprapubic catheters or straight catheters for intermittent catheterization are not defined as CAUTIs.) Insertion technique, duration of catheter use, catheter care, and resident susceptibility influence the risk of developing a CAUTI.^{4,5} Bacteria can enter the urinary tract through the external or internal surfaces of the catheter. External entry can occur from contamination caused by poor aseptic technique during insertion, colonization of the external surface through creation of a biofilm, or from capillary action.⁴ Internal entry can occur from urine reflux into the bladder from the drainage bag; failure to maintain a closed, sterile drainage system; or damage to the bladder mucosa, which facilitates biofilm formation.^{5,8}

The Pennsylvania Patient Safety Authority participated in a national project led by the Health Research & Educational Trust (HRET), an affiliate of the American Hospital Association, and funded by the Agency for Healthcare Research and Quality (AHRQ). It was called the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI. Pennsylvania was part of HRET's Cohort 2, which ran from November 2014 through December 2015 and consisted of nine states. The Authority was the organizational lead for participants in Pennsylvania and was responsible for identifying and recruiting facilities to participate in the project. Further, the Authority worked with the facilities to form teams and set individual CAUTI reduction goals, monitored facility involvement in educational offerings and data submission, and analyzed submitted data. As an organizational lead, the Authority was tasked with enrolling at least 15 facilities in the project, which was offered to all LTC facilities in Pennsylvania. To assist with recruitment, Authority analysts queried PA-PSRS for reports of events that occurred from April 1, 2014, through May 31, 2014, to obtain LTC CAUTI rates. Fifteen Pennsylvania facilities completed the project.

Goals of the Project

HRET goals were as follows:

- Develop and adapt evidence-based CAUTI elimination and safety practices for LTC facilities
- Reduce CAUTI rates
- Improve safety culture through improved teamwork and communication

Additional Authority goals were as follows:

- Increase implementation of evidence-based CAUTI-prevention process measures



- Increase collaboration among individual LTC facilities and between facilities and the Authority
- Work with individual facilities to develop facility-based CAUTI reduction goals

The project had data requirements and time commitments. The facilities were encouraged to convene a process improvement team to work on the project. Each facility administrator signed a commitment letter of participation, acknowledging that the facility would comply with the requirements of the project, including the following:

- At least one team member attends the five onboarding webinars, four training modules, and the monthly content and coaching calls
- At least one team member attends the three in-person learning sessions
- Data collection and submission requirements are complied with
- Monthly team safety meetings are held to review CAUTI outcome, process, teamwork, and communication data
- Project improvement tools are learned and implemented

At the end of the project, 10 of the 15 facilities completed an online survey to measure the effectiveness of the project activities. Survey results are presented in the companion *Pennsylvania Patient Safety Advisory* article, “Evaluating the Effect of Infection Control Practices on Reducing CAUTIs in Pennsylvania Long-Term Care Facilities.”

METHODS

The CAUTI project used several methods to engage the participants and improve practice, including on-site visits, coaching support, educational sessions, and process improvement tools.

On-site Visits

Authority infection prevention analysts visited each of the participating facilities

in March and April 2015 to meet with the CAUTI teams. All staff at the participating facilities were given the opportunity to complete the Culture of Safety survey. The survey assesses staff perception of resident safety in the facility. Educational materials and process improvement tools were given to the teams along with encouragement and support. Data reports and the facility Culture of Safety survey results were reviewed with each team. The facilities were taught how to use their Culture of Safety survey results to develop action plans to address their own identified issues and how to use the skills assessments to identify areas of need of education resources. The visits allowed Authority analysts to work directly with the facility team to answer questions and provide education and support.

Coaching Calls

Coaching support was provided to all participating facilities through monthly coaching calls, monthly newsletters, and individual communication via telephone and email. Facilities were encouraged to participate in the monthly calls. The coaching calls reviewed current Pennsylvania project facility data, highlighted facility successes, and provided education on identified areas of need such as antibiotic stewardship or the correct application of infection criteria. The monthly newsletter provided information on upcoming educational webinars, reviewed data-entry requirements and deadlines, and highlighted facility successes.

Educational Sessions

In-person learning sessions were held in August 2014, April 2015, and October 2015. The goals of the sessions were to facilitate collaboration among the facilities and to provide education on basic infection prevention, antibiotic stewardship, and the use of the process improvement tools. Facilities identified as having engaged teams or who had implemented effective processes during the on-site visits

were invited to share their stories with the other participants.

Process Improvement Tools

Process improvement tools were provided to the participating facilities along with training on how to use them in their facilities. The process improvement tools provided were the Culture of Safety survey, Skill questionnaires for licensed and unlicensed staff, the Team Communication Guide, Learn from Defects tool, T.E.A.M.S mnemonic infographic, and C.A.U.T.I. mnemonic infographic.⁹

Culture of Safety survey. This survey assessed staff perception of the following:

- Overall perceptions on resident safety
- Feedback and communication about Incidents
- Supervisor/manager expectation and actions promoting resident safety
- Organizational learning
- Management support for resident safety
- Training and skills
- Compliance with procedures
- Teamwork
- Handoffs
- Communication openness
- Nonpunitive response to mistakes
- Staffing

All staff were provided the opportunity to complete the survey. The anonymous survey was administered early in the project and again at its end. The survey assesses and measures conditions that can lead to resident harm, identifies strengths and areas for improvement, and raises staff awareness of the importance of resident safety. The two main areas the survey strives to assess are the staff perception of resident safety in the facility and whether they would recommend the facility to friends as a safe home for their family.

Skill questionnaires. The skills questionnaires for licensed staff and certified nursing assistants were given early in the

project and again at its end. They do the following:

- Assess staff knowledge of the principles of CAUTI prevention (the staff education on CAUTI-prevention principles was provided in the onboarding webinar)
- Identify areas of need, to target educational needs
- Assess the effectiveness of the provided education

Team Communication Guide. The guide is a three-section tool that evaluates facility progress in instituting the T.E.A.M.S. intervention and CAUTI reduction strategies and in overcoming barriers to team progress. It is used as follows:

- Provides quarterly assessment
- Measures process improvement
- Evaluates compliance with best practice process measures
- Identifies opportunities for improvement
- Assists in directing educational resources

Learn from Defects. This tool identifies the factors that contribute to a safety event or situation. It is used as follows:

- Helps review a safety event or situation that the facility does not want to happen again
- Helps plan the next steps to be taken to prevent the event from happening again
- Identifies ways to learn from the event

C.A.U.T.I. intervention. The C.A.U.T.I. mnemonic provides evidenced-based interventions to reduce CAUTI. It focuses on reducing unnecessary catheter use and using best practices for catheter insertion and maintenance care. The mnemonic components include five prevention and control strategies: Catheter removal, Aseptic insertion, Use regular assessments, Training for catheter care, and Incontinence care planning.

Information on the prevention and control measures is presented in the companion

Advisory article, “Evaluating the Effect of Infection Control Practices on Reducing CAUTIs in Pennsylvania Long-Term Care Facilities.”

T.E.A.M.S intervention. The T.E.A.M.S. mnemonic provides specific interventions to promote a culture of safety. The mnemonic includes five team- and culture-building strategies: Team formation, Excellent communication, Assessment of what’s working, Meeting monthly, and Sustaining efforts.

Data Collection

Facilities submitted into an online collaborative database (CDS) the number of CAUTIs, the number of urinary catheter devices, and the number of resident days monthly, from November 2014 through October 2015. This data was collated by staff at HRET and entered into the CDS. The participating facilities could access their own facility’s reports and the Pennsylvania aggregate data on safety culture, CAUTI rates, and device use rates. HRET provided the information on slides to be used within the facility. The facilities were encouraged to share this information with administration, staff, the facility medical director, and medical staff and to review the information at the Quality Assurance Process Improvement (QAPI) meetings.

RESULTS

On-Site Visits

All of the participating facilities were visited by the Authority infection prevention analysts.

Coaching Support

A total of 11 monthly coaching calls were held. Calls were not held the months of the in-person sessions. Participation in the calls decreased over the course of the project: The first coaching call had 80% facility participation and the last coaching call had 27% facility participation.

Educational Sessions

Of the 15 facilities, 12 (80%) participated in the first in-person learning session, 10 (67%) participated in the second session, and 6 (40%) participated in the final session.

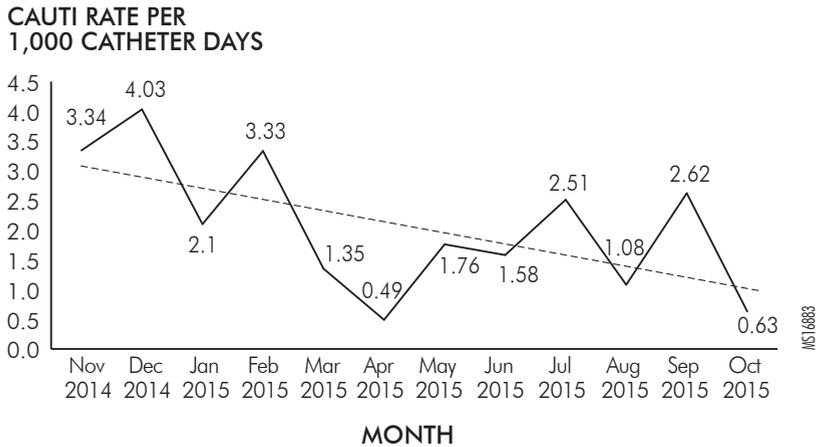
Process Improvement Findings

- Seventy-nine percent of staff (2,268 of 2,863) completed the initial Culture of Safety survey: The areas identified as opportunities for improvement were nonpunitive responses to mistakes, improving staffing levels, and enhancing communication openness. Ninety percent of the surveyed staff believe their facility is safe for residents and 96% would recommend their facility to friends as a safe place for family members.
- Skills questionnaires: Comparing the second skills questionnaire to the initial results showed an increase in staff knowledge of team building, CAUTI definitions, resident safety culture, hand hygiene, antibiotic stewardship, and epidemiology, surveillance, and reporting. Staff knowledge of antibiotic stewardship had the greatest increase, from 65% to 78%. Decreases were noted in staff knowledge of equipment and environmental training, standard and transmission-based precautions, and case studies to identify CAUTI.
- Team Communication Guide: The barriers identified by the guide concerned lack of administrative involvement. Some facilities documented few meetings between the administrative champion and the CAUTI team or low participation in safety rounds.

