



PATIENT SAFETY

June 2020 | Vol. 2, No.2

D[☠]: Crisis

Clinician burnout has been discussed for decades. Now in the face of the pandemic, how can we care for those who are caring for us?

2019 PA-PSRS Analyses:

Reviews from the nation's largest event reporting database

COVID-19 and its impact on Pennsylvania's healthcare facilities

Vaccines save 3 million lives each year. Prevent the preventable risks.

LETTER

From the Editor



*Regina Hoffman,
Editor-in-Chief
Patient Safety*

What a difference three months makes. Since the last issue of *Patient Safety*, our worlds have been turned upside down and inside out. We've been called to evaluate what matters most in both our personal and professional lives; we've been thrust into unplanned roles; and, like so many of you, the staff at

the Patient Safety Authority (PSA) and their families have been directly affected by an invisible enemy. Most recently, we've watched our nation react to an unconscionable act of hatred—we've cried, we've cursed, and we've watched our cities burn. Through all of this, healthcare workers showed up at hospitals, nursing homes, private homes, and emergency scenes. They showed up and they continue to show up. We dedicate this issue to our healthcare heroes. We appreciate you.

From our cover feature, SaraKay Smullens, social worker and bestselling author, and Dr. Stanton Smullens, board chair of the PSA, sat down and talked about clinician burnout, depression, and COVID-19's effect on an already growing crisis. Their collective personal experiences with these issues bring the reader into their space as they share their stories and offer solutions that so many of us can use right now.

Also, in this issue: an aggregate look at data submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS). While our dedicated team of patient safety analysts brings you articles each quarter that highlight findings from PA-PSRS and issues advisement for improvement, once a year we provide broad analysis of this data to help inform decision making at the local and statewide levels. Some highlights from this year include distribution of reports by

harm score, breakdown of top reported events, and events by care area. We also include articles that highlight COVID-19-related event reports, pediatric vaccine safety, overdoses in the hospital setting, denture impactions, and more.

Finally, thank you to all the presenters and poster authors who contributed wonderful information to what would have been our third Pennsylvania Patient Safety Symposium (P2S2). In lieu of the canceled event, some of our presenters agreed to provide their sessions in webinar format over the next few months. All PSA webinars are provided at no charge to participants. In addition, posters that were accepted for the symposium are showcased in this issue and upcoming issues, so be sure to check them out.

If you have research, improvement initiatives, or perspectives that contribute to our collective knowledge, please consider submitting your next manuscript to *Patient Safety* at patientsafetyj.com.

Stay safe for you, for those you love, and for those who show up for all of us!

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 inform and advise clinicians, administrators, and patients on preventing harm and improving safety, by providing evidence-based, original research; editorials addressing current and sometimes controversial topics; and analyses 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.

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Patient Safety Authority
333 Market Street - Lobby Level
Harrisburg, PA 17101
patientsafetyj.com
patientsafetyj@pa.gov
717.346.0469

Together we save lives

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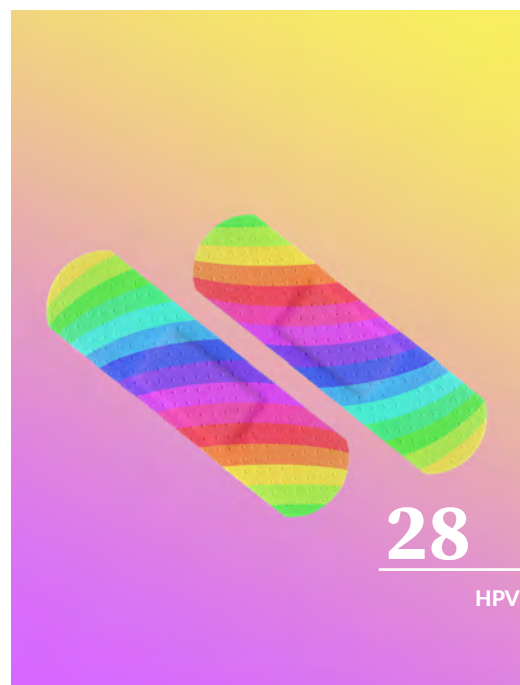
Our annual conference may have been canceled, but that doesn't mean all is lost.

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Before the pandemic, over half of frontline clinicians were reporting feeling burned out, and physician suicide rates were more than double the general population. How can we care for our caregivers?



Hospice Saved My Mother's

By Ann E. Green, PhD[◇]



◀ Mom in her wheelchair with flowers at a personal care home; she always loved flowers, so we brought them to her as often as we could (September 20, 2019)

[◇]Saint Joseph's University
Disclosure: The author declares that they have no relevant or material financial interests.

Life

“How are you doing with all of this?” asked the hospice social worker. We sat in a small recreation room in the skilled nursing facility. I had just signed the paperwork to put my 81-year-old mother on hospice. I didn’t know how to answer the question. In the last three months, my father had passed away, my mother had fallen and broken a hip, and then fallen again in rehab and broken her other hip. Post hip repairs, instead of recovering, Mom had almost stopped eating; had a hard-to-shake urinary tract infection; developed a pneumonia that needed IV [intravenous] antibiotics; and, worst of all, had a rapid cognitive decline.

Mom broke the first hip in the driveway of her home while walking to get the mail. She wasn’t found for some time, so in addition to the break, she developed hypothermia. When she broke her second hip, it was 18 hours before she was transported from the nursing home to the ER. Delirious with pain, she began undressing in the exam room, and the ER doctor recommended hospice for late-stage dementia. We opted for a second hip repair.

Back in rehab, she developed multiple infections and kept running out of Medicaid coverage for PT [physical therapy] because she wasn’t making progress, probably due to the infections. We appealed the Medicaid decisions and won, but Mom’s progress was still limited. While she recognized my sisters and me and had moments of clarity, she slept a lot, was often unresponsive, and was sometimes delusional.

I don’t remember how I responded to the social worker’s question about how I was doing. I might have shrugged. There was too much to put into words, I was so tired, and the rapid decline was overwhelming. I lived about three hours from Mom’s home, and during each emergency either my sisters or myself would need to drive back to manage the crisis. We were also driving back and spending hours each weekend with Mom, urging her to eat, observing her physical therapy, and wheeling her around the nursing home. We consulted with her surgeon and her primary care doctor and the social worker at the nursing home, who set up consults with a speech therapist. A psychiatrist had evaluated Mom via computer because of the rural isolation. We had advocated for Mom the best we could since her first hip break, but her decline continued.



- ▲ Mom at her favorite restaurant where she and my father dated 50 years before, with her favorite snack, ice cream
- ◀ Mom, Dad, and me on the front porch with Daphane the beagle (Summer 2014)
- ▼ Mom being blessed at a church service in her new nursing home (November 2019)

“

...hospice was good at interpreting nonverbal cues that might ensure a patient's comfort.



The social worker discussed the specifics of hospice: the biweekly visits by visiting CNAs [certified nursing assistants] and RNs [registered nurses], the social worker who would stop by, and the spiritual visits. Even though I was familiar with hospice's goals of pain management, comfort, and emotional and spiritual care for the patient and their family during the patient's last six months of life, I still hesitated to call in hospice. While I thought continuing to treat Mom was only causing her additional pain, there was a part of me that didn't want to sign a paper that agreed that my mother had six months or less to live.

In early January 2016, a couple of weeks after my father's funeral, my mother told me she wouldn't last long without him. She said, "And don't try and argue with me. You get your stubbornness from me, and I have decided." I attributed that to grief, but I also kept her words in mind when she broke one hip and then the other. I did some googling, and it looked like the survival rates for a hip break after 80 were low. I found little about mortality and two hip breaks.

We had a halting conversation with Mom to see what she wanted to do. She agreed to hospice, but it was unclear what she understood about her own situation. She was not the same person she had been three months before. I was her healthcare power of attorney, and I wanted to respect what I knew of her wishes. My father had always said no nursing homes, no hospitals. His death, a heart attack in the kitchen, was exactly the death he had hoped for. He died at home, a couple of hundred yards from the farmhouse where he had been born 80 years earlier. When my parents and I had signed their healthcare powers of attorney in 2001, they had been clear about their wishes, but wishes can change. Signing Mom up for hospice was my best guess for her happiness.

The ER doctor who initially suggested hospice did not know Mom—or us—and his recommendation was based on what he saw: an 81-year-old woman with a second broken hip transported from the local nursing home, hallucinating, in what he thought was a late-stage dementia. Since my sisters and I lived far away, none of us had visited Mom the day she broke her second hip, so we could not advocate for her and get her to the ER more quickly. It took my sister time to get to the ER, and during this period, there was no one with Mom to tell her story. Because the initial suggestion to consider hospice was so abrupt, it was harder for us to

consider hospice later. Hospice conversations require trust and time. Listening to the family and the patient is crucial as the patient absorbs this new way of thinking about care. For us, the possibility of losing both of our parents within a couple of months of each other was devastating. We were grieving our father as well as advocating for our mother. Hospice should not be offered in an ER without context or conversation.

My mother is alive because of hospice. The decision we made to put her on hospice when she survived two broken hips and stopped eating was the best decision we could have made, and more than that, it substantially improved her quality of life as her cognition and her body broke down. While this seems counterintuitive, as Atul Gawande [surgeon, researcher, and author of *Being Mortal: Medicine and What Matters in the End*] and others have found, the paradox of hospice is that by stopping curative treatment and focusing on quality of life, a patient can live longer. This is what we have found with my mom. Hospice and its kindnesses—its ability to address pain, anxiety, and discomfort over “curative” treatments—improved Mom's life and extended it. Four years after her hip breaks, she has “graduated” from hospice, and, while suffering from dementia, seems to be experiencing joy and pleasure in simple things like eating ice cream, going to mass, and singing songs from *The Wizard of Oz*. We are amazed and grateful that we have continued to have time together.

On hospice, Mom improved incrementally. Hospice worked with her doctor to eliminate unnecessary medications like her cholesterol and blood pressure pills. Mom had also recently been prescribed an iron pill for anemia, but this was discontinued. In my experience, it's uncommon for doctors to recommend unprescribing medications, but when hospice eliminated them, they also eliminated the side effects. Something relatively benign like an iron pill can cause constipation, diarrhea, and stomach upsets, and when a person has dementia, they might not be able to communicate their discomfort. Someone with dementia cannot advocate for him or herself, but hospice was good at interpreting nonverbal cues that might ensure a patient's comfort. Mom improved with fewer meds, gaining weight and increasing her mobility. Even the act of swallowing so many pills each day had been challenging.

When the facility took Mom fishing and she scraped her leg, hospice monitored the wound to make sure it didn't break down or become infected. The pictures from Mom's fishing trip showed her happiness at being outside. For us as a family, giving Mom pleasure was our priority. If that came with risk, that was OK, because hospice helped us ensure she was looked after. Hospice recognized that managing someone's emotional health can be just as important as monitoring their physical state.

Most importantly, hospice supported us as a family. We received calls, emails, and texts with updates on Mom, and one of the hospice nurses was always available to us by text to alleviate our concerns. One evening when I was with Mom, she lost the ability to speak entirely for about half an hour. A phone call to hospice reassured me that as long as her blood pressure and temperature were OK, there was no reason to take her to an emergency room, and the spell passed. Hospice visited the following morning, and Mom was OK. They continued to monitor her for other symptoms, but avoiding an ambulance ride, an ER visit, and the additional confusion that would accompany them was helpful. (Mom had no memory of her “poor spell.”)

We had family meetings with hospice where we could ask about Mom’s symptoms. Hospice talked with us about the best way to treat the extreme anxiety that sometimes came with Mom’s confusion. Communication has been key to our growing understanding of Mom’s condition, and we really have appreciated the medical professionals, mostly from hospice, who have helped us reconcile with Mom’s dementia and physical decline, understand death as a part of life, and treasure our time with her.

Inpatient Hospice

In order to qualify for hospice, you need a diagnosis. And Mom’s diagnosis for hospice was late-stage heart failure. Dementia and Alzheimer’s don’t generally qualify patients for hospice until very late in the disease progression when the patient cannot eat or talk, and “the dwindles,” the general decline experienced by the frail elderly, does not qualify someone for hospice at present. At almost 82, Mom was otherwise in good health. She had survived a melanoma without complications years before. Her primary care doctor’s major concern before the hip breaks was Mom’s weight; she was too thin. While on hospice, Mom continued to lose weight and become weaker, but her condition was not as clear as someone with a late-stage cancer diagnosis who might have weeks to live.

When crises emerged, like an unexplained fever or difficulty swallowing or another broken bone, any of which could have led to Mom’s death, she was able to spend a few days in inpatient hospice for monitoring or medication adjustment. Sacred Heart’s 10-bed facility had a fountain in the atrium, a kitchen, a living area, a meditation room, and large homelike patient rooms with a sofa for family to nap on. Rather than the confusion of an ER visit and scans and tests or a hospital stay where alarms and beeps interrupt sleep at all hours of the day and night, inpatient hospice was calm and soothing. In my memories of inpatient hospice, I do not remember the computers and charting that intrude on patients and caregivers in hospitals. Sacred Heart didn’t even smell like a hospital.

Another gift of the hospice caregivers was their willingness to see Mom as a person—not a dementia patient. Early on in our journey I had an argument with a nursing home nurse who told me Mom was undressing in the lobby because of her Alzheimer’s. At that point, Mom had just had two major surgeries and no diagnosis of dementia or Alzheimer’s. I asked the nurse to check for a urinary tract infection as I suspected that my very modest mother who rarely gets fevers could be sick. (Delirium can be a symptom of a UTI.) Mom did, indeed, have an undiagnosed infection. While I was angry that her infection had been missed, I was more angry that the healthcare professional had assumed a condition rather than reading Mom’s chart (where there was no dementia diagnosis) or investigating other causes for Mom’s odd behavior.

While Mom changed because of what was eventually called a dementia, she was—and is—still a person. Her needs and desires have evolved over the past four years, and hospice was helpful in helping us recognize and accept these changes.

For us, hospice was not giving up on Mom, but a way of advocating for her quality of life. It meant acknowledging that additional scans, tests, and treatments would not return her to her previous life or cure her comorbidities. Like many families that opt for hospice, we struggled with the decision and the path was not always clear. At the present moment, Mom lives at a skilled nursing facility near my home, her third placement since her hip breaks. She has graduated from hospice twice. The time we spend together includes bringing her milkshakes, rubbing lotion on her hands, touching up her manicure, taking her to the rosary, and taking her to mass. While most people do not opt for hospice until the last few weeks of a patient’s life, it is my hope that when people understand the comforts it can bring, more patients and families can ask for hospice sooner. Death is inevitable. The way we approach it can make all the difference.

Author Bio

Ann Green is a professor of English at Saint Joseph’s University in Philadelphia.



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*Communication has
been key to our growing
understanding of
Mom's condition...*

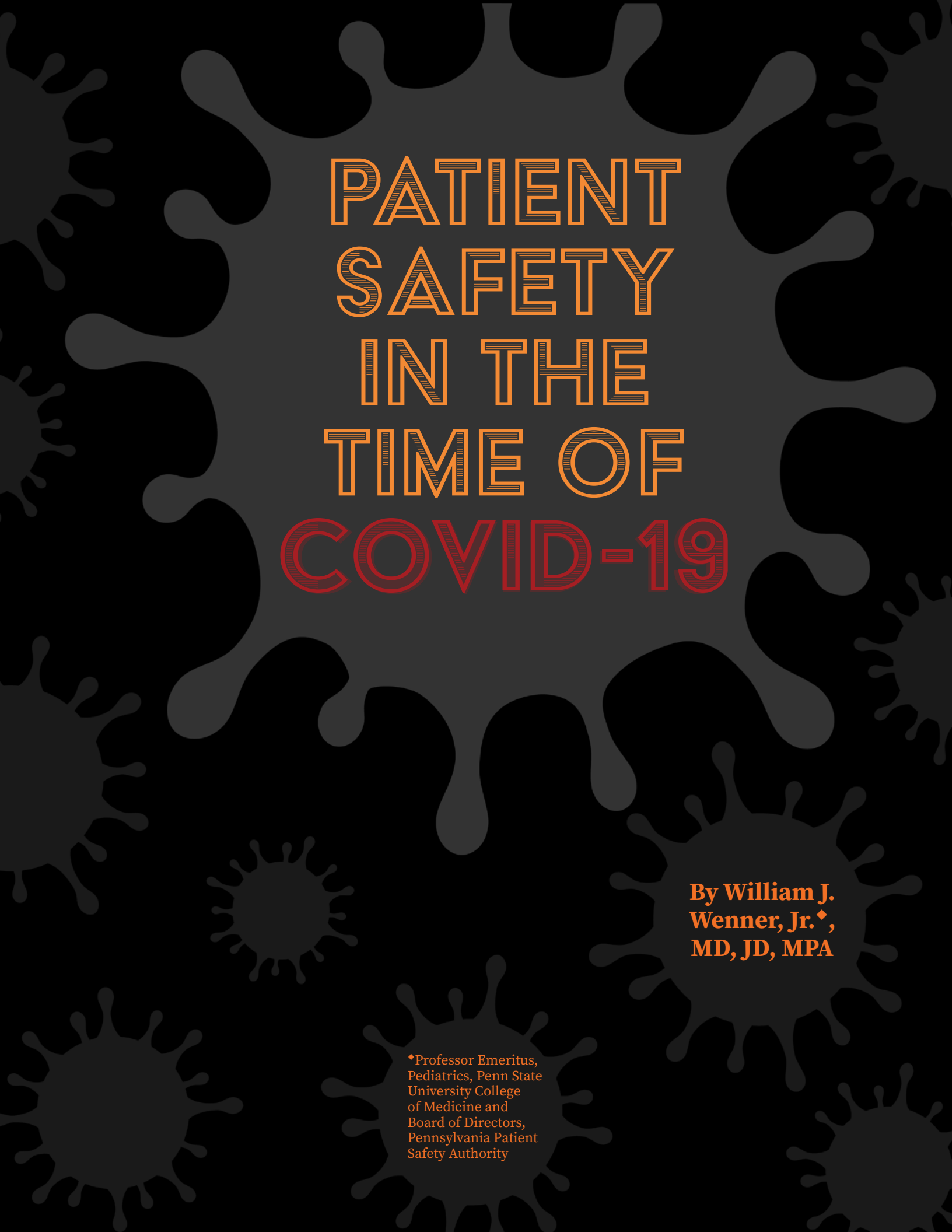
- ▲ Mom and me at a Christmas party at the skilled nursing facility (December 2018)
- Me, mom, and Daphane at Mom's 82nd birthday party at the skilled nursing facility (March 2016)
- ▼ Mom and caregivers from assisted living on a fishing outing with the therapy dog





Disclosure: None

Disclaimer: Views presented are solely those of the author and do not reflect those of Penn State University nor the Patient Safety Authority



PATIENT SAFETY IN THE TIME OF COVID-19

**By William J.
Wenner, Jr.♦,
MD, JD, MPA**

♦Professor Emeritus,
Pediatrics, Penn State
University College
of Medicine and
Board of Directors,
Pennsylvania Patient
Safety Authority



Our health system is experiencing a crisis unlike any in modern times. Since late 2019, the COVID-19 pandemic has been creating unprecedented stress on the system. In early May 2020, there were 3.8 million confirmed cases and 270,000 deaths worldwide. The United States has had over 1.2 million confirmed cases and 76,000 deaths.¹ This crisis has been overwhelming. Things that were unimaginable were and are now deemed necessary. Patient and provider safety issues fill the news media. Transmission of the virus and high fatality rates in nursing homes has been well documented. Healthcare providers have had to work with inadequate personal protective equipment. Patients have died without family support or consolation.

The pandemic has forced those responsible for healthcare to reorder priorities, and in doing so the standard of care has been lowered. The CDC's [Centers for Disease Control and Prevention] face mask strategy is an example of lowered standard of care: It is based on levels of "surge" in patient volume and severity, yet there are no specific qualifications or trigger points for application. The CDC admits that in crisis capacity, "strategies that are not commensurate with U.S. standards of care (would and have been implemented). These

measures, or a combination of these measures, may need to be considered during periods of known face mask shortages."² The CDC did advise that these strategies should not be implemented until other (strategies) have been found overwhelmed, including such unheard-of policies of reducing face-to-face HCP [healthcare personnel] encounters with patients and excluding visitors to patients with confirmed or suspected COVID-19.

Changes in routine are to be expected in a time of crisis, but attention has yet to be directed to the impact of these changes on traditional patient safety. It is important to remember that underneath the current crisis, another long-present healthcare crisis continues to take lives. And despite years of effort, that crisis remains without a cure: Preventable medical errors kill between 100,000–300,000 patients per year in the United States. While comparing lethality can be problematic, COVID-19 is predicted to kill 100,000–200,000.^{3,4}

Two emergency changes in the patient safety structure during the pandemic are particularly striking: the change in family involvement and the change in oversight of healthcare. These elements have been the cornerstones in protecting patients.

Recognition of the role of patient and family in patient safety and error prevention has been one of the most significant developments in healthcare of the past 50 years. Prior to the pandemic, incontrovertible evidence showed the value of patient and family involvement in patient safety. Patients and family provide three key contributions to the quality of their own care: their knowledge of the historical background, their self-interest and motivation for a good outcome, and their availability and proximity.⁵ Unfortunately, this involvement has had to be minimized in the response to the pandemic. The impact of this reduction is unknown.

Oversight of care by outside entities such as The Joint Commission, licensing boards, and tort liability have been the traditional foundation of patient safety. But due to the crisis, the usual protections of oversight have been suspended or significantly curtailed. The Joint Commission has suspended all regular, on-site surveys of hospitals and other healthcare organizations, effective March 16, 2020.⁶ Per CMS [Centers for Medicare & Medicaid Services] directive, states have suspended standard (recertification) surveys (including life safety and emergency preparedness elements) for nursing homes, hospitals, home health agencies, hospices, and intermediate care facilities. Suspended activities include revisit or follow-up surveys not associated with immediate jeopardy.^{7,8} And in what appears to be an unprecedented move, tort liability, by which patients are compensated for preventable medical errors, has been lessened or removed in some areas.^{9,10}

Post Corona

This crisis will resolve. There will be a new normal. Those responsible for healthcare will have to make critical decisions, none less important than what we will do about patient safety. We will need to be open and honest about what happened during the crisis. We will need to conduct the needed postmortem analysis without retribution, fear, secrecy, or fraud.

The safeguards that existed prior to the pandemic must be restored and strengthened. Proper oversight of healthcare must return. Patients and family must be directly involved in their care. They must return to their proper role at the center of healthcare improvement.

It will be even more tragic if the progress made on patient safety and medical errors in the past decades also becomes a victim of the coronavirus. The horror of the COVID-19 pandemic should not prevent us from rededicating to the mission of curing the other

pandemic of preventable medical errors that has killed countless millions.

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Author Bio

William Wenner (wwenner@pennstate-health.psu.edu) is professor emeritus of Pediatrics at Penn State University College of Medicine and a member of the Board of Directors of the Patient Safety Authority.

Patient Safety Concerns in COVID-19– Related Events

A Study of 343 Event Reports
From 71 Hospitals in Pennsylvania

By **Matthew A. Taylor**, PhD^{♦♦},
Shawn Kepner, MS[◇],
Lea Anne Gardner, PhD, RN[◇]
& **Rebecca Jones**, MBA, RN[◇]

DOI: 10.33940/data/2020.6.3

[♦]Corresponding author
[◇]Patient Safety Authority

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Abstract

COVERID-19 (i.e., coronavirus disease 2019) was declared a pandemic and has had a profound impact on healthcare systems, which may increase the risk of patient harm. We conducted a query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify COVID-19-related events submitted by acute care hospitals between January 1 and April 15, 2020. We identified 343 relevant event reports from 71 hospitals and conducted a descriptive study to identify the prevalence of and relationships between 13 categories of associated factors and six categories of event outcomes. We found that 36% (124 of 343) of events had more than one associated factor and 24% (83 of 343) had more than one outcome. The most frequently identified factors were Laboratory Testing (47%; 161

of 343), Process/Protocol (25%; 87 of 343), and Isolation Integrity (22%; 74 of 343). The two most frequent outcomes were Exposure to COVID-19 Positive or Suspected Positive Patient (50%; 173 of 343) and Missed/Delayed Test or Result (31%; 108 of 343). Finally, the findings showed that seven of the associated factors had a notable impact on the frequency of Exposure to COVID-19 Positive or Suspected Positive Patient outcome. Overall, we anticipate that the results can be used to identify areas of greatest need and risk, which could help to guide allocation of resources to mitigate risk of patient harm.

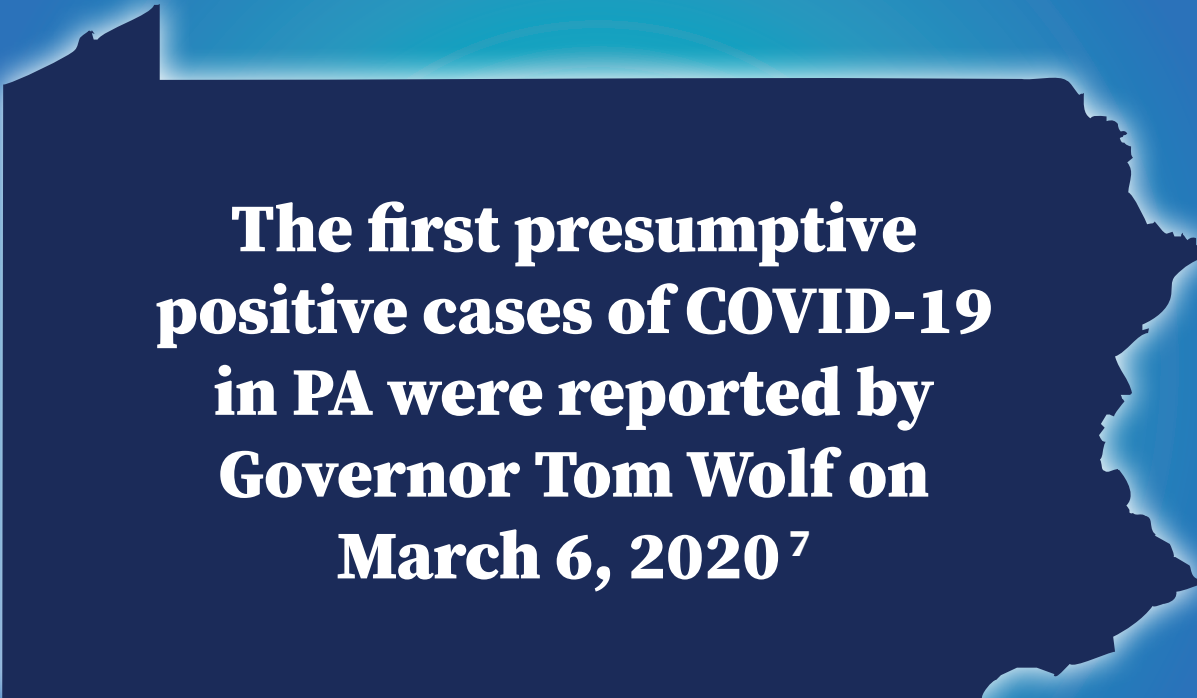
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Keywords: *patient safety, associated factors, COVID-19, SARS-Cov-2, coronavirus*

Introduction

Coronaviruses are a family of viruses that cause a range of respiratory illnesses, ranging from the common cold to severe acute respiratory syndrome (SARS) and pneumonia.¹ In late December 2019, a cluster of pneumonia cases were reported in Wuhan in the Hubei Province of China, and the pathogen was subsequently identified as a novel coronavirus, which was named SARS-CoV-2.¹⁻³ The associated disease was named coronavirus disease 2019, abbreviated COVID-19.³

The virus began to spread quickly in China and then around the world.² The first case of COVID-19 in the United States was confirmed on January 20, 2020, in a 35-year-old man in Snohomish County, Washington, who became ill after returning from a trip to Wuhan.⁴ Since then, positive COVID-19 cases have been identified throughout the United States.³ The World



**The first presumptive
positive cases of COVID-19
in PA were reported by
Governor Tom Wolf on
March 6, 2020⁷**

Health Organization (WHO) declared the COVID-19 outbreak a global pandemic on March 11, 2020.⁵ Pandemics of respiratory disease are characterized by several distinct phases, beginning with investigation, followed by recognition, initiation, acceleration, and deceleration.⁶

The first two presumptive positive cases of COVID-19 in Pennsylvania were reported by Governor Tom Wolf on March 6, 2020.⁷ As of April 15, 2020, there were 26,490 cases and 647 deaths reported by the Pennsylvania Department of Health (DOH).⁸ Given the many challenges associated with managing care and treatment for patients with COVID-19 and the burden placed on healthcare systems,⁹ we became concerned about how the pandemic may impact patient safety. As a result, we began monitoring the Pennsylvania Patient Safety Reporting System (PA-PSRS)* database and identifying COVID-19-related events occurring in acute care facilities. To better understand the nature of these COVID-19-related events, we designed a descriptive study to identify associated factors and outcomes. We sought to provide timely information that may help healthcare facilities and policymakers better understand how the COVID-19 pandemic has impacted certain aspects of patient safety in Pennsylvania. Additionally, we anticipate that the findings may be used to identify areas of greatest need, which could

help to guide allocation of resources to mitigate risk of patient harm.

Methods

Sample

We queried the PA-PSRS database for event reports submitted by acute care facilities between January 1 and April 15, 2020. In the query we applied keyword inclusion filters (e.g., “coronavir” OR “corona vir” OR “covid” OR “cov-2” OR “cov2” OR “sars”) and exclusion filters (e.g., “covidien” OR “covidien” OR “covidien”) to the free-text narrative fields. Based on the query criteria, the output had a total of 473 event reports.

Subsequently, one author manually reviewed the free-text narrative fields in each of the 473 reports to identify events that are consistent with the scope of the study. Events were included if they met at least one of the following criteria:

- Described a patient who was COVID-19-positive or suspected as positive and included a patient safety concern.
- Described a COVID-19 negative or non-suspected patient, or staff member, who, while in hospital, experienced or expressed concern for a higher than necessary level of risk of exposure to COVID-19.

We excluded event reports in which non-COVID-19 patients were indi-

rectly impacted by the pandemic (e.g., non-suspected patient had a delay in care at an emergency department due to competing demands related to management of COVID-19-positive patients). While these reports reflect an incredibly important topic, we felt that it would be best addressed in a separate study. We also excluded reports that described a hospital-acquired COVID-19 infection, as the Patient Safety Authority issued a program memorandum in concurrence with the DOH on March 27, 2020, advising that acute care facilities are not required to report any COVID-19 infections to PA-PSRS.

Based on our manual review of the 473 event reports and application of the inclusion criteria, we identified a total of 343 relevant events. The 343 events represent several types of acute care hospitals, including children’s hospitals and rehabilitation hospitals. (Psychiatric hospitals and ambulatory surgical facilities were not represented in the final dataset.)

Variables Coded

Across all 343 event reports, we explored two sets of variables. The first set was coded by event reporters (i.e., hospital-designated staff who submitted the reports to PA-PSRS) and included the following demographic and clinical variables: patient age and gender, event classification (Serious Event† vs. Incident‡), and care area group. §

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

†Serious Event is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.¹⁰

‡Incident is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.¹⁰

§Within PA-PSRS, there are 179 care areas to capture the location where an event occurs. To cross-tabulate a more manageable number of category elements with other variables of interest, the authors placed each of these care areas into higher-level care area groups.

Table 1. Factors Associated With Patient Safety Concerns Within COVID-19–Related Events

Associated Factor	Examples
1. Admission Screening 	Admission staff missed or had notable delay in screening the patient for COVID-19 signs/symptoms or recent high-risk travel.
	Admission staff conducted patient screening, but findings were unreliable in identifying patients that warranted COVID-19 testing.
2. Communication 	Staff failed to communicate patient's COVID-19–positive or suspected positive status during handoff to other staff.
	Transport staff failed to notify clinical staff that a COVID-19–positive patient with fall-risk status was returned to the isolation room. While unattended, the patient fell at the bedside.
	The paging system malfunctioned, which delayed staff from consulting infection control about whether COVID-19 testing was warranted for a patient.
	Hospitals failed to notify Emergency Medical Service (EMS) when a patient later tested positive for COVID-19.
3. Imaging 	Portable x-ray unit was not charged overnight, which caused imaging delays for COVID-19–suspected patients.
	Magnetic resonance imaging (MRI) staff members refused to see a patient because of suspected COVID-19–positive status.
	Computerized Tomography (CT) scan was not performed while a COVID-19–suspected patient was in the emergency department, causing a delay in results.
4. Inadequate Disinfection 	Staff performed a CT scan of a COVID-19–suspected patient and failed to prevent other staff and patients from entering the room during the subsequent hour.
	A room previously occupied by a COVID-19–suspected patient was not terminally cleaned prior to admitting a new patient into the same room.
	A thermometer being applied directly to visitors' foreheads was not disinfected between each use.
5. Isolation Constraints 	Staff who were outside an isolation room were unable to hear a device alarm (e.g., ventilator, infusion pump) located inside the room.
	Staff were unable to communicate or observe the patient from outside of an isolation room, preventing timely detection of changes in the patient's health status (e.g., fall, self-extubation, change in level of consciousness).
	Notable time required to attain and don personal protective equipment (PPE), which caused delays in entering an isolation room.
	Error in connecting extended infusion pump tubing from outside of isolation room to the patient, which caused a drug omission.
6. Isolation Integrity 	A non-suspected-COVID-19 patient was assigned a roommate who was suspected to be positive.
	Order for isolation precautions for a COVID-19–suspected patient were not recognized and adopted by staff in a timely manner.
	A COVID-19–suspected patient was placed in a room without a negative-pressure system or the room had a negative-pressure system, but it was not turned-on.
	Staff failed to don (apply) adequate PPE when interacting with a COVID-19–positive or COVID-19–suspected patient or failed to doff (remove) potentially COVID-19–contaminated PPE.
	A COVID-19–suspected patient did not don a mask and was unnecessarily transported through a non-COVID-19 unit.

Table 1. Factors Associated With Patient Safety Concerns Within COVID-19–Related Events (cont.)

Associated Factor	Examples
7. Knowledge Deficit 	Staff were unaware of what would be considered adequate PPE to prevent exposure and proper PPE doffing technique. Medical residents were untrained and unprepared to interact with a suspected-positive patient. Laboratory employees were unclear about adequate sources for COVID-19 specimen (e.g., endotracheal aspirate) or how to handle and manage specimens.
8. Laboratory Testing 	Specimen collection delay or poor collection technique. Specimen was mislabeled, without a label, mishandled, misplaced, erroneously disposed, or processed with a delay. False negative or false positive result. Specimen had to be recollected.
9. Medication 	A COVID-19–suspected patient was prescribed or used an inappropriate drug delivery device (e.g., drug treatment via nebulizer), which may aerosolize the virus particles. Patient missed drug treatment because breath-actuated inhalers were incompatible with mechanical ventilation and the patient’s drug treatment was not switched to a compatible device. Staff did not complete medication reconciliation for a COVID-19–suspected patient due to fear of infection, which resulted in errors in drug treatment.
10. Patient 	COVID-19–suspected patient failed to inform staff of their COVID-19–positive status. COVID-19–suspected patient manipulated equipment or device. COVID-19–suspected patient behaved erratically and aggressively toward staff. Non-suspected patients left the facility against medical advice to avoid potential exposure to COVID-19.
11. Process / Protocol 	Staff failed to use a sign-in sheet before entering an isolation room and the observer of the isolation rooms failed to manage and uphold protocol for monitoring staff interactions with COVID-19–positive patients. Patient’s status was changed to COVID-19–positive or COVID-19–suspected, but isolation and PPE signage were not placed on patient’s door. COVID-19–positive or COVID-19–suspected patients were discharged to home without isolation instructions.
12. Resource Availability 	Challenge with availability of a resource due to its shortage, malfunction, or being soiled. Types of resources included infrastructure (e.g., isolation room); medical equipment (e.g., x-ray, CT scanner, negative air system, ventilator, heart monitor); medical supplies (e.g., curtains); disinfection supplies (e.g., bleach wipes); PPE (e.g., eye protection, N95 mask, full-face shield); and staff (e.g., phlebotomist).
13. Other 	Staff failed to recognize that a patient developed signs and symptoms of COVID-19 while in hospital. Physician deferred or ICU refused to accept a patient due to their COVID-19–suspected or COVID-19–positive status. Limited positioning of COVID-19 patient led to pressure injuries.

Table 2. Outcomes From COVID-19–Related Events

1. Exposure to COVID-19–positive or suspected-positive patient*
2. Fall
3. Missed/delayed care or treatment
4. Missed/delayed test or result
5. Wasted resource
6. Other

*This outcome includes events where a patient and/or staff member experienced or expressed concern for a higher-than-necessary level of risk of exposure to COVID-19

The second set of variables were coded by one of the study authors who manually reviewed the free-text narrative field in each event report and identified one or more *associated factors* that had implications for patient safety. Our coding scheme consisted of 13 categories

of associated factors, which are described in **Table 1**. Additionally, while reviewing each report we identified one or more *outcomes* related to each event. Our coding scheme of outcomes included six categories, which are listed in **Table 2**.

During our review of the event reports, additional data were coded to better understand the nature of the events. For example, we collected data on whether the challenges with personal protective equipment (PPE) involved donning or doffing (i.e., applying or removing) and whether it involved the patient or staff. Throughout this descriptive study, all variables were measured, analyzed, and compared by frequency or percentage of occurrence.

Results

Patient Age and Gender

Within the sample of event reports, 53% (181 of 343) of the patients were reported as male and 47% (162 of 343) were female. The median patient age was 62 years and the interquartile range was 35–72 years (25th and 75th percentile). (See **Figure 1** for the distribution of patient age.)

Event Classification (Serious vs. Incident) and Care Area Group

The reports revealed that 1% (5 of 343) of the events were classified as Serious, which included one patient death. The remaining 99% (338 of 343) of events were classified as Incidents. The reports also revealed that the events occurred across 19 care area groups. Events were most frequently associated with the following care area groups: Emergency Department (26%; 88 of 343), Medical/Surgical Unit (22%; 75 of 343), Intensive Care Unit (17%; 59 of 343), Laboratory (7%; 25 of 343), and Specialty Units (6%; 20 of 343).

Hospitals

Across the 343 event reports, we found that all 71 acute care hospitals submitted at least one report and a median of two reports per hospital (maximum of 29 reports for an individual hospital). Also, events were reported by hospitals of various sizes, but a majority were from those with more than 300 beds (58%; 200 of 343).

Figure 1: Distribution of Patient Age in Years

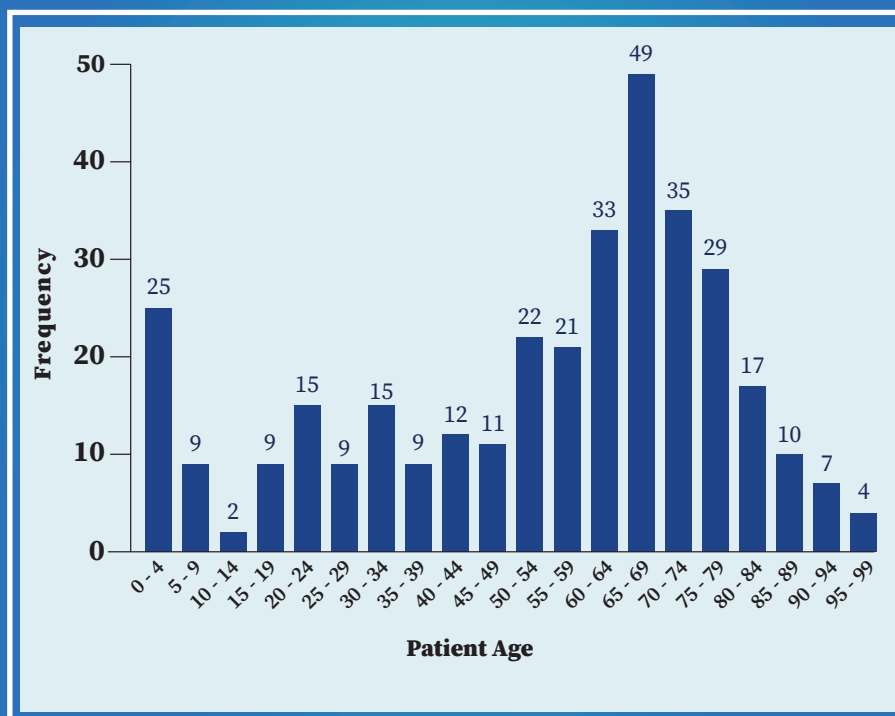


Table 3. Frequency of Associated Factors by Care Area Group and Across All 343 Event Reports

Care Area	Laboratory Testing	Process/Protocol	Isolation Integrity	Communication	Medication	Other	Resource Availability	Isolation Constraints	Knowledge Deficit	Patient	Inadequate Disinfection	Admission Screening	Imaging	Grand Total
Administration	1	1												2
Emergency	61	10	13	11	4	8	3		4			1	2	117
ICU	22	15	11	8	8	12	6	4	3	5				94
Imaging/Diagnostic		6	7	6			3			1	3		2	28
Intermediate Unit	4	7	9	6	1		4	1						32
Labor and Delivery	4			1										5
Laboratory	24	2		1										27
Med/Surg	23	27	19	12	18	7	3	13	3	1	1		1	128
Nursery	1													1
OB/GYN Unit		1	1											2
Other	2	1	1	1	1	1			1		1			9
Outpatient/Clinic	6	1	1			2								10
Pediatric	3	1		2			1	1						8
Pharmacy							1							1
PICU	3	1		1		2								7
Psychiatric Unit		1	1	1										3
Rehab Unit	1							1		1				3
Specialty Unit	5	11	9	5	4	2	1				2	1		40
Surgical Services	1	2	2	1			1			1	1	4		13
Grand Total	161	87	74	56	36	36	22	19	11	9	8	6	5	530

Note: The grand total below each column represents the number of events that were impacted by each associated factor. The grand total at the end of each row reflects the sum occurrence of all associated factors across all events, by care area group.

Variables Based on Manual Review of Event Reports

In this section, we report results related to event-associated factors and event outcomes. The findings are based on all 343 event reports.

Associated Factors

As shown in **Table 3**, the 13 associated factors had varying impact on the 343 COVID-19-related events submitted to PA-PSRS. We found that 36% (124 of 343) of events had more than one associated factor, for a total of 530 occurrences of associated factors across all 343 events. Overall, the most frequently identified associated factors were Laboratory Testing (47%; 161 of 343), Process/

Table 4. Frequency of Subcategories Within the Laboratory Testing Associated Factor

Mishandled	52
Re-Collection Required	45
Mislabeled or Missing Label	31
Post-Collection Processing Delay	30
Collection Delay	15
Misplaced or Erroneously Disposed	11
False Result	11
Order Error	6
Order Delay	6
Specimen Not Collected Due to Restrictive Criteria	3
Poor Collection Technique	2
Other	7
Total	219

Note: Across the 161 events with a Laboratory Testing associated factor, we identified 12 subcategories of this factor. The subcategories were not mutually exclusive, which is why the total of 219 is greater than the 161 events with a Laboratory Testing associated factor.

Protocol (25%; 87 of 343), and Isolation Integrity (22%; 74 of 343). **Table 3** also shows that the frequency of the associated factors varied by care area group. For example, the Laboratory Testing factor was most frequently related with the Emergency Department, and the Process/Protocol factor was most frequently linked with the Medical/Surgical Unit.

To provide further insight into the 161 events with a Laboratory Testing associated factor, we coded those events according to 12 subcategories, which were not mutually exclusive. As shown in **Table 4**, the following subcategories

were the most frequent across the 161 events: Mishandled (52 of 161), Re-Collection Required (45 of 161), and Mislabeled or Missing Label (31 of 161).

We also explored the 74 events with an Isolation Integrity associated factor and found that 44 of those events described staff, patients, and/or visitors failing to correctly use PPE. More specifically, staff failed to don PPE in 23 of the events and failed to doff potentially contaminated PPE in 3 events. Also, we found that COVID-19-positive or suspected-positive patients were not wearing PPE in 22 events and vis-

itors failed to use PPE in 2 events. These findings suggest that there are notable challenges with use of PPE for both staff and patients.

