



# PATIENT SAFETY

December 2019 | Vol. 1, No.2

## What's Your *One* Thing?

---

*How one  
boy changed  
patient safety*

How One Coalition  
Transformed Care in  
Camden, NJ, Seven  
Days at a Time

Analyzing Telemetry  
Monitoring Errors:  
Learn the Risks

Leveraging Trigger  
Tools to Identify  
Medication Errors



# LETTER

## *From the Editor*



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

**T**hank you to every reader, author, reviewer, editorial board member, and staff person for making the launch of *Patient Safety* a success. In a short period of time, nearly 7,000 people from over 120 countries and all 50 United States read the inaugural issue. I also extend a special thanks to our patient representatives, who dedicate their time and energy

through this journal and many other initiatives to make care safer for others.

Our December issue features a patient perspective piece by Kristin Aaron, who shares the tragic healthcare journey of her son, Jenson (featured on our cover), and how great change often starts with a single step. Our back inside cover features The Walking Gallery jacket #160 *Cancer for Christmas*. Casey Quinlan, diagnosed with breast cancer just days before Christmas in 2007, leveraged her experience to help others navigate cancer treatment. Quinlan was a charter author for Patients Included™, a nonprofit inspiring organizations to include patients in their work. I am proud to say *Patient Safety* is a Patients Included™ publication.

Also from our cover: Cait Allen, director of engagement and managing editor with the Patient Safety Authority, sat down with Kathleen Noonan, chief executive officer of the Camden Coalition of Healthcare Providers, to talk about some innovative solutions to meet the needs of a very at-risk population. Elizabeth Kukielka and co-authors discuss the findings of a database analysis related to telemetry monitoring; this article was inspired by a deep dive into events in

Pennsylvania that cause high harm and death to patients. And finally, Sara Kolc Brown and co-authors share one facility's initiative to decrease adverse drug events by using trigger tools. Their work contributes to further development of prevention strategies.

I never imagined that one of the most difficult tasks in the publication process would be selecting the papers to feature on our cover. There are so many that equally deserve the spotlight. I hope this will continue to challenge me with each issue. The information, achievements, risk reduction strategies, lessons learned, and individual perspectives are integral pieces to improving patient safety for all. This journal is one avenue to share these valuable resources freely with others. 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](http://patientsafetyj.com).

Wishing you and yours the most joyous holiday season!

## ABOUT PATIENT SAFETY

As the journal of the Patient Safety Authority, committed to the vision of “safe healthcare for all patients,” *Patient Safety* (ISSN 2689-0143) is fully open access and highlights original research, advanced analytics, and hot topics in healthcare.

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

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

All articles are published under the Creative Commons Attribution – Noncommercial license, unless otherwise noted. The current issue is available at [patientsafetyj.com](http://patientsafetyj.com).

The patient is central to everything we do. *Patient Safety* complies with the Patients Included™ journal charter, which requires at least two patient members on the editorial board; regular publication of editorials, reviews, or research articles authored by patients; and peer review by patients.

This publication is disseminated quarterly by email at no cost to the subscriber. To subscribe, go to [patientsafetyj.com](http://patientsafetyj.com).

## PRODUCTION STAFF

**Regina M. Hoffman**, MBA, RN, *Editor-in-Chief*  
**Caitlyn Allen**, MPH, *Managing Editor*  
**Eugene Myers**, BA, *Associate Editor*  
**Jackie Peck**, BS, *Layout Editor*  
**Shawn Kepner**, MS, *Data Editor*

## EDITORIAL BOARD

**Joshua Atkins**, MD, PhD, *Hospital of the University of Pennsylvania*  
**Russell Baxley**, MHA, *Beaufort Memorial Hospital*  
**Mark E. Bruley**, BS, *ECRI Institute (retired)*  
**Michael A. Bruno**, MD, *Penn State Milton S. Hershey Medical Center*  
**Michael R. Cohen**, RPh, MS *Institute for Safe Medication Practices*  
**Daniel D. Degnan**, PharmD, *Purdue University School of Pharmacy*  
**Barbara Fain**, JD, MPP, *Betsy Lehman Center for Patient Safety*  
**Kelly Gleason**, PhD, RN, *Johns Hopkins School of Nursing*  
**Hitinder Gurm**, MD, *Michigan Medicine*  
**Julia A. Haller**, MD, *Wills Eye Hospital*  
**Jennifer Hamm**, BS, *Fred Hamm, Inc.*  
**Ann Hendrich**, PhD, RN, *Building Age-Friendly Health Systems, John A. Hartford Foundation; formerly Ascension Healthcare*  
**Mark Jarrett**, MD, MBA, MS, *Northwell Health*

**Matthew Keris**, Esq., *Marshall, Dennehey, Warner, Coleman & Goggin*  
**Stephen Lawless**, MD, *Nemours Children’s Health System*  
**Michael Leonard**, MD, *Safe & Reliable Healthcare, LLC*  
**James McClurken**, MD, *Doylestown Health, Lewis Katz School of Medicine at Temple Univ.*  
**Patrick J. McDonnell**, PharmD, *Temple Univ. School of Pharmacy*  
**Dwight McKay**, BSL, *Lancaster Rehabilitation Hospital*  
**Ferdinando L. Mirarchi**, DO, *UPMC Hamot*  
**Dona Molyneaux**, PhD, RN, *Thomas Jefferson University Hospital*  
**Gina H. Moore**, BSN, RN, *Christiana Care Health Services*  
**Rustin B. Morse**, MD, *Children’s Health System of Texas*  
**Adam Novak**, MA, *Michigan Health & Hospital Association*  
**Barbara Pelletreau**, RN, MPH, *Dignity Health*  
**Julia C. Prentice**, MSPH, PhD, *Betsy Lehman Center for Patient Safety*  
**Mitesh Rao**, MD, MHS, *Stanford School of Medicine*  
**Cheryl Richardson**, MPH, RN, *Penn State Milton S. Hershey Med. Center*  
**Lisa Rodebaugh**, BS, *Mercy Ministries*  
**Jeffrey Stone**, PhD, *Penn State University*  
**Jennifer Taylor**, PhD, *Drexel University*  
**Carlos Urrea**, MD, *Hill-Rom*  
**Linda Waddell**, MSN, RN, *Wolff Center at UPMC*  
**Eric Weitz**, Esq., *The Weitz Firm, LLC*  
**Margaret Wojnar**, MD, MEd, *Penn State College of Medicine*  
**Zane R. Wolf**, PhD, RN, *LaSalle University*

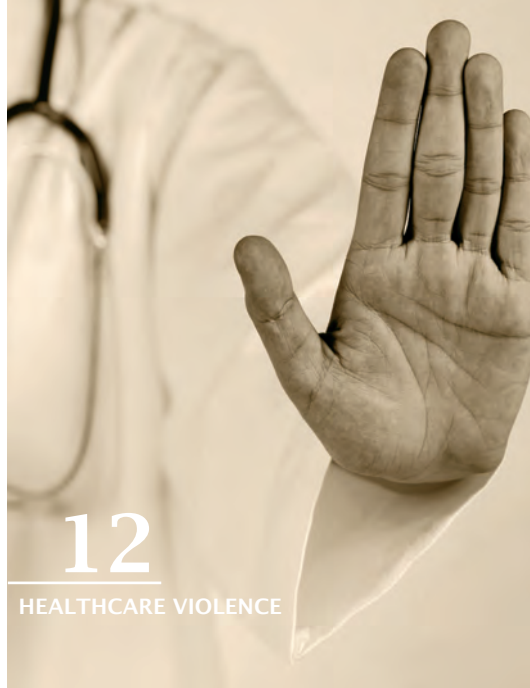
## ACKNOWLEDGMENTS

A special thanks to our reviewers:

**Mark E. Bruley**, BS, *ECRI Institute (retired)*  
**Michael R. Cohen**, RPh, MS *Institute for Safe Medication Practices*  
**Deborah A. Cruz**, MSN, CRNP, *Jefferson Health*  
**Marjorie Funk**, PhD, RN, *Yale School of Nursing*  
**Trenya Garner**, MPA, *Children’s Hospital of Philadelphia*  
**Matthew Grissinger**, RPh, *Institute for Safe Medication Practices*  
**John Gottsch**, MD, *Johns Hopkins*  
**Leslie Hyman**, PhD, *Wills Eye Hospital*  
**Mark Jarrett**, MD, MBA, MS, *Northwell Health*  
**Benjamin Kohl**, MD, *Jefferson Health*  
**Adam J. Krukas**, PharmD, MSHI, *National Center for Human Factors in Healthcare*  
**Patrick J. McDonnell**, PharmD, *Temple University School of Pharmacy*  
**Rustin Morse**, MD, *Children’s Health*  
**Chirag Shah**, MD, MPH, *Ophthalmic Consultants of Boston*  
**Rachele Wilson**, DVM  
**Margaret Wojnar**, MD, MEd, *Penn State College of Medicine*