CAUTI Rate

For the 12-month period, the 15 participating Pennsylvania facilities reported a significant reduction (54%) in CAUTIs and a modest reduction (3%) in catheter use. See Figures 1 and 2.

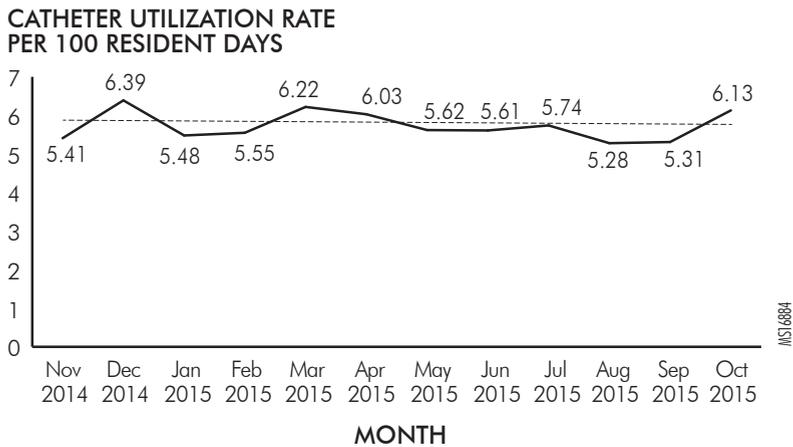
Figure 1. CAUTI Rate of Participating Pennsylvania Nursing Homes



Source: CAUTI events reported by participating facilities to the Health Research & Educational Trust Comprehensive Data System from November 1, 2014, through October 31, 2015.

CAUTI, Catheter-associated urinary tract infection.

Figure 2. Catheter-Use Rate of Participating Pennsylvania Nursing Homes



Source: Catheter device use data reported by participating facilities to the Health Research & Educational Trust Comprehensive Data System from November 1, 2014, through October 31, 2015.

DISCUSSION

The project was successful in reducing CAUTI rates in the participating facilities despite minimal reduction in catheter use. The small reduction in catheter use can be attributed to the resident population at some of the facilities enrolled in the project who required chronic indwelling catheters, such as residents with spinal cord injuries or other physiological issues resulting in neurogenic bladders, without volitional bladder control. Indications for an indwelling catheter include acute urinary retention or bladder outlet obstruction, sacral or perineal wound healing in incontinent patients, and end-of-life care. When catheters cannot be removed, it is important to follow best practices for catheter care and maintenance. Project results suggest that improved catheter maintenance awareness and technical skills may result in decreased incidents of CAUTI, even in populations for whom long-term indwelling catheters are indicated. The decrease in staff knowledge of basic infection prevention practices noted on the skills questionnaire could be due to the frequent staff turnover observed in the participating facilities.

The participating facilities increased their knowledge of infection prevention and safety, became more proficient in using screening criteria and data collection, and became more adept at data analysis. The facilities perceived the on-site visits from the infection prevention analysts to be helpful. The project also raised awareness of the Authority by developing relationships between the facilities and the infection prevention analysts.

CONCLUSION

Facilities in this project, which used evidence-based infection prevention practices, data analysis, and caregiver education, decreased the incidence of CAUTI among their residents despite minimal decrease in catheter use. Adopting best

practices for catheter insertion and maintenance are key in reducing CAUTI in residents for whom an indwelling catheter is necessary. The use of process improvement tools can greatly enhance resident care by identifying opportunities for improvement, providing visual reminders

of appropriate care, and improving staff knowledge of infection prevention and control.

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Evaluating the Effect of Infection Control Practices on Reduction of CAUTIs in Pennsylvania Long-Term Care Facilities

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ABSTRACT

The Pennsylvania Patient Safety Authority recruited Pennsylvania long-term care (LTC) facilities to participate in a 14-month national catheter-associated urinary tract infection (CAUTI) collaborative led by the Health Research & Educational Trust, an affiliate of the American Hospital Association, funded by the Agency for Healthcare Research and Quality (AHRQ). High-level project goals were to develop and adapt evidence-based CAUTI elimination and safety practices for LTC facilities, to reduce CAUTI rates, and to improve safety culture through improved teamwork and communication in the LTC setting. In December 2015, 10 of the 15 LTC facilities completing the project participated in an online survey to assess whether the AHRQ tools designed for the national project were useful in meeting project goals. The survey results revealed that the project tools were valuable to the majority of respondents by improving CAUTI identification, process and outcome measurement, CAUTI case root-cause analysis, and CAUTI prevention and control measures. (Pa Patient Saf Advis 2016 Dec;13[4]:154-159.)

INTRODUCTION

In 2015, Pennsylvania long-term care (LTC) facilities reported 1,079 catheter-associated urinary tract infections (CAUTI) through the Pennsylvania Patient Safety Reporting System (PA-PSRS).¹ The Pennsylvania Patient Safety Authority recruited Pennsylvania LTC facilities to participate in a 14-month national CAUTI collaborative led by the Health Research & Educational Trust (HRET), an affiliate of the American Hospital Association, funded by the Agency for Healthcare Research and Quality (AHRQ). The project's goals were to develop and adapt evidence-based CAUTI elimination and safety practices for LTC facilities, to reduce CAUTI rates, and to improve safety culture through improved teamwork and communication in the LTC setting.

The national project team developed tools to help facilities implement prevention and control measures, structure surveillance activities and identification of CAUTI cases, track and measure performance and outcomes, perform a simple root-cause analysis, and provide robust education and support to participant and facility staff and clinicians. At the project's end in December 2015, the 15 participants of the Pennsylvania cohort were encouraged to participate in an online survey to evaluate the impact of specific tools and practices used by individual LTC facilities to implement project tasks.

METHODS

The Authority designed the survey to measure the usefulness and application of practice improvement tools developed by the HRET national project team for the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI. The tools were grouped into five categories: (1) prevention and control measures, (2) process and outcome measurement, (2) root-cause analysis, (4) CAUTI identification, and (5) staff education and support. Survey questions for each practice tool provided two response options. The first response option instructed the respondents to answer "yes" or "no" to specific practice and outcome questions for each of the tools. The second response option instructed the respondents to comment on use of the tools or barriers to implementing the tools or to make any other comments. The survey was sent to the team leaders of each of the 15 facilities that completed the AHRQ safety program. Team leaders functioned in various roles in their facilities and were directors and assistant directors of nursing, infection preventionists, and nurse managers.

RESULTS

Of the 15 LTC facilities that completed the CAUTI project, 11 responded to the survey, and 10 of 11 respondents answered all the questions.

General Responses

All 11 respondents agreed overall use of the program tools increased staff knowledge about infection control, and helped the infection prevention designee's job performance; 10 of 11 respondents agreed that the program tools helped identify specific areas to direct infection-control resources and contributed to a decrease in CAUTI. The respondents' comments included the following:

"The tools were useful visual reminders about all aspects of CAUTI prevention, helpful in staff education, transferrable to myriad other areas, and supplemented corporate tools."

"Staff let me know how much was learned by sharing bits of information along the way on a one-on-one basis, in morning standup meeting, and small groups."

Table. Positive Responses to Yes-No Survey Questions on Use of AHRQ CAUTI Prevention Project Tools

TOOL CATEGORY	PRACTICE TOOL	NUMBER OF RESPONDENTS WHO USED TOOL	PRE-SET SURVEY QUESTIONS SURVEY ASKED USERS TO CHECK "YES" OR "NO" FOR OF THE FOLLOWING QUESTIONS:	USER "YES" RESPONSES
CAUTI identification tools	CAUTI case review form	6 of 11	Did the case review form help your facility identify resident care issues, barriers to care?	5 of 6
			Were the results of the CAUTI case review discussed at Quality Assurance Process Improvement Committee meetings?	5 of 6
			Did the case review result in a change in practice/policy/procedure?	5 of 6
			Were the case review results addressed and shared with clinicians and administrators?	5 of 6
NHSN Definition CAUTI criteria pocket cards	7 of 10	Was the CAUTI criteria tool easily accessible for staff use?	7 of 7	
		Did the CAUTI criteria tool help staff appropriately identify residents with signs/symptoms of a CAUTI?	7 of 7	
		Did the CAUTI criteria tool help educate staff on appropriate/inappropriate urine culture testing	7 of 7	
CAUTI outcome data definitions	7 of 10	Did the tool improve your staff's knowledge about outcome data definitions?	6 of 7	
		Was the outcome data definitions tool easy to understand and apply? Did your staff feel more confident the CAUTI definitions are hardwired into practice?	6 of 7 6 of 7	
Long-term care CAUTI surveillance worksheet	7 of 10	Did the tool make it easy to identify residents that met or did not meet NHSN criteria for a suspected CAUTI?	7 of 7	
Process and outcome measurement tools	Indwelling urinary catheter insertion checklist	8 of 10	Did the indwelling urinary catheter insertion criteria assist your staff to identify residents who did not meet catheter insertion criteria?	8 of 8
			Was the tool used EVERY TIME a new catheter was initiated for a resident?	2 of 8
	Indwelling urinary catheter maintenance checklist	5 of 10	Did you use the indwelling urinary catheter maintenance checklist to standardize indwelling catheter maintenance?	5 of 5
			Was the use of the indwelling urinary catheter maintenance checklist associated with helping decrease CAUTIs?	4 of 5
Has the use of the indwelling urinary catheter maintenance checklist helped educate staff and residents? Has the use of the indwelling urinary catheter maintenance checklist aided in timely catheter removal when applicable?			5 of 5 5 of 5	
Sustainability assessment tool and action plan	5 of 10	Did the sustainability tools help you identify areas of weakness that may impede the future progress of your hard work during this project? Did the sustainability action plan assist you in creating a realistic plan to overcome barriers and continue support and momentum for the project?	5 of 5 4 of 5	
Root-cause analysis tools	Learn From Defects tool	10 of 10	Did the Learn from Defects tool help identify catheter care issues?	10 of 10
			Did the Learn from Defects tool help you understand the systems/processes behind an identified defect?	9 of 10
			Did the Learn from Defects tool lead to a change in practice/policy/procedure?	7 of 10
Staff safety assessment	6 of 10	Has this tool helped identify potential or actual safety issues? Has your facility encouraged staff to use this tool and follow up with concerns?	5 of 6 4 of 6	

Source: These materials, provided on the Agency for Healthcare Research and Quality (AHRQ) Web site, are government works and are in the public domain only in the United States.