Event Outcomes

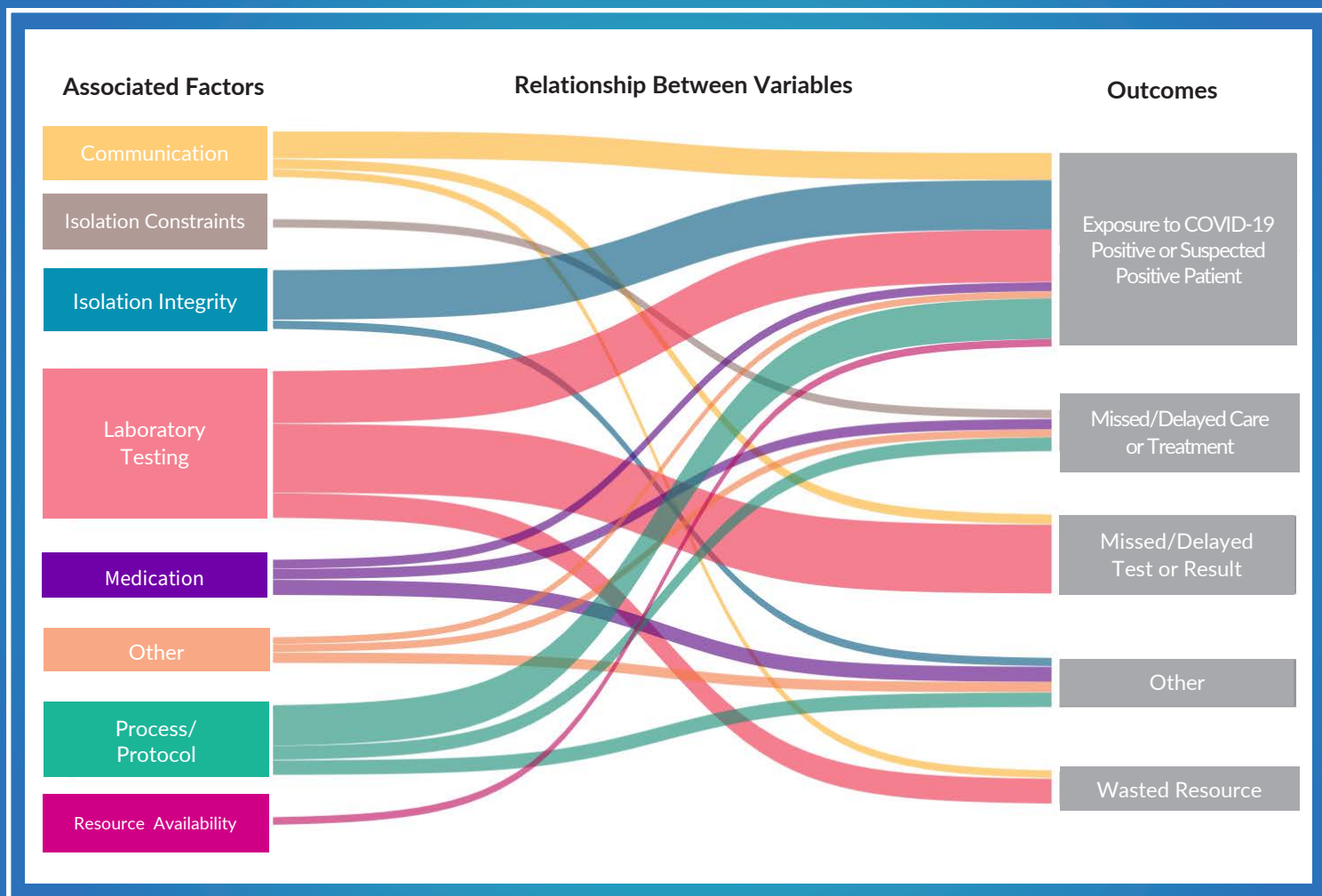
During our manual review of the 343 event reports, we identified six types of event outcomes. We found that 24% (83 of 343) of events had more than one outcome, for a total of 442 outcomes identified across all 343 events. **Table 5** shows that the two most frequent outcomes were Exposure to COVID-19 Positive or Suspected Positive Patient (50%; 173 of 343) and Missed/Delayed Test or Result (31%; 108 of 343). Additionally, **Table 5** reveals that

Table 5. Frequency of Event Outcomes by Care Area Group and Across All 343 Event Reports

Care Area	Exposure to COVID-19 Positive or Suspected Positive Patient	Missed/Delayed Test or Result	Other	Wasted Resource	Missed/Delayed Care or Treatment	Fall	Grand Total
Administration		1		1			2
Emergency	43	43	3	16	13		118
ICU	30	15	14	9	10		78
Imaging/Diagnostic	9	2			1		12
Intermediate Unit	13	2	4	2	2	1	24
Labor and Delivery	2	2		1			5
Laboratory	15	7	5	1			28
Med/Surg	30	16	19	12	14	8	99
Nursery		1					1
OB/GYN Unit	1						1
Other	3	1	1	1	1		7
Outpatient/Clinic	2	7				1	10
Pediatric	1	3	1	1	1		7
Pharmacy			1				1
PICU	1	3	1	1			6
Psychiatric Unit	1			1			2
Rehab Unit		1			2	1	4
Specialty Unit	14	4	5	2	1		26
Surgical Services	8			1	2		11
Grand Total	173	108	54	49	47	11	442

Note: The grand total below each column represents the number of events that were impacted by each Outcome. The grand total at the end of each row reflects the sum occurrence of all Outcomes across all events, by Care Area Group.

Figure 2. Relationships Between Associated Factors and Outcomes



Note: The thickness of lines between the event-associated factors and outcomes reflects the frequency of the relationship identified across event reports. The figure only shows relationships that were identified in 10 or more event reports. Five associated factors and one outcome were excluded from the figure due to an infrequent relationship with other variables.

the two aforementioned outcomes were most frequently associated with the Emergency Department.

To better understand the Exposure to COVID-19 Positive or Suspected Positive Patient outcome, we reviewed each of the 173 reports to identify the person who was potentially exposed to COVID-19 (note: more than one person may have been exposed in each event). Across all 173 events, we found that staff were potentially exposed in 162 of the events, patients in 22 events, visitors in 2 events, and unknown persons in 6 events. Overall, the event reports indicate that staff

were at greatest risk for exposure to COVID-19.

Relationships Between Associated Factors and Event Outcomes

In **Figure 2**, the thickness of lines between the associated factors and outcomes represents the frequency of the relationship identified across event reports. For example, the thickest line in **Figure 2** is between the Laboratory Testing factor and the Missed/Delayed Test or Result outcome, as this was the most frequently occurring relationship (29%; 100 of 343). As another example, the third most

prevalent relationship was between the Isolation Integrity factor and the Exposure to COVID-19 Positive or Suspected Positive Patient outcome (21%; 72 of 343).

Figure 2 also reveals that there were 19 different relationships between eight categories of associated factors and five outcomes (note: the figure only shows relationships that were identified in 10 or more event reports). Six of the associated factors had an influence on two or three outcomes. Additionally, the figure shows that the five categories of outcomes were each influenced by two or more asso-

ciated factors. In particular, the Exposure to COVID-19 Positive or Suspected Positive Patient outcome was related to seven of the eight associated factors.

Discussion

COVID-19 is caused by a novel virus. As with any novel virus, understanding its life cycle, mode and ease of transmission, and impact on people is paramount to an effective infection prevention and control program. Infectious disease experts are working hard to better understand this virus; however, information is evolving and more research is needed. Given the current knowledge gap, we sought to provide insight into how COVID-19-related events are impacting patient safety.

In our descriptive study, we explored factors with an influence on outcomes that have implications for patient safety. Taking into consideration the novelty and broad impact that COVID-19 has had on healthcare facilities, we chose to explore a relatively high-level set of variables that would capture the challenges encountered across all care areas in a facility. As you may expect, we found that the occurrence of associated factors and outcomes varied by care area. Furthermore, we found a rather dynamic and complex relationship among the associated factors and outcomes. For example, several of the outcomes had a notable relation with four or more associated factors. This type of finding conveys the potential difficulty of developing a comprehensive solution, which likely will require a multidisciplinary and individualized approach at the local level. Considering the differences from one facility to another, it is difficult for us to make sweeping recommendations. Instead, we urge facilities to use our findings to help guide their prioritization of efforts and re-

sources when developing solutions and an implementation plan.

Even though COVID-19 is a novel virus, foundational patient safety strategies remain applicable in addressing this emerging concern. As a result, we urge readers to reference experts and literature on the following topics: using standard precautions,¹¹ providing infection prevention education for all staff,¹¹⁻¹³ continued tracking and trending of COVID-19-related events to aid in learning about strengths and areas for improvement,^{14,15} and reassessing your organization's pandemic preparedness plan.^{16,17} For more information about development and refinement of a pandemic preparedness plan, see resources offered by the Centers for Disease Control and Prevention (CDC) and WHO.^{16, 17}

Limitations

Events classified as Incidents must be reported to PA-PSRS in a timely manner, typically within 90 days of occurrence. Given the timeliness of this article, it is likely that some of the Incidents that occurred from January 1 to April 15, 2020, have yet to be reported to PA-PSRS. Furthermore, the pandemic has placed a notable burden on healthcare facilities; therefore, delayed reporting of events may have occurred due to competing demands.

As a result, we caution readers against using our findings as a reflection of the absolute frequency of events across Pennsylvania. Readers should also note that the findings reflect events during the onset and early stages of the pandemic. It is likely that challenges experienced across Pennsylvania will evolve over time and our findings may not reflect the challenges encountered in the future. Finally, while our findings come from both urban and rural areas, and small

and large hospitals, it is unclear to what extent our findings are representative of healthcare facilities beyond those included in our sample.

Conclusion

Following the first confirmed case of COVID-19 in Pennsylvania, facilities began submitting patient safety reports to PA-PSRS related to management of this emerging infection. Events in our analysis most often took place in the Emergency Department, on a Medical/Surgical Unit, or in the Intensive Care Unit. The most common associated factors were laboratory testing (e.g., mishandling of a specimen or the need to recollect a specimen), process/protocol (e.g., COVID-19-positive patient was discharged without isolation instructions) and isolation integrity (e.g., failure to don or doff PPE appropriately). The most frequent outcome was exposure to a COVID-19-positive or COVID-19-suspected patient. Although most events identified in our analysis were not Serious Events, the data highlight potential areas of focus for healthcare facilities as they develop best practices to safely care for patients amidst concerns about the potential spread of COVID-19.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

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Author Bios

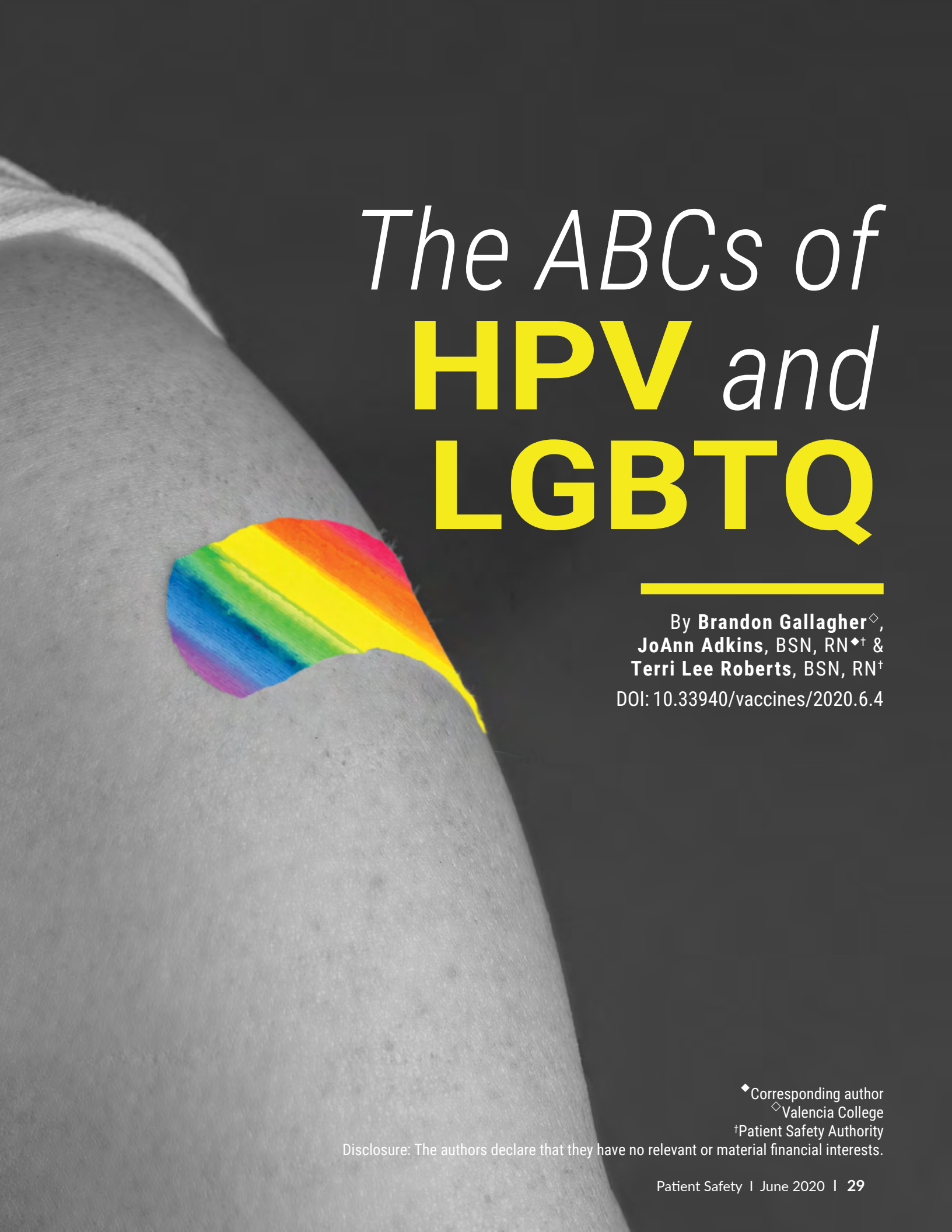
Matthew A. Taylor (MattTaylor@pa.gov) is a patient safety analyst at the Patient Safety Authority.

Shawn Kepner is a data analyst and statistician at the Patient Safety Authority.

Lea Anne Gardner is a patient safety analyst at the Patient Safety Authority.

Rebecca Jones is the director of Data Science and Research for the Patient Safety Authority.



A close-up photograph of a person's arm, showing a tattoo of a rainbow-colored heart. The heart is composed of horizontal stripes in the colors of the rainbow: red, orange, yellow, green, blue, and purple. The tattoo is located on the upper arm, near the shoulder. The background is dark and out of focus.

The ABCs of **HPV and** **LGBTQ**

By **Brandon Gallagher**[◇],
JoAnn Adkins, BSN, RN^{◇†} &
Terri Lee Roberts, BSN, RN[†]

DOI: 10.33940/vaccines/2020.6.4

[◇]Corresponding author
[◇]Valencia College

[†]Patient Safety Authority

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

Human Papillomavirus

HPV

Human papillomavirus (HPV) is a group of more than 200 viruses.¹ These are small, nonenveloped viruses that infect the skin or mucous membranes. Approximately 40 of these subtypes are spread through sexual contact, making HPV the most common sexually transmitted disease. Approximately 79 million Americans are infected with HPV.² This infection usually occurs in the late teens and early 20s, often with the first sexual encounter.³

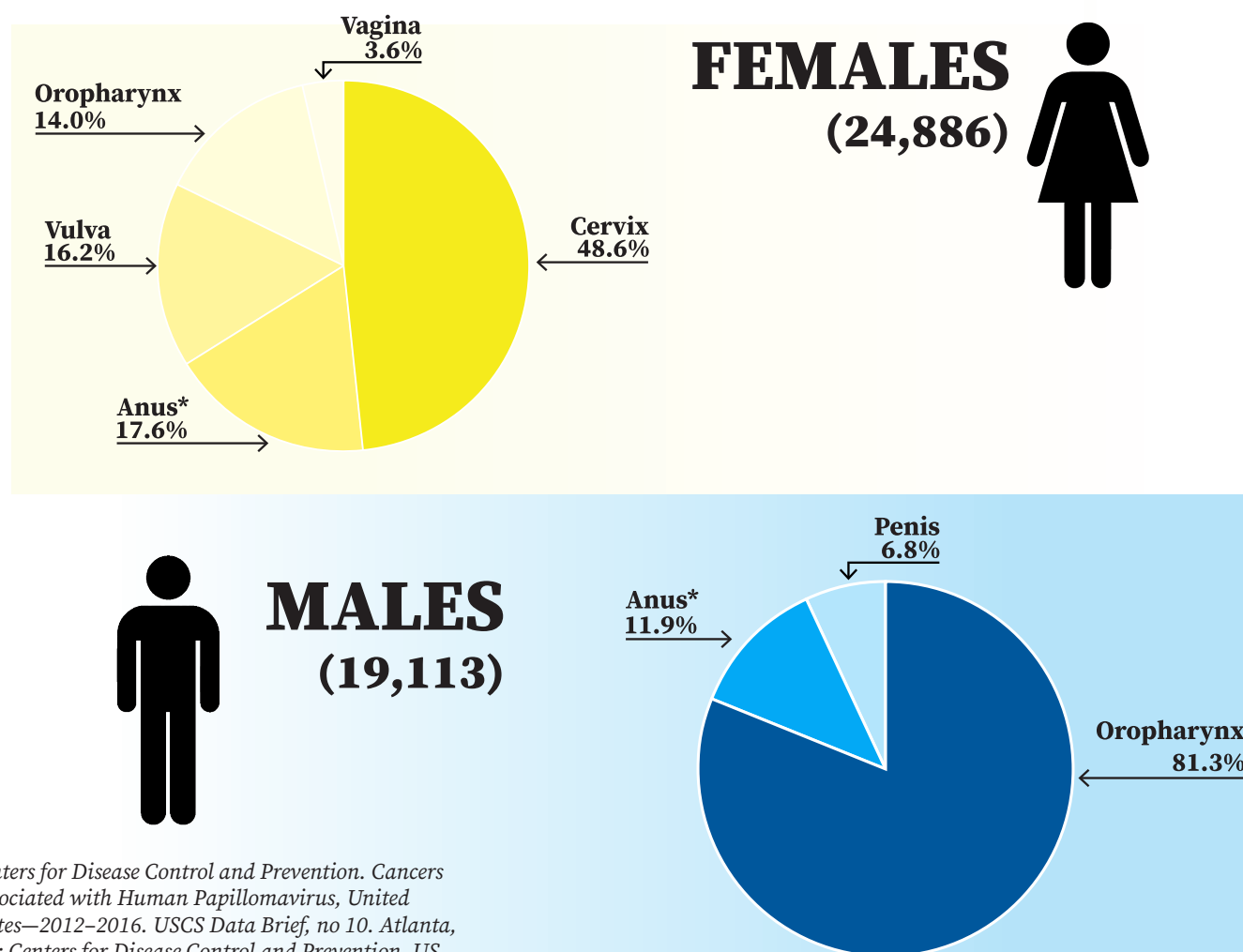
HPV infections typically are asymptomatic and resolve on their own, but unresolved infections caused by certain subtypes can result in other medical conditions, including genital warts, recurrent respiratory papillomatosis, and cancer.

Centers for Disease Control and Prevention (CDC) reports approximately 44,000 HPV-associated cancers occur annually in the United States. HPV infection has been

associated with cervical dysplasia and cervical, oropharyngeal, anal, penile, vaginal, and vulvar cancers. It is thought to be responsible for over 90% of all anal and cervical cancers, 60% of all penile cancers, and 70% of all oropharyngeal cancers.⁴ Reference **Figures 1 and 2.**

HPV subtypes 16 and 18 are responsible for most HPV-associated cancers: anal, cervical, oropharyngeal, penile, vaginal, and vulvar.⁴

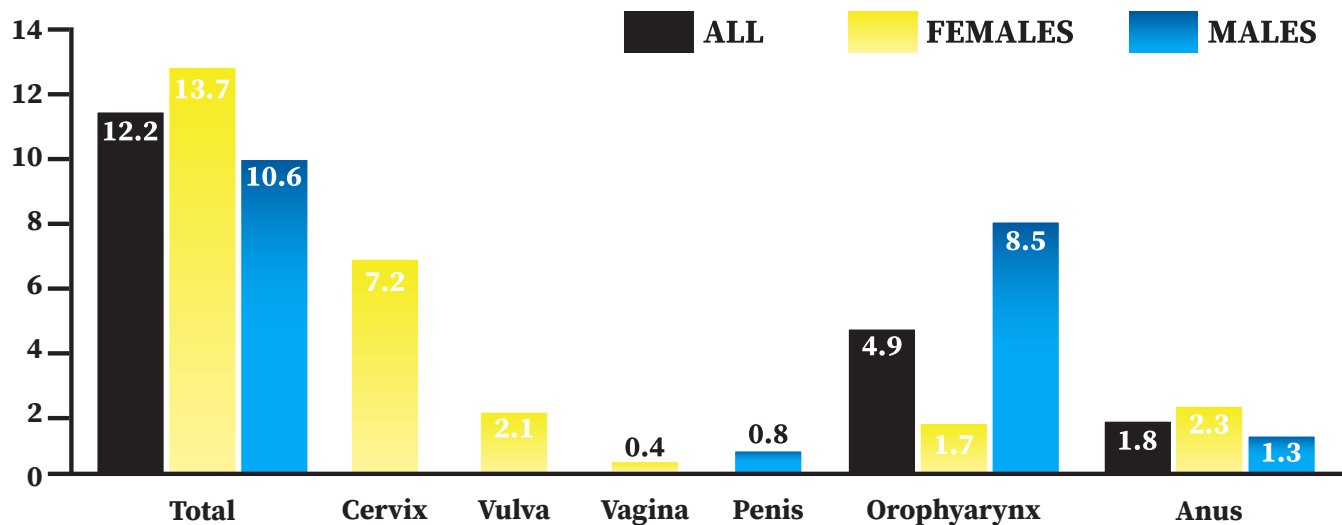
Figure 1: Number of New HPV-Associated Cancer Cases Each Year



Centers for Disease Control and Prevention. Cancers Associated with Human Papillomavirus, United States—2012–2016. USCS Data Brief, no 10. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2019.

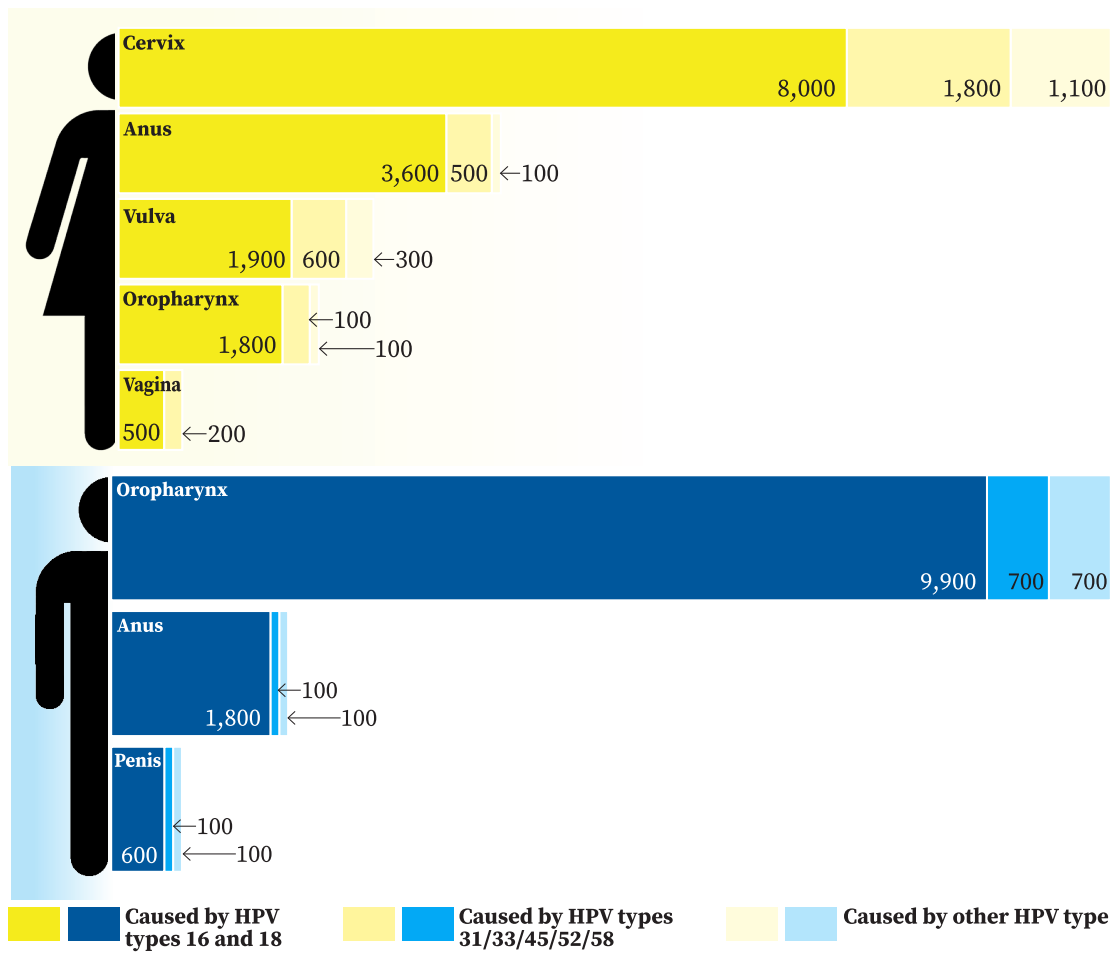
*Includes anal and rectal squamous cell carcinomas

Figure 2: Rate of HPV-Associated Cancers by Sex and Cancer Type



Centers for Disease Control and Prevention. Cancers Associated with Human Papillomavirus, United States—2012–2016. USCS Data Brief, no 10. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2019.

Figure 3: Estimated Annual Number of Cancer Cases Attributable to HPV by Sex, Cancer Type, and HPV Type



Centers for Disease Control and Prevention. Cancers Associated with Human Papillomavirus, United States—2012–2016. USCS Data Brief, no 10. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2019.

VACCINE

Reference **Figure 3.** Studies have shown the LGBTQ community to be at increased risk for developing some of these cancers. Approximately 30% of this community does not have a regular provider or may not discuss health issues due to fear of discrimination.⁵ Gay men are at an increased risk of anal cancer caused by HPV compared to heterosexual men, with HIV-positive gay men being at the highest risk.⁶ Lesbian women are at risk for HPV infection and development of cervical cancer, as they often do not have cervical cancer screening or do not follow up on abnormal test results.⁵

HPV Vaccine

HPV vaccination can prevent infection with the virus and development of associated diseases, including cancer. An effective HPV vaccine has been available for 14 years. Three vaccines are licensed in the United States: 9-valent, quadrivalent, and bivalent. Since 2016, only the 9-valent is used as it protects against the subtypes shown to cause cancers.

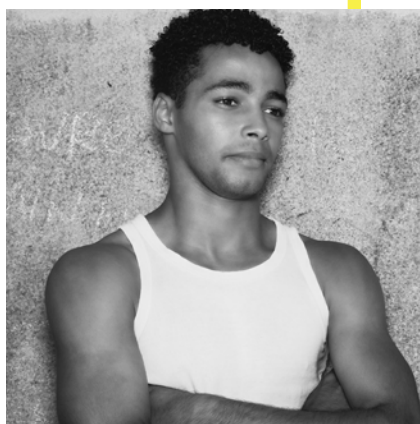
HPV vaccine should be given before exposure to the virus; CDC's Advisory Committee on Immunization Practices (ACIP) recommends HPV vaccination for girls and boys at age 11 or 12, but the vaccine can be given at age 9. ACIP recommends catch-up vaccination for everyone who has not been vaccinated through age 26. ACIP also recognizes that unvaccinated people ages 27 through 45 may be at risk for developing infection from HPV subtypes they had not been exposed to before, and recommends patients and providers discuss and make the decision on vaccinating.³

The HPV vaccines were extensively studied in clinical trials and have been proven to be safe and effective in preventing HPV infections associated with cancers. So far, in the 14 years since the vaccine has been available, immunity has remained with no evidence of decreasing;² however, HPV vaccination rates are

lower than other vaccines—especially among males—but are increasing.⁴

HPV vaccination is one of the most important breakthroughs in modern sexual health, and the potential benefits of cancer prevention for the LGBTQ community cannot be overstated. The LGBTQ community has faced intentional and unintentional discrimination and marginalization among the American medical establishment, and in their wake, misinformation and lack of accurate medical information has grown.^{6, 7} The same holds true for HPV vaccination. Five members of the LGBTQ community were interviewed to ascertain the identified attitudes within the LGBTQ community towards modern prevention strategies and illuminate potential target areas to provide education and help increase vaccination.

General trends among all five respondents seem to illuminate one pressing issue with regards to HPV vaccine as a potential preventative measure for cancer: a lack of information due to a perceived bias against them as members of the LGBTQ community. All three male respondents have not received the vaccination to the best of their knowledge, while the sole transgender male respondent received Gardasil in his early adolescence, as did the sole female respondent. Statistically speaking, it is not surprising that these are the only two to have received the HPV vaccination. In a 2017 cohort study published in *LGBT Health*, 56% of female respondents had received greater than or equal to one dose of the vaccination, in contrast to 8% of male respondents, with a significantly lower rate of vaccination among completely heterosexual men. This lack of vaccination is perplexing, as HPV is nondiscriminatory in infection. All five of the respondents expressed surprise at the ability of HPV to cause cancers other than cervical cancer, as most of the available medical literature on the subject solely focuses on vaccination for prevention of cervical cancer.



James* identifies as a homosexual male and is a 24-year-old first-generation Haitian American. He seemed interested in the potential for HPV vaccination as a cancer preventative measure but showed reluctance to receiving the vaccine since his primary care physician (PCP) had not recommended it. James is financially independent from both of his parents, possesses his own health coverage through his employer, and is not currently engaged in any significant relationship, despite frequent casual sexual contact with other males. James uses contraceptive measures when having anal penetrative sex, but not oral sex, and was unaware that HPV infection of the throat is possible. James also stated that he has a prescription for the pre-exposure prophylaxis (PrEP) for HIV, but only received treatment *after informing his doctor* of its potential benefit based on his sexual habits: “My doctor didn’t know what PrEP was. I had to educate him on it. I’m on it now. ...He doesn’t seem comfortable talking about gay sex.” When questioned about perceived discrimination, James, as did all other respondents, felt very strongly that the broader American medical establishment prioritizes treatment and prevention of HIV over any other diseases when providing care to the LGBTQ community.



Chris* identifies as a homosexual male and is 21 and Caucasian. He also has frequent casual sex with other males and seemed distressed at the potential of HPV to cause various forms of cancer, having been diagnosed with genital warts four years ago. He discloses his previous status to his potential partners. Despite this, Chris has not disclosed his diagnosis to his PCP but could not provide adequate reasoning for why. Chris still resides with his parents and is not financially independent from them, relying on his father’s insurance for coverage. He was unaware that men can be vaccinated for HPV, that there are various virus types, and that the vaccine covers more than just sexually transmitted types. Chris did not feel that he was discriminated against by his PCP and has a good relationship with him; he does feel, however, that the focus in most LGBTQ-centric advertising campaigns is primarily about HIV and sexual assault against trans individuals. “My doctor is great, but it probably doesn’t hurt that he’s also gay. He got me on PrEP and I get tested every three months for STDs. I trust him completely.”



David* is a bisexual male, 48, and white. He is in an ongoing monogamous relationship with a female, whom he has been married to for 19 years. He has two daughters of undisclosed ages. He was unaware that men can receive the HPV vaccination and was unsure whether he had received it, as he trusts his PCP’s recommendations. He disclosed that his wife and daughters have both received Gardasil, but he was unaware of which version. Unlike James and Chris, David was not open to the idea of vaccination, as he felt it was generally unnecessary since he is in a committed relationship and does not have any sexual contact outside of his wife, who is already vaccinated. David has not disclosed his previous sexual history with males to his wife but was tested for sexually transmitted diseases before having children. David felt incredibly strongly that the LGBTQ community continues to face discrimination stemming from the HIV epidemic and panic of the 1980s, but noted that it only seemed to affect patients based on their *perceived* sexual preferences. David noted that as someone who presents as heterosexual, he feels he is better cared for than other members of the LGBTQ community, but could not provide any specific instances of perceived discrimination outside of moralization and lack of empathy displayed by the medical community towards transgender individuals.



Luis* is a heterosexual transgender male and is 20 years old. He is from Puerto Rico and received the HPV vaccination at 13. Luis is currently taking hormone replacement therapy (HRT) and has constant contact with his doctor, despite his general distrust of the medical establishment based on his experiences as a transgender individual. Luis expressed reluctance at the idea of being vaccinated as an adult, due to the discrimination he faced while attempting to receive his HRT. Luis was unaware that HPV can cause penile cancers and is not a chronic infection, and stated that the trans community at large needed better access to healthcare and information about *all* sexual health topics, not just HPV. “The whole system needs a reset. It’s a good thing I was vaccinated when I was, because I wouldn’t go to the doctor now to ask for it. I can barely get my hormones without a fight, and those are more important than a vaccine for something everyone gets at some point. In a perfect world, I wouldn’t have to fight for basic medicine, and everyone would know that genital warts can cause cancer and be vaccinated, whether you’re a boy or a girl or something else.”



Finally, Emma* is a lesbian, 29, and Caucasian. She received the HPV vaccination while in high school and was aware that HPV can cause various forms of cancer. Emma stated that while she has not faced specific discrimination while receiving healthcare, other women who identify as lesbian, especially people of color and transgender individuals, have bad experiences and distrust the medical establishment as a whole because of it. Emma also claimed that the marketing and campaigns for HPV vaccination need to target gay males and bisexual males as opposed to solely women, since that seems to be where vaccination rates are lowest. “Well it’s usually recommended for women, so I’m not sure you need to worry about lesbians. I mean—everyone needs to be vaccinated, but your effort should be towards vaccinating gays and bisexuals if you’re specifically aiming at the gay community. Also, I know a lot of people have bad experiences with their doctors. They need to be compas-

sionate and understand that they aren’t there to judge us. That’s how you lose people.”

These five individuals are part of a community that, historically, has faced both intentional and unintentional discrimination from the American medical community.⁷ When questioned about stigmas and discrimination because of their sexuality, all of them responded in some capacity about the AIDS crisis and, in all respondents except David, the perception that because they are nonheterosexual or transgender, they are sexually degenerate.

Summary

HPV vaccine is an important cancer preventative measure for all. It is safe and effective, but vaccination rates are low, especially among males. HPV vaccination is one of the most important breakthroughs in modern sexual health, as millions of Americans are infected with HPV, often during the first sexual encounter.

Studies have identified several HPV-associated cancer sites that may disproportionately affect LGBTQ populations. Interviews with members of the LGBTQ community revealed a lack of knowledge on HPV infection and distrust of the medical community. Due to the increased risk of these cancers among the LGBTQ community, it is important for patients, friends, family members, and the medical community to reach out and provide support and education on HPV to help increase vaccination in the LGBTQ community.

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COMPASIVO
COMBASTIVO

BE COMPASSIONATE

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Author Bios

Brandon Gallagher is a student of psychology at Valencia College and an LGBTQ activist. During his time as a student at Harrisburg Area Community College, he served as president on the administrative board for Allies, the college's LGBTQ organization, leading various public seminars on sexual health and ethics, advocating comprehensive sex education, and organizing fundraisers for Alder Health Services in Harrisburg.

JoAnn Adkins (joaadkins@pa.gov) is a registered nurse and a senior infection preventionist for the Patient Safety Authority. Prior to joining the PSA, she was the manager of Infection Prevention and Control for several years at a 315-bed acute care hospital, where she initiated and facilitated several process improvements to decrease hospital-acquired infections and enhance patient safety. Adkins is a Fellow of the Association for Professionals in Infection Control and Epidemiology

(APIC), serves on APIC's Member Services Committee, and is board-certified in infection control and epidemiology. She is a 2019 recipient of APIC's Heroes of Infection Prevention Award for Education. Adkins is a member of APIC's East Central Chapter, the Sigma Theta Tau International Nursing Honor Society (STTI), the Pennsylvania Association Directors of Nursing Administration Long Term Care (PADONA), and the Central Pennsylvania Association for Healthcare Quality (CPAHQ).

Terri Lee Roberts is a registered nurse and a senior infection preventionist for the Patient Safety Authority. She has an extensive background in critical care nursing, infection prevention and control, and emergency preparedness. Roberts has authored and co-authored many infection prevention and control articles, including publications in *Clinical Infectious Diseases*, *Infection Control and Hospital Epidemiology*, and the *Journal of the Pediatric Infectious Diseases Society*, as well as abstracts for the Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, and Southwestern Pennsylvania Organization of Nurse Leaders. She is a Fellow and faculty member of the Association for Professionals in Infection Control and Epidemiology (APIC), and a 2019 recipient of APIC's Heroes of Infection Prevention Award for Education. Roberts is a member of the APIC Three Rivers Chapter and serves on the executive committee for the Allegheny County Immunization Coalition.

Pediatric **Vaccine** *Administration*

Sustaining an Improved Process in a Primary Care Setting

Marianne L. Durham^{◆◇}, DNP, RN,
Ines Didovic[◇], DNP, RN &
Monica J. Gingell[◇], DNP, RN

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Background: Pediatric vaccine errors may lead to patient harm, including unknown disease vulnerability requiring costly revaccination.

Local Problem: Pediatric vaccine administration errors (expired and wrong vaccine) in a Federally Qualified Health Center prompted a root cause analysis. System and human factors issues were identified, including a variable and complex administration process; multiple administering staff (medical assistants, registered nurses, nurse practitioners); competency training gaps; and storage opportunities driving error.

Methods: Using Plan-Do-Study-Act cycles, the administration process and storage system were improved.

Interventions: A simplified and standardized pediatric vaccine administration process was implemented. Administering staff completed 10 hours

of education and competency training. Audits with feedback were conducted to monitor process behaviors linked to achieving the five rights of medication administration.

Results: Twenty-four audits were conducted over a six-month period after implementation to monitor steps in the process. Early post-implementation analysis revealed performance variability and additional improvement activities were deployed. Behaviors have improved over time and are nearing consistent performance and no reported vaccine errors.

Conclusions: Continuous analysis and improvement are needed to sustain safe practice until behaviors to achieve the five rights are normalized and impact patient outcomes.

Keywords: vaccine error, quality improvement, sustainability, patient safety

◆ Corresponding author

◇ University of Illinois at Chicago

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



Vaccines are the most economical and beneficial clinical preventive service provided to children, reducing mortality due to infectious disease by 2 to 3 million deaths per year.¹⁻⁴ Global immunization initiatives and vaccine innovations resulted in the eradication of smallpox, the imminent eradication of polio, and substantial declines in an additional 14 infectious diseases.²⁻⁴ Despite these successes, some children remain vulnerable to vaccine-preventable diseases due to limited access to healthcare, parental hesitancy, and vaccine-related errors.⁵⁻⁷ Vaccines are given in many settings and consistent steps to ensure safe administration must be followed to produce safe patient outcomes.³ Ordering providers and clinical staff administering vaccines need to be informed about potential vaccine errors and the system-based strategies necessary to avoid possible confusion and patient harm.³

Problem Description

Pediatric vaccine administration errors (one expired and two wrong vaccine) at a Federally Qualified Health Center (FQHC) prompted a team to conduct a root cause analysis that identified the complex administration process as the principal source. Other causal factors included variable workflow, such as omitting steps of the medication administration process, including verification of five rights of medication administration³ and multiple types of clinical staff able to administer vaccines (certified medical assistants, registered nurses, nurse practitioners); human factors (rushing and confirmation bias); and improper vaccine storage. Staff member interviews revealed variability in staff comfort and skill in vaccine administration, anxiety and confusion surrounding the process, and a desire for more training. The existing process lacked a standardized



575

Vaccine-Related
Events Reported

100

More reports
compared to
prior years

27%

Errors occurred
in a pediatric setting

54%

Errors involved
medical assistants

48%

Errors occurred in a
family practice setting

approach, increasing the risk for errors and potential adverse events jeopardizing patient safety.

Available Knowledge

Errors

Vaccine-related adverse events are an ongoing patient safety concern. Medication-related patient safety events are likely underreported in primary care.⁸ There were 575 vaccine-related events reported to the Institute for Safe Medication Practices National Vaccine Errors Reporting Program (ISMP VERP) in 2017, an increase of more than 100 reports compared to prior years; 48% of all errors occurred in a family practice setting, and 27% in a pediatric setting, with more than half of all reported errors (54%) involving medical assistants.⁹ The

most frequently reported vaccination errors include administering the wrong vaccine, wrong dose, expired or contaminated vaccines, and inaccurate vaccination based on age.⁹ There are 45 different single and combination vaccines available today from multiple manufacturers worldwide with similar labeling, packaging, abbreviations, and brand or generic names that increase the risk for error.⁷ For example, between 2012–2016, similar vaccine abbreviations and brand name confusion resulted in 60 reported errors in which DTaP (diphtheria, tetanus, and acellular pertussis) was administered instead of Tdap (tetanus, diphtheria, and acellular pertussis) and vice versa.⁷ While these individually reported errors did not cause immediate patient harm, there are potential last-

ing effects on public health, herd immunity, costly revaccination, and potential consumer refusal of future vaccination.⁹

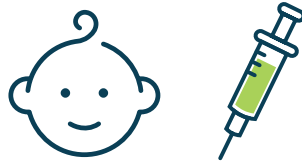
Human Factors

Thirty vaccinations are necessary to immunize a child in the United States, and it is estimated that an error occurs in 27–35% of vaccine administrations, posing a substantial risk for vaccine-related errors to children from birth to 6 years of age.^{3,6,7,10,11} Vaccine-related medication errors occur due to lack of knowledge surrounding age-related vaccine administration, selecting the wrong vaccine but believing it is correct (confirmation bias), hurrying through the administration process due to competing priorities, and other factors.^{12, 13}

Systems and Process

The majority of medical errors are not a result of careless healthcare workers but more commonly are caused by complex systems, multi-step processes, and conditions that fail to prevent latent errors.¹⁴⁻¹⁵ The current approach to failure analysis suggests most errors are a result of poorly designed systems and complexity, inconsistency, and human slips or lapses that can lead to process failures.¹³⁻¹⁵ Prevention strategies, such as standardization and reducing reliance on human memory, can make systems safer.^{13,16-17} Standardization of processes combined with evidence-based practice provides structured workflow eliminating ambiguity and forgetfulness.¹⁸ Healthcare organizations are responsible for developing processes to ensure safe medication practices. Improvements must be made in the systems designed for staff to achieve this outcome.¹⁹ Staff administering medications, including vaccines, must be adequately trained and accountable for following steps in the process and other systems that result in safe patient outcomes.

Common Causes of Vaccine-Related Medication Error



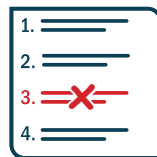
Age-related administration



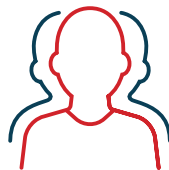
Selecting the wrong vaccine



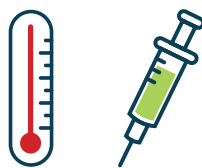
Rushing through the process



Omitting process steps



Human factors



Improper vaccine storage

The Centers for Disease Control and Prevention (CDC) recommends that all healthcare providers who administer vaccines receive comprehensive training on vaccine administration policies and procedures while following a standardized process.²⁰ Annual competency training can maintain skill.

Behavior Change and Sustainability

Successful adoption of a new process into clinical practice and its long-term sustainability comes with challenges that may cause individuals to revert to old routines. Healthcare organizations invest significant resources and staff time on improvement initiatives yet many fail to sustain their gains.²¹ Threats to long-term sustainability must be identified and addressed early in the process change with project stakeholders who help define measures of success.²²⁻²⁴

Factors such as modification and adaptability of the program, trust and belief in the program, short communication lines with the project team, and adoption of the program by other sites were found to influence sustainability more than the original implementation process.²⁵ Other factors include perceived value of the quality improvement (QI) interventions, integration of improvements in current workflow, leadership strategies reinforcing project value, and implementation of a data-driven feedback system.^{22,25-28}

Rationale

A root cause analysis with action planning was completed to address the system and human factors causes. The Model for Improvement and Plan-Do-Study-Act (PDSA) cycles were used to set aims, implement changes, and sustain improvements.²⁹ Despite its relative simplicity, the PDSA cycle has an inherent complexity requiring users

to address improvement challenges through stages and small-scale tests, with an end goal of scaling up the intervention.²⁹⁻³⁰ Ultimately, the desired impact is to sustain the process and scale up to other primary care clinics within the health system. This project consists of two cycles: 1) process improvement and standardization; and 2) adoptability and sustainability of the new process in practice.

Specific Aims

The purpose of this QI project was to simplify and standardize the pediatric vaccine administration process and improve staff knowledge and safe administration behaviors to prevent errors. The purpose of this article is to share improvement and monitoring activities for vaccine administration that can be adapted to similar settings to impact safe outcomes. By drawing from the current literature on sustainability factors, the project was designed to influence adoptability and sustainability of the process.

Methods

Context

The FQHC provides primary care and holistic health services to the local community in partnership with an academic medical center. There were 264 pediatric primary care visits from 145 distinct patients in calendar year 2019 in a small and growing practice. Two hundred thirty-one vaccines were administered to 96 individual pediatric patients. In this setting, the staff includes certified medical assistants (CMAs), the nurse manager, and advanced practice registered nurses (APRNs)—specifically

nurse practitioners—who all may administer pediatric vaccines with overlapping workflows. Two doctor of nursing practice (DNP) students led the project while partnering with leadership and staff in the setting.