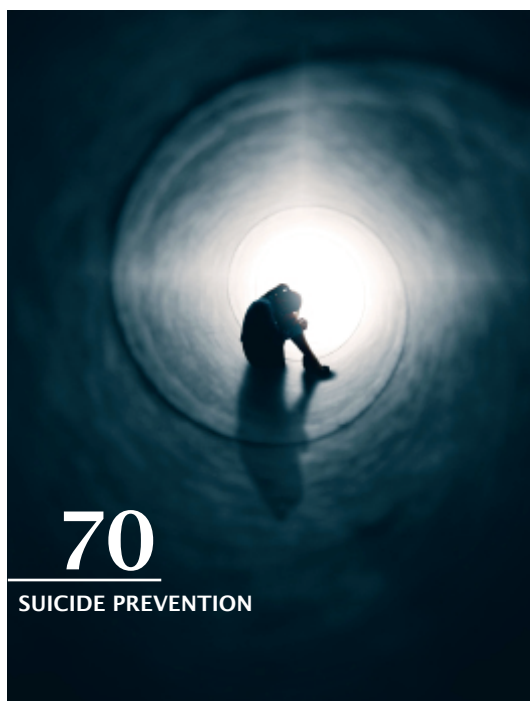
Patient Safety Authority  
333 Market Street - Lobby Level  
Harrisburg, PA 17101  
[patientsafetyj.com](http://patientsafetyj.com)  
[patientsafetyj@pa.gov](mailto:patientsafetyj@pa.gov)  
717.346.0469

# Together we save lives



12

HEALTHCARE VIOLENCE



70

SUICIDE PREVENTION



14

ADVERSE DRUG EVENTS

# Contents

December 2019 | Vol. 1, No.2

## 2 LETTER FROM THE EDITOR

### PERSPECTIVES

#### 6 PATIENT PERSPECTIVE

*KRISTIN AARON*

Cancer was just the beginning for 2-year-old Jenson Aaron. His mother, Kristin, shares his battle with a rare illness; the effects of contracting multiple healthcare-acquired infections; and how her family overcame tragedy to make a lasting, measurable difference.

#### 12 VIOLENCE AGAINST HEALTHCARE WORKERS

*REGINA HOFFMAN*

Assault rates in hospitals this year were the highest on record. Yet, despite bipartisan support, legislative protections across states is inconsistent. How can we ensure violence against healthcare workers is a never event?

#### 82 ONE-ON-ONE: KATHLEEN NOONAN

Camden, New Jersey—when most people were dismissing it as the “Murder Capital of America,” a group of providers saw an opportunity. Seventeen years later, the Camden Coalition has proven that when hard work and ingenuity are mixed with the right blueprint, lasting success can happen anywhere.

### ORIGINAL ARTICLES

#### 14 ADVERSE DRUG EVENTS

*SARA BROWN AND OTHERS*

Adverse drug events are the most common source of patient injury. With the IHI Global Trigger Tool, one hospital was able to identify events more easily than ever before, supporting the old adage “the first step to solving a problem is identifying it.”

#### 24 ENDOPHTHALMITIS

*LYNETTE HATHAWAY AND REBECCA JONES*

An analysis of post-cataract surgery endophthalmitis rates from the Pennsylvania Patient Safety Reporting System and prevention strategies

#### 36 TELEMETRY

*ELIZABETH KUKIELKA AND OTHERS*

Telemetry-related events pose a unique challenge. While they are not the most frequently reported category, those that are reported are typically serious events.



## 45 NEWBORN FALLS

*ELIZABETH KUKIELKA AND OTHERS*

Newborn falls are rare occurrences—or are they? A review of data from the nation's largest event reporting database reveals they may be more common than you think.

## 54 DATA SNAPSHOT: FALLS

*SUSAN WALLACE AND CAITLYN ALLEN*

One in 56 patients fall every year in Pennsylvania hospitals. See the breakdown by age, harm score, and patient days.

## 60 DATA SNAPSHOT: INFUSION PUMPS

*MATTHEW TAYLOR AND REBECCA JONES*

Every day in every hospital, infusion pumps deliver vital medications and nutrients to patients. But what happens when these lifesaving devices stop working?



60  
INFUSION PUMPS

## PATIENT SAFETY INITIATIVES

### 70 SUICIDE PREVENTION

*CHRISTOPHER MAMROL AND OTHERS*

What do IV pumps, clocks, and faucets have in common? They've all been used as ligature points in attempted suicides. Think you know all the risks? Read about the Patient Safety Authority's 2018 keystone project to be sure.

### 78 ANTIBIOTIC STEWARDSHIP

*JOANN ADKINS*

Antimicrobial resistance—when bacteria are no longer sensitive to drugs that have killed or inhibited their growth in the past—is one of the largest global health threats. Learn how Pennsylvania nursing homes addressed the crisis, and ask yourself, “Are you prepared?”



24  
ENDOPHTHALMITIS

## MEDICAL HUMANITIES

### 88 THE WALKING GALLERY: CANCER FOR CHRISTMAS

*CAITLYN ALLEN*

The typical reactions following a cancer diagnosis include devastation, anger, and paralysis—but not for Casey Quinlan. Rather than succumbing to feelings of helplessness, the “Mighty Casey” chose to chronicle her adventures navigating treatment and the healthcare system to guide others on similar journeys.



45  
NEWBORN FALLS

WHAT'S  
YOUR  
**ONE**  
THING?

By Kristin Aaron



I didn't see it coming...  
and it would change  
**everything.**



I had recently returned to work from maternity leave having given birth to our second child, Jenson. Thankfully he was the easiest baby ever: mellow, snuggly, content. But something seemed off.

Bizarre skin conditions kept showing up whenever Jenson got a simple cold or virus. They looked like a scatterplot of red tattoos on his back and groin area. After several outbreaks that looked worse each time, our pediatrician referred us to a pediatric dermatologist, who ordered a biopsy.

I got the phone call at work. The dermatologist introduced herself and got down to business: "I am calling with the results of Jenson's skin biopsy." No small talk, just a long pause. "Jenson has histiocytosis."

"Could you spell that please?" I asked, a hint of fear infecting my voice.

I wrote each letter on a yellow Post-it. As I repeated it back, I hoped this little yellow square could quickly be tossed into the trash. Hopefully histio-whatever was no big deal.

"What is histio-sigh-toe-systs?" I asked curiously, certain I had slaughtered the pronunciation.

"It is a rare blood disorder. It is treated by hematologists and oncologists. Whatever you do, don't go on the internet as there is all kinds of bad information on there," she informed me.

My stomach dropped. A lump filled my throat. Tears welled in my eyes. "Oncologists? Is it cancer?"

"It is a very rare blood disease affecting the immune system. I

am not an expert on it, but I can put you in touch with someone in oncology. I am very sorry," she replied with palpable sincerity. This must be the worst part of her job. We both paused for a moment in awkward silence, said a normal "good-bye" pleasantry, and hung up.

I gazed out my office window in disbelief. We knew the bizarre red dots on Jenson's back weren't normal, but oncologists in his future? There must be some mistake. He was only 5 months old.

I went on the internet to wrap my mind around this bomb that just blew up our lives. I wondered how to tell this news to my husband, Doug, and our young daughter, Sydney.

I quickly learned that with Langerhans cell histiocytosis, the body overproduces white blood

cells, which usually help heal itself when it's under attack by an infection. But in a cruel twist, too many good cells can have the same effect as too many bad cells, and they attack the body instead—eating away at normal tissue and organs. It's treated with chemotherapy by oncologists. It can result in death, especially in children 2 years or younger.

Thoughts circled like vultures. Oncologists? Can result in death?

Shock set in as I shared the news, and we headed down a deep, dark path into the mysterious land of chemo cocktails. Our world had been flipped upside down.