Note: Of the 15 long-term care facilities completing the project, 11 responded to the survey, and 10 of 11 answered all the questions.

CAUTI, Catheter-associated urinary tract infection; NHSN, National Healthcare Safety Network.

Prevention and Control Measures

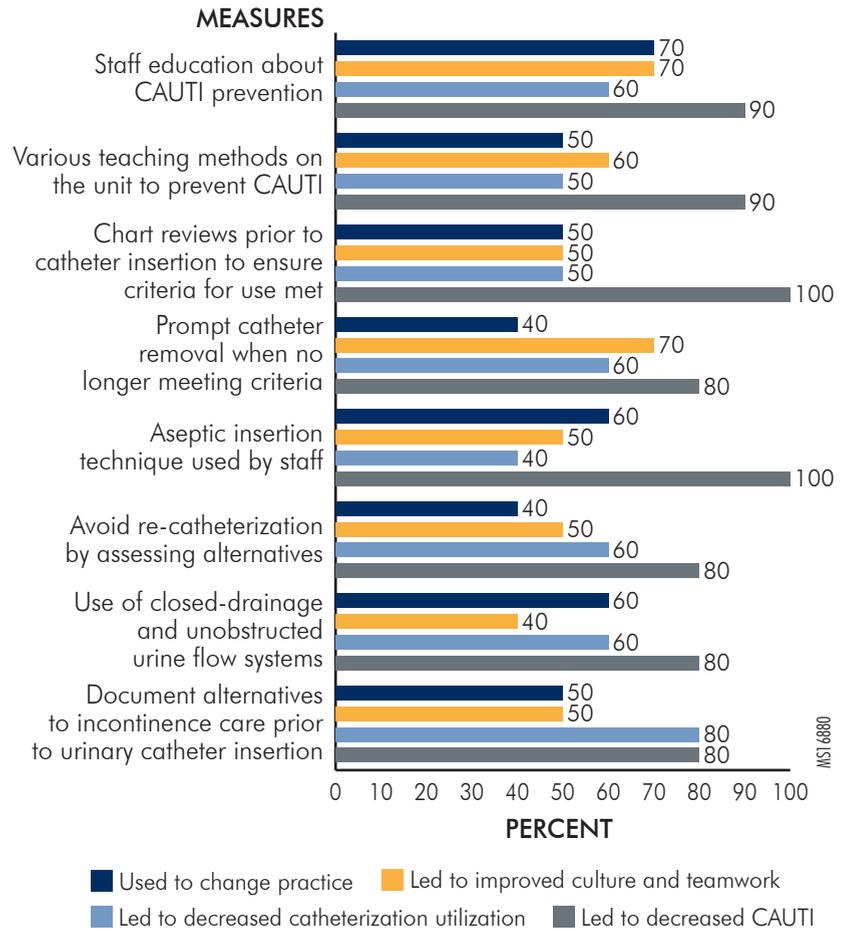
The HRET National Project Team developed colorful mnemonic infographic posters to display and enhance staff recall of multiple CAUTI prevention practices and team building processes.

Figures 1 and 2 summarize responses to four outcome questions aimed at identifying improved systems and outcomes as a result of using eight CAUTI prevention practices and four team building practices listed in the mnemonic infographic posters. The questions asked whether the tools: (1) were used to change practice, (2) led to improved culture and teamwork, (3) led to decreased catheter utilization, and (4) led to decreased CAUTI.

C.A.U.T.I. intervention. All of the 10 survey respondents used the C.A.U.T.I. intervention tool to implement all prevention and control strategies. Survey responses to usefulness of the C.A.U.T.I. intervention show effectiveness of the components in all four outcomes, the most impressive being that 80% to 100% of the respondents who used the C.A.U.T.I. intervention tool said implementing one or more practices in the intervention tool led to a decrease in CAUTI (see Figure 1). The definition of the C.A.U.T.I. and the T.E.A.M.S. mnemonic is listed with figures 1 and 2 and in the companion *Pennsylvania Patient Safety Advisory* article, “Participating in a National Project, Pennsylvania Nursing Homes Reduce CAUTIs.”

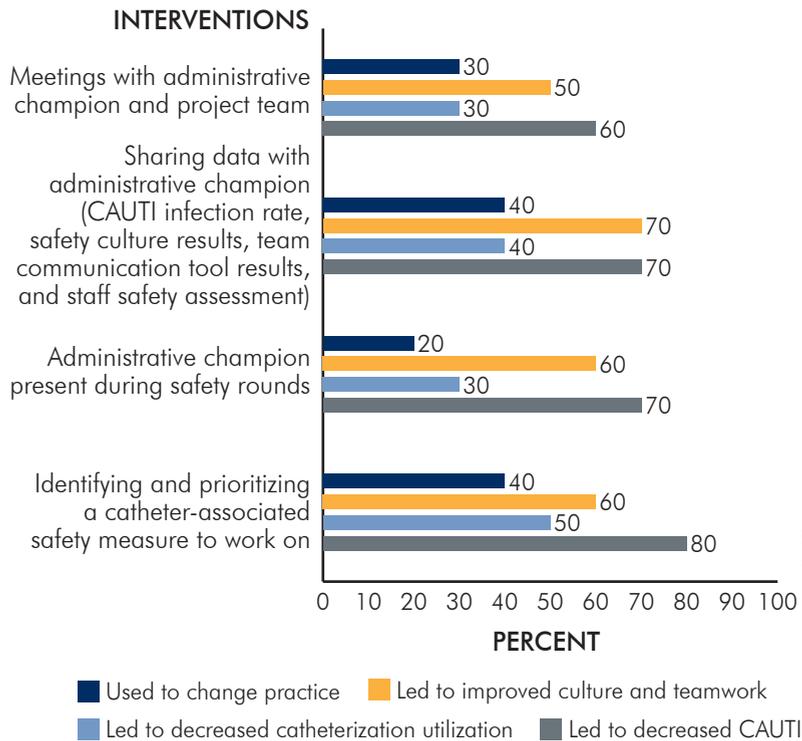
T.E.A.M.S. Intervention. All 10 survey respondents used the T.E.A.M.S. intervention to implement all team and culture building strategies. Although there was some progress, the low improvement responses to the survey questions on implementation of the T.E.A.M.S. intervention demonstrate the struggle the project participants experienced in improving facility-specific culture and teamwork (see Figure 2).

Figure 1. Survey Responses: Effectiveness of CAUTI Prevention and Control Measures



Note: Ten of 10 survey respondents used the C.A.U.T.I. tool and responded to each practice question. The components of the C.A.U.T.I. mnemonic infographic are seven prevention and control interventions (some have subcategories): Catheter removal, Aseptic insertion, Use regular assessments, Training for catheter care, and Incontinence care planning.

Figure 2. Survey Responses: Use of the T.E.A.M.S. Intervention to Improve Teamwork And Culture



Note: Ten of 10 survey respondents used the T.E.A.M.S. tool and responded to each practice question. The T.E.A.M.S. mnemonic infographic includes team and culture building interventions: Team formation, Excellent communication, Assessment of what’s working, Meeting monthly, and Sustaining efforts.

CAUTI Identification

Four project tools were provided to participating LTC facilities to identify CAUTI, review CAUTI events, perform surveillance, and calculate outcome rates (Table).

CAUTI case review form. Six of 11 respondents used the case review; 5 of 6 users indicated it helped identify resident care issues, facilitated sharing case-review results with staff and the Quality Assurance/Process Improvement (QAPI) Committee, resulted in change in practice, and decreased CAUTI.

NHSN definition CAUTI criteria pocket cards. Seven of 10 respondents used pocket cards that list the National

Healthcare Safety Network (NHSN) definitions of CAUTI; all 7 users agreed that the pocket cards helped educate staff on appropriate and inappropriate urine-culture testing and to appropriately identify residents with signs and symptoms of a CAUTI.

CAUTI outcome data definitions. Seven of 10 respondents used the definitions; 6 of 7 users agreed it improved staff knowledge about outcome data definitions and was easy to understand and apply.

Long-Term Care CAUTI Surveillance Worksheet. Seven of 10 respondents used the surveillance worksheet; all 7 users agreed that the surveillance tool

facilitated identification of residents who met the (PA-PSRS) criteria for a suspected CAUTI.

Additional respondents’ comments about usefulness of the CAUTI identification tools included the following:

“[The tools] showed me I was incorrectly defining CAUTI.”

“Good comprehensive guidelines for review of each CAUTI case and was beneficial in completing QI [quality improvement] projects for reducing CAUTI.”