Interventions

PDSA Cycle 1 - Process Improvement and Standardization

A root cause analysis was conducted to identify sources of error specific to this pediatric practice. Using the current state pediatric vaccine administration process, observations and interviews with the health center staff were performed to understand variation. A process map analysis was completed to identify potential high-risk variation and failure points (Figure 1) and to determine value added or non-value-added steps considering the organization's policy and CDC guidelines.²⁰

Future state process mapping was conducted with staff to associate behaviors that identify the right patient, vaccine, dose, route, time, expiration date, and workflow. The process was simplified by removing non-value-added steps. A safe vaccine administration checklist was

developed to highlight potential failure points and increase awareness during administration (Figure 2).

The revised process was aligned with the organization's policy and CDC guidelines²⁰ and standardized throughout the setting through education and training. Variation was addressed by limiting the administration of vaccines to the nurse manager and CMAs who completed training and demonstrated competency. A laminated visual display of the revised process map was posted in the vaccine preparation area and all patient rooms.

A stand-alone pharmaceutical-grade refrigerator was purchased for vaccine storage. Laminated vaccine identification labels were added to the outside of each shelf for ease in locating the right vaccine and to minimize temperature fluctuations caused by door openings. A schedule was created for monthly rotation of inventory so vaccines and diluents with earliest expiration dates are used prior to those with later expiration dates. 5S, a methodology that results in a workplace that is clean, uncluttered, safe, and well organized to help reduce waste and optimize productivity, was conducted on the new vaccine refrigerator and in workspace areas where vaccines are prepared.

Administering staff (nurse manager/CMAs) identified a lack of education and training as barriers to performing the process. A comprehensive educational program was developed with the nurse manager and APRNs, including input from the CMAs. Administering staff completed seven hours of education including general vaccine information, administration techniques, re-

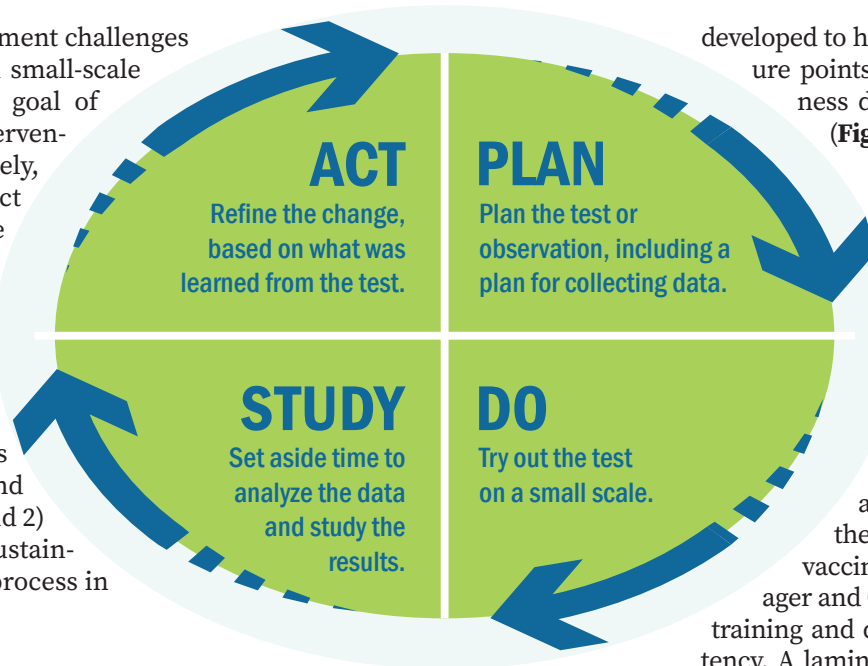


Figure 1. Process Map With Failure Points. A process map was developed in collaboration with project stakeholders at the beginning of the quality improvement project. The left column indicates failure points in the process and the right column indicates lessons learned and key questions.

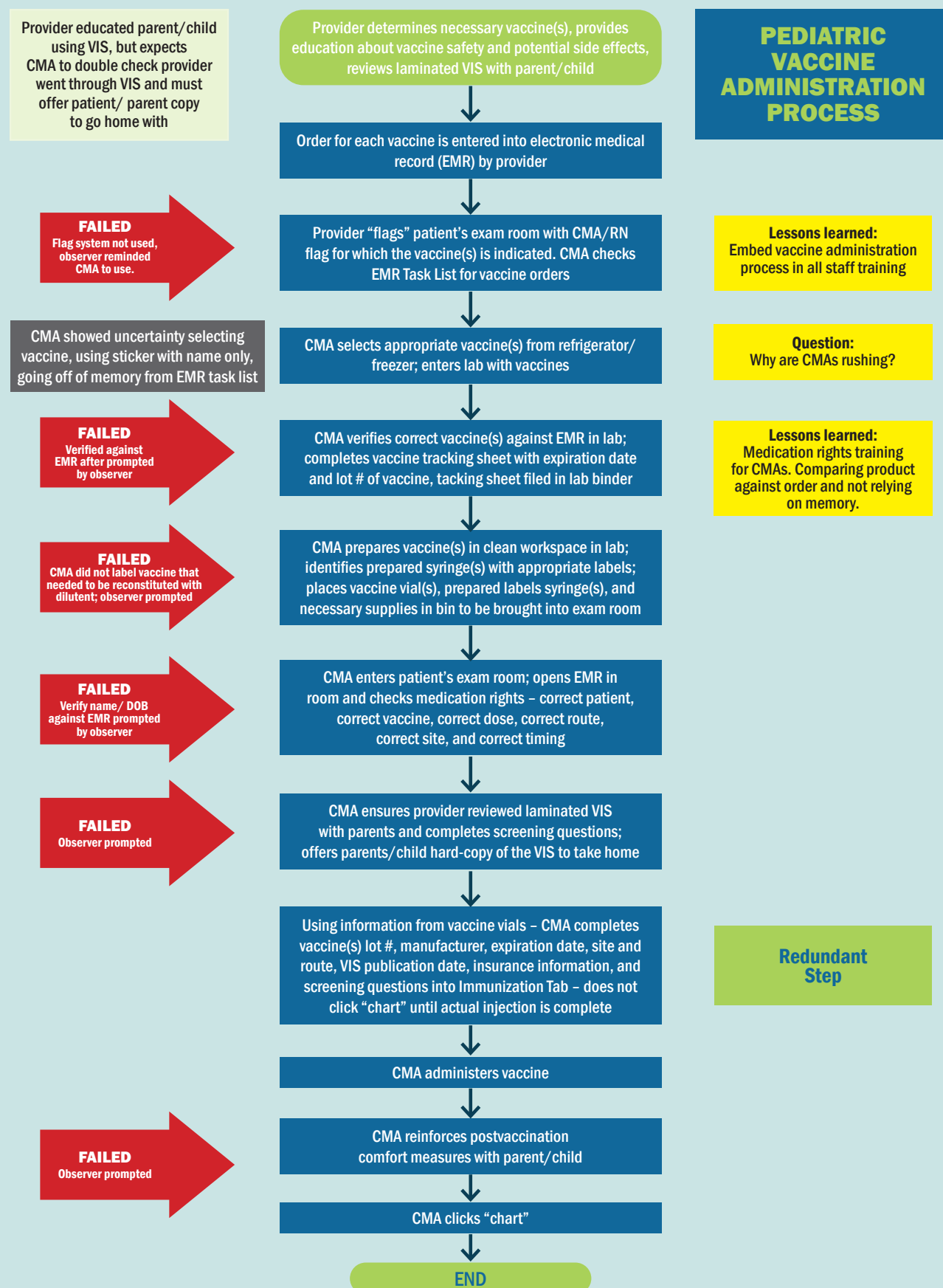


Figure 2. Checklist: Safe Vaccine Administration

CHECKLIST: SAFE VACCINE ADMINISTRATION	
Completed in lab	
Correct vaccine(s)	Does the vaccine(s) I obtained from the refrigerator/freezer match the EMR order?
Labeled vaccine(s)	Do all the vaccine syringes have labels after preparation?
Completed in patient exam room	
Medication Rights 	Open EMR in exam room and check medication rights: 1. Is this the correct patient? <i>a. Ask patient name and DOB; verify against EMR</i> 2. Do I have the correct vaccine(s)? <i>a. Verify vaccine(s) against EMR order</i> 3. Is this the correct dose? <i>a. Verify vaccine dose against EMR order</i> 4. Do I know the correct route and correct site? 5. Is this the correct timing?
Vaccine Information Statement (VIS)	• Was the VIS reviewed with the patient and/or parent? • Does the patient or parent want a copy of the VIS?
Chart before vaccination 	Did I chart using the information on the vaccine vial <i>before</i> vaccination? • Vaccine name, lot number, and expiration are charted in EMR • Click “chart” after vaccination

refrigerator orientation, individualized simulation, and teach-back training, and received hard-copy handouts. Behaviors were validated using the Immunization Action Coalition Skills Checklist for Vaccine Administration.³¹ Weekly audits of seven process behaviors for the first two months of the project rollout were completed, with real-time feedback given as necessary (**Table 1**).

Study of the Interventions

In the study phase of the first cycle, the DNP students conducted individual discussions with the CMAs

to assess comfort with steps of the new process. CMAs were also asked to provide insight regarding barriers and facilitators to new process adoption and to identify educational gaps that remained. This analysis was used to plan for the next cycle.

PDSA Cycle 2: Adoptability and Sustainment of the Improved Process

A decrease in performance of safe behaviors prompted an additional three hours of individual education, simulation training, and teach-back for the CMAs. Simulation training consisted of each CMA performing

the steps of the process with observation and real-time feedback by project leaders. Validation of vaccine administration competency was added to the annual competency training. The CMAs were trained on the audit process and how to conduct peer observations to facilitate engagement. The CMAs were encouraged to discuss audit results and offer input at monthly staff meetings to monitor the process. Staff are more engaged in improvement efforts when they receive information on process performance, which can be communicated through visual metric boards

Table 1. Key Behaviors Audit Tool

PEDIATRIC VACCINE ADMINISTRATION AUDIT			
Date:			
Auditor Name:			
Measure		Completed (Yes/No)	Comments* If key measure was not completed as stated, please note what was observed.
1	Flag system used to alert CMA to check EMR task list for vaccine order		
2	CMA verifies correct vaccine(s) against EMR in lab after obtaining them from refrigerator/freezer		
3	Vaccine(s) for individual patient are prepared in lab room		
4	Vaccine syringes appropriately labeled after preparation		
5	CMA opens EMR in patient's exam room and checks medication rights (correct patient, correct vaccine, correct dose, correct route, correct site, and correct timing)		
6	Vaccine Information Statement (VIS) reviewed with patient and parents prior to vaccination		
7	Vaccine name, lot number, and expiration charted in EMR (in patient's exam room) using information on vaccine vial prior to vaccination		

or team huddles.³² Our small celebrations included cheering efforts of the staff privately and in the meeting, providing treats, and sharing visuals (charts) of team successes.

Engagement of frontline leaders (APRNs and nurse manager) was a priority for the success of this project. DNP students briefed leaders on progress via email and monthly meetings, and incorporated their input in project modifications. Additionally, DNP students analyzed staff gaps in knowledge and barriers to performance of all steps of the process with the nurse manager. A new issue arose when leaders expressed a desire to allow APRN students to administer vaccines, as this is a low frequency, medium-to-high-risk process and they were unfamiliar with standardized processes.

The DNP students recommended education and simulation training be conducted in collaboration with the APRN student's preceptor, nurse manager, and a CMA, as they previously had received extensive training from the project leaders. The students also recommended that if a critical vaccine administration error occurs, the current process should be stopped and only the nurse manager be allowed to administer vaccines until root cause analysis has been completed and a new action plan is in place.

Measures

To facilitate monitoring of the process, behaviors which led to identifying the five rights of medication administration were validated with the nurse manager. Two standard-

ized patient identifiers, name and date of birth, are used to determine the right patient; the ordered vaccine is confirmed and verified by comparing the vaccine and dose against the electronic medical record (EMR) order; and self-checks on the correct route, time, and expiration date are performed. Process mapping with staff and identification of failure points (**Figure 1**) helped create a checklist (**Figure 2**).³¹ The checklist incorporates questions that prompt behaviors, including vaccine preparation and labeling to prevent identified failure points. Seven behaviors were identified and audited for process compliance as a measure of a successful safe vaccine administration, with a target of 100% (**Table 1**). Two weeks after implementation in PDSA Cycle

1, project leaders began observation audits and real-time feedback to support ongoing training for administering staff at the point of care.

During PDSA Cycle 2 the process was handed off to the nurse manager to continue monitoring. Administering staff were educated on the components of the audit (Table 1). Each CMA was assigned two days per month to audit pediatric vaccine administrations. The nurse manager posted audit results in a chart on the health center's quality board (Figure 3) and included audit results as an agenda item at monthly staff meetings.

Analysis

Auditing and monitoring with a bar chart were chosen as means to evaluate compliance with key step behaviors (Figure 3). Twenty-four audits were conducted after implementation and monitoring is ongoing. Early analysis of audits after

implementation, revealed variability; therefore, further improvement activities were deployed in Phase 2. DNP students emailed a weekly update of observations to leadership and clinical staff to disclose audit results and to promote awareness and discussion of barriers. Adaptions of the process were presented to administering staff for analysis during in-person meetings.

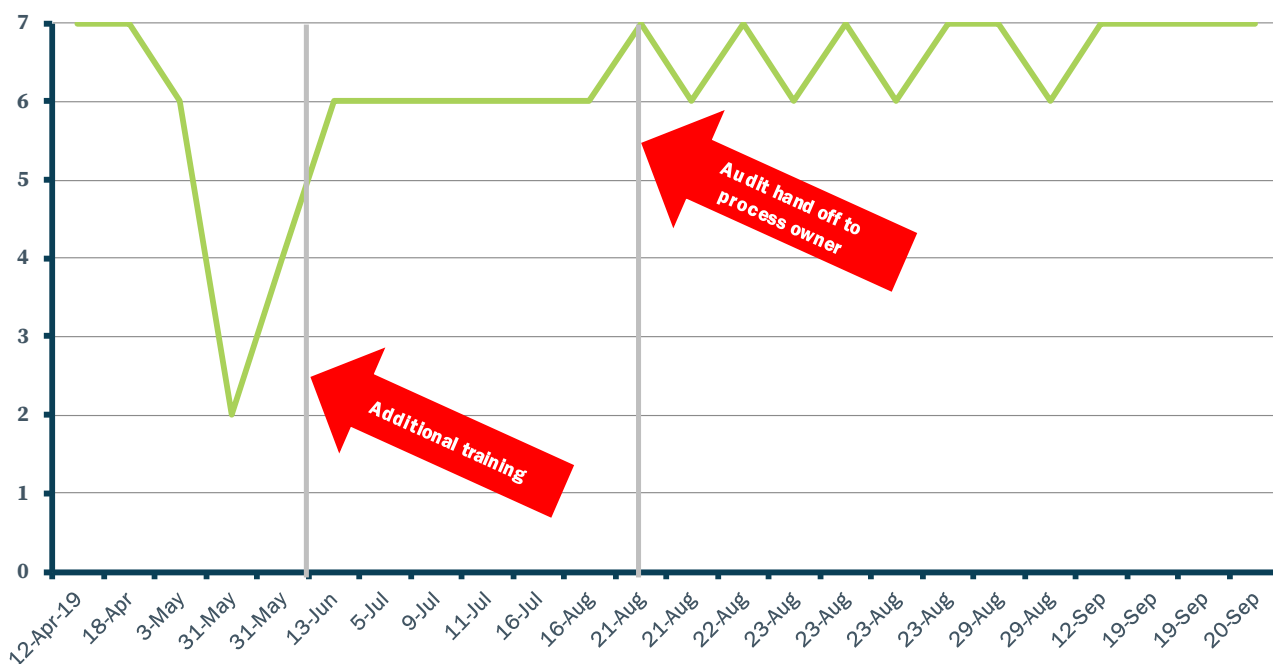
Celebrating successes

Results

One-month post implementation, performance using the seven prescribed behaviors was 29% and 57% by two CMAs (Figure 3) which prompted additional education and simulation training for administering staff. Compliance remained variable at 86% from May through August 2019, with one of two behaviors being missed; staff were inconsistent in using

the flag system and reviewing Vaccine Information Statement (VIS) forms with patients. Access to VIS forms was a barrier to performing this step 100% of the time, which was addressed by ensuring that each patient room had a laminated binder containing VIS forms. CMAs and APRNs admitted to relying on one another to review VIS forms with patients, which contributed to this step being missed. Staff roles were clarified to establish an understanding of individual responsibilities for reviewing VIS forms. Behaviors of key steps have improved over time and are approaching an acceptable and consistent performance rate resulting in zero reported vaccine errors post implementation. CMAs will continue to conduct twice-monthly peer audits to promote accountability. The nurse manager will collaborate with CMAs and APRNs to determine when audits are no longer

Figure 3. Performance of Key Behaviors During Vaccine Administration Audit Post Implementation



Note: Each data point represents one observation of one administering staff for a single patient encounter. One person performed 2/7 and another person 4/7 on the same day so additional training was delivered. Audit process was initiated by DNP student project leaders, with handoff to process owner as indicated above.

required based on sustained behaviors with key steps.

Discussion

This article describes drivers of the vaccine administration problem and targeted interventions in an FQHC. Because of a small volume, the impact of positive outcomes cannot be strongly linked with interventions. Continued PDSA cycles and learning will facilitate improved thinking and prevention strategies among staff administering vaccines. A strength of this project is it was led by students who objectively received input from all members of the team and were able to use this qualitative data for improving a process and impacting safe vaccine outcomes. Strong leadership support during a lengthy and complex project facilitated progress throughout the cycles. Vaccine administration is a multifaceted process. Students were able to improve upon the multiple identified drivers of error based on input from staff and leaders.

This project aims to simplify and standardize the process, and provide a model for continuous process improvement. Annual competency training will supplement initial education and training based on current interventions. Vaccine administration education and training will be incorporated into new CMA employee orientation.

Limitations

This is a single-site study, yet processes and lessons learned may be transferable to other primary care settings. A small number of vaccines are administered in this FQHC relative to larger primary care clinics or acute care settings, making it difficult to calculate error rates representative of meaningful outcomes.

Conclusion

Vaccines are fundamental to pediatric preventive care; however, similar to any medication, there is potential for harm if administered incorrectly. This quality improvement project incorporated best practice guidelines into a simplified and standardized process to prevent errors and improve patient safety.

A formal project handoff was made to succeeding DNP students to monitor, sustain, and adapt the process to align with a planned EMR upgrade. Focus will continue on process improvement strategies, work toward process integration following an EMR upgrade, and will facilitate the eventual roll-out of this standardized work to other primary care clinics within the health system.

Continuous analysis and improvement are needed to sustain safe practice until required behaviors are hardwired. Multiple interventions after implementation of the new process were needed to prevent the process from reverting back, including additional education and leadership support, especially during a time of staff turnover. Accountability for the new process improved through partnering with administering staff on every step of the project and transition to peer auditing. Accountability is an essential component of sustainability and helps engage staff in process improvement.³² Visual displays of audit results were shared for understanding project progression. Small celebrations of success at monthly staff meetings energized the team to continuously improve. Although this is a single study performed at one clinic, processes and lessons learned are transferrable to other primary care settings.

Conflicts of Interest

The authors declare that there are no conflicts of interest, including financial, consultant, institutional, and other relationships.

Ethical Considerations

This is a QI project and does not involve human subjects research as defined by university policy. Therefore institutional review board (IRB) approval was not required by the Office of Protection of Research Subjects.

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About the Authors

Marianne L. Durham, DNP, RN, is a clinical assistant professor in the Department of Health Systems Science at the College of Nursing at the University of Illinois at Chicago. Her scholarship interests include quality improvement and patient safety in multiple settings.

Ines Didovic, DNP, RN, is a registered nurse in a neonatal intensive care unit and earned a Doctor of Nursing Practice degree with a family nurse practitioner population focus from the College of Nursing at the University of Illinois at Chicago.

Monica J. Gingell, DNP, RN, is a registered nurse in a pulmonary step-down unit and earned a Doctor of Nursing Practice degree with a family nurse practitioner population focus from the College of Nursing at the University of Illinois at Chicago.

HOSPITAL



EMERGENCY





Medication Safety During Transitions of Care: The Importance of Checklists in Preventing Patient Harm

By Laressa Bethishou^{◆◆}, PharmD,
APh, BCPS, Olivia Lounsbury[†] &
Donna Prosser[†], DNP, RN

^{◆◆}Corresponding author

[◆]Chapman University School of Pharmacy

[†]Patient Safety Movement Foundation

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There is a need to optimize patient safety as patients navigate through the health-care system. With each transition of care, patients are vulnerable to changes that may cause adverse effects, including changes in their healthcare team, health status, and medications. The Centers for Medicare & Medicaid Services (CMS) defines a transition of care as “the movement of a patient from one setting of care to another.”²¹ While the concept itself may seem simple, this definition fails to capture the many potential handoff complications which classify these transitions as high risk for patients.¹ With 67% of patients facing unin-

tended medication discrepancies in the hospital and more than 40% of medication reconciliation errors resulting from miscommunications in handoffs, medication safety has become a leading priority for patients and caregivers.^{2,3} The World Health Organization articulated the need to improve communication specifically during points of transition.⁴ Differences in communication styles, distracting environments, and the lack of standardization are the primary factors contributing to the 80% of medical errors resulting from transitional miscommunication.⁵⁻⁷

This need for both efficiency and quality has prompted healthcare

professionals to adopt the use of checklists from the aviation industry as a tool to mitigate the risks for error and standardize the patient care process.⁸ Checklists have been shown to further patient care in areas from detecting medication errors⁹ to surgical safety¹⁰ to reducing communication errors in handoffs.¹¹ Checklists during handoffs have been proven to ease communication,⁶ maintain guideline adherence,¹² and promote situational awareness to produce high-reliability clinical interventions.¹³ With regards to medication administration, checklists have been found to promote the punctual antibiotic delivery necessary for infection prevention¹⁴ and reduce

Table 1: Actionable Patient Safety Solutions (APSS)

APSS Number	APSS Title
1	Culture of Safety
2	Healthcare-Associated Infections (HAIs)*
3	Medication Safety*
4	Monitoring for Opioid-Induced Respiratory Depression
5	Patient Blood Management
6	Hand-Off Communications
7	Neonatal Safety*
8	Airway Safety*
9	Early Detection and Treatment of Sepsis
10	Systematic Prevention and Resuscitation of In-Hospital Cardiac Arrest
11	Optimizing Obstetric Safety*
12	Embolic Events*
13	Mental Health
14	Falls and Fall Prevention*
15	Nasogastric Tube Placement and Verification
16	Person and Family Engagement
17	Patient Safety Curriculum
18	Post-Operative Delirium in Older Adults

*Indicates that these APSS have associated subchallenges under the same category. To view a full list of these APSS and for more detail, please visit www.patientsafetymovement.org.

medical errors that could potentially result in adverse events without hindering workflow.¹⁵

The Patient Safety Movement Foundation (PSMF), a nonprofit organization with the mission of reaching a goal of zero preventable patient deaths, has created Actionable Patient Safety Solutions (APSS) to address challenges which lead to patient harm (see **Table 1**).

Each APSS has been curated with a multidisciplinary healthcare team and includes the patient voice, as the foundation recognizes the importance of patient and family member engagement. The Hand-Off Communications APSS #6 provides a series of checklists for creating and sustaining safe practices during handoff communications.

The Medication Management During Transitions of Care Checklist focuses specifically on optimizing medication safety during healthcare transitions (see **Figure 1**).

Medication reconciliation should be completed at each transition of care, including changes in practice setting, level of care, and healthcare provider. Medication lists should be evaluated for appropriate indication, dosing, frequency, and route as changes to the patient's health status, treatment plan, and level of care may impact medication regimens. Errors of omission, duplication, incorrect dosing, and drug interactions should be identified and resolved.

Healthcare providers can further support patients by identifying and resolving financial and access barriers, addressing educational deficits, and coordinating appropriate follow-up to ensure safe and effective medication management during transitions of care. The Medication Safety APSS #3 provides specific recommendations about high-risk medications, including opioids, diabetes agents, and anti-coagulants. Interdisciplinary collaboration between physicians,

67%
of patients
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medication
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80%
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were due to:



**Differences in
communication
styles**



**Distracting
environments**



**Lack of
standardization**

pharmacists, nurses, case managers, and other healthcare providers is key in anticipating and addressing patient-specific needs and ensuring access to medications. Equally important is engagement of patients and caregivers. Patients should be educated on changes to their medication regimen, as well as required follow-up and monitoring.

The PSMF aims to not only inform and raise awareness, but also to ignite and inspire action from all healthcare professionals. Equally, the PSMF believes that patients should be at the forefront of this change in quality. Therefore, the above APSS were not only written and published by clinicians, administrators, and pharmacists, but also led by patients or family members. The patient voice in the Hand-Off Communications APSS #6 in particular is critical, as patients have the capacity to notice changes in their treatment and should feel empowered to raise questions when a hand-off seems to contain misinformation or lack essential information. The involvement of the patient in all stages of care is pivotal to progression in the healthcare world. It has been shown that when patients do raise concerns, potential medication errors are addressed and eliminated.¹⁶ Currently, however, barriers to patient involvement, such as confusion¹⁷ and fear of challenging medical professionals,¹⁸ undermine proactive communication between healthcare professionals and patients. In tandem, the Hand-Off Communications APSS #6 and the Person and Family Engagement APSS #16 offer extensive strategies for engaging patients in handoffs, which in turn can lead to a significant decrease in medication error (see **Table 1**).

Beneficial implementation of checklists is contingent upon an organizational culture of safety mindset, extensive and interactive training, and routine constructive criticism.¹⁹ It is imperative to

acknowledge that each handoff is unique based on the context and environment, but a standardized approach and execution of handoffs is essential for proper documentation, communication, patient care, and research in the future. Therefore, the Hand-Off Communications APSS #6 offers 18 checklist models specific to the senders and receivers in the situation. These checklists outline all of the conversational interactions and subsequent documentation that should occur in order to avoid harm.

Each is built as a standard model which can then be adjusted and applied with ease to the organizational context of a specific institution.

An example of a successful tailoring of the Hand-Off Communications APSS #6 to a context-specific health-care organization is illustrated by Parrish Medical Center's Chief Nursing Officer Edwin Loftin, who has implemented all of the APSS in his organization and has since witnessed vast improvements in qual-

ity and efficiency.²² Parrish Medical Center's team devised a way to implement the APSS in the most suitable way for their organization:

"Since implementation of this APSS we continue to have regular action-oriented meetings every other week to evaluate all transitions. This allows a real-time continuous improvement process. We have witnessed and have documented improved communication, teamwork, and elimination in preventable errors." - Edwin Loftin, DNP, MBA, RN, Chief Nursing Officer, Parrish Medical Center

Table 2: Available checklists curated by interdisciplinary workgroups from the PSMF

Checklist Title
From emergency department to hospital ward team
From emergency department to operating room
From emergency department to anesthesiology team
From emergency department to surgery team
From emergency department to critical care unit
From emergency department to testing unit (radiology, etc.)
From hospital unit (ward or ICU) to operating room
From hospital unit (ward or ICU) to outpatient clinic
From hospital unit (ward or ICU) to long-term care unit
From hospital unit (ward or ICU) to testing unit (radiology, etc)
From hospital unit (ward or ICU) to home (discharge instructions)
Within the same unit: shift changes
Within the same unit: Medication Management Hand-Off Communication During Transitions of Care Checklist
From operating room to post-anesthesia care unit (PACU)
From operating room to hospital unit (ward or ICU)
From operating room to home (ambulance or surgery)
From paramedics to emergency department
From paramedics to hospital unit (ward, ICU)
From paramedics to long-term care unit

While the APSS and the checklists offered can offer pragmatic use on the floor of these organizations, the emphasis on collaboration with the patient and family members who can be or have been directly impacted by medication errors at handoffs cannot be overstated. As stated above, the APSS were curated through extensive and equal authorship from patients and family members and clinicians, as well as advocates and politicians. Active patient participation in initiatives to improve patient safety has been shown to not only influence behaviors of healthcare workers but also improve decision making and chronic care treatment.²⁰

The high-speed environments inherent in many modern healthcare organizations can increase likelihood of error due to inadequate processes and step-by-step quality assurance. Medication errors are a common occurrence without systematic processes guiding administration. Checklists, such as those mentioned above, ensure consistency and careful planning in patient care; however, while checklists serve as a tool to enhance patient safety in individual healthcare organizations, future research should focus on interoperable checklists across organizations to increase consistency and aid in patient safety in all healthcare facilities, not just the hospital.

Figure 1: Medication Management During Transitions of Care Checklist

This checklist was created to set up the process of medication management during transitions of care. Once your institution imbeds it in their workflow, it is not necessary to use as a traditional checklist. While this list focuses on aspects important for hospital discharge, your organization should apply the principles of medication reconciliation in this list during all hand-offs. Roles may vary by institution, but it is important to clearly define the roles for who takes ownership of these activities.

Ensure medication reconciliation is completed in EHR by physician

- ☐ Reconciliation of full medication list including prior to admission, as an inpatient, and at discharge
 - ☐ Evaluate for appropriate indication, dosing, frequency, and route
 - ☐ Identify and resolve errors of omission, duplication, drug interactions, and incorrect dosing
 - ☐ Update medications based on changes to patient health status and appropriate labs
- ☐ Prescriptions ordered to preferred pharmacy

Ensure collaboration between pharmacist, nursing, and care management

- ☐ Screen for and identify high-risk patients requiring medication review and education
- ☐ Plan for discharge:
 - ☐ Identify time and date of discharge
 - ☐ Coordinate with co-learners if indicated
 - ☐ Identify and address barriers to medication use

Ensure patient can access medications

- ☐ Identify financial barriers
 - ☐ Resolve prior authorization
 - ☐ Switch to cheaper alternatives when available
 - ☐ Coordinate social work and care management if patient doesn't have insurance
- ☐ Identify and resolve barriers to medication access
 - ☐ Ensure stock of medication
 - ☐ Coordinate compounding when indicated
 - ☐ Comply with prescribing requirements (REMS)
 - ☐ Arrange transportation or medication delivery to bedside when indicated
 - ☐ Order appropriate medical equipment
- ☐ Provide patient education about medications
 - ☐ Address language barriers, such as using interpreter, patient educational resources
 - ☐ Coordinate with caregiver and co-learner
 - ☐ Reinforce teaching around high-risk medications and educational deficits
 - ☐ Use "teach-back" method

Ensure follow-up and monitoring

- ☐ Schedule appropriate follow-up visits
- ☐ Schedule labs and monitoring
- ☐ Coordinate home healthcare when indicated

Conflicts of Interest: Olivia Lounsbury works for the Patient Safety Movement Foundation. Laressa Bethishou works for Chapman University School of Pharmacy, which has committed to and has implemented the APSS.

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Ensure

Medication
reconciliation
is completed
in EHR by
physician

Collaboration
between
pharmacist,
nursing,
and care
management

Patient can
access
medications

Follow-up and
monitoring

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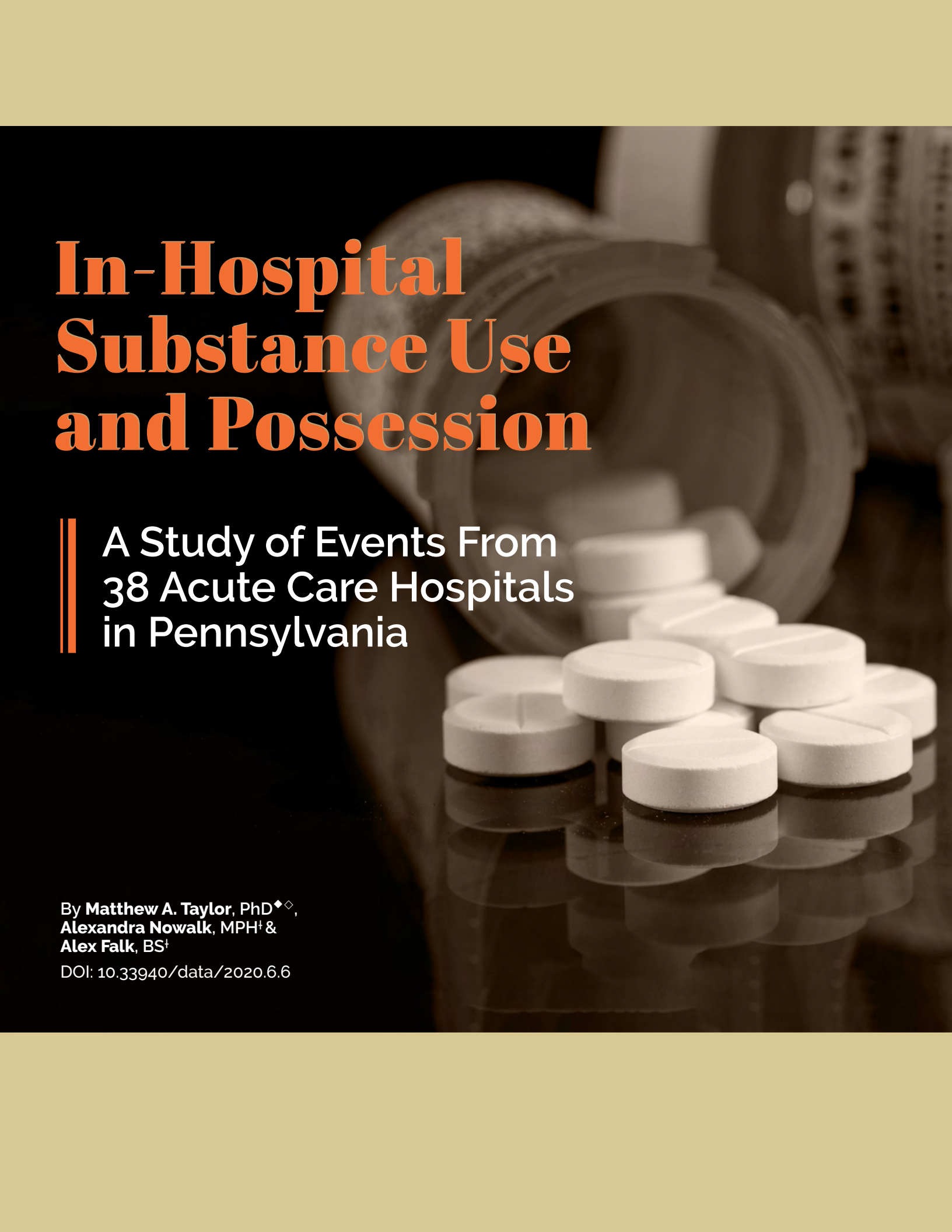
About the Authors

Laressa Bethishou (bethisho@chapman.edu) is assistant professor and director of co-curriculum, Pharmacy Practice, at Chapman University School of Pharmacy in Irvina, California. Her research interests include evaluating the impact of pharmacist interventions on high-risk patient populations, such as heart failure patients, asthma and COPD exacerbations, and pneumonia admissions.

Olivia Lounsbury is a clinical intern at the Patient Safety Movement Foundation and a junior at Chapman University in Orange, California, where she is pursuing a double major in Health Science and Policy and Behavioral Studies.

Donna Prosser is chief clinical officer at the Patient Safety Movement Foundation. She is a Fellow in the American College of Healthcare Executives and is board certified as a Nurse Executive by the American Nurses Credentialing Center and as a Patient Advocate by the Patient Advocate Certification Board.

In-Hospital Substance Use and Possession



A Study of Events From
38 Acute Care Hospitals
in Pennsylvania

By Matthew A. Taylor, PhD^{◆◆},
Alexandra Nowalk, MPH[†] &
Alex Falk, BS[†]

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Patients' substance use and possession at acute care hospitals is an understudied topic. To learn more about this topic, we queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) for events that occurred during calendar year 2018. We identified 106 reports from 38 acute care hospitals (excluding psychiatric, detox, and behavioral health units and facilities) where a patient possessed and/or misused a substance (e.g., heroin, oxycodone, liquor). We analyzed these reports to better understand how hospital personnel attempt to prevent in-hospital substance use and manage patients who are at risk for using a substance. We explored a range of variables, including antecedent conditions and hospital personnel's actions post-detection of a patient's substance use or possession. We found that a relatively low percentage of patients (26%) were identified as having a prior history of substance use, despite later using or being in possession of a substance in hospital. In our sample, patients frequently acquired the substances from visitors, more than half of the substances were consumed intravenously, and opioids were the most common substance. The most prevalent actions taken by hospital personnel were conducting searches for substances and paraphernalia, use of a patient sitter or video monitor, moving patients to a different room, and implementing visitor restrictions. Based on our findings and previous research, hospitals should consider increasing their use of substance use disorder (SUD) screening tools, pharmacotherapy, and referring patients to treatment. Overall, our results can help personnel better understand the nature of and strategies that may reduce the likelihood of in-hospital substance use.

Keywords: *substance use, paraphernalia, substance use disorder, in-hospital, addiction, opioid, risk mitigation, patient safety*

◆Corresponding author

◇Patient Safety Authority

†School of Pharmacy, University of Pittsburgh

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Introduction

Substance use, including street drugs, pharmaceuticals, and alcohol, is a well-known and documented public health problem. According to a recent study, 20.2 million adults in the United States meet the criteria for a substance use disorder (SUD).¹ Unfortunately, that study also estimated that fewer than 8% of those adults received SUD treatment at a specialty facility. With a relatively low percentage of adults receiving treatment, it is likely that SUDs will continue to have a notable impact on many areas of society, including the healthcare industry.

Several studies have reported that persons who engage in substance use or who have an SUD are more likely to visit the emergency department or seek medical care than persons without an SUD or abstain from substance use entirely.²⁻⁴ Furthermore, a recent study found that the rate of emergency department visits among persons with an SUD increased yearly from 2006 to 2013, increasing by a cumulative 37%.⁵ The opioid epidemic and drug-related overdoses have exacerbated this increase in emergency department visits. From 2016 to 2017, cases of nonfatal drug overdoses presenting to the emergency department significantly increased for a majority of drug types.⁶ These findings may not be surprising to many hospital personnel; nevertheless, the increasing prevalence of patients who engage in substance use creates challenges for acute care hospitals and their ability to ensure high-quality care.⁷

Substance Use Disorder (SUD)

is a condition ranging from mild to severe involving continual alcohol or other drug use despite social or physical harm resulting in significant changes in social and psychological functioning.

Reference: American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA: American Psychiatric Publishing.



A recent study found that the rate of emergency department visits among persons with an SUD increased yearly from 2006 to 2013, increasing by a cumulative 37%.⁵

Antecedent conditions are defined as any information considered or actions taken by hospital personnel prior to detecting the patient's in-hospital substance use or possession.



When a person with an SUD seeks medical care, the providers are often unaware of the disorder or may not anticipate how the disorder could impact the person's behavior while under care.^{8,9} For example, a provider might be surprised to

find a patient intravenously using heroin while in hospital and even more surprised to find the patient unresponsive due to an overdose. Despite the reality of this problem, we identified only three studies of patients' substance use while at an acute care hospital.¹⁰⁻¹² In two of those studies, more than 40% of patients with an SUD had engaged in substance use while in hospital.^{10,11} Despite the value of these studies, only one of the studies was conducted in the United States, and that study had a sample of 42 patients.¹⁰

The purpose of this descriptive study was to evaluate event reports from acute care hospitals to better understand how they attempt to prevent in-hospital substance use and manage at-risk patients. In our study, we explored a range of variables, including antecedent conditions and hospital personnel's actions post-detection of a patient's substance use or possession. The findings will help hospitals consider various strategies for helping at-risk patients and reducing the likelihood of in-hospital substance use and possession. Additionally, with our results and other supporting information, we anticipate that hospitals could develop educational material to promote awareness among staff.

Methods

Sample

The first author conducted a query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) data-

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Examples of In-Hospital Substance Use

Example #1: The patient was admitted for an overdose earlier in the day. A nurse reported that the patient was in the bathroom for an extended period of time and would not open the bathroom door. The staff forced the door open and found the patient unresponsive. Naloxone was administered and the patient became responsive. The patient communicated that she had snorted fentanyl in the bathroom. She acquired the drug from her clothing, which were in the room and had not been searched prior to the event.

Example #2: Staff were cleaning the patient's bathroom. Under a towel, staff found a used syringe and spoon with white residue. Security confiscated the paraphernalia.

Example #3: Patient was diaphoretic and engaging in rocking behavior. The patient admitted to consuming a bag of heroin with a visitor. Staff searched the room and found seven empty bags and multiple needles. The patient was transferred to a higher level of care for closer monitoring, and the visitor left the hospital.

Note: information in each event example was modified to ensure confidentiality.

base.* The query was restricted to events that occurred at hospitals between the dates of January 1 and December 31, 2018. The query included 103 unique keyword filters, each of which consisted of a single phrase ($x = 14$; e.g., “heroin”, “stamp bag”, “snort”, “glass pipe”) or a combination of two phrases ($x = 89$; e.g., “security” AND “substance”, “police” AND “room search”, “visitor” AND “drug”). Using the aforementioned criteria, the query produced a total of 522 events.

The next step was to apply a filter, reducing the data set from 522 to 366 events by excluding events that occurred in psychiatric and chemical dependency units. These events were removed from the data set because psychiatric and chemical dependency units often operate under more restrictive policies and security protocols than other service lines and units throughout hospitals. All events included in this study occurred at acute care hospitals and did not include events from behavioral health hospitals.

Based on the remaining 366 events, the first author manually reviewed the free-text narrative fields for each event and removed any events that were inconsistent with the scope of the study. Events were considered relevant to the scope of the study if they met one or more of the following criteria:

1. While in hospital, a patient possessed and/or used an illicit substance.
2. While in hospital, a patient intentionally used a pharmaceutical (prescribed or not prescribed) without endorsement by the hospital and that substance appeared to be causing abnormal behavior or an unexpected change in

condition (e.g., unresponsive, lethargic, disoriented, slurred speech, tachycardia).

3. While in hospital, a patient possessed and/or consumed alcohol.

Based on the filters and inclusion criteria, we identified 106 relevant events.

Variables Coded

In this descriptive study, two types of variables were explored across all 106 events. The first type of variable was coded by event reporters (i.e., hospital-assigned personnel who formally submit event reports to PA-PSRS). In all event reports, the reporters provided data on the following variables: patient age and gender, event classification (Serious Event[†] vs. Incident[‡]), care area of hospital, and geographic region in Pennsylvania.

The second type of variable was based on manual review of the free-text narrative field for all 106 event reports. The first author reviewed and coded each event report for 33 categorical variables, which ranged in topic from antecedent conditions to outcomes resulting from the patient's in-hospital substance use and possession. It is our intention that information gathered from these variables will help healthcare personnel better understand the various conditions and challenges associated with in-hospital substance use and possession.

While manually reviewing the event reports, 25 of the 33 variables were binarily coded for presence or absence of the target factor. For example, all 106 events were coded for whether or not the report mentioned involvement of paraphernalia. Additionally, 8 of the 33

[†] Serious Event is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.¹³

[‡] Incident is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.¹³

variables required that all variations of the condition or action were recorded, which allowed us to create an inclusive list of all relevant information. For example, in each report, notes were taken on each type of paraphernalia mentioned (e.g., syringe, spoon, straw, pipe, substance wrapper), which helps us better understand the specific nature of in-hospital substance use and possession.

In this descriptive study, all variables were measured, analyzed, and compared by frequency of occurrence.

Results

Patient Age and Gender

Across the 106 event reports, 55% (n=58) of the patients were identified as male and 45% (n=48) were female. Among the 106 patients, the median male age was 38 years

(range: 23–70) and median female age was 33 years (range: 19–58). As indicated in **Figure 1**, the distribution of in-hospital substance use and possession differs by age group and gender. Although the sample is limited, the findings suggest that males of a greater age (e.g., 61–70 years) are associated with in-hospital substance use in comparison to females.

Event Classification (Serious vs. Incident) and Care Area

Based on the reports, no patient death or permanent harm was associated with substance use or possession. Overall, 8% (8 of 106) of the events were classified as *Serious* and 92% (98 of 106) were categorized as an *Incident*. These findings indicate that, at worst, patients experienced temporary harm that may have required prolonged hospitalization. As shown in **Table 1**,

the events occurred across 11 care area groups.

Hospitals and Geographic Regions

According to the 106 reports, patient in-hospital substance use and possession was reported at 38 hospitals, with a median of 2 events per hospital (range: 1–12). The events occurred at facilities in each category of bed size (1–100, 101–200, 201–300, and >300), but were most prevalent at hospitals with >300 beds (58%; 61 of 106) and least common at hospitals with 1–100 beds (3%; 3 of 106). The events occurred in 21 of the 67 counties in Pennsylvania, with a median of 3 events per county. The greatest percentage of events were reported in the following counties: Allegheny (32%; 34 of 106), York (12%; 13 of 106), and Philadelphia (8%; 9 of 106).