White blood cells raged out of control in Jenson's body, attacking his skin and GI tract, which severely restricted his ability to eat. Chemo treatments at University of California San Francisco (UCSF) became a regular occurrence. I was in awe of the commitment and dedication of the entire oncology staff. You could see their protective nature and deep care of their little patients.

After over a year filled with 25 rounds of chemo, our doctor ordered scans and x-rays to check our progress. The results can be summed up in one evil five-letter word we'd been avoiding since this journey began. A word I hoped to

never hear. Tumor. They said it was a small one in his skull, but the emotions and worry it stirred up felt gigantic and crushing.

It meant several more years of chemo on the horizon and changing up the chemo cocktail mix. We needed help to survive this thing, so we moved to the Dallas area to live near extended family.

A trusted doctor and histiocytosis expert referred us to Children's Medical Center Dallas (Children's Health) and their excellent oncology team. They blew us away with their level of compassion and protection for their patients. Two-year-old Jenson quickly bonded with the





hospital staff. As we'd pull up to Children's Health, he'd proudly point at the red balloon on the logo and say, "That's my hospital."

After three months of treatments on the new chemo cocktails, we felt hopeful. It seemed to be working. It was time to run tests and find out for sure.

Jenson went in for a "routine" endoscopy/colonoscopy to check the status of his GI tract. I sat in the waiting room while Doug paced the halls as usual. I looked up from my book and saw our doctor walking through the waiting room still in his disposable surgery gown. I called Doug and told him to come back immediately. The doctor had a report in his hand and a picture of a dark red/black spot. My heart sank.

He gave us the potential good news—potential because it wouldn't be confirmed until the biopsies came back. "The upper endoscopy procedure went well, and it looks really good in there. I couldn't find any abnormal tissue, so I just biopsied different areas to send out. The colon also looks pretty good although I couldn't get all the way up there, so I biopsied a few spots in there as well."

As he shared the results I kept thinking, Why did he come to meet us in his gown in the family waiting area? That never happens. Then came the bad news about the ugly picture. The physician explained that he had accidentally nicked Jenson's bowel with the scope. We could tell he felt absolutely horrible. In short, it meant emergency surgery to repair the nick. It meant we might lose our little boy.

“

*Yay! It's me. I'm  
the one that gets  
to help Jenson.*



Jenson made it through the procedure with the leak contained. The doctor again sincerely apologized, and we accepted his apology. No one goes into work looking to hurt a child. This would be a day that would haunt him for years to come. But what followed was unthinkable.

As we spent time in other departments at the hospital, I noticed safety processes that differed from those the oncology staff followed: A steady flow of people entered and exited our room without cleaning their hands. I stopped anyone I saw and asked them to clean their hands, but what was happening at night when Doug was sleeping? Why was this department so different from the oncology floor? What else was happening that I wasn't seeing?

My concerns came true as Jenson got three separate hospital-acquired infections while recovering from his surgery. We couldn't believe it. A nicked colon, surgery to repair it, plus three infections from being in the hospital. Aren't hospitals supposed to help you get better?

I had to do more to try to protect Jenson.

I reached out to Jenson's oncology nurses and asked them to teach me, in detail, the best ways to protect him. I learned that the oncology unit treats most, if not all, their patients with special infection precautions while other floors may not do so. The oncology nurses said first and most important in preventing infection is to clean hands. "Don't let anyone touch him who hasn't cleaned their hands with either soap and water or hand sanitizer," they instructed me. "And if they touch a surface anywhere in the room, make them clean their hands again before touching him."

They talked about how to help prevent staph infections by keeping the line that runs to his port clean. "Always wear gloves. No touching the line without gloves. Scrub the hub for 15 seconds with a sterile alcohol pad. Let it dry for 15 seconds more before anything is given into the line."

I took copious notes and swore I'd never let another hospital-acquired infection hurt my boy.

Meanwhile, Jenson's body and disease went into overdrive, sending an overabundance of white blood cells to the rescue. Chemo treatments had to be delayed because he wasn't strong enough to receive them. As Jenson continued his recovery in the hospital, Doug found a bump on Jenson's head. X-rays confirmed our worst fear: Jenson had several tumors in his head.

"How many is several? Two? Ten?" we asked. Jensen's oncologist paused and then said, "Too many to count."

Too many to count. I couldn't hold back the tears. We had failed to protect Jenson. Now the disease had the upper hand.

We tried multiple treatment options before our only path forward became clear. Jenson needed a bone marrow transplant. His 5-year-old sister, Sydney, was his match.

While eating dinner at Jack in the Box, I talked to Sydney about it—random location but right moment.

Sydney dipped her curly fries in a mound of ketchup. "Syd," I said, "remember how they took blood at the hospital to see if mommy, daddy, or you could help Jenson? Well, the tests came back, and one of us can help him."

"Who is it?" she asked curiously.

"Who do you think it is?"

She guessed mommy, then daddy, and then a huge grin appeared on her face. "It's me. Yay! It's me. I'm the one that gets to help Jenson." She beamed with purpose and excitement.

Sydney donated her cells, and we

waited on pins and needles, hoping and praying it worked. Jenson seemed to make progress, so four months after the procedure we began preparing to continue his post-transplant recovery at home.

One day, I sat in his hospital room reflecting. I was so thankful for the incredible care from the bone marrow team; they had given us the gift of time. Jenson absolutely adored his "nurse friends." Without their love and support, we wouldn't have made it through. And his incredible oncologist and nurses had cared for and protected our kids with an unwavering commitment to safety and with compassionate care. It proved a magical combination, a bright spot.

But I couldn't shake the medical errors that caused Jenson's disease to flare up. Horrible mistakes such as a nicked colon can happen, but I knew from my business experience as a director at a Fortune 500 company that process breakdowns like hospital-acquired infections can be fixed.

I had to do something to protect our kids. Maybe sharing our story and some suggestions would make it real for people. I pulled out my laptop and wrote a letter to the

CEO of Children's Health that highlighted both the amazing bright spots we experienced while also calling out the problems that needed to be addressed.

Shortly after my letter was mailed, Jenson passed away. Our world crumbled.

How are you supposed to move forward after the loss of a child?

A few months later, I received a call from the chief quality officer at Children's Health, Dr. Rustin Morse.

"I'm in receipt of your letter... I've never received a letter like this before," Rustin said. I secretly wondered what kind of faux pas I had committed as I tried to remember exactly what I wrote. But he really liked my letter, and he said it inspired him to want to drive change. He liked an idea I had shared about making a video highlighting a specific patient story for the hospital staff. He asked if I'd be willing to share our story as part of the video. Would I also be the first parent on his Quality and Patient Safety Committee?

I said yes to the video and no to the committee.

While filming the video, I saw



L to R: Sydney, Kristin, and Doug Aaron

“  
*How are you  
supposed to move  
forward after the  
loss of a child?*”



“  
Change  
didn't happen  
overnight. But it  
has happened...  
one small step at  
a time.



Dr. Rustin Morse and Kristin

Rustin's deep care and compassion for his patients. He used our story to kick off a new hospitalwide safety campaign and said he'd keep me posted on the progress. He asked again if I'd join his committee, telling me he'd plan the meeting time around my schedule. I said no again.

A few weeks later while running errands, I happened to drive by the Children's Health location near our house. When I saw the sign, I flashed back to the time Jensen proudly pointed at the red balloon on it and declared, "That's my hospital."

The third time Rustin asked me to join his committee, I said yes.

Since 2012, we have been working together with a team of committed healthcare providers to improve safety at Children's Health. And we are making incredible progress in reducing harm to patients, including hospital-acquired infections. I used my business skills around strategic planning to lead Rustin and his team through a session to identify our two-

to-three-year safety roadmap. The safety-and-quality plan is being implemented with a focus on 100% hand hygiene compliance, best practices, ownership at all levels, and a spirit of continual improvement.

Change didn't happen overnight. But it has happened... one small step at a time. Lives are being saved, all because someone listened and acted, people agreed everyone deserves safe care, and they decided not to accept "unacceptable results," but instead strive for excellence and zero harm. I thank Dr. Rustin Morse, his team, and the entire staff at Children's Health for leading the charge and making change happen—for making life better for children.

How can one person drive change? Start with one thing. I never imagined myself as a patient safety advocate, but I took that first step and wrote a letter, which led to sharing our story, which led to becoming a parent safety advocate on a quality and

patient safety committee, which led to leading a strategic planning session, and on it goes.

