PATIENT SAFETY

September 2019 | Vol. 1, No.1

Allergy-Related Medication Errors

Diving deep into data to examine breakdowns in process

How Pennsylvania is Fighting the Opioid Crisis: An Interview with Pennsylvania's Secretary of Health, Dr. Rachel Levine

Best Practice Implementation—See How You Compare

Central Versus Peripheral Lines—Know the Risks

LETTER *From the Editor*

Regina Hoffman, Editor-in-Chief
Patient Safety

I am delighted to share with you the inaugural issue of *Patient Safety*, the only journal that highlights the intersection of patient safety science and real human experience. We know that behind every event, every research project, every performance improvement initiative are people. People like you and me, those we care about, and those we care for. In each issue you will read not only about new insights and strategies to improve care but also stories that create a bridge between providers and patients.

It was also important to create a publication accessible to everyone—free from financial burdens for authors or subscribers and completely open access. Patient safety should not be a competition, and knowledge should be freely shared.

> *"In each issue you will read...stories that create a bridge between providers and patients.*

Our first patient commentary, written by Dwight McKay, describes the importance that everyone plays in safe care (*Page 5*). He describes his own experiences over the past 35 years and drives home the impact that a lack of health literacy can have. The painting featured on our back inside cover by artist Regina Holliday illustrates Joe Lavelle's experience navigating healthcare. Each issue will include artwork from The Walking Gallery, a very visual reminder of why we do what we do.

From our cover: In a database analysis, lead author Matthew Grissinger discusses the occurrence of medication allergies and how systematic failures continue (*Page 18*). Michelle Bell and co-authors share findings from a statewide survey of best practice implementation at hospitals and ambulatory surgery facilities, which can help you identify areas in your own practice and organization that may not quite be hitting the mark (*Page 42*). Lynette Hathaway and co-authors explore the complications related to peripheral and central lines and remind that each has associated risks (*Page 28*). And in an interview with Pennsylvania Secretary of Health Rachel Levine, MD, she discusses one of the largest health crises that we face, the opioid epidemic (*Page 60*). Levine speaks frankly about its far-reaching effects and outlines the progress Pennsylvania has made to combat this nondiscriminating killer.

I hope these papers and stories, along with the many others in this issue, contribute to your awareness of the problems facing patients and providers today, and that you take something with you to help improve patient safety in this complex world of healthcare. If you have important work to share or stories to tell, please consider submitting your manuscripts at patientsafetyj.com.

See you again in December!

ABOUT *PATIENT SAFETY*

As the journal of the Patient Safety Authority, committed to the vision of "safe healthcare for all patients," *Patient Safety* (ISSN 2641-4716) is fully open access and highlights original research, advanced analytics, and hot topics in healthcare.

The mission of this publication is to give clinicians, administrators, and patients the information they need to prevent harm and improve safety—including evidence-based, original research; editorials addressing current and sometimes controversial topics; and analysis from one of the world's largest adverse event reporting databases.

We invite you to submit manuscripts that align with our mission. We're particularly looking for well-written original research articles, reviews, commentaries, case studies, data analyses, quality improvement studies, or other manuscripts that will advance patient safety.

 The current issue is available at patientsafetyj.com.

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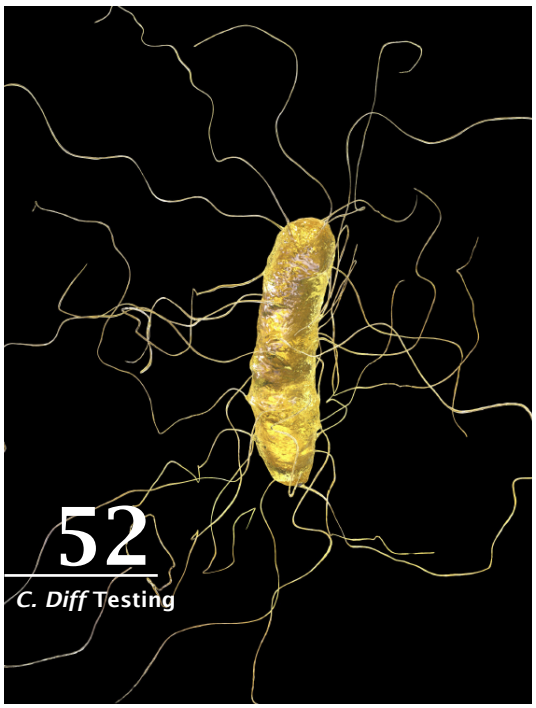

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IN EVERY ISSUE

ORIGINAL RESEARCH, ARTICLES & COMMENTARIES

Dwight McKay

Dwight McKay, BSL, retired in 2005 from a career that included roles as a pastor and facility security manager. He is a co-founder of the Amputee Support Team of Lancaster, currently volunteers for Lancaster Rehabilitation Hospital, and is a member of the Patient Safety Authority's Patient Advisory Panel and the* Patient Safety *editorial board. In our first patient commentary, Dwight shares his healthcare experience and underscores the importance of health literacy.

I recently had a conversation about disability with an acquaintance who told me that his wife has "always had a heart for disability issues." He said that he, on the other hand, had never given it much thought until his son was born with Down syndrome. That changed his perspective and changed his life.

I think patient safety is like that in some ways.

Everyone knows that falls and other injuries take place in the healthcare environment. Wrong-site surgeries and retained surgical items sometimes make the news. There is awareness that medication errors or misdiagnoses are possible. But for most people, these and other similar occurrences are not front-burner concerns—at least not until they hit close to home. When something adverse happens to you or someone you care about, that issue not only moves to the forefront, but becomes all consuming.

On top of the public's general disinclination to focus on patient safety until they're personally affected is the staggering gap between what people should know about their own healthcare and what they actually know. The 2003 National Assessment of Adult Literacy, a study sponsored by the National Center for Education Statistics, found that only 12 percent of English-speaking adults demonstrated proficient health literacy.[1]

My own intimate connection with the negative side of patient safety started almost 35 years ago, when I began experiencing pain in my right leg and foot. The problems were intermittent, so each time a new diagnosis was offered, and a new treatment regimen was initiated, the pain went away. Temporarily.

After almost two decades on the merry-go-round of misdiagnoses, ineffectual treatments, and symptom relief and reappearance, a major pain event drove me to the emergency room, where a simple ultrasound revealed the truth. My problem was not, as I had been told, my Achilles tendon, nor any of the other opinions that had been suggested, including a heel spur, gout, and plantar fasciitis.

My problem was a five-centimeter aneurism in my right popliteal artery. That aneurism had been there since birth, and it had eventually grown to the point where it was almost a vacation spa for my blood. As blood slowed going through the aneurysm, some of it clotted. The clots were dispensed toward my foot, where they eventually interfered with circulation, robbed my muscles of oxygen, and caused my pain.

The ultrasound revealed the truth, but the damage already had been done, and 14 years ago my right leg was amputated below the knee. I'm grateful for the

Patient safety is everyone's responsibility. It is certainly something that the patient and their support system should care about deeply.

success of that surgery and for the new normal of my life as an amputee. But I regret the necessity of that procedure, and when I think through all this, I wonder at the fact that for almost two decades no one thought to look for vascular problems.

Today I am much more health literate than I was 35 years ago. Since then I have learned important lessons about the need to advocate for myself in healthcare processes and to have strong advocacy in place when I am unable to act personally.

Efforts are underway on several fronts to close the understanding gap between providers and patients. Providers are encouraged to offer instructions and commentary in plain, easily understood language whenever possible. Techniques such as the teach-back method are increasingly used to verify that patients and their family caregivers understand instructions.

Similar energy is being expended to improve the general state of health literacy. When almost 9 out of 10 people are inadequately literate about their own healthcare, that clearly becomes a patient safety issue. Patient compliance with matters such as medication schedules and dosing, therapy routines to be carried out at home, and follow-up physician visits is at risk if patients don't understand the "why" as well as the "what."

Patient safety overall can only improve if the level of health literacy rises and awareness of the safety issues surrounding medical treatment and procedures becomes more common.

But on the other side of the patient safety coin is the medical professional. It would be comforting to imagine that all patients and family caregivers can be encouraged and trained to be well-functioning patient safety participants. However, human nature being what it is, that's probably a reach too far. In contrast, medical professionals are expected to be… well, professional.

As a doctor friend recently reminded me, patients like to feel they are in control of the things happening around them, but that isn't always possible. Patients may not understand all the technical issues involved in necessary procedures, and they absolutely must cede some control when they are overly tired or medicated.

In the three days immediately before my amputation I went through four surgeries—heroic, but unsuccessful, attempts to save my foot. I remember nothing from that period, since it was an almost constant blur involving anesthesia and recovery from its effects. Add my pain to the mix, and it would have been impossible for me to make any kind of thoughtful and reasoned decision during that time.

I had to trust that both my advocate (my wife) and the professionals who were treating me had my best interest in mind. And even with my miniscule understanding of patient safety back then, I had to trust that the right procedures would be followed everywhere, from the surgical suite to the dietary department.

My inner cliché alarm goes off when I say this, but it is true nonetheless: Patient safety is everyone's responsibility. It is certainly something that the patient and their support system should care about deeply. And it just as certainly is something that every person at every level of the healthcare world needs as a major focus.

The facility CEO, the practice manager, or the patient safety officer do not have the same role in patient safety as the nurse who assists with patient toileting or the maintenance worker who puts the "Wet Floor" sign in the hallway or the pharmacist who selects the proper drug and its correct dosage. But no one can afford to sit back uninvolved, believing that someone else will take care of things.

We can all hope that someday soon our culture's health literacy will reach a more satisfactory level and patients will be increasingly proactive concerning their own safety. But right now, because patients' lives and quality of life are the stakes, every healthcare professional must maintain constant awareness of patient safety and recognize it as part of their daily routine. And patient safety has to be more than a line item in a job description, instead considered akin to a calling: a cause that simply never goes away no matter what else is happening.

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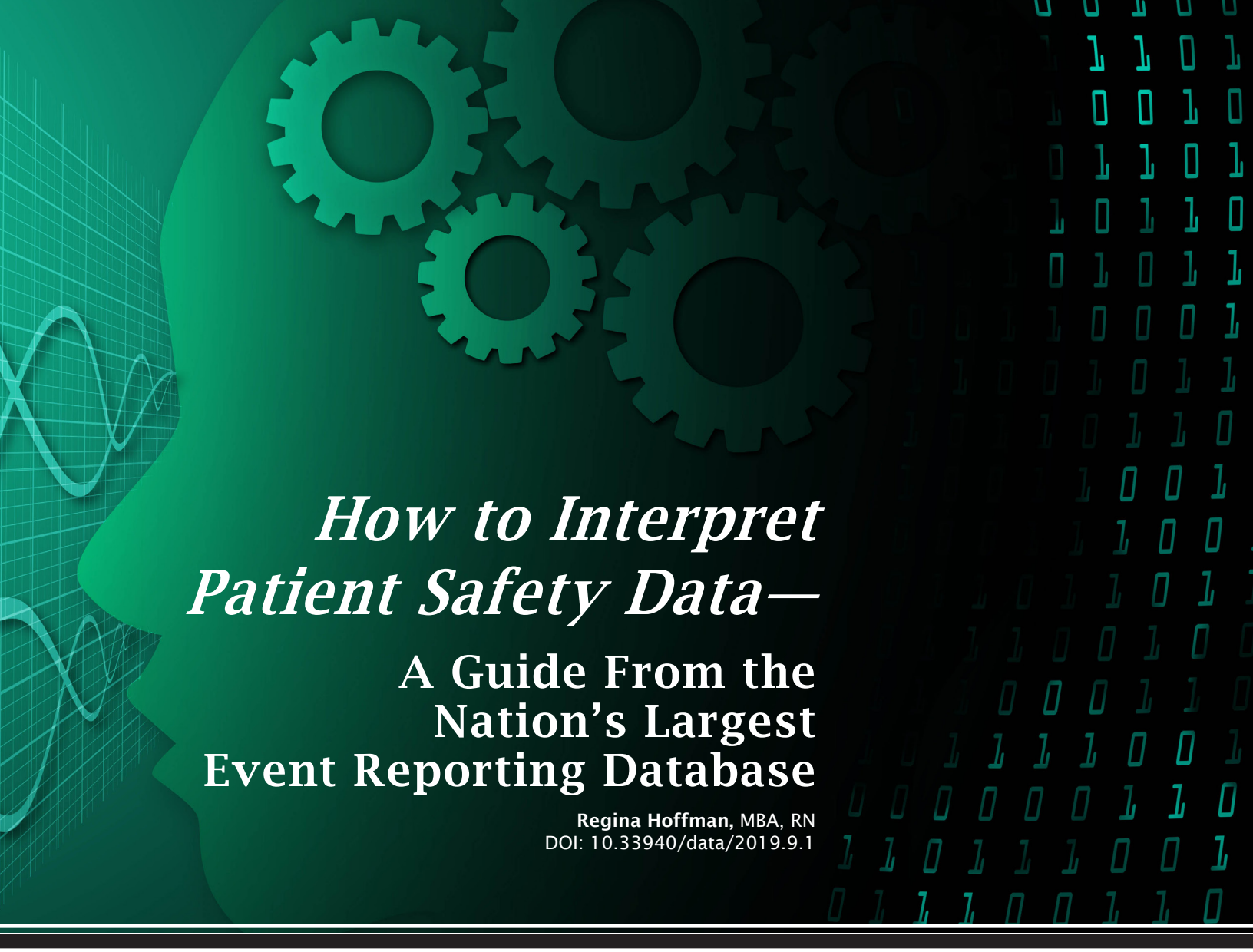


How to Interpret Patient Safety Data—

A Guide From the Nation's Largest Event Reporting Database

Regina Hoffman, MBA, RN
DOI: 10.33940/data/2019.9.1

Patient safety metrics are recurrent headlines. Intentional or not, they are often sensationalized, conflated, or misconstrued to tell a story in which patients are frequently harmed by irresponsible, negligent clinicians. The truth is far less dramatic. Although medical error does occur and real people suffer real harm, the vast majority of encounters go as expected. So it's crucial to understand how to interpret patient safety metrics to distinguish true areas of concern from embellished front-page stories.

It is also important to understand that each database has its own reporting criteria and each research study its own methodology, and while there is no universal definition for medical error, medical error is not synonymous with patient harm. **Reported events do not necessarily equate to instances of medical error, nor are all instances of harm preventable.** For example, a patient may have a serious allergic reaction to a medication that they have never taken previously.

The Patient Safety Authority (PSA) is charged with capturing every occurrence of harm or potential harm to patients in Pennsylvania, whether attributable to medical error or not, and providing tools to prevent its recurrence. Since its inception in 2004, more than 3.8 million confidential event reports have been added to the PSA's database, the Pennsylvania Patient Safety Reporting System (PA-PSRS)—the largest event reporting database in the United States and one of the largest in the world.

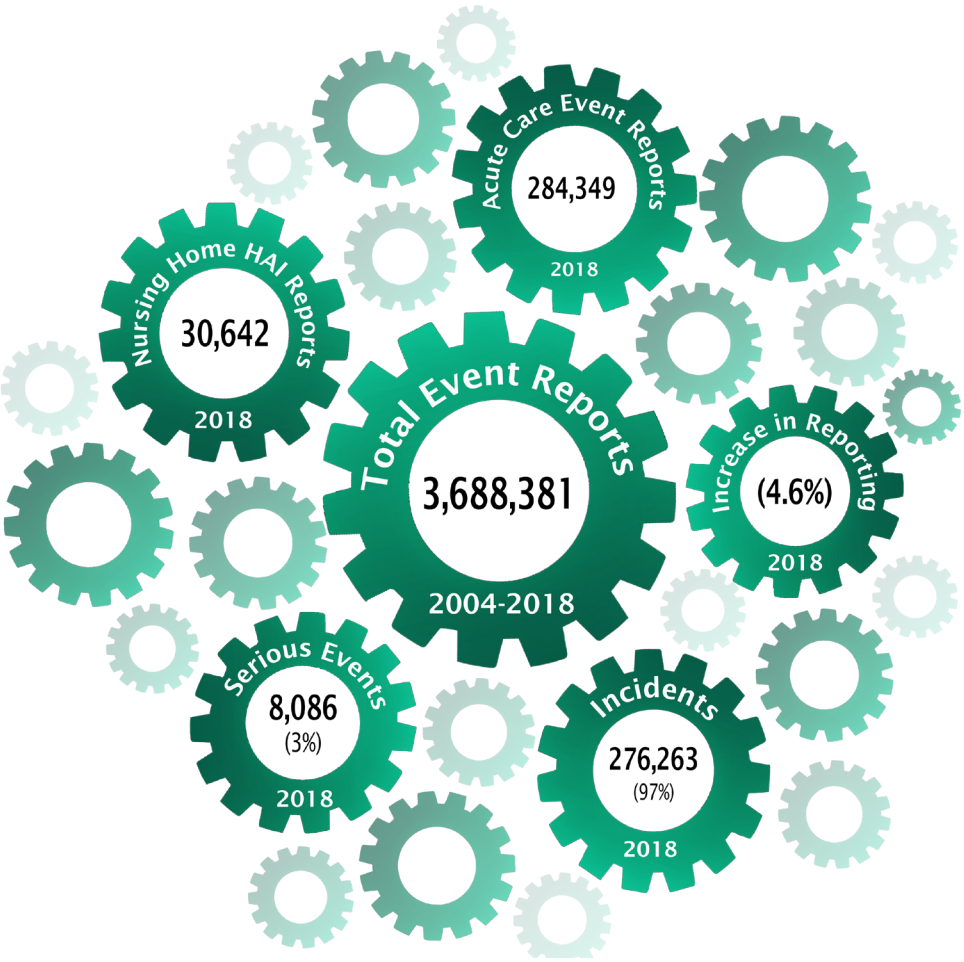
The number of events reported into PA-PSRS has increased from 2004 to 2018; however, this was anticipated as a result of a maturing safety culture, and one cannot conclude from the data whether the actual number of events went up or the uptick is solely due to

increased reporting. Caution should be given to inferences like "medical error is increasing" that cannot be substantiated from event reports. It may seem counterintuitive, but a facility with a low number of reports may be more concerning than one with a higher number, as this could indicate a culture where safety and transparency are not supported.

What is certain is that since 2004 in Pennsylvania, the number of reported incidents (events without harm) has increased; the number of reported serious events (events with some level of harm) has not trended up or down; and the number of high-harm events (those causinglife-threatening injury, irreversible harm, or death) has declined.

Approximately 97% of the reports in PA-PSRS are incidents. These types of events are often overlooked in healthcare, as **Pennsylvania continues to be the only state that requires healthcare facilities to report no-harm events**. Incidents often indicate potential patient harm, and the difference between a "near miss" and a "serious event" may have been happenstance or an intervention not guaranteed to recur.

Though PA-PSRS cannot conclusively address medical error incidence, its millions of datapoints provide insights into emerging trends that are unapparent to individual facilities. As such, it provides the framework for a larger system that transforms data into actionable information to reduce harm. Thorough ongoing analyses drive an education agenda, identify opportunities for collaborative improvement projects, and prioritize issues across Pennsylvania and the United States—in healthcare facilities and in individual practice. The PSA's work in these areas is published and shared in *Patient Safety* and elsewhere, and read by healthcare providers in 49 states and 44 countries.



2018 PA-PSRS Highlights

The Impact of Education and Feedback on the Accuracy of Pressure Injury Staging and Documentation by Bedside Nurses

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DOI: 10.33940/HAPI/2019.9.2

Abstract

Background: Pressure Injuries (PIs) are largely preventable. Accurate documentation of PI stage or progression is a key quality measure.

Local Problem: Nurses frequently fail to accurately assess and document their findings in the electronic medical record. This project sought to increase nurses' knowledge and accuracy of staging and documentation of PIs.

Method: Educational interventions; direct observation of PI status; review of nurse documentation; feedback; and referrals to wound, ostomy, and continence nurses (WOCNs).

Interventions: Nurses completed a pre- and post-test and online training modules, and participated in training sessions. Clinical experts completed direct skin observations and provided feedback about PI staging.

Results: There was a statistically significant improvement in nurses' knowledge about PIs ($p = 0.004$). Skin assessments were conducted on 108 patients (13 PIs identified). The bedside nurse accurately assessed a PI stage in only 31% of these observations. Referrals to WOCNs increased by 18% compared to the baseline period.

Conclusions: Educational interventions enhanced nurses' knowledge; however, appropriate PI staging may require skills development and validation to build competency.

Keywords: *pressure injury, pressure ulcer, wound care, prevention, evidence-based practice, prevalence, assessment, documentation, education*

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Problem Description

Pressure injuries (PIs) are painful, costly, and largely preventable, and they represent key opportunities for nurses to improve the quality of patient care. The National Pressure Ulcer Advisory Panel defines a PI as the "localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device."[1] Patients at higher risk for PI development include those with poor nutritional status, impaired tissue perfusion, immobility, and comorbidities such as diabetes.[1,2] In 2014, the Agency for Healthcare Research and Quality reported that PIs affected over 2.5 million patients annually at a cost of $20,900 to $151,700 per pressure injury. Each year, approximately 60,000 deaths are a direct result of a PI.[3] The Patient Safety Authority (PSA) described hospital-acquired pressure injuries (HAPI) as the fifth-most common event reported through the electronic interface by patient safety officers.[4]

Documentation of PI risk poses many challenges, including variability in assessment skills, knowledge deficit, type of skin risk assessment scale utilized, and electronic medical record inefficiencies. The Medical Care Availability and Reduction of Error (MCARE) Act was enacted in Pennsylvania in 2002 and defined patient safety events and required reporting structures for patient injuries.[5] In 2008, the Centers for Medicare and Medicaid Services (CMS) included PIs in the Hospital-Acquired Condition Reduction Program and no longer reimburses hospitals for care expenses that result from the development of a Stage 3 or Stage 4 PI.[6] The PSA issued guidelines effective January 1, 2018, that require Pennsylvania hospitals to report HAPIs that develop and/or progress or worsen as patient safety events, regardless of the patients' illness, contributing factors, and/or care refusal.[7,8]

In anticipation of these new reporting requirements, the patient safety officer reviewed documentation congruence between the hospital occurrence reporting system and nurse documentation in the medical record compared to observations noted by wound, ostomy, and continence nurses (WOCNs). Significant variation in staging of PIs was noted between staff nurses and WOCNs. For example, some PIs identified by bedside nurses as Stage 2 were assessed by WOCNs to be either Stage 3 or incontinence-associated dermatitis. Improving accurate nursing assessment and documentation of PIs is essential to enhance patient safety and reduce patient discomfort and risk for increased morbidity and mortality.[1] Inaccurate documentation of publicly reported quality metrics "including PIs" can negatively impact hospital reimbursement and financial viability.[3]

The purpose of this quality improvement project was to enhance the accuracy of bedside nurse assessment and documentation of PIs following completion of an online training module and direct feedback about the nurses' assessment and documentation.

Rationale

The literature describes limited evidence of the accuracy of nurses' assessment skills and knowledge related to PI staging and documentation. Only 55% of 647 nurses responding to a wound care study conducted in 2012 were able to identify the stages of PIs in their patients. The authors also noted that only 32% of the respondents to this survey acknowledged that they had received sufficient education on chronic wounds in their basic nursing education program.[9] Dahlstrom et al. conducted a quality improvement campaign to improve identification, documentation, and treatment of PIs. The authors noted complete documentation (including stage, size, and location) of the PIs improved from 29% to 46% following the implementation of a wound assessment form and point-of-care reminders. While this campaign demonstrated a significant increase in complete documentation, more than 50% of the reported injuries were inappropriately documented.[10] Clearly, problems have been identified with nurses' knowledge of how to accurately stage and document pressure injuries.