Figure 1. Frequency of In-Hospital Substance Use and/or Possession by Gender and Age Group during 2018 (n = 106)

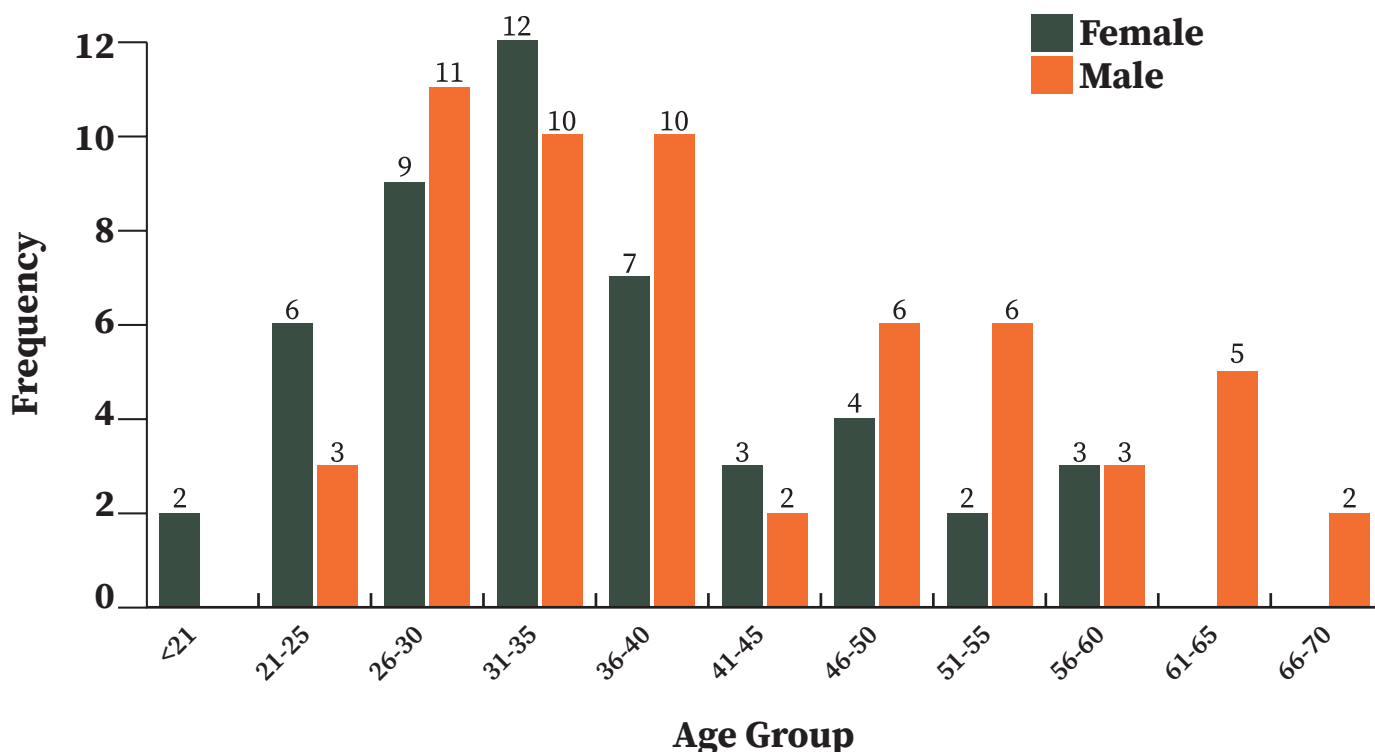


Table 1. Frequency of In-Hospital Substance Use and/or Possession by Care Area Group and Event Classification during 2018

Care Area Group	Event Classification		Total Events
	Incident	Serious	
Medical/Surgical Unit	38	5	43
Specialty Unit	15	0	15
Intermediate Unit	10	1	11
Intensive Care Unit (ICU)	10	0	10
Emergency	9	1	10
Other	5	0	5
OB/GYN Unit	4	0	4
Labor and Delivery	3	0	3
Physical Rehabilitation Unit	2	1	3
Surgical Services	1	0	1
Respiratory	1	0	1
Total Events	98	8	106

Note: There are a total of 23 Care Area Groups but only the above 11 were associated with an event.

Coding of Variables Based on Manual Review of Event Reports

In the subsequent sections, we present findings related to the following six categories of information: event antecedents, event detection, nature of substance use, substances and paraphernalia involved, location of substances and paraphernalia, and event outcomes. All the findings were derived from data collected by manual review of the free-text narrative field for all 106 event reports.

Antecedents to In-Hospital Substance Use and/or Possession

This category of variables tracks information that was available to and actions taken by hospital personnel prior to the event. Overall, the findings suggest that hospitals had at least one or more indications that 26% (27 of 106) of patients may have had an SUD. In a majority of these reports, the patient was noted to

have a known history of substance use. Also, 12% (13 of 106) of the reports indicated that the patient had a health condition secondary to substance use (e.g., substance overdose, cellulitis, abscess, encephalopathy, hepatitis C, septic emboli, compartment syndrome). Finally, 6% (6 of 106) of the reports stated that the patient had a positive urine drug screen prior to the event.

Hospitals' actions to prevent and deter substance use varied. **Table 2** contains detailed information about actions taken prior to events. As indicated by the table, 11% (12 of 106) of event reports described one or more of the following pre-event actions (not mutually exclusive): belongings searched (4 of 12), sitter or video monitor (4 of 12), on-person search (3 of 12), and visitor restrictions (2 of 12). Despite these actions, each of the 12 patients were later found to possess or use a substance while in hospital.

Detection of In-Hospital Substance Use and/or Possession

This category of variables focused on the conditions that provided suspicion or clear indication that a patient possessed and/or was using a substance. Based on review of the 106 event reports, only 53 identified the role or relationship of the person who detected the substance use and/or possession. Among those reports, 66% (35 of 53) of the persons who detected the event were identified as nurses; 9% (5 of 53) were support staff (e.g., nurse assistant, sitter, or video monitor); 8% (4 of 53) were nonclinical staff (e.g., housekeeper, registration staff, security); 8% (4 of 53) were technologists or therapists; and the remaining 9% (5 of 53) were physicians, visitors, or other patients.

Across all 106 events, substance use and/or possession was detected based on the observation of one or more of the following variables (not mutually exclusive): change in patient's behavior or condition (60%; n=64), visible substance (33%; n=35), visible paraphernalia (31%; n=33), patient admitted to using a substance (5%; n=5), and/or patient was observed using a substance (5%; n=5). Changes in the patient's behavior or condition included abnormal clinical assessment findings (e.g., lethargy, disorientation, hyperactivity, diaphoresis, slurred speech) and unresponsiveness. **Figure 2** depicts the distribution of behavioral and clinical conditions used to detect substance use and/or possession across all 106 events.

Nature of In-Hospital Substance Use and/or Possession

This category of variables focused on conditions associated with the patients' in-hospital substance use and acquisition of the substance. Based on a manual review of the 106 event reports, 3% (n=3) of patients acquired the substance from the hospital. In these three events,

Table 2. Hospitals' Patient-Specific Actions Prior to In-Hospital Substance Use and/or Possession

1. Pre-event, search was performed, visitor restrictions were implemented, and/or a sitter/video monitor was assigned.	11% (12 of 106)
2. Pre-event, patient received a social services/psychiatric consult and/or was administered a screening tool for substance use disorder.	4% (4 of 106)
3. Pre-event, patient was prescribed or administered medication to aid with substance craving or withdrawal (pharmacotherapy).	2% (2 of 106)
4. Pre-event, patient was denied or restricted specific medications.	2% (2 of 106)

the patients were prescribed an oral medication, but did not consume it as intended and instead self-administered it intravenously. Also, 26% (28 of 106) of the reports indicated that the patient received or likely received a substance from a visitor. Upon further review of those events, we found that 15 of the 28 visitors had an identified relation with the patient. Among those with an identified relation, 40% (6 of 15) were a “spouse” or “partner,” 33% (5 of 15) were “family” (e.g., a sibling), and 27% (4 of 15) were a “friend.”

While reviewing the event reports, we also learned that at least 82% (87 of 106) of the patients had likely consumed a substance while in hospital. Though it was often unclear what substance(s) was consumed, 66% (57 of 87) of the event reports indicated the method of consuming the substance. Among those reports, a substance was consumed intravenously by 63% (36 of 57) of the patients, intranasally by 18% (10 of 57), orally by 14% (8 of 57), and as non-nicotine based smoking/vaping by 5% (3 of 57). Finally, the event reports revealed that an opioid reversal agent (e.g., naloxone) was administered to 26% (23 of 87) of the patients who engaged in in-hospital substance use.

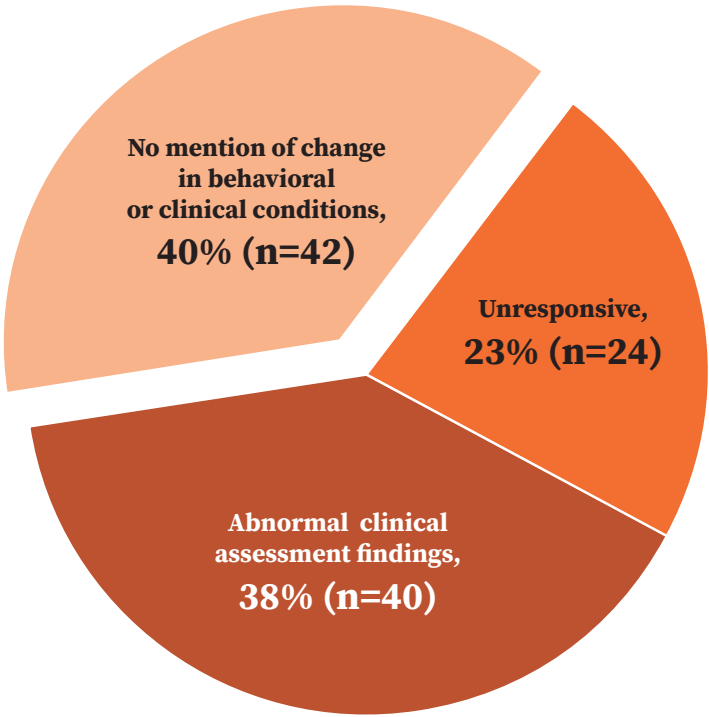
Substances and Paraphernalia Involvement

Many of the event reports indicated the specific illicit items that were found or involved in the event. Hospital personnel often acquired this information by questioning patients and/or conducting a search. The event reports were coded to

identify involved substances and paraphernalia. Overall, paraphernalia was involved in at least 53% (56 of 106) of the events. According to the reports, 40% (42 of 106) of the patients had and/or used a syringe. The reports also mentioned the following paraphernalia: straw, pipe, spoon, lighter, substance wrapper (e.g., heroin stamp bag), tourniquet, pill crusher, razor blade, and non-nicotine vape device.

The reports were also coded for substances involved and/or confiscated during the event. In 45% (48 of 106) of the reports, the substance was not identified, often because the patient refused or was unable to provide information. In the remaining 55% (58 of 106) of the reports, the narrative indicated the type of substance. Among those reports, 17% (10 of 58) of the patients used and/or possessed two or more substances while in hospital (e.g., cocaine and heroin, fentanyl and morphine). Across all the events that provided some

Figure 2. Distribution of Events Where Patients' In-Hospital Substance Use and/or Possession Was Detected by Change in Behavioral and Clinical Conditions



information about the type of substance, we found that pharmaceuticals were the most common. Additional information about the types of substances involved or confiscated during the events is located in **Table 3**.

Location of Substances and Paraphernalia

The reports were reviewed to identify where the substances and paraphernalia were placed or hidden by patients. We found that 74% (78 of 106) of the reports provided at least some information about the location of the illicit items. (Note: these locations may not reflect where the substance was used, only where the items were found.) Among the reports that provided this information, we learned that the patient placed or hid the items in two or more locations during 28% (22 of 78) of the events.

In the reports that provided information about location of the illicit items, 45% (35 of 78) specified the area of the room. Among those reports that provided this information, 51% (18 of 35) of the events involved a substance or paraphernalia being found in the bathroom and 26% (9 of 35) involved the patient's bed. Other areas of the room included the floor and bedside table.

While reviewing the event reports, we discovered that personal property was another common location where illicit items were hidden or placed. Across all of the reports that provided information about the location of illicit items, 41% (32 of 78) mentioned that a substance or paraphernalia was located inside personal property. Among these reports, 59% (19 of 32) stated that the illicit items were found in a patient's bag or purse, 9% (3 of 32) in a wallet, and another 9% (3 of 32) in a cigarette box. The remaining personal property identified by the event reports included phone case,

Table 3. Substances Involved In or Confiscated During Event

Category	Sub-Category	Percentage (Frequency)
Unidentified	-	41% (40 of 116)
Pharmaceutical 33% (n = 38/116) 	Unidentified	12% (14 of 116)
	Opioid (<i>Fentanyl, Hydromorphone, Methadone, Morphine, Oxycodone</i>)	11% (13 of 116)
	Benzodiazepine (<i>Alprazolam, Clonazepam, Diazepam</i>)	5% (6 of 116)
	Opioid/opioid antagonist (<i>Buprenorphine/naloxone</i>)	2% (2 of 116)
	Anticonvulsant (<i>Gabapentin</i>)	2% (2 of 116)
	Anxiolytic (<i>Buspirone</i>)	1% (1 of 116)
Street Drug 24% (n = 28/116) 	Heroin	14% (16 of 116)
	Marijuana	5% (6 of 116)
	Cocaine	3% (4 of 116)
	Methamphetamine	1% (1 of 116)
	Synthetic Marijuana	1% (1 of 116)
Alcohol 	Liquor	2% (2 of 116)

Note: Across all 106 event reports, there were 116 substances involved or confiscated; 10 of the reports described a patient with two or more substances.

food bag, hat, and tampon wrapper.

Finally, we learned that illicit items were frequently located on person (42%; 33 of 78), according to reports that provided sufficient information. Among those reports, items were located in one or more of the following locations: pocket, sock, IV site/port, bra, lap, and genitalia.

Outcomes From In-Hospital Substance Use and/or Possession

The 106 event reports were reviewed to determine the various outcomes post-detection of substance use and/or possession. In 4% (n=4) of the events, the patient left care against medical advice. Also, just 4% (n=4) of the reports stated that the patient was referred to substance treatment or detox. The most common patient-specific action was to confiscate all

substances and paraphernalia by searching the patient's room, belongings, and/or person. For further information about hospital personnel reactions to detecting substance use and/or possession, see **Figure 3**.

Discussion

Findings from the current study are consistent with previous research, which indicates that patients' in-hospital substance use and possession are a challenge in acute care hospitals.¹⁰⁻¹² Based on our study, the problem is prevalent in both male and female patients, across a wide range of ages, in many care areas of hospitals, and geographically distributed across Pennsylvania, including in both urban and rural communities. These findings highlight the breadth of the problem and suggest that our

findings could be representative of many acute care hospitals, both within and outside of Pennsylvania.

Educational Material for Hospital Personnel

Our findings, combined with information from other published research, could be transformed into educational material to help hospital personnel better understand the challenges and conditions associated with in-hospital substance use and possession. For example, the material could highlight that a high percentage of substances were brought into the facility by visitors, including family. Additionally, it could inform staff that more than half of the substances were consumed intravenously, and opioids were the most common category of pharmaceutical and street drug. Many of the illicit

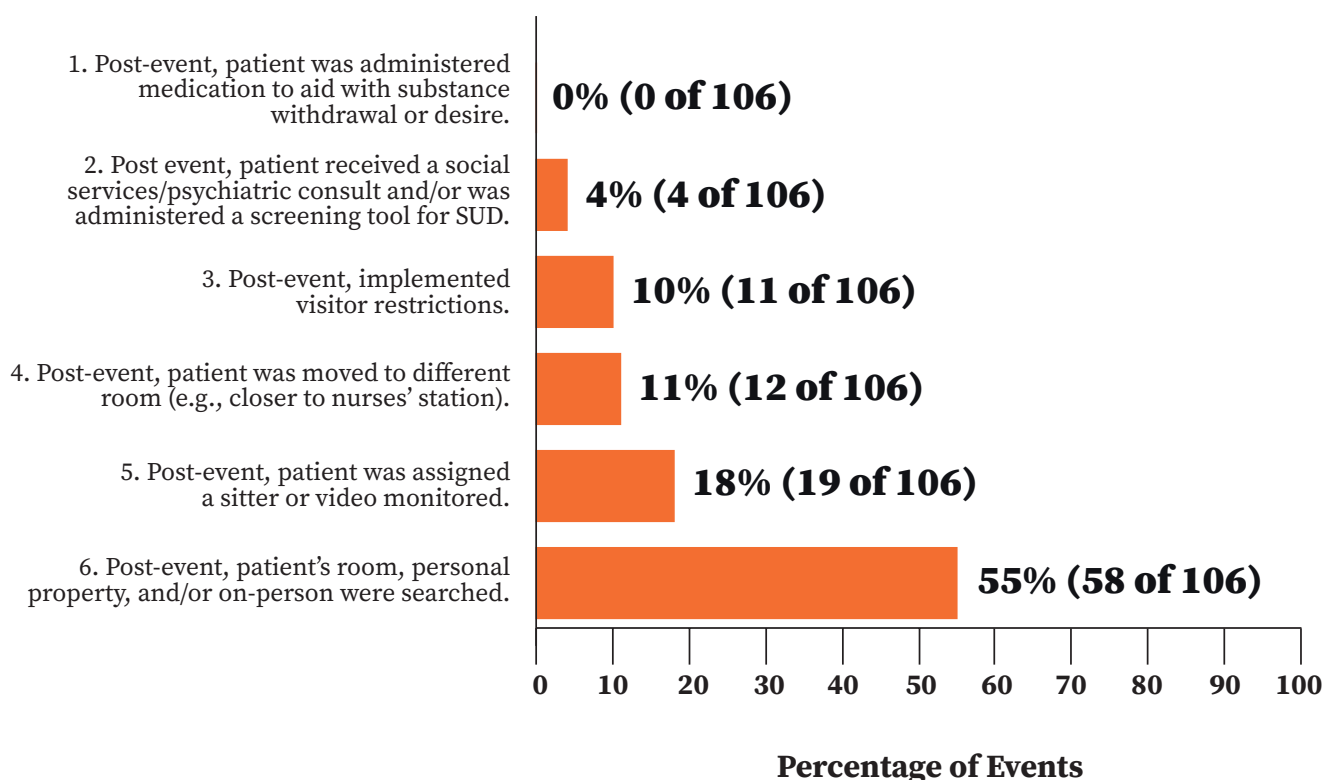
items were found in personal property (e.g., bag/purse), on person (e.g., pocket, sock), and frequently in multiple locations. Overall, this type of information could be useful for many categories and levels of staff, including those who are new to healthcare and staff who are frequently around patients, but do not have clinical responsibilities (e.g., housekeeper, security). Depending on the learning objectives, the educational material could range from a one-page document that highlights key points to a computer-based training with images, videos, and a learning assessment. Regardless of the medium and depth of educational material, the goal should be to help personnel more accurately identify and understand conditions with implications for patient safety. Most importantly, language used in both

provider and patient-facing materials should be nonjudgmental to minimize perpetuating stigma associated with SUD and to increase patient engagement.^{14, 15}

Approaches to Identifying Patients At Risk for In-Hospital Substance Use

As noted previously, a relatively low percentage of event reports (26%) identified patients as having a history of substance use, despite later being found using or in-possession of a substance. This indicates that hospitals should explore additional approaches to increase their accuracy of identifying patients with an SUD. Traditionally, clinicians have used chart reviews, interviews, blood alcohol concentration level tests, urine drug screens, and physical exam findings to guide identification of patients who may have

Figure 3. Hospitals' Patient-Specific Actions to Prevent Further In-Hospital Substance Use and/or Possession



an SUD.¹⁶⁻¹⁸ More recently, hospitals have been increasing their use of validated screening assessments and tools to identify patients with an SUD. For example, a provider may use the Clinical Opiate Withdrawal Scale (COWS) to assess a patient's behavior and withdrawal symptoms to determine the degree of opioid dependence.^{19, 20} With many of the screening tools, patients are administered a brief "prescreen" consisting of one to three questions. Common validated initial screening instruments include the National Institute on Alcohol Abuse and Alcoholism (NIAAA) single-question screen for alcohol;²¹ the National Institute on Drug Abuse (NIDA) single-question screen for drug use;²² the Alcohol Use Disorders Identification Test – Consumption (AUDIT-C);²³ and the Alcohol, Smoking and Substance Involvement Screening Test – Frequency and Concern (ASSIST-FC).²⁴ If patients screen positive during the prescreen, then a full screening tool should be administered to further assess for at-risk substance misuse, including SUD.

From a workflow perspective, substance use screening within acute care facilities is typically administered during the patient intake or triage process.^{25, 26} SUD screening tools often take fewer than five minutes to administer but may take longer if patients are engaging in polysubstance use, which may require the administration of multiple screening tools. Time constraints and lack of training are commonly cited as barriers to the full integration of substance use screening within clinical workflows, especially in emergency departments. However, using a brief prescreen and administering full screens to only patients that score positive on the initial screen (i.e., AUDIT-C) saves significant time and eliminates the need for staff to conduct a full screen with all patients. Providing training to nurses

and other medical staff can help overcome stigma and discomfort when introducing screening to patients.²⁷ Overall, there are various approaches to identifying patients with an SUD and there is substantial evidence to support use of validated screening tools; nevertheless, simply identifying the at-risk patients will not prevent in-hospital substance use.

Approaches to Preventing and Deterring In-Hospital Substance Use

As indicated by our findings, hospitals may take various approaches to preventing and deterring substance use. In our study, the most prevalent actions were conducting a search for substances and paraphernalia, use of a sitter or video monitor, moving a patient to a different room, and implementing visitor restrictions. Although these were the most common approaches and can be effective in some situations, there are undoubtedly real challenges and potential negative outcomes associated with these approaches. For example, some may argue that these approaches would infringe on patient rights. Additionally, hospitals may be subject to patient lawsuits for infringement of privacy and patients may choose to leave care against medical advice (AMA).^{28, 29} Previous research reported that patients with an SUD are more likely than other patients to leave AMA,^{30, 31} which was an outcome observed in 4% of the event reports in our study. Previous research reported that the most common reasons for leaving AMA were untreated withdrawal symptoms, stigma, and restricted access to other areas of the hospital (e.g., unable to leave room).³⁰ Clinical staff should be aware that their behavior and language can directly impact a patients' motivation to engage in treatment^{14, 15} or leave AMA.³² As a result, staff should consider various strategies and interventions, such

as motivational interviewing, to facilitate care of the patient.³³

In our study, we found that only 2% of the event reports indicated that patients were administered medication, either pre- or post-event, to help with their in-hospital withdrawal symptoms and substance cravings (i.e., pharmacotherapy). Recent literature, which was primarily focused on medium- and long-term reduction of opioid substance use, highlights some benefits of administering buprenorphine in hospital.³⁴ While we are not aware of any research specifically focused on administering in-hospital pharmacotherapy to prevent in-hospital substance use, it seems likely it could be an effective approach and may also deter patients from leaving AMA by mitigating their withdrawal symptoms. As noted by others, further research is needed on the use of in-hospital pharmacotherapy, such as buprenorphine, as there might be unintended and negative consequences.³⁵

Finally, our findings indicate that few patients (4%) were being referred to substance detox or treatment. From a public health perspective these events can possibly be reduced, or even prevented, by detecting at-risk behaviors early, intervening to reduce risk, and linking patients to specialty treatment, as appropriate. Screening, Brief Intervention, and Referral to Treatment (SBIRT) is one such evidence-based practice which involves universal screening and early intervention with individuals at-risk for developing an SUD.³⁶ Traditionally, public health approaches to substance use have largely focused on primary prevention (e.g., delaying or inhibiting the onset of substance use) or tertiary treatment (e.g., providing specialized treatment to individuals that have already developed an SUD). Thus, patients who are engaging in risky substance-use behaviors



Screening, Brief Intervention, and Referral to Treatment (SBIRT)

“is a comprehensive and integrated approach to the delivery of early intervention and treatment services through universal screening for persons with substance use disorders and those at risk.”

Reference: Babor, T. F., McRee, B. G., Kassebaum, P. A., Grimaldi, P. L., Ahmed, K. & Bray, J. (2007). Screening, Brief Intervention, and Referral to Treatment (SBIRT): Toward a Public Health Approach to the Management of Substance Abuse. *Subst Abuse*, 28(3), 7-30. doi:10.1300/J465v28n03_03

but have yet to develop an SUD are not typically identified via existing clinical pathways. SBIRT fills these gaps and provides a comprehensive continuum of care by linking patients to an appropriate intervention tailored to meet the patient's level of risk.

The evidence base for SBIRT within acute care facilities is robust, leading to improved patient outcomes and reduced healthcare costs. For example, Pringle et al. found in a 2018 study that integrating SBIRT within an urban-based emergency department led to a 21% reduction in healthcare costs and a significant reduction in one-year emergency department-readmissions amongst patients that received SBIRT services.³⁷ Further, referring patients to SUD treatment (via facilitated warm handoffs from the facility to SUD treatment providers) has been shown to drastically increase the likelihood a patient will engage and be retained in treatment.^{38, 39} Embedding dedicated staff, such as case managers, social workers, counselors, or certified peer recovery specialists/coaches, can directly facilitate the referral process.⁴⁰⁻⁴² The cost for these positions is typically covered through savings in downstream healthcare costs.³⁷ In Pennsylvania, the Department of

Health (DOH) and Department of Drug and Alcohol Programs provide guidance to acute care facilities seeking to establish a facilitated referral process between their facility and local SUD treatment providers.⁴³ Overall, referring patients with an SUD—particularly those engaged in-hospital substance use—to specialty treatment will help to address many challenges associated with substance use, including those regularly observed in acute care hospitals.^{44, 45}

Limitations

We caution readers against using our results as a reflection of the true prevalence of in-hospital substance use and possession, as the observed frequency likely is an underestimation due to many events going undetected, unreported, or instead being reported to the DOH. We urge readers to use our data to better understand the nature of in-hospital substance use and possession, and leverage that information to guide strategies to improve patient safety. Readers should also keep in mind that our findings are based on 106 events from 2018 and it is possible that the patterns among our findings may differ from those in 2019 or subsequent years. Furthermore, despite our data reflecting regions across the state, it is possible that our findings may not be generalizable to or reflect challenges faced in other parts of the United States, given the differences in substance availability and regional cultures.⁴⁶⁻⁴⁸

Conclusions

Our findings indicate that patient in-hospital substance use and possession is a challenge across Pennsylvania in both rural and urban communities. Based on the event reports summarized in our study, it is evident that hospitals' approaches to proactively prevent and reactively address substance

use and possession vary. This could be due to the wide-ranging contexts of the events, variability of hospital protocols, availability of resources, or disagreement on best practices to prevent and mitigate in-hospital substance use and possession. Based on our findings and previous research, hospitals should consider increasing their use of SUD screening tools, pharmacotherapy, and referring patients to treatment. These practices were infrequently mentioned in event reports, yet they help hospitals more accurately identify patients at-risk for in-hospital substance use and reduce the likelihood of substance use both in-hospital and post-discharge. In future studies, we recommend that investigators critically explore the benefits, disadvantages, and challenges of the various approaches to preventing and deterring in-hospital substance use.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

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Author Bios

Matthew A. Taylor (MattTaylor@pa.gov) is a patient safety analyst at the Patient Safety Authority.

Alexandra Nowalk is a program manager in the Program Evaluation and Research Unit at the University of Pittsburgh School of Pharmacy.

Alex Falk is a research specialist and data analyst at the Program Evaluation and Research Unit at the University of Pittsburgh School of Pharmacy.

Swallowed De[🦷]ntures

An Analysis of Denture Impaction Events in Pennsylvania

By Elizabeth Kukielka^{◆◇}, PharmD, MA, RPH
& Rebecca Jones[◇], MBA, RN

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◆Corresponding author

◇Patient Safety Authority

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Abstract

Tooth loss is a prevalent health concern affecting two-thirds of the geriatric population in the United States. Most patients replace missing teeth with dentures, which have the potential to become dislodged, swallowed, and stuck somewhere along the gastrointestinal tract (termed denture impaction). We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) and identified 68 denture impaction events reported from 2004 to 2019. An in-depth analysis revealed that patients were most often male, and the median patient age was 77 years. The most common symptoms reported by patients with denture impaction included difficult and/or painful swallowing, breathing trouble or respiratory distress, sore throat, foreign body sensation in the throat, throat obstruction preventing insertion of a tube or scope, choking, excessively thick and/or bloody oral secretions, and vomiting or regurgitation of food. The pharynx was the most common site of denture impaction, and x-ray imaging was the most common diagnostic test mentioned. The most common method of removal was surgery, and the most common surgical procedures employed were esophagogastroduodenoscopy and laryngoscopy. We believe that we have identified a category of denture impaction events that has not previously been characterized. Our study, coupled with the existing medical literature, suggests that all patients, along with their caregivers and healthcare providers, should be aware of the proactive steps to avoid denture impaction, as well as signs and symptoms of impaction for early identification and treatment.

Keywords: *choking, denture, denture impaction, edentulism, intubation, swallowed dentures, delayed diagnosis*



IN THE UNITED STATES

**At least
10%**
*of individuals
have no teeth.*

**More than
1/3**
*are missing at
least one tooth.*

WITHIN THE GERIATRIC POPULATION IN THE UNITED STATES

2/3
*of individuals are
either missing at least one
tooth or have no teeth.*

90%
*of individuals with
tooth loss have some
type of denture.*

Introduction

Tooth loss is a prevalent health concern in the United States and worldwide. At least 10% of individuals in the United States have no teeth (termed complete edentulism), and more than one-third are missing at least one tooth (termed partial edentulism).¹ Within the geriatric population in the United States, two-thirds of individuals are either partially or completely edentulous.¹

Individuals with edentulism often desire to replace missing teeth to improve the outward appearance of their smile and to prevent or restore normal eating and speech. Approximately 90% of individuals with edentulism have some type of denture, which may be partial or complete, and permanent or removable.¹ Complete removable dentures are used by patients with complete edentulism. An implant may replace a single missing natural tooth. Partial dentures may be attached to surrounding natural teeth or even implants either as a permanent bridge or as a removable partial denture, sometimes termed a dental plate or partial plate.

Whether permanent or removable, dentures have the potential to become dislodged from the usual site; the patient may then inadvertently swallow the denture once it is loose in the mouth. Depending on the size and shape of a denture as well as the circumstances surrounding a denture-swallowing event, a denture may then be lodged somewhere along the gastrointestinal (GI) tract (termed denture impaction). After reading about a denture impaction event involving a man in England who swallowed his dentures while under anesthesia for a surgical procedure, we queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) to identify and analyze denture impaction events that have occurred in Pennsylvania.³ Although the patient safety event reports reviewed are only from acute care facilities, we believe the insights from our analysis will be universally beneficial to healthcare providers in all practice settings—including primary care providers and dentists—as well as to patients who wear dentures or their caretakers.

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002).² All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Methods

We queried PA-PSRS for events that occurred between May 1, 2004, and October 31, 2019. We searched the event detail for events containing a combination of one of the following keywords: “denture,” “partial plate,” “false teeth,” “bridge,” “artificial teeth,” or “dental implant;” AND one of the following keywords: “swallow,” “choke,” “lodg,” “stuck,” “impact,” “throat,” “esophag,” or “pharyn.” We independently reviewed and coded each report and resolved any discrepancies through joint analysis and consensus.

We conducted a preliminary review of each report to identify events for inclusion and exclusion in our analysis. An event was included in the analysis if it involved a patient who experienced the dislodgement of any number of artificial teeth from the usual site; artificial teeth could include dentures, partial dentures, partial plates, bridges, or implants. All other events were excluded. We then reviewed each event that met the inclusion criteria and classified it as either a near miss or a denture impaction. A *near miss event* was defined as an event in which the artificial tooth or teeth were dislodged but immediately removed from the mouth upon identification and before causing an obstruction. A *denture impaction event* was defined as an event in which the artificial tooth or teeth were dislodged but not immediately identified, and subsequently were found somewhere along the GI tract.

We performed a descriptive analysis of denture impaction events to identify trends in patient age and gender, as well as event classification and harm score. We then performed an in-depth qualitative analysis of

denture impaction events, coding each report for the following: type of dental appliance involved, diagnostic studies performed to locate the denture, anatomical site along the GI tract where the denture was lodged, whether the denture impaction occurred prior to or during the present admission, the activity that contributed to the denture dislodgement and subsequent impaction, the patient’s physical location when the activity that contributed to the denture dislodgement occurred, and whether there was a delay in diagnosing the denture impaction. We performed a brief qualitative analysis of near miss events, coding each event according to the type of dental appliance involved and the activity that contributed to the near miss.

Results

The query returned 229 event reports; two separate event reports described a single event, so the total number of events was 228. We classified 68 events as denture impaction events and 86 events as near misses. The remaining 74 event reports were determined to be unrelated to denture impaction and were excluded from the analysis; many of the events that were excluded described injuries to the bridge of the nose.

In-Depth Analysis of Denture Impaction Events

Descriptive Analysis

Patients who experienced a denture impaction were more often male (75%; 51 of 68) than female (25%; 17 of 68). Patients ranged in age from 20 to 94 years old. The median patient age was 77 years (interquartile range = 65 to 83 years).

A total of 51 events (75%) were classified by the reporting facility as incidents[†]w%) were classified as serious events.[‡] One event contributed to or resulted in the patient’s death.²

Qualitative Analysis

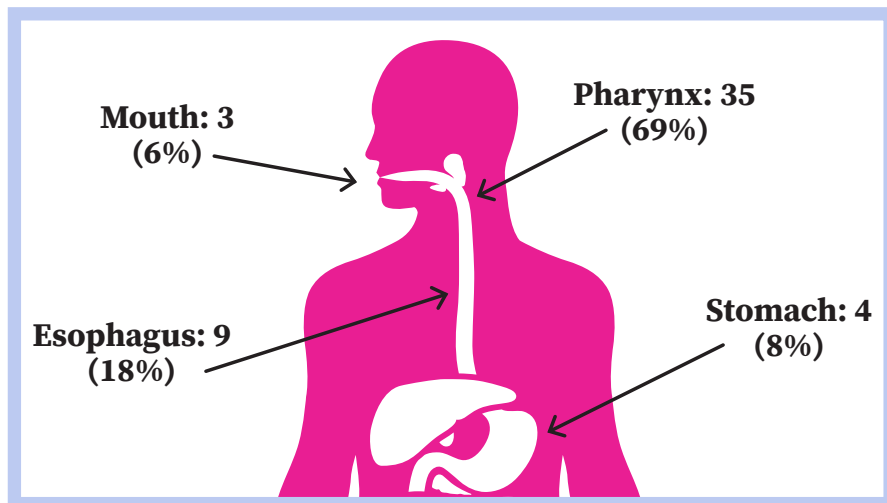
We reviewed free text fields in each PA-PSRS report, including Event Detail, Event Recommendation, and Event Comments, to gather additional information about each event. The dental appliance involved in each denture impaction event was either a denture (81%; 55 of 68) or a bridge (19%; 13 of 68). Some events involving a denture further specified that the appliance was a partial denture (22%; 12 of 55) or a partial plate (38%; 21 of 55). More than one-third (38%; 26 of 68) of the events indicated that one or more diagnostic tests were performed to locate the impacted denture. X-ray imaging was the most common diagnostic test (n=22), followed by swallowing studies (n=3), CT scans (n=2), and laryngoscopy (n=1). Dentures were found at multiple points along the GI tract, from the mouth to the stomach. The anatomical site of denture impaction was specified in 75% (51 of 68) of events.

The terminology used in events to describe the site of denture impaction was varied; terminology included epiglottis, esophagus, hypopharynx, mouth, oropharynx, pharynx, stomach, and throat. We grouped events into one of four anatomic areas in the upper GI tract: mouth, pharynx (which included events that specified the site of impaction as the pharynx, oropharynx, hypopharynx, epiglottis, and throat), esophagus, and stomach (see **Figure 1**). The pharynx was

[†]An “incident” is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.²

[‡]A “serious event” is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.²

Figure 1. Anatomic Sites of Denture Impaction, N=51



the most common site of denture impaction, mentioned in 35 events. Sufficient information was provided in 87% (59 of 68) of events to determine when the denture impaction likely occurred. We determined that 25% (15 of 59) of events occurred prior to the present admission, while 75% (44 of 59) of events occurred during the present admission. Among events that occurred prior to admission, the most common locations were a nursing home or skilled nursing facility (40%; 6 of 15) and at the site of a prehospital emergency (33%; 5 of 15). Among events that occurred during the present admission, the most common locations were in an operating room (41%; 18 of 44) or a nursing unit (36%; 16 of 44).

The activity that likely contributed to the denture impaction was identified in 62% (42 of 68) of events. The most common activities were intubation (62%; 26 of 42), eating (14%; 6 of 42), a motor vehicle accident (5%; 2 of 42), and application of a BiPAP mask (5%; 2 of 42) (see **Figure 2**). Other activities that likely contributed to the denture impaction included sleeping, seizure activity, and oral suctioning.

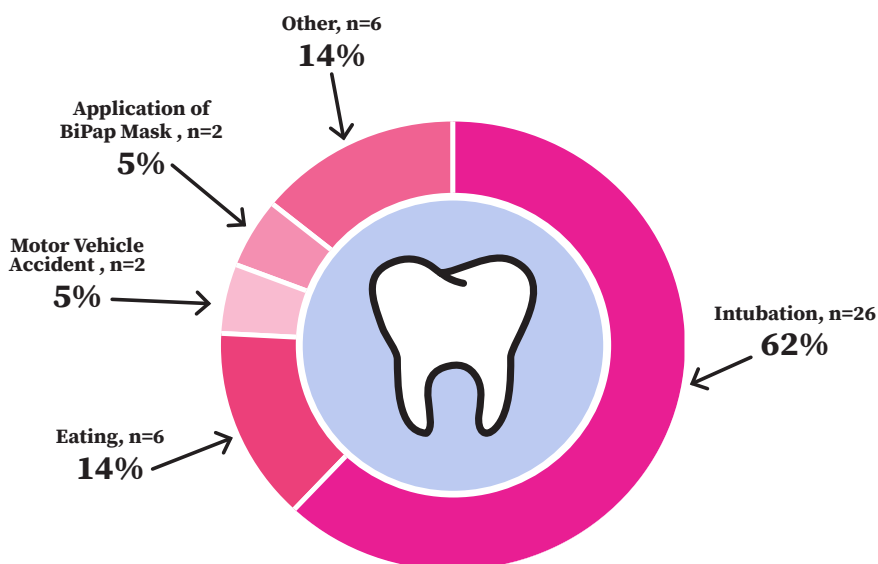
Details about signs and symptoms of denture impaction were described in 35 events. The most common symptoms included: dif-

ficult and/or painful swallowing (23%; 8 of 35), breathing trouble or respiratory distress (20%; 7 of 35), sore throat (17%; 6 of 35), foreign body sensation in the throat (14%; 5 of 35), throat obstruction preventing insertion of a tube or scope (14%; 5 of 35), choking (14%; 5 of 35), excessively thick and/or bloody oral secretions (11%; 4 of 35), and vomiting or regurgitation of food (6%; 2 of 35). In one-quarter (17 of 68) of events, the patient or their family noted that the artificial tooth or teeth were missing; in 7 of these events, the patient was asymptomatic. We identified clear evidence of a delayed diagnosis of

denture impaction in 15% (10 of 68) of the events.

Information about the method of removal for the impacted denture was included in 59% (40 of 68) of events. The impacted denture was manually removed in 20% (8 of 40) of events, in some cases with the assistance of a tool or medication, such as forceps (n=3) or midazolam (n=2). The impacted denture required surgical removal in 58% (23 of 40) of events. The most common surgical procedures employed were esophagogastroduodenoscopy (EGD; 43%; 10 of 23) and laryngoscopy (26%; 6 of 23). The reporting facility had to transfer the patient to an outside hospital for treatment in 8% (3 of 40) of events. A health-care provider or team removed the impacted denture in 69% (47 of 68) of events; specific providers mentioned in events included the treating physician or team (17%; 8 of 47), a specialist physician or team (17%; 8 of 47), and a nurse or allied health provider (11%; 5 of 47). Intervention was not necessary in 6 events for the following reasons: the loose denture fell out of the patient's mouth (n=1); the patient expectorated (n=1) or vomited (n=1) the impacted denture; or the patient swallowed the denture and it

Figure 2. Activity That Likely Contributed to Denture Impaction, N=42



reached the stomach (n=3). The patient or a family member removed the denture in 3 events.

Brief Analysis of Near Miss Events

The most common dental appliance involved in near miss events was a bridge (47%; 40 of 86), a single artificial tooth (34%; 29 of 86), or a denture (20%; 17 of 86). Patients who experienced a near miss were more often female (59%; 51 of 86) than male (41%; 35 of 86). Patients ranged in age from 16 to 91 years old. The median patient age was 64 years (interquartile range = 53 to 74). Intubation and/or surgery were identified as a contributing factor in 92% (79 of 86) of near miss events. Other activities that contributed to near miss events included eating, sleeping, and swallowing medication.

Discussion

To our knowledge, our study is the first of its kind to analyze patient safety events related to denture impaction reported by acute care facilities. It also included more denture impaction events than any other analysis published in the last decade and therefore adds considerable information to the current body of knowledge on the subject. To compare our findings with the existing literature, we analyzed 35 individual case reports and three case series (describing a total of nine patients) published during a 10-year period from January 1, 2010, through December 31, 2019.³⁻⁴⁰ We also analyzed six retrospective reviews of denture impaction in the esophagus published during the same time period.⁴¹⁻⁴⁶ These case reports, case series, and retrospective reviews were reported by providers from 20 different countries across six continents.³⁻⁴⁶

Gender and Age Distribution

In our study of denture impaction events, three-quarters of patients

were male (see **Figure 3**). We observed a similar trend in the medical literature. Patient gender was specified in all but one case report and in all case series, and about 8 out of every 10 patients were male.^{3-11, 13-40} Patient gender was specified for patients in all but one of the retrospective reviews that were analyzed; nearly 7 out of 10 patients in these reviews were male.⁴¹⁻⁴⁵ While it seems clear that men are more likely to experience a denture impaction event, the reason for this is unclear. Interestingly, women are more likely than men to experience tooth loss (although this difference is becoming less pronounced in North America), and women are more likely than men to have partial dentures.^{47, 48}

The median patient age in our study was 77 years, which was older than the median age of patients that we observed in the medical literature. Age was specified for nearly all patients in the case reports and case series we analyzed, in which patients ranged in age from 31 to 85 years old.³⁻⁴⁰ Half of the retrospective reviews we analyzed were from Nigeria, and the median age of patients in those reviews ranged from 50 to 57 years, which was lower

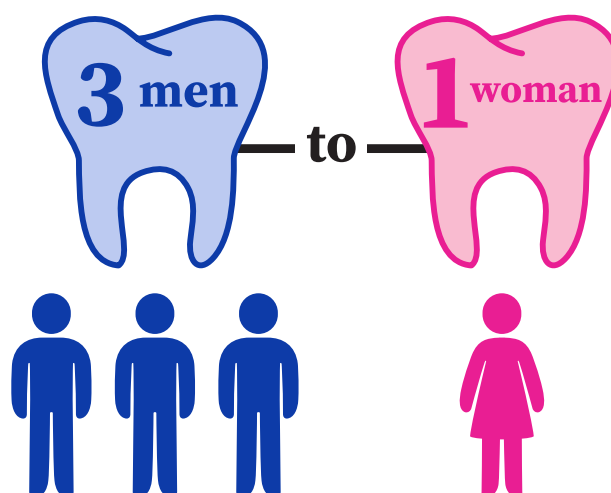
than both the median patient age in our study and in the case reports and case series we reviewed.^{41,43,46}

The differences we observed in median age may be reflective of the accessibility of dental care services around the world.⁴⁹ According to the World Health Organization (WHO), dental care services in developing countries are typically focused on pain relief and emergency services rather than on preventive services.⁴⁹ The differences in care may in part be attributable to the scarcity of dental providers; for example, the dentist to population ratio in industrialized countries is 1 dentist per 2000 individuals, compared to 1 dentist per 150,000 individuals in African countries.⁴⁹ Another factor that may have influenced the observed difference in median age is the difference in life expectancy. According to recent data, life expectancy in the United States is 79 years, while the life expectancy in Nigeria is 62 years.⁵⁰

Activity Leading to Denture Impaction

In the subset of denture impaction and near miss events for which the activity that likely contributed was

Figure 3. Ratio of Men to Women Experiencing Denture Impaction in Pennsylvania



identified, more than two-thirds of denture impaction events and almost all of the near misses were iatrogenic in nature. In contrast, nearly all the denture impaction events reported in the medical literature were the result of an accidental swallowing of a denture prior to admission.³⁻⁴⁶ We attribute this difference to the unique nature of our database, which captures events that happen within acute care facilities. We believe that we have identified a category of denture impaction events that has not previously been characterized in the medical literature. Healthcare providers should be aware that denture impaction is a possible complication of treatment, especially among patients who undergo intubation. In some events in our study, the patient did not alert the healthcare provider about the presence of a denture prior to a procedure. Acute care facilities may be able to prevent denture impaction events by developing more effective screening practices to identify dentures prior to surgical procedures. Some patients may not understand that the term denture can refer to any kind of removable or temporary dental work. It is important to ensure that the patient understands the terminology used when they are being asked about the presence of a denture prior to a procedure. Future research related to iatrogenic denture impaction in acute care facilities could further expand the knowledge base and lead to improved screening tools.