Imagine if each of us picked one way to make it safer for patients, and that one thing turned into the next thing, and we started a patient safety revolution. We can't do it alone, but we can do it together.

***Everyone deserves safe care. What's your one thing?***

.....  
*Kristin Aaron is a mom, wife, and patient safety advocate sharing Jensen's story at healthcare meetings and conferences to remind healthcare providers to be a bright spot. She is director of Innovation & Business Development at The Clorox Company in the Professional Products Division with a focus around creating safer, healthier public spaces to reduce the burden of illness. In her free time, she enjoys writing, creating handcrafted jewelry, and painting modern art.*

# First Do Not Be Harmed:

## Reducing Violence Against Healthcare Workers

Regina Hoffman\*, MBA, RN

**W**hile working in healthcare has always carried an inherent amount of danger, I can tell you with certainty that the last time I was a staff nurse (in the spirit of transparency—it's been a while) I never once feared going to work. The worst thing that might happen to me on my shift was a patient spitting their applesauce at me while I tried to give them their medications. I never worried about getting shot, stabbed, beaten, or raped.

Violence toward our workforce is unacceptable and is one of the most pressing issues of our time. The International Association for Healthcare Security and Safety Foundation's (IAHSSF) 2019 Healthcare Crime Survey showed assault rates of 11.7 per 100 beds, the highest since IAHSSF began collecting this data in 2012. The report also showed an all-time high rate of disorderly conduct (e.g., disturbing the peace, use of profanity) of 45.2 per 100 beds.<sup>1</sup> The U.S. Bureau of Labor and Statistics reported that 16,890 private industry workers experienced nonfatal trauma from workplace violence in 2016, with 70% of these workers from the healthcare and social assistance industry.<sup>2</sup>

Keep in mind, this is only what gets reported. One study in Michigan showed the rate of injury among healthcare workers was up to three times higher than what was reported by the Bureau of Labor and Statistics.<sup>3</sup> Another study from two large health systems in North Carolina and Texas showed 50.4% of respondents experienced type 2 violence—physical assault, physical threat, and verbal abuse—during their careers, and 39% of respondents experienced the same in the previous 12 months. Only 19% of these incidents were reported into their formal reporting structure, and 38% of these workplace violence victims feared for their safety.<sup>4</sup>

Think about that for a moment—38% of respondent victims are working in fear. If staff are constantly

worried about their own physical safety, and that of their coworkers and patients, how can they be expected to concentrate during a 12-hour shift? Studies show exposure to violence impacts healthcare workers and leads to missed time, burnout, decreased productivity, and an overall reduction in job satisfaction.<sup>5,6,7</sup> This is nothing less than a crisis.

### Tackling Violence

So, what can we do? There are no easy answers. Violence in our society is a multifactorial problem that requires broad-based intervention. Research on reducing workplace violence is limited or difficult to find. One recent study, conducted by the College of Human Medicine at Michigan State University, examined seven hospitals' efforts to standardize workplace violence reporting and prioritize areas of risk using a risk matrix strategy.<sup>10</sup> The next phase observed the ability of specific interventions to reduce workplace violence. Key takeaways included: specific unit-level data was provided to each intervention group; unit-level action planning reflected guidelines from the Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control, National Institute for Occupational Safety and Health (CDC, NIOSH); and, while the incidence rate of events and injuries did not show a decrease from baseline in the intervention group, the control group did show a significant increase in incidence rate of post-intervention events and injuries.<sup>11</sup> While this study makes an important contribution to the field, more research must be done. A lot more. This, however, cannot be an excuse for inaction.

Hospitals, communities, and legislators will have to work together to even begin to make a dent. There are numerous resources available for hospitals through

\*Patient Safety Authority  
Disclosure: The author declares that they have no relevant or material financial interests.



sources such as OSHA, professional societies, and local and state law enforcement agencies, but their use isn't mandated. Federal bills H.R. 1309 and S. 851, the Workplace Violence Prevention for Health Care and Social Service Workers Act, which would require certain healthcare facilities to develop and implement workplace violence prevention plans, were introduced on February 19, 2019, and March 14, 2019, respectively; despite bipartisan support, both sit in committee.<sup>8,9</sup>

Several bills to prohibit violence against healthcare practitioners are also currently pending in Pennsylvania. These include Senate Bill 351 and House Bill 1879, which would expand current legislation to upgrade penalties for assault against all healthcare practitioners,<sup>12,13</sup> and House Bill 39, Senate Bill 842, and House Bill 1880, which would allow healthcare employees to omit their last names from hospital ID badges.<sup>14-16</sup>

“

*Protection of our healthcare workforce shouldn't be dependent upon where they work, and violence should never be a condition of employment.*

To reduce violence in healthcare, we must also address violence in the community. Just as healthcare doesn't stop at the hospital exit, our societal problems don't stop at the entrance. One relatively simple but critical starting point may be partnering with key stakeholders and conducting community health needs assessments (CHNAs). Interestingly, in a study of the CHNAs of 77 hospitals in 20 high-violence U.S. cities, only 32% identified violence as a high priority, and 26% of the CHNAs made no mention of violence at all. This study concludes that hospitals may not see violence as an actionable item that they can address.<sup>11</sup> We must resolve this disconnect.

Unfortunately, not all dangerous situations are avoidable. There are times that involuntary mental impairments prohibit a person from knowing they are committing an act of violence. That patient who spit their applesauce on me had advanced Alzheimer's disease. Some patients have terrible, uncontrollable, and unpredictable reactions to general anesthesia that make them hallucinate and become violent as they awaken. Others can experience episodes of acute delirium due to disease process or medications.

Those situations are not the same as willfully harming staff, including when under the influence of illegal drugs and alcohol. Someone's accountability for their actions doesn't stop at the point of intoxication just because they are in a hospital, the same as accountability doesn't stop when they are behind the wheel of a car. Those patients may no longer be in control, but that should not absolve them of the consequences of their actions. We need to support our staff and hold perpetrators accountable to the full extent that the law allows.

Clearly, our work is cut out for us.

What practices have you put in place to reduce violence? We would love to read about your studies, your stories, and your opinions related to this critical issue. Send them to [PatientSafetyJ@pa.gov](mailto:PatientSafetyJ@pa.gov).

## References

1. Vallani KH. 2019 *Healthcare Crime Survey*. International Association for Healthcare Security & Safety; April 5 2019. IAHSF-F CS-19. Available from: <https://iahsf.org/assets/2019-Healthcare-Crime-Survey-IAHSF-Foundation.pdf>.
2. The National Institute for Occupational Safety and Health. Occupational Violence. <https://www.cdc.gov/niosh/topics/violence/fastfacts.html>. Accessed: Oct 11, 2019.
3. Rosenman KD, Kalush A, Reilly MJ, Gardiner JC, Reeves M, Luo Z. How Much Work-Related Injury and Illness Is Missed by the Current National Surveillance System. *J Occup Environ Med*. 2006;48(4):357-365.
4. Pompeii LA, Schoenfisch AL, Lipscomb HJ, Dement JM, Smith CD, Upadhyaya M. Physical Assault, Physical Threat, and Verbal Abuse Perpetrated Against Hospital Workers by Patients or Visitors in Six U.S. Hospitals. *Am J Ind Med*. 2015;58:1194-1204.
5. Eker HH, Özder A, Tokaç M, Topçu İ, Tabu A. Aggression and Violence Towards Health Care Providers, and Effects Thereof. *Arch Psychiatry Psychother*. 2012;14(4):19-29.
6. Wolf L, Delao AM, Perhats C. Nothing Changes, Nobody Cares: Understanding the Experience of Emergency Nurses Physically or Verbally Assaulted While Providing Care. *J Emerg Nurs*. 2014;40(4):305-310.
7. Nachreiner NM, Gerberich SG, Ryan AD, McGovern PM. Minnesota Nurses' Study: Perceptions of Violence and the Work Environment. *Ind Health*. 2007(45):672-678.
8. Workplace Violence Prevention for Health Care and Social Service Workers Act, H.R.1309. <https://www.congress.gov/bills/116th-congress/house-bill/1309>.
9. Workplace Violence Prevention for Health Care and Social Service Workers Act, S. 851(2019). <https://www.govtrack.us/congress/bills/116/s851>. Accessed: Oct 23, 2019.
10. Arnetz JE, Hamblin L, Ager J, et al. Application and Implementation of the Hazard Risk Matrix to Identify Hospital Workplaces at Risk for Violence. *Am J Ind Med*. 2014(57):1276-1284.
11. Arnetz JE, Hamblin L, Russell J, et al. Preventing Patient-to-Worker Violence in Hospitals: Outcome of a Randomized Controlled Intervention. *J Occup Environ Med*. 2017;59(1):18-27.
12. Senate Bill 351. <https://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=202019&sInd=0&body=S&type=B&bn=0351>. Accessed: Oct 11, 2019.
13. House Bill 1879. <https://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=2019&sInd=0&body=H&type=B&bn=1879>. Accessed: Oct 11, 2019.
14. House Bill 39. <https://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=2019&sInd=0&body=H&type=B&bn=0039>. Accessed: Oct 11, 2019.
15. Senate Bill 842. <https://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=2019&sInd=0&body=S&type=B&bn=0842>. Accessed: Oct 11, 2019.
16. House Bill 1880. <https://www.legis.state.pa.us/cfdocs/billInfo/billInfo.cfm?sYear=2019&sInd=0&body=H&type=B&bn=1880>. Accessed: Oct 11, 2019.