Process and Outcome Measurement

The project participants were introduced to three project tools designed to measure compliance with appropriate, aseptic catheter insertion and maintenance best practices and outcomes and sustainability of program improvements (see Table).

Indwelling urinary catheter insertion checklist. Eight of 10 respondents used the tool; all 8 used it to identify residents who did not meet national guidelines for needing an indwelling urinary catheter, but only 2 of 8 used it for every catheter insertion.

Indwelling urinary catheter maintenance checklist. Five of 10 respondents used the tool; all 5 agreed that the checklist helped standardize indwelling catheter maintenance, educate staff and residents, and aided timely catheter removal when applicable; 4 of 5 users agreed that the tool helped reduce CAUTI.

Sustainability assessment tool and action plan. Five of 10 respondents used the sustainability assessment tool and action plan; all 5 users agreed that the tools identified areas of weakness that may impede the future progress of project work and 4 of 5 users agreed that the tools assisted in creating a realistic plan to overcome barriers and continue support and momentum for the project. Survey respondents’ comments about usefulness of the process and



outcome measuring tools included the following:

“[The tools] helped update policies and develop a facility specific checklist.”

“Managers used the tools to determine if practices were consistent with facility policy.”

“The action plan helped to set goals and evaluate outcomes.”

Root-Cause Analysis

The program provided two tools to the project participants: one to perform a simple root-cause analysis on CAUTI cases and a second to anonymously ask staff whether they believed another person could be harmed from a CAUTI and how to prevent it (see Table).

Learn from Defects tool. All 10 respondents used this tool to help identify catheter care issues; all 10 users agreed the tool helped them identify catheter care issues, 9 agreed it helped them understand the systems or processes behind an identified defect, and 7 agreed that use of the tool led to a change in practice or policy and procedure.

Staff safety assessment. Six of 10 respondents used this tool; 5 users agreed that it helped identify potential or actual safety issues and 4 users encouraged staff to use this tool and follow up with concerns.

Survey respondents’ comments about the usefulness of the root-cause analysis tools included the following:

“The tools helped me concisely communicate the importance of reviewing infections with my staff.”

“A simple method to work on system problems.”

“The information was used in QI projects and safety committee meetings.”

Education and Support

Participating facility teams were offered essential live one-on-one support in the form of coaching calls and on-site visits. Onboarding and educational webinars and live learning and collaborative sessions enhanced the implementation of project goals. Education and support details are discussed in the companion *Advisory* article “Participating in a National Project, Pennsylvania Nursing Homes Reduce CAUTIs.”

On-site visits. All 10 respondents agreed that the authority staff visits to each individual facility improved project participation, supported progress and administrative engagement, and provided personalized assistance. Respondents’ comments about the usefulness of the site visits included the following:

“Personalized review of how we measure up to like facilities.”

“Knowledge sharing with administration to see the importance of the project and to present at board meetings.”

“Was the pep talk needed to get on track and realize positive outcomes.”

Coaching calls. Eight of 10 respondents who participated in monthly coaching calls with the Authority staff described helpful takeaways, as follows:

“Evidenced-based research to support practice changes.”

“Came away with feeling of making progress and the time and effort was well worth it.”

“Helped to stay focused and learn from others’ success.”

Onboarding webinars. Eight of 10 respondents participated with their staff in webinars on team building and CAUTI definitions; 6 of 10 respondents participated in webinars on safety culture and surveillance for CAUTI. One facility commented that the education provided

information on new technology and offered insight and support.

Live learning sessions. Six of 10 respondents attended one or more of the live learning sessions; 4 of 6 attended the first two sessions; 3 of 6 attended the final learning session (lower participation was because the distance to the event was too far for some). Responses to the question about which session was the most helpful and why included the following:

“It was an opportunity to network with like-minded nurses and use the project tools.”

“The information participants provided helped me to see that other facilities encountered challenges and gave me ideas of how to circumvent some of the challenges this facility encountered.”

DISCUSSION

The generally positive responses from the practice survey suggest that project tools and individual support from the Authority staff were beneficial to the participants in CAUTI prevention and team building. The responses to the practice survey demonstrated the value of the unique project tools to: (1) evaluate CAUTI prevention and control practices, (2) identify practice changes instituted as a result of the project, (3) identify CAUTI, (4) monitor outcome and process measures, (5) facilitate root-cause analysis of CAUTI events, and (6) improve team culture.

Several of the tools can improve outcomes in myriad other resident safety areas. For example, the T.E.A.M.S. intervention can be applied to any QAPI project, and root-cause analysis can facilitate investigation and elimination of resident safety problems other than CAUTI.

Participating clinicians and administrative teams became more engaged after the personalized on-site visits. Authority staff worked with each facility on the best methods for applying the interventions

using their available resources and demonstrated the advantages to their investment, including resident safety, regulatory compliance, and fiscal savings.

Barriers

Survey respondents shared challenges to implementing one or more of the project tools including: (1) changes in nursing, infection control, and administrative staff, (2) time required to complete some tools, (3) requirement to use a corporate tool rather than a tool provided by the project, (4) lack of buy-in from colleagues, (5) competing priorities, and (6) new administration or upper-level management failing to follow up on concerns. Barriers to use of the indwelling urinary catheter insertion checklist include staffing and time challenges, unavailability of a reviewer in the room at the time of the procedure to observe technique, and lack of staff training, competency, or approved policies and procedures. Some survey respondents commented that implementing team building practices was compromised because of the inability to develop a CAUTI team or to engage administrators

in safety rounds. Lack of time was cited as a barrier to attending webinars and coaching calls; prohibitive distance was the most frequent barrier to attending live learning sessions. Engagement of the entire facility team was problematic for some participants because of changes in nursing directors and administration's disinterest in the project. The specific barriers listed in the survey comments identify specific areas to direct infection-control resources.

CONCLUSION

Results of the CAUTI prevention practice survey demonstrated that facilities found the project tools valuable to improve CAUTI-prevention systems and practices, improve teamwork, reduce device use, and reduce the rate of CAUTI. The Authority continues to evaluate sustained improvement through review of CAUTI numbers, rates, and device use reported through PA-PSRS, and one-on-one ongoing contacts with participants as needed. Project details are discussed in the companion *Advisory* article "Participating in a National

Project, Pennsylvania Nursing Homes Reduce CAUTIs."

The tools developed for this national program were unavailable to the public during the course of the program. However, AHRQ selected project tools for release to the *AHRQ Safety Program for Long-Term Care* public website after the conclusion of the project in September 2016.² This practice survey demonstrates that respondents shared successes and suggests that implementing a facility-specific, structured CAUTI-prevention program in a supportive collaborative structure using evidence-based practices and standardized tools to improve systems and teamwork can lead to decreased resident harm from CAUTI.

Acknowledgments

Christine Roper, MSN, RN, CPEN, of Children's Hospital of Philadelphia Clinical Documentation Improvement Team, assisted in developing the survey and in presenting data outcomes at the third learning session. Christina M. Hunt, MBA, MSN, RN, HCM, CPPS, Director of Collaborative Programs at the Pennsylvania Patient Safety Authority, and JoAnn Adkins, BSN, RN, CIC, Infection Prevention Analyst at the Pennsylvania Patient Safety Authority, contributed feedback on the survey before its administration.

NOTES

1. Pennsylvania Patient Safety Authority. 2015 Pennsylvania Patient Safety Authority annual report. 2016 Apr 29. 98 p. Also available: http://patientsafetyauthority.org/patientsafetyauthority/documents/annual_report_2015.pdf.
2. AHRQ safety program for long-term care: preventing CAUTI and other HAIs. [internet]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2016 Sep [accessed 2016 Oct 05]. Available: <http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/cauti-ltc/index.html>.

Update on Wrong-Site Surgery: Reports from Ambulatory Surgical Facilities

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From July 2004 through September 2016, 717 wrong-site operating room (OR) surgery events, including wrong-site anesthesia events, were reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) and analyzed by the Pennsylvania Patient Safety Authority.

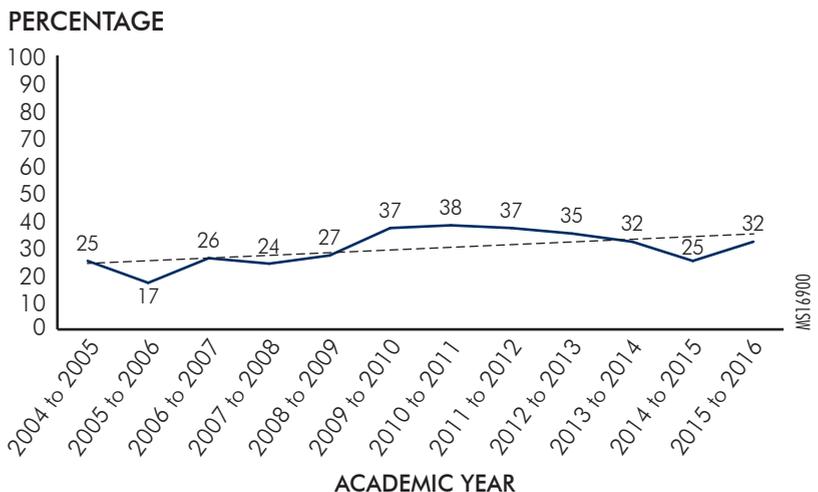
Analysis of wrong-site surgery events reported to the Authority by ambulatory surgical facilities (ASFs) identified an increase in these reported events over time. The average incidence of wrong-site surgery* in Pennsylvania ORs continues to be about one event each week.¹ Analysis of events reveals that ASFs reported about 29% of all wrong-site surgery events between July 2004 through June 2016 (i.e., 203 of 702); an average of one event every three weeks. Figure 1 demonstrates an increase in the percentage of wrong-site events reported from ASFs over the 12-year period. The rising trend is apparent in the most recent seven academic years (i.e., July 2009–2010 year through June 2015–2016) for which the percentage of events increased from 29% to 34.2% (i.e., 129 of 377).