Problems With Nursing Staging

Beal and Smith conducted a retrospective study of initiatives to reduce inpatient PI prevalence in a large community hospital over a 10-year period. The PI prevalence rate in this institution was consistently above the national average. The organization created a wound committee charged with oversight of PI activities. Over six years, they implemented several initiatives to reduce the incidence, including standardized PI prevention training with a self-learning staging module, implementation of evidence-based practices, and care plan prompts in the electronic medical record. Their relentless efforts resulted in a 6.4% reduction in HAPIs.[11]

Critical care nurse knowledge related to PI prevention and staging was described in a post-intervention descriptive study by Miller et al. Over a two-year period, nurses in the medical and surgical intensive care units were provided with various educational programs (e.g., lectures, self-learning modules, wound care nurse shadowing). The authors utilized the Pieper-Zulkowski PI knowledge test to evaluate nursing knowledge of prevention, risk identification, and staging. The overall score for knowledge of PI staging was 81%, compared to an overall score of 70% for knowledge of prevention strategies.[12]

The Veterans Health Administration (VHA) embarked on a journey to reduce PIs in all settings (i.e., hospital, long-term care, outpatient) utilizing a virtual breakthrough series model. This approach used a rapid cycle of change coupled with evidence-based practices, clinical expert and quality improvement coaching on each multidisciplinary team, and a prevention bundle. A total of 38 teams throughout the VHA network participated in this study. The most common interventions were implemented with the following frequencies: staff education 68% (26 out of 38), documentation templates implemented 61% (23 out of38), and utilization of equipment (e.g., protective dressings, chair cushions) 55% (21 out of 38). These interventions led to a 44% reduction in PI development, decreasing the PI incidence from 1.6/1000 to 0.9/1000 bed days. This was statistically significant ($p = 0.017$).[13]

Problems with Documentation

Accurate documentation of patient's condition, plan of care, and treatments is an essential component of quality nursing care. Thoroddsen and colleagues conducted a cross-sectional descriptive study to review the completeness of PI documentation. Accuracy and completeness of documentation was defined as the correlation between the data, the patient's presentation, and the care delivered. Their findings indicated that only 60% of the documentation in the medical record reflected a PI and only 42% of the patients' records included documentation of PI prevention interventions. Risk factors for PIs were rarely identified. The authors concluded that the lack of documentation can impact patient safety and lead to adverse outcomes.[14]

No studies were identified that evaluated the impact of educational interventions in combination with direct feedback to nurses following expert skin assessment and documentation review.

Project Aims

The specific aims of this quality improvement project were to:

1. Increase bedside nurse knowledge of PI assessment, staging, documentation, and occurrence reporting
2. Improve the accuracy of bedside nurse assessment and staging of PIs
3. Improve bedside nurse documentation of PIs in the medical record and occurrence reporting system
4. Increase the number of wound, ostomy, and continence nurse (WOCN) referrals

Methods

Donabedian's theoretical model for assessing health quality in terms of structure, process, and outcomes guided the development of this project. The project occurred within the structure of a medical/surgical inpatient unit. Improvement in nurse knowledge regarding assessment and staging of PIs served as the processes examined in this project. Outcomes were evaluated comparing pre- and post-intervention scores demonstrating changes in nurse knowledge and accuracy of pressure injury staging and the number of WOCN referrals.[15] The Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0 Guidelines provided a framework for this project.[16]

Setting

This quality improvement project took place in a 315-bed, community-based, acute-care hospital and Level II trauma center affiliated with a large integrated delivery network in Western Pennsylvania. A 43-bed medical-surgical unit served as the intervention pilot unit. This unit was identified in 2017 as having one of the highest rates of PIs in this hospital (4.17%). Patients on this unit were thought to be at higher risk for PIs due to long length of stay and complex care needs.

Sample

The patient sample included all patients admitted to

the 43-bed medical-surgical pilot unit from August–November 2018. The patient population on this unit included patients with varied medical diagnoses (e.g., stroke, diabetes) and post-operative surgical patients (e.g., colorectal, vascular, or other surgical procedures). The staff sample included all 41 registered nurses (RNs) and two licensed practical nurses (LPNs) on this medical-surgical unit.

Ethical Considerations

This project was approved by the health system's institutional review board and the hospital's evidence-based practice and research councils. An abstract of the project was submitted to the university's human research protection office, which agreed that this is a quality improvement project and did not require full review by the institutional review board. All data collected was identified, documented in an Excel spreadsheet, and stored in a cloud-based data storage secured through the health system's information technology network with restricted access, and, if applicable, was transmitted utilizing encryption to safeguard the information.

PI Staging Discrepancy Assessment

A baseline assessment to identify possible PI staging discrepancies was completed using occurrence reports submitted from August through November 2017 and was repeated during the intervention period from August through November 2018. The project coordinator compared the description of the PI in the occurrence report with nurse documentation in the medical record.

Education Program

A two-part education program targeted toward improving nurses' knowledge related to PI staging was delivered to nurses on the pilot unit. Before and after the education interventions, nurses completed a 15-question test developed by the project coordinator. This pre- and post-test included 10 case descriptions of PIs, and participants were asked to identify the appropriate PI stage. Five additional questions addressed reporting and appropriate documentation requirements. The test content was reviewed by a random sample of WOCNs in the health system to assure clinical accuracy.

Part 1: All nurses on the pilot unit were asked to complete a pre-test to assess their knowledge related to PIs and were assigned the online National Database of Nursing Quality Indicators (NDNQI) pressure injury training modules 1 and 2 (v. 5.0). Module 1 addressed PIs and staging; module 2 covered other wound types and skin injuries (e .g., diabetic ulcer, venous stasis ulcers). Nurses were asked to complete these modules as a part of their scheduled work within a 30-day period. Each nurse that completed the training modules provided an electronic certificate to the project coordinator.

Part 2: The project coordinator provided four face-to-face educational sessions regarding assessment, staging, and appropriate documentation of PIs, as well as the required MCARE reporting.

Nurses then completed a post-test within 28 days of completing the online and face-to-face training sessions. The project coordinator provided direct feedback to the bedside nurses on the results of their pre- and post-test results. For each incorrect answer selected, the project coordinator reviewed the appropriate stage and the rationale with the nurse.

Skin Observations

Skin observations were conducted once a month for four consecutive months. The project coordinator conducted a full assessment of all patients on the pilot unit along with unit-based skin care champions.These bedside nurses are required to complete the four NDNQI PI training modules (PIs and staging, other wound types and skin injuries, PI survey guide, and community vs. hospital/unit acquired PIs); accompany the WOCN on their unit to assess PIs; and attend monthly educational meetings. This assessment included a head-to-toe inspection of the patients' skin, noting the color, turgor, temperature, presence of wounds or lesions, and any areas of moisture.

Medical Record Audits

The project coordinator reviewed the skin assessment documented in the medical record to determine congruence between the observation and the last documented skin assessment. Patients with Stage 2 or greater PIs were referred to a WOCN. The project coordinator discussed any discrepancies between the nurse's documentation of PI stage and the findings noted by the skin care champion or WOCN with the nurse caring for the patient, reinforcing information from the online training modules and documentation in service training. The project coordinator shared a summary of assessment and documentation findings during the monthly staff meetings to give feedback for all nurses on this unit. Nurses absent from the staff meetings received the information in a secure email.

WOCN Referrals

The average number of WOCN consults per month for the four-month intervention period was compared with the same period in 2017 to ascertain if there was an increase following the educational intervention and direct observations.

Results

Sample Description

The sample of nursing staff completing the education program included 41 RNs and two LPNs on a medical or surgical unit in a community hospital.

PI Skin Discrepancies

Twenty-three PIs were reported through the occurrence reporting system in the baseline period of August–November 2017 on the pilot unit. The WOCNs noted PI staging discrepancies in 22% (n = 5) of the cases reporting in the baseline period. Thirty-eight PIs were reported in the occurrence reporting system in the post-intervention period of August–November 2018. The WOCNs noted PI staging discrepancies in 24% (n = 9) of the cases reported in the post-intervention period.

Education Program Outcomes

Thirty-two RNs (74%) and two LPNs (100%) completed the two online NDNQI pressure injury training modules. Staff also attended a face-to-face training offered by the project coordinator addressing skin assessment, staging, prevention strategies, and documentation.

The pre- and post-test results and follow-up staff discussions were entered in an Excel spreadsheet. Individual questions were evaluated by absolute frequency and the percent correct for the pre- and

Table 1. Pre/Post-test Results

Question	Pre N = 32	Post N = 32
Q1	31 (93.9%)	31 (96.9%)
Q2	29 (87.9%)	21 (65.6%)
Q3	32 (97.0%)	29 (90.6%)
Q4	33 (100%)	32 (100%)
Q5	28 (84.8%)	31 (96.9%)
Q6	30 (90.9%)	32 (100%)
Q7	24 (72.7%)	28 (87.5%)
Q8	15 (45.5%)	25 (78.1%)
Q9	33 (100%)	32 (100%)
Q10	17 (51.5%)	31 (96.9%)
Q11	31 (93.9%)	31 (96.9%)
Q12	33 (100%)	32 (100%)
Q13	17 (51.5%)	26 (81.3%)
Q14	33 (100%)	32 (100%)
Q15	30 (90.9%)	27 (84.4%)
Total	84.1 + 9.08%	91.4% + 8.33%

Overall Knowledge Improvement $p = 0.004$

Table 2. Comparison of Pressure Injuries Assessment

Bedside Nurse	Skin Care Champion/ Project Coordinator	WOCN
Stage 2	Stage 2	Stage 2/Early Stage 3
Stage 1	Stage 2	Stage 2
Abrasion	Abrasion	Stage 2
Incontinent-Associated Dermatitis	Stage 2	Stage 2
Abrasion	Abrasion	Deep Tissue Injury
Unstageable	Stage 3	Stage 2
Stage 2	Suspected Deep Tissue Injury	Yeast Infection
Stage 3/Possible Deep Tissue Injury*	Stage 4	Stage 3
Missed Assessment*	Missed Assessment	Stage 2

* PI coccyx/ischium, same patient

post-test respectively, noting the direction of change per question. Thirty RNs and two LPNs completed the pre- and post-test. Nurses demonstrated improved knowledge in eight of the 15 questions on the post-test. The total score for the pre- and post-test questions was calculated by using a paired sample t-test. Utilizing the Statistical Package for the Social Sciences (SPSS) software version 25.0.0 for Windows, a p value of .05 was considered statistically significant. The average pretest score mean was 84.1% + SD 9.08% and the average post-test mean score was 91.4% + SD 8.33%. There was a statistically significant improvement ($p = 0.004$) in nurse knowledge about PIs following the completion of the online educational modules and face-to-face training sessions offered by the project coordinator (Table 1).

Skin Observation and Medical Record Audit

A "snapshot" observation was conducted on one day each month for four consecutive months between August–November 2018 on the pilot unit. The project coordinator, a unit-based bedside nurse identified as a skin care champion, and a WOCN conducted the observations. On the days of the direct observations, 143 patients were admitted to the pilot unit. A skin assessment was conducted on 108 (76%) of these patients. (Note: A few patients refused a skin assessment or were off the pilot unit for tests at the time of the skin assessment.) A full skin assessment included a head-to-toe inspection of the patient's skin, noting its color, turgor, and temperature, as well as any presence of wounds, lesions, or areas of moisture. Thirteen PIs were identified. The project coordinator noted nine staging discrepancies between the documented stage of the PI by the bedside nurses and the stage identified by the skin care champion and project coordinator. For example, a nurse assessed a patient as having incontinence-associated dermatitis; however, the skin care champion and project coordinator assessed the wound as a Stage 2 PI. The bedside nurse documented accurate PI staging in only 31% of PI observations. The staging discrepancies noted between the bedside nurse, skin care champion/project coordinator, and WOCN are noted in Table 2.

WOCN Referral Results

The monthly WOCN referrals increased by 18% compared to the baseline period. Twenty-eight WOCN referrals were submitted from August through November 2017.

Thirty-two referrals were submitted from August through November 2018.

Discussion

This quality improvement project was designed to improve the accuracy of nurse assessment, staging, and documentation of PIs by the bedside nurses following completion of an online educational module, reinforced by a face-to-face session highlighting appropriate documentation of PIs. The project incorporated a review of documented PI assessment and staging by the bedside nurse and direct observations with immediate feedback for any discrepancies noted. A statistically significant improvement in knowledge regarding PIs following these interventions was identified through administration of a pre- and post-test. The direct observation feedback served to reinforce accurate PI assessment and staging. For example, during one of the direct observations, the bedside nurse assessed a PI as unstageable (wound covered in eschar and slough), but based on the characteristics (partial thickness loss of the dermis layer, red or pink wound bed) and WOCN evaluation, it was determined to be a Stage 2 PI. These results were consistent with findings noted by Miller et al. that described improved staging of PIs following educational programs including self-learning modules and lectures.[12]

There was a negligible increase in PI staging discrepancies from the baseline data in the occurrence reporting system (22% to 24%). Notably, 44% of the PIs reported in this system in the post-intervention phase were entered by nurses who had not completed the online or face-to-face training. Nurses in this study failed to document an accurate assessment of the PI stage in 69% of the observed cases. Appropriate PI assessment and staging are skills that may develop over time and may require validation by clinical experts to build competency.

Thoroddsen et al. noted that incomplete or inaccurate documentation could lead to missed hand-off communication opportunities affecting patient safety and outcomes. In this project, 9% (n = 10) of the skin assessments and 30% (n = 108) of the preventive interventions were noted to be inconsistently documented or absent in the electronic medical record. Although a review of documented interventions was not a defined objective of this quality improvement project, the project coordinator noted the lack of documentation of interventions used to treat or prevent PIs. This project heightened awareness of accurately assessing and staging PIs as well as drew attention to the need to document preventive strategies. Results of the project findings were shared through the monthly staff meetings and daily care huddles.[14]

The Wound, Ostomy and Continence Nurses Society's scope of practice outlines the contribution of the WOCN to improve "the quality of care, life, and health of healthcare consumers with wound, ostomy, and/or continence care needs."[17] This project demonstrated the enhanced value of the expertise of the WOCN to support accurate assessment of PIs and enhance bedside nurse competency. WOCN referrals may be an underutilized resource in the care of patients with PIs. There may be an opportunity to use telemedicine to enhance a WOCN's ability to assess, diagnose, and manage PIs and other chronic wounds; the successful use of telemedicine in dermatology suggests the promising potential of bringing clinical expertise to the management of PIs and capitalize on limited WOCN resources.[18]

Limitations

This project was piloted on one nursing unit and included a small convenience sample. The project coordinator was not able to require or mandate training for this quality improvement project; however, nurses were strongly encouraged to participate in the education strategies. Nurse scheduling complicated the conduct of this quality improvement project. It was not possible to assess improvement in individual nurse assessment skills, as different nurses frequently were assigned on each of the observation days. This project did not include an assessment of prevention or treatment interventions that were incorporated into the plan of care.

Implications for Practice

Pressure injuries represent a serious patient safety concern that may be prevented or minimized with accurate assessment by the bedside nurse and referral to a WOCN. As PIs develop or worsen, they can prolong hospitalization, lead to infection, impair mobility, and increase morbidity and mortality. This project demonstrated increased nurse knowledge following an online and face-to-face educational program about PIs. The project confirmed that nurses frequently fail to correctly assess, stage, and document their findings. It

is imperative that nurses accurately assess and stage PIs in order to implement appropriate interventions for prevention and treatment.

The education program and assessment strategies described in this paper would be enhanced with mandatory participation in the education strategies and ongoing feedback provided to the bedside nurses regarding the accuracy of their assessment, staging, and documentation of PIs, with support from a WOCN. Ongoing education about PI assessment, staging, and documentation requirements should be incorporated into the annual nursing competencies to ensure appropriate actions are implemented. The NDNQI pressure injury training modules may serve as an effective educational strategy to increase nurse knowledge about appropriate assessment and care of pressure injuries; however, this online training may be insufficient by itself and should be supported with regular skin surveillance rounds with direct feedback from clinical experts to enhance nurses' assessment and staging skills. Hospitals will need to determine available resources to accomplish an improvement in accurate assessment, staging, and documentation of PIs. Future projects are warranted to evaluate interventions to prevent PI development or progression, and to study the impact of utilizing TeleWOCN[18] in rural areas as well as hospitals that do not possess a WOCN.

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Allergy-Related Medication Error Reports Submitted to a Large Patient Safety Reporting System

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Abstract

Medication allergies can and do cause patient harm. Managing a patient's allergies is a challenge for institutions because failures can happen throughout the medication-use process. A total of 854 Medication Error events associated with patient allergies that occurred between July 2016 and June 2018 were reported through a large event reporting database. Analysts categorized these events into the following five stages: obtaining information from the patient, documenting allergies in the record, ordering medications, verifying orders, and administering medications. More than half (56.3%; n=481) of the events reached the patient. Most likely to reach patients were events involving breakdowns when obtaining information from the patient (74.7%, n=68 of 91) and administering medications (97.6%, n=281 of 288). In reports that indicated allergies were properly documented, the majority (87.3%, n=289 of 331) of the events that reached patients passed through two or more stages. Organizations may use this information to inform proactive efforts to implement system-based strategies to improve the medication-use process.

Keywords: *drug allergy, drug reaction, medication errors, medication safety, patient safety*

Introduction

Since the 1980s, the validity of medication allergy documentation has often been questioned, but with the exception of adding an electronic method to document and screen allergies, not much has changed.[1] Yet the selection of appropriate medications and dosages depends on the availability and review of this critical patient information. Without detailed information about a patient's allergy history, healthcare practitioners cannot develop safe and effective treatment plans.

It is estimated that about one-third of patients confuse drug allergies with intolerances, making it difficult to

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define which allergies are significant.[2] Additionally, when a standardized approach is lacking in collecting, documenting, and interpreting allergies, practitioners are limited to using a less efficacious agent to treat a patient who has an inaccurately documented allergy. Because of this, patient harm, increased cost of hospital stays, and increased mortality can occur.[2-4] Likewise, patients can experience life-threatening reactions if they receive a medication to which they have a true allergy.

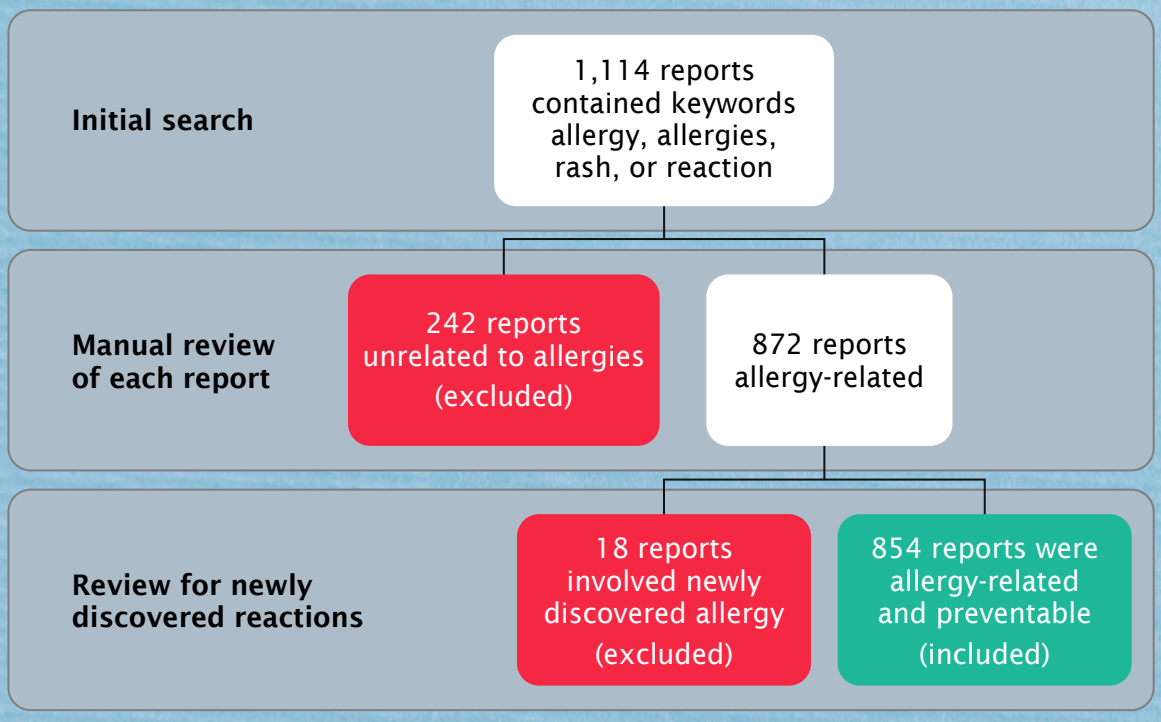
Although the topic of errors related to drug allergies was covered in the *Pennsylvania Patient Safety Advisory* in 2008,[5] analysts observed continued submission of these reports since then. The continued occurrence of these events, along with increased reliance on health information technology to document and alert practitioners to potential drug-allergy issues, warrants an analysis of recent reports to identify new or persistent factors contributing to errors. This article identifies the stages in documenting and using allergy information in which failures can occur and provides system-based strategies to reduce the risk of medication errors associated with allergies.

Methods

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS), a statewide, mandatory, patient safety event reporting system database for Medication Error events that occurred from July 2016 through June 2018 using the following criteria:

- Reports submitted with the detailed event type "Medication Error, Monitoring Error, Documented Allergy".
- Reports submitted with the top-level event type "Medication Error" and assigned the monitor codes PI2 or rf04. The design of PA-PSRS allowed patient safety analysts at the Patient Safety Authority (PSA) to code reports with predefined codes during ongoing event report review to enable retrieval of those reports. The monitor codes PI2 and rf04 were used to tag events involving unrecognized, undetected, overlooked, or documented patient allergies.
- Reports submitted with the detailed event type "Medication Error, Other" which contained the keywords "allergy," "allergies," "rash," or "reaction" in their event narratives. These keywords were selected based on years of reviewing individual PA-PSRS event reports and with the intent to identify potential allergy events.

Figure 1. Inclusion Criteria



The search returned 1,114 reports. After manual review of the data, 242 event reports were excluded because the events were unrelated to allergies (see Figure 1). Reports (n = 18) in which the event description explained that the patient had no known allergies before administration of the medication were also excluded because these allergy events could not have been prevented. A total of 854 events were included in final analysis.

The medications involved in the reports were provided by the reporting facilities and were standardized by an analyst to generic names. When a medication name field was blank, but the name was provided in the event description, an analyst adjusted the medication name field. The reporting facility provided the facility type, patient care area, patient age, node of the medication-use process, event type, and event description.

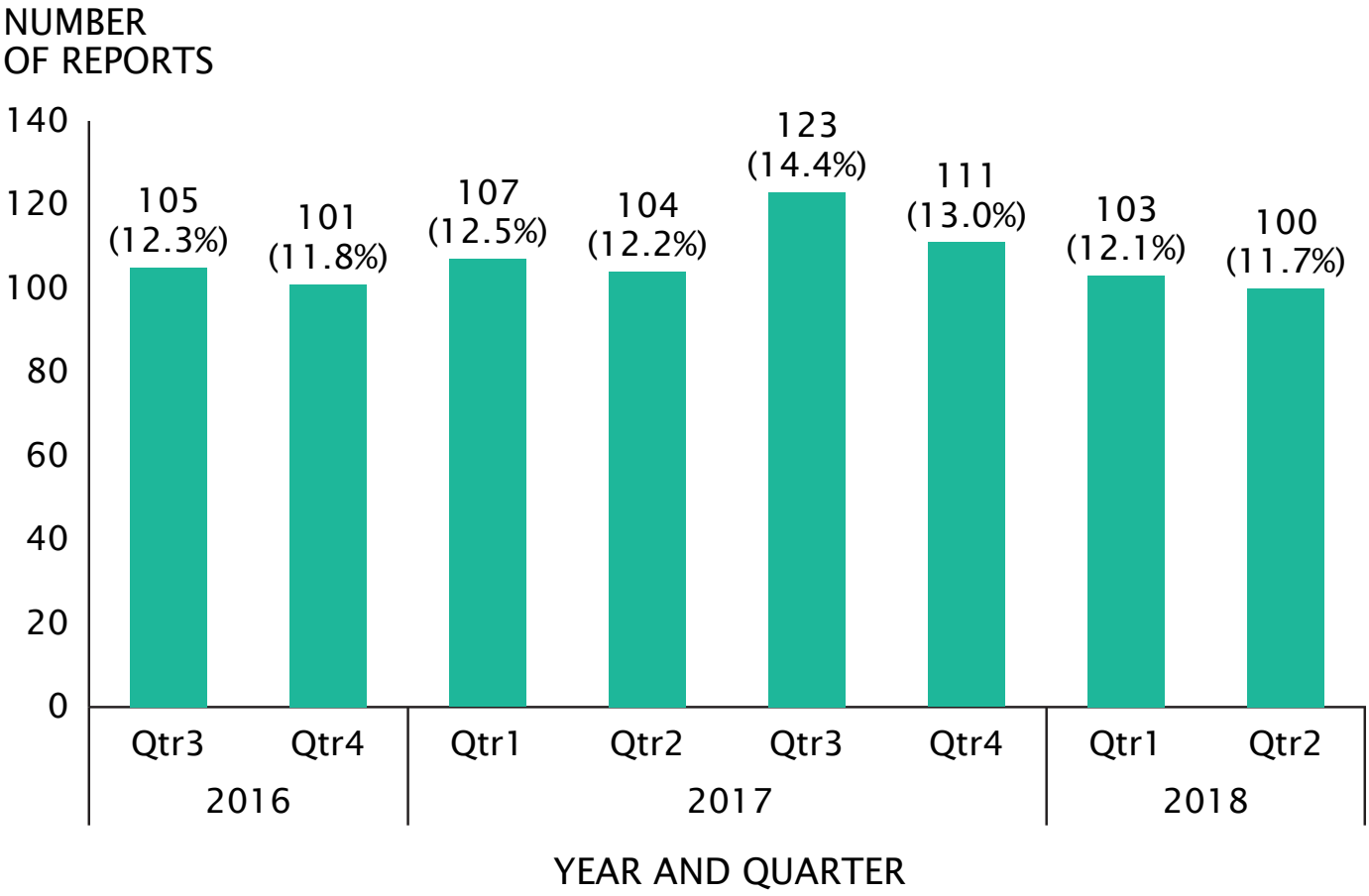
Based on information included in the event descriptions, reports were categorized into three groups: the event reached the patient, the event was caught before reaching the patient (i.e., near miss), and it was unclear whether the event reached the patient. Analysts defined five stages and then categorized each event into one of those five stages in which allergy-related failures occurred. (See Table 1 for definitions of each stage.) Events that reached the patient were also analyzed to determine whether there was a reaction to the administered medication and if any intervention was conducted.