# Evaluation of Trigger Tool Methodology Related to Adverse Drug Events in Hospitalized Patients

By Sara Kolc Brown<sup>♦◇</sup>, PharmD,  
Jacob Peterson<sup>+</sup>, PharmD,  
Shayne Harris Schiedel<sup>◇</sup>, PharmD, MBA  
& Kari Vavra Janes<sup>\*</sup>, PharmD, BCPS

DOI: 10.33940/med/2019.12.2

<sup>♦</sup>Corresponding author

<sup>◇</sup>Meijer Pharmacy

<sup>+</sup>Spectrum Health

<sup>\*</sup>Spectrum Health, Ferris State University

At the time of the project, Dr. Brown, Dr. Peterson, and Dr. Schiedel were PharmD students at the Ferris State University College of Pharmacy in Big Rapids, Michigan.

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







## Abstract

**Purpose:** To determine why an inpatient has had one of the following occurrences in the electronic health record due to an adverse drug event (ADE): international normalized ratio (INR) > 6, plasma blood glucose  $\leq$  50 mg/dL, or naloxone administration use. Utilizing the Institute for Healthcare Improvement (IHI) Global Trigger Tool, the information gathered will be used to determine how to prevent these events from occurring in the future.

**Summary:** The positive predictive value (PPV) for elevated INR was 35% (confidence interval [CI] 21–53%), hypoglycemia was 70.4% (CI 62–78%), and 53% for naloxone administration (CI 45–60%). Drug interactions were the most common factor that may have contributed to an elevated INR, with a mean INR of 7.9. Basal insulin monotherapy, recent diet changes, decreases in renal function, and discontinuation/tapering of corticosteroids were all observed to be contributing factors to hypoglycemia events. The mean trigger glucose level was 42.98 mg/dL. Dose range order sets, high morphine milligram equivalents (MME), and decreased renal function may have contributed to naloxone administration. Polypharmacy was attributed to some of these adverse events, with the average inpatient MME of 100.5 mg.

**Conclusion:** The use of trigger tool methodology was useful for identifying ADEs related to hypoglycemia with insulin, moderately useful for naloxone administration, and least successful for elevated INR with warfarin. The ADEs that were identified revealed a wide variety of contributing factors that can be used as areas of interest when creating new policies and procedures to reduce ADEs in the future.

**Keywords:** *global, trigger, tool, naloxone, INR, hypoglycemia*

## Introduction

The Institute for Healthcare Improvement (IHI) defines patient harm as “unintended physical injury associated with medical care that requires additional monitoring, treatment, or hospitalization, or that results in death.”<sup>1</sup> Adverse drug events (ADEs) are the most common source of patient injury and have been estimated to affect 19% of inpatients in Western countries.<sup>2,3</sup> An ADE

is defined as an injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses.<sup>4</sup> To reduce patient harm and improve patient care, Spectrum Health in Grand Rapids, Michigan, has partnered with the Michigan Health & Hospital Association Keystone Center (MHA Keystone Center), which is part of the Great Lakes Partners for Patients Hospital Improvement

Innovation Network (Great Lakes HIIN).<sup>5</sup> The emphasis of the HIIN is national harm reduction, with 11 areas being specifically mentioned.<sup>6</sup> One of the core areas of harm that the HIIN seeks to reduce is ADEs with a focus on warfarin-induced international normalized ratio (INR) > 6, insulin related plasma glucose  $\leq$  50 mg/dL, and naloxone administration.<sup>6</sup> The MHA Keystone Center measures and reports these areas of harm monthly.<sup>7</sup> Each of the agents implicated for ADEs (warfarin, insulin, and opioids) is considered a high-alert medication by the Institute for Safe Medication Practices (ISMP).<sup>8</sup> The objective of this quality-improvement project was to determine why an inpatient has had one of the following adverse event triggers: an INR > 6, a plasma glucose  $\leq$  50 mg/dL, or naloxone administration. The data from this project could be used by the institution to help establish new policies and procedures to prevent these events from occurring in the future.

“  
*The use of trigger tool methodology was useful for identifying ADEs related to hypoglycemia with insulin and naloxone administration.*”

Trigger methodology is designed to detect ADEs through a systematic search for “flags” such as the administration of a reversal agent or specific laboratory values.<sup>2</sup> Trigger methods have been found to have higher sensitivity and specificity compared to more conventional methods for detecting ADEs, such as voluntary reporting systems.<sup>9</sup> Although this trigger methodology provides rapid identification of potential ADEs, a deeper understanding of the causes and trends of ADEs should be examined to prevent future occurrences.<sup>2</sup> Inpatient facilities of the institution currently quantify ADE triggers for elevated INR, hypoglycemia in insulin-receiving patients, and naloxone administration, but have not previously used the trigger tool to identify underlying trends.

## Methods

---

This project retrospectively reviewed adverse event triggers for patients with an INR > 6, a plasma glucose ≤ 50 mg/dL, or naloxone administration at all of the institution’s inpatient adult facilities. An institutional review board (IRB) protocol was submitted; however, it was deemed a quality-improvement project and exempt from IRB approval. A quality reports dashboard was utilized to capture trigger events. For each trigger, the dashboard reported the time and date of the event, the location, the patient identification number, and the lab value (for INR and blood glucose) or naloxone administration. The electronic health record (Cerner®) was then reviewed for each trigger event to determine eligibility. Trigger events starting January 1, 2017, were reviewed by three fourth-year student pharmacists, and data was collected until 100 adverse events were identified, or until a trigger event date of August 1, 2017, was reached. Of note, patients with multiple triggers during an admission were only counted as one event.

Eligible patients had to have inpatient status. Vulnerable populations, including children (less than 18 years of age), pregnant women, and prisoners, were excluded. These populations were excluded based on the initial IRB application to the institution and as stated in the Code of Federal Regulations.<sup>9</sup> Additional inclusion and exclusion criteria for each trigger are listed in **Table 1**.

After determining eligibility for inclusion, each trigger was then assessed using a screening tool. Trigger events had to meet all screening criteria to be considered an adverse drug event. The screening

tool criteria was adapted from another institution and modified for this project. Screening criteria for each trigger are listed in **Table 2**.

Trigger events meeting all inclusion and screening criteria then underwent a full chart review and data collection. Data collected for all triggers included age, sex, reason for hospitalization, creatinine clearance (CrCl), liver function, chronic health conditions, if the patient transferred, whether a code blue was called, and whether a medication error occurred (including type of error and cause). Additional data collection points included the dose, route, and timing of precipitating agent(s); dose and timing of the reversal agent(s); patient status (e.g., symptoms, severity, respiratory rate, and oxygen saturation for the naloxone trigger); and opioid naïve status and home opioid regimen (for the naloxone trigger). Finally, data pertaining to risk factors that may have contributed to the trigger event was collected (e.g., interacting medications, diet changes, inappropriate dosing for age or weight, etc.).

## Data Analysis

Data was deidentified and analyzed in Excel. Descriptive statistics were utilized for baseline characteristics, and a positive predictive value (PPV) was calculated for each trigger using the number of adverse events that met the screening tool criteria divided by the total number of trigger events that met the inclusion criteria.