Based on the analysis of wrong-site events reported by ASFs in the most recent seven academic years (N = 129), the most commonly reported events and procedures are noted in Figure 2 and included the following:

- Wrong side (60.5%, n = 78): blocks (by anesthesiologists and surgeons), pain management procedures, and eye procedures
- Wrong site (31.8%, n = 41): excisions and biopsies, pain injections, hand procedures (e.g., incision placement)
- Wrong procedures (7.8%, n = 10): tonsillectomy (e.g., instead of or in addition to adenoidectomy when only adenoidectomy was intended) and hand procedures

* For this analysis, the average number of wrong-site surgery events reported weekly over 12 academic years (i.e., July 2004 through June 2016) was calculated as follows: 702 events ÷ (12 × 52 weeks/year).

Figure 1. Percentage of Wrong-Site Surgery Events Reported by Ambulatory Surgical Facilities by Academic Year



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

(e.g., carpal tunnel surgery instead of trigger finger release)

- Although ASFs and hospitals reported similar types of “wrong” events, there were two notable differences in the events reported from hospitals, which reported: (1) wrong-level spinal procedures were the most commonly reported wrong-site procedure, and (2) the wrong patient received an unintended procedure in about 2% of reported events.

UPDATE ON WRONG-SITE SURGERY

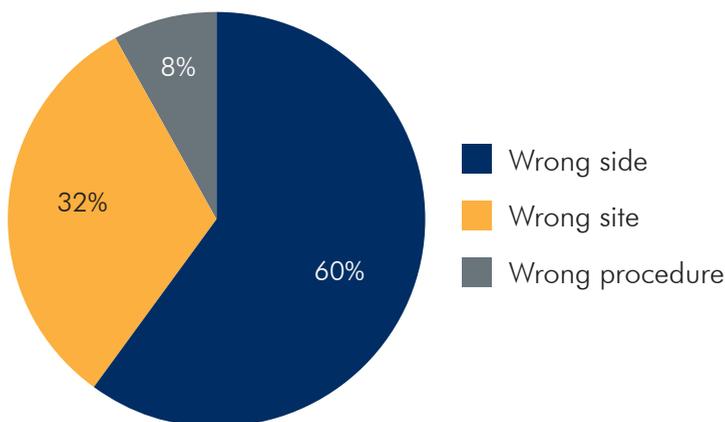
From July 2004 through September 2016, 717 wrong-site operating room (OR) surgery events, including wrong-site anesthesia events, were reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) and analyzed by the Pennsylvania Patient Safety Authority. The three most common types of wrong-site procedures reported through PA-PSRS since July 2004 have remained consistent and account for about 50% of all wrong-site surgery events:

1. Perioperative anesthesia blocks administered by anesthesiologists and surgeons (25.9%, n = 186 of 717)
2. Spinal procedures (e.g., wrong level; 13.0%, n = 93)
3. Pain-management procedures (11.4%, n = 82)

The percentage of wrong-site anesthesia blocks marginally decreased from the last update² in June 2016 (i.e., 26.4%* to 25.9%). However, a broader analysis reveals a 6.5% improvement in the percentage of wrong-site blocks reported over the last eight quarters (i.e., from 27.7% in the second quarter of 2014–2015 to

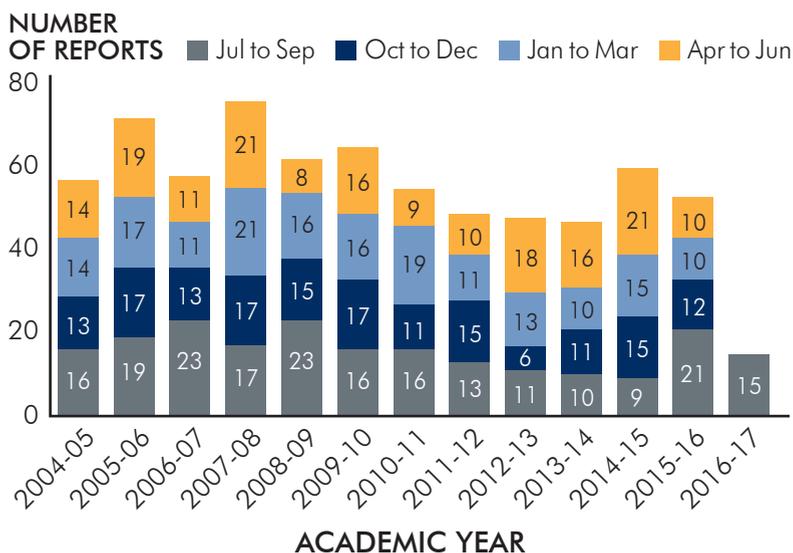
* The percentage of wrong-site anesthesia blocks reported in the June 2016 update (i.e., 26.6%) differs from percentage noted above (i.e., 26.4%) because three additional wrong-site surgery events were reported to the Authority through March 2016 (i.e., 692 instead of 689).

Figure 2. Type of Wrong Surgery Events Reported by Ambulatory Surgical Facilities from July 2009 through June 2016



MS16901

Figure 3. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year



MS16899



25.9% through the first quarter of 2016–2017). Further analysis of these events in the last eight quarters revealed that 40% of wrong-site anesthesia blocks were administered by anesthesiologists and 60% by surgeons. During this two-year time period, the surgeons most commonly involved in wrong-site blocks were hand specialists, ophthalmologists, and orthopedists.

The percentage of wrong-site surgeries related to wrong-level spinal procedures and wrong-site pain-management procedures were essentially unchanged from the June update. Since July 2004, the majority of wrong-level spinal procedures were performed at the lumbar level (53%, n = 49 of 93), followed by the cervical level (27%, n = 25), and thoracic level (16%, n = 15). The spinal level was not specified in 4% (n = 4) of the reported events.

Twenty-five wrong-site surgery events were reported from Pennsylvania facilities since the last published analysis in June. One of the most common types of event reported was a spinal procedure performed at the wrong level, which accounted for 20% (n = 5 of 25); three were performed at the incorrect lumbar level and two procedures were performed at the incorrect cervical level. Anesthesia blocks accounted for 12% (n = 3), one of which

was administered by an anesthesiologist on the wrong side of the body and two by hand surgeons at the wrong site of the correct hand. Similarly, pain management procedures (the majority of which were wrong-side spinal injections) accounted for 12% (n = 3) of the reported events.

Additional wrong-site surgery events reported in the most recent two quarters were as follows:

- Wrong-side procedures (20%, n = 5 of 25); including one ureteroscopy/ureteral stent placement
- Wrong-site procedures (16%, n = 4); including two wrong-site biopsies
- Wrong procedures (16%, n = 4); including one ophthalmology procedure (i.e., incorrect strabismus procedure)
- Wrong patient (4%, n = 1); a wrong (intended for another patient) gynecologic procedure

Please note: one wrong-site event was belatedly reported or recognized in each of the following academic quarters: the second quarter of 2009–2010; the first quarter of 2014–2015; and the third quarter of 2015–2016. Adjustments in the number of reported events are reflected in Figure 3.

SUMMARY

The data trends outlined in this update demonstrate the most common types of wrong-site events reported from Pennsylvania facilities that provide surgical services. Sharing this, and data collected internally, with surgical staff and surgeons may help to identify potential areas for process improvement. Please reference the Authority's "Preventing Wrong-Site Surgery" toolkit at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx> for patient safety tools (e.g., Self-Assessment Checklists, Observational Monitoring Tools, Principles for Reliable Performance of Correct-Site Surgery) developed to assist facilities prevent wrong-site surgery and patient harm. The Authority also has a consultation program for Pennsylvania facilities that wish to evaluate their opportunities to improve wrong-site surgery prevention processes, particularly following a wrong-site event or near miss in a surgical suite. Those interested in this program should contact the Authority office or their regional patient safety liaison (PSL). The Authority's PSLs can help facilities assess their policies and procedures and arrange for onsite observations to evaluate surgical team compliance using the resources developed by the Authority.

NOTES

1. Quarterly update on the Preventing Wrong-site Surgery Project. Pa Patient Saf Advis 2010 Sep; [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7\(3\)/Pages/108.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7(3)/Pages/108.aspx).
2. Arnold TV. Update on wrong-site surgery: use patient engagement to enhance the effectiveness of the universal protocol. Pa Patient Saf Advis 2016 Jun;13(2):77-8. Also available: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2016/jun;13\(2\)/Pages/77.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2016/jun;13(2)/Pages/77.aspx).

Data Snapshot: Maternal Serious Events

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INTRODUCTION

A request from the Health Care Improvement Foundation (HCIF) for an update to a 2009 *Pennsylvania Patient Safety Advisory* data snapshot on maternal events led Pennsylvania Patient Safety Authority analysts to query the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for maternal events (see also the Letter to the Editor in this issue). Analysts limited the search to Serious Events over a five-year period, resulting in an examination of 537 events.

METHODS

Analysts searched the database to identify Serious Events among female patients 12 to 49 years of age which were reported from January 1, 2011, through December 31, 2015. Events were identified satisfying any of the following search criteria: (1) event types that include maternal complication of procedure/treatment/test, (2) events reported from care areas related to obstetrics, labor and delivery, and operating room venues, (3) event descriptions related to delivery with search terms including placenta, maternal, and C-section with variations (e.g., CS), or (4) event descriptions with the following terms in combination with care areas (i.e., ob*, gyn*, labor[^a]*, post-partum*): bled, bleed, blood pressure, “clot,” dehis*, deliver, edema, em*, embolism, hematoma*, hemm*, hemor*, high bp, htn, hypertens*, hypotens*, intubat*, lacera*, low bp, mom, mother, neurop*, pe, pph, pulm*, seroma, skelet*, transfus*. The wildcard character (*) ensured that the search also yielded events containing other word forms (e.g., pulm* returns both pulmonary and pulmonologist).