Review and analysis of deidentified reports submitted through the database have been exempted from institutional review board review by the Drexel University College of Medicine Office of Regulatory Research Compliance. Any narratives provided in the manuscript have been contextually deidentified.

Results

A total of 854 documented events were identified. No increase or decrease was evident in the number of events reported per quarter (see Figure 2). The three most common drug classes mentioned in reports were anti-infectives (37.4%, n = 319 of 854), opioid analgesics (14.8%, n = 126), and nonopioid analgesics (10.1%, n = 86). The most common reported patient care

Figure 2. Allergy Events by Quarter (N = 854)



areas for allergy-related events were the emergency department (20.3%, n = 173), perioperative services (e.g., operating room, ambulatory surgery, pre- and postoperative care areas; 17.7%, n = 151) and general medicine/surgical units (13.6%, n = 116).

Analysts identified that 56.3% (n = 481 of 854) of the events reached the patient and 41.9% (n = 358) did not. Analysts were unable to determine whether the event reached the patient in 1.8% (n = 15) of the reports.

Analysts identified that allergies were reported to be properly documented in 60.9% (n = 520 of 854) of the events. Nearly two-thirds (63.7%, n = 331 of 520) of these events reached the patient, with 87.3% (n = 289 of 331) passing through two or more stages.

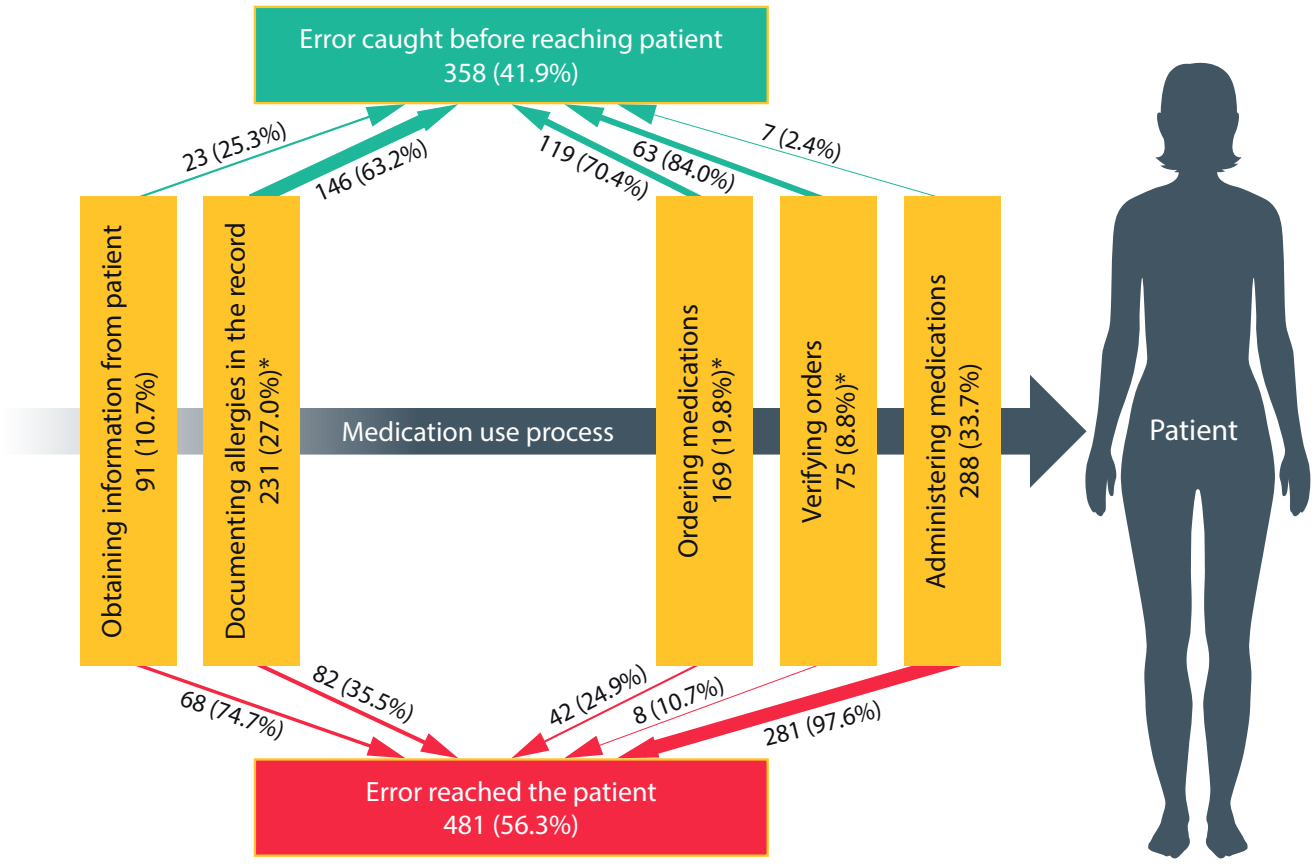
Stages in the Processes to Obtain and Use Allergy Information

Events were categorized into one of five event failure stages (see Figure 3). The most common stages were administering medications, documenting allergies in the record, and ordering medications. In almost 75% of events involving breakdowns in obtaining a complete allergy history from the patient or caregiver, the patient received at least one dose of a medication to which they were allergic. In the other stages, except for administering medications, a lower percentage of reported errors reached the patient. Either the patient or a caregiver intercepted 2.4% of failures in the administering medications stage before administration of the medication. Refer to Table 2 for examples of the events listed below.

Obtaining Information from the Patient

About 10% of the reported events were categorized in the obtaining information stage. Almost 95% (94.5%; n = 86 of 91) of these events were related to errors in gathering accurate information from a patient. The reporter stated that the patient forgot about their allergy in the remaining 5.5% (n = 5).

Figure 3. Stage of Medication-Allergy Errors



Note: Data reported from July 2016 through June 2018. Percentages in the figure are based on N = 854. Totals do not equal 100% because of rounding.

* Analysts were unable to determine whether 15 (1.8%) events (3 documenting, 8 ordering, 4 verification) reached the patient.

Documenting Allergies in the Record

More than a quarter of the events were categorized in the documentation stage. The most common reason for failures were due to personnel not documenting known allergies in the medical record (52.4%; n = 121 of 231). The other failures in the documentation stage included documentation practices or system designs that precluded practitioners from seeing the allergies (e.g., listing allergy as an adverse drug event; listing the allergy on a sticky note; having multiple, disparate systems or locations in which to document allergies [28.1%, n = 65]; and documenting an allergy in such a way that an electronic alert was not triggered upon ordering, verifying, or administering medications [19.5%, n = 45]. More than a third (35.5%, n = 82) of the events reached the patient. The majority (79.5%, n = 116 of 146) of the events that did not reach the patient were caught during safety rounds or chart reviews.

Ordering Medications

Almost 20% of the reports were classified in the ordering medications stage. The most common failure in this stage was ordering medications before conducting an allergy review (62.1%; n = 105 of 169). Another 34 events (20.1%) were related to practitioners electronically overriding a warning or deciding to order medication regardless of allergy. The other contributing factors were information unavailable, unnoticed, or not readily accessible at the time of order (14.8%; n = 25) and procedural errors (3.0%; n = 5), such as missing orders for premedications, orders copied forward, or confusing medication names. Almost a quarter (24.9%; n = 42) of the events classified in this stage reached the patient.

Verifying Orders

Failures during the verifying orders stage accounted for 9% of all reports. Events related to this stage mostly involved the pharmacy either missing or overriding the allergy warning (74.7%; n = 56 of 75). These were all caught before administration to the patient.

About 13% (13.3%; n = 10 of 75) of the events involved mechanisms that bypass pharmacy verification. These mechanisms include autoverification of orders (i.e., electronic systems that verify orders based on specific parameters set by the healthcare institution and thus bypass pharmacy review) and automated dispensing cabinet (ADC) override functionality that allows vending of medication without pharmacy review.

The final 12.0% (n = 9 of 75) of reports involved food, dye, latex, or diet allergies that the verifying orders

Table 1. Definitions of the Stages in Which Medication Allergy Related Failures Occurred

Stage	Definition
Obtaining information from the patient	Missed, incomplete, or inaccurate allergy information obtained from the patient or caregiver upon start of encounter or admission.
Documenting allergies in the record (electronic or paper)	Inaccurate or incomplete allergy information added to patient's record.
Ordering medications	Breakdowns when prescribers order medications, including failure to review or bypassing known, documented allergies. This stage was selected when an order was caught in the verification phase or when the prescriber directed administration of a medication despite the apparent knowledge by the provider of a documented allergy.
Verifying orders	Failure to stop an order that was prescribed to the patient with a known, documented allergy. This stage was selected if an order was caught in the administering medications phase, the verification process was automated and bypassed pharmacy review, or pharmacy dispensed the medication directly to the patient.
Administering medications	Failure to stop the administration of a medication that may or may not have been verified but was prescribed to a patient with a known, documented allergy. This stage was selected when the order was discovered after administration of the medication. This stage was also selected if the error was caught by the patient or caregiver at the time of administration.

step failed to capture but were caught during the administering medications stage. Eight (10.7%) events categorized in this stage reached patients, with five events involving autoverification processes.

Administering Medications

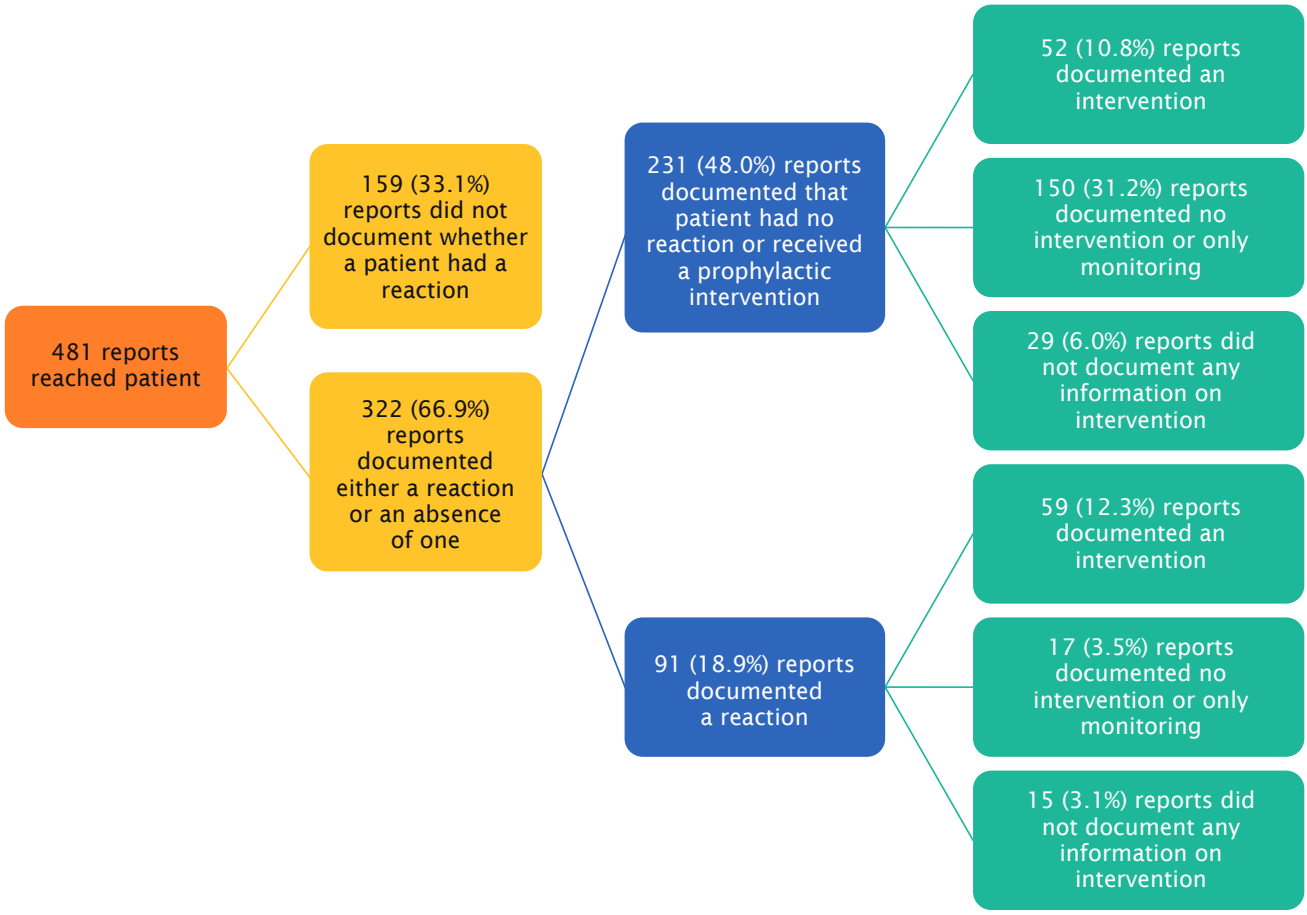
The final stage in which an allergy-related error can be intercepted before the medication reaches the patient is that of administering medications. A third of all analyzed events reached this stage. Most of these events (66.3%, n = 191 of 288) were errors that made it through the institution's standard system of checks (e.g., prescriber ordering the medications and pharmacy verifying the orders). It was impossible to reliably tell how many of the reports were verified by pharmacy, but analysts identified 61 (21.2%) reports that stated pharmacy verification was bypassed. This bypass occurred for reasons such as use of procedural solutions and preparations to which the patient had an allergy, the use of verbal or standing orders, or medication administration by ancillary services. The other events involved allergies to nonmedication substances such as food, dye, and latex (8.7%, n = 25) and other factors (3.8%, n = 11) such as system downtime, premedications not given despite orders, barcode not scanned, and allergies to a specific brand of medications.

Reactions and Interventions

Out of the 481 events that reached the patient, 322 (66.9%) reports mentioned information about reactions, including absences of a reaction (see Figure 4). In 48% of the events, the reporter stated that the patient did not experience a reaction or that an intervention was being conducted prophylactically. In almost 19% of the events, a reaction was noted. In these reports, there were 113 statements describing various reactions (more than one statement could be contained in a single report). The most common reactions mentioned were rash (5.8%, n = 28 of 481); face, lips, throat swelling, including anaphylaxis (4.8%, n = 23); itching (3.3%, n = 16); and hives (1.9%, n = 9).

Interventions were reported in 111 events (52 events in the group with no reaction and 59 events in the

Figure 4. Allergy Documentation* (N = 481)



Note: Data reported from July 2016 through June 2018. Percentages in the figure are based on N = 481.

* As reported in medication-allergy-related events that reached the patient.

group which experienced reactions); in the events that reported an intervention, 141 statements referencing various interventions were noted (multiple interventions could be reported). The most common interventions were administration of diphenhydramine (14.8%, n = 71 of 481), administration of steroids (3.7%, n = 18), admission to ED, activation of a rapid response team or intubation (2.3%, n = 11), and rinsing the affected area (2.3%, n = 11).

Discussion

The findings from this analysis indicate that systematic failures in addressing patient allergies continue to occur. These failures are associated with obtaining accurate allergy information as well as documenting, ordering, verifying, and administering medications.

In this analysis, more than a third of allergy-related events occurred when gathering and documenting information from the patient. These are critical functions of the medication-use process that if bypassed or inappropriately completed, can impact the effectiveness of other safety barriers. Fewer than half of the events in those two stages reached the patient, while almost two-thirds of the events in the ordering, verification, and administering medications stages reached the patient. More than a third of the events in the obtaining and documenting allergy data stages were intercepted during chart reviews or safety rounds, demonstrating the potential positive impact of such reviews. Incorporating clinical pharmacists in the intake process, conducting a thorough interview with the patient or caregiver, reviewing previous encounters, communicating with other healthcare professionals (e.g., the patient's primary care physician, community pharmacist), and appropriately documenting that information can help avoid errors when gathering and documenting allergy information.[6-10]

Nearly two-thirds of events where allergies were properly documented still reached the patient. This number may be skewed by reporting bias where practitioners often believe that errors that do not reach the patient do not need to be reported.[11,12] Nevertheless, it is concerning that so many events still made it through all safety steps and reached patients. All the failures that occurred in these events reaching the patient passed through at least one stage, but more than 87% (87.3%; n = 289 of 331) passed through two or more stages.

In the ordering medications stage, more than a quarter of events reached the patient. In those events, analysts determined that the prescriber likely controlled or justified the ordering, verification, and administration of the medication. Although some of these events took place during emergencies, it is important for institutions to examine these situations, develop better clinical decision support functions in the medical record, and attempt to minimize practices that bypass safety barriers. The other events categorized in the ordering medications stage did not reach the patient because they were caught during either order verification or medication administration.

Analysts identified bypassing pharmacy verification as a contributing factor in at least 19% of events that reached patients in the ordering, verifying, and administering stages. The use of autoverification and ADC override functionality contributed to some of these events. Autoverification functions are often used in the ED to avoid having pharmacy verify each order.[13] If these functions are to be used, they should be used with caution, taking care to disallow automatic overrides that bypass standard safety features. It is important for institutions to determine when pharmacy verification is bypassed and consciously define safety protocols or procedural limitations that add additional safety measures.[14]

Risk-Reduction Strategies

Organizations can use the information presented here to review processes in place to gather, document, retrieve, and use patient allergy information when delivering patient care. System-based improvements are more effective and produce results with less variability. Consider the strategies described below, which are based on a review of current literature, events submitted to the database, and observations from the analysts.

- Ensure that all pertinent information regarding allergies is available to practitioners when ordering, verifying, and administering a medication.[5] Note and clearly communicate throughout the patient record any lack of current allergy information. Ensure that the display of allergy information is prominent throughout the patient record.
- Review or create standardized allergy collection forms, either electronic or paper-based. Require the inclusion of a description of the reaction; date of the reaction (or approximation); date the

allergy is recorded; and what intervention, if any, was done previously.[5] A specific, standardized questionnaire can help the patient give more accurate data.[7] Ensure that all services (e.g., ED, operating room, imaging services, general medical/surgical care areas) are using this form.[5]

- Determine which practitioners will document allergy information and ensure that this documentation happens before medication administration or procedural interventions.[5] If it is impossible to document allergy information before administering initial doses (e.g., during an emergency), implement a process to reconcile allergies and administered medications afterwards to reduce impact, ensure practitioner awareness, and prevent future improper use. Reinforce with all practitioners the importance of checking allergy documentation before ordering, verifying, or administering medications.
- Consider employing clinical pharmacy services to assist with allergy documentation and identification of possible errors.[10]
- Configure EHR systems to require adding allergy information to patient records before allowing entry of medication orders. (Exceptions are emergencies that require medications to be administered before allergy documentation.)
- Access and incorporate allergy information from archival systems or other organizations upon patient transfer to help build a complete allergy history for a patient. Determine a method to reconcile those records with the current chart. Keep in mind that records from other facilities may include allergies already removed from the patient's profile in your organization and may not include newly diagnosed allergies.[5]
- Conduct chart reviews and spot checks regularly to look for inconsistent or absent documentation of allergies. Data in this article show that using such checks may prevent errors from reaching patients. These checks also allow institutions to assess whether policies for allergy documentation are being followed and identify workarounds or deviations from the standard work that may indicate a need for system redesign and improvement.
- Develop a policy and method for the timely modification or removal of an allergy when a qualified professional determines that an allergy is invalid or needs to be updated. The policy should include requirements for practitioners to document when and why an allergy was modified or removed.
- When an allergy is overridden, require documentation of the reason by the practitioner.
- Inform the prescriber that the patient has allergies during the receipt of verbal or telephone orders.[5,15] Develop policies and perform spot checks to ensure that allergy information is communicated properly.
- Configure ADCs to optimize use of the profiled mode. This function allows vending of a medication included on the patient-specific medication list on the ADC screen only after an order has been verified by a pharmacist. Use the profiled mode in ADCs throughout the organization, including those in the ED and perioperative care areas.[14]
- Establish policies to limit the use of overrides to bypass pharmacy verification (e.g., emergency situations).[14]
- Investigate the possible use of diagnostic tests (e.g., sensitivity skin tests) to determine the patient's sensitivity to specific allergens.
- Provide education to all practitioners on the procedures and safety strategies in place to accurately collect, document, and use patient allergy information. This includes education on how to best conduct patient interviews to recognize allergic reactions.
- Provide education to patients and patient-interest groups explaining the differences between allergies and adverse reactions. Inform patients about the importance of keeping a current record of allergies, dates of reactions, and the nature of reaction.
- Review reported allergy events in the organization to determine areas that may need additional support. Use triggers such as the use of stat doses of diphenhydramine, methylprednisolone, and epinephrine to determine whether additional review is necessary.[5]

Limitations

This review has limitations of scope and data. This data was submitted through PA-PSRS. As such, the PA-

PSRS database contains only data submitted by facilities required to submit reports to the database. Error reporting programs in general are limited by the quantity and quality of reports, which are highly dependent on the ease or complexity of the reporting system as well as the ability of each reporting facility to identify events and submit complete and accurate information. Also, although the data fields in the database are standard for all reporting facilities, there is variability in the type and amount of infor-

Table 2. Selected Event Report Narratives for Each Stage in the Processes to Obtain and Use Allergy Information*

Stage	Narrative
Obtaining information from the patient	Pt [patient] told medications that were being given and when finished pushing morphine pt states I am allergic to that med. ED [emergency department] MD [physician] notified and [diphenhydrAMINEdiphenhydramine] given.
	Pt had anaphylaxis reaction to morphine. Pt stated it is a newer allergy that pt forgot to mention for allergy list or to RN [nurse] before administering medication. Pt recalled allergy to morphine after administration. RN notified MD. Patient had hives. Pt did not suffer any injuries and remained stable after medications.
Documenting allergies in the record (electronic or paper)	Conflicting allergy information was listed on the medical record. Pharmacy dispensed the medication based on NKDA [no known drug allergies]. Elsewhere in the record, patient had a [ciprofloxa-cin] allergy listed.
	Allergy field only identifies allergies to 3 meds, but the midwife's clinical note identifies 4 meds. I noticed this as I read the clinical notes in preparation for safety rounds. Accordingly, I added clindamycin to the patient's allergy field.
Ordering medications	ED [emergency department] doctor ordered [ciprofloxacin] IV. Pt had documented allergy of skin flushing to Cipro. Pharmacist called MD to clarify order and MD wanted [ciprofloxacin] continued. [MD stated] reaction was not anaphylaxis and [he] would monitor pt. After 2 doses, pt developed red rash on chest and arms. ABX [antibiotic] changed.
	Percocet was ordered for a patient with an [oxycodone and aceta-minophen] and codeine allergy. The allergy warning was answered with "aware and will monitor." Prescribing physician was contacted and pain medication changed. He was unaware of the allergy even after answering the allergy notification.
	MD ordered enoxaparin for patient with coded heparin allergy. Reaction "unknown." Called to clarify. Investigated records. Confirmed that patient has history of HIT [heparin-induced thrombocy-topenia]. Updated allergy profile and recommended changing to fondaparinux. Orders changed accordingly.
Verifying orders	OxyCODONE was ordered and verified by pharmacy with a listed allergy to oxyCODONE on the chart. RN paged team, medication was not given.
	Pt was ordered for cefTRIAXone in the ED. Pt has allergy to cefepime documented as throat tightening and SOB [shortness of breath]. Order was auto verified without pharmacist review before administration.
	Pt allergic to red dye. Prescribed 5 mg of [oxycodone] oral solution. Oral solution has red dye. Pt pointed out med error before med was administered.
Administering medications	50 yo [year old] was seen in the ED and received amoxicillin, a listed drug allergy. Before discharge, the nurse verified verbally with the patient and known allergies. Patient verified that he had none. Patient took amoxicillin. Amoxicillin is listed as a known drug allergy. Nurse did not verify in the EHR [electronic health record]. No harm reached the patient. No additional services were required.
	At end of procedure, standing order for erythromycin ointment. Ointment was placed in eye and, when scanned, it showed a possible reaction with azithromycin. Physician was notified and he washed out eye and applied [tobramycin and dexamethasone] ointment.