Signs and Symptoms of Denture Impaction

More than one-third of denture impaction events in our study did not include any information about signs or symptoms, indicating that either the patient was asymptomatic or that the information was simply not recorded, reported, or observed. The most common signs and symptoms reported by patients in both our study and

across the literature who experienced denture impaction in the pharynx or the esophagus included difficult or painful swallowing, difficulty breathing or respiratory distress, foreign body sensation in the throat, voice changes, choking, sore throat, and chest pain.³⁻⁴⁶ Although none of the patients in our study experienced denture impaction in the small intestine, large intestine, or colon, we did observe several cases with lower GI tract involvement in the case reports and case series we reviewed. Among those patients with denture impaction in the lower GI tract who were symptomatic, patients most often reported abdominal pain and altered bowel habits.^{7-9,14,16,18,24,27,28,38,39} The most common symptoms of denture impaction regardless of anatomic site of impaction are presented in **Figure 4**.

Type of Dental Appliance

Although most of the denture impaction events in our study involved a denture, some events did involve a bridge. In addition, nearly half of the near misses we identified in our study also involved a bridge. In our review of the medical literature,

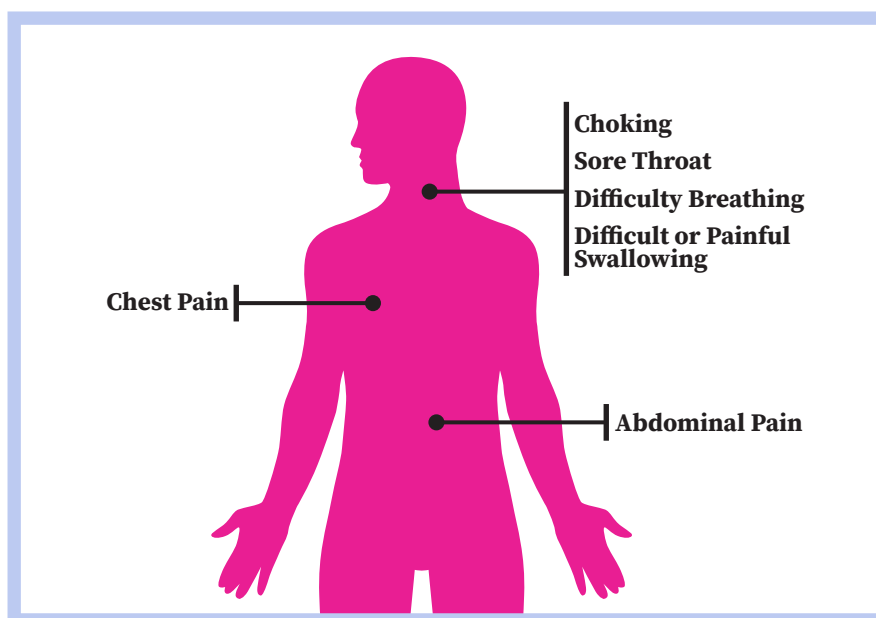
we found that all events involved a denture.³⁻⁴⁶ Based on these findings, we speculate that dentures, especially partial dentures that are irregularly shaped or have sharp edges and metal clasps, may be more likely to become impacted along the GI tract, especially in the esophagus. In addition, identifying reports in the medical literature that involved a bridge may be challenging because the term bridge is used in other contexts (e.g., bridge of the nose or bridge in therapy).

Diagnostic Studies

The most common diagnostic studies identified in our analysis and in the medical literature were x-rays (especially of the chest and abdomen) and CT scans.³⁻⁴⁶ While partial dentures with metal clasps may be more readily apparent on x-ray, the radiolucent nature of some dentures and bridges may prevent visualization on x-ray. Some clinicians suggested that CT scans may be more sensitive in detecting an impacted denture when an x-ray fails.^{21, 42}

We think that diagnostic imaging is an effective tool for identifying denture impaction in most (but

Figure 4. The Most Common Symptoms of Denture Impaction



not all) cases. In some cases in the medical literature, an abnormality was visualized on imaging, but the abnormality was not identified as a denture. While we are mindful of the need to avoid overtesting, additional alternative studies may be required to identify an impacted denture. In cases in which all types of imaging have failed but denture impaction is still suspected, a scoping procedure—such as an EGD or colonoscopy—may be necessary.

Delayed Diagnosis of Denture Impaction

We identified clear evidence of a delayed diagnosis of denture impaction in 15% of the events in our study, but the true number is likely much higher. Many of the event descriptions were suggestive of a delay, but the information provided by the reporter was either incomplete or unclear, which prevented a definitive determination. In more than half of the events involving a clear delay in diagnosing the denture impaction, the patient complained of sore throat and a missing denture.

Although imaging studies may be a useful tool in identifying impacted dentures, many events in which the diagnosis was delayed involved imaging studies and their associated challenges. In one event, despite initially considering denture impaction as the possible cause of the patient's complaints, the physician ultimately dismissed the diagnosis due to overreliance on an imaging study performed at a single location along the GI tract. Though the initial study did not show a foreign body, the patient's condition continued to worsen, and imaging studies performed on additional anatomical sites more than a month later revealed the denture impaction. In another event in which the physician suspected possible denture impaction, a note in the patient's chart indicated that an x-ray would be performed, but the

order was never entered. Another event described a retrospective review of multiple x-rays that showed dentures lodged in the patient's throat, yet the finding was not noted in any of the radiology reports.

The diagnosis of denture impaction was also delayed in some of the case reports and case series that we reviewed. Several patients were unaware that they had swallowed a denture, so the healthcare provider lacked that information when attempting to identify the etiology of the patient's symptoms.^{3,9,29,33,36} Notably, the patient's symptoms in two cases were initially attributed to a suspected malignancy in the sigmoid colon, but surgical resection led to the identification of an impacted partial plate in both cases.^{9,16}

Anatomic Site of Denture Impaction

In our study, the most common anatomic site of denture impaction was the pharynx, and the second most common site was the esophagus. In contrast, the most common anatomic site of denture impaction identified in the case reports and case series that we reviewed was the esophagus, and only two case reports identified the site of impaction as the pharynx.³⁻⁴⁰ The esophagus was also the site of denture impaction for all events included in the retrospective reviews we analyzed.⁴⁰⁻⁴⁶ As mentioned previously, none of the events in our study involved denture impaction beyond the stomach, while numerous events in the case reports and case series that we reviewed involved impaction in the lower GI tract.^{7-9,14,16-18,24,27,28,38,39}

The method of data collection may have influenced the events that were identified in our study and in the medical literature. In our study, we searched for keywords within free text fields in our database that we thought would be most likely to identify a denture impaction event,

We identified clear evidence of a delayed diagnosis of denture impaction in 15% of the events in our study, but the true number is likely much higher.



and we included the keywords “pharynx” and “throat.” Among the case reports and case series we analyzed, the events were reported because the authors felt the event was unusual or complicated.³⁻⁴⁰ In the retrospective reviews that we analyzed, study authors relied on certain diagnosis codes within their health system to identify denture impaction events, resulting in identification of a specific subset of events.⁴¹⁻⁴⁶ We would hesitate to suggest that a denture is more likely to become impacted at any particular anatomical site; rather, we did observe that identifying and removing an impacted denture may become more challenging as it moves along the GI tract, and thus more likely to be reported in the medical literature.

Method of Removal

Among events in our study that specified the method of removal for the impacted denture, surgical intervention was necessary in more than half of the events. Scoping procedures (e.g., EGD, esophagoscopy, or laryngoscopy) were the most common surgical intervention in our study and across the medical literature.³⁻⁴⁶ More complicated cases in the medi-

cal literature required more invasive surgical procedures, such as esophagotomy, tracheotomy, thoracotomy, enterotomy, laparotomy, and surgical resection.³⁻⁴⁶

Limitations

Despite mandatory event-reporting laws in Pennsylvania, our data are subject to the limitations of self-reporting. In addition, because PA-PSRS only collects reports of patient safety events from acute care facilities, our analysis likely did not capture most denture impaction events that occurred in other healthcare settings or that were not considered patient safety events by the reporting facility, such as events that took place prior to admission and that received prompt diagnosis and treatment at the reporting facility. Because a standard taxonomy for reporting denture impaction events does not exist, it is possible that relevant event reports were missed with our query.

Conclusion

Although missing dentures are more often lost or misplaced somewhere in the external environment, our analysis reveals that denture impaction along the GI tract occurs more often than one might expect. All patients, along with their caregivers and healthcare providers, should be aware of the proactive steps to avoid denture impaction, as well as signs and symptoms of impaction for early identification and treatment. Many denture impaction events identified in our analysis were iatrogenic in nature and associated with intubation. Strategies to prevent denture impaction in acute care facilities should include thorough screening of each patient scheduled to undergo a surgical procedure to ensure dentures are identified and removed if possible. Future research in this space may provide additional insight into contributing factors,

All patients, along with their caregivers and healthcare providers, should be aware of the proactive steps to avoid denture impaction, as well as signs and symptoms of identification and treatment.



timely diagnosis, and novel prevention strategies.

Denture impaction may be obvious in some patients, especially those who present to a primary care provider or hospital with the report of a missing denture along with complaints of difficult or painful swallowing, difficulty breathing, foreign body sensation in the throat, voice changes, choking, sore throat, or chest or abdominal pain. Other patients may present with similar symptoms but be unaware they have swallowed their denture, and in these cases the healthcare provider should question the patient about the possibility of a lost denture to avoid a possible delay in diagnosis. When a denture goes missing from a patient's mouth during an inpatient stay, healthcare providers should investigate the possibility that the dental appliance has been dislodged and swallowed during intubation or another surgical procedure.

Based on the findings in our study and in the existing literature, men are more likely than women to experience a denture impaction, and patients of any age with an artificial tooth or teeth are susceptible to a possible event. Diagnostic imaging such as x-ray and CT scan may contribute to the identification of an impacted denture, but a careful medical history is just as essential for prompt diagnosis and treatment.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

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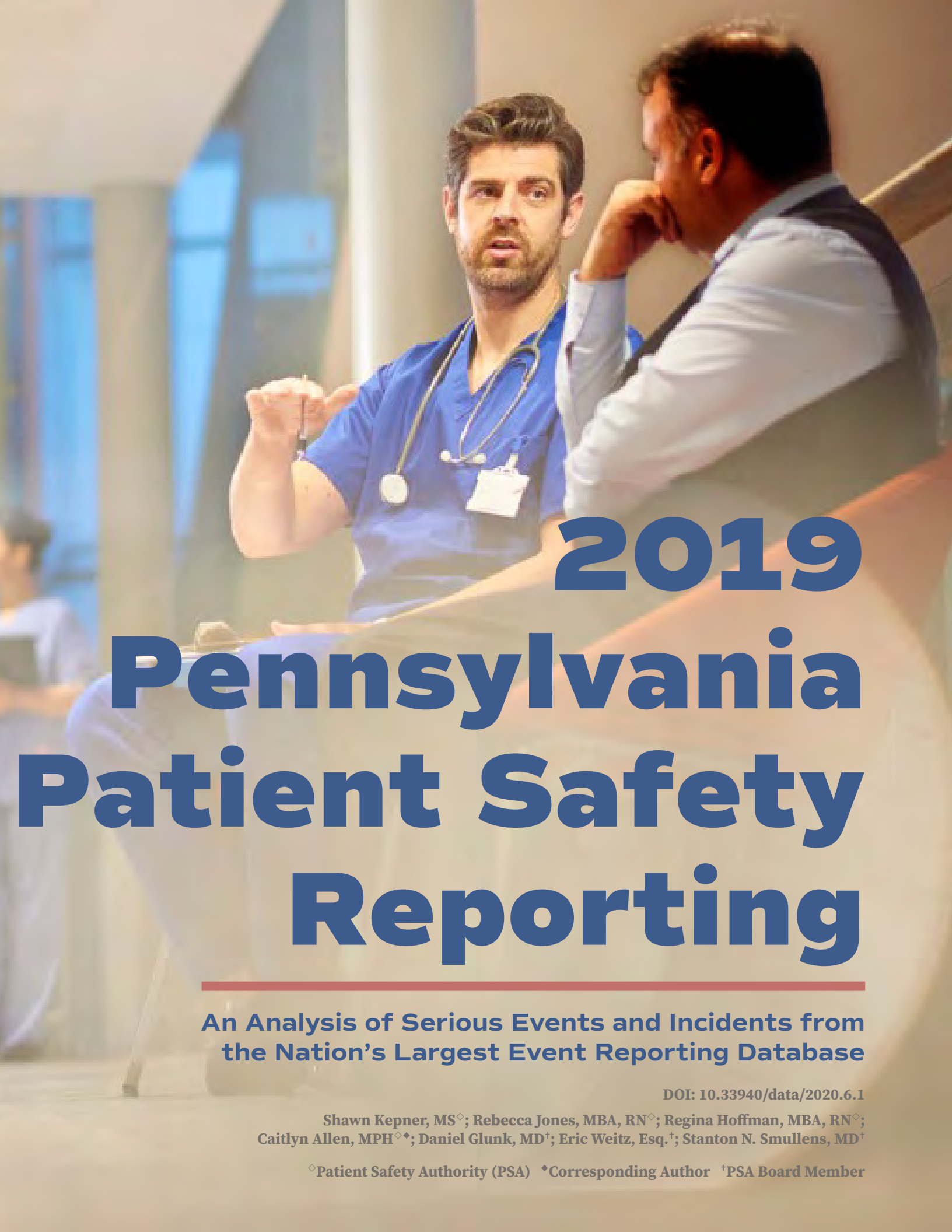
About the Authors

Elizabeth Kukielka (ekukielka@pa.gov) is a patient safety analyst on the Data Science and Research team at the Patient Safety Authority. Before joining the PSA, she was a promotional medical writer for numerous publications, including *Pharmacy Times* and *The American Journal of Managed Care*. Kukielka also worked for a decade as a community pharmacist and pharmacy manager, with expertise in immunization delivery, diabetes management, medication therapy management, and pharmacy compounding.

Rebecca Jones is director of Data Science and Research at the Patient Safety Authority, where she also founded and serves as director of the Center of Excellence for Improving Diagnosis. Her previous roles at the PSA include director of Innovation and Strategic Partnerships, and regional patient safety liaison. Before joining the PSA, Jones served in various roles leading patient safety efforts and proactively managing risk in healthcare organizations. She currently is chair of the Practice Committee of the Society to Improve Diagnosis in Medicine and serves on the Advisory Committee of the Coalition to Improve Diagnosis.







2019 Pennsylvania Patient Safety Reporting

**An Analysis of Serious Events and Incidents from
the Nation's Largest Event Reporting Database**

DOI: 10.33940/data/2020.6.1

Shawn Kepner, MS[◇]; Rebecca Jones, MBA, RN[◇]; Regina Hoffman, MBA, RN[◇];
Caitlyn Allen, MPH^{◇♦}; Daniel Glunk, MD[†]; Eric Weitz, Esq.[†]; Stanton N. Smullens, MD[†]

[◇]Patient Safety Authority (PSA) [♦]Corresponding Author [†]PSA Board Member

Abstract

Pennsylvania is the only state that requires acute healthcare facilities to report all events of harm or potential for harm. With over 3.6 million acute care event reports, the Pennsylvania Patient Safety Reporting System (PA-PSRS) is the largest repository of patient safety data in the United States and one of the largest in the world. Of the 293,400 patient safety event reports submitted by Pennsylvania's acute care facilities in 2019, 97% were from hospitals, and 3% were from ambulatory surgical facilities (ASFs).

The vast majority of these reports were Incidents (284,847), rather than Serious Events (8,553). Reporting rates for both hospitals and ASFs increased 26% from 2015 to 2019, which is likely due to changes in reporting guidance in 2015. For each of the last five years, the most frequently reported event type was "Error Related to Procedure/Treatment/Test," (EPTT), with this event type accounting for 33% of all submitted acute care event reports in 2019. "Medication Error," "Complication of Procedure/Treatment/Test" and "Fall" events were also reported frequently, accounting for 18%, 16%, and 11% of all submitted event reports in 2019, respectively.

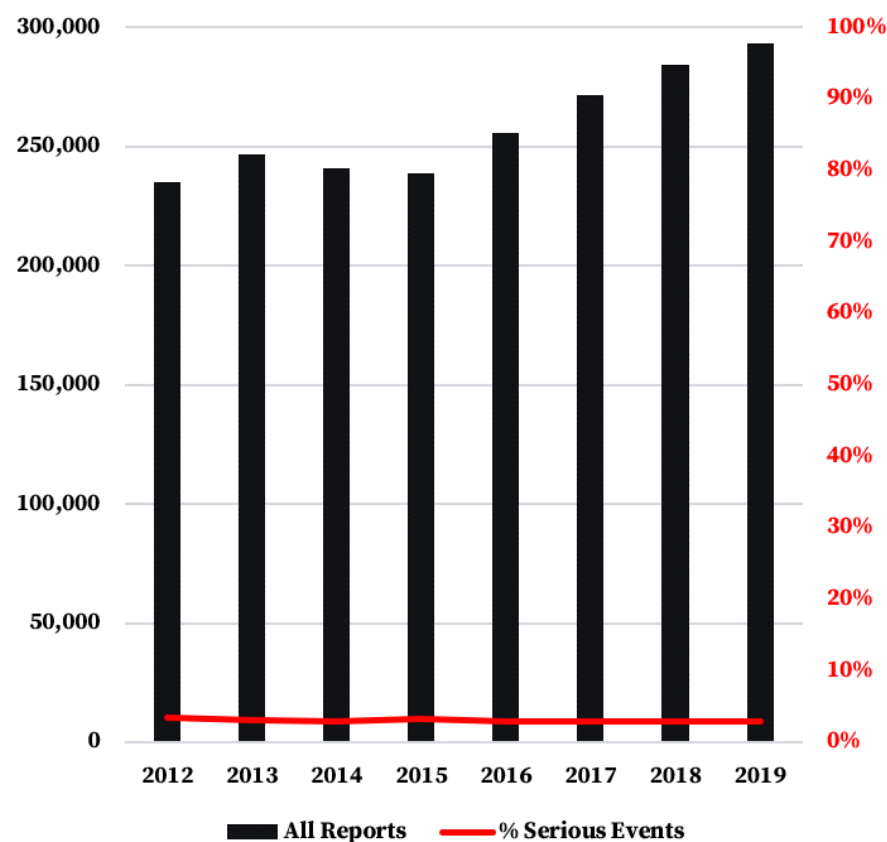
The increase in reporting rates each year may reflect improvements in patient safety culture across the Commonwealth, and the analysis within this article highlights a number of areas in which continued patient safety efforts can be applied to reduce harm in acute care settings.

Introduction

Pennsylvania is the only state that requires healthcare facilities to report all events of harm or potential for harm. Serious Events and Incidents are reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS)*, which is the largest repository of patient safety data in the United States, and one of the largest in the world, with over 3.6 million acute care records. The overwhelming majority (97.1%) of all acute care event reports are Incidents. For 2019, there were 284,847 Incidents and 8,553 Serious Events for a total of 293,400 reported events.

The counts of all events and the percentage that are Serious Events reported over the last eight years are provided in **Figure 1**. The total number of event reports has increased during the last four years. The number of reported Serious Events has increased over the past three years with the largest annual increase occurring in 2019 (+5.7%). This article will show details of the PA-PSRS acute care data along with longitudinal and categorical insights that can be used for improving patient safety.

Figure 1. All Reports and Serious Event Reports by Year



Definitions

Terms describing patient safety occurrences, including "serious event," "medical error," "adverse event," "harm," and "incident" are often used interchangeably. However, within the context of this manuscript they have distinct meanings and indications for whether they must be reported in Pennsylvania under Act 13. (See **Figures 2 and 3** for a detailed description.)

Methods

The data from PA-PSRS event reports were extracted on January 30, 2020 to include all reports submitted during calendar year 2019.

We also obtained data from the Pennsylvania Health Care Cost Containment Council* (PHC4), and those data represent January 1 through June 30, 2019. Therefore, any 2019 rates based on PHC4 data used to normalize reporting trends were estimated via projections of Q3 and Q4 2019, which were based on the rates of increase for the 2018 quarters.

Results

Harm Scores

Harm scores are assigned by healthcare facilities at the time of reporting. **Table 1** describes the categories of harm

Table 1. PA-PSRS Harm Scores

Harm Score		Definition
Incidents	A	Circumstances that could cause adverse events
	B1	An event occurred but it did not reach the individual
	B2	An event occurred but it did not reach the individual because of active recovery efforts by caregivers
	C	An event occurred that reached the individual but did not cause harm and did not require increased monitoring
	D	An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm
Serious Events	E	An event occurred that contributed to or resulted in temporary harm and required treatment or intervention
	F	An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization
	G	An event occurred that contributed to or resulted in permanent harm
	H	An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life)
	I	An event occurred that contributed to or resulted in death

Table 2. All Reports by Facility Type

		2017	2018	2019
 ASFs	Incidents	6,728	6,946	7,348
	Serious Events	1,820	1,756	1,887
	All Reports	8,548	8,702	9,235
 Hospitals	Incidents	257,249	269,309	277,499
	Serious Events	6,066	6,338	6,666
	All Reports	263,315	275,647	284,165
 All Reports	Incidents	263,977	276,255	284,847
	Serious Events	7,886	8,094	8,553
	Total	271,863	284,349	293,400

Note: ASFs (Ambulatory Surgical Facilities) includes ambulatory surgery centers, birthing facilities, and abortion facilities).

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002).¹ All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

*The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of healthcare, and increasing access to healthcare for all citizens regardless of ability to pay. PHC4 has provided data to this entity in an effort to further PHC4's mission of educating the public and containing healthcare costs in Pennsylvania. PHC4, its agents, and its staff, have made no representation, guarantee, or warranty, express or implied, that the data—financial, patient, payor, and physician-specific information—provided to this entity are error-free, or that the use of the data will avoid differences of opinion or interpretation. This analysis was not prepared by PHC4. This analysis was done by the Patient Safety Authority. PHC4, its agents and its staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

Patient Safety Event¹

an event, occurrence, or situation that could have resulted or did result in harm to a patient and can be but is not necessarily the result of a defective system/process design, a system breakdown, equipment failure, or human error. They can also include adverse events, no-harm events, near misses, and hazardous conditions.

Adverse Event²

an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient, and may or may not have been preventable.

Incident³

an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.

Serious Event³

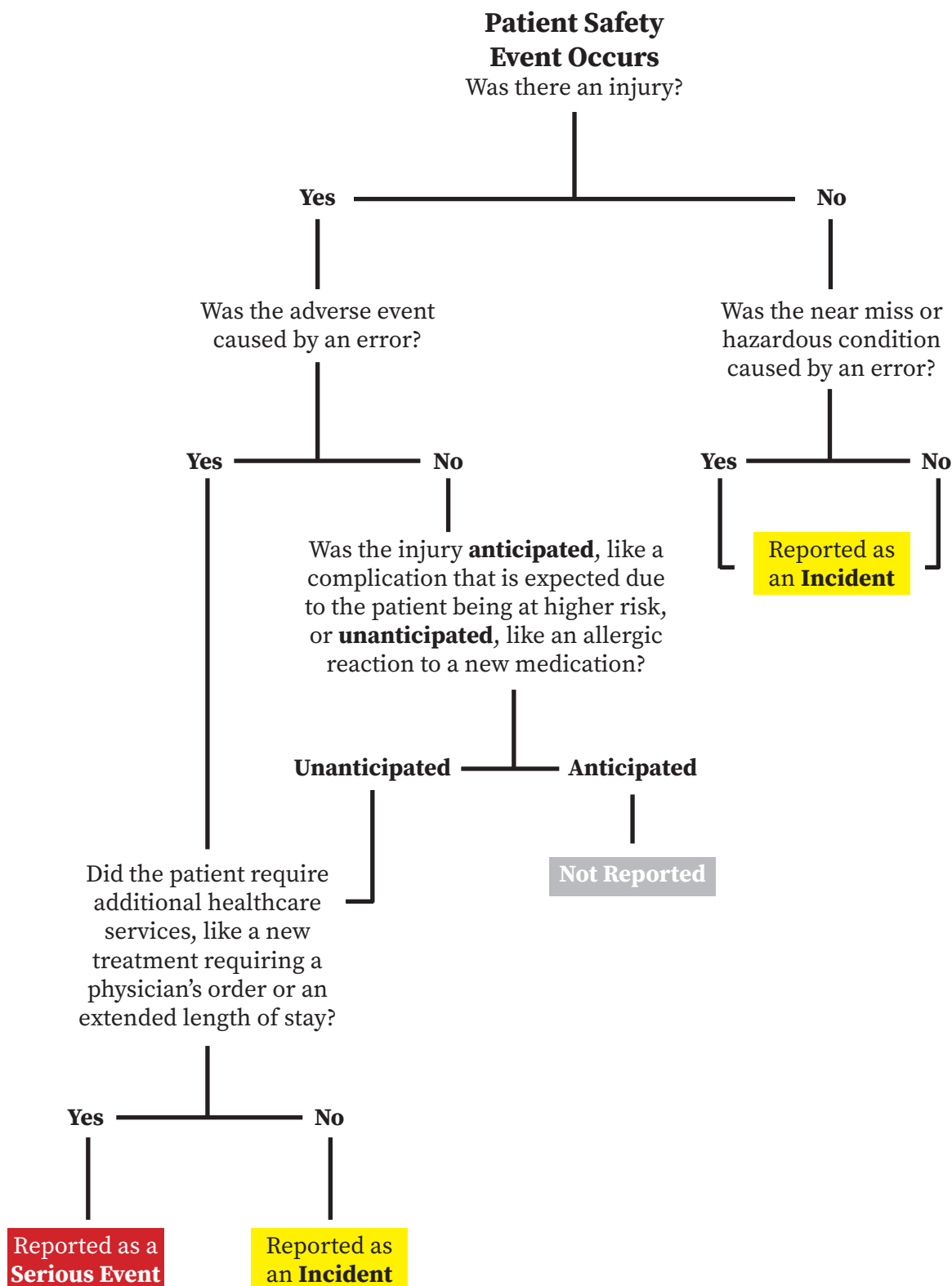
an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.

Medical Error⁴

failure of a planned action to be completed as intended; the use of a wrong plan to achieve an aim; or failure of an unplanned action that should have been completed.

Figure 2. Patient Safety Event Reporting in Pennsylvania

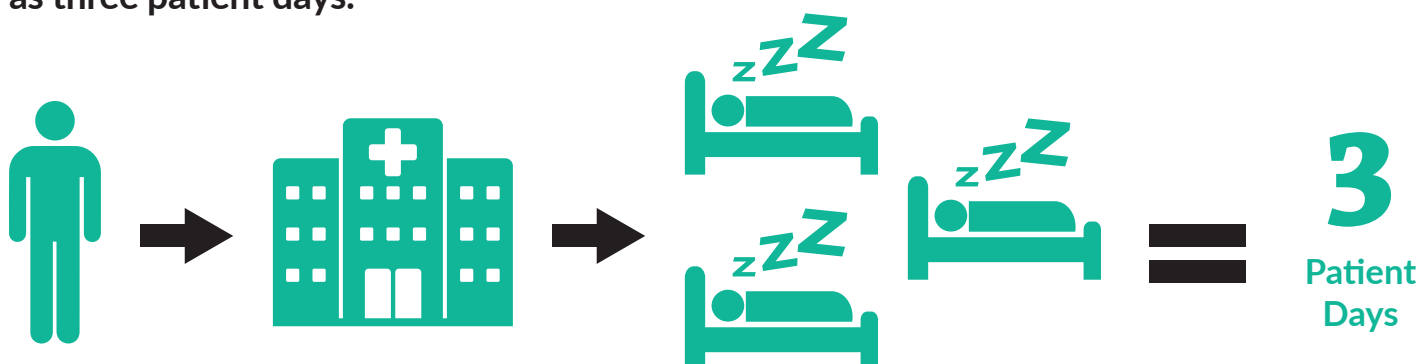
How Patient Safety Events Are Reported in Pennsylvania



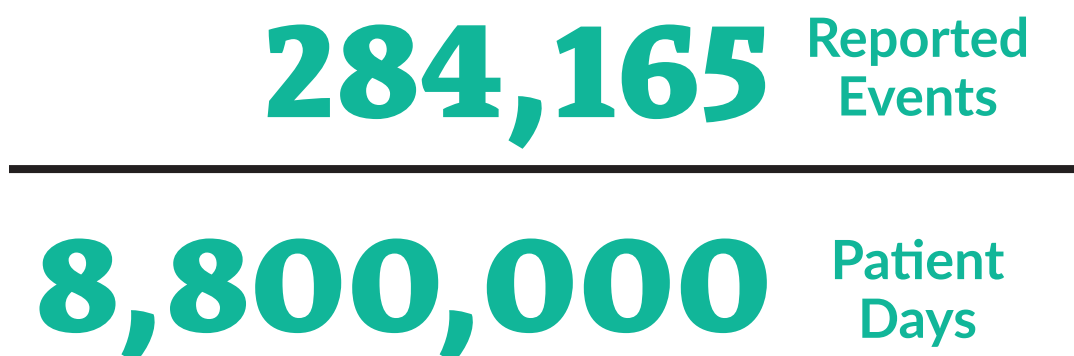
Note: Figure 2 is meant to provide a high-level overview of event reporting in Pennsylvania and is not meant to replace the Reporting Guidance issued in 2016. For more information, visit patientsafety.pa.gov.

Figure 3. Hospital Patient Days and Reported Events in Pennsylvania – 2019

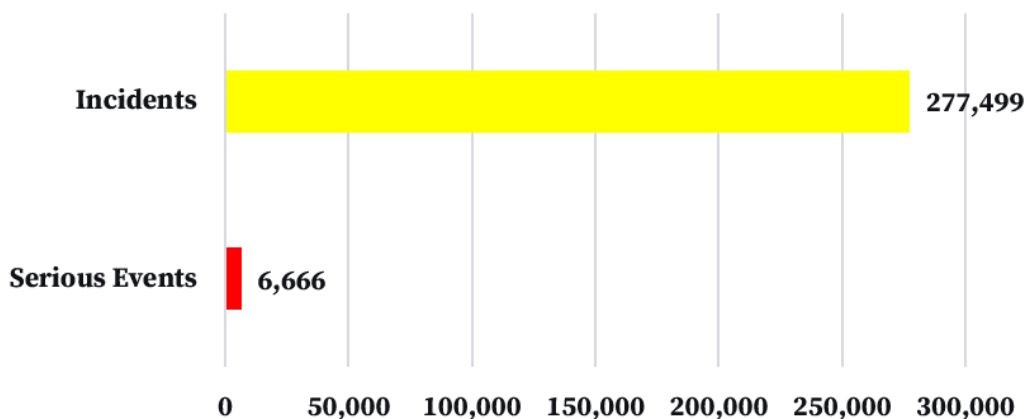
A patient day is the basic unit to show the total amount of time someone is in the hospital. If Mr. Smith is admitted to a hospital and spends three days there, that would be counted as three patient days.



In 2019, there were an estimated 8,800,000 patient days for Pennsylvania hospitals and an 284,165 reported events (1 reported event for every 31 patient days).



Of those 284,165 reported events, only 2% were **Serious Events**, meaning the vast majority of reported events in Pennsylvania are **Incidents**.



Note: Identifiable patient information (e.g., name and date of birth) is not reported. Therefore, there is no way to know if a patient experienced more than one event over the course of the year.

Figure 4: Distribution of Reports by Harm Score by Year (2017–2019)

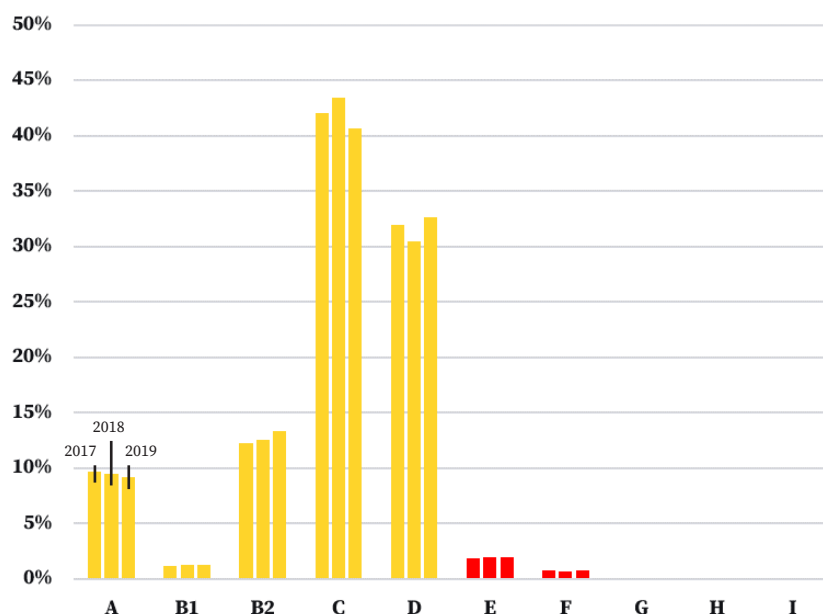


Table 4: Percentage of Reports by Harm Score by Year (2017–2019)

	A	B1	B2	C	D	E	F	G	H	I
2017	9.7	1.2	12.3	42.0	31.9	1.9	0.8	0.0	0.0	0.1
2018	9.5	1.3	12.5	43.4	30.5	2.0	0.7	0.0	0.0	0.1
2019	9.2	1.3	13.3	40.7	32.6	2.0	0.8	0.0	0.0	0.1

Note: The raw numbers for harm scores G and H are greater than zero, even though they are shown with 0.0% above due to rounding to the nearest tenth of a percent.

Table 3: All Reports and High Harm Event Reports by Year

Submission Date	High Harm Reports	All Reports
2005	726	169,069
2006	623	195,860
2007	595	211,792
2008	573	219,758
2009	572	226,398
2010	507	225,255
2011	519	228,856
2012	417	235,247
2013	364	246,609
2014	396	240,777
2015	473	238,882
2016	410	255,716
2017	445	271,863
2018	343	284,349
2019	415	293,400

Figure 5: All Reports and High Harm Event Reports by Year

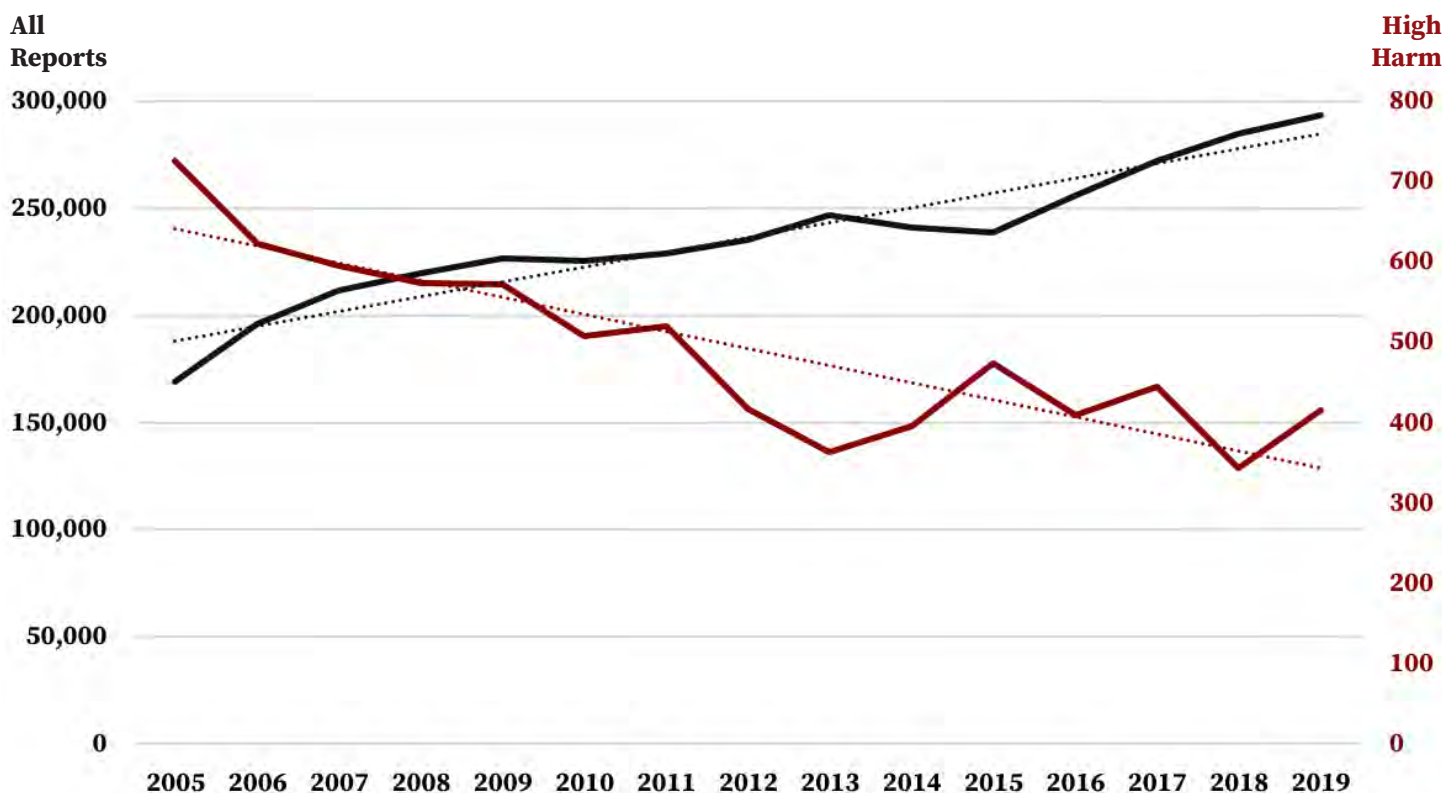
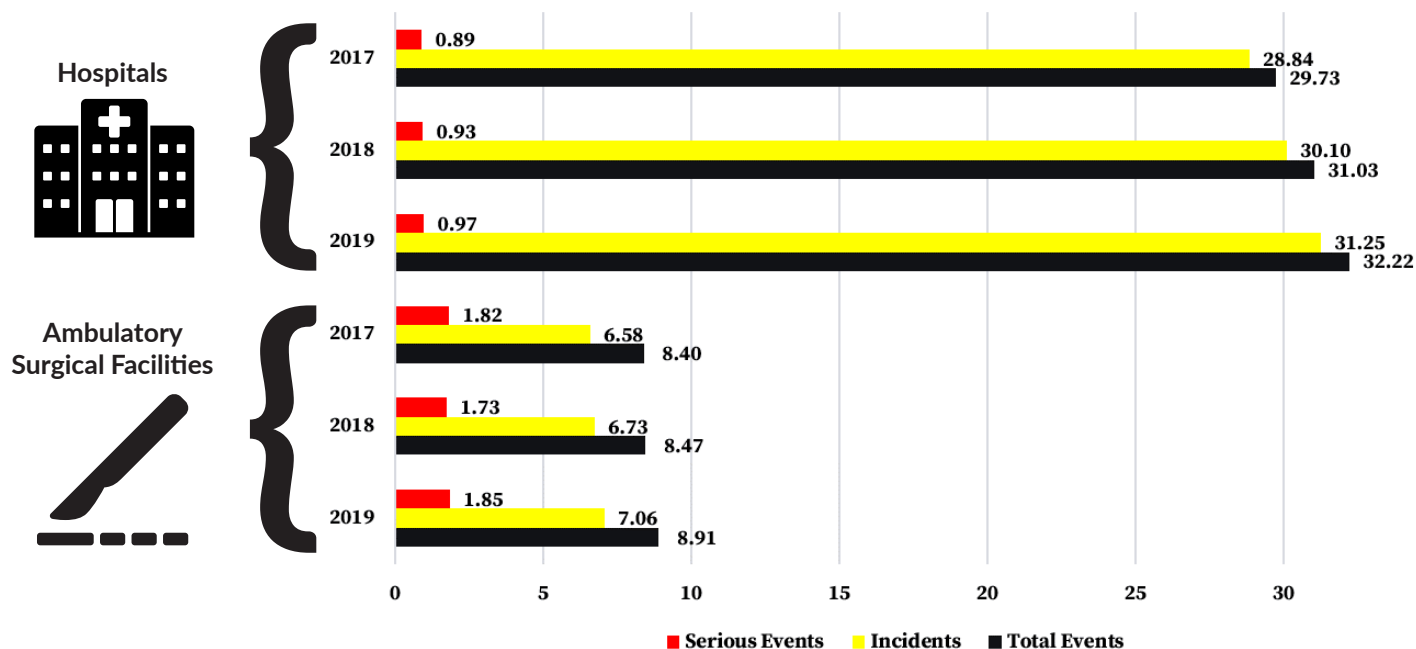


Figure 6. Event Reporting Rates by Hospitals (per 1,000 patient days) and Ambulatory Surgical Facilities (per 1,000 Surgical Encounters) by Year



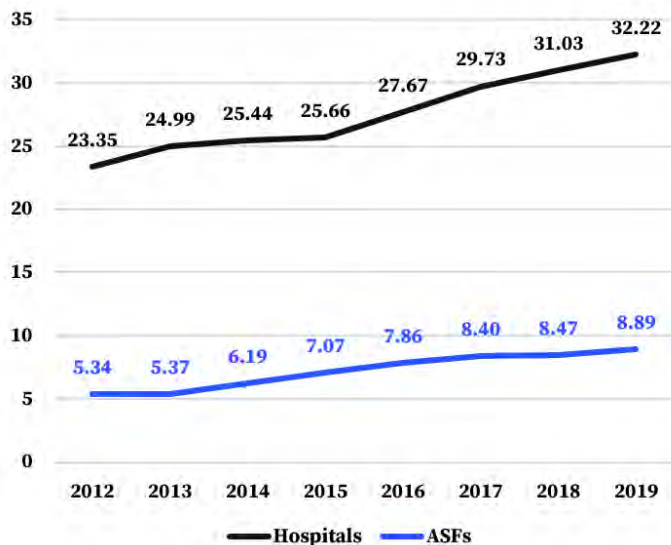
scores across an increasing level of patient harm. Harm scores A through D are classified as Incidents, harm scores E through I are classified as Serious Events, and harm scores G, H, and I are considered High Harm events. **Table 2** shows a breakdown of Incidents and Serious Events by facility type from the last three years.

The distribution of all events by harm score submitted during years 2017–2019 is shown in **Figure 4** and **Table 4**. Consistently, the largest number of acute care events are reported with a harm score of C (4 out of every 10), followed by harm scores D, B2, and A. Together, these four

harm scores account for 96% of all event reports submitted during years 2017–2019. Also, among Serious Event reports, approximately two-thirds are classified as harm score E.

Next, the High Harm reports are trended over time along with the total for all reports (**Figure 5** and **Table 3**). While the total number of reports submitted each year is on a linear increasing trend, the number of High Harm events has decreased by 311 (43%) from 2005 to 2019. The decrease was sharper from 2005–2013 and plateaued during 2012–2019. The number of High Harm events increased from 343 in 2018 to 415 in 2019 (a 21% increase). However, this increase was not unexpected given the trend for High Harm events reported over time. The number of High Harm events reported in 2018 was lower than expected by the trend, which may be responsible for the larger than expected increase between 2018 and 2019.

Figure 7: Reporting Rates for Hospitals (per 1,000 Patient Days) and ASFs (per 1,000 Surgical Encounters)



Reporting Rates

In addition to looking at increases or decreases in the total number of acute care events, normalized data—such as rates—can be used to assess changes in reporting per patient days for hospitals and per surgical encounters for ambulatory surgical facilities (ASFs). As shown in **Figure 6**, ASFs have a higher rate of reporting Serious Events compared to hospitals. The reporting rate for both hospitals and ASFs (**Figure 7**) increased 26% from 2015 to 2019, which is likely due to changes in reporting guidance in 2015.

Event Types

When a report of an Incident or Serious Event is submitted to PA-PSRS, an event type along with one or two more levels of subtype are chosen to reflect the nature of the event.