RESULTS

The query identified 685 event reports; 148 were excluded because they were unrelated to the scope of the query (e.g., a hysterectomy in a non-pregnant woman) or addressed a non-maternal complication event (e.g., fall), leaving 537 events for analysis.

Examination of event descriptions revealed 34 categories of possible harm or treatment (see Table). Some events could be assigned to more than one category, resulting in a total of 976 entries. The top five event categories in order of frequency were (1) unanticipated blood transfusion, (2) laceration of the birth canal, (3) unplanned transfer to the intensive care unit, (4) postpartum hemorrhage, and (5) bladder injuries. These categories were not necessarily independent (e.g., a patient may have required an unanticipated blood transfusion and an unplanned transfer to the intensive care unit). Of the 537 events analyzed, 11 (2.0%) resulted in death.

Unanticipated Blood Transfusion

Unanticipated blood transfusion was cited in 121 of the events and was the most commonly reported maternal complication. Reasons cited for bleeding included lacerations, uterine ruptures, uterine dehiscence, intra-abdominal hemorrhages, and hematomas.

Examples are as follows:*

Patient with previous C-section, attempting vaginal delivery; [fetus] had variable decelerations despite corrective action. Decision made to take patient for C-section. On entry into the abdomen in the operating room, a uterine dehiscence was identified and

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

(continued on page 165)

Table. Maternal Serious Events Reported by Event Category, 2011 through 2015*

CATEGORIES	NUMBER OF EVENTS	PERCENTAGE
Unanticipated blood transfusion	121	12.4
Laceration of the birth canal	99	10.1
Unplanned transfer to intensive care unit	76	7.8
Postpartum hemorrhage	74	7.6
Bladder injury	66	6.8
Other events requiring treatment for bleeding complications (e.g., uterine artery bleeding, blood clots)	65	6.7
Hysterectomy	59	6.0
Hematoma	57	5.8
Unplanned return to operating room	54	5.5
Retained placental products	50	5.1
Retained surgical item (e.g., retained sponge)	27	2.8
Uterine atony	27	2.8
Anesthesia event (e.g., spinal block headache)	24	2.5
Cardiac condition (e.g., cardiomyopathy, tachycardia)	19	1.9
Uterine rupture	18	1.8
Preeclampsia	16	1.6
Bowel injury	13	1.3
Infection	13	1.3
Placental abruption	13	1.3
Death	11	1.1
Pulmonary issues (e.g., embolism, respiratory depression)	11	1.1
Unplanned transfer to tertiary care facility	11	1.1
Wound dehiscence	10	1.0
Medication event (e.g., wrong patient, wrong drug)	7	0.7
Uterine inversion	7	0.7
Seizure	6	0.6
Skeletal/Muscular injury	5	0.5
Neuropathy	4	0.4
Placenta previa	3	0.3
Seroma	3	0.3
Amniotic fluid embolism	2	0.2
Thermal burn	2	0.2
Unattended delivery	2	0.2
Hernia rupture	1	0.1
Total	976	100

* Some reports described more than one maternal complication event category.

(continued from page 163)

repaired. Patient required PRBC [packed red blood cells].

Physician performed rupture of membranes. A large amount of bright, red blood noted. STAT C-section performed. Infant delivered under general anesthesia. Mother with low hemoglobin and hematocrit, received two units of packed red blood cells.

Patient rang call bell to say that she was bleeding. Patient in pool of blood with large clots. Approximately 600 cc blood noted. Physician notified.

Pitocin, Methergine and Cytotec administered. Uterine massage by physician. Bleeding stopping and fundus firm. Patient received 2 units of blood.

Laceration of the Birth Canal

Birth canal laceration was cited in 99 of the events. Third- and fourth-degree perineal lacerations, or tears, were the most commonly associated condition; seven of these reports cited newborns weighing more than 8 lb.

Examples are as follows:

Patient with excessive vaginal bleeding following delivery. Patient to operating room for vaginal exam and vaginal laceration repair.

Arrived in spontaneous labor, and pushed for three hours. The physician assisted with fetal descent by vacuum application. After delivery of the head, the anterior shoulder got stuck. The patient had a 3rd degree laceration and was taken to the operating room for repair under spinal.

Unplanned Transfer to the Intensive Care Unit

Unplanned transfer to the intensive care unit was cited in 76 events. Reasons for the unplanned transfers included cardiac

* HELLP is an abbreviation for the three main features of the syndrome: Hemolysis, Elevated Liver enzymes and Low Platelet count.

and/or respiratory arrests, HELLP syndrome,* uterine atony, uterine rupture and post-partum hemorrhage.

Examples are as follows:

Patient having C-section. Patient is obese with maternal weight [of nearly 160 kg]. [Patient] was given spinal, and after patient positioned, she complained of difficulty breathing. Oxygen saturation decreased after a minute, and the patient was bagged. The patient was transferred to an intensive care unit.

Physician in to see patient with previous C-section; attempting vaginal delivery, and patient was 8 centimeters on vaginal exam. Blood noted in Foley tubing and with exam. Patient then moved to the operating room for delivery by C-section. During surgery, it was noted that uterus and bladder had ruptured. Urologist consulted to repair bladder. Patient was transferred to the intensive care unit.

Postpartum Hemorrhage

Postpartum hemorrhage was cited in 74 events. Reasons for hemorrhage included retained placenta and uterine atony. Treatment included medications, dilation and curettage, and hysterectomy.

Examples are as follows:

Patient had a primary C-section. Returned to operating room for postpartum hemorrhage with uterine atony. Exam performed under anesthesia and balloon catheter placed. Patient tolerated procedure well.

Patient taken back to main operating room after C-section due to change in patient condition. Patient had exploratory laparoscopy with ligation of the right uterine artery to control hemorrhage.

Bladder Injury

Bladder injury was cited in 66 events. Bladder laceration was the most commonly reported bladder injury. Treatment included repair by a urologist.

Examples are as follows:

During a C-Section that was complicated by placenta previa, a placenta accreta was discovered and trauma to the bladder occurred. Urologist assisted in bladder repair.

Patient experienced an incidental bladder laceration during a cesarean section requiring urology surgeon intra-operative consultation and suture closure of bladder.

Deaths

Eleven maternal deaths were reported, including one with intra-uterine fetal death. Deaths were associated with disseminated intravascular coagulopathy, amniotic fluid emboli, gram negative bacteremia, and chronic myocarditis. Three of the patients had hysterectomies to manage postpartum bleeding. Three event reports did not specify a cause of death.

Limitations

Analysis of Serious Events is limited by the information reported through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete.

CONCLUSION

Analysis of PA-PSRS data revealed that the most common maternal Serious Events reported are laceration of the birth canal, postpartum hemorrhage, and bladder laceration. Life-threatening events can occur during and after delivery and, rarely, can contribute to maternal and intra-uterine fetal death. Reporting detailed circumstances related to maternal Serious Events can contribute to a better understanding of harm prevention and improved patient safety.



Patient Safety Events Involving Simulation in Pennsylvania

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Although many organizations collect and analyze information about Serious Events,* it is unusual to collect and analyze information about healthcare incidents that do not result in patient harm.† Providing opportunities to learn from a wide spectrum of patient care events is an important requirement of Pennsylvania's Medical Care Availability and Reduction of Error (MCARE) Act.¹ Compared with other states, Pennsylvania requires reporting the broadest range of events.² Identifying and reporting hazardous conditions allows facilities such as hospitals and ambulatory surgical facilities to manage risks that might result in patient harm even before an individual patient is impacted. Notably, reporting is based on patient harm, which may or may not involve patient care errors. Facilities submit reports, which include harm scores,³ through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

During simulations, such as when a team gathers to practice managing a simulated patient during a simulated medical crisis, hazardous conditions may be identified. Before opening a new or renovated patient care unit, simulations can be used to intentionally probe the availability and placement of equipment, signage, electronic access, or other features, as well as to refine patient care protocols. Even when not designed as intentional probes, simulations conducted *in situ*, in actual patient care settings, may serendipitously reveal hazardous conditions, such as missing or broken equipment, or impractical protocols. If simulations reveal a specific widespread knowledge deficit (e.g., unfamiliarity with using an epinephrine auto-injector), that could also be considered a system-wide unsafe condition. Because simulation, including *in situ* simulation, is becoming more widely used in healthcare settings and could be a source of data for improving patient safety, analysts searched the PA-PSRS database for event reports associated with simulation.

METHODS

Analysts queried the database for events reported during the 11-year period from July 1, 2006, through June 30, 2016, in which the event details contained terms which might be associated with simulation; 2,431 reports were identified (Figure 1). The details in each event report were reviewed, and reports that were irrelevant were excluded, leaving 22 relevant event reports.

The 22 reports were analyzed with respect to the relationship between simulation and the event, harm score, and whether the simulation involved a process or protocol or an object (e.g., supplies, patient care equipment, calibration devices).

RESULTS

The term "simulation" was often, but not always, associated with an equipment calibration process, rather than an educational or training process. Simulations involving objects such as equipment, supplies, or products comprised two-thirds (15 of 22) of the reports; the remaining reports involved processes or protocols.

The relationships between simulation and events were complex; in eight reports, simulations were used in response to events, and in three reports each, simulation may have prevented or contributed to events (Figure 2). In the reports in which the event reached

* Serious Event as defined in the MCARE Act: "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident."¹

† Incident as defined in the MCARE Act: "an event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event."¹

the patient and the patient required monitoring or intervention to prevent harm, simulation identified or prevented an event for a specific patient in one report, simulation was conducted in response to an event for four patients, and simulation may have contributed to an event for one patient. Analysts identified no reports in which simulation contributed to harm, or in which simulation was used in response to harm.