## Results

---

### Elevated INR

A total of 77 positive triggers were identified for INR > 6 (**Figure 1**). Of these, 37 met inclusion criteria and 13 met screening criteria for classification as adverse drug events. The PPV was calculated to be 35% (CI 21–53%). Patients were initially included for chart review if they had an INR > 6 trigger and were also receiving warfarin therapy. If the INR > 6 was present on admission, patients were excluded. The 24 patients that did not meet screening criteria included those for whom no reversal agent was given (n=9), warfarin reversal was used for procedure (n=2), a laboratory error occurred (n=5), or no bleeding occurred (n=8). Patients were considered to have experienced an ADE if the elevated INR was associated with the anticoagulant, if there was a clinical intervention, and if there was evidence of bleeding. For the 13

**Table 1: Trigger Inclusion and Exclusion Criteria**

	Inclusion Criteria	Exclusion Criteria
<b>Elevated INR</b>	INR > 6 Receiving warfarin anticoagulation therapy	INR > 6 present on admission
<b>Hypoglycemia</b>	Plasma glucose ≤ 50 mg/dL	Patients with hypoglycemia present on admission Non-insulin-receiving patients
<b>Naloxone</b>	Patient received opioid medications (any route) Naloxone was administered	Naloxone administration in the emergency department or freestanding/independent surgery centers

**Table 2: Trigger Screening Criteria**

	Screening Criteria	Notes
<b>Elevated INR</b>	Associated with anti-coagulant?	Exclude if high INR but not on warfarin or other anticoagulant that has an INR effect or high INR with liver disease or malnutrition.
	Clinical intervention?	Patient must have received vitamin K, FFP, or other treatment agent. Holding a dose of warfarin is not considered a clinical intervention. Planned reversal before/after a procedure is not an intervention.
	Bleeding?	Some evidence of bleeding must be present (hemoglobin drop, nosebleeds, etc.). <sup>a</sup>
<b>Hypoglycemia</b>	Legitimate screen?	Exclude if bedside point-of-care glucose is low, but subsequent plasma glucose is > 50 mg/dL.
	Associated with insulin?	Exclude if patient is not receiving insulin.
	Clinical intervention?	Patient must have received D50W, glucagon, juice, etc. Reducing or holding a dose of insulin is not included as an intervention.
<b>Naloxone</b>	Legitimate screen?	Exclude if naloxone is not charted as administered.
	Associated with narcotic?	Exclude if naloxone is given to rule out symptoms caused by opioids with no response.
	Clinical intervention?	Reducing or holding a dose of opioid is not a clinical intervention. Planned reversal, such as naloxone reversal following a procedure, is also not a clinical intervention.
	Oversedation?	Exclude if the patient only experienced nausea or pruritus. Also, exclude if the respiratory symptoms can be attributed to something other than opioids.

<sup>a</sup>The original screening criteria only specified a hemoglobin drop; however, the criteria was later revised to a hemoglobin drop ≥ 2 g/dL, as this is more clinically significant

ADEs, 61.5% (n=8) of patients were female, the mean age was 70.3 years, and 61.5% (n=8) of patients had been on warfarin at home versus newly starting it in the hospital. Atrial fibrillation was the most common reason for therapy (n=7), followed by cardiac thrombosis (n=4), venous thromboembolism (n=3), and aortic stenosis (n=1). Two patients had more than one indication noted. The mean INR was 7.9. Patients often had more than one INR > 6, but the

first triggering INR was used to determine the mean. The most common reversal agent was vitamin K 5 mg by mouth (16 doses) followed by vitamin K 2.5 mg by mouth (3 doses), fresh frozen plasma (FFP) (3 doses), and vitamin K 5 mg subcutaneously (2 doses). Patients often received more than one dose of vitamin K. Factors contributing to INR > 6 included liver dysfunction (n=3), drug interactions (n=6), nutrition changes (n=1), and inappropriate dosing/titration



(n=3). Two patients had more than one contributing factor and another two did not have any identifiable factors. Interacting medications of note included piperacillin/tazobactam, azithromycin, fluconazole, hydrocortisone, cefepime, and metronidazole.

### Hypoglycemia

A total of 148 positive triggers were identified for plasma glucose  $\leq 50$  mg/dL. Of these, 142 met inclusion criteria and 100 met screening criteria for classification as adverse drug events. Of the 6 patients excluded, 5 had hypoglycemia upon admission and 1 patient was pregnant. For events that did not meet screening criteria, the top reasons for the event being screened out as an ADE were no intervention given for hypoglycemia (n=19), plasma glucose  $>50$  mg/dL upon recheck (n=13), and the patient having no recent exposure to hypoglycemia agents that could have led to the hypoglycemia (n=10). The PPV was calculated to be 70.4% (CI 62–78%). **Figure 2** outlines the chart review process for the hypoglycemia trigger. For the 100 ADEs, 43% (n=43) of patients were female, the mean age was 63.97 years, and 88% (n=88) of patients had diabetes mellitus. Decreased renal function was common with 30% (n=30) and 27% (n=27) of patients having a creatinine clearance  $< 30$  mL/min or 31–60 mL/min, respectively. Insulin glargine alone (n=49, 49%) and insulin glargine/insulin lispro (n=30, 30%) were the most common insulin regimens associated with hypoglycemia. Insulin lispro alone, insulin regular (IV continuous or IV push), and other subcutaneous agents were less commonly involved. The mean trigger glucose level was 42.98 mg/dL. Patients often had more than one glucose level  $\leq 50$  mg/dL, but the first triggering glucose was used to determine the mean. The most common reversal agent was dextrose 50% (50 events) followed by oral glucose tablets (32 events), food/sugary beverage (10 events), and a combination of interventions (8 events). Factors contributing to plasma glucose  $\leq 50$  mg/dL included diet changes (n=42) and co-administration of dysglycemic agents (n=20). Contributing factors could not be identified for all patients. Diet changes incorporated patients with nothing by mouth (NPO) orders, decreased appetite, or diet reinitiation without adjusting the home insulin dose. The most common dysglycemic agent class was corticosteroids, which were either discontinued or tapered without sufficient insulin dose adjustment in 15% of events (n=15).

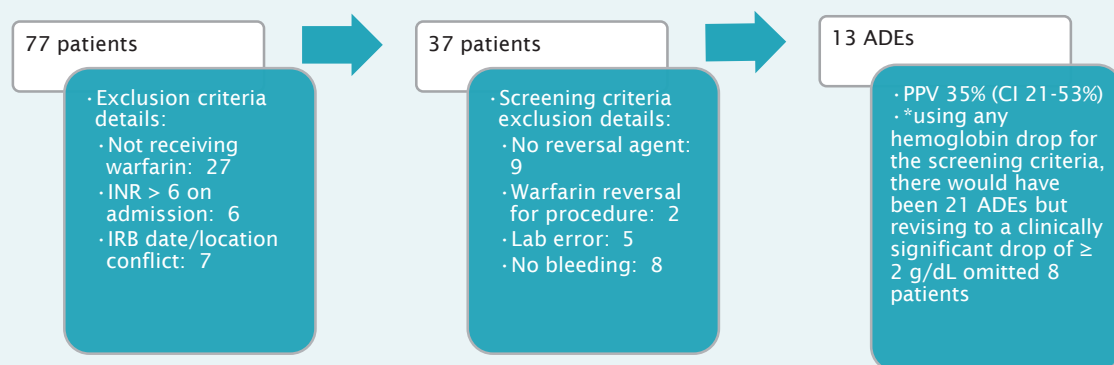
### Naloxone

A total of 201 positive triggers were identified for naloxone. Of these, 190 met inclusion criteria and 100 met screening criteria for classification as adverse drug events. The 90 patients that did not meet screening criteria were due to a few reasons, such as naloxone was administered, but the patient was never given a narcotic, or naloxone was used as a planned, clinical intervention (e.g., used to wake up a patient following surgery). The PPV was calculated to be 53% (CI 45–60%). **Figure 3** outlines the chart review process for the naloxone trigger. For the 100 ADEs, 57% (n=57) of patients were female, the mean age was 64.5 years, and 49% (n=49) patients were opioid naïve prior to hospitalization. Chronic health conditions of note included renal dysfunction (CrCl  $< 50$  mL/min) in 30 patients (30%), liver dysfunction in 3 patients (3%), respiratory disease in 41 patients (41%), heart disease in 44 patients (44%), and pain in 63 patients (63%). The mean home morphine milligram equivalents (MME) in a 24-hour period was 56.1 mg (range 0–564 mg) with 47 patients (47%) receiving 0 mg. The mean inpatient MME in a 24-hour period was 100.5 mg (range 0–683 mg) with 60 patients (60%) receiving  $\geq 50$  mg. The mean difference between home and inpatient MME was -44.3 mg (range -490 to 470 mg) indicating that patients received more MME inpatient than outpatient. The mean naloxone dose was 0.24 mg (range 0.04–2 mg) and the mean number of naloxone doses was 1.6 (range 1–9; one patient received a naloxone infusion). Factors contributing to the need for naloxone administration included concomitant sedatives (n=33), sleep apnea (n=12), concomitant antihistamines (n=5), polypharmacy (n=91), obesity (n=13), coincidental stroke (n=3), and inappropriate dosing for age or weight (n=4). Patients could have more than one contributing factor. A variety (n=22) of other contributing factors were identified such as pneumonia, anemia, chronic obstructive pulmonary disease (COPD), etc.