* All narratives have been contextually deidentified.

mation reports recorded in various fields, including the event description field. This reduces the ability to identify factors that contributed to the event.

Conclusion

Information about patient allergies may not be documented accurately or utilized fully when providing patient care. When breakdowns occur, the risk is increased that medications to which patients are allergic will be administered and cause harm. Analysis of Medication Error event reports associated with patient allergy information found that more than the half of reported allergy-related events reached the patient. It is important to continue to assess and implement systems-based strategies to improve the accuracy and use of allergy information. Improved education and communication among patients, practitioners, healthcare facilities, EHR vendors, and network operators is needed to improve the flow of timely and accurate allergy information to the point of care.

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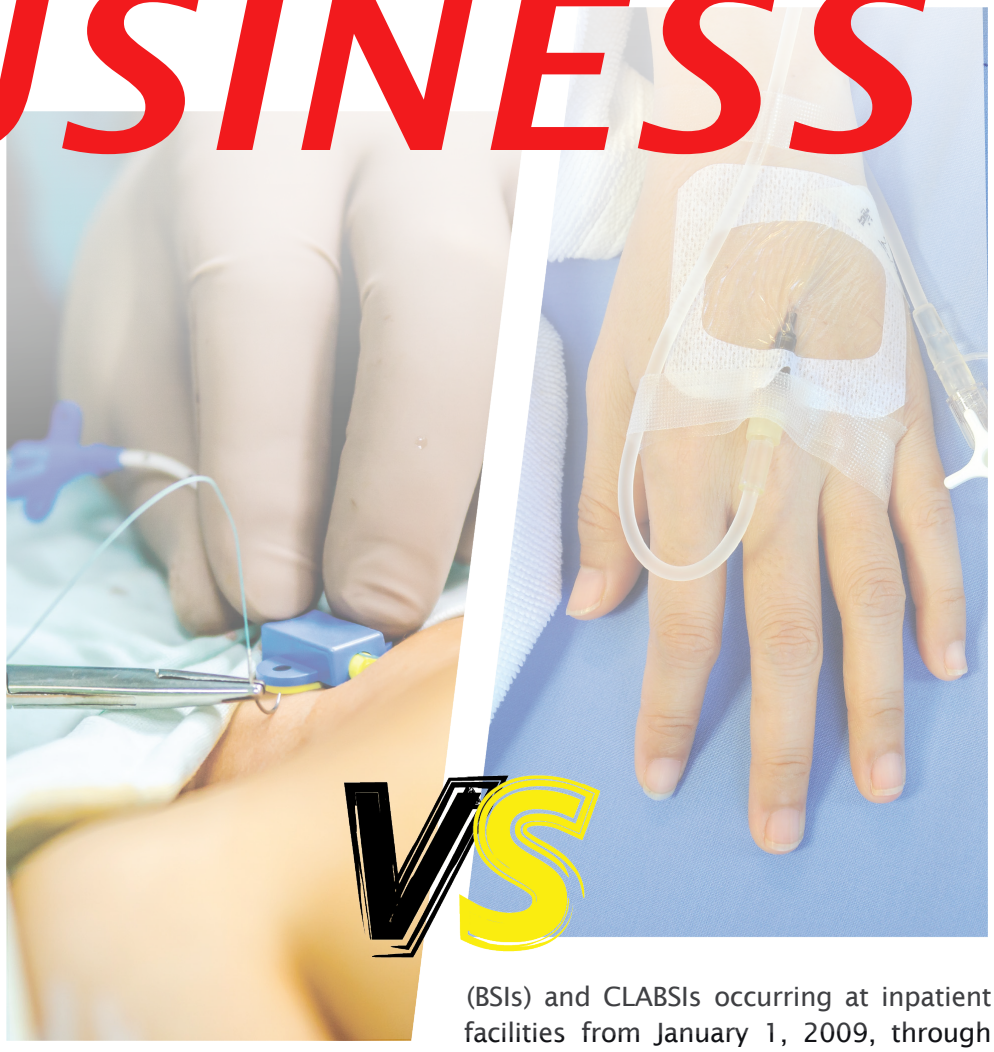

Peripheral and Central Venous Catheters Both Pose Risks

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Abstract

Venous access is an essential method of providing life-saving therapy. As part of intensive efforts to decrease the incidence of central line–associated bloodstream infections (CLABSIs), healthcare facilities may be increasing the use of short (noncentral) peripheral venous catheters (PVCs). To investigate this, the Patient Safety Authority (PSA) sought to explore the relationship of actual to predicted complications per central venous catheters (CVCs) and PVCs over a nine-year period. In addition, as PVCs are not without risk and CVCs pose risks aside from infection, we sought to identify the type and relationship of PVC to CVC complications and to quantify the timing and types of PVC and CVC complications and their associated risk factors.

A query of the PSA's statewide event reporting database, the Pennsylvania Patient Safety Reporting System (PA-PSRS), for venous catheter complication events and a query of the National Healthcare Safety Network (NHSN) database for both primary bloodstream infections (BSIs) and CLABSIs occurring at inpatient facilities from January 1, 2009, through December 31, 2017, yielded 115,937 events. A methodical sampling of PA-PSRS yielded 2,413 PVC and CVC events. These were analyzed for the timing of complications reported, the type of complication reported, and any identified risk factors.

Overall reports of PVC complications increased, and the correlation between actual and predicted PVC events over the nine years studied is strong and statistically significant. The slight decrease in the number of reported CVC complications was not statistically significant. The authors used regression analysis to determine the best-fitting line through the predicted and actual observed events during the period of observation. These data are not intended to present a predictive model of future events. No correlation was found between the numbers of PVC and CVC complications.

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The greatest number of PVC complications, particularly infiltration, occurred during catheter maintenance. Excluding NHSN-reported CLABSIs, the greatest number of CVC complications, particularly pneumothorax, occurred during catheter insertion.

Education and training are key to preventing intravascular device–associated complications. Healthcare facilities are encouraged to evaluate policy, procedures, and actual practices to eliminate complications and improve outcomes. In addition, quality improvement efforts aimed at decreasing CLABSIs should include measuring CVC complications and all PVC complications as a balancing metric.

Keywords: *peripheral venous catheter, central venous catheter, patient safety*

Introduction

The deidentified patient safety event below involving a fatal complication associated with a PVC prompted analysis of data reported through PA-PSRS.

> *Patient with multiple comorbidities was admitted with hematuria. A peripheral intravenous (IV) catheter was placed in patient's arm upon admission. The IV was removed 72 hours later because of pain at the insertion site. An ultrasound of the vein showed thrombosis. Patient was subsequently discharged but returned to the hospital complaining of increased discomfort and swelling and readmitted. Cultures obtained on the new fluid collection at the old IV site were positive. The patient became bacteremic then septic, and expired within 2 weeks of readmission.*

PVCs are the most commonly used medical device during hospitalization, providing fluids and other essential medications to patients.[1] Although many providers assume PVCs are benign, this event narrative illustrates that PVC use has risks.

In the United States, IV therapy—whether delivered centrally or peripherally—is the most common therapy provided to hospitalized patients. An estimated 85% of hospitalized patients receive IV therapy.[2,3] It is used to deliver medical treatment and as a component of life-saving therapy. Annually, about 330 million PVCs are used[4,5] and more than five million central venous catheters (CVCs) are inserted.[6] The selection of a PVC versus a CVC is determined by the types of infusions necessary, the anticipated duration of therapies, and the patient's overall medical condition.[7]

Failure to remove an infected catheter places the patient at risk of developing septic thrombophlebitis with PVCs and septic thrombosis of a great vein with CVCs.[8] Patients' pain and fears related to PVC replacements and failed attempts cost healthcare facilities in both money and patient satisfaction.[4,9]

Complications of CVC use, especially infection, are well documented,[8,10] while the incidences of infection and other complications related to PVCs are not well defined.[2] Reducing the number of CVC insertions is one strategy to reduce the number of CLABSIs and, as a byproduct, the incidence of other central line complications. Healthcare facilities may attempt to decrease the use of CVCs, if appropriate (or as medically necessary), by increasing PVC insertions. Analysts investigated whether decreases in the number of CVCs and CLABSIs are associated with an increase in the number of PVC complications as reported in PA-PSRS.

Methods

Level I Methods—NHSN and PA-PSRS

Data Queries

To compare numbers of PVC and CVC complications over time, analysts queried PA-PSRS for PVC and CVC complications *and* queried the NHSN for CLABSIs and primary BSIs occurring from January 1, 2009 (the first full year of NHSN reporting), through December 31, 2017. Infections, which are the majority of CVC complications, are reported through NHSN while the majority of PVC complications are reported through PA-PSRS. Due to facility reporting practices, an occasional infection may be reported through PA-PSRS. NHSN does not specify reporting the device for primary BSIs unless a CVC is involved.[7] By definition, a primary BSI is not secondary to an infection at another body site.[11] Although some primary BSIs unassociated with a CVC could still be associated with a PVC, in the absence of a better measure, analysts used NHSN primary BSIs in the general query as a surrogate for noncentral line peripheral catheter–associated BSIs.

The PA-PSRS query included the following event subtypes, which are designated pathways for reporting PVC and CVC complications:

- IV site complication
- Extravasation of drug or radiologic contrast
- Intravascular air embolism
- Pneumothorax

Analysts applied a keyword formula to identify and

distinguish peripheral from central catheter events in the PA-PSRS data query.

NHSN data for BSIs and CLABSIs are reported as whole numbers in accordance with established definitions and not open to interpretation. The authors did consider patient days; however, the current best practice for rate-based analysis is to use catheter days, which are only collected and reported for central lines. We could not have obtained catheter days for peripheral lines.

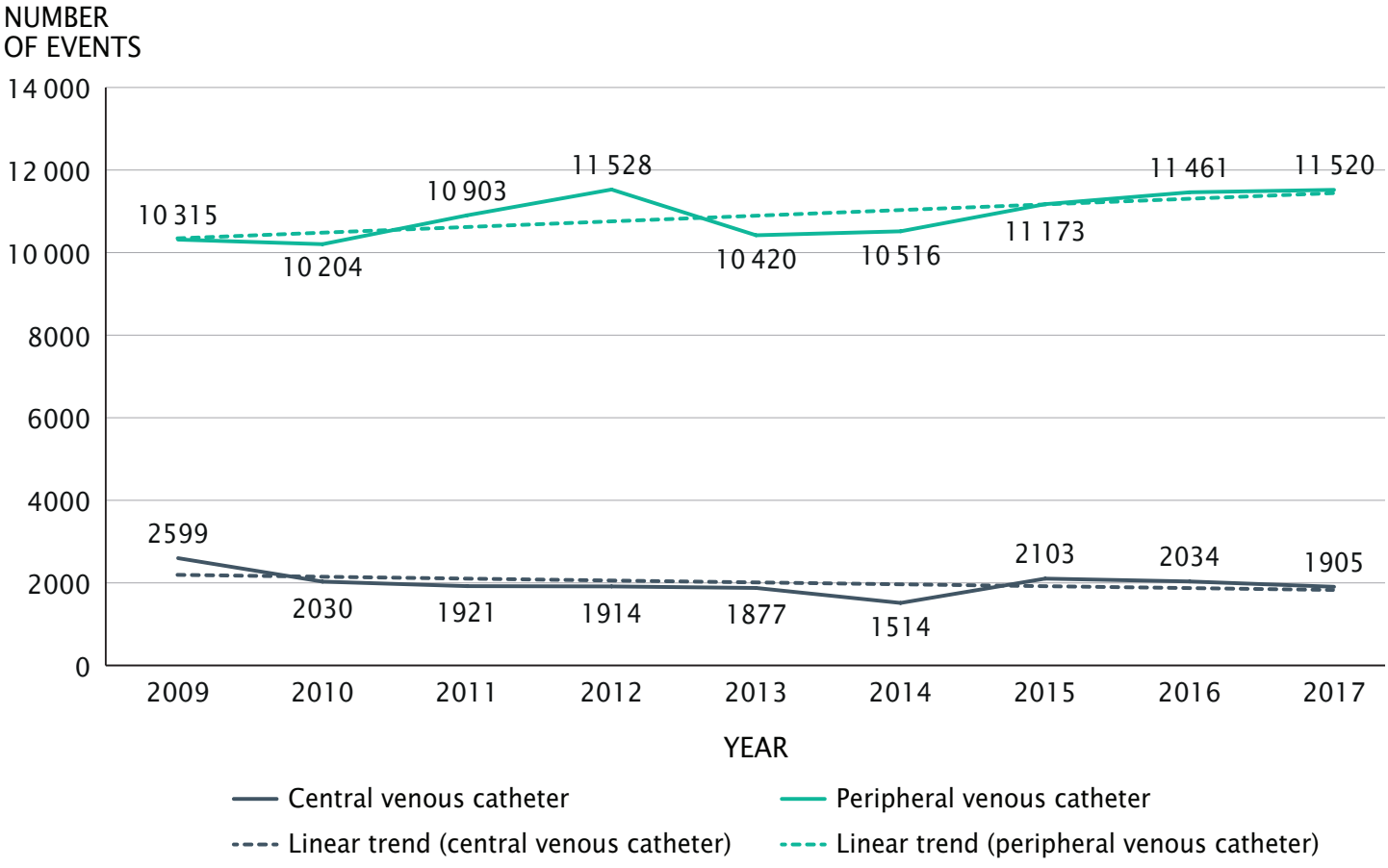
Review and analysis of deidentified reports submitted through PA-PSRS has been exempted from institutional review board review by the Drexel University College of Medicine Office of Regulatory Research Compliance. Any narratives provided in the manuscript have been contextually deidentified.

Definitions

PVCs were defined as midline catheters (the tip of the catheter ends in a peripheral vein) and peripherally inserted short IV catheters with and without fluids infusing.

CVCs were defined as peripherally inserted central catheters; catheters placed centrally in the femoral,

Figure 1. Peripheral and Central Venous Catheter Complications by Year with Linear Trend (N = 115 937)



Data sources: The Pennsylvania Patient Safety Reporting System was queried for venous catheter complication events in the following subtypes: intravenous site complication, extravasation of drug or radiologic contrast, intravascular air embolism, and pneumothorax. The National Healthcare Safety Network (NHSN) was queried for primary bloodstream infections (BSIs) and central line-associated BSIs.

Note: Complications include infection, air embolism, pneumothorax, phlebitis, infiltration including extravasation, leakage/bleeding, occlusion, nerve injury, bruising, and hematoma.

No correlation was found between catheter types in the relationship *between* the actual numbers of peripheral venous catheter (PVC) events and central venous catheter events ($r = 0.15$, $P = .69$).

For reporting purposes, NHSN does not specify reporting a device for primary BSIs; therefore, not all primary BSIs are associated with a PVC.

subclavian, or internal jugular vein; ports; permanent catheters; and umbilical catheters.

Inclusions and Exclusions

Reports in PA-PSRS involving inpatients from acute care, pediatric, and long-term acute care hospital types were included. Reports involving patients designated as outpatients, nonadmitted emergency department patients, and outpatient clinic and ambulatory surgery facility patients were excluded because the majority of patients who have catheters in these settings would be more likely to have a CVC, which may have skewed the results. Reports from rehabilitation and behavioral health hospitals and those units within acute care hospitals were excluded because patients in those settings are unlikely to have a venous catheter. Reports involving nonvenous catheters such as arterial and intrathecal catheters were excluded.

Sampling for Keyword Accuracy

Analysts developed a keyword formula to distinguish PVC from CVC events in data from PA-PSRS. Because the PA-PSRS subtype IV site complication included more than 79,000 events, analysts randomly sampled 10% of that subtype to assess the predictive value of the keyword formula. Peripheral keyword prediction accuracy was 96% and central event keyword prediction accuracy was 95%. The formula also was applied to the extravasation of drug or radiologic contrast subtype.

Fewer intravascular air embolism and pneumothorax event subtype reports were identified in PA-PSRS; each of these events was reviewed manually.

Statistical Analysis

Query results were used to

- Quantify and compare the number of PVC and CVC complications per year
- Determine the linear incidence trend over time
- Calculate percentage change from year one to year nine
- Determine the average annual percent change

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 Excel.[12] The starting point of the linear regression (i.e., y-intercept) was used as the baseline value and was used to predict baseline performance. Regression analysis was used to determine the best-fitting line through the predicted and actual observed events during the period of observation. These data are not intended to present a predictive model of future events.

The relationships between actual and predicted number of events per catheter type and between PVC and CVC were analyzed using the regression analysis tool in Excel.[12] The regression function calculates the correlation coefficient (Pearson's r), performs linear regression using the least squares method, and provides a p-value for the association. Alpha was set at 0.05.

Level II Methods—PVC and CVC Complications

Looking only at data from PA-PSRS, analysts used sampling to analyze more than 91,000 PVC and CVC complications.

Data Sampling

To compare complication types across event subtypes and years, IV site complication and extravasation of drug or radiologic contrast subtypes were randomly sampled to yield 2,293 of 91,769 events. The goal of sampling was to achieve a confidence interval of 95% with a 2.5% margin of error.

For each year, the ratio of PVC to CVC events was applied to the number of events sampled per year per catheter type. For sampled CVC events in the IV complications subtype, the resultant annual sample size had few data (i.e., single digits) so analysts sampled 20 events per year to increase result validity. The annual number of CVC extravasation events was also fewer than 20 per year, and analysts reviewed all of these events.

Analysts reviewed all 12 of the intravascular air embolism and all 259 pneumothorax event subtypes. In all, analysts sampled 2,564 events.

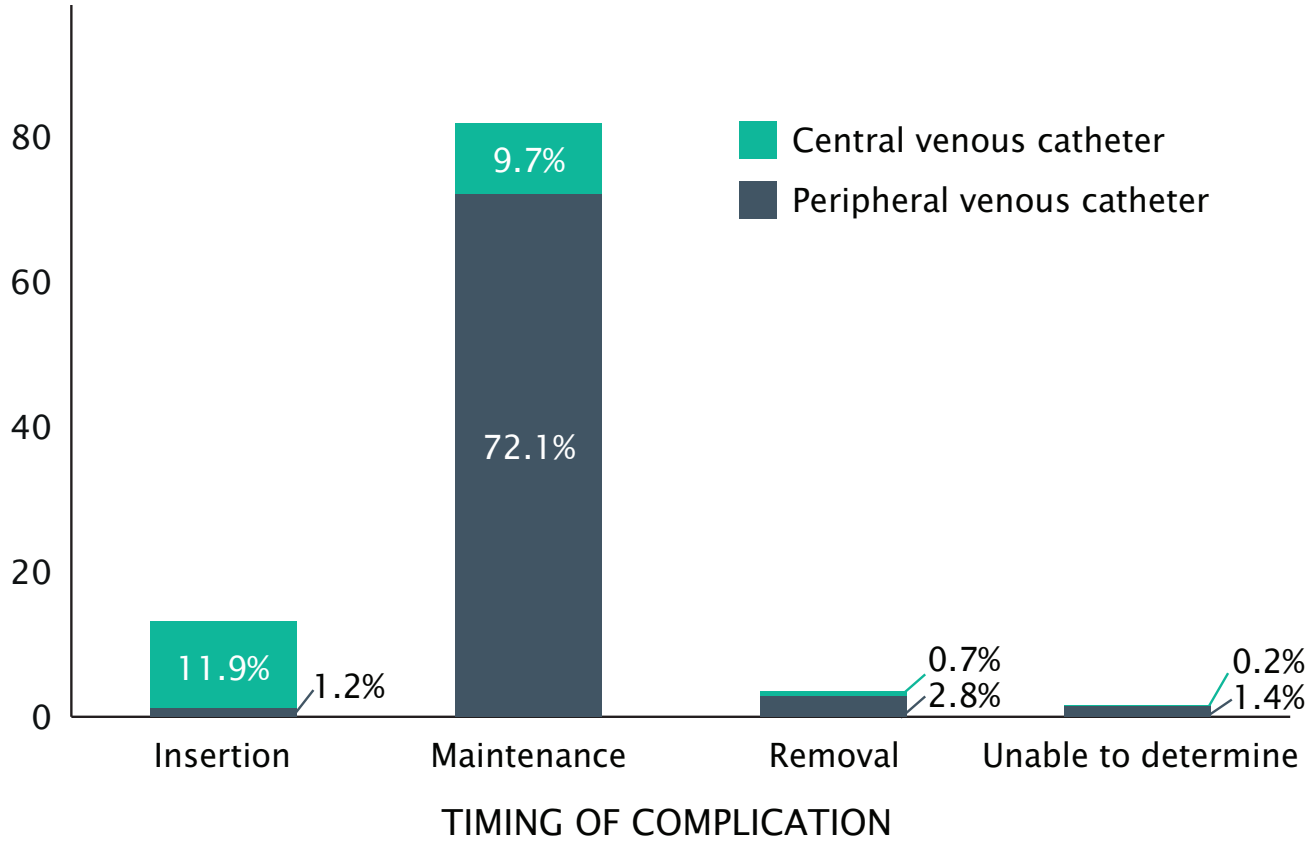
Timing

Analysts reviewed the 2,564 events in the sample and categorized the timing of the complication as occurring either during insertion, maintenance, or removal.

Type of Complications

Analysts sorted events by the following complication types: absence of blood flow or occlusion; ecchymosis, hematoma, or bruising; leakage or bleeding; infiltration (including extravasation); IV pulled, dislodged, or broken; phlebitis; pneumothorax; and other. If an event described multiple complications,

Figure 2. Timing of Complications by Venous Catheter Type (N = 2413)



Note: Sampled data as reported through the Pennsylvania Patient Safety Reporting System, January 1, 2009, through December 31, 2017, in the subtypes IV site complication, extravasation of drug or radiologic contrast, pneumothorax, and intravascular air embolism. Data on the timing of primary blood stream infections and central line-associated blood stream infections from the National Healthcare Safety Network database are excluded.

Abbreviations: CVC, central venous catheter; IV, intravenous; PVC, peripheral venous catheter.

each was categorized separately; the data are not mutually exclusive.

In events involving more than one catheter, each catheter counted as an individual event and complications were attributed to the appropriate catheter. If two catheters were mentioned in the event detail and it was obvious that the event was about only one, analysts attributed complications to the catheter which was the focus of the event.

Risk Factors

Analysts identified conditions described within PA-PSRS event details that could place the patient at risk for developing a complication, such as placing a PVC in a suboptimal location or CVC caps not being cleaned according to policy.

Results

Level I Results—Analysis and Comparison of PVC with CVC

The query from PA-PSRS resulted in 91,769 events: 87,928 PVC and 3,841 CVC events. The NHSN query resulted in 24,168 reports: 10,112 primary BSI (surrogate for PVC-related infections) and 14,056 CLABSI reports. NHSN data were not analyzed but queried only for the number of events reported. This high-level analysis totaled 115,937 events.