Deidentified examples of event reports follow:*

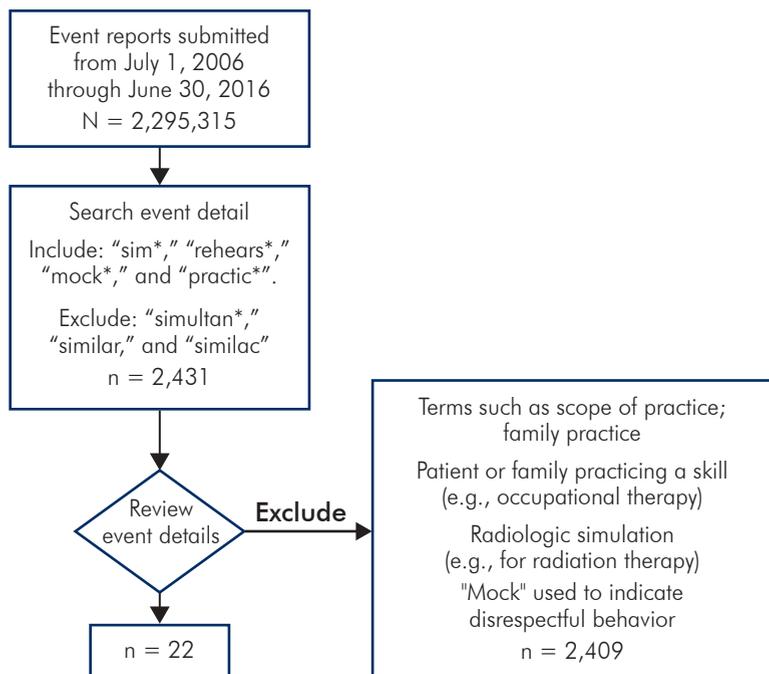
- Simulation identified or prevented an event for a specific patient: During a mock review of patient-care processes, a hazard relevant for a specific patient was identified.
- Simulation as routine test of device function prior to use indicated a problem: Device error message received before use on patient.
- Simulation may have contributed to event: Device intended for practicing a procedure was used on a real patient; simulation distracted from patient care.
- Simulation conducted in response to an event: Simulation was used to investigate a device malfunction after device use on a patient.

DISCUSSION

Analysts have identified Incident reports that reference simulation in the PA-PSRS database. Although small in number, PA-PSRS reports involving simulation cover a broad range of relationships between simulation and patient care, with simulation potentially contributing to, preventing, and being used to investigate and mitigate hazardous conditions. The small number of reports about simulation in PA-PSRS may reflect limited use of simulation as an intentional probe to

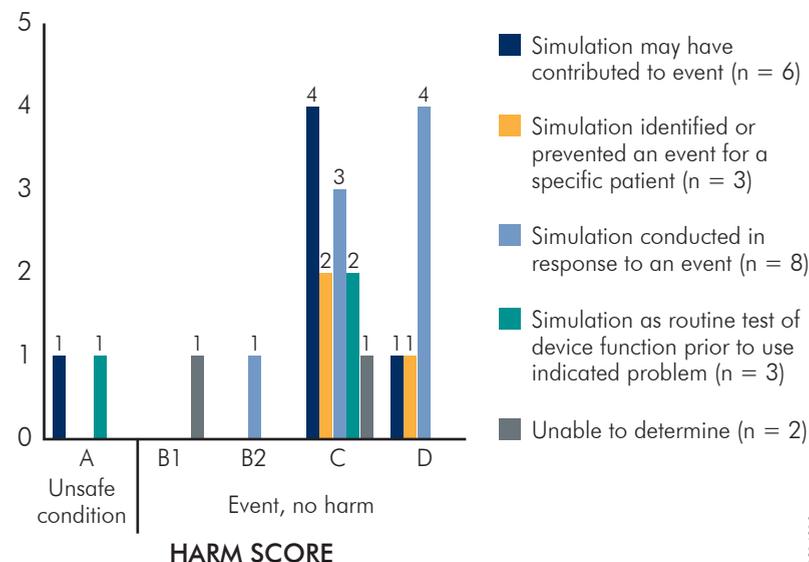
* Details of PA-PSRS event narratives in this article have been modified to preserve confidentiality.

Figure 1. Flowchart for Analysis of Simulation Events Reported through PA-PSRS



* Asterisk indicates a wildcard, allowing multiple words from the same root (e.g., Simulate, simulated, simulation).

Figure 2. Relationship between Simulation, Event, and Harm Score as Reported through PA-PSRS, July 2006 through June 2016



Note: N = 22 simulation reports out of 2.2 million total reports for this time period.



improve system safety, or it may reflect a lack of understanding that hazards identified in simulations that do not involve a specific patient can be reported through PA-PSRS.

The use of healthcare simulation to enhance the capabilities of both individuals and teams has blossomed over the past decade. Simulation experts are also beginning to appreciate the value of simulation for improving the social and technical systems that are integrated with healthcare providers⁴⁶ as these systems support—or

constrain—safe healthcare delivery. In Pennsylvania, unsafe conditions identified during simulations can be reported through PA-PSRS in a manner similar to other hazards; if the circumstance does not involve a specific patient, harm score A (circumstances that could cause an adverse event) might be appropriate.

CONCLUSION

Patient safety events involving simulation can be reported through PA-PSRS, but analysts identified few reports of

simulation contributing to, or being used to mitigate or prevent patient safety events and no reports of patient harm related to simulation reported through PA-PSRS during the past 11 academic years. Analysts reviewing reports involving simulation look for patterns, generalizable knowledge, and risk reduction strategies as they do for other events reported through PA-PSRS. Reporting unsafe conditions identified during simulation through PA-PSRS may expand our knowledge and advance patient safety.

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Can Simulation *in situ* Improve Patient Safety?

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The increasing availability of simulation offers many creative opportunities to improve the capabilities of individuals, teams, and even healthcare delivery systems to improve patient safety.^{1,6} Simulation is “a technique that creates a situation or environment to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain understanding of systems or human actions.”⁷ Simulation can be used to create learning opportunities based on the needs of learners, at the relative convenience of the learner and the teacher, in circumstances that avoid direct risk to patients.^{8,9}

Simulations can be conducted either in simulation centers or *in situ*, that is, in actual patient care locations; these different settings provide complementary opportunities. Simulation centers offer controlled conditions and provide reproducible experiences in standardized settings, but the simulations may not fully reflect the actual circumstances of patient care. Simulations conducted *in situ*, involving real teams, and sometimes using actual patient-care supplies and equipment, more fully represent the ways in which patient care and patient safety is impacted by the complex components of the healthcare delivery system.

SIMULATION *IN SITU* FOR INDIVIDUALS

Many facilities have implemented simulation programs to enhance the skills of individuals. For example, in Pennsylvania, clinicians at the Children's Hospital of Philadelphia (CHOP) implemented a simulation *in situ* program in an effort to improve the hospital's central line-associated bloodstream infection (CLABSI) rate.¹⁰ The central venous catheter “dress rehearsal” used a utility cart with skill-trainer manikins and dressing-change supplies, which was rolled into patient care areas to provide nurses with “just in time” training (conducted before a potential dressing change) and “just in place” training (conducted at or near the patient bedside). The “train to excellence” protocol allowed cognitive and psychomotor skill testing while requiring the nurse to repeat the task until the dressing change on the manikin could be completed in full compliance with policy and procedure without needing corrective prompts. On average, the simulations were completed within 20 minutes. The program improved nurses' knowledge, self-confidence, and psychomotor skill performance on manikins; the program was associated with improved procedural competence on real patients and temporally associated with decreased hospital CLABSI rates.

SIMULATION *IN SITU* FOR TEAMS AND FOR HEALTHCARE SYSTEMS

Teams participating in simulation *in situ*—whether single specialty or inter-professional—can engage in deliberate practice of teamwork and communication skills¹¹ and may further refine skills and processes that were feasible in a simulation center, but are more challenging *in situ*. Conducting simulations *in situ* to improve team skills almost inevitably provides opportunities to identify hazards lurking in the systems that surround, and are inextricably linked with, patient care. Simulation *in situ* may identify vulnerabilities in personnel and care systems, even though regulatory requirements may have been met.^{12,13} Simulations conducted to improve staff preparedness and evaluate operational readiness for new or renovated patient care areas have identified issues that were not readily apparent using traditional modeling and preparatory efforts,^{6,14} such as a finding that a moving pillar system was unstable for equipment trays and monitors.⁶

CHOP conducted simulations *in situ* prior to the separation of conjoined twins, using a model of the twins constructed from two dolls, and color coded tubing, equipment and monitors.¹⁵ The simulations allowed the peri-operative team to develop a process

to maintain sterility while transferring one twin immediately post-separation to a second table in the operating room. Several facilities in the United States have conducted simulations *in situ* to evaluate and improve preparations for patients with Ebola. Often simulations *in situ* involving coordination or patient care transitions between departments provide rich information. Even simulations of routine patient-care processes conducted *in situ* have revealed missing or broken equipment, conflicting protocols, or difficulty accessing necessary resources. Useful information may be intentionally sought or serendipitously discovered, and may reveal hazards or help inform solutions.