### Discussion

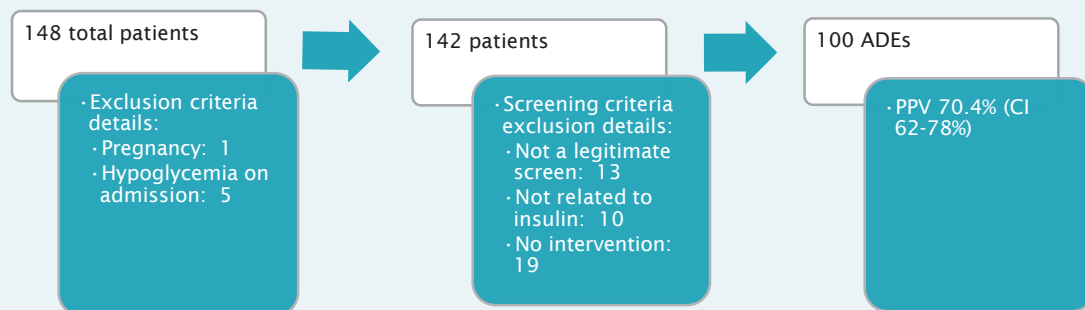
A systematic review by Musy et al. evaluated and described 10 studies using trigger methodology.<sup>11</sup> Their review included consideration of INR, hypoglycemia, and naloxone triggers. The observed PPV ranged from 10.8–100% for INR, 15.8–60% for hypoglycemia, and 20–91% for naloxone.<sup>11</sup> Musy et al. noted significant variation between the studies

**Figure 1: Chart review process for INR > 6 trigger**



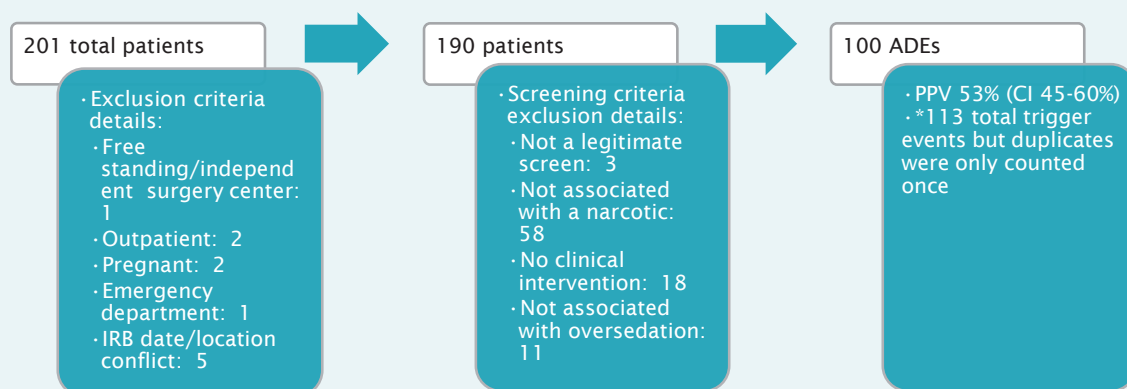
INR: international normalized ratio; IRB: institutional review board; ADEs: adverse drug events; PPV: positive predictive value; CI: confidence interval

**Figure 2: Chart review process for plasma glucose  $\leq 50$  mg/dL trigger**



ADEs: adverse drug events; PPV: positive predictive value; CI: confidence interval

**Figure 3: Chart review process for naloxone trigger**



IRB: institutional review board; ADEs: adverse drug events; PPV: positive predictive value; CI: confidence interval

in terms of PPV despite the use of similar triggers and recommended greater standardization of trigger studies, especially with regard to population, ADE and trigger definitions, reviewers, methods, and reporting.<sup>11</sup> With our project, we focused on adult patients over the course of a seven-month period, and the other studies looked at adults or children over shorter or longer periods.<sup>2,9,12-19</sup> For INR, some of the studies used INR > 4 as the trigger.<sup>12-14</sup> For hypoglycemia, some of the studies used the same glucose level  $\leq 50$  mg/dL trigger, while others had a different glucose threshold and/or used IV glucose bolus administration as the trigger.<sup>2,13,15-18</sup> For naloxone, all of the studies used naloxone administration as the trigger, but some added additional specifications (e.g., opioid order, respiratory depression, etc.).<sup>9,12,13,15,19</sup> Our project was done retrospectively while some studies were evaluated in real-time shortly thereafter instead of months later.<sup>2,9,12-19</sup> Some studies had ADEs verified by an expert (e.g., endocrinologist, anesthesiologist, etc.) which was not done in our project.<sup>2,9,12-19</sup> Although our quality-improvement project found comparable PPVs to other studies, it is difficult to make conclusions about our findings relative to other studies given the aforementioned variables.

### **Elevated INR**

Drug interactions were the most common factor that may have contributed to an elevated INR. Some of these patients were already taking warfarin when an interacting medication was started, while others were started on warfarin while taking an interacting medication. In both cases, the warfarin dose was not adjusted accordingly.

This institution does not currently have a warfarin dosing protocol, but rather it is provider specific. Currently, a pharmacist-led warfarin dosing service is being developed. This will hopefully result in more standardized dosing protocols, and decrease the amount of variability in dosing. Additionally, INR monitoring will be followed more closely with this service; therefore, there will be closer review of drug-drug interactions, nutrition concerns, dosing, and liver function assessment.

### **Hypoglycemia**

Basal insulin monotherapy, recent diet changes,

decreases in renal function, and discontinuation/tapering of corticosteroids were all observed to be contributing factors to hypoglycemia events. Interventions to reverse hypoglycemia, especially sugary liquids or foods, were not documented in one universal location in the electronic health record. In some instances, the ambiguity of intervention documentation excluded the event from being considered an ADE.

This institution does not currently have an insulin dosing adjustment protocol beyond initial dosing recommendations, but rather adjustments are provider specific. Dosing algorithms and alerts for renal dysfunction, basal insulin monotherapy, and high insulin doses could be considered.<sup>20</sup> Limiting high dose insulin orders to endocrinology staff and/or a protocol to taper supplemental insulin along with the corticosteroid taper might be useful as well.<sup>21,22</sup> Although there is not one evidence-based method for solving hypoglycemia related to diet changes within health systems, improving communication and documentation could prevent hypoglycemia events. Education, improved documentation of the times and plans for meals and insulin coverage in the electronic health record, and increased communication could decrease hypoglycemia in these situations. Lastly, compliance requiring one specific location for hypoglycemia reversal could improve documentation related to trigger events for quality improvement purposes and improve the PPV of the trigger tool.

### **Naloxone**

Dose range order sets, high MME, and decreased renal function may have contributed to naloxone administration. At the time of this project, the order sets within Cerner® included dose ranges (e.g., hydrocodone/acetaminophen 5/325 mg 1–2 tablets by mouth every four hours. Start with one tablet and if pain not controlled, may increase to two tablets). The higher end of the range was commonly given before trialing the lower end of the range. Despite the average MME being 56.1 mg outpatient, inpatients were receiving almost double that amount, with an average of 100.5 mg. Although most opioids do not have to be renally adjusted, if a patient is not clearing the drug, the metabolites are building up and can cause an adverse event. This project had 87 patients (87%) that were greater than or equal to 50 years old.