The number of PVC complications showed a statistically significant 11.7% increase (r = 0.68, p = .04) and an average annual change of 2.3% (calculated using the number of years for which there are data minus 1). CVC complications showed a 26.7% decrease without statistical significance (r = 0.45, p = .22) and an average annual change of 1.3% from 2009 through 2017 (Figure 1).

Level II Results—PVC and CVC Complications

Of the 2,564 events sampled from PA-PSRS, 151 were deemed nonapplicable for the following reasons: analysts were unable to determine what type of line was being described, a PVC was found in the CVC sample or vice versa, or the care area was determined to be outpatient. The following PVC and CVC complications analysis is based solely on data from PA-PSRS and derived from a final 2,413 sampled events (2.6% of 91,769). It is important to note that Level II analysis excludes CLABSIs.

Timing of the Complication

Analysts identified the complication timing for 2,374 (98.4%) of the PVC and CVC sample events (Figure 2). The remaining 39 events lacked sufficient information for categorization.

Overall, 81.8% of complications for both catheter types (n = 1973 of 2413) occurred during maintenance, primarily driven by the number of PVC events. However, for CVCs alone, the largest percentage of complications occurred during insertion (53.4%, n = 286 of 536).

The trends of complication timing per catheter type were relatively stable year to year.

The following events are examples of timing-related complications.

Insertion

> *Patient admitted with history of respiratory illness. Deterioration of patient's condition despite bilevel positive airway pressure caused the patient to require mechanical ventilation and respiratory status stabilized. Due to poor venous access, CVC was inserted and the patient went into cardiac arrest. An emergent chest tube was placed to relieve possible pneumothorax [author's note: pneumothorax is a possible complication of central line insertion; presumably providers were attempting to alleviate any conditions potentially contributing to the cardiac arrest]. Resuscitation efforts were futile.*

Maintenance

> *Patient had reported painful IV site to nursing staff each time intermittent intravenous medications were administered for 24 hours. When the IV team assessed the site the IV was immediately removed due to phlebitis and signs of infiltration.*

Removal

> *During removal CVC patient was placed in Fowler's [sitting] position. Once the CVC was removed patient developed shortness of breath and cardiac arrest. Patient required intubation and cardio-stimulatory drugs. Subsequent chest x-ray confirmed pneumothorax requiring chest tube insertion. The patient did not recover.*

Type of Complication

Eight complication categories encompassed 2,376 (98.5%) of the 2413 event sample; 2,933 complications were identified (n = 2,304 for PVC and n = 629 for CVC). See Figure 3 for percentages of complication categories. The remaining 37 events lacked sufficient information for categorization.

Infiltrations and extravasations accounted for 60.3% (n = 1,390 of 2,304) of PVC complications, followed by phlebitis, which accounted for 30.1% (n = 693), together comprising more than 90% of PVC complications in the event sample.

Pneumothorax was the most common CVC complication (41.3%, n = 260 of 629) followed by infiltration and extravasation (17.5%, n = 110). Pneumothorax was primarily associated with CVC insertion among the data sample.

Cardiac arrest accounted for 0.3% (n = 11 of 2,933) of the complications reported through the PA-PSRS sample. Most cardiac arrest events (81.8%, n = 9 of 11) occurred during CVC insertion and were attributable to air embolism or pneumothorax. The remaining two cardiac arrest events occurred during CVC removal. There were no cardiac arrest events identified in the PVC event sample.

The following events are examples of catheter complications:

Infiltrations

IV Team was consulted to assess placement of a new IV on a patient with a known infiltration. The primary nurse informed IV team that the patient's IV medication had continued to be infused until the new IV was inserted. Assessment of the patient's IV site shows an area swollen and painful with evidence of acute nerve injury due to IV infiltration.

During assessment of PIV [peripheral IV] site, noted area to be red and inflamed. No medications or infusions had been administered for the past day. Physician notified, PIV discontinued, and culture of PIV site wound collected. Patient required surgical intervention at PIV wound site and a PICC [peripherally inserted central catheter] inserted to deliver long-term antibiotics to promote healing of this PIV wound site.

Phlebitis

Upon assessment, patient found to have palpable venous cord with redness, pain, and warmth. Phlebitis protocol implemented.

Pneumothorax

Physician attempted to place a central line and the patient developed a pneumothorax as evidenced by CXR [chest x-ray image] and symptoms of

Table 1. Risk Factors

TYPE OF RISK FACTOR	CVC	PVC	TOTAL
Policy and procedure not followed (e.g., outdated dressing, outdated femoral catheter lines, nonocclusive dressing/catheter exposed)	13	14	27
Filters/caps/hubs/tubing concern	11	3	14
Substandard site placement	0	10	10
Communication concern	2	3	5
PICC used without confirmation x-ray/no physician order for x-ray	4	0	4
Patient reports pain, but IV site still used	0	3	3
Port not accessed/improperly accessed	2	0	2
Continued IV infusion despite infiltration	0	2	2
Condensate inside cap/tubing	2	0	2
Handcuff/BP cuff/PVC in same arm	0	2	2
IV site without visual assessment/inspection	0	2	2
CVC not sutured	1	0	1
Incompatible IV drugs in close proximity/line not flushed	1	0	1
Tourniquet not removed	0	1	1
Patient refused IV site change	0	1	1
PVC inserted in wrong direction (away from the heart)	0	1	1
Did not know patient had PICC/antibiotic delayed	1	0	1
IV placed in infected hand	0	1	1
No assessment for medical necessity of IV	0	1	1
Total	**37**	**44**	**81**

Note: As reported to the Pennsylvania Patient Safety Reporting System, January 1, 2009, through December 31, 2017, in the event subtypes IV site complication, extravasation of drug or radiologic contrast, intravascular air embolism, and pneumothorax. Because data on primary blood stream infections and central line-associated blood stream infection risk factors are not included in the National Healthcare Safety Network database, those complication types are not reported in the table.

Abbreviations: BP, blood pressure; CVC, central venous catheter; IV, intravenous; PICC, peripherally inserted central catheter; PVC, peripheral venous catheter.

shortness of breath and chest pain. A chest tube was needed.

Risk Factors

In 81 events, a risk factor—such as policy and procedure for CVC site care not being followed—was reported (3.4% of 2413 sampled events). See Table 1. The two main risk factors identified included breaches in policy and procedure (including outdated dressings) and problems related to filters, hubs, and tubing of IV catheters.

Discussion

Level I Discussion—Catheter Analysis and Comparison of PVC and CVC

Relationship of PVC and CVC Complications

With important and long-standing attention focused on CVCs and in particular CLABSI reduction, the scope and impact of PVC complications is often overlooked.[6,8,10] This study identified that serious harm can be related to PVCs, consistent with information in the literature.[2,14-17]

Although this study found no correlation between the increasing number of PVC complication events and the decreasing number of CVC events (based on aggregating the PA-PSRS and NHSN data), it did determine that the increasing number of reported PVC complication events and the correlation between actual and predicted PVC events over the nine years studied is strong and statistically significant.

The authors cannot conclude that a reduction in CVC complications is leading to or causing an increase in PVC complications. However, from a quality-improvement perspective, facilities can consider monitoring and measuring PVC use and complication rates as a balancing measure to those used for CLABSI reduction initiatives.

Level II Discussion—Analysis of PVC and CVC Complications

Timing of the Complication

Almost three-quarters of the PVC sample events occurred during the maintenance phase. Little consensus exists on the timing of IV site rotation. Many PVCs remain idle or continue to be used with symptomatic patients, and they are often inserted in substandard anatomical sites.[3,4,15] The Infusion Nurses Society's standard of practice supports site rotation based on clinical indications rather than a predetermined interval.[3]

The largest number of CVC sample events occurred during insertion. Although previous analysis demonstrated that most CLABSIs occur during maintenance,[18] NHSN data, which include CLABSIs, are excluded from this level II analysis because of differences in structured data fields. The availability of a discrete event report subtype may have facilitated reporting pneumothoraces through PA-PSRS.

Although complications during CVC removal may be rare in the literature as well as in this analysis, outcomes—including cardiac arrest—may be devastating and fatalities have been documented.[19,20]

Much attention is directed toward the practice of CVC insertion; similar attention to the process of CVC removal may also be warrented.[3,19,20]

Type of Complication

Infiltration and phlebitis are the most prevalent complications of PVC use and can result in swelling, pain, and tissue damage.[2,14,21-24] Estimates of PVC infiltrations in the literature range from 11.8% to 48.0%.[14,24] In one extreme case, a rare biceps brachii tear occurred as a result of PVC infiltration.[17]

In contrast to other publications,[21,24,25] this study found more than 60% of PVC complications were related to infiltrations, including extravasations. PA-PSRS has a reporting pathway specifically formatted to capture infiltrations and extravasations, which might facilitate reporting and contribute to the larger percentage.

Our finding that PVC phlebitis was the second-most commonly reported complication is consistent with the literature.[14,16,24,25]

Most CVC noninfection complications are related to mechanical processes, such as puncture and thrombosis formation, which can lead to pneumothorax, vascular damage, and occlusion.[26-28]

The number of non-CLABSI and nonprimary BSI infections reported through PA-PSRS was small. Analysts applaud quality improvement initiatives that have effectively reduced the number and rate of CLABSIs.[29-32] Peripheral BSI reduction has progressed slower than CLABSI reduction; this analysis, as well as other recent research, points to the importance of preventing PVC BSIs.[10,15,33]

When specific quality improvement and patient safety initiatives such as reducing CLABSIs are prioritized, the tendency is to focus attention and resources on that initiative; balancing measures are needed to ensure recognition and management of untoward effects that can result from improvement efforts. As this study suggests, measuring PVC complications may prove beneficial during CLABSI reduction initiatives.

Risk Factors

Risk factors were identified in this analysis. Overall the number of PVC and CVC risk factors were almost equivalent and included breaches in following policy and procedure, similar to what is described in the literature.[1,16]

Risk Reduction Strategies

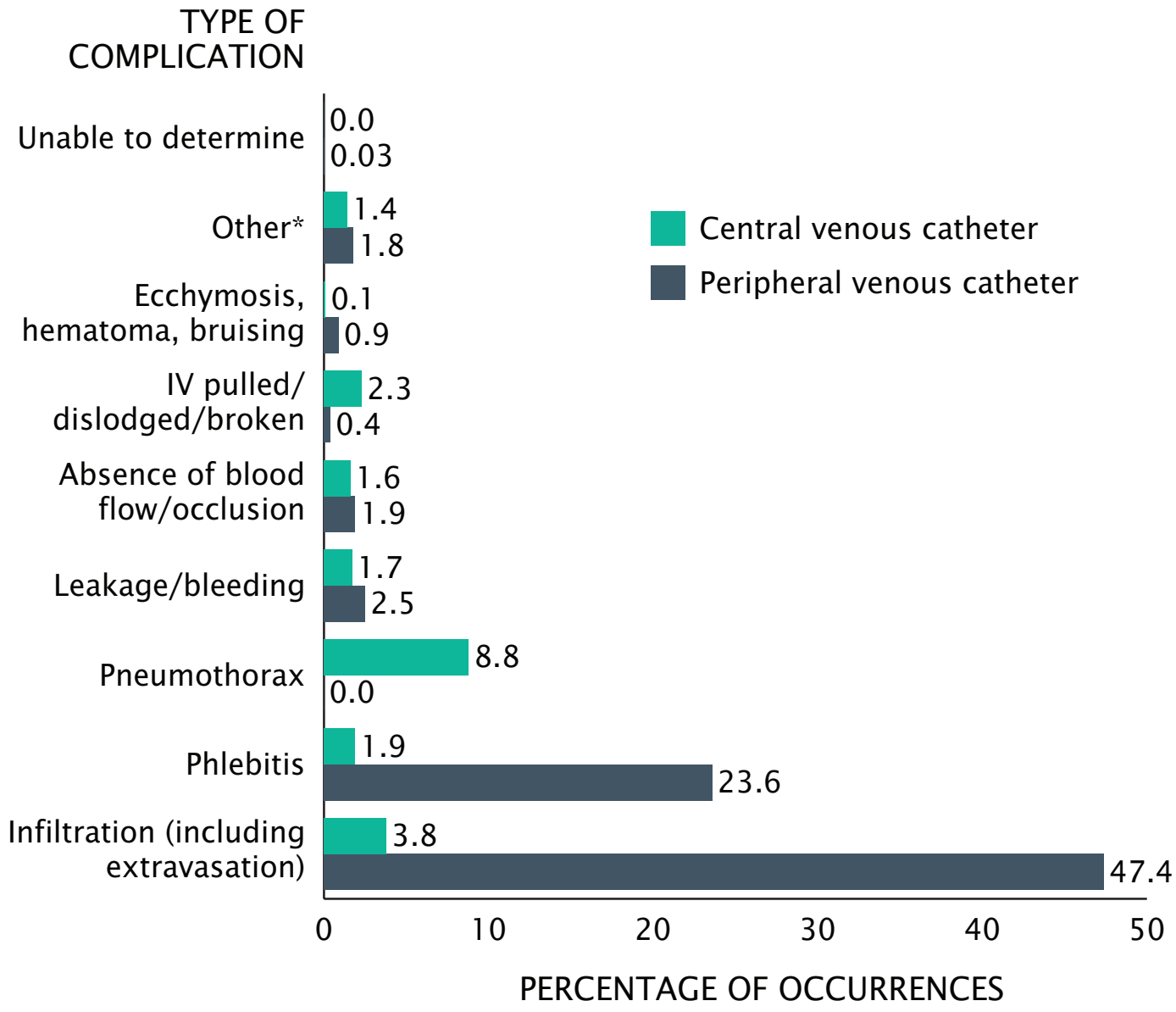
Consider the following strategies that may reduce the incidence of venous catheter–related complications, based on a review of current literature, analysis of events submitted to PA-PSRS, and observations within the practice of nursing:

- Encourage frontline caregivers to identify potential risks before an adverse event occurs[34-36]
- Perform hand hygiene and clean the catheter hub before use[37]
- Visually check catheter sites without active infusions at least every four hours and more frequently if there is an infusion[3]
- Monitor infusions and palpate the site if patient reports pain, pins and needles, numbness, burning, stinging, and/or tightness at or around insertion site, catheter tip, or entire venous pathway; stop the infusion and remove the catheter[3]
- Use a transparent, semipermeable dressing to provide visualization and potentially reduce bacterial contamination at the insertion site[1]
- Examine insertion site where the catheter enters the skin for signs of redness, pain, leakage, or swelling; if any of these signs are present, stop the infusion and remove the PVC, unless the PVC will be used to administer antidote directly to tissue according to facility protocol [16]
- Encourage patient engagement during catheter insertion, maintenance, and removal[9]
- Implement nurse-driven protocols, as appropriate, removing catheters that have not been accessed within the preceding 24 hours and may no longer be medically necessary[4]
- Inspect all components of the IV system including end caps, hubs, filters, and tubing compatibility to prevent hazards and identify potential complications such as cracks, disconnections, and condensation[7]
- Review CVC insertion procedures and consider the use of ultrasound during CVC insertion[28]
- Recognize that after two unsuccessful cannulation attempts, the rate of CVC-insertion complications increases, particularly the risk for pneumothorax[28]
- Consider adopting the Infusion Nurses Society's special precautions for preventing air embolism during placement and removal of CVC, including[3]
  - Ensure patient placement in a position (supine or in Trendelenburg) such that the CVC insertion site is at or below the level of the heart
  - Have patient perform the Valsalva maneuver at the appropriate point during catheter withdrawal, unless contraindicated
  - Upon removal of the CVC, apply digital pressure using manual compression with a sterile dry gauze pad until hemostasis is obtained
  - Place a sterile, petroleum-based ointment with the sterile dressing to the access site for at least 24 hours to seal the skin-to-vein tract
  - Encourage the patient to remain in a flat or reclining position, if tolerated, for 30 minutes after CVC removal

Limitations

Despite mandatory reporting laws[38], the number of reports and completeness of report data depends on the reporter as well as on the design and

Figure 3. Type of Complication by Venous Catheter Type (N = 2933)



Note: Sampled data as reported through the Pennsylvania Patient Safety Reporting System, January 1, 2009, through December 31, 2017, in the event subtypes IV site complication, extravasation of drug or radiologic contrast, pneumothorax, and intravascular air embolism. Data on number of primary bloodstream infections and central line-associated bloodstream infections (CLABSIs) from the National Healthcare Safety Network (NHSN) database are excluded. For context, 14,056 CLABSIs were reported through NHSN during this time period.

Total does not equal 100% because of rounding.

Because more than one complication can be reported per event, this resulted in 2933 complications identified (n = 2304 for PVC and n = 629 for CVC).

* Includes air embolism, blister, cardiac arrest, infection, nerve injury, and skin tear.

Abbreviations: CVC, central venous catheter; IV, intravenous; PVC, peripheral venous catheter.

implementation of facility reporting systems.

Reporting patterns may change over time as facilities contend with ever-changing quality and patient safety priorities and values. PA-PSRS and NHSN may contain duplicate reports; differences in structured data fields precluded direct comparisons of some data. In addition, our contention is that the number of PVC and CVC complications is a meaningful representation of the magnitude of the problem and provides complementary information.

The process used to generate the PA-PSRS event sample may have overrepresented uncommon complications.

NHSN does not require that devices associated with primary BSIs are specified; therefore, it is likely that the incidence of PVC-associated BSIs is underrecognized.

Because of taxonomy changes, reports submitted to PA-PSRS before 2012 may have included outpatients.

Database reports often lacked dwell times, which may have impacted interpretation of complication data.

The possible impact of an aging population was not explored, and data to accomplish risk adjustment or assess patient frailty was not available.

Conclusion

Decreases in the number of CVCs and CLABSIs were not found to be associated with an increase in the number of PVC complications as reported in PA-PSRS.

The significant increase in PVC complications reported most commonly occurred during maintenance. Complications of CVC, excluding CLABSIs, most commonly occurred during insertion.

Healthcare providers are advised to examine policy, procedures, and practices to minimize venous catheter complications and improve patient outcomes. In the context of improvement efforts focused on the reduction of CVC complications, healthcare facilities may find benefits in concomitant efforts to measure and reduce PVC complications.

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How Do You Prevent Blood Poisoning? Hire Miss Sepsis!

Caitlyn Allen, MPH
DOI: 10.33940/sepsis/2019.9.5

Forty percent of Americans have never heard of sepsis—a condition that kills more people than breast cancer, stroke, AIDS, and opioid overdoses combined.[1] Sepsis, put simply, occurs when the body's immune system goes into overdrive, backfires, and attacks its own organs, and it takes the lives of 270,000 Americans each year.[1] The only two diseases that kill more Americans are heart failure and cancer.

Even more troubling is how easy the condition is to get. A common misconception, even among clinicians, is that sepsis only occurs in the hospital. But the truth is that 8 out of 10 cases are community-acquired,[1] and sepsis can stem from almost any infection, even those seemingly benign like strep throat, a splinter, or a scraped knee.

The symptoms are nonspecific and include one or a combination of six signs—high fever or chills, confusion, elevated heart rate, shortness of breath, sweaty or clammy skin, and extreme pain or discomfort[2]—with many survivors reporting they felt like they were "going to die" or believed they had a bad case of the flu.

The good news? As difficult as sepsis can be to detect, it can almost as easily be prevented. The best way to do that is by making sepsis top of mind—for someone who has quickly become sick for no apparent reason to assume that it may be sepsis and seek immediate medical attention.

Enter Miss Sepsis, a fictional young girl who contracted sepsis after she scraped her knee and her parents missed the signs—and the focal point of the Patient Safety Authority's new awareness campaign. She recounts her tale and reminds everyone "Don't Miss Sepsis." The concept was to create a character whom viewers would see as their own child, spurring a protective instinct to prevent a similar fate. Thankfully, Miss Sepsis survived, but she also provides statistics to inform that many are not so lucky.

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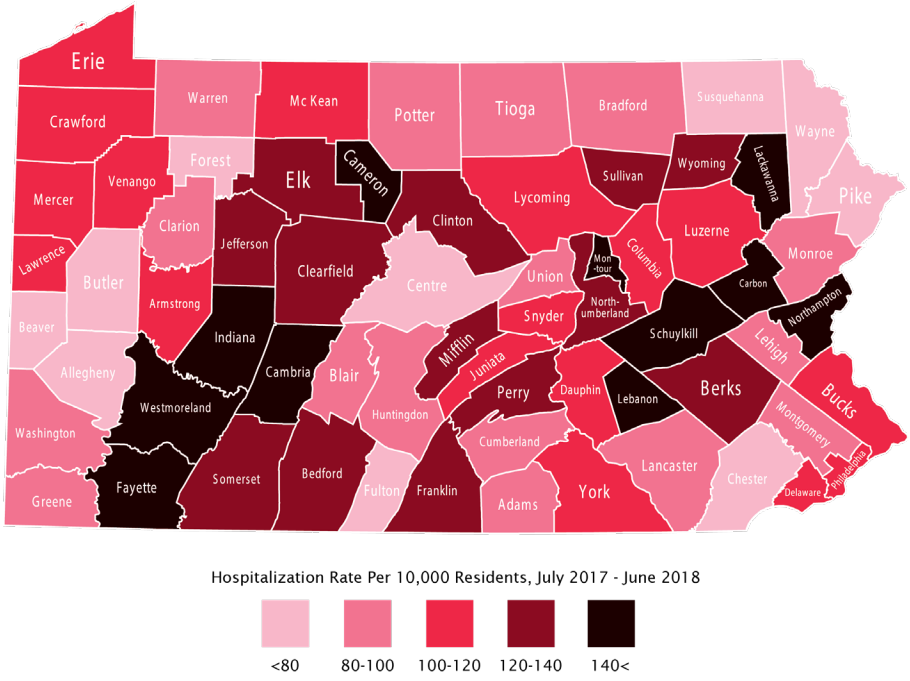
Sepsis Hospitalizations in Pennsylvania by County (July 2017 - June 2018)

County	Total Number of Sepsis Hospitalizations, FY 2018	Hospitalization Rate Per 10,000 Residents, FY 2018
Forest	43	65.1
Cameron	65	171.3
Fulton	65	55.7
Sullivan	66	122.6
Potter	116	86.6
Pike	181	39.8
Susquehanna	214	64.0
Montour	218	148.8
Juniata	226	118.2
Greene	248	84.0
Clarion	266	86.1
Wyoming	271	123.3
Tioga	276	84.7
Warren	293	91.3
Union	296	82.5
Elk	299	122.2
Huntingdon	319	86.6
Snyder	332	104.9
Wayne	334	78.0
McKean	362	109.5
Clinton	371	121.2
Venango	418	100.2
Bradford	434	91.0
Mifflin	443	122.6
Perry	443	121.7
Jefferson	447	129.2
Bedford	510	130.2
Armstrong	558	104.9
Columbia	633	119.3
Lawrence	702	100.8
Crawford	706	104.0
Adams	773	95.0
Carbon	791	153.0

County	Total Number of Sepsis Hospitalizations, FY 2018	Hospitalization Rate Per 10,000 Residents, FY 2018
Centre	812	61.2
Somerset	828	135.2
Clearfield	912	139.7
Mercer	918	102.5
Blair	927	94.7
Indiana	1,007	147.6
Northumberland	1,035	139.5
Lycoming	1,066	118.2
Beaver	1,068	79.8
Butler	1,089	73.2
Monroe	1,196	89.2
Washington	1,375	82.6
Lebanon	1,571	145.5
Fayette	1,587	149.1
Franklin	1,617	134.6
Schuylkill	1,795	155.8
Cumberland	1,820	92.0
Cambria	1,867	174.3
Erie	2,146	100.1
Lehigh	2,337	82.5
Dauphin	2,568	119.7
Lackawanna	2,617	156.3
Luzerne	2,905	114.0
Chester	2,992	74.8
Northampton	3,523	145.9
Lancaster	3,824	92.4
York	3,860	110.9
Berks	4,272	132.2
Delaware	4,578	104.3
Westmoreland	4,307	149.6
Montgomery	5,520	85.1
Bucks	5,533	110.6
Allegheny	7,665	77.5

Data provided by the Pennsylvania Health Care Cost Containment Council, August 2019