IT'S NOT ALWAYS EASY

There are several challenges to implementing simulation *in situ*. Simulation experts address concerns about the potential to confuse or contaminate actual patient care equipment and medications¹⁶ by using a combination of vigilance and constraints. Some scheduling obstacles

can be overcome with creativity, flexibility, sensitivity to local workload, and collaboration with local leadership.² Somewhat ironically, cancelling a simulation because of excessive workload or shortages of equipment inherently provides information about a system's lack of margin should any other system stress arise. Legitimate concerns about possible adverse impacts should be balanced with the potential value of improved teamwork and system safety developed through simulation *in situ*, and the risk of patient care hazards that may exist but are unidentified. Patterson et al conducted a series of 90 simulations *in situ* in an emergency department (ED) over the course of a year, and found that, compared with simulations conducted in the simulation center, the simulations *in situ* identified about seven times as many latent safety threats. Identified hazards included malfunctioning equipment, knowledge gaps related to critical medications, and delayed or absent responses of vital team members.¹¹ Simulation *in situ* allowed deliberate practice of teamwork and communication

skills; and 71 of 73 latent safety threats identified were remedied by ED staff and leadership. The cancellation rate decreased as training matured, and about halfway through the project, ED leadership believed the training had become so valuable that they required mandatory participation.¹¹

IMPACT ON PATIENT SAFETY

A companion article in this issue of the *Pennsylvania Patient Safety Advisory* explores events related to simulations reported through the Pennsylvania Patient Safety Reporting System during the most recent 11 academic years. Simulations *in situ* have the potential to reveal safety hazards, as well as to provide a mechanism to elicit and test possible solutions at a systems level. Safety hazards, as well as solutions, often have applicability beyond a single patient care unit, or even a single facility. Simulations conducted *in situ* have the potential to enrich our understanding and management of patient safety hazards and thereby improve patient safety.

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SAVES, SYSTEM IMPROVEMENTS, AND SAFETY-II

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

Exceeding “Routine” Checks of AEDs

A healthcare worker completing routine checks on an AED (automated external defibrillator) noted that the defibrillation electrodes (pads) in the emergency cart were not compatible with the AED. Further investigation revealed that multiple AEDs throughout the facility were affected. The correct pads were ordered and installed.

AEDs may be needed in emergencies when seconds count and delays in treatment can contribute to poor neurologic outcomes or even death. Imagine discovering an equipment mismatch in the middle of a resuscitation and having to scramble to find the right parts. Even though this healthcare worker was completing a routine—perhaps even a mundane—task, he or she went beyond just “checking the box” that all of the necessary parts were available and made sure that all of the parts fit together correctly. This person even went a step further, recognized that this mismatch could affect more than one AED, and checked on the other similar devices throughout the facility. These actions helped to ensure that if an AED were needed for an emergency anywhere in the facility, it would be fully functional.

LETTER TO THE EDITOR: POSTPARTUM HEMORRHAGE

We would like to commend the Pennsylvania Patient Safety Authority for its excellent review and analysis of postpartum hemorrhage (PPH) events in the article “Pregnancy-Related Unplanned Returns to the Operating Room” in the September 2015 *Pennsylvania Patient Safety Advisory*. We write this letter to demonstrate how the strategies outlined in the article for reducing the incidence of PPH were applied in a statewide quality improvement collaborative.

As a partner to the Hospital and Healthsystem Association of Pennsylvania in the Pennsylvania Hospital Engagement Network, the Health Care Improvement Foundation (HCIF) led a multi-year obstetrical adverse events collaborative with hospitals across Pennsylvania.* With funding from the Centers for Medicare and Medicaid Services through *Partnership for Patients*, hospitals worked together over a four-year period to reduce adverse events in labor and delivery units, including PPH.

The 2015 *Advisory* article cites evidence that PPH is the fourth leading cause of pregnancy-related mortality in the United States. For this reason, Pennsylvania obstetrical leaders made the reduction of PPH a collaborative priority. The article also points to literature that demonstrates improved outcomes with the implementation of evidence-based protocols, specifically, the rapid identification and treatment of PPH. One evidence-based protocol that served as the basis for collaborative learning in Pennsylvania and was referenced in the *Advisory* article was the OB Hemorrhage toolkit developed by the California Maternal Quality Care Collaborative (CMQCC) OB Hemorrhage Task Force. The toolkit is designed to assist organizations with the implementation of the *National Partnership for Maternal Safety Hemorrhage Bundle*. In 2012, CMQCC Task Force Co-Chairs, Audrey Lyndon, PhD, and David Lagrew Jr., MD, audioconferenced with collaborative hospitals and presented the toolkit and the lessons they learned from its implementation.

Over the next four years, Pennsylvania hospitals implemented bundle strategies and shared their experiences, tools, and resources with one another.

Examples include the following:

- **Readiness:** The formation of rapid response teams, implementation of PPH emergency response carts, development of massive transfusion protocols, and simulation training.
- **Recognition:** Prenatal risk screening; the adoption of a risk assessment checklist used on admission to identify patients at low, medium, and high risk for PPH; and nursing education and training on quantifying blood loss (as opposed to estimation).
- **“Response”:** The implementation of a PPH management protocol and checklist, earlier administration of prophylactic oxytocin during the third stage of labor, and improved communication and processes for the timely release and delivery of blood from the blood bank.

Collaborative hospitals measured their progress by collecting and reporting data on the following three PPH metrics: compliance in

* The analyses upon which this publication is based were performed under Contract Number HHSM-500-2015-00300C, entitled, “Partnership for Patients Hospital Engagement 2.0 Contract.”

assessing risk on all patients admitted to Labor and Delivery, blood transfusion rates, and rate of severe morbidity in women with PPH. Collaborative teams used their results to drive improvement.

The *Advisory* article includes information about the value of simulation training as an effective strategy for improving patient outcomes. Patient safety concepts and approaches were integrated into the collaboration’s program and included safety huddles for high-risk patients, post-event debriefs, and simulation training. Over the course of the collaborative, a number of educational activities were conducted, highlighting some of the state’s leading simulation programs. A favorite activity was the “simulation showcase,” in which video clips of hospital simulations were featured during a webinar accompanied by brief presentations in which each hospital described its training and debriefing experiences. In the last year of the collaborative, Ellen Deutsch, MD, clinical director for the Pennsylvania Patient Safety Authority and editor of the *Advisory*, was a featured webinar presenter on simulation. She also contributed her time and expertise through the “Office Hours with Dr. Ellen Deutsch: Designing Simulations”; a networking call in which collaborative participants were given the opportunity to ask Dr. Deutsch questions about their maternal simulation programs. Topics that were discussed included suggestions for getting a program started, tips for engaging physicians, new and innovative simulation scenarios, ways to involve other disciplines, staffing challenges, and the benefits of conducting simulations in common areas visible to patients and visitors.

In the final year of the collaboration, an “OB Regional Coalition Program” was conducted, bringing together obstetrical leaders across the commonwealth to better understand causes of Pennsylvania’s maternal adverse events and to propose solutions to system shortfalls and gaps. The call by the American College of Obstetricians and Gynecologists (ACOG) and the Joint Commission for a systematic review of all maternal mortalities and morbidities made this program especially relevant. The standardized event reporting categories and definitions as outlined in the Authority’s Pennsylvania Patient Safety Reporting System (PA-PSRS) user manual were the basis for the event reporting discussion at two in-person coalition meetings. Meeting findings and recommendations were disseminated to hospitals across Pennsylvania through a written report and a webinar. A few examples of recommendations include the need to standardize maternal event definitions, a maternal event reporting taxonomy in PA-PSRS, better multi-disciplinary involvement in the adverse event review process, demonstration of the financial impact of maternal adverse events and the value of solutions, and forums to continue these discussions.

Although the collaboration concluded in September, Pennsylvania hospitals are well positioned to continue this important work through the relationships they developed, the strategies they implemented, and the resources and tools they shared with one another.

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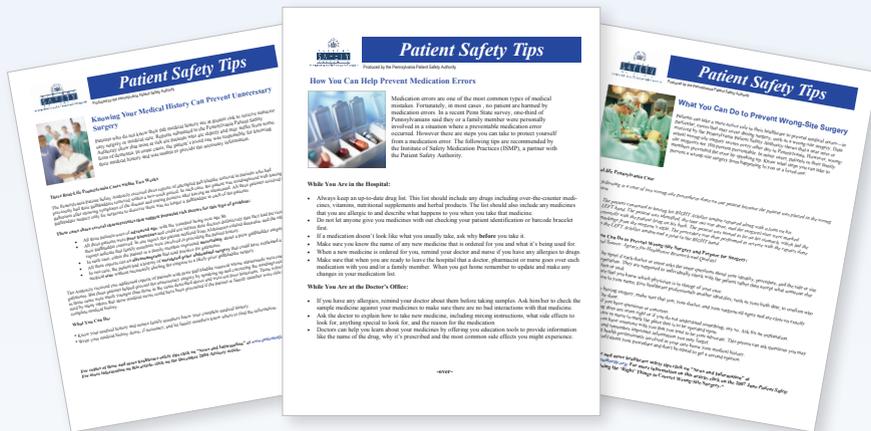
SHARE PATIENT SAFETY BEST PRACTICES TO KEEP YOUR PATIENTS SAFE

The Pennsylvania Patient Safety Authority is committed to providing consumers of the healthcare industry with information they can use to receive quality care as a patient. Authority data shows the more a patient participates in his or her healthcare, the more likely he or she is to have a positive outcome when using the healthcare system.

Help your patients and their families participate more in their healthcare by making consumer tips available in your waiting rooms or patient areas.

REMEMBER TO ENCOURAGE YOUR PATIENTS TO SPEAK UP!

The Authority has published consumer tips on a variety of topics that include but are not limited to medication errors, wrong-site surgery, color-coded wristbands, C. difficile, methicillin-resistant *Staphylococcus aureus* (MRSA), negative-pressure wound therapy, magnetic resonance imaging (MRI) scans, lower respiratory tract infections, dialysis, and living wills.



P A T I E N T
S A F E T Y
A U T H O R I T Y

An independent agency of the Commonwealth of Pennsylvania

Certain patient safety tips are also available online en Español.

For more information, visit the Pennsylvania Patient Safety Authority website at www.patientsafetyauthority.org.



Scan this code with your mobile device's QR reader to access the Authority's Patient Safety Consumer Tips.

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 nearly 50 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.