Figure 8: Number of Reports Submitted by Event Type in Descending Order by 2019 Frequency

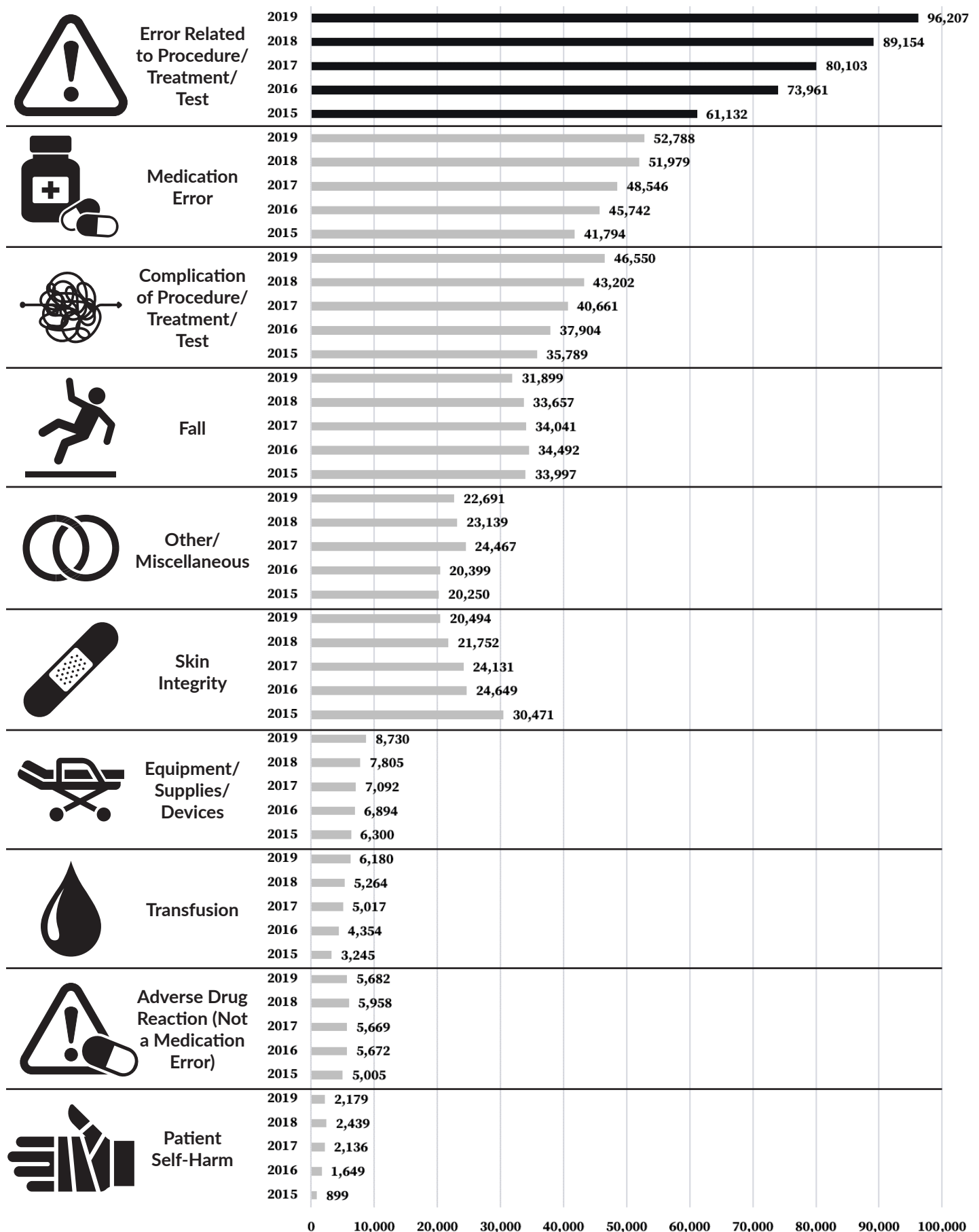


Figure 9: Number of **Serious Event** Reports for Error Related to P/T/T by Sub Type in Descending Order by 2019 Frequency

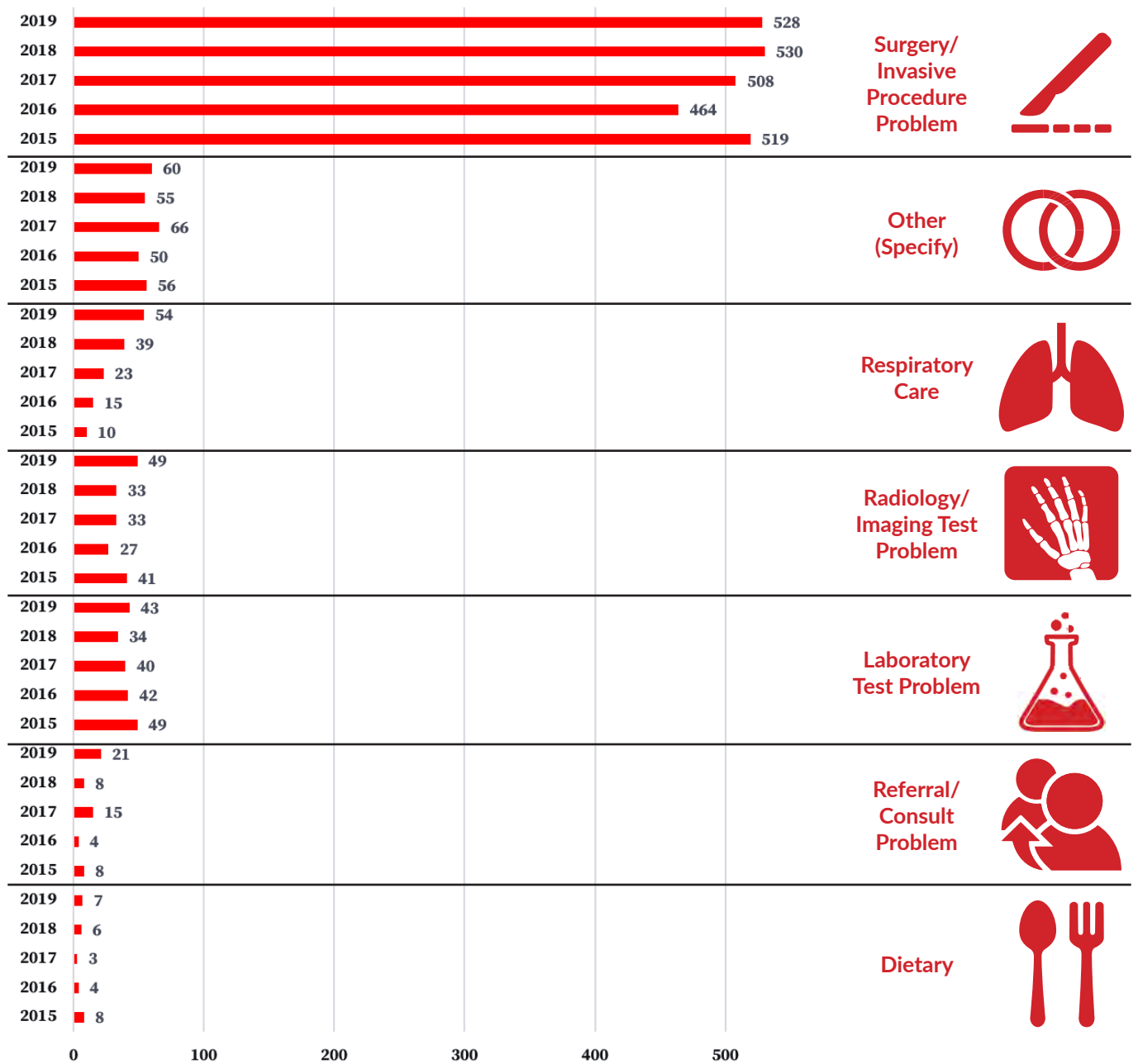
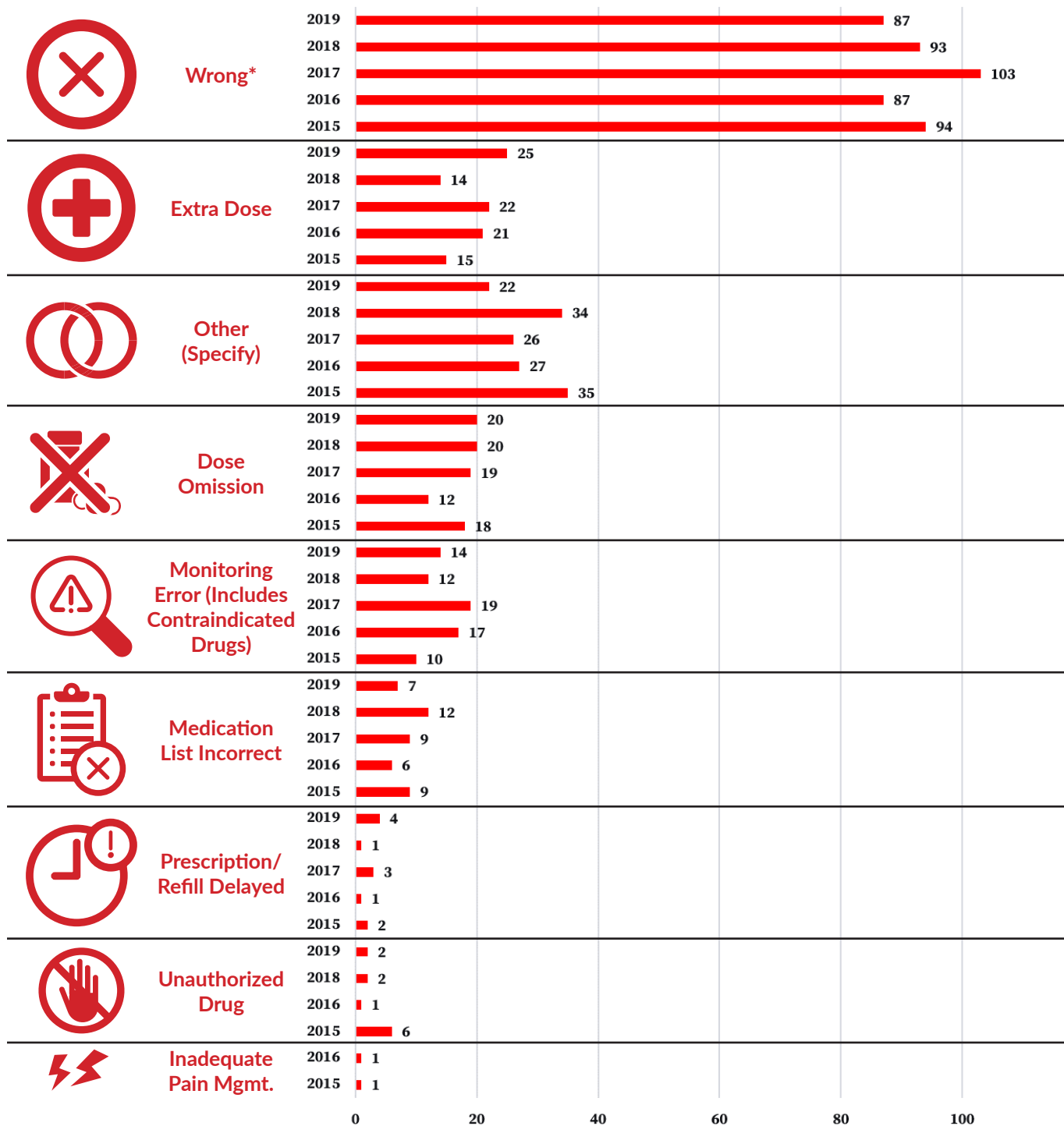
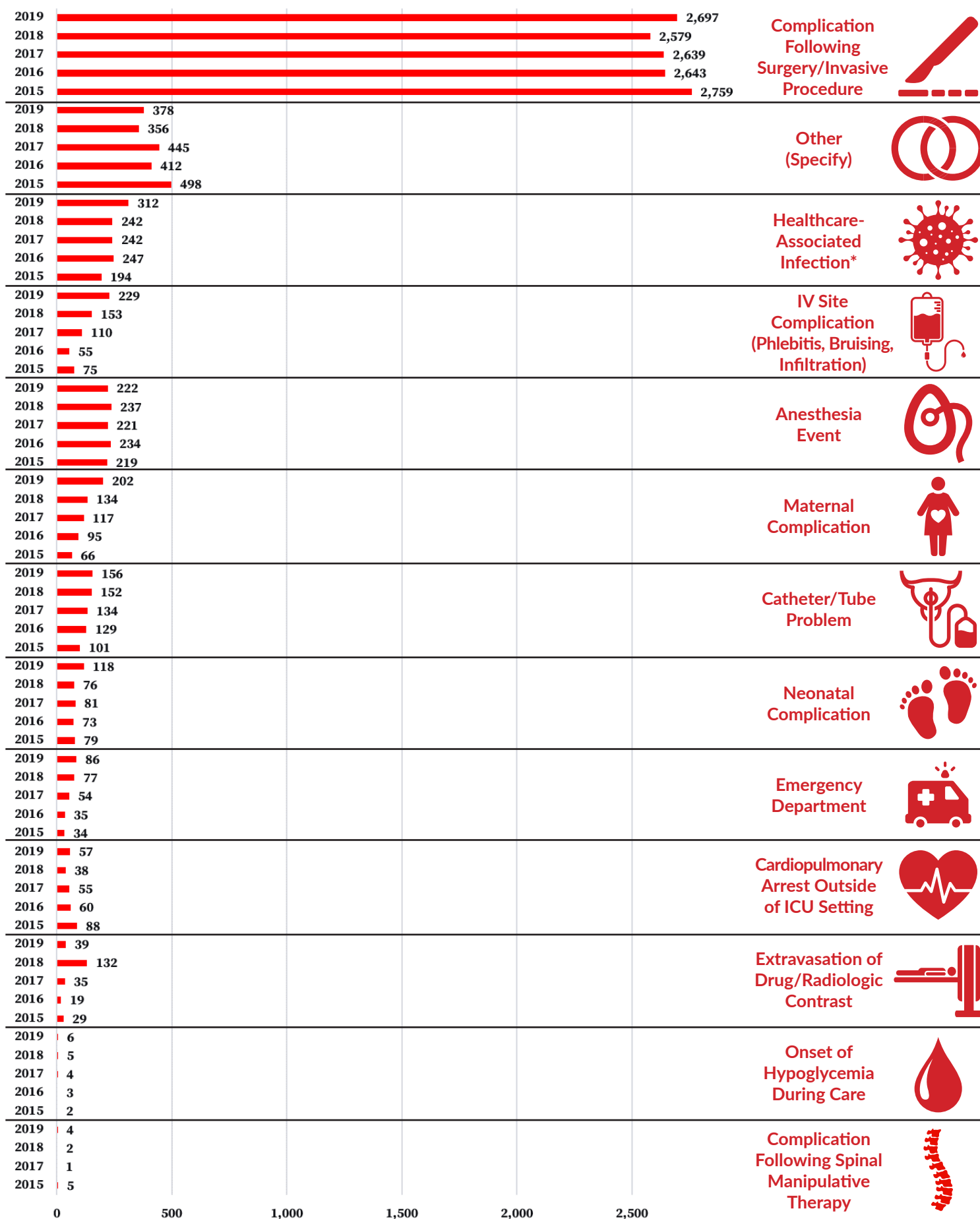


Figure 10: Number of **Serious Event** Reports for Medication Error by Sub Type in Descending Order by 2019 Frequency



*Wrong covers several types of events such as wrong dose, drug, dosage form, rate, time, route, concentration, etc.

Figure 11: Number of **Serious Event** Reports for Error Related to P/T/T by Sub Type in Descending Order by 2019 Frequency



*Includes only healthcare-associated infections (HAIs) reported in PA-PSRS; Does not include infections reported by hospitals to CDC's National Healthcare Safety Network (NHSN)

Events are defined by 228 possible combinations of event types and subtypes. In the PA-PSRS reporting taxonomy for Incidents and Serious Events, there are 10 main event types, and **Figure 8** shows the number of reports submitted for each event type over the past five years. For each of the last five years, the most prevalent event type was “Error related to Procedure/Treatment/Test;” in 2019, this event type accounted for 96,207 reports, which accounted for 33% of all submitted acute care event reports. This category of event type has shown an increase each year since 2015 and an overall increase of 57% from 2015 to 2019.

The second most common event type was “Medication error.” This event type accounted for 52,788 reports in 2019, which was 18% of all submitted reports. The third most prevalent event type was “Complication of Procedure/Treatment/Test,” with 46,550 reports submitted, which accounted for 16% of all events. Finally, event type “Fall” accounted for 11% of reports submitted in 2019.

Error Related to Procedure/Treatment/Test

Across all event reports, an increase in laboratory test problems drives the increase in the Error Related to Procedure/Treatment/Test category. However, according to **Figure 9**, laboratory test problems are not associated with an increase in Serious Events. The increase in reports of laboratory test problems was predominately due to a few facilities with increasing attention to specimen quality issues that did not cause harm to the patients.

Medication Error

Over half of all events involving medication errors are reported under the event subtype “Wrong.” However as shown in **Figure 10**, there has been no increase in Serious Events in this subcategory of medication error reports.

Figure 12: Number of Reports Submitted by Event Type and Harm Score by Year

Year of Event Submission	Event Harm Score	Error Related to Procedure/Treatment/Test	Medication error	Complication of Procedure/Treatment/Test	Fall	Other / Miscellaneous	Skin Integrity	Equipment / Supplies / Devices	Transfusion	Adverse Drug Reaction	Patient Self-Harm
2017	A	12,772	2,929	2,102	225	4,065	1,686	1,267	1,069	51	281
	B1	1,321	776	143	75	670	15	166	62	6	8
	B2	10,393	18,337	659	315	1,839	38	1,073	634	25	24
	C	42,898	18,258	10,866	19,475	8,739	6,463	3,293	2,351	1,202	612
	D	12,031	8,045	22,753	13,006	8,336	15,322	1,228	883	4,142	1,048
	E	462	143	2,400	673	544	598	50	14	186	131
	F	173	45	1,480	251	202	7	12	4	47	19
	G	22		40	6	7	1			1	1
	H	9	7	79	8	10		1		5	2
	I	22	6	139	7	55	1	2		4	10
	Total	80,103	48,546	40,661	34,041	24,467	24,131	7,092	5,017	5,669	2,136
2018	A	13,735	3,013	2,308	208	4,184	1,053	1,193	965	53	194
	B1	1,453	1,010	161	85	677	10	149	75	4	5
	B2	10,960	20,182	617	320	1,768	52	1,053	600	15	39
	C	49,364	19,888	12,067	19,641	7,990	5,579	3,882	2,730	1,370	861
	D	12,937	7,698	23,866	12,442	7,721	14,279	1,472	877	4,299	1,151
	E	489	140	2,606	717	538	758	47	11	163	159
	F	180	44	1,391	224	189	21	8	5	43	18
	G	9	1	25	1	3					
	H	6	1	51	11	11				6	
	I	21	2	110	8	58		1	1	5	12
	Total	89,154	51,979	43,202	33,657	23,139	21,752	7,805	5,264	5,958	2,439
2019	A	14,697	2,889	2,018	201	3,806	741	1,192	1,251	56	24
	B1	1,909	963	113	63	496	21	161	98		6
	B2	12,930	21,253	573	383	1,941	45	1,412	523	25	38
	C	50,972	18,970	11,542	17,091	6,461	5,125	4,124	3,120	1,358	680
	D	14,937	8,532	27,798	13,232	9,010	13,910	1,762	1,136	4,003	1,256
	E	547	124	2,710	707	667	632	63	39	176	151
	F	173	52	1,550	205	245	16	10	11	43	17
	G	8	1	34	3	4	4	2		1	
	H	13	3	71	5	8		2	1	11	1
	I	21	1	141	9	53		2	1	9	6
	Total	96,207	52,788	46,550	31,899	22,691	20,494	8,730	6,180	5,682	2,179

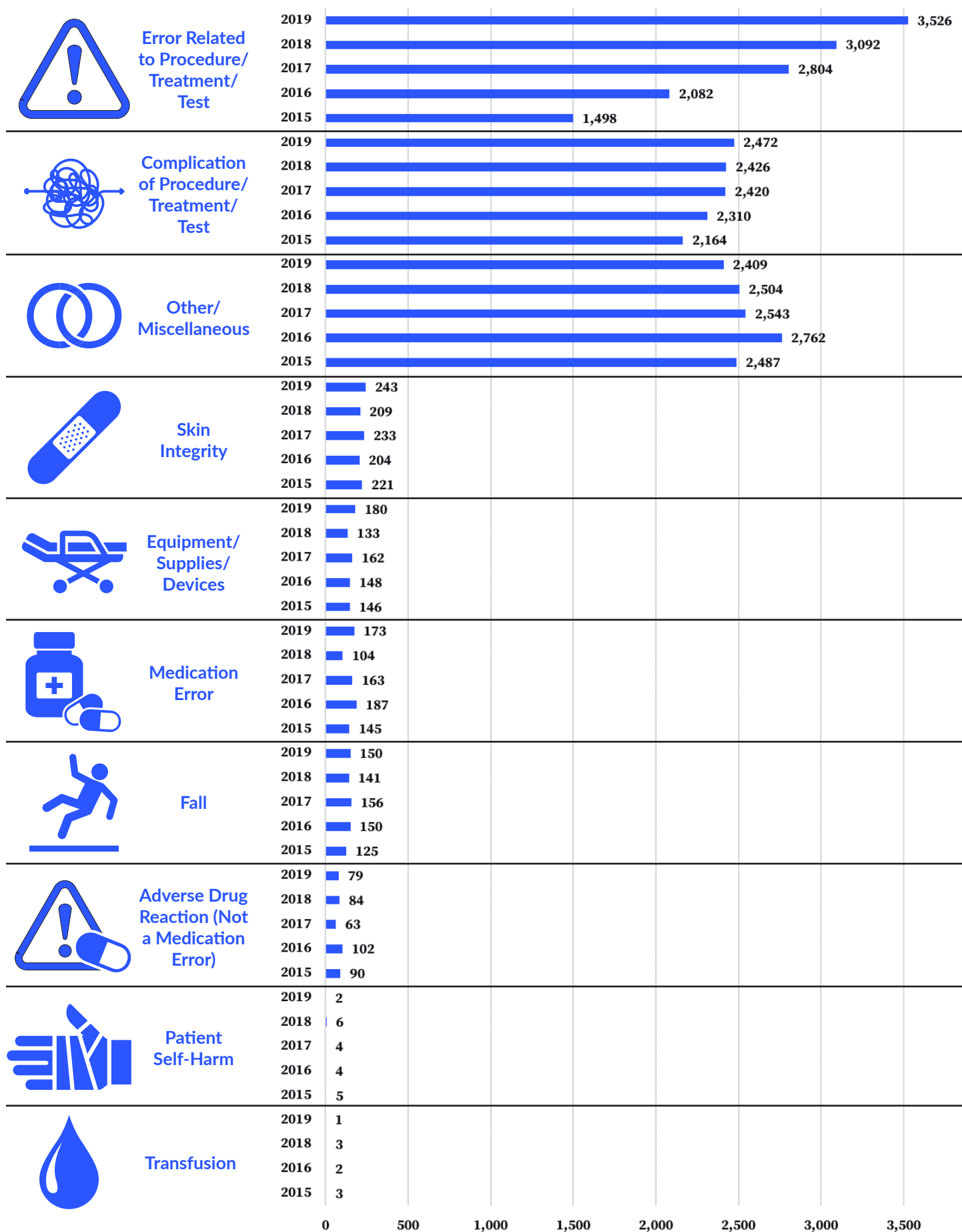
Figure 13: Number of Event Reports by Care Area Group and Harm Score – 2019

Care Area Group	A	B1	B2	C	D	E	F	G	H	I	Grand Total
Administration	99	10	137	122	73	10	3				454
Emergency	4,782	401	2,794	13,026	5,784	230	77	5	8	21	27,128
ICU	2,078	231	1,716	9,736	10,307	478	42	4	11	29	24,632
Imaging/Diagnostic	1,153	153	1,313	6,327	6,384	213	106	1	9	10	15,669
Intermediate Unit	701	147	592	3,543	4,003	110	21	2	4	7	9,130
Labor and Delivery	474	46	285	1,428	2,934	145	29	3	5	9	5,358
Laboratory	909	405	1,755	6,019	1,436	21	6				10,551
Med/Surg	5,187	542	4,089	23,583	23,520	861	186	6	11	34	58,019
NICU	286	35	1,879	3,450	926	27	2	1	2	2	6,610
Nursery	87	14	64	460	706	18	2		1		1,352
OB/GYN Unit	413	95	382	1,429	1,800	134	52	4	3	5	4,317
Other	1,091	218	1,977	4,750	3,266	243	122	4	2	7	11,680
Outpatient/Clinic	831	191	1,829	3,877	2,916	146	72	4	2	6	9,874
Pediatric	933	138	6,446	5,147	1,344	31	12				14,051
Pharmacy	199	94	1,381	1,180	604	1	4				3,463
PICU	589	40	5,964	4,512	657	15	2		2	4	11,785
Psychiatric Unit	426	58	307	4,585	4,801	481	58		2	10	10,728
Rehab Services	106	9	70	935	754	26	8			1	1,909
Rehab Unit	453	53	459	4,363	3,834	164	34	1	1	8	9,370
Respiratory	97	13	62	457	115	2					746
Specialty Unit	1,553	157	1,185	6,747	7,349	218	63		8	14	17,294
Surgical Services	4,428	780	4,437	13,767	12,063	2,242	1,421	22	44	76	39,280
Grand Total	26,875	3,830	39,123	119,443	95,576	5,816	2,322	57	115	243	293,400

Figure 14: Number of Event Reports by Care Area Group and Event Type – 2019

Care Area Group	Error Related to Procedure / Treatment / Test	Medication Error	Complication of Procedure / Treatment / Test	Fall	Other / Misc	Skin Integrity	Equipment / Supplies / Devices	Transfusion	Adverse Drug Reaction	Patient Self-Harm	Grand Total
Administration	113	186	44	8	74	8	9	8	3	1	454
Emergency	13,756	3,435	2,829	2,285	2,626	312	423	993	359	110	27,128
ICU	7,524	4,275	3,824	1,162	1,101	4,641	738	1,054	283	30	24,632
Imaging/Diagnostic	6,464	245	5,118	758	623	572	488	31	1,367	3	15,669
Intermediate Unit	2,320	1,563	1,433	1,241	997	1,014	161	265	125	11	9,130
Labor and Delivery	1,164	452	3,125	110	250	56	83	91	27		5,358
Laboratory	9,813	35	105	83	137	24	42	304	7	1	10,551
Med/Surg	12,383	10,886	9,620	10,883	5,241	6,093	847	1,322	628	116	58,019
NICU	2,851	2,254	704	13	194	132	365	91	6		6,610
Nursery	485	68	695	10	58	16	16	4			1,352
OB/GYN Unit	1,204	684	1,643	185	276	107	107	85			4,317
Other	4,792	1,749	1,331	1,179	1,176	493	334	295	309	22	11,680
Outpatient/Clinic	3,960	1,470	826	773	539	227	243	215	1,609	12	9,874
Pediatric	2,905	7,243	1,534	590	897	242	464	121	42	13	14,051
Pharmacy	86	3,231	12	2	27	1	10		94		3,463
PICU	3,228	6,441	967	55	268	284	437	100	5		11,785
Psychiatric Unit	284	1,213	192	4,880	1,919	295	26		115	1,804	10,728
Rehab Services	214	59	166	893	191	333	42	2	6	3	1,909
Rehab Unit	909	1,914	695	2,877	1,006	1,771	87	19	82	10	9,370
Respiratory	220	299	64	24	63	23	50	1	2		746
Specialty Unit	3,641	3,277	2,513	3,313	1,745	1,595	301	593	285	31	17,294
Surgical Services	17,891	1,809	9,110	575	3,283	2,255	3,457	586	304	10	39,280
Grand Total	96,207	52,788	46,550	31,899	22,691	20,494	8,730	6,180	5,682	2,179	293,400

Figure 15: Number of Reports Submitted by Event Type and Year – ASFs Only



Complication of Procedure/Treatment/Test

Although the total number of events reported as Complications of Procedure/Treatment/Test has increased each year since 2015, **Figure 11** shows that the associated Serious Events have had a small effect on the increase.

Event Type and Harm Score

Figure 12 contains submitted reports distributed by harm score for each of the 10 main event types. This is the first visualization in this article that cross tabulates the report counts across two of the main categorical topics mentioned at the beginning of this section. For the most prevalent event type, “Error related to Procedure/Treatment/Test,” harm score C is reported most frequently; the intersection of this event type and harm score was the most common in 2019, with a total of 50,972 events and representing 17% of all reported events. The next most common intersection is “Complication of Procedure/Treatment/Test” and harm score D, representing 27,798 events in 2019.

Care Area

Care area is an informative dimension to look at to determine whether there are indications of patient safety concerns specific to particular care areas. Within the acute care data, there are 179 care areas to capture where events occur. These care areas are placed into one of 23 possible care area groups in order to cross tabulate a more manageable number of category elements with other variables of interest. In **Figure 13** we show a cross tabulation of care area group with harm score. Highlighting and shading is used to show the cells in which event report counts were concentrated in 2019. In this figure, the largest concentrations of event reports appear in the cross sections of the Med/Surg care area group and harm scores C and D. Also, Surgical Services is responsible for large portions of harm scores E and F. There are other insights that can be acquired by looking at the table across a row or down a column to see the distribution of event reports over a care area group or a harm score.

A cross tabulation of care area group and event type is provided in **Figure 14**. Almost half of the Medication Errors in 2019 were from the Med/Surg, Pediatric, and PICU care area groups. Also, the largest two concentrations of event reports are at the intersections of “Error Related to Procedure/Treatment/Test” with Surgical Services and Emergency care area groups. The Med/Surg, Laboratory, ICU, and Imaging/Diagnostic care area groups also contribute large numbers to the “Error Related to Procedure/Treatment/Test” event type.

Ambulatory Surgical Facilities

Hospitals submitted 97% of the 293,400 acute care event reports in 2019. Therefore, it is helpful to look at the facilities other than hospitals, which are grouped as Ambulatory Surgical Facilities (ASFs), comprised mostly of ambulatory surgical centers, along with abortion facilities and birthing centers. The distribution of event reports across the event

types for ASFs is shown in **Figure 15**. ASFs show a different distribution compared to the overall data distributed in **Figure 8**. Compared to all reports, medication errors and falls drop down the list for ASFs. Also, the relatively large increase in reported errors related to procedures, treatments, and tests at ASFs is due in large part to an increase in reported cancellations of procedures.

Conclusion

There were 293,400 acute care events reported in PA-PSRS during 2019, representing a 3.2% increase over 2018. Reports of Incidents and Serious Events have increased each year since 2016. The number of reported high harm events has decreased from 726 in 2005 to 415 in 2019. The top four event types, accounting for more than three quarters of the acute event reports in 2019, are “Error Related to Procedure/Treatment/Test,” “Medication Error,” “Complication of Procedure/Treatment/Test,” and “Fall.” Overall, the increase in reporting rates each year may reflect improvements in patient safety culture across the Commonwealth, and the analysis within this article has highlighted a number of areas in which continued patient safety efforts can be applied to the greatest effect in acute care facilities.

Note: This analysis was exempted from review by the Advarra Institutional Review Board.

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About the Authors

Shawn Kepner is a statistician at the Patient Safety Authority.

Rebecca Jones is the director of Data Science and Research for the Patient Safety Authority.

Regina Hoffman is the executive director of the Patient Safety Authority.

Caitlyn Allen (caiallen@pa.gov) is the director of Engagement at the Patient Safety Authority.

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Eric Weitz is a board member of the Patient Safety Authority.

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Healthcare-Associated Infections in the Long-Term Care Setting

An Analysis of Reports from Pennsylvania

DOI: 10.33940/data/2020.6.2

Shawn Kepner, MS[†], **Amy Harper, PhD, RN[†]**, **Rebecca Jones, MBA, RN[†]**,
Caitlyn Allen, MPH[†]◇, **Regina Hoffman, MBA, RN[†]**, **Daniel Glunk, MD[†]◆**,
Eric Weitz, Esq.[†]◆, & **Stanton N. Smullens, MD[†]◆**

The Pennsylvania Patient Safety Reporting System (PA-PSRS) is the largest repository of patient safety data in the United States. In addition to over 3.6 million Acute Care records, PA-PSRS has collected more than 330,000 Long-Term Care (LTC) healthcare-associated infection reports since 2009. A total of 28,310 infections were reported in 2019, representing a 9% decrease from the prior year. The Northwest region of the state had the highest infection reporting rate, with 1.25 reports per 1,000 resident days. There was a 20% reduction in both the number and reporting rate of respiratory tract infections from 2018 to 2019; however, respiratory tract infections remained the most frequently reported infection type overall. Cellulitis, soft tissue, or wound infection was the most frequently reported infection subtype in 2019, followed by pneumonia and symptomatic urinary tract infection. With this information, nursing homes and interested parties can determine which trends or characteristics of the data are relevant for reduction in infections in nursing homes. Overall, this analysis demonstrates areas in which continued education and infection prevention measures can be applied to further enhance the safety for residents in long-term care facilities.

◇Corresponding author

†Patient Safety Authority

◆Patient Safety Authority Board Member

The Pennsylvania Patient Safety Reporting System (PA-PSRS) is the largest repository of patient safety data in the United States. In addition to over 3.6 million Acute Care records, PA-PSRS has collected more than 330,000 Long-Term Care (LTC) healthcare-associated infection reports since 2009. In 2019, 28,310 healthcare-associated infections (HAIs) were reported.

Methodology

The LTC data from PA-PSRS were extracted on February 25, 2020, to allow additional time for rate calculation based on resident and device utilization days. With respect to infection rates, facilities and care areas were included for each month in which the facility reported resident and device days.

Results

On average 29,928 infections were reported each year over the last five years (see **Figure 1**). The number of reports for 2019 decreased by 9% from 2018.

The distribution of LTC infections submitted in 2019 by region is shown in **Figure 2**. The Southeast region reported the highest number of infections, with 8,954 reports. The Northwest region had the highest rate of reports per 1,000 resident days (rate=1.25).

Figure 1: LTC Infections Submitted by Year

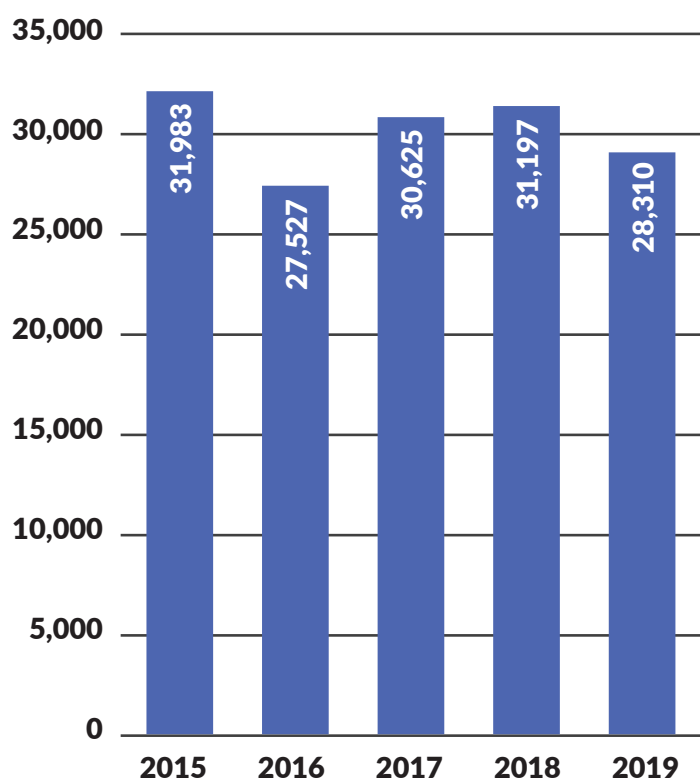
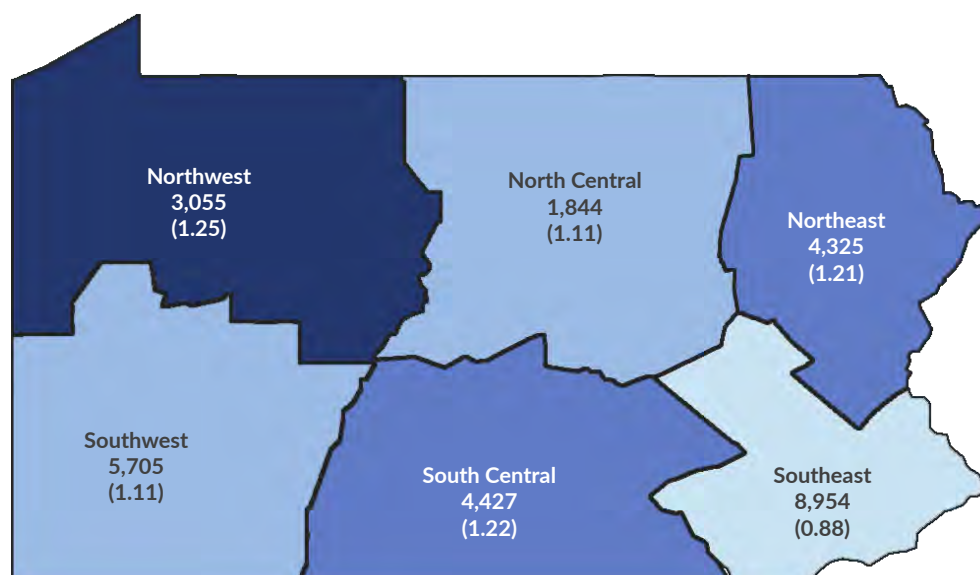


Figure 2: LTC Infections and Infection Rates per 1,000 Resident Days by Region in 2019

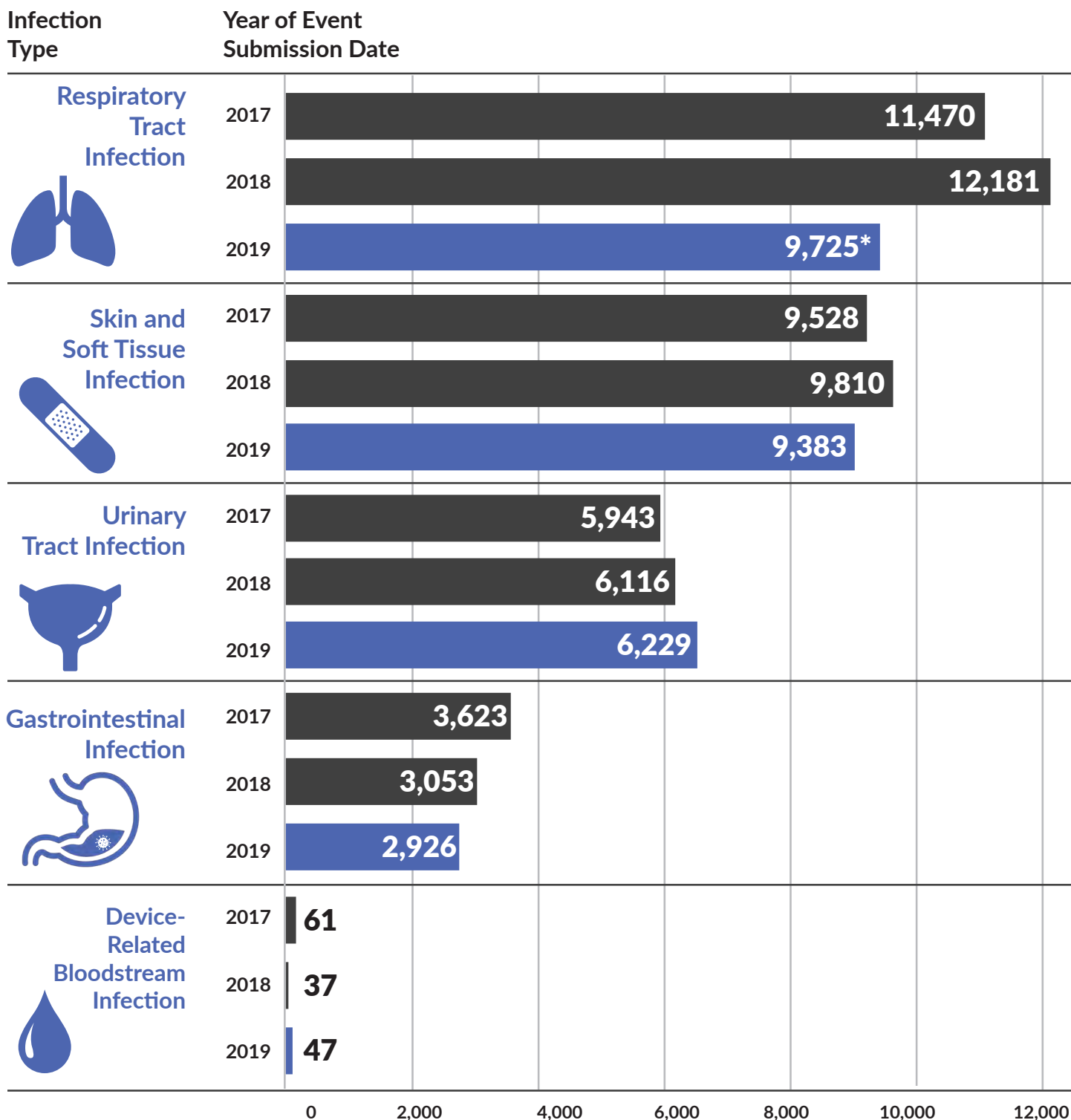


LTC Healthcare-Associated Infections

Reports submitted to PA-PSRS are classified into five main infection types (see **Figure 3**). Respiratory tract infections have typically accounted for the largest number of reports

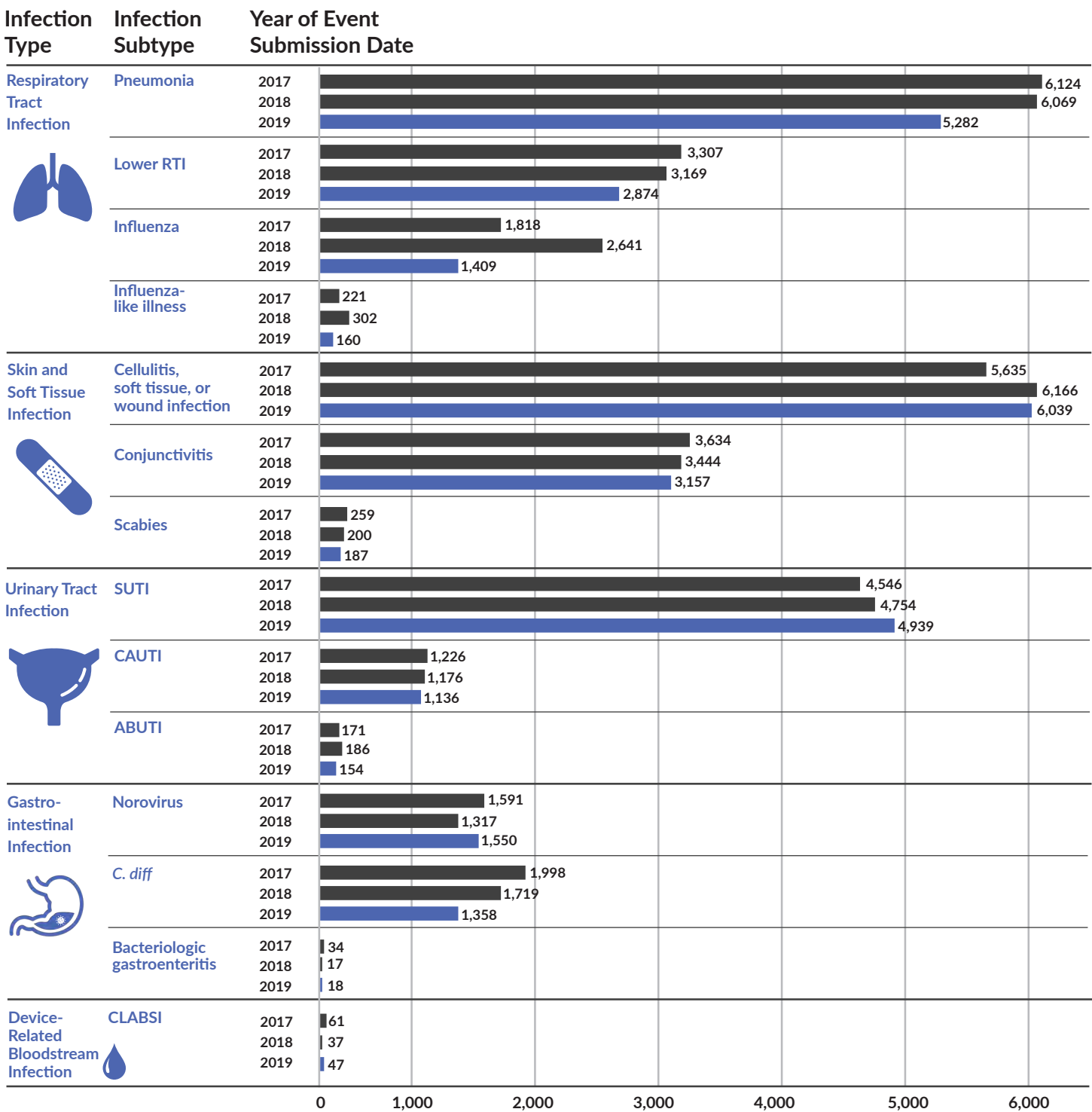
in previous years. However, in 2019 there was a 20% reduction in the number of respiratory tract infection reports from the previous year ($p < 0.0001$), and the decrease in respiratory tract infection reports comprises 85% of the decrease for all reports.