Sepsis Hospitalizations per 100,000 Residents (July 2017–June 2018)



Hospitalization Rate Per 10,000 Residents, July 2017 - June 2018

Results of the Patient Safety Authority's

2018 Process Measures Survey

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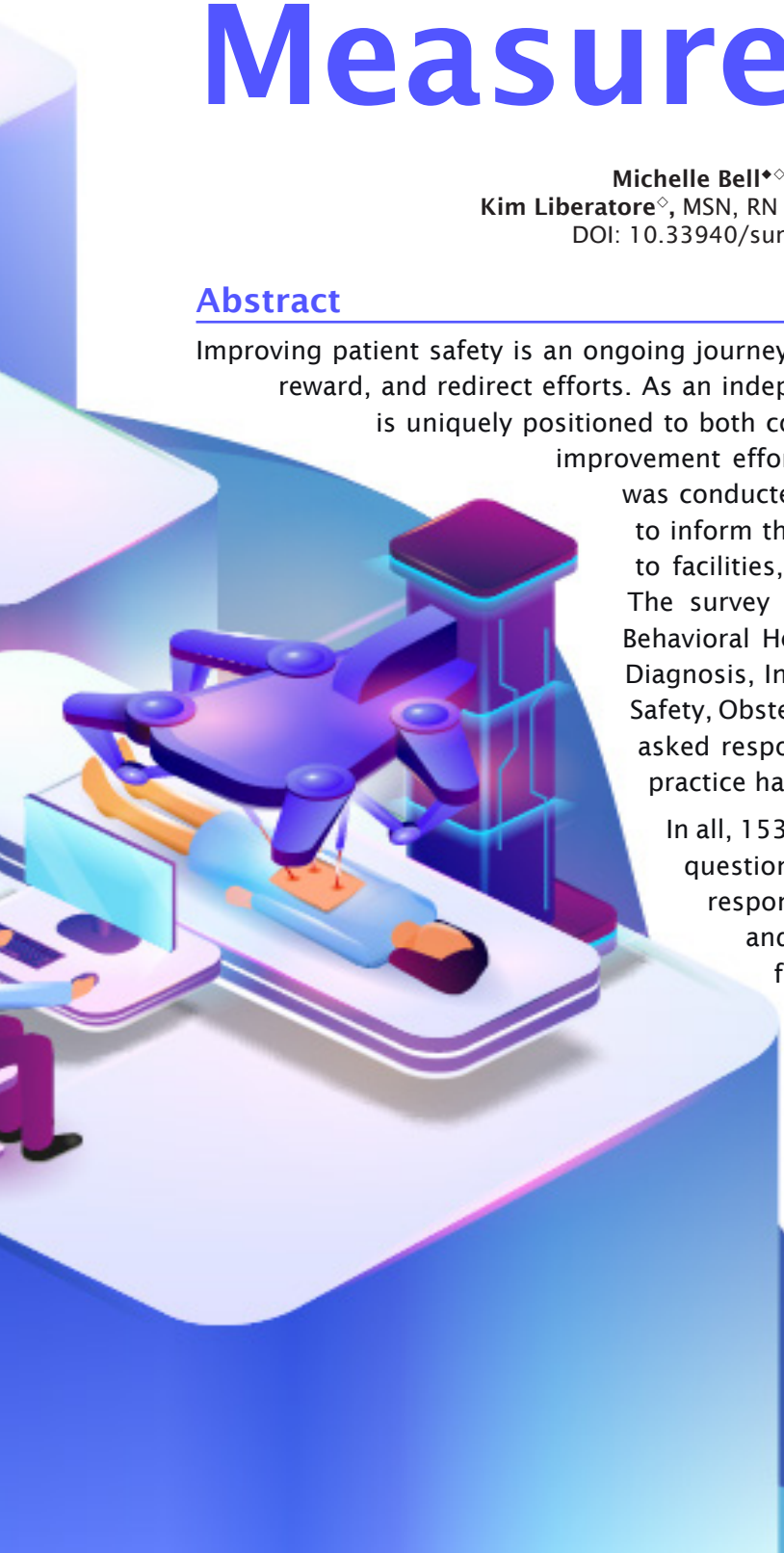
DOI: 10.33940/survey/2019.9.6



Abstract

Improving patient safety is an ongoing journey that benefits from periodic assessment to recognize, reward, and redirect efforts. As an independent state agency, the Patient Safety Authority (PSA) is uniquely positioned to both conduct comprehensive safety assessments and support improvement efforts. A process measures survey of acute care facilities was conducted in November and December 2018. The purpose was to inform the PSA's strategic direction, provide benchmarking data to facilities, and understand the current patient safety landscape. The survey consisted of 48 questions divided into 10 domains: Behavioral Health, Falls, Health Information Technology, Improving Diagnosis, Infection Prevention and Control, Leadership, Medication Safety, Obstetrics, Safe Surgery, and Transition of Care. Each question asked respondents to report the degree to which a specific safety practice has been implemented at their facility.

In all, 153 unique facility responses with at least 30% of the survey questions completed were received and analyzed. According to respondents, the domains Safe Surgery, Infection Prevention and Control, and Obstetrics had the highest percentages of full implementation, while Behavioral Health, Medication Safety, and Improving Diagnosis had the lowest. Looking across domains, two new themes emerged: first, a high percentage of full implementation of safety practices to support communication about patient safety with frontline staff and second, a low percentage of full implementation of safety practices that promote patient engagement in organizational efforts to support safe patient care. These results will inform the PSA's focus over the next several years.

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Disclosure: The authors declare that they have no relevant or material financial interests.

Keywords: *safety culture, process measures, safe surgery, infection prevention, infection control, behavioral health, medication safety*

Introduction

Many believe that patient safety has improved substantially in recent years, yet measuring this progress has proven surprisingly tricky. Although outcomes such as mortality or readmissions may be the ultimate gauge, measuring underlying organizational structures and processes may provide a more actionable assessment of a facility's safety.[1]

The Patient Safety Authority (PSA) is an independent, nonregulatory state agency that is uniquely positioned to learn from one of the nation's largest event reporting databases and provide individualized support to more than 1,200 hospitals, ambulatory surgical facilities, abortion facilities, birthing centers, and nursing homes in Pennsylvania. Recognizing that the patient safety landscape has changed considerably since conducting its last comprehensive assessment of patient safety practices in 2008, the PSA embarked on the development and distribution of a new process measures survey in 2018.

Survey questions consisted of updated indicators of mature safety structures and processes, many of which were not on the radar of safety champions a decade ago. Results of the survey will inform the PSA's strategic work aimed at reducing and eliminating medical errors over the next three to five years and provide participating facilities with updated benchmarking data to focus their improvement efforts.

Methods

The process measures survey was carried out using an exploratory approach; descriptive statistics are presented. Based on organizational priorities, PSA leadership identified areas of focus ("domains") for the survey, which were assigned to internal subject matter experts for preliminary question development. Subject matter experts drew upon best practices highlighted in recent PSA work (e.g., webinars, articles, and collaboratives), trends in PSA's event reporting database, and the literature to develop questions reflective of a mature safety culture. All questions were then vetted by PSA leadership for clarity, relevance, consistency, and prioritization.

A final set of 48 questions comprised the following 10 domains:

- Behavioral Health
- Falls
- Health Information Technology
- Improving Diagnosis
- Infection Prevention and Control
- Leadership
- Medication Safety
- Obstetrics
- Safe Surgery
- Transition of Care

Response options for all questions consisted of a five-point Likert implementation scale:

A. This item is fully implemented throughout the organization
B. This item is fully implemented in some areas of the organization
C. This item has been partially implemented in all or some areas of the organization
D. This item has been formally discussed and considered
E. There has been no activity to implement this item

For select questions (e.g., in the Obstetrics domain), an additional response option of F, "This item does not apply to my organization," was included; all other questions were felt to be universally applicable (e.g., in the Leadership domain). For a full copy of the process measures survey questionnaire, see Appendix.

Pennsylvania's acute care facilities as of November 12, 2018, consisting of 237 hospitals and 345 ambulatory facilities (i.e., ambulatory surgical facilities, abortion facilities, birthing centers), were invited to participate in the survey between November 14, 2018, and December 14, 2018. A convenience sample was obtained by promoting the survey via direct emails to facility patient safety officers, the PSA's website, social media (e.g., Facebook, LinkedIn), and through contact with facilities by the PSA's field staff. Any facility that submitted multiple surveys was contacted to determine which version should be analyzed.

Based on analysis of the data, a clear dropoff in the level of survey engagement was recognized. Analysts determined a threshold response rate of 30% for inclusion; 13 surveys with response sets less than 30% were excluded.

Results of the survey were analyzed by domain and question, both in aggregate and by facility type of hospital and ambulatory facilities. Because of differences in the number of questions in each domain and the number of responses to each question, analysts evaluated the results as both a percentage of all survey responses and a percentage of only those facilities that indicated the safety practice applied to their facility (i.e., excluding answer choice F). Missing responses were excluded from the denominator of all calculations.

Recognizing that the survey's answer choices were subject to respondent interpretation, and that nodes of full implementation within an organization are valuable indicators of an established framework for spread, the answer choices A and B were combined for the purposes of analysis. A percentage of "full implementation" was calculated by collapsing the number of response options A and B, and dividing by the total number of responses A through E for that particular question or all questions in a domain.

Analyzing by question and combining relevant questions to calculate a collective percentage of full implementation resulted in the identification of additional themes.

Results

The PSA received 153 unique survey submissions with at least 30% of the survey questions completed. The response rate for surveys was 32.5% of hospitals (n = 77 of 237) and 22% of ambulatory facilities (n = 76 of 345); the average respondent answered 94.1% of the questions (45.19 of 48 questions), and the median response rate was 100% of 48 questions.

Highest Percentage of Full Implementation

The domains for which respondents reported the highest percentage of full implementation included Safe Surgery, Infection Prevention and Control, and Obstetrics.

The Safe Surgery domain had the highest percentage of full implementation in aggregate and for ambulatory facilities alone. The specific safety practice of checking all products for latex had the highest percentage of full implementation within this domain, followed by identifying surgical fire risk in preoperative briefings. For both practices, ambulatory facilities reported higher percentages of full implementation than hospitals.

The Infection Prevention and Control domain had the second highest percentage of full implementation in aggregate and the top percentage for hospitals alone. This domain contains three of the five questions with the highest percentage of full implementation in aggregate: educating patients about preventing surgical site infections, notifying key stakeholders when surgical-suite environmental conditions are out of range (e.g., insufficient air exchanges), and providing feedback to frontline workers about infection rates and prevention measures.

Only 25% of the total survey responses indicated that the safety practices in the Obstetrics domain applied to the organization. Yet at facilities where the safety practices applied, having immediate access to obstetric hemorrhage prevention medications and supplies had one of the highest percentages of full implementation of the 48 safety practices.

Lowest Percentage of Full Implementation

Among respondents, the Behavioral Health, Medication Safety, and Improving Diagnosis domains had the lowest percentages of full implementation (see Figures 1 and 2). Although the Behavioral Health domain had the lowest percentage of full implementation in aggregate, a significant performance gap existed between the two facility types: Fewer than 25% of ambulatory facilities reported full implementation in this domain; however, nearly 80% of hospitals reported full implementation. The specific questions with the greatest differences in percentage of full implementation included universal suicide-risk screening and use of an evidence-based suicide assessment tool.

The Medication Safety domain had the second-lowest percentage of full implementation for both hospitals and ambulatory facilities. Fewer than 50% of ambulatory facilities reported full implementation of a process to weigh patients in metric units on admission, and fewer than a quarter reported full implementation of formal risk assessments when introducing new drugs to the formulary. Although nearly 80% of hospitals reported full implementation of a process to weigh patients in metric units, fewer than 50% reported full implementation of formal risk assessments when introducing new drugs to the formulary.

The Improving Diagnosis domain had the third-lowest percentage of full implementation in aggregate and the lowest percentage for hospitals alone. For hospitals, the safety practice of having projects designed to improve the diagnosis of cancer had the lowest percentage of full implementation within this domain.

Figure 1: Hospital Implementation by Domain and Question

Leadership

A. Fully implemented throughout
B. Fully implemented in some areas
C. Partially implemented in all or some areas
D. Formally discussed and considered
E. No activity to implement this item
▲ Percentage of full implementation (ie, responses A and B)

	% Fully Implemented	% N/A
You communicate "lessons learned" about patient safety events to Administration, the Governing Board, and healthcare workers.	77.7%	0.0%
You have established a regularly scheduled (open and nonthreatening) forum that allows the Administration and/or Governing Board to interact with frontline healthcare workers about your organization's patient safety needs.	73.9%	0.0%
Within the past two years, your Board has participated in formal quality & patient safety education.	64.4%	0.0%
You include patient and family representation on your Governing Board.	37.6%	0.0%
You provide education to healthcare workers on ways to build effective partnerships with patients and family advisors.	65.2%	0.0%
You have developed a formal plan to support transparency of patient safety events between healthcare workers and patients (including disclosure of medical errors).	85.4%	0.0%
You have a clear and consistently applied model of accountability that addresses the need for individual accountability while not holding individuals responsible for system failures beyond their control.	80.7%	0.0%
You have developed a formal plan to support transparency of patient safety events between leadership and healthcare workers.	78.4%	0.0%
You have developed a formal plan to support transparency of patient safety events between your organization and other healthcare organizations.	52.2%	0.0%

Falls

	% Fully Implemented	% N/A
You perform post-fall huddles or analysis after each fall event.	82.6%	0.0%
You have implemented a fall prevention mobility program.	76.2%	0.0%
You develop individualized fall prevention plans based on the patient's assessment.	91.8%	0.0%
Your fall review team includes a patient or community member.	32.9%	0.0%

Infection Prevention

	% Fully Implemented	% N/A
You provide to surgical patients education about preventing surgical site infections.	77.0%	16.1%
You provide to patients with indwelling devices (e.g., urinary catheters, central lines) education about preventing device-associated infections.	77.0%	3.4%
You provide patient education related to hand hygiene.	85.1%	0.0%
You employ only certified surgical technicians to reprocess surgical/endoscopic instrumentation and devices.	47.1%	21.8%
You notify key stakeholders (e.g., Administration/Facility/Engineering, Safety/Infection Prevention) immediately when monitored air exchanges, temperature, or humidity of surgical suites are out of range, so that appropriate investigation and mitigation can be conducted.	81.4%	11.6%
You monitor and measure patient hand hygiene compliance and reports findings to the Patient Safety and/or Infection Prevention Committee.	55.2%	0.0%
Your infection prevention program provides feedback to frontline staff related to identified healthcare-associated infection rates and associated prevention measures.	89.7%	0.0%
You have processes in place to recognize early signs of sepsis and a method to evaluate the effectiveness of those processes.	83.0%	4.5%

Transition of Care

	% Fully Implemented	% N/A
You use a standard format for handoffs during transitions of care.	72.3%	0.0%
You evaluate safety events (including readmissions) for communication failures during transitions of care to identify opportunities for improvement.	73.2%	0.0%
You involve the patient/family in handoff discussions during transitions of care.	61.0%	0.0%

Behavioral Health

	% Fully Implemented	% N/A
You screen all patients (including all patients w/o an identified behavioral health concern) for suicide risk.	87.2%	0.0%
You use a valid, evidence-based tool to assess suicide risk for behavioral health patients and patients with a positive suicide risk screen.	81.4%	0.0%
You train healthcare workers in using evidence-based de-escalation strategies and noncoercive management techniques for treating agitated patients.	70.9%	0.0%

Health IT

	% Fully Implemented	% N/A
In the past two years, your electronic health record (EHR) has been evaluated for its ability to intercept potentially fatal errors (e.g., allergy/drug contraindication, 1,000 x overdose).	67.9%	11.5%
You analyze the role of health information technology (IT) in safety events for learning and improvement opportunities.	81.7%	0.0%
You analyze data related to clinical-alert overrides to reduce unnecessary alerts.	62.2%	6.1%
You analyze data related to clinical-alert overrides to identify opportunities for safety interventions.	63.4%	6.1%

Safe Surgery

	% Fully Implemented	% N/A
You have an established process for checking all product labels for latex content before beginning a procedure for any patient with a latex sensitivity.	70.4%	14.8%
If your preop briefing/time-out includes identification of procedures with increased risk for surgical fires, it also includes a discussion of procedure-specific mitigation strategies when appropriate.	60.5%	19.8%
You require a standard mark for nerve blocks distinct from the surgical mark and requires a separate time-out from the surgical procedure.	55.1%	23.1%

Improving Diagnosis

	% Fully Implemented	% N/A
You have disease- or department-specific measures related to improving diagnosis.	54.2%	0.0%
You have a project/projects designed to improve the diagnosis of cancer.	32.9%	29.3%
You have a project/projects designed to improve the diagnosis of vascular events.	43.9%	19.5%
You have a project/projects designed to improve the diagnosis of infections.	70.7%	6.1%
You are collecting and tracking events related to the diagnostic process in your internal event reporting system.	62.7%	0.0%

Medication Safety

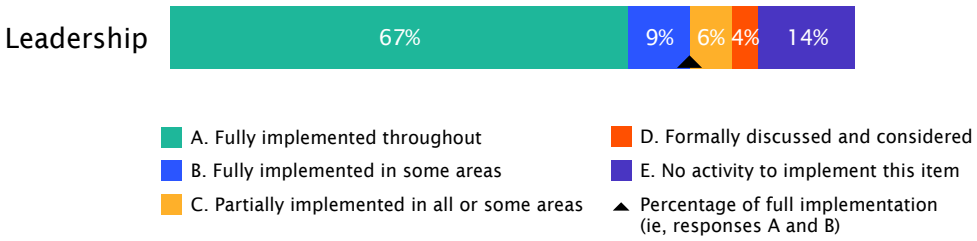
	% Fully Implemented	% N/A
You have a process in place to weigh each patient in metric units as soon as possible on admission.	80.5%	0.0%
You have established an opioid stewardship program.	56.3%	3.8%
You use individualized patient insulin regimens rather than sliding scale insulin alone to manage blood glucose levels (e.g., basal, nutritional, and correctional components).	61.0%	1.3%
You dispense meds for pediatric patients in a patient-specific, ready-to-administer form.	45.7%	37.0%
You conduct a formal risk assessment (e.g., failure modes and effects analysis) when introducing a new drug to the formulary.	45.6%	0.0%

Obstetrics

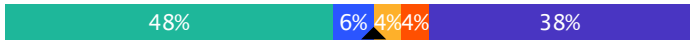
	% Fully Implemented	% N/A
Your healthcare workers have immediate access to hemorrhage prevention medications and supplies in areas where obstetric patients are treated.	40.5%	58.2%
You have established & use a standard, objective (not estimated) measure of postpartum blood loss.	40.5%	58.2%
You use a standard protocol for early recognition and treatment of maternal sepsis.	21.5%	59.5%
You use a standard protocol that addresses identification and management of elevated maternal blood pressure.	35.0%	57.5%

Note: Percentage of responses by implementation level reported in the Patient Safety Authority's 2018 Process Measures survey, November 14, 2018, through December 18, 2018. Responses were received from 77 hospitals and 76 ambulatory facilities. Percentages reflect the combined reported implementation levels for all questions in the domain excluding the answer choice "F. This item does not apply to my organization."

Figure 2: ASF Implementation by Domain and Question

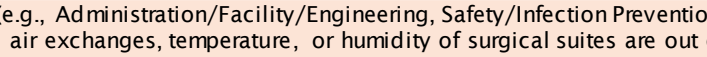


	% Fully Implemented	% N/A
You communicate "lessons learned" about patient safety events to Administration, the Governing Board, and healthcare workers.	87.8%	0.0%
You have established a regularly scheduled (open and nonthreatening) forum that allows the Administration and/or Governing Board to interact with frontline healthcare workers about your organization's patient safety needs.	83.8%	0.0%
Within the past two years, your Board has participated in formal quality & patient safety education.	73.8%	0.0%
You include patient and family representation on your Governing Board.	29.9%	0.0%
You provide education to healthcare workers on ways to build effective partnerships with patients and family advisors.	65.8%	0.0%
You have developed a formal plan to support transparency of patient safety events between healthcare workers and patients (including disclosure of medical errors).	93.5%	0.0%
You have a clear and consistently applied model of accountability that addresses the need for individual accountability while not holding individuals responsible for system failures beyond their control.	86.8%	0.0%
You have developed a formal plan to support transparency of patient safety events between leadership and healthcare workers.	95.9%	0.0%
You have developed a formal plan to support transparency of patient safety events between your organization and other healthcare organizations.	67.5%	0.0%



	% Fully Implemented	% N/A
You perform post-fall huddles or analysis after each fall event.	54.9%	0.0%
You have implemented a fall prevention mobility program.	64.8%	0.0%
You develop individualized fall prevention plans based on the patient's assessment.	57.7%	0.0%
Your fall review team includes a patient or community member.	39.4%	0.0%

	% Fully Implemented	% N/A
You provide to surgical patients education about preventing surgical site infections.	72.4%	21.1%
You provide to patients with indwelling devices (e.g., urinary catheters, central lines) education about preventing device-associated infections.	27.6%	69.7%
You provide patient education related to hand hygiene.	73.7%	0.0%
You employ only certified surgical technicians to reprocess surgical/endoscopic instrumentation and devices.	32.9%	15.8%
You notify key stakeholders (e.g., Administration/Facility/Engineering, Safety/Infection Prevention) immediately when monitored air exchanges, temperature, or humidity of surgical suites are out of range, so that appropriate investigation and mitigation can be conducted.	93.4%	1.3%
You monitor and measure patient hand hygiene compliance and reports findings to the Patient Safety and/or Infection Prevention Committee.	35.5%	0.0%
Your infection prevention program provides feedback to frontline staff related to identified healthcare-associated infection rates and associated prevention measures.	89.5%	0.0%
You have processes in place to recognize early signs of sepsis and a method to evaluate the effectiveness of those processes.	35.5%	60.5%



	% Fully Implemented	% N/A
You use a standard format for handoffs during transitions of care.	80.6%	0.0%
You evaluate safety events (including readmissions) for communication failures during transitions of care to identify opportunities for improvement.	68.2%	0.0%
You involve the patient/family in handoff discussions during transitions of care.	68.7%	0.0%

Behavioral Health

	% Fully Implemented	% N/A
You screen all patients (including all patients w/o an identified behavioral health concern) for suicide risk.	17.3%	0.0%
You use a valid, evidence-based tool to assess suicide risk for behavioral health patients and patients with a positive suicide risk screen.	13.3%	0.0%
You train healthcare workers in using evidence-based de-escalation strategies and noncoercive management techniques for treating agitated patients.	37.3%	0.0%

Health IT

	% Fully Implemented	% N/A
In the past two years, your electronic health record (EHR) has been evaluated for its ability to intercept potentially fatal errors (e.g., allergy/drug contraindication, 1,000 x overdose).	29.4%	45.6%
You analyze the role of health information technology (IT) in safety events for learning and improvement opportunities.	52.2%	0.0%
You analyze data related to clinical-alert overrides to reduce unnecessary alerts.	52.2%	0.0%
You analyze data related to clinical-alert overrides to identify opportunities for safety interventions.	21.2%	68.2%

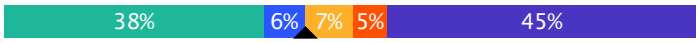
Safe Surgery

	% Fully Implemented	% N/A
You have an established process for checking all product labels for latex content before beginning a procedure for any patient with a latex sensitivity.	80.0%	12.3%
If your preop briefing/time-out includes identification of procedures with increased risk for surgical fires, it also includes a discussion of procedure-specific mitigation strategies when appropriate.	56.9%	33.8%
You require a standard mark for nerve blocks distinct from the surgical mark and requires a separate time-out from the surgical procedure.	24.2%	65.2%

Improving Diagnosis

	% Fully Implemented	% N/A
You have disease- or department-specific measures related to improving diagnosis.	36.6%	0.0%
You have a project/projects designed to improve the diagnosis of cancer.	21.9%	69.9%
You have a project/projects designed to improve the diagnosis of vascular events.	16.4%	71.2%
You have a project/projects designed to improve the diagnosis of infections.	54.8%	32.9%
You are collecting and tracking events related to the diagnostic process in your internal event reporting system.	66.7%	0.0%

Medication Safety



	% Fully Implemented	% N/A
You have a process in place to weigh each patient in metric units as soon as possible on admission.	43.3%	0.0%
You have established an opioid stewardship program.	28.4%	53.7%
You use individualized patient insulin regimens rather than sliding scale insulin alone to manage blood glucose levels (e.g., basal, nutritional, and correctional components).	19.4%	74.6%
You dispense meds for pediatric patients in a patient-specific, ready-to-administer form.	14.9%	76.1%
You conduct a formal risk assessment (e.g., failure modes and effects analysis) when introducing a new drug to the formulary.	22.7%	0.0%

Obstetrics

	% Fully Implemented	% N/A
Your healthcare workers have immediate access to hemorrhage prevention medications and supplies in areas where obstetric patients are treated.	6.2%	92.3%
You have established & use a standard, objective (not estimated) measure of postpartum blood loss.	3.1%	93.8%
You use a standard protocol for early recognition and treatment of maternal sepsis.	4.8%	95.2%
You use a standard protocol that addresses identification and management of elevated maternal blood pressure.	6.2%	93.8%

Note: Percentage of responses by implementation level reported in the Patient Safety Authority's 2018 Process Measures survey, November 14, 2018, through December 18, 2018. Responses were received from 77 hospitals and 76 ambulatory facilities. Percentages reflect the combined reported implementation levels for all questions in the domain excluding the answer choice "F. This item does not apply to my organization."

Disease- or department-specific measures related to improving diagnosis also had a low percentage of full implementation for hospitals and an even lower percentage for ambulatory facilities.

New Themes

Looking across domains, a theme emerged among the questions with the highest percentage of full implementation: communication about patient safety with frontline staff. When the following four related questions were combined, the resulting percentage of full implementation (85%) exceeded that of any of the 10 domains.

- Communicates "lessons learned" about patient safety events to administration, the governing board, and healthcare workers
- Has established a regularly scheduled (open and nonthreatening) forum that allows the administration and/or governing board to interact with frontline healthcare workers about your organization's patient safety needs
- Has developed a formal plan to support transparency of patient safety events between leadership and healthcare workers
- Infection prevention program provides feedback to frontline healthcare workers related to identified healthcare-associated infection rates and associated prevention measures

A theme also emerged among the questions with the lowest percentage of full implementation when looking across domains: patient engagement in organizational efforts to support safe patient care. These safety practices promote a higher level of patient involvement that fosters accountability and bidirectional communication. When the following five related questions were combined, the resulting percentage of full implementation (48%) fell below that of any of the 10 domains.

- Includes patient and family representation on the governing board
- Provides education to healthcare workers on ways to build effective partnerships with patients and family advisors
- Monitors and measures patient hand hygiene compliance and reports findings to the patient safety and/or infection prevention committee
- Falls review team includes a patient or community member
- Involves the patient or family member in handoff discussions during transitions of care

Discussion

The results of the process measures survey demonstrate many encouraging trends at respondent facilities. Safety topics within the domains with the highest percentages of full implementation, such as surgical fires, latex allergies, infection control, and safety culture, have all been areas of focus in recent work done by the PSA, based on trends in the event reporting database and facility inquiries. Interestingly, the emerging theme of communicating with frontline staff about patient safety is a common priority expressed by facilities. The survey results show high levels of full implementation of processes that support partnership, transparency, and feedback—all core elements of strong safety culture.

The results of the survey also demonstrate where there is more work to be done. Managing the behavioral health population, especially in nonpsychiatric settings, is a particularly timely and challenging safety threat. The survey data demonstrate an opportunity for ambulatory facilities to consider incorporating suicide screening into their workflow and to be prepared to appropriately respond to patients with positive screens.

Ambulatory facilities may draw upon the learnings and practical implementation strategies of The Joint Commission–accredited hospitals and behavioral health facilities that were charged with implementing such safety measures as using a validated suicide screening tool for all behavioral health patients by July 1, 2019.[2]

Within the Medication domain, potential areas for future focus include establishing a process at ambulatory facilities to weigh patients in metric units and performing proactive risk assessments when introducing medications to the formulary at both ambulatory facilities and hospitals.

Formal risk assessment tools, such as failure modes and effects analysis (FMEA), can be used by facilities to proactively mitigate potential hazards in a process, such as those that may occur when introducing new medications at a facility. PSA's field staff can assist any Pennsylvania healthcare facility that is unfamiliar with the process of conducting a proactive risk assessment or using FMEA in this application.

The PSA recognizes diagnostic error as a top challenge facing facilities. To help with this emerging and evolving patient safety priority, the organization offers opportunities for collaboration, learning, and facility-level consultation. In 2018, the PSA formalized work in this domain to provide leadership, guidance, and support for facilities, providers, and patients. Future work in this area will focus on facility-level efforts and will share successful implementation models from across the Commonwealth of Pennsylvania.

Engaging patients not only in their own care, but in organizational efforts that support decreasing harm—ranging from emphasizing handwashing to participating on the facility's governing board—provides opportunities for continued facility work. Identification of this emerging theme was unexpected and interesting given the recent ubiquity of such concepts as patient engagement, the patient voice, and patient-centered care. Part of the PSA's strategy is two-fold: to recognize the importantance of including the patient perspective within its own work, and providing support to facilities that are interested in new ways to involve patients from bedside to the boardroom. The insight and ideas generated when patients and hospital personnel collaborate can truly transform a safety program.

The PSA will utilize these survey results to systematically prioritize topics for its future offerings and focus the individualized support provided to facilities on an everyday basis by PSA field staff. Future process measures surveys may be utilized to gauge progress in the key areas of opportunity identified in 2018 and explore new indicators of a mature safety culture that will inevitably emerge.

Limitations

This analysis has several limitations. The evolution of the survey questions from 2008 to 2018 precluded any comparison of results for this 10-year period. Survey questions and response options underwent extensive internal review, but were not field tested. Although all patient safety officers of Pennsylvania facilities were invited to participate in the survey, facilities that responded were a self-selected group that may not be representative of nonresponders. The reported degree to which each safety practice has been implemented at the facility level is subject to reporter interpretation of the question and the response options, as well as their individual or a collective assessment of the facility's current state. The response option F was not included in survey questions that were felt to be universally applicable, which might have affected response selection.

Conclusion

Results of the 2018 process measures survey validate enduring efforts to improve patient safety, particularly in the areas of surgery, infection prevention and control, obstetrics, and communication about patient safety with frontline staff. Behavioral health, medication safety, improving diagnosis, and patient engagement provide opportunies for further evaluation and focus. The PSA will share the insights participating facilities gain through their individualized benchmarking reports. The pace of the journey to improve patient safety is such that opportunities and improvements may go unrecognized; therefore, the PSA strives to assist facilities with recognizing, rewarding, and redirecting their safety efforts, and turning insights, such as the process measures survey, into action.

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Inappropriate Testing for *Clostridioides difficile* in Long-Term Care: Implications Highlight the Need for an Algorithm

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Abstract

This article provides clear guidance related to appropriate testing for *Clostridioides difficile (C. diff)* and identifies the negative implications of inappropriate testing, repeat testing, and testing for cure. Residents of long-term care (LTC) facilities are at increased risk for developing *C. diff*. Complications can arise if a resident does not have an active *C. diff* infection (colonization) and has a positive *C. diff* laboratory test result. The authors share a fictional bedside story illustrating the negative consequences that can result from inappropriate *C. diff* testing, and present an algorithm that promotes mindful application of testing, which may result in cost savings and prevent adverse resident outcomes.

Keywords: C. diff, *long-term care, test, diarrhea, stool, algorithm, treatment, diagnosis*

Bedside Story

Sherry was a 68-year-old mother of two and grandmother of five very active grandchildren. She was retired and a widow of two years, and she babysat her grandchildren in her free time. She also played the piano at her church, where she led the women's missionary committee. Following her retirement, she and her best friend Donna saw each other every day. They gardened, walked for exercise, and traveled the world.

After falling on the ice while leaving church, Sherry was admitted to the hospital with a fractured right hip and right clavicle. She developed pneumonia during her hospitalization, was started on antibiotics, and became weak. She was transferred from the hospital to Cedar Springs, a LTC facility, for rehabilitation services. Sherry was frustrated about being unable to care for herself and was eager to recover so she could go home and resume her normal activities. Her children, grandchildren, and Donna had been visiting her at the hospital and promised to continue visiting at the LTC facility.

During her first 24 hours at Cedar Springs, Sherry had one liquid stool. The aide reported this finding to an RN, who in turn reported it to the physician on-call. The physician ordered a *Clostridioides difficile (C. diff)* test, and the staff initiated contact precautions and moved Sherry to a private room. The laboratory processed the *C. diff* specimen, which showed a positive result, so antibiotics were prescribed for treatment. Over the following two weeks, Sherry had only one bowel movement per day, ranging from unformed to soft.

While in isolation, Sherry was unable to participate

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Disclosure: The authors declare that they have no relevant or material financial interests.

Disclaimer

Sherry's story is a composite of cases from the authors' professional nursing experiences. Adverse outcomes were fictionalized according to research related to the implications of contact isolation, and Sherry, Donna, and the nursing facility Cedar Springs are fictitious.

The algorithm depicted in Figure 1 is based on *Clinical Practice Guidelines for* Clostridium difficile *Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA)7;* however, the algorithm does not reflect these guidelines verbatim. [7]

in group activities, interacted less with healthcare staff, and and received physical therapy in her room. Visits from her children, grandchildren, and Donna decreased significantly. Sherry had been an active person who enjoyed spending time with others—going on trips, babysitting, and participating in church activities. Following her *C. diff* diagnosis, she became increasingly depressed, slept more, and lost motivation to exercise and actively engage in physical therapy. She had no appetite, lost 15 pounds, and developed a pressure injury on her sacrum.

Several weeks after her *C. diff* diagnosis, Sherry tried to get out of bed by herself to go to the bathroom. Due to her weakened condition, she fell and hit her head. A nurse found Sherry unconscious and called 911. Sherry was admitted to the hospital and found to have a subdural hematoma.

Unfortunately, Sherry passed away two days later.

Introduction

The bacteria *Clostridioides difficile* (*C. diff*) is a significant health threat which can lead to diarrhea, colitis, and even death. In 2017, *C. diff* caused nearly half a million infections among people in the United States, more than 100,000 of whom were residents in LTC facilities.[1] Many risk factors contribute to the development of *C. diff* infection, including an age of 65 years and older, a weakened immune system, a history of previous *C. diff* infection, and recent hospitalization.[2] Medications that suppress gastric acid production are also contributory factors.[3]

A significant risk factor for developing *C. diff* infection is antibiotic use. Antibiotics can result in weeks to months of suppression of gut microbiota bacteria that defend against infection. When "good" gut bacteria are suppressed, there is an increased risk of becoming infected from ingesting the *C. diff* spore through contact with another person or a contaminated surface.[1]

Residents of LTC facilities are at increased risk for developing a *C. diff* infection. For this reason, they may also be subject to overtesting. Testing for *C. diff* outside of the recommended guidelines—such as testing of asymptomatic residents—can result in overdiagnosis and overtreatment. Inappropriate testing can lead to increased costs and implications for residents stemming from contact isolation and unnecessary antibiotics.[4]

In 2010, a joint expert panel appointed by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) provided guidelines[6] to improve the diagnosis and management of *C. diff* infection in adults. In 2017, IDSA and SHEA issued updated guidelines[7] containing significant changes in the recommended management of *C. diff* infection and best practices for diagnosis.

Challenges Facing LTC Facilities

In recent months, infection prevention experts at the Patient Safety Authority (PSA) have received many questions from infection prevention designees and other leaders from Pennsylvania long-term care facilities related to *C. diff* testing. These questions concern whether residents should be screened for *C. diff* on admission to rule out infection, if a specimen should be sent at the first sign of a liquid stool to rule out *C. diff,* and the nature of the difference between colonization and active infection. In light of the questions and subsequent conversations with facility representatives, there appears to be a knowledge deficit regarding the IDSA and SHEA guidelines.

Testing and Treatment Implications

While antibiotic therapy and contact precautions are indicated for active *C. diff* infection, asymptomatic colonization of *C. diff* does not require treatment. The adverse effects of treatment and isolation can harm residents who are tested outside the recommended guidelines. Antibiotics can disrupt the normal bacterial flora of the intestine. Normal bacterial flora is important, as it assists with the breakdown and absorption of food nutrients, metabolizes medication, and protects against harmful bacteria.[4] Oral vancomycin, often used in treating *C. diff*, may allow production of vancomycin-resistant enterococci (VRE),[5] which can make future treatment difficult. Contact precautions, which are intended to prevent and reduce transmission of organisms throughout the facility and from person to person,[8] can have a negative impact on facilities and residents.

Contact precautions can be costly for LTC facilities. They require personal protective equipment—e.g., gown and gloves—each time someone enters the room. This results in direct costs for the materials, as well as labor time for healthcare workers donning and doffing their gear.[9] Additional costs are associated with a private room, including the inability to place another resident not infected with *C. diff* in the same room. If an isolation room or private room is not available, a resident may need to be transferred to another facility.

Contact precautions also can have detrimental effects on residents. In their systematic review of the literature based on research performed in inpatient settings,[10] Morgan and colleagues identified many adverse outcomes related to contact precautions, including a twofold increase in falls, pressure injuries, and fluid and electrolyte imbalances. Contact precautions were associated with fewer resident-healthcare worker interactions and fewer visits from friends and family members. Isolated residents were more likely to feel bored and socially isolated, resulting in depression, anxiety, and anger. In another study,[11] the observations of healthcare workers made during contact precautions in skilled nursing facilities identified potentially harmful consequences, such as confusion, depression, and a decrease in self-esteem.

Avoiding Overtesting

Asymptomatic *C. diff* colonization is common among residents of LTC facilities.[12] Therefore, it is imperative that testing be performed in accordance with recommended guidelines to avoid overdiagnosis and overtreatment. Recent studies have shown that mindful application of testing guidelines can save money, prevent overtesting, and decrease *C. diff* infections.[13-14]

Parada and colleagues conducted a study to review *C. diff* order appropriateness. The study was conducted during a six-month trial by a 10-person team, based on an algorithm guideline for testing. Review of 678 *C. diff* orders showed that 428 (63.1%) were approved and 250 (36.9%) were rejected. A mandatory review was performed on all *C. diff* testing orders. Orders that correlated with the algorithm were approved. Orders that did not correlate with the algorithm were rejected and communicated to the care team. Appeals to the rejection of testing could be made on a case-by-case basis to the medical director of infection control. This study also included early identification of community-acquired *C. diff* to quickly initiate contact isolation and prevent diagnosis being classified as hospital-acquired. As a result of the study, the facility saved approximately $15,000 in laboratory testing costs, avoided overdiagnosing colonized patients as having *C. diff* infection, and achieved a significant drop in their infection numbers.[13]

In another study, a hospital revised its in-house *C. diff* testing guidelines to correlate with the 2017 IDSA/SHEA guidelines. The facility changed documentation requirements to help providers test more appropriately, limited testing to patients with three or more unformed stools per day, and excluded testing within 24 hours of laxative use. The laboratory also rejected specimens sent within seven days of previous negative results. *C. diff* testing decreased by 47%, from 358 to 188 tests per month. The number of *C. diff* infections decreased by 39% in one year (from 141 to 83). The facility also targeted improvements in hand hygiene, antimicrobial stewardship, and cleaning and disinfection of the facility. By revising the guidelines and documentation requirements, *C. diff* cases and overdiagnosis decreased.[14]

Although these studies were conducted in a hospital setting, similar outcomes may be achieved in LTC facilities by using an algorithm and testing in accordance with guidelines.

Improving *C. Diff* diagnosis

LTC facilities can decrease overdiagnosis of *C. diff*—and the various implications for residents and

facilities—by implementing strategies from the 2017 IDSA/SHEA clinical practice guidelines for *C. diff* infection.[6]

1. Understand that the preferred population for *C. diff* testing is residents with unexplained liquid stool (diarrhea) and new onset of three or more liquid stools (diarrhea) in 24 hours. Conditions and circumstances commonly associated with diarrhea include irritable bowel syndrome, recent laxative use, and therapies such as enteral tube feedings and intensive chemotherapy. Consider testing for *C. diff* if a resident has diarrheal symptoms *not* clearly attributable to these underlying conditions (i.e., unexplained).
2. Align policies with the guidelines and educate all members of the care team, including physicians, advanced practice providers, nurses, aides, and other allied health professionals.
    a. Follow guidelines for testing residents with a new onset of three or more unformed liquid stools (diarrhea) in 24 hours that are not otherwise explained by a condition or treatment that could cause diarrhea.
    b. Only submit a specimen that is liquid stool (diarrhea) and takes the shape of a container.
    c. Educate nurses and aides regarding the definitions of key terms, including "unformed liquid stool," "unexplained stool," and "new onset."
    d. Teach about contraindications for testing, such as laxatives. Staff may be unfamiliar with the brand and generic names of laxatives, so provide examples.
3. Do not screen for *C. diff*. There is insufficient data to recommend screening and contact precautions for asymptomatic carriers.
4. Define clinical symptoms that a resident may experience during a *C. diff* infection, such as leukocytosis or abdominal pain. In some cases, residents could experience fulminant *C. diff* (severe/complicated) showing signs of hypotension, shock, ileus, or megacolon.
5. Use a supportive decision-making tool, such as the algorithm for appropriate testing of *C. diff in* Figure 1, before collecting a specimen for *C. diff*.
6. If possible, develop a relationship with the laboratory to distinguish testing methods. Senior leadership may need to be involved in collaboration efforts. Develop a hard-stop protocol to reject specimens that have been tested during the same episode of diarrhea (within seven days), and do not test stool from asymptomatic residents, except for epidemiological studies such as during an outbreak.
7. During the same episode of diarrhea, do not repeat testing (within seven days).
8. Residents should not be tested to determine if their *C. diff* infection has been cured. Testing should only be performed as described above.

Reflection on the Bedside Story

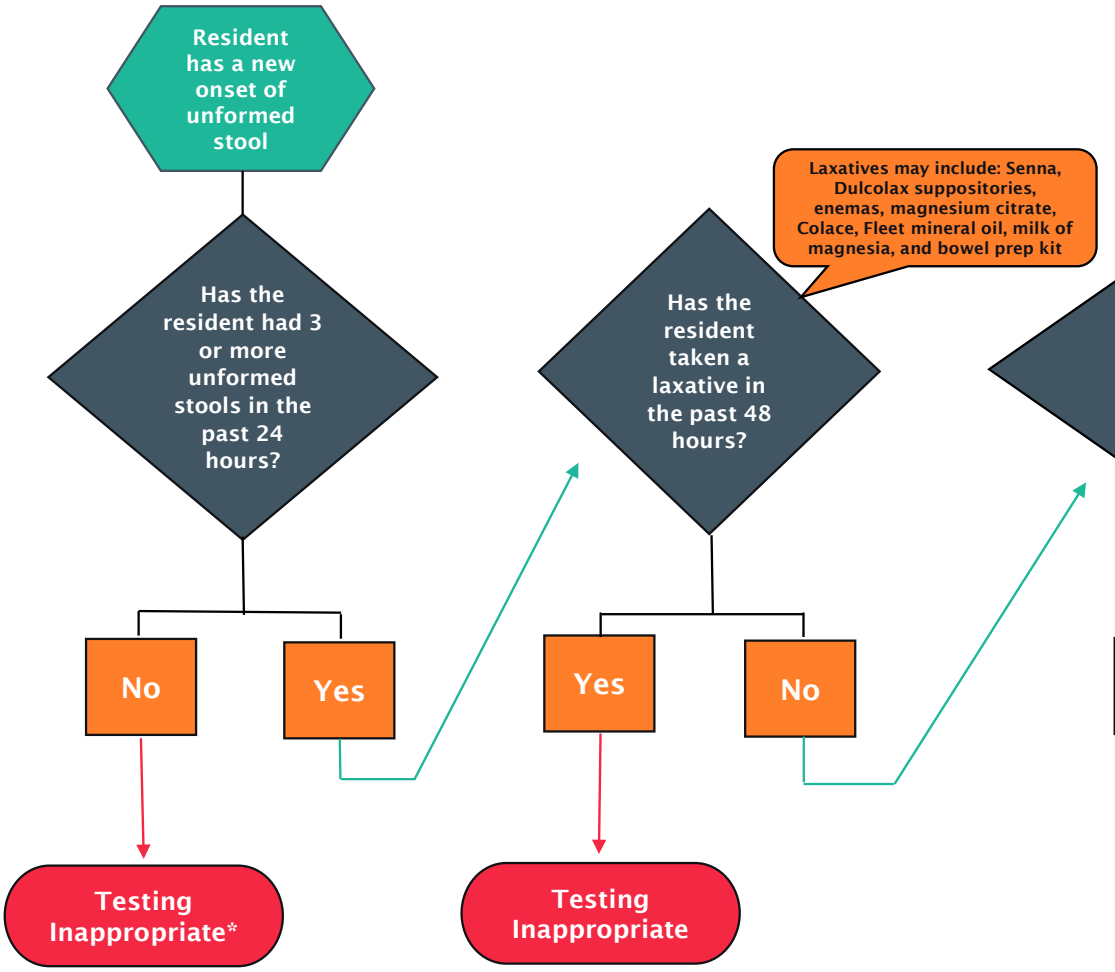
Following Sherry's death, her family and friends were overcome with grief. They could not understand how someone who was once was so active and full of life could be gone so quickly.

Cedar Springs performed a root cause analysis related to Sherry's fall. During chart review, they discovered that Sherry did not meet the testing criteria of unexplained liquid stool (diarrhea) and new onset of three or more liquid stools in 24 hours—she had only one liquid stool in 24 hours. She also had laxative tablets that day, which may have contributed to the liquid stool. If the IDSA/SHEA clinical practice guidelines had been followed, Sherry's story could have ended very differently, with her returning home to enjoy retired life with her friends and family.

Conclusion

As illustrated by Sherry's case, the significant implications of unnecessary *C. diff* testing are avoidable. By using the algorithm for appropriate testing of *C. diff* and applying the strategies outlined in this article, LTC facilities can ensure *C. diff* testing is performed according to best practices, thereby avoiding unnecessary costs and, potentially, preventable adverse patient outcomes.

Figure 1. Appropriate Testing of *Clostridioides difficile*



*On rare occasion, residents may experience fulminant *C. diff* (severe/complicated) showing signs of hypotension, shock, ileus, or megacolon. Clinical judgment is advised.

KEY CONSIDERATIONS

- Do not screen residents for *C. diff*. Testing in the absence of a new onset of 3 or more unformed stools in 24 hours is not recommended.
- Do not perform repeat testing during the same episode of diarrhea (within 7 days).
- Do not test stool from asymptomatic residents.

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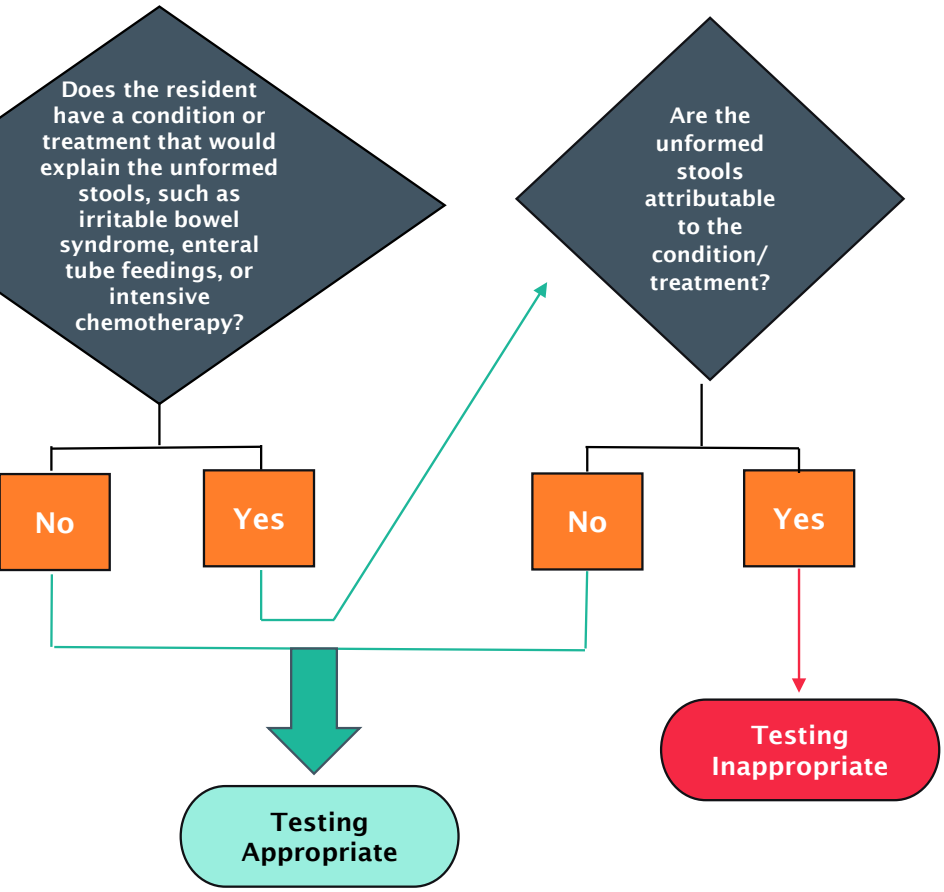

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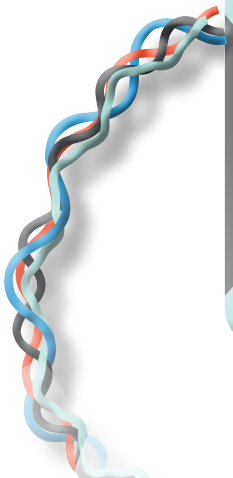
Batteries Gone Bad



Batteries power countless medical devices, making reliable performance essential. The effect of unanticipated battery failure can range in severity from benign inconvenience to a clinical emergency.