Figure 3: LTC Infections by Type and Year



*Significant decrease from 2018 ($p \leq 0.0001$)

Figure 4: LTC Infections by Infection Type, Infection Subtype, and Year



RTI = Respiratory Tract Infection

SUTI = Symptomatic Urinary Tract Infection

CAUTI = Catheter-Associated Urinary Tract Infection

ABUTI = Asymptomatic Bacteremic Urinary Tract Infection

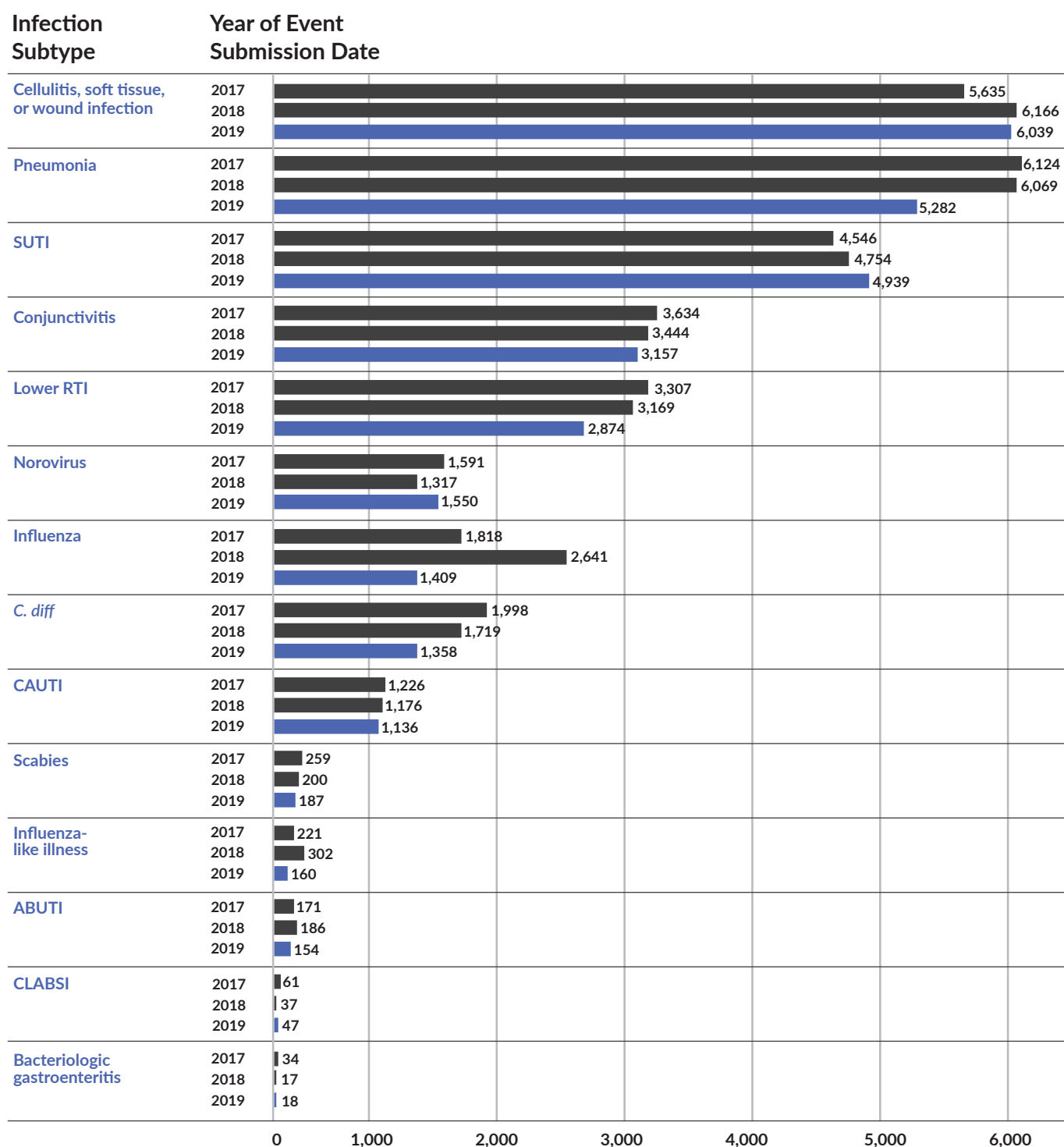
CLABSI = Central Line-Associated Blood Stream Infection

LTC-Specific Infection Types

The main infection report types can be further subdivided into more specific infection types (see **Figures 4 and 5**). Reporting of all subtypes of respiratory tract infections and skin and soft tissue infections decreased from 2018 to 2019 (**Figure 4**). However, the number of reports for symptomatic urinary tract infections (SUTI), norovirus, catheter-associated blood-stream infections (CLABSI), and bacteriologic gastroenteritis increased from 2018 to 2019 (**Figure 5**).

Cellulitis, soft tissue, or wound infections; pneumonia; and SUTI are the three most frequently reported infection types (**Figure 5**). Also, influenza reporting was relatively high in 2018, which coincides with the severe flu season in Pennsylvania in the early part of that year^{1,2} (**Figure 5**). The number of reports of pneumonia, conjunctivitis, lower respiratory tract infections (lower RTI), *Clostridioides difficile* (*C. diff*), catheter-associated urinary tract infection (CAUTI), and scabies have declined each year since 2017 (**Figure 5**).

Figure 5: LTC Infections by Infection Subtype in Descending Order by 2019 Report Count



Care Area

Figure 6 shows the distribution of infection reports in 2019 by the five types of care areas. Skilled nursing/short-term rehabilitation units account for the largest number of reports. Those units also have the most resident days. Respiratory tract infections are reported more than any other infection type in all care areas, except for dementia units.

Figure 7 shows the distribution of specific types of infections in 2019 by the five types of care areas. Cellulitis, soft tissue, or wound infections account for the largest number

of reports in all units except for ventilator-dependent units, in which pneumonia is the most frequently reported infection.

Infection Rates

Figure 8 shows infection rates per one thousand resident days for the five infection types for 2017–2019. The rate for respiratory tract infections decreased by 20% from 2018 to 2019.

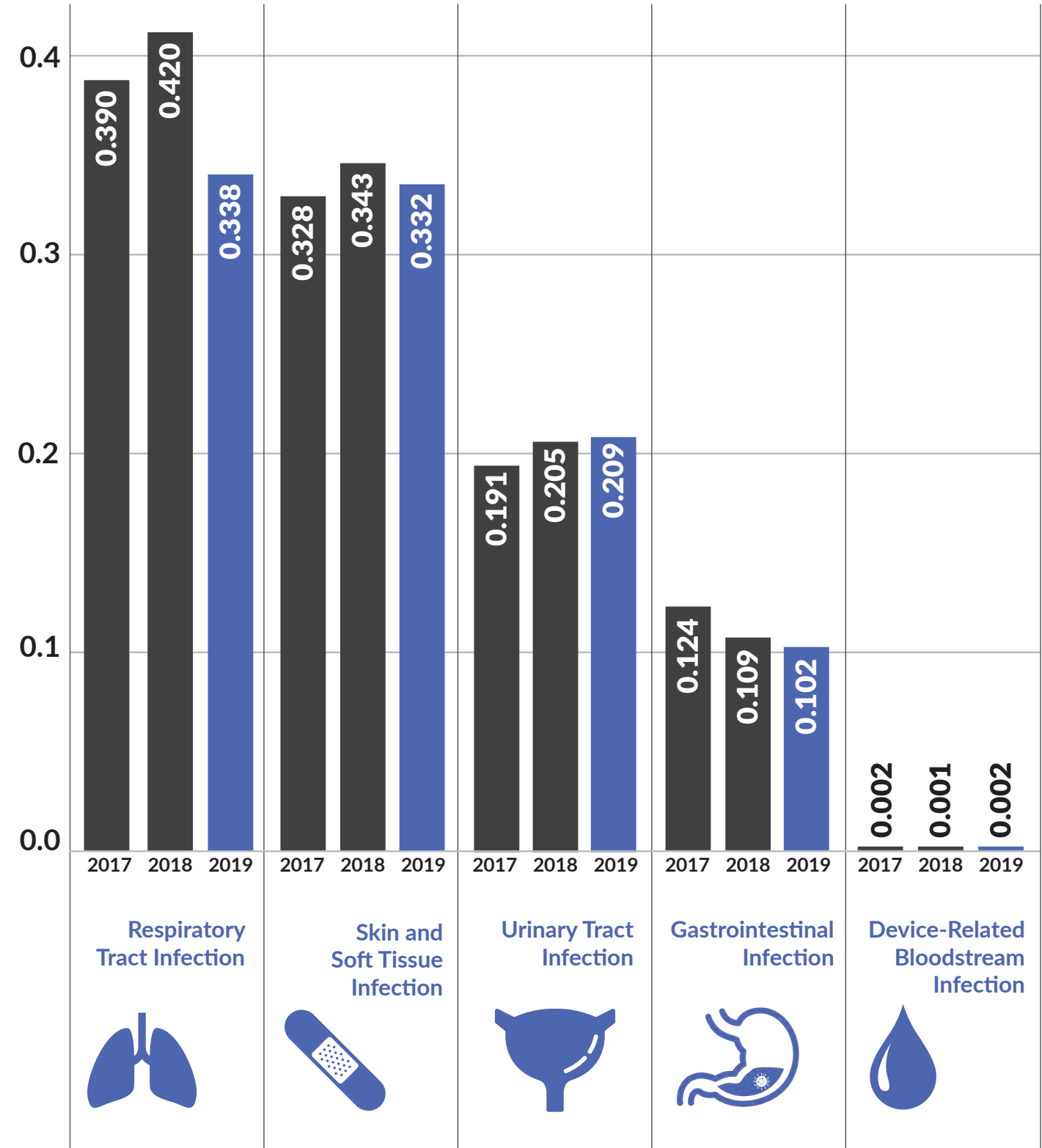
Figure 6: LTC Infections by Care Area and Infection Type - 2019

Infection Type	Dementia Unit	Mixed Unit	Nursing Unit	Skilled Nursing/ Short-Term Rehabilitation Unit	Ventilator- Dependent Unit	Grand Total
Device-Related Bloodstream Infection		7	12	23	5	47
Gastrointestinal Infection	237	814	766	1,092	17	2,926
Respiratory Tract Infection	649	2,795	2,571	3,548	162	9,725
Skin and Soft Tissue Infection	652	2,668	2,559	3,436	68	9,383
Urinary Tract Infection	329	1,697	1,550	2,587	66	6,229
Grand Total	1,867	7,981	7,458	10,686	318	28,310

Figure 7: LTC Infections by Care Area and Infection Subtype - 2019

Infection Subtype	Dementia Unit	Mixed Unit	Nursing Unit	Skilled Nursing/ Short-Term Rehabilitation Unit	Ventilator- Dependent Unit	Grand Total
ABUTI	6	47	42	58	1	154
Bacteriologic gastroenteritis		5	7	6		18
C. diff	36	320	347	638	17	1,358
CAUTI	45	291	255	489	56	1,136
Cellulitis, soft tissue, or wound infection	355	1,681	1,666	2,302	35	6,039
CLABSI		7	12	23	5	47
Conjunctivitis	271	943	843	1,067	33	3,157
Influenza	87	413	397	504	8	1,409
Influenza-like Infection	13	53	37	57		160
Lower RTI	226	823	813	962	50	2,874
Norovirus	201	489	412	448		1,550
Pneumonia	323	1,506	1,324	2,025	104	5,282
Scabies	26	44	50	67		187
SUTI	278	1,359	1,253	2,040	9	4,939
Grand Total	1,867	7,981	7,458	10,686	318	28,310

Figure 8: LTC Infections per 1,000 Resident Days by Infection Type

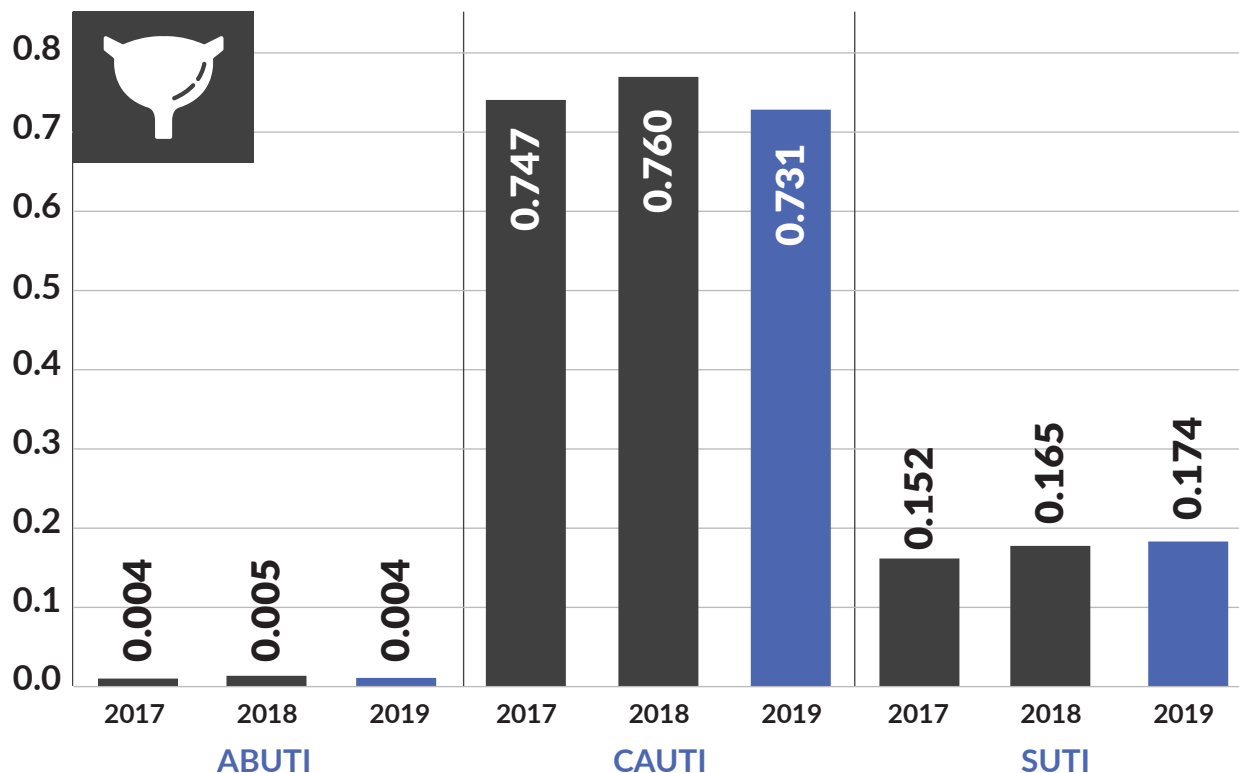


In **Table 1**, overall infection rates are shown for each infection subtype for years 2017–2019. While the CAUTI rates decreased in 2019, SUTI rates have shown a steady increase during the past two years (**Figure 9**). All types of respiratory infection rates decreased in 2019 from the previous year (**Figure 10**). This may be due, in part, to a less severe influenza season in 2019 than was seen in 2018.¹⁻³ *C. diff* rates have steadily decreased since 2017 (**Figure 11**). However, rates for norovirus increased in 2019 (**Figure 11**). Rates for conjunctivitis and scabies decreased in 2019 (**Figure 12**). **Figure 13** shows the rate of CLABSI.

Table 1: Overall Infection Rates by Year

	2017	2018	2019
Pneumonia	0.207	0.211	0.185
Lower RTI	0.113	0.108	0.101
Influenza	0.063	0.090	0.049
Influenza-like illness	0.008	0.011	0.006
Cellulitis, soft tissue, or wound infection	0.194	0.215	0.215
Conjunctivitis	0.127	0.122	0.114
Scabies	0.008	0.007	0.005
SUTI	0.152	0.165	0.174
CAUTI	0.747	0.760	0.731
ABUTI	0.004	0.005	0.004
Norovirus	0.054	0.049	0.057
<i>C. diff</i>	0.069	0.059	0.047
Bacteriologic gastroenteritis	0.001	0.001	0.001
CLABSI	0.116	0.076	0.098

Figure 9: Urinary Tract Infection Rates



ABUTI and SUTI rates are per 1,000 resident days; CAUTI rate is per 1,000 catheter days

Figure 10: Respiratory Tract Infection Rates per 1,000 Resident Days

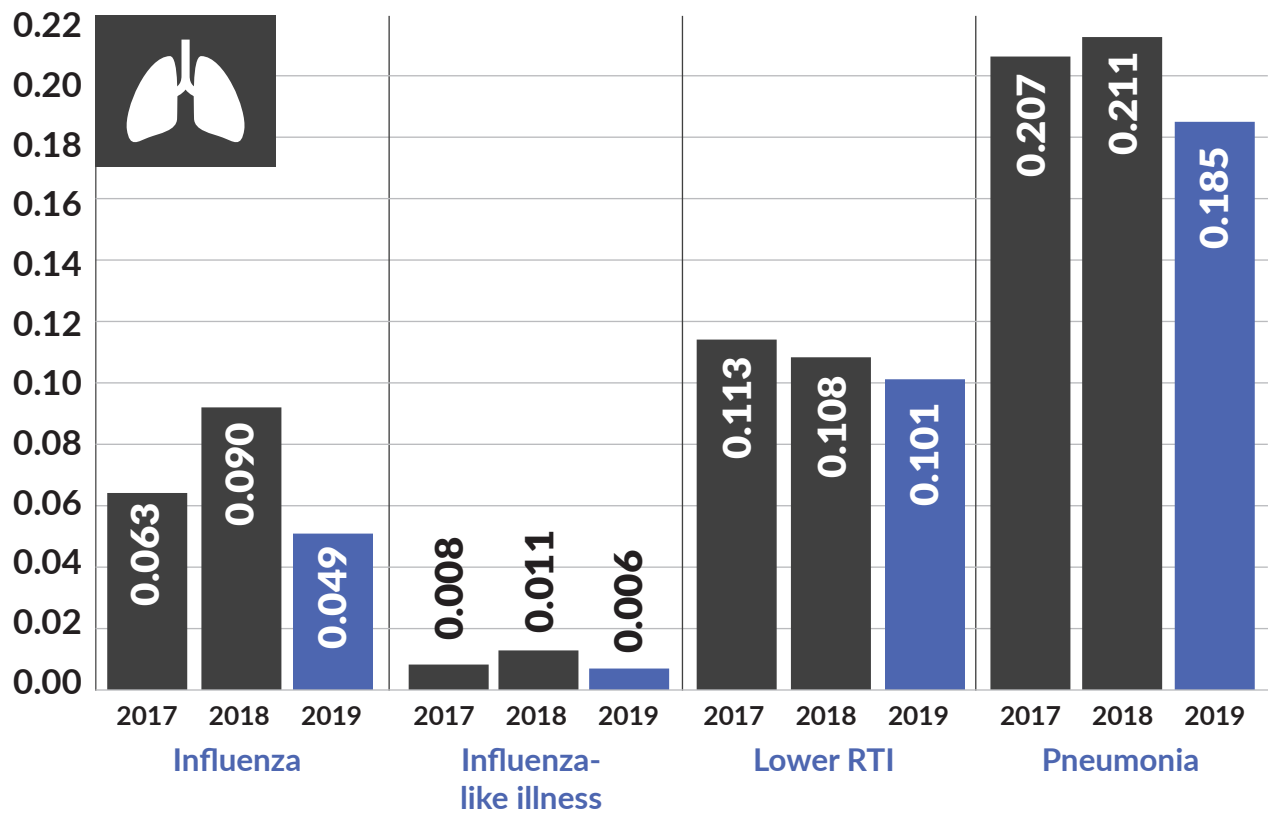
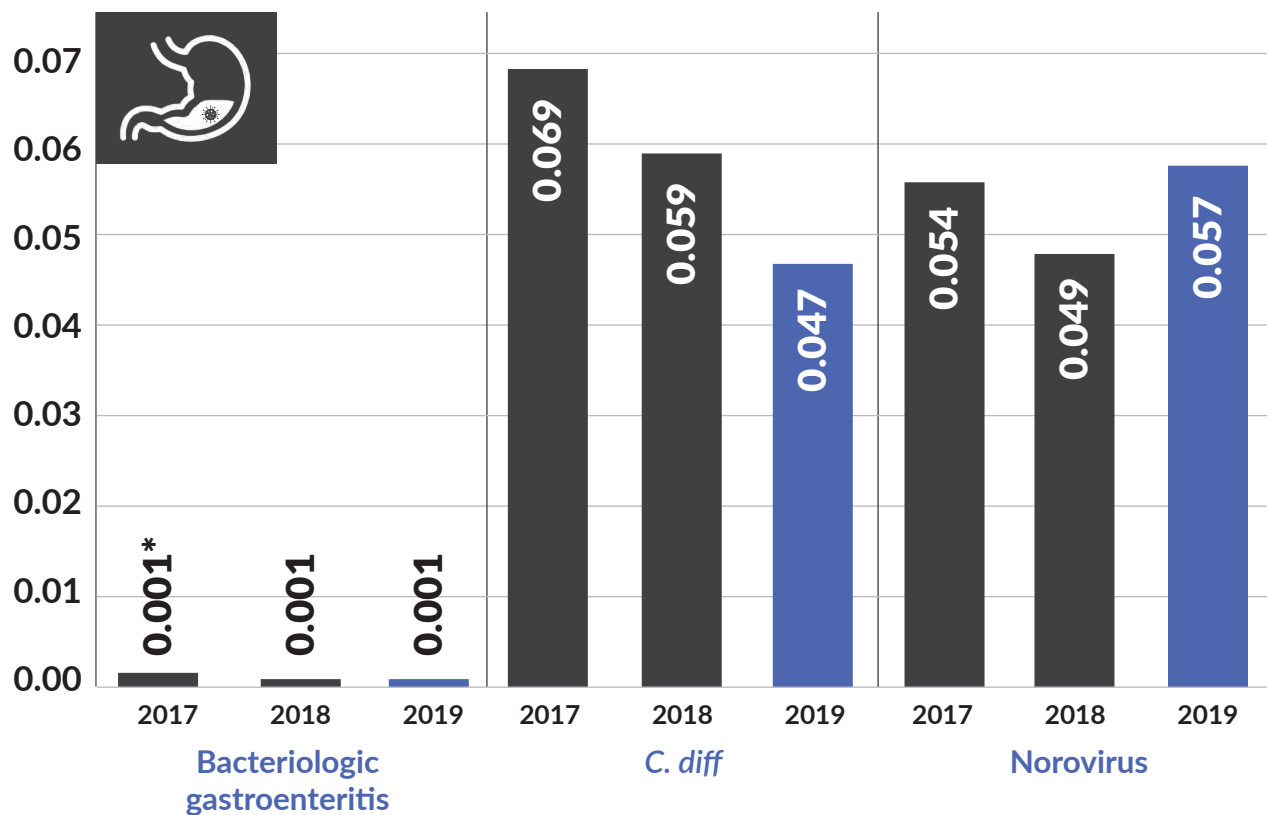


Figure 11: Gastrointestinal Infection Rates per 1,000 Resident Days



* The bar for 2017 is higher than those for 2018 and 2019 even though the rates are all shown as 0.001. This is due to rounding rates to the nearest thousandth.

Figure 12: Skin and Soft Tissue Infection Rates per 1,000 Resident Days

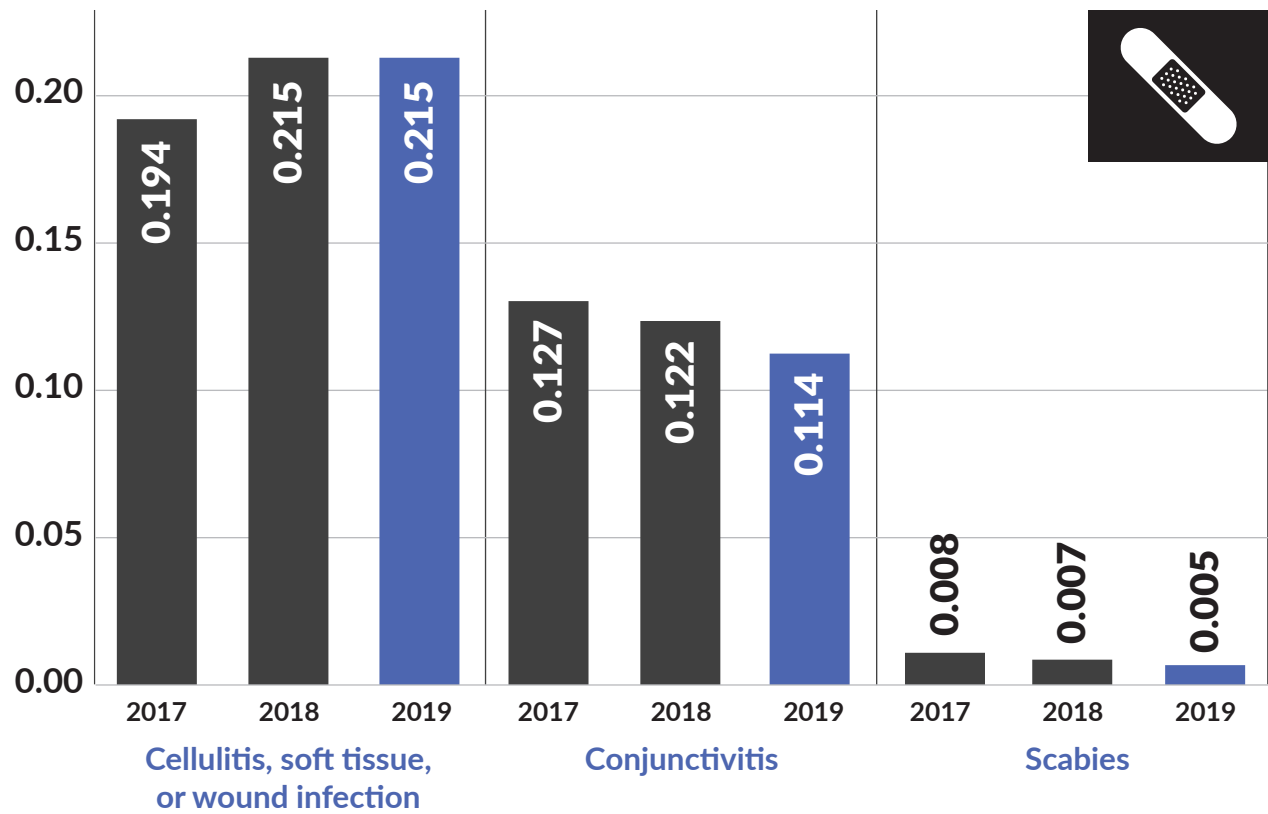
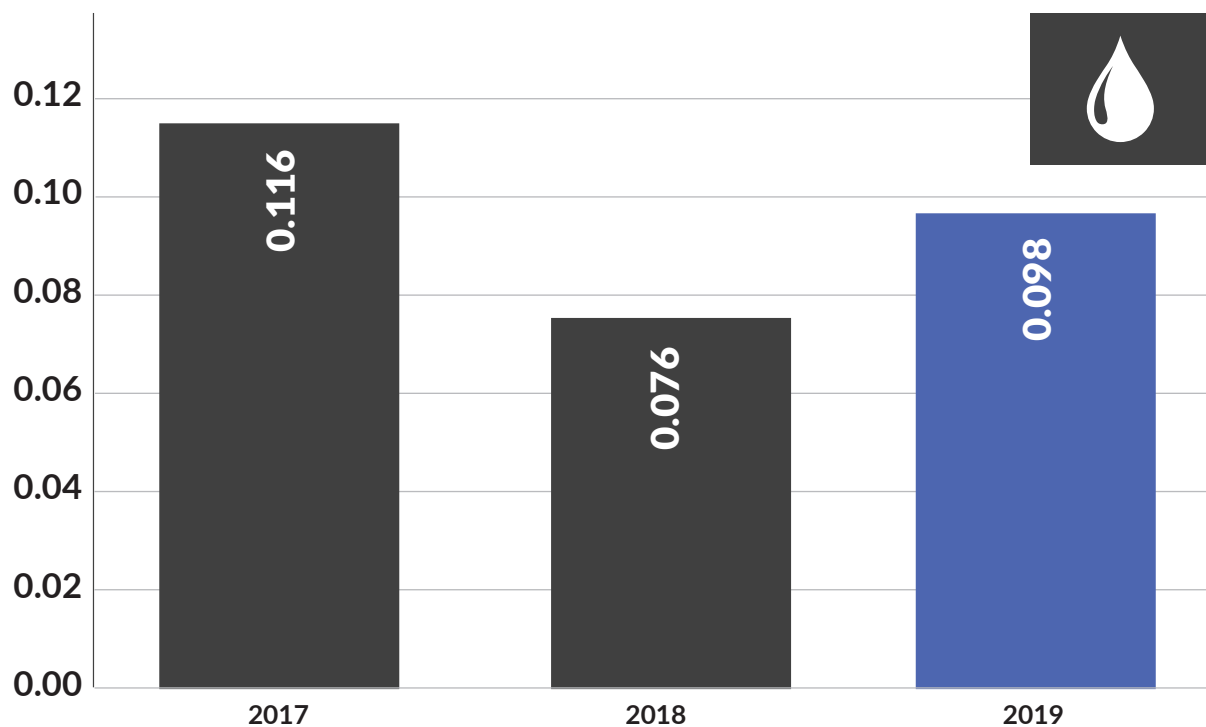


Figure 13: CLABSI Infection Rates per 1,000 Central Line Days



In **Figure 14**, the infection rates are displayed by year for care areas and infection subtype. CAUTI rates increased for dementia and nursing units in 2019 from the previous year (**Figure 14**) despite the overall combined CAUTI rate decrease in 2019 (**Figure 9**). For ventilator-dependent units, the rates for SUTI and CAUTI declined in 2019 (**Figure 14**). However, the lower respiratory tract infection rate for ventilator-dependent units more than doubled from 2018 to 2019 despite similar pneumonia rates (**Figure 14**). Furthermore, the central line-associated infection (CLABSI) rates reported in ventilator-dependent units as well as skilled nursing/short-term rehabilitation units also increased in 2019, despite declines for this infection type in all other types of units for 2019. Notably, CLABSI rates for mixed nursing units decreased by nearly 52%. It is suggested that care be used when interpreting comparisons of rates due to low n sizes in terms of the number of reports for certain categories such as ventilator units and CLABSI.

Figure 14: Infection Rates per 1,000 Resident/Device Days by Care Area

Care Area Type	Infection Subtype	2017	2018	2019
Dementia Unit	ABUTI	0.007	0.001	0.004
	Bacteriologic gastroenteritis	0.002	0.000	0.000
	C.diff	0.027	0.022	0.016
	CAUTI	0.744	0.765	1.121
	Cellulitis, soft tissue, or wound infection	0.150	0.169	0.167
	CLABSI	0.162	0.000	0.000
	Conjunctivitis	0.144	0.134	0.128
	Influenza	0.048	0.075	0.040
	Influenza-like Infection	0.007	0.008	0.006
	LRTI	0.121	0.117	0.100
	Norovirus	0.067	0.088	0.101
	Pneumonia	0.171	0.162	0.145
	Scabies	0.019	0.012	0.012
	SUTI	0.113	0.110	0.128
Mixed Unit	ABUTI	0.006	0.006	0.005
	Bacteriologic gastroenteritis	0.001	0.000	0.001
	C.diff	0.066	0.053	0.040
	CAUTI	0.872	0.816	0.648
	Cellulitis, soft tissue, or wound infection	0.197	0.225	0.216
	CLABSI	0.098	0.088	0.042
	Conjunctivitis	0.131	0.121	0.117
	Influenza	0.067	0.089	0.052
	Influenza-like Infection	0.011	0.013	0.007
	LRTI	0.118	0.114	0.104
	Norovirus	0.051	0.041	0.058
	Pneumonia	0.219	0.226	0.189
	Scabies	0.009	0.005	0.005
	SUTI	0.170	0.181	0.173
Nursing Unit	ABUTI	0.006	0.006	0.005
	Bacteriologic gastroenteritis	0.001	0.000	0.001
	C.diff	0.046	0.044	0.037
	CAUTI	0.627	0.544	0.601
	Cellulitis, soft tissue, or wound infection	0.186	0.203	0.197
	CLABSI	0.037	0.090	0.083
	Conjunctivitis	0.124	0.121	0.102
	Influenza	0.065	0.076	0.044
	Influenza-like Infection	0.006	0.011	0.004
	LRTI	0.103	0.101	0.095
	Norovirus	0.045	0.060	0.052
	Pneumonia	0.195	0.194	0.153
	Scabies	0.005	0.007	0.005
	SUTI	0.135	0.143	0.144
Skilled Nursing/ Short-Term Rehabilitation Unit	ABUTI	0.005	0.010	0.006
	Bacteriologic gastroenteritis	0.001	0.001	0.000
	C.diff	0.100	0.087	0.067
	CAUTI	0.727	0.902	0.878
	Cellulitis, soft tissue, or wound infection	0.208	0.229	0.240
	CLABSI	0.095	0.047	0.099
	Conjunctivitis	0.119	0.120	0.118
	Influenza	0.061	0.107	0.052
	Influenza-like Infection	0.007	0.010	0.006
	LRTI	0.116	0.108	0.103
	Norovirus	0.062	0.037	0.048
	Pneumonia	0.212	0.223	0.215
	Scabies	0.008	0.007	0.004
	SUTI	0.164	0.186	0.214
Ventilator- Dependent Unit	ABUTI	0.006	0.000	0.008
	Bacteriologic gastroenteritis	0.000	0.008	0.000
	C.diff	0.186	0.101	0.106
	CAUTI	0.887	0.396	0.205
	Cellulitis, soft tissue, or wound infection	0.186	0.233	0.220
	CLABSI	0.219	0.000	0.149
	Conjunctivitis	0.212	0.117	0.212
	Influenza	0.006	0.031	0.045
	LRTI	0.122	0.062	0.189
	Pneumonia	0.514	0.459	0.492
	Scabies	0.006	0.000	0.000
	SUTI	0.032	0.148	0.038

Figure 15: LTC Infection Rates Trending for Seasonal Infection Subtypes by Event Confirmation Quarter

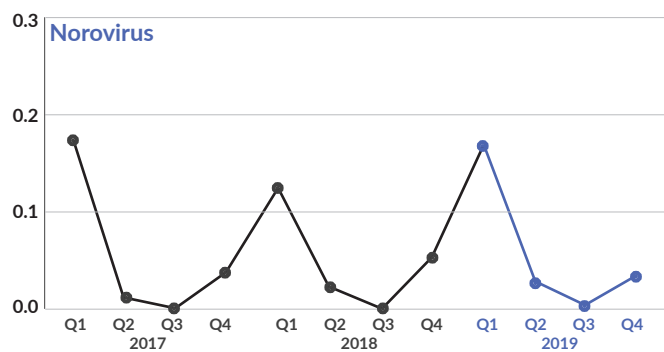
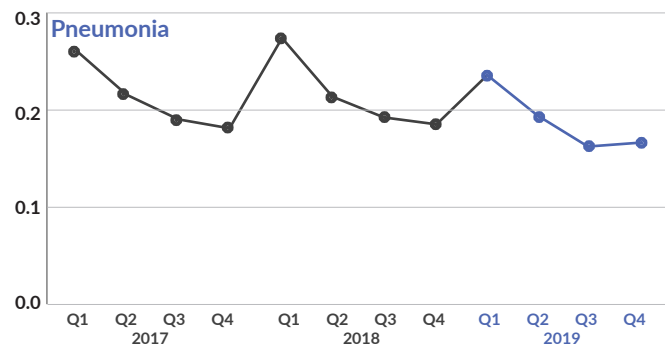
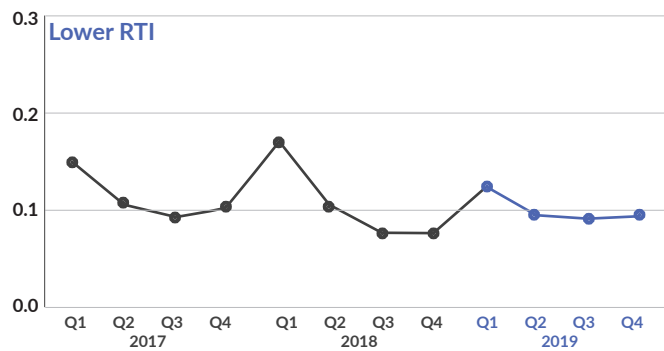
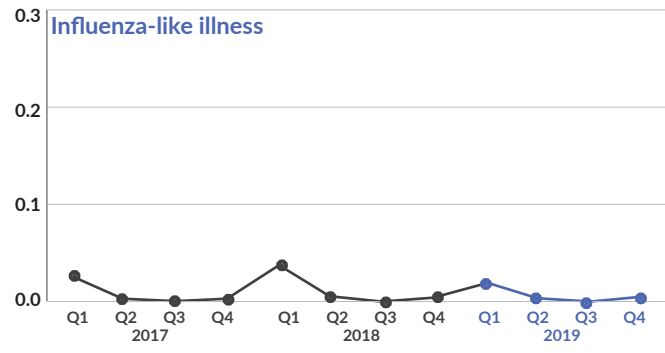
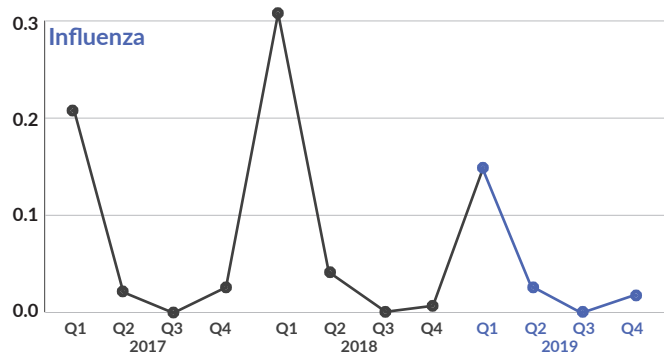


Table 2: Overall Seasonal Infection Rates by Year

		Influenza	Influenza-like illness	Lower RTI	Pneumonia	Norovirus
2017	Q1	0.205	0.024	0.148	0.256	0.169
	Q2	0.020	0.003	0.106	0.210	0.011
	Q3	0.000	0.000	0.094	0.185	0.000
	Q4	0.024	0.003	0.104	0.176	0.035
2018	Q1	0.308	0.035	0.169	0.267	0.121
	Q2	0.041	0.005	0.107	0.208	0.023
	Q3	0.000	0.000	0.078	0.188	0.000
	Q4	0.008	0.003	0.078	0.181	0.051
2019	Q1	0.148	0.017	0.123	0.230	0.164
	Q2	0.026	0.002	0.096	0.188	0.027
	Q3	0.000	0.000	0.093	0.158	0.000
	Q4	0.017	0.003	0.093	0.162	0.032

Figure 15 displays the infection rate for influenza, influenza-like illness, pneumonia, lower respiratory tract infection, and norovirus by quarter for 2017–2019. Seasonal rate increases peak in quarter 1 of each year (Figure 15).

Conclusion

Pennsylvania's long-term care facilities reported 28,310 healthcare-associated infections in PA-PSRS in 2019. This represents a 9.3% decrease in reports from 2018. Although declines in reporting of skin and soft tissue and gastrointestinal infections were noted, respiratory tract infection reports decreased by 20% from 2018. For specific infection types, cellulitis, soft tissue, or wound infections; pneumonia; and SUTI were the three most frequently reported infection subtypes in 2019. The number of reports for most subtypes of infections have decreased; however, SUTI reports have increased each year since 2017. As expected, the respiratory tract and norovirus infection rates have seasonal trends.

The skilled nursing/short-term rehabilitation units account for most of the reports in 2019, and respiratory and skin and soft tissue infections account for two-thirds of all reported infections. Analysis of infection rates generally demonstrates similar infection profiles in the various types of long-term care units across Pennsylvania. However, this article further highlights some notable differences, including increases in CAUTI rates for dementia units, increases in lower respiratory tract infection rates for ventilator-dependent units, and increases in CLABSI rates for ventilator-dependent and skilled-nursing/short-term rehabilitation units in 2019. We also noted a decrease in CLABSI rates for mixed nursing units. Overall, the analysis demonstrates areas where continued education and infection prevention measures can be applied to further enhance the safety for residents in long-term care facilities.

Note: This analysis was exempted from review by the Advarra Institutional Review Board.

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About the Authors

Shawn Kepner is a statistician at the Patient Safety Authority.

Amy Harper is an infection prevention analyst at the Patient Safety Authority.

Rebecca Jones is the director of Data Science and Research for the Patient Safety Authority.

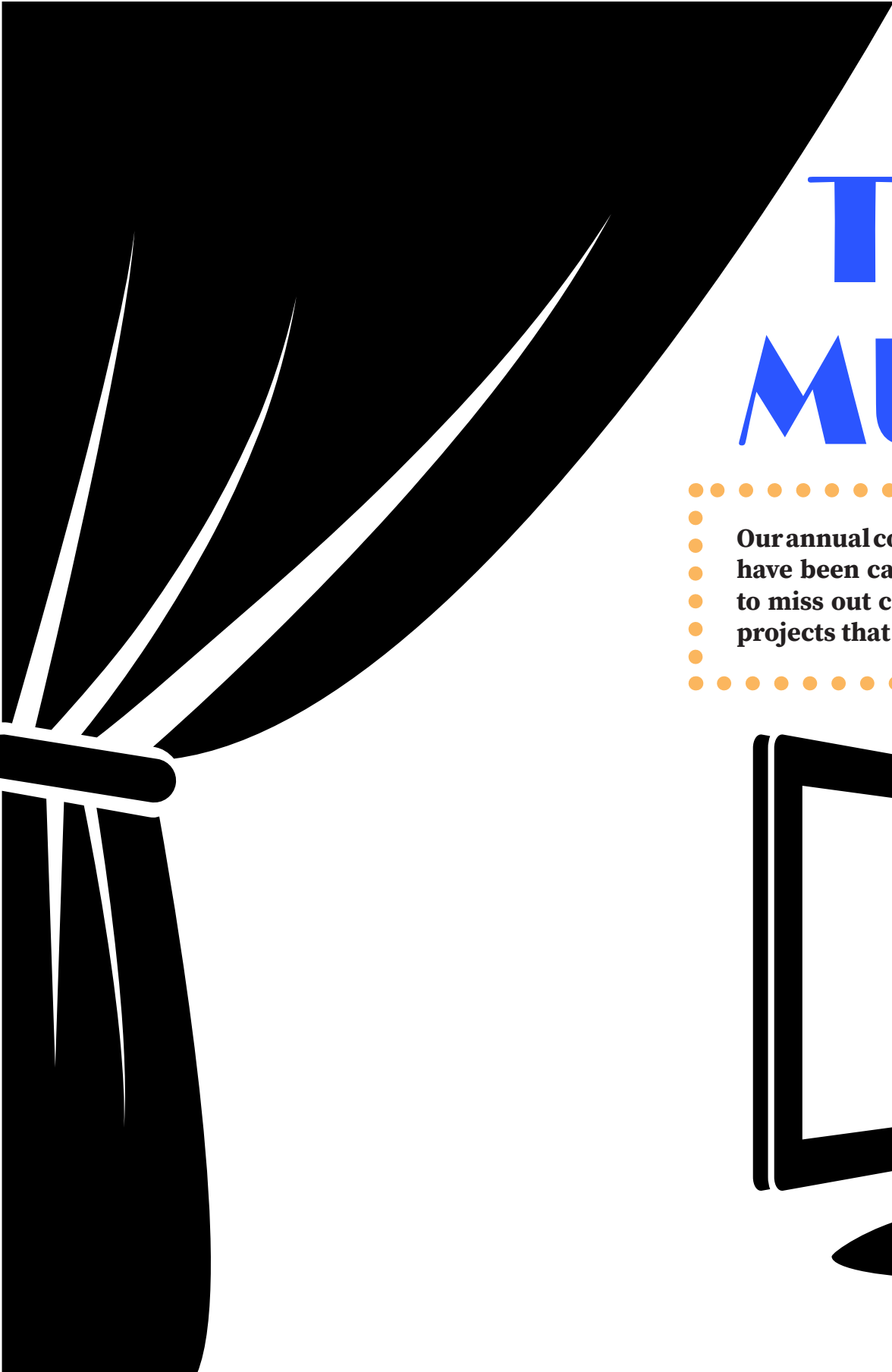
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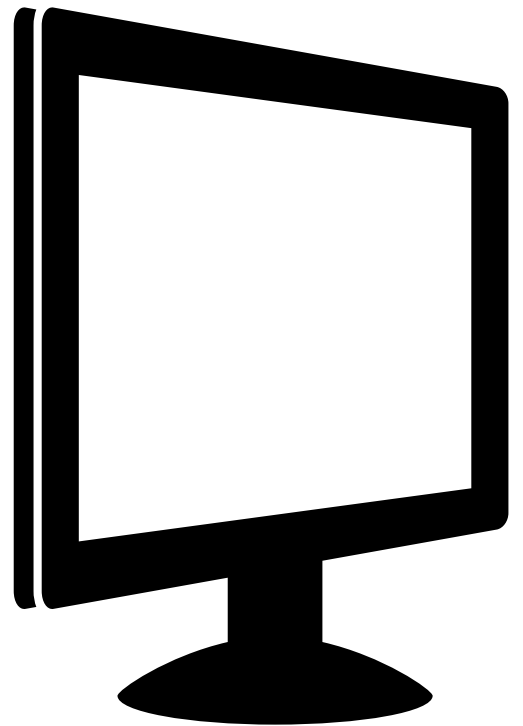
Eric Weitz is a board member of the Patient Safety Authority.