By Kim Liberatore[•◇], MSN, RN & Barry Kohler[◇], MESE

DOI: 10.33940/data/2019.9.8

A battery's moment of death may come as a beep, a red warning light, or a complete surprise. If you are lucky (i.e., prepared), you have a power cord or backup battery handy. If you are unlucky (i.e., unprepared), you may find yourself scrambling to resuscitate the device and possibly even the patient.

Batteries afford portability and convenience to countless medical devices. The type of battery, single-use or rechargeable, affects device performance and the potential for device failure.

Single-use batteries, also known as primary batteries, are the typical AA found in telemetry packs and the button batteries found in hearing aids.[1] Types of single-use batteries include alkaline, which are the most common, and lithium, which cost more but provide higher energy output and a longer life for devices such as implantable pacemakers.[1, 2]

Rechargeable or secondary batteries may recharge when the device is plugged in or require removal and placement in a charger.[1] Types of rechargeable batteries include lead-acid, nickel-cadmium (NiCd), nickel-metal hydride (NiMH), and lithium-ion (Li-ion or LIB).[1] Lead-acid are the oldest, most inexpensive, and most common secondary battery, typically large in size and found in devices such as wheelchairs.[2] NiCd and their less toxic successor, NiMH, provide higher power than lead-acid batteries at a lighter weight, making them practical for such devices as laryngoscopes.[1]

Li-ion batteries have become increasingly more common, offering the highest energy density and number of recharging cycles for devices such as smartphones and laptops.[2]

Analysts queried the PA-PSRS database for events involving battery failure submitted between January 1, 2018, and December 31, 2018, containing the keywords "battery" and "batteries" in the report narrative or equipment name field. The query identified 363 reports, of which 169 were excluded, leaving 194 reports for further analysis.

Four events did reach the patient and resulted in harm or death (i.e., Serious Events). Nearly 98% of the 194 relevant reports did not involve patient harm (i.e., Incidents).

Limitations

Despite mandatory reporting laws in Pennsylvania, PA-PSRS data is subject to the limitations of self-reporting and the complexity of reporting. The ability to categorize the type of device and battery-related failure is limited by the information provided by the reporter.

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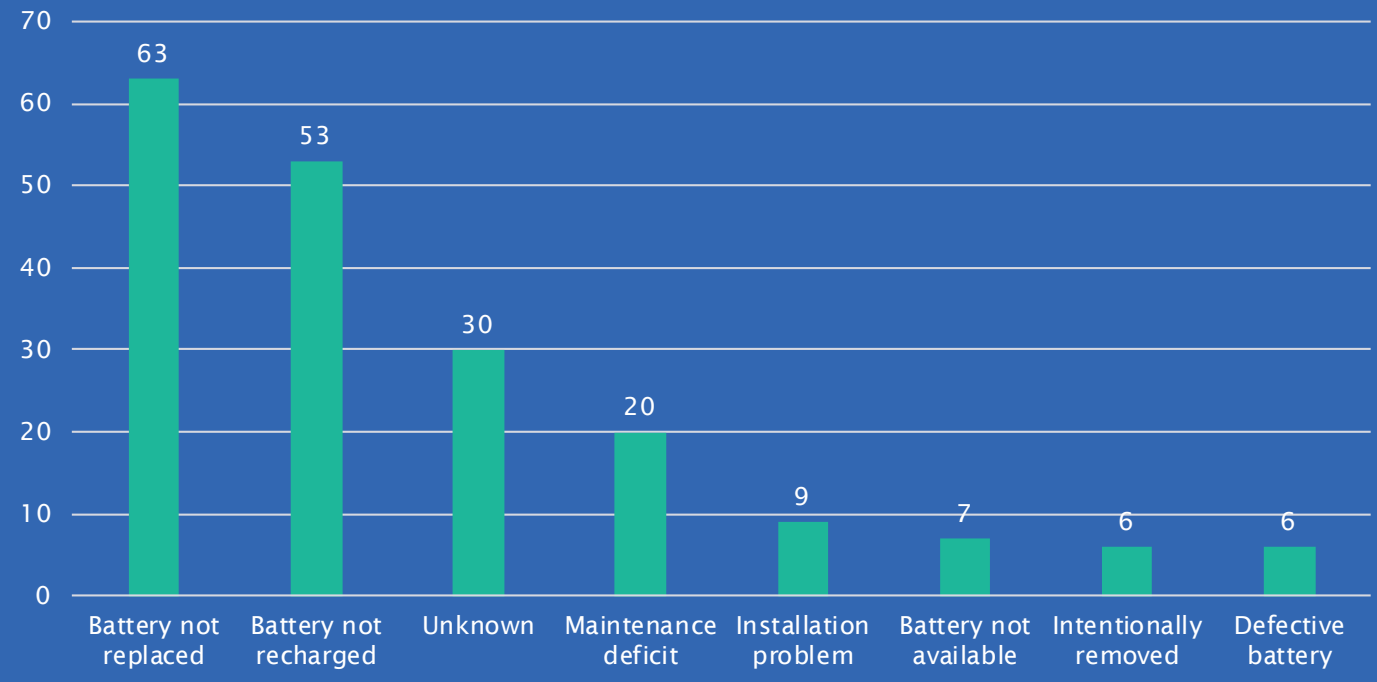
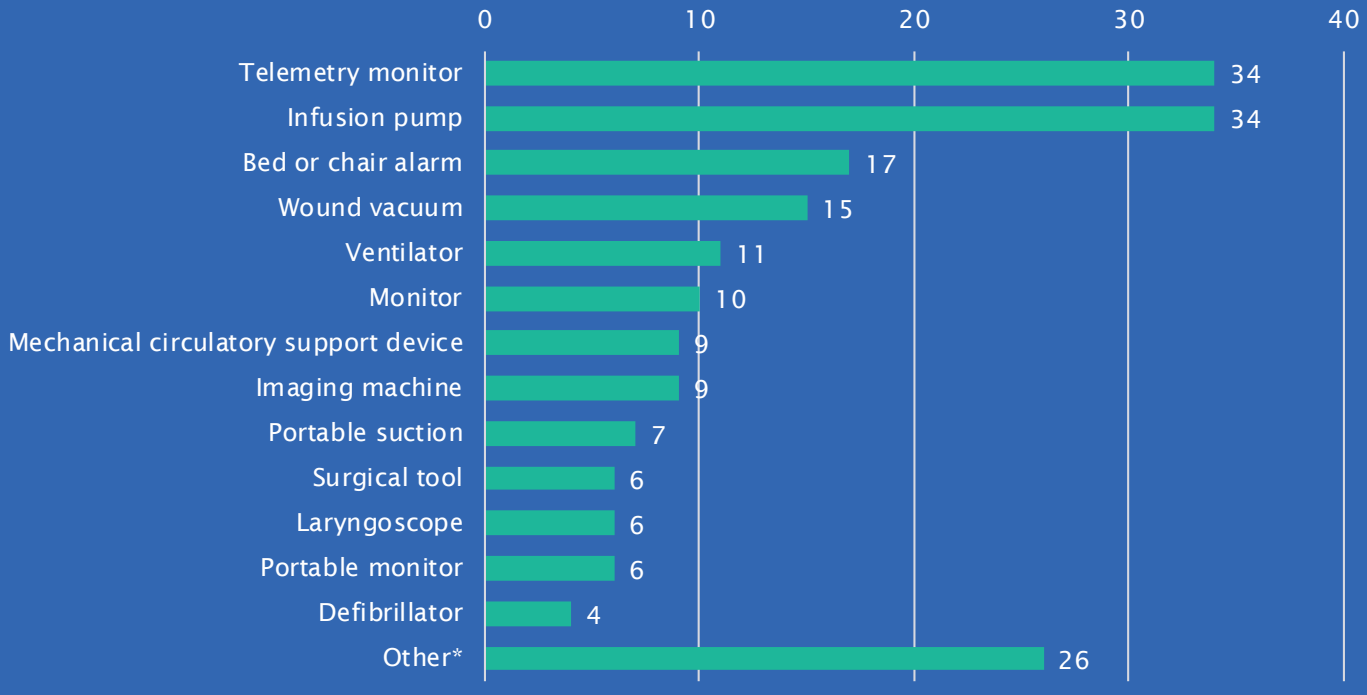
◇Patient Safety Authority
Disclosure: The authors declare that they have no relevant or material financial interests.

Number of Reports by Battery-Related Failure Mode (N=194)



Note: Reported through PA-PSRS, January 1, 2018 through December 31, 2018

Number of Battery-Related Reports by Type of Device (N=194)



Note: Reported through PA-PSRS, January 1, 2018 through December 31, 2018
*Other includes types of devices with fewer than 4 reports

Dr. Rachel Levine

Rachel Levine, MD, is secretary of health for the Commonwealth of Pennsylvania and a professor of pediatrics and psychiatry at Penn State. An accomplished authority on many topics, including adolescent health, eating disorders, and LGBTQ medicine, Dr. Levine recently spoke with Susan Wallace, MPH, senior patient safety liaison at the Patient Safety Authority, about Pennsylvania's efforts to combat the national opioid crisis, the Governor's multistep plan, and what she would like to see next for the Department of Health.

One of your signature areas of focus is the opioid epidemic.

By far the biggest public health crisis that we face in Pennsylvania, and arguably in the nation, is the opioid crisis. It is an epidemic. Usually we think of epidemics as being an infectious illness, but this issue has actually reached those proportions; by far more people die in Pennsylvania and in the nation from overdoses than from car accidents. This has been a significant issue from the day I started in the Wolf administration.

What I have been talking about for four years now is that this is a medical condition, not a moral failing. The surgeon general of the United States called addiction a chronic relapsing brain disorder. We have to view it in that context, as a condition, like diabetes or heart disease. That helps inform our treatment.

We have been working at the Department of Health (DOH), as well as through the entire administration, to get that message across—to get past the stigma. This is an urban issue, this is a suburban issue, and this is a rural issue. This is an issue for men and for women. This is an issue that spans any demographic group: age, race, religion, etcetera, that you might look at. We're all in it together to try to overcome it.

◀ *Pennsylvania Governor Tom Wolf, Louise Bruderle, Pennsylvania Department of Health Secretary Dr. Rachel Levine, and Pennsylvania Department of Health Executive Deputy Secretary Sarah Boateng*

Should there be different ways to fight the opioid epidemic based on demographics?

Yes and no. We're talking about the opioid crisis, and so you absolutely need to tailor interventions to specific communities. Interventions that might be very important in Philadelphia and in the Kensington area of Philadelphia might be much less appropriate in a rural area.

> *By far the biggest public health crisis that we face in Pennsylvania, and you could argue in the nation, is the opioid crisis.*

You do need to target specific prevention, rescue, and treatment efforts to the specific communities. You have to make sure that you're addressing other demographic groups, the African American community, the Hispanic community, etcetera. Yet there are similarities about opioid addiction that will inform our response as well, so it's kind of both.

What would you say to people who have heard that fentanyl is mixed in for heroin usage and don't want to come in contact with it because they are scared of overdosing?

Fentanyl is a very serious aspect of the opioid crisis. The biggest spike in overdoses over the last three years has been with synthetic fentanyl compounds. This is not diversion of the medicine fentanyl, this is synthetic fentanyl and related compounds produced primarily in China, and then brought in either through the mail or through the cartels from Mexico.

Fentanyl is 50 to 100 times more powerful than morphine. It can be up to 50 times more powerful than heroin. So you can see the risk of overdose and death. Fentanyl might be used on its own, or it might be used to cut another drug like heroin; unfortunately, drug dealers make a lot of money off fentanyl because of how concentrated it is.

The public has been appropriately concerned about fentanyl, but although it's very powerful, it's not easily absorbed through the skin—you have to inhale it or ingest it in some way. We want the public to be cautious, but first responders for the most part are not at risk from fentanyl. They might wear gloves, but it's not as if you touch a couple grains with your finger that it's going to absorb through the skin and you're going to overdose.

Pennsylvania recently updated its plan to fight opioid addiction. Can you outline some of the highlights?

Governor Wolf is committed to addressing the opioid crisis. From the beginning it has been all hands on deck. It has been all different agencies working together, another point emphasized by the governor's collaboration.

We're working now under a disaster declaration. A year ago, the governor ordered a disaster declaration for the opioid crisis in Pennsylvania. They last 90 days, and that has been renewed six times now. That has brought 17 different agencies together to our Opioid Operational Command Center at the

Everyone deserves a chance at life and recovery.

Pennsylvania Emergency Management Agency. We meet every week, with many phone calls in between to work on our collective response. There are three pillars to our response: prevention, rescue, and treatment.

Some of our prevention efforts are with the schools, with youth, and some are with the public. The efforts that I have been focusing on are working with the medical community to learn to prescribe opioid pain medications more carefully and judiciously. The term I like to use for that is opioid stewardship. To that end, we have developed a set of core competencies for every graduating medical student about these issues. We have developed continuing medical education credits for current physicians and other medical professionals. It's actually a legislative requirement now for our license. We have developed up to 12 prescribing guidelines about opioids that are specialty and location-specific. We have academic detailing, where people go out and do continuing education right in doctors' offices. We have a prescription drug monitoring program, which started in August 2016, to work with physicians in terms of monitoring their prescribing. We have a lot of efforts.

Our next pillar is rescue efforts. In 2015, as physician general, I signed two standing order prescriptions for naloxone. One was for first responders to have naloxone, and the other is for the public to have access to this lifesaving medication: I signed a standing prescription for the state—anyone in Pennsylvania can go to any pharmacy and obtain naloxone, either as a nasal spray or an auto-injector. First responders, such as basic life support, fire departments, and police, have saved well over 25,000 lives in the last number of years with this access to naloxone.

[In December], we had Naloxone Day, where we distributed over 6,100 kits of this medication free to the public. We want to save people's lives. I reject completely the idea that someone suffering from opioid

use disorder or heroin addiction is not worth saving. Everybody deserves a chance at life and recovery.

Now I do understand, however, that naloxone is absolutely necessary, but it's not sufficient. We have to get people into treatment. That goes to our third pillar. The first part of that is a warm handoff: a facilitated referral to treatment, for instance from the emergency department. Then we've expanded treatment in the Wolf administration. Through the Department of Human Services (DHS), the governor started 45 centers of excellence for patients, predominantly with Medicaid, throughout the state. Then, through the DOH and other agencies, we've started a program called PAC-MAT. That's not Pac-Man, that's a different thing. PAC-MAT: Pennsylvania (PA) Coordinated Medication Assisted Treatment. This is a hub-and-spokes model to try to expand access to medication-assisted treatment throughout Pennsylvania. There are eight PAC-MAT programs supported with federal funding.

What other programs would you like to see in the future for Pennsylvania?

There are four priorities that we have right now at the DOH. The first we've been talking a lot about, and that's the opioid crisis. The second is public health preparedness.

It's critical that our department, and working with our other state agencies as well as communities and the federal government, be prepared for any emergency. That can include the usual things we see in Pennsylvania—floods, snowstorms, etcetera—which can be very severe. But we need to be prepared for other illnesses. We need to be prepared for Ebola, or any other illness that could arrive in Pennsylvania that we would have to cope with. So public health preparedness. We're working very hard in terms of our regulations, licensure of nursing homes, as well as hospitals.

And finally, this year we're working on maternal child health programs. Other things that we have concentrated on, medical marijuana. We have I think one of the best, if not the best, medical marijuana programs in the country, to really use all the benefits of medical marijuana to be able to help patients with serious medical conditions. We're trying to support rural hospitals in Pennsylvania. We're trying to work on environmental health in Pennsylvania.

Again, the mission of the DOH is to help people from a public health perspective with a broader brush. I am absolutely so proud and grateful to be Pennsylvania's secretary of health and to work in Governor Wolf's administration.

*Visit **Patientsafetyj.com** to see an extended video interview with Dr. Rachel Levine about the opioid crisis and other health topics.*

Those seeking treatment for heroin and opioid use disorder may visit **www.pa.gov/guides/opioid-epidemic/** for a helpful guide and resources.

For information about how to access substance abuse disorder treatment in Pennsylvania, for yourself or your loved ones, call the 24/7 Get Help Hotline: **1-800-662-4357**

To view data behind Pennsylvania's response to the opioid crisis, collected through Governor Wolf's Opioid Disaster Declaration, visit the Opioid Data Dashboard at **https://data.pa.gov/stories/s/Pennsylvania-Opioids/9q45-nckt/**

> *It was a concept that if we could paint the patients' stories on our backs and walk as docents of our own lives, we could spread the word in a movement. There are hundreds of us now.*
>
> *— Regina Holliday*

Caitlyn Allen, MPH

Forget wearing your heart on your sleeve, to have the biggest impact, wear your story on your back! So says Regina Holliday, founder of The Walking Gallery—a self-proclaimed army of patient advocates who wear jackets depicting their experiences with the healthcare system. Most of the 500 jackets were hand-painted by Holliday, who founded the Gallery in 2011 after the death of her husband, Fred. Fred was diagnosed with metastasized kidney cancer in March 2009, and he and Holliday requested a copy of his medical records to make an informed decision about his care. They were told the records would cost $0.73/page and be available after a 21-day wait. Fred passed away shortly after the records would've been received.

Later that year, a friend was attending the American Medical Association (AMA) conference and suggested Holliday paint a jacket for her to wear portraying Fred's story—a way to include patients at the event.

In 2011, while attending the opening for Kaiser Permanente's Center for Total Health, inspiration struck. What the Center needed was an art gallery—not one with paintings hung on the wall, but a walking gallery, where patients could serve as docents for their own lives. Nearly a decade later, The Walking Gallery is as vibrant as ever with dozens of people joining each year.

In each issue, we'll feature a jacket as a reminder about what it can feel like to navigate our complex healthcare system. While everyone may not provide patient care, each of us has been a patient or loved one doing their best when they're feeling at their worst.

Photo credit: Ted Eytan

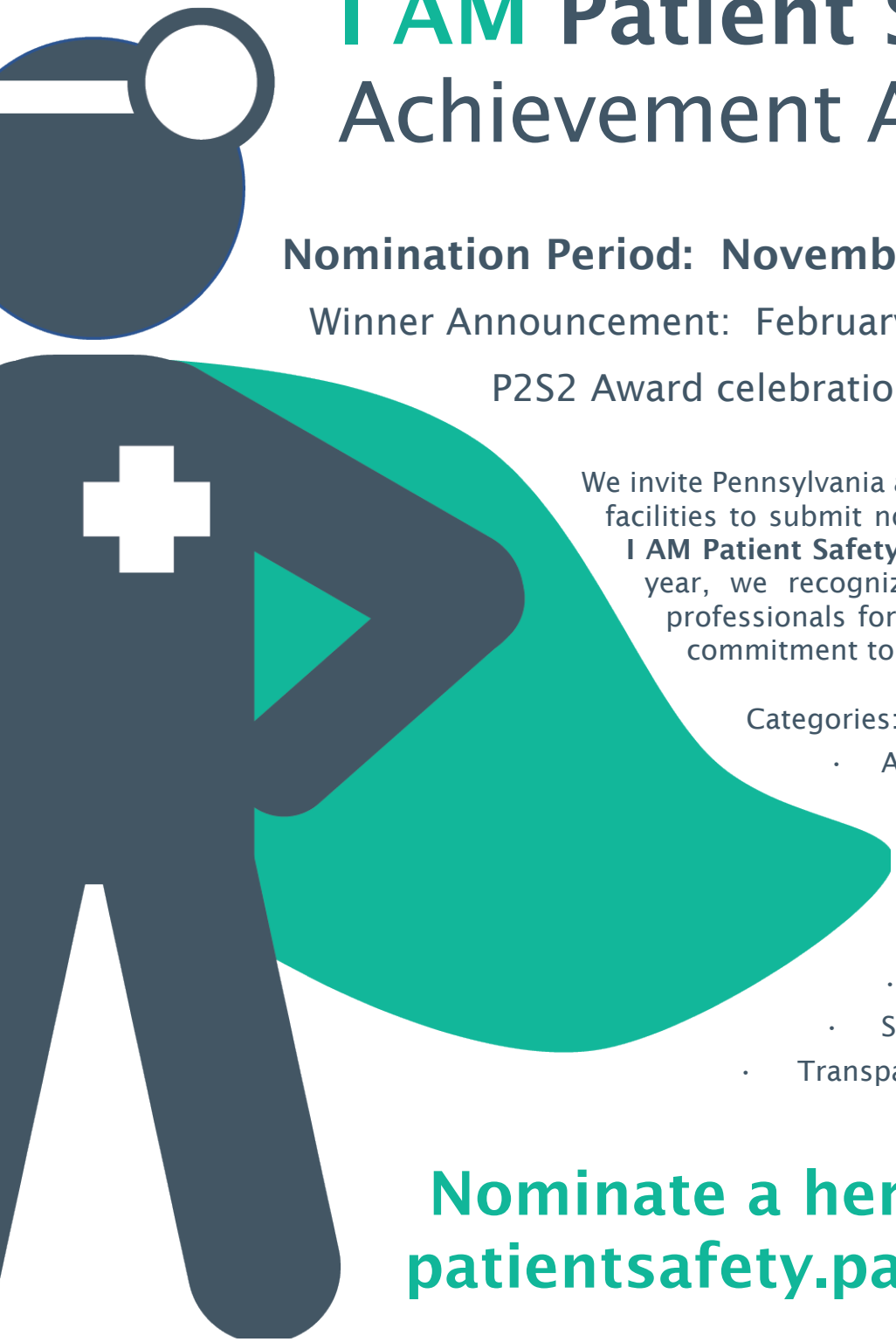
Jacket #399 "This Is My First Rodeo" for Joe Lavelle ▶

We chose Joe Lavelle's jacket, #399 "This Is My First Rodeo," for our first issue, because it accurately describes how many patients feel about the healthcare system—your life is in your hands with a constant fear of being thrown off. Healthcare professionals are thoughtful, assiduous people who work tirelessly to save lives and care for others. Our hope is this journal, and the rest of our work, will build a bridge between both groups and bring some calm.

**Most of the jackets featured in The Walking Gallery were painted by Regina Holliday.*

7th Annual

I AM Patient Safety Achievement Awards



Nomination Period: November 1–29, 2019

Winner Announcement: February 2020

P2S2 Award celebration: April 28, 2020

We invite Pennsylvania acute care and long-term care facilities to submit nominations for the 7th annual **I AM Patient Safety Achievement Awards**. Each year, we recognize and celebrate healthcare professionals for their individual and/or team commitment to improving patient safety.

Categories:

- Ambulatory Surgery Facility
  - Focus on the Patient
  - Improving Diagnosis
  - Individual Impact
  - Innovation
  - LTC Facility
- Safety Story/Near Miss
- Transparency and Safety

Nominate a hero at patientsafety.pa.gov!

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