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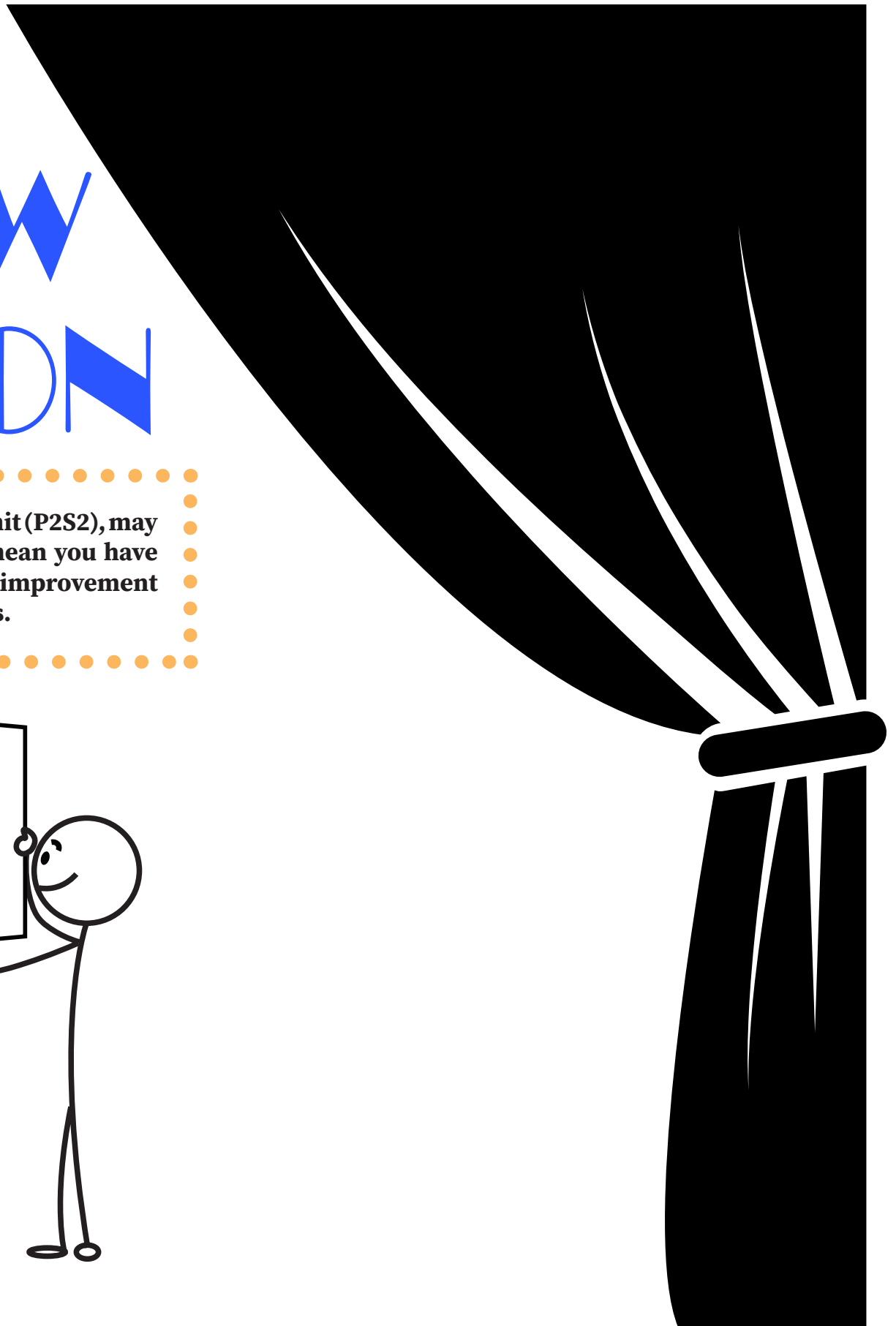
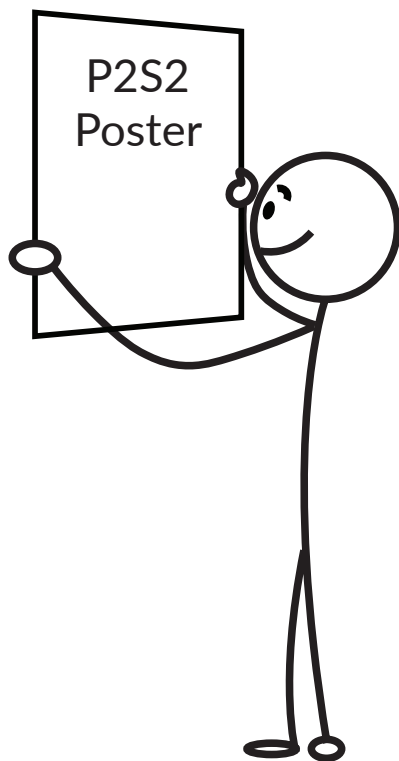
THE S MUST

Our annual conference, the Pennsylvania
have been canceled due to the pandemic
to miss out completely. Here are some
projects that would have been displayed



SHOW GO ON

nia Patient Safety Summit (P2S2), may
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yed as academic posters.



"Walking Out" VTE on an Orthopaedic Unit

Allegheny Health
Network—Forbes Hospital
Dennise Gitzen, MSN, RN

Description: Venous thromboembolism (VTE) events affect nearly 600,000 Americans annually and are directly or indirectly responsible for at least 100,000 deaths per year. VTE events impact hospital quality, safety, and value-based programs. Also, missed doses can impact our VTE rate and are a cause for alarm. During 2018, 39% of our VTE events were attributed to our Orthopaedic unit.

Baseline data: Two indicators were selected for baseline metrics: VTE events and missed doses. In 2018, there were 2 to 4 VTE events quarterly for this unit. Any VTE event that was coded as Orthopaedic or Neuroscience was reflected in the data. The percentage of missed doses (VTE SQ prophylaxis) was also tracked and trended. The baseline for missed doses was approximately 20%.

Interventions: An audit tool was developed for interdisciplinary walking rounds. Baseline data and the go-live date were shared with the Orthopaedic staff. Rounds were standardized at every other Tuesday from 11 a.m. to 12 p.m. and began November 2018. Staff and patients were engaged during rounds for education and feedback. Real-time problem solving occurred during rounds, e.g., replacing missing equipment. VTE medication was reviewed for documentation errors, e.g., missed doses, and reconciled with antithrombotic guidelines. Educational tools were placed in admission packets for reference.

Results: The number of VTE events in 2019 Q1 was zero. The percent of missed doses declined from approximately 20% to 11% (a 9% improvement).

Relevance: Nursing leadership is imperative to improving the quality and safety of our patients. Strategies such as walking rounds empower the staff to make improvements in real time, address concerns, and involve the patients in their care. With the success of our pilot unit, this proactive approach has been adopted and spread to our other medical-surgical unit.

Reducing Complications Through the Imple

Geisinger; Rachel Van Loan, BS; Thomas Hoffman, MS;
Steven Endress, MSN; and Joseph

Introduction: ProvenRecovery™ is a modification of a similar program (ERAS®). Literature identifies that through implantation, organizational length of stay (LOS) and cost for colorectal and other surgeries.

Aim: In implementing ProvenRecovery™ for elective surgeries, the goal was to reduce readmissions by 10%, and cost by 5% overall for colorectal, hysterectomy, transplant, and bariatric surgeries by July 2019.

Methods:

- Provided patients with an overview of their surgery and discharge instructions
- Established standard orders
- Provided immunonutritional supplementation five days pre- and postoperative
- Utilized opioid-sparing techniques intraoperatively and postoperatively
- Developed standard guidelines for early ambulation

Discussion: Despite early implementation struggles across nine services, the program achieved overall cost savings of over \$3 million dollars from our two-year baseline. The assessment shows that complications have a direct correlation to LOS. The program has the ability to transition across multiple elective surgeries with implementation. Programs like ERAS® have shown similar results, but lack the aggressive approach.

Conclusion: ProvenRecovery™ spread over multiple procedures and services, which will help reduce complications and improve patient outcomes, implying that based on our program quickly and expand to emergent surgery. Further investigation is needed to be prescribed during and at discharge to ensure that pain is controlled.

MOVES Program for Hospital

Conemaugh Memorial Medical Center; Michelle Wozniak

Description: For most patients, hospitalization results in prolonged immobility to walk. Although immobility is known to cause functional decline, it is the most often missed element of nursing care. Hospitalized older adults experience a loss of activities of daily living functioning that are worse than their baseline. The program changed from daily visits to the concentrated model that is used today. The goal is that patients are out of bed. To encourage staff to make ambulating patients a priority, the Safely (MOVES) program was created.

Intervention: A nursing-driven, evidence-based assessment to evaluate patient mobility was formed. Then a second assessment is completed to determine the level of mobility. The protocol requires nursing staff to ambulate all patients scoring a 3 or 4. Patients scoring a 2 on the ambulation assessment were required to have a nurse present. Documentation was added to our EMR [electronic medical record] to include mobility assessment. Compliance graphs were added to the nursing quality dashboard.

Results: Timeline graphs showing improvement in length of stay, hospital-acquired pneumonia (VTE), and the readmission rate are included on the poster. PI Data obtained through LifePoint data analytics from implementation showed a decrease from 6.25 in Q1 2017 to 5.69 in Q2 2019, decrease in hospital-acquired pneumonia from 14.3% to 11% in Q2 2019.

Discussion: In conclusion, implementing an early mobility program

Implementation of ProvenRecovery™

Grant Walter, MS; Mary Connell, CRNP;
John Mlinarich, MBA

Program known as Enhanced Recovery After Surgery
outcomes have improved complications and decreased

goal was to reduce complications by 10%, LOS by 5%,
craniotomy, craniotomy, spine, plastic, cystectomy, vascu-

large expectations

st surgery
eratively

ce lines, we have exceeded our goals and can show an
ine after one year of implementing programs. Primary
S, cost, readmissions, and mortality, and the program
proved outcomes. Current implementation of similar
ive spread of this methodology to other service lines.

d service lines has shown the ability to reduce com-
results there is benefit to continue spreading the
ation is needed into the amount of opioids that are

Utilized Patients

niak, MSN, and Jane Drzewiecki, BSN

d periods of bedrest even when they have the ability
or complications, inpatient ambulation emerged as
adults are often discharged from acute care hospitals
baseline functioning. As the model of physical therapy
y, physicians rely more on the nursing staff to ensure
g patients a priority, the Move Often, Very Early, and

te if a patient is medically stable for ambulation is per-
l of assistance needed for ambulation. The ambulation
a minimum of three times a day. At the end of 2019,
be up to a chair twice a day as well. Electronic docu-
le the assessment as well as to monitor for ambulation
ashboard.

ospital-acquired pneumonia, venous thromboembo-
DSA (Plan-Do-Study-Act) is the applied methodology.
n through Q2 of 2019 show a decrease in length of stay
d pneumonia and deep vein thrombosis (DVT), and a

a improves care quality in a hospital setting.

Safety Reporting Across the Care Continuum

WellSpan Health;
Stacey Goldfarb, BSN, RN

Background: WellSpan Health is an integrat-
ed delivery network with all components of
the care continuum except for skilled nursing
facilities (SNFs). To improve care coordina-
tion and patient outcomes with SNFs and other
post-acute care providers, WellSpan developed a
preferred provider network (PPN).

Care transitions are critical phases in a patient's
care journey which are prone to errors and
hence safety concerns. Traditional safety report-
ing systems do not transcend silos for multiple
entities and care settings to report and evaluate
transition-related patient safety events. Addition-
ally, traditional safety reporting systems lack interop-
erability to capture safety events that may occur for
SNF patients receiving care in the outpatient setting.

Objective: WellSpan Health identified an opportunity
to create and implement tools which allow stakehold-
ers across the continuum to utilize a standard method
to report patient safety events. For quality improvement,
workflows are necessary to review and investigate these
concerns. A key value was established to share learning from
safety investigations with involved colleagues and promote
shared learning among other facilities in the network, thus
potentially preventing similar incidents in future. A mecha-
nism for tracking and trending events was necessary to study
the impact of interventions initiated after investigating an
event or a pattern of error types.

Method: WellSpan Health utilizes a third-party vendor (TPV)
safety portal to capture and analyze safety events originating
in WellSpan facilities or on WellSpan grounds. On July 1, 2018,
the TPV safety portal was modified to allow WellSpan employ-
ees to begin reporting non-WellSpan, post-acute safety events.
PPN SNFs do not have access to the TPV safety portal. In Feb-
ruary 2019, a safety reporting tool was added to the Post-Acute
Portal. This tool provided the PPN facilities a venue for sub-
mitting WellSpan transition of care-related safety concerns.
This functionality has created bidirectional, cross-continuum
safety reporting capability.

Analysis: The enhanced patient safety reporting system has re-
sulted in increased reporting focusing on patient-centered care
while maintaining a just culture philosophy. Increased report-
ing has allowed opportunities for clinicians in acute care and
post-acute care to collaborate regarding safety issues impacting
mutual patients. Event investigation has led to education, stan-
dardized communication processes, and focused discussions.

D^o: Crisis

An Informal Conversation With Stanton N. Smullens, MD, FACS,
and SaraKay Smullens, MSW, LCSW, About Burnout, Depression,
and COVID-19

Before the pandemic, clinicians were experiencing high rates of burnout, and physician death by suicide was occurring at an alarming rate. COVID-19 has exacerbated a dire situation. As this crisis was unfolding, we sat down (i.e., zoomed) with Dr. Stanton N. Smullens, chair of the Patient Safety Authority, and his wife, SaraKay Smullens, therapist and best-selling author who completed five years of research on burnout, to discuss a growing crisis, the effects of the coronavirus, and why the future may be more positive than you think.

By Caitlyn Allen, MPH

Cait: Stan and SaraKay, precisely, what is burnout? Is it the same thing as depression?

Stan Smullens: No. Burnout is a different entity. The World Health Organization in 2019 called it “a syndrome relating to chronic workplace stress that has not been successfully managed,” and for the first time, has given it an ICD [International Classification of Diseases] coding separate from depression. SaraKay has spent a lot of time looking at this. She did five years of research and published a book on burnout in 2015—one of the earliest ones. She has also worked with patients suffering from depression for many years.

SaraKay Smullens: This topic most often concentrates on our professional environment. When our work is overwhelming us, the literature stresses that in healthy settings, there is someone we trust to go to who will help us address depleting experiences and concerns.

However, if the one we report to is unable or unwilling to intervene, the anxieties will persist. The literature also shows there are manifestations of burnout that emanate from overload in other parts of our lives, which interact with each other. Personal burnout involves internal upheaval in our cognitive, intellectual, emotional, psychological, or spiritual lives. In social (or relational)

burnout, all our relationships are affected, ranging from our most intimate and interdependent to those we are involved with less intensely. Physical burnout looks at physiological responses to stress. In essence, our bodies are a readout for our stress. Our bodies react, and our bodies remember. Stan and I have addressed these interactions in various presentations. But there is a further recognizable burnout manifestation, societal burnout, which I am now researching.

Societal burnout—a psychological state resulting from grave, looming, unaddressed systemic problems involving safety, opportunity, the environment, and our health and



well-being—is marked by a sense of mourning for an unrealized future and deep fear for our families and our country. The crisis of COVID-19 has left a devastating wake intensified by relentless expressions of hatred, prejudice, rage, and violence. No area, including schools and faith communities, offer safety or protection. As a nation, we are divided about the best path forward but united in our constant states of anxiety and unrest.

The wisest strategy to ease our threatening, menacing overload is decisive and coordinated leadership on every level, one committed to facing and solving our problems together. Those in healthcare professions are not alone in feeling overwhelmed, overloaded, and overburdened. But our present enormous challenges and responsibilities are unprecedented in our lifetimes. All manifestations of burnout are interconnected and, if unaddressed, take a severe toll in every area of our lives.

Stan: Burnout is a complete sense of physical and emotional exhaustion, a state of being when you just can't do anything anymore. There's also a sense of isolation where you cannot connect with your patients; you can't connect with your family or your friends; and then finally, in its most severe forms, there's a sense of total failure—where everything you do appears not to work, and your life feels like a complete disaster on all fronts.

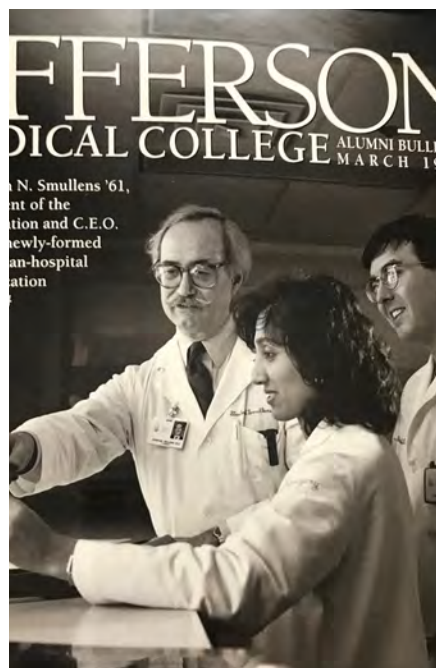
SaraKay: One of the ways we used to be able to determine whether we were burned out or depressed was if we went on holiday and felt refreshed when we returned (which, of course, is not possible during this pandemic); that's most likely burnt out. If, on the other hand, we return from a holiday and feel overwhelmed, sad, and stressed, the cause is likely to be depression.

There's much ongoing discussion on what constitutes depression,



▲ In 2018, SaraKay was one of five graduates of the University of Pennsylvania School of Social Policy and Practice selected for the school's inaugural Hall of Fame.

▼ Dr. Smullens, on a 1996 cover of an *Alumni Bulletin*, was chairman of the Jefferson Alumni Association and CEO of the newly formed JeffCare, a physician-hospital organization.



the forms it takes, and appropriate treatments. Also, clinical depression is usually far more complicated to treat than burnout, which in the past could be alleviated and prevented with proper personal and professional attitudes, programs, and strategies. Today, of course, everything has changed. The surreal and frightening realities of COVID-19 are intensifying both burnout and depression. And we see significant and heightened interaction between the two.

For example, an April 2020 U.S. Census Bureau emergency survey to assess the pandemic's impact revealed that one-third of Americans showed signs of clinical anxiety or depression. This upheaval was highest among younger adults, women, and the poor. The emotional overload in societal burnout, exemplified by our lack of preparedness for a foreseen pandemic, has unquestionably led to despair about our future.

Cait: Stan said, for several years you have worked with adults suffering from depression. Can you comment on your experiences with successful care approaches?

SaraKay: In my experience, and I want to emphasize this is my experience and treatment approach that has developed from over 30 years in practice, unresolved conflicts either now or during your formative years, as well as the inability to progress in a life you wish to live—what I define as cultivating an “emotional sense of direction”—leads to sadness and depression. Both are an understandable response to ongoing conflict and feeling stymied and unable to carve out a meaningful and fulfilling path.

Also, depression can be rooted in real environmental circumstances—an understandable reaction to unsettling and traumatic life events. If we're ill, if somebody we love is ill, if a beloved dies, if we're abandoned by someone we love, if a

trusted friend betrays us, if there's connivance in a professional relationship, or if we are fired from a job—each a life event compounded by fear and anxiety—sadness and depression often follow. Talk therapy (with someone you trust and have a connection) and short-term drugs, as indicated, usually lead to recovery. The availability of a caring family and community is crucial to this success.

When one does not begin to regain equilibrium; or a black cloud has descended for no reason that a patient can determine, impairing hope and confidence; or a diagnosis of bipolar illness (formerly known as manic depression) is confirmed; or, of course, when there is a psychotic episode, framing depression moves from emotional turmoil anchored in real-life circumstances to a psychiatric illness. In these situations, I have also seen that talk therapy, medication, and other agreed-upon evidence-based approaches aid recovery. With time, patience, proven cognitive approaches, and care and connection with others, these expressions of depression usually diminish. If they do not lift entirely, with support one can learn to live meaningfully, despite them.

Today, we find overload in the most extreme dimensions in our medical communities, which is our focus. Often in the past, hard-working, seemingly tireless, devoted professionals could deny the lack of fulfillment in relationships and direction noted above. Now with regularity, constant overload, exhaustion, and limited social contact and activities force unresolved conflicts to our consciousness.

Stan: Yes, everything is more intense. Healthcare professionals, with limited supplies, are risking their own lives to help others. Exhaustion, fear, and anxiety are the norm. Attempts to bury long-simmering personal problems become increasingly difficult.

Cait: How do burnout, depression, and the combination present in physicians? How may this affect patient care?

Stan: Physicians, as well as nurses, have difficulty admitting when we are on overload. Our commitments are 24/7! And physicians have difficulty recognizing personal challenges in our lives, such as those noted. We're taught to persist beyond a point of exhaustion, regardless of the cost, for days on end. The goal set before us is of tireless superhero. Without adjusting this expectation with appropriate self-care attitudes and strategies, we reach the point of being unable to concentrate, focus, or function.

And ongoing personal problems, such as loneliness and constant conflict with those we're closest to, drain us further, as does disappointment that outside forces place on our care of patients. The suicide rate among physicians, particularly the young, middle-career physicians, is over two-and-a-half times that of the general population. The rate among women physicians is higher—most likely due to shouldering much of the family/home responsibilities in addition to their enormous professional duties.

SaraKay: Stan, what you point to is reflective of the whole health team. In various surveys, almost 50% of physicians and a plurality of nurses and medical social workers suffer symptoms of burnout. Unless we care for ourselves, we will be unable to care for anyone else. We must be able to reach the point when we can recognize that we are either burned out, depressed, or a combination. And seek the necessary help.

Stan: Yes, this is crucial. Many physicians don't want the "stigma" of depression and will avoid treatment. Also, there are potential licensing and credentialing issues that bring risk if you are diagnosed with depression. A more enlightened view of this crisis is growing, but far too slowly. However, the syndrome of burnout carries no such stigma. If you're feeling symptoms of overload, address them immediately, before they intensify. Nothing will go on your record that could impair your professional future.

SaraKay: As evidenced in this pandemic, when there is no ability to protect our patients and ourselves, our burdens seem insurmountable: We have nowhere to turn. We long to do our jobs. We want to be there for our patients. We want to be

“

Anxiety and tears are appropriate reactions.

We're human.



Portrait by artist Nelson Shanks (1937-2015)

▲ Dr. Smullens' 2010 Portrait Presentation to Thomas Jefferson University

there for our colleagues. But, without sufficient personal protective equipment and adequate supplies for our patients, dealing with an entirely new, enormously complex disease, doctors, nurses, frontline professionals are being asked to do what is seemingly impossible. This intersection coalesces into the perfect storm of societal, professional, physical, and personal burnout.

Stan: Still, regardless of the realities of this pandemic, doctors, nurses, social workers, all healthcare providers know that we are in an intense fight and that we're in it together. Yes, our roles are different, but we're all vulnerable to this disease. We must learn from COVID-19 and be prepared for the future since we know other pandemics will come.

Cait: Do you think that the problem of burnout permeates the care continuum equally, or does it affect different specialties in varying ways and degrees? Either now during the pandemic or in normal times?

Stan: There is a difference in various specialties, and the ones that seem to be the most affected by burnout are those with the most direct patient contact. For example, OB-GYNs; critical care medicine; the various internal medicine specialties, such as endocrinologists and family medicine, are feeling the stress. Both urology and neurology, where physician shortages exist, also report a high degree of exhaustion. And of course our current situation has only made this worse.

SaraKay: Social science research points to innumerable ways to address, alleviate, and prevent burnout, and I hope that those reading this will study options. It's important to select strategies that are right for you and to allow yourself to think and plan creatively. But to focus specifically on approaches to minimize stress in the medical community: A professional boundary is essential!

Recognize: "My patient and I have a professional relationship. I'm doing

everything I can, and I am giving all I can, but I must know my role and hold to an essential demarcation."

For clarity in my writing, I have concentrated on three primary "attendant syndromes" or faces of what can, without awareness, lead to burnout: **Compassion fatigue** results when we give, and we give. But when the cup is becoming empty we must take a break and care for ourselves. **Vicarious trauma** is lessened by understanding that "the trauma I'm facing now is one that a loved one or I may face, but right now, I'm going to concentrate only on my patient." Sadly, there are times when what we face has really happened in our lives, like taking care of COVID patients after watching a loved one battle the disease. In this case, processing with a colleague or professional can be very helpful.

And there's also **countertransference**—what happens when we deal with draining people in our professional lives. The patients we treat may be challenging; the people we work with may be difficult, and it's important to say to ourselves, "This person is so impossible that I would like to..." It's completely OK not to be "pure in thought," as long as we don't act on it. In other words, you fantasize about throwing a glass of water on someone, but it would be unwise to do so.

Further, some colleagues or patients may make us uncomfortable (to quote a resident, "squirm") because of an unrecognized connection. Awareness through what I call an "Inner-Self Dialogue" reduces anxieties. As an example, in consultation, an internist realized an abusive patient was depleting him because he reminded him of his physically violent dad. This understanding brought relief. The next appointment with this patient was far easier. The physician prepared for this appointment by reminding himself: "Although he seems so much like him, my patient is not

the parent who abused my mom and me. He is a patient requiring my care, which I can offer.” Fortunately, we also see patients who remind us of our delightful grandmother, our wonderful uncle, our generous parent, the terrific others in our lives who bring us joy. And again, appropriate boundaries are always necessary.

Cait: Do you think there are differences between how younger clinicians are coping versus those with more experience? What about how today’s crisis may be affecting nurses differently than physicians?

Stan: There’s a term in healthcare—the second victim—when a patient whose care you have been deeply involved and invested in dies, you are so upset, often grief-stricken. In times like these, it is wise to process this loss with a partner, trusted friend, or professional. When this happens in SaraKay or my professional lives, we always discuss the loss together. But to respond to your question, someone who’s been in practice for a while, who’s dealt with unfairness and grief and developed self-awareness, has practice creating a necessary emotional separation. But that does not mean that pain does not hit—and hit hard. Today it is harder than ever before in my memory.

And yes, I believe that a crisis of loss is harder on younger nurses who are spending many more hours at the bedside than the physician, giving their all. They must have support. They must have people on staff whom they can turn to—trusted colleagues—a place to express and process their feelings freely. Again, I have learned from experience: Don’t bury your feelings. Talk about them. Seek this vital, necessary attention. It’s critical.

SaraKay: To follow Stan’s point about seeking help: People often mistakenly believe that therapy teaches you how to avoid life’s difficulties (and that therapists know

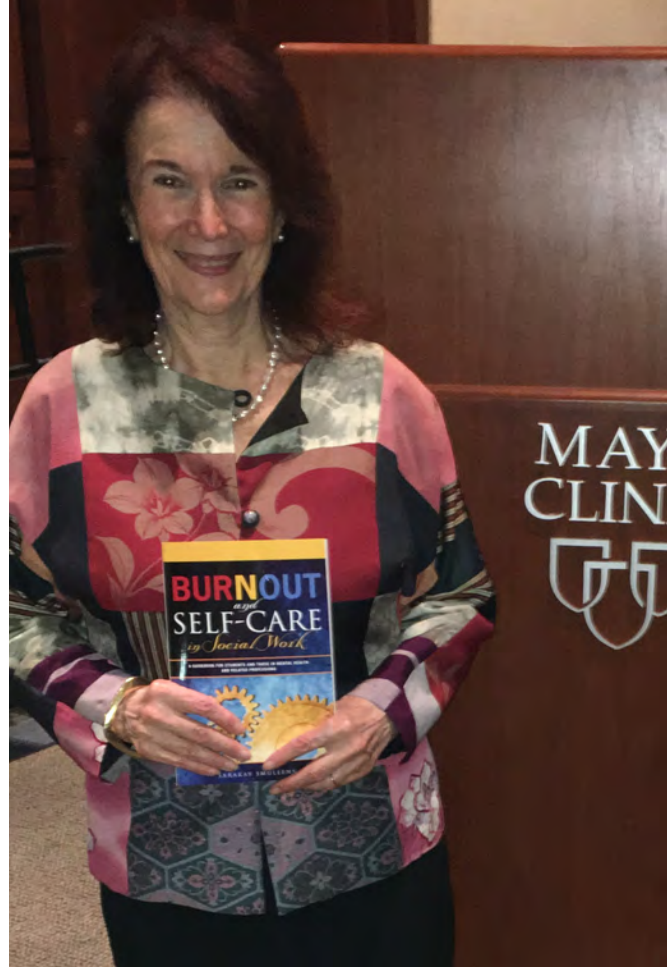
how to do this). Not true! Yes, counseling can help you prevent avoidable problems, such as building your life with untrustworthy people. But living brings unavoidable struggle and pain. What therapy offers are insights, coping strategies, and emotional direction—knowing where to turn when you need help, or in my grandmother’s words, “when life bites.”

Anxiety and tears are appropriate reactions. We’re human. It’s necessary to allow yourself to feel sad and to mourn—this awareness and self-acceptance help to safeguard our emotional and physical strength. Built into every hospital system should be mechanisms to overcome sadness and grief.

As Stan said, we are not supermen and superwomen. Yes, we want so much for our patients, and yet, there are times when life offers us no control other than the way we handle it.

Stan: With this in mind, all systems must provide training and resources to help those on front lines deal with loss and tragedy, and this is happening. A growing number of hospitals and nursing groups are aware of the toll of high-stress, emotionally depleting work, and many institutions have hired wellness officers who ensure the necessary resources and offer training for young physicians, nurses, social workers, and physician assistants—and the entire team.

SaraKay: What Stan and I are pointing to is the interconnectedness of every facet of our lives. When you’re stressed at work, going home to someone who cares is a gift. Not everybody has that. And that’s where friends and supportive extended family members are so important. In addition to those dealing with ill-



▲ SaraKay discussing her book *Burnout and Self-Care* at the Mayo Clinic in Minneapolis, Minnesota

ness, those having the hardest time now are in unstable relationships or return to empty homes.

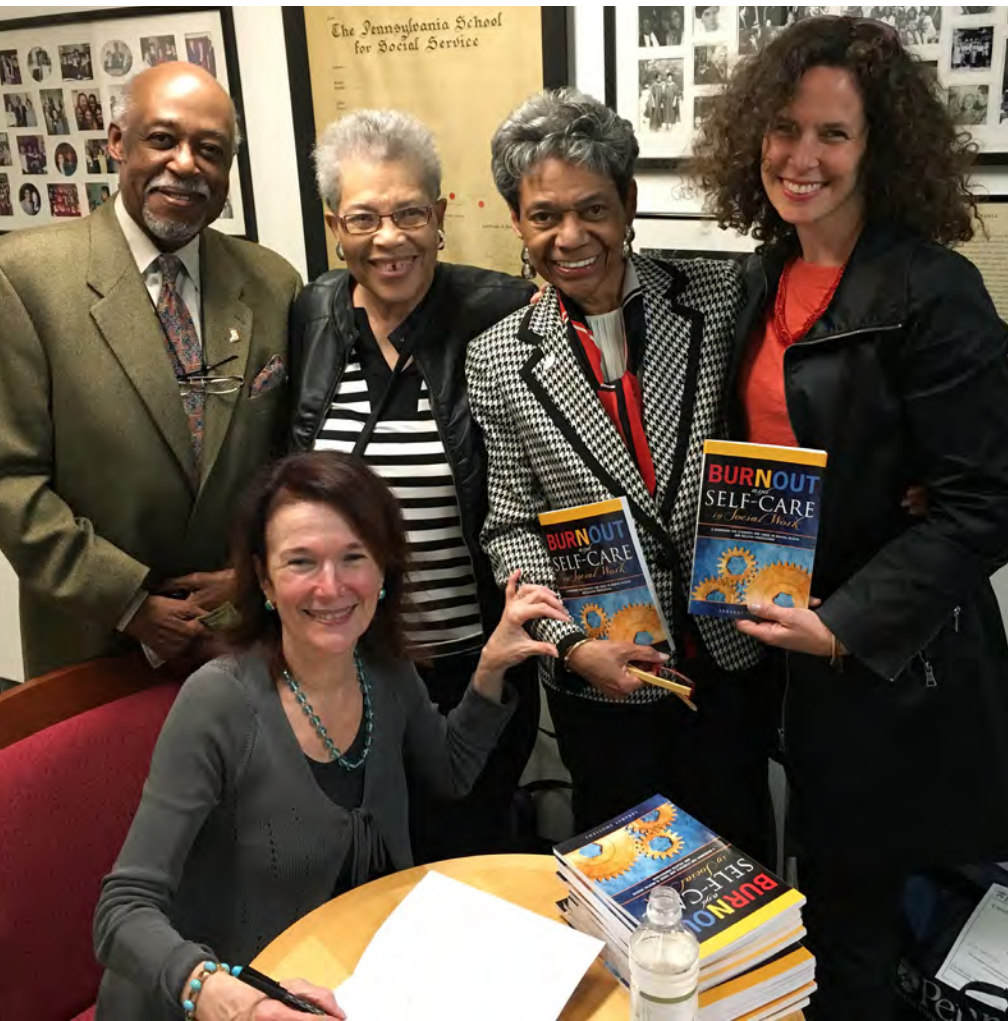
It is essential for those who can connect with and support people who live alone or are in frightening relationships, and, when necessary, offer help and protection. Often, however, our friends who are suffering will not tell us, and our “being there” can make all the difference.

We also have to understand the stresses on parents now who have children to care for day in and day out; who have little time or no time to work out, or just relax; who are adjusting to their or their partner’s work stress (and in frontline families dealing with danger); and who may fear losing their livelihood. Also, parents are now expected to become adept in homeschooling and often quickly realize how long it’s been since they studied the Pythagorean Theorem or the periodic table.



▲ Dr. Smullens being sworn in as chair of the Patient Safety Authority in 2018

▼ SaraKay in 2015 signing books for alumni and faculty at her alma mater, Penn



Cait, with this in mind, I want to describe a zoomed session with a mother of three young children, recovering from breast cancer, who was experiencing both depression and burnout. Her youngest child has severe asthma, and just before our session she learned that her husband lost his job. Of course, in therapy, each intervention to alleviate suffering, offer hope, and restore coping capacity is made with care and awareness.

But before I describe time with my patient, it is essential to emphasize that the suffering, illness, and terror that caregivers see day in and day out stays with us, and today's challenges are unprecedented. Yet, with the tincture of time, teamwork, support, and shared expressions of caring, even the most devastating realities become less piercing and take on a different perspective. And accompanying our memories is sincere gratitude for the privilege of our work—and as Stan always emphasizes—the opportunities to build a better future.

To speak of my patient and our time together: As our session began, her words were frantic, her sobs overwhelming, as she told me, "I have no idea where to turn first. I'm completely overloaded, one thing after another, just as my health and energy were beginning to return." As she described her fear and voiced her anger, tears subsided, and she asked me if I had ever faced overload and overriding fear. I responded with what my life and work have taught me: "Sometimes, when life feels as bad as it can get, that's when it appears to get even worse."

But somehow, we can still find the strength we didn't know we had to get through it." After we did breathing exercises, my patient and I developed a pandemic-adjusted coping action plan and scheduled our next appointment.

Then, a thought came to me, one I had faith in. I knew to lift her spirits

as she returned to myriad responsibilities and drains, I needed something utterly out-of-the-box—something that I believed would make her smile: I suggested we sing together. I won't tell you the song, but I will tell you that I cannot carry a tune. Yet despite all, she laughed; I laughed, and we laughed together. Sometimes laughter really can be the best medicine. Our goodbye was, "To be continued."

Cait: I've also learned the importance of finding hope where you least expect to. This crisis is amplifying the best and the worst parts of human nature. While the negatives often get the most attention, what about other positives? What are some of the bright spots in these dark times that you've been seeing? Do you think any will last as we get through the pandemic?

Stan: With consistency, we see people reaching out to one another. There are many marvelous, deeply inspiring examples of people giving all they can in every way that they can with bravery and positivity, putting themselves in harm's way to do the necessary jobs to safeguard and uplift communities: teachers and principals continuing to educate through social distancing, and so many who staff services, such as markets and food banks, providing depended-upon services. There are neighbors visiting neighbors, in safe ways, and countless examples of compassion and connection everywhere.

SaraKay: Everybody now can see what healthcare professionals give—administering tests, going into hospitals, holding the hands of terrified patients knowing they're also at risk. Separating from their own families and doing everything possible to provide support and calm. The promise of every doctor, nurse, social worker, physician assistant, and healthcare professional is to do all we possibly can for the greater good.



We know there will be other viruses in the future, and we know that each of us is stronger working together than we could ever be as individuals.

I've had a pro bono practice since the mid-90s. It began when Philadelphia District Attorney Lynne Abraham referred carefully selected families involving first-time offenders in domestic violence to me for intensive therapy, rather than incarceration. It now constitutes half of my practice.

Recently, one of my pro bono patients died of COVID-19. I grieve deeply with her compassionate, devoted family. Two other patients are gravely ill, and I must point to the generous, brave care contributions of houses of worship and faith communities and food banks at this surreal and treacherous time. I also feel compelled to say that I long for the time when the most vulnerable among us will be guaranteed healthcare. I cannot wrap my mind around the reality that America does not provide this.

Stan: SaraKay, you are addressing an overwhelming frustration. In addition to being the only industrialized country not to provide healthcare to all, among industrialized nations we have the most expensive per-person healthcare, compounded by the lowest life expectancy. Hopefully, the political process will lead to common ground to confront looming problems bringing societal overload—and highlight that we've got to work together to address what divides and threatens us.

Specifically in medicine: We know there will be other viruses in the future, and we know that each of us is stronger working together, providing care for one another, than we could ever be as individuals.

SaraKay: In our conversation during this critical, frightening period, I think the three of us are talking about the best humankind can offer—doing all that we can, in act and attitude, and we are also talking about love.

Cait: I love this uplifting segue. Stan and SaraKay, where do you think—where do you hope—we might be 10 years from now?

Stan: I hope we'll come through this in a way to make us more ably prepared for the next pandemic because, as stated, there will be another one. I was involved with the H1N1 pandemic of 2009, and since then, we've had SARS, MERS, Ebola. They're coming frequently in our connected world, and my hope is also that this inevitability will improve relationships between countries. I'm cautiously optimistic about that. Our lives depend on global cooperation. The virus knows no borders. We must institute a permanent national pandemic committee, one committed to the importance of science to guide us.



America's ability to grow into adulthood lies in our determination to confront and address what has been simmering, yet long ignored, and come together as one country—simultaneously as a single nation and as a collective 330 million individuals—to finally form a more perfect union.

Maybe most importantly, we need to understand what happened this time. When a safety event occurs, and we seek to understand what transpired, we do a root cause analysis. That information is shared with the hospital and healthcare providers to avoid its recurrence. That is the fundamental way to address an issue where something did not progress as you had hoped.

SaraKay: Stan and I have been talking about this endlessly. Our country, this unpredictable experiment in democracy, is young. We are, in effect, in our adolescence—a period always marked with enormous confusion and conflict. One reason adolescence marks a dangerous, stormy period is the realization of how imperfect our parents are, even those who have done their best, and that they can no longer protect us once we reach adulthood. Those of us who reach adulthood with the most confidence have worked out “unfinished business” with their parents, allowing mutual respect for individuality, ideas, and autonomy.

Like parents with high expectations, we, as a country, were found-

ed with lofty ideals, hope, and promise, and yet, with enormous “unfinished business” in the forms of racism, sexism, prejudice, and hatred toward other human beings. Overtly and subliminally, these pathologies have plagued our society in myriad ways, including in medicine, where patients have been misdiagnosed, mistreated, excluded, or marginalized solely based on fundamental characteristics like race or gender.

Previous attempts to address these destructive forces, while some have been bold, have been largely unsuccessful. Now, following recent, horrific events, strongholds are being forced to hear and listen. America's ability to grow into adulthood lies in our determination to confront and address what has been simmering, yet long ignored, and come together as *one* country—simultaneously as a single nation and as a collective 330 million individuals—to *finally* form a more perfect union.

Stan: I was a history major in college, and I studied how great civilizations fell. I do not believe that the promising underpinnings of

our democracy and our best values will allow us to fail. I am optimistic that together Americans will meet the challenges before us. This is a dream that can and must come true.

Cait: You both have had such accomplished careers that are arguably high stress. Whether as a surgeon doing very complex, high-risk types of surgery—or as a therapist offering everything you can to those in the most difficult, frightening situations of their lives. Have either one of you ever experienced burnout?

Stan: Yes. There have been many times when things have gotten out of hand, but the time that I remember the most distinctly was when I was a senior resident. In those days, we worked every other night, every other weekend. And I remember one period when another resident became ill, and I was on three days straight during an exceedingly busy time—a lot of trauma cases. There were also a couple of patients with vascular emergencies. In one, an artery occluded. In another, an aneurysm ruptured, and emergency operations were necessary, which meant I was up for at

least 48 straight hours and found myself washed out physically and emotionally. I didn't think I could do it anymore. For a short time, I thought, "What am I doing here? Why do I need this? I'm failing."

This period was probably the worst I've ever had. But sunshine came out the next day, and I was able to keep going. SaraKay has also discussed personal burnout. At the time, I did not recognize the exhaustion I was also facing at home. That divorce in my life could not be avoided—for my well-being and the welfare of my children.

SaraKay: My burnout didn't originate from work. I was in my early 30s, had two little children, and realized the necessity of divorce. I didn't have an extended family support system. My family was my two little girls, 4 and 7, and me. I was not depressed; I knew divorce was both right and necessary. But I was overwhelmed and frightened, i.e., burned out. I did not know that term at the time but learned that terror could be a powerful motivator.

I was so fortunate. I had received a full scholarship and modest stipend (a fortune to me!) toward an inspiring graduate degree, an MSW [Master of Social Work]. Throughout my work experience, I was able to get further training and, in time, to afford a divorce and therapy necessary to go through the process. And my burnout morphed into confidence. Sometimes we fall very low, and from that point, find the resilience to become who we want and hope to be.

Stan: You used journaling to help you through it, and that led to your first book, *Whoever Said Life is Fair*?

SaraKay: Cait, Stan jokes that when we met, I was pregnant with my first book. It was published—born—several months later. And yes, I kept a journal to process my thoughts, and, in this way, find strength and direction, and that journal grew

into my first book. Journaling is now an essential part of my self-care that provides an emotional outlet and a place to work through whatever issues I'm currently facing. The process is my search for missing pieces to complete a puzzle and led to each of my books.

Cait: That's such a positive note. Let's end there. Is there anything else that you would like to add?

Stan: Cait, I think we have covered what SaraKay and I try to offer in presentations and webinars. Crisis can lead to hope, and hope can lead to the conviction to come together.

SaraKay: Yes, to come together, heal, and do what is necessary to ensure our future.

Biographies

SaraKay Smullens is a social worker, family therapist, and best-selling author. A diplomate in clinical social work, she is certified as both family life educator and group psychotherapist, as well as a contributor to peer-reviewed literature, and local and national press. SaraKay has written several books, including *Burnout and Self-Care in Social Work: A Guidebook for Students and Those in Mental Health and Related Professions*, which examines primary factors leading to burnout, and the individualized self-care strategies, activi-

ties, and attitudes that address and prevent it. During the past two years her efforts to educate about burnout and self-care have taken her to settings in this country and abroad. A recipient of both a Social Worker of the Year and Lifetime Achievement Award from National Association of Social Workers Pennsylvania Chapter, SaraKay was one of six chosen for the Inaugural Hall of Fame of her graduate school alma mater, the University of Pennsylvania School of Social Policy and Practice.

Stanton N. Smullens is chair of the Patient Safety Authority Board of Directors, a clinical professor of Surgery at Sidney Kimmel Medical College, and a lecturer in the Jefferson College of Population Health. He was the founding president and CEO of JeffCare, the Physician Hospital Organization of Thomas Jefferson University Hospital, and served as chief medical officer of Jefferson Health System from 1997 to 2014. Subsequently he was chief medical officer and then medical director of Network Performance and Quality for the Delaware Valley Accountable Care Organization. Stan is a member of many local and national medical societies and has published widely in the medical literature.

Caitlyn Allen (caiallen@pa.gov) is the director of Engagement of the Patient Safety Authority.



***Crisis can lead to hope,
and hope can lead to the
conviction to come together.***

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