Additionally, naloxone indication documentation was an issue encountered during this project, leading to many patients being excluded.

This institution currently does not have any type of pain protocol or stewardship program in place. Adjustments to current practice to address the above contributing factors could include requiring documentation that the patient has tried lower dose ranges before increasing the dose, adding a calculation system for MME into the electronic health record, and/or creating a renal dose adjustment policy for opioids. The indication for naloxone administration should be charted along with the time of administration. The institution is currently working on a variety of projects and policies to prevent ADEs. There is an ongoing audit with the medication history team to help assess gaps, monthly naloxone use data is being followed by the Pain Management and Opioid Prescribing Steering Committee, and a pain stewardship program was planned to be piloted in April 2018.

## Strengths and Limitations

The data collected during this quality-improvement project was from 2017 and very relevant to the patient population we aim to serve today. Data was collected by three fourth-year student pharmacists, with one student being responsible for each of the trigger medication categories, to reduce variances in chart reviewing and improve overall consistency. Additionally, a screening tool was utilized for each of the triggers to assist the students in determining if an ADE truly occurred. Using a screening tool ensured that ADEs were determined objectively. Collecting data from all of the institution's inpatient facilities allowed for a wide range of contributing factors to be observed, since data was collected from small and large facilities.

There were many limitations that may have affected the results of this quality improvement project. Due to the data being collected directly from patient charts, the results of this project were dependent on documentation by staff. Data collected for trigger events took place months after the event occurred and prospective data collection would have allowed for input from frontline staff involved with the event. Since our screening tool criteria was adapted, perhaps it was too strict, which would have caused some triggers to be excluded when they were in fact ADEs. Also, the results of this project may differ from

current trends in ADEs at the institution, with the transfer to a different electronic health record after data collection took place. To collect data for a wide variety of events, the goal was to collect data for 100 events for each trigger, but due to the sample size of elevated INR triggers, there may be contributing factors that were not found during this project. Lastly, this quality-improvement project did not look at a comparator group, so sensitivity and specificity were unable to be calculated to further validate the use of these triggers.

## Conclusion

The use of trigger tool methodology was useful for identifying ADEs related to hypoglycemia with insulin, moderately useful for naloxone administration, and least successful for elevated INR with warfarin. Other types of trigger methodology may be beneficial to review in regards to ADEs, perhaps in the emergency department or related to mental health. The ADEs that were identified revealed a wide variety of contributing factors that can be used as areas of interest when creating new policies to reduce ADEs in the future.

## References

1. Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2009. Available from: [www.IHI.org](http://www.IHI.org)
2. Muething SE, Conway PH, Kloppenborg E, Lesko A, Schoettler PF, Seid M, Kotagal U. Identifying Causes of Adverse Events Detected by an Automated Trigger Tool Through In-Depth Analysis. *Qual Saf Health Care*. 2010 Oct;19(5):435-9.
3. Laatikainen O, Miettinen J, Sneek S, Lehtiniemi H, Tenhunen O, Turpeinen M. The Prevalence of Medication-Related Adverse Events in Inpatients—A Systematic Review and Meta-Analysis. *Eur J Clin Pharmacol*. 2017 Dec;73(12):1539-49.
4. Office of Disease Prevention and Health Promotion [Internet]. Adverse drug events. 2019; Available from: [https://health.gov/hcq/ade.asp#\\_ftn1](https://health.gov/hcq/ade.asp#_ftn1)
5. Michigan Health & Hospital Association [Internet]. Okemos: Michigan Health & Hospital Association; c2017. Quality Improvement in Health-care; Available from: <http://www.mha.org/MHA-Keystone-Center-Patient-Safety-Organization/Quality-Improvement>
6. Centers for Medicare and Medicaid Services [Internet]. Baltimore: Center for Medicare and Medicaid Services; c2017. Partnership for Patients and the Hospital Improvement Innovation Networks: Continuing Forward Momentum on Reducing Patient Harm; 2016 Sep 29; Available from: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-09-29-2.html>
7. Great Lakes Partners for Patients HIIN. Appendix A: Encyclopedia of Measures [Internet]. Great Lakes Partners for Patients HIIN; 2016 Sep 30; 30 p. Available from: [https://www.alliance4ptsafety.org/IHAMAPS/media/media/EOM\\_HIIN-Measures\\_v-1-0\\_20160930\\_for-release\\_508.pdf](https://www.alliance4ptsafety.org/IHAMAPS/media/media/EOM_HIIN-Measures_v-1-0_20160930_for-release_508.pdf)
8. High-Alert Medications in Acute Care Settings [Internet]. Institute for Safe Medication Practices. Available from: <https://www.ismp.org/recommendations/high-alert-medications-acute-list>

9. Lim D, Melucci J, Rizer MK, Prier BE, Weber RJ. Detection of Adverse Drug Events Using an Electronic Trigger Tool. *Am J Health Syst Pharm*. 2016 Sep 1;73(17\_Supplement\_4):S112-20.
10. Criteria for IRB approval of research, 21 C.F.R. Sect. 56.111 (2019).
11. Musy SN, Ausserhofer D, Schwendimann R, Rothen HU, Jeitziner MM, Rutjes AW, Simon M. Trigger Tool-Based Automated Adverse Event Detection in Electronic Health Records: Systematic Review. *J Med Internet Res*. 2018 May 30;20(5):e198.
12. Nwulu U, Nirantharakumar K, Odesanya R, McDowell SE, Coleman JJ. Improvement in the Detection of Adverse Drug Events by the Use of Electronic Health and Prescription Records: An Evaluation of Two Trigger Tools. *Eur J Clin Pharmacol*. 2013 Feb;69(2):255-9.
13. O'Leary KJ, Devisetty VK, Patel AR, Malkenson D, Sama P, Thompson WK, Landler MP, Barnard C, Williams MV. Comparison of Traditional Trigger Tool to Data Warehouse Based Screening for Identifying Hospital Adverse Events. *BMJ Qual Saf*. 2013 Feb;22(2):130-8.
14. Patregnani JT, Spaeder MC, Lemon V, Diab Y, Klugman D, Stockwell DC. Monitoring the Harm Associated With Use of Anticoagulants in Pediatric Populations Through Trigger-Based Automated Adverse-Event Detection. *Jt Comm J Qual Patient Saf*. 2015 Mar;41(3):108-14.
15. Stockwell DC, Kirkendall E, Muething SE, Kloppenborg E, Vinodrao H, Jacobs BR. Automated Adverse Event Detection Collaborative: Electronic Adverse Event Identification, Classification, and Corrective Actions Across Academic Pediatric Institutions. *J Patient Saf*. 2013 Dec;9(4):203-10.
16. Dickerman MJ, Jacobs BR, Vinodrao H, Stockwell DC. Recognizing Hypoglycemia in Children Through Automated Adverse-Event Detection. *Pediatr*. 2011 Apr;127(4):e1035-41.
17. Moore C, Li J, Hung CC, Downs J, Nebeker JR. Predictive Value of Alert Triggers for Identification of Developing Adverse Drug Events. *J Patient Saf*. 2009 Dec;5(4):223-8.
18. Shea PL, Spaeder MC, Sayal P, Jacobs BR, Stockwell DC. Hypoglycemia Adverse Events in PICUs and Cardiac ICUs: Differentiating Preventable and Nonpreventable Events\*. *Pediatr Crit Care Med*. 2013 Oct;14(8):741-6.
19. Call RJ, Burlison JD, Robertson JJ, Scott JR, Baker DK, Rossi MG, Howard SC, Hoffman JM. Adverse Drug Event Detection in Pediatric Oncology and Hematology Patients: Using Medication Triggers to Identify Patient Harm in a Specialized Pediatric Patient Population. *J Pediatr*. 2014 Sep;165(3):447-52.e4.
20. Kilpatrick CR, Elliott MB, Pratt E, Schafers SJ, Blackburn MC, Heard K, et al. Prevention of Inpatient Hypoglycemia With a Real-Time Informatics Alert: Prevention of Inpatient Hypoglycemia. *J Hosp Med*. 2014 Oct;9(10):621-6.
21. Lee SY, Askin G, McDonnell ME, Arnold LM, Alexanian SM. Hypoglycemia Rates After Restriction of High-Dose Glargine in Hospitalized Patients. *Endocr Pract*. 2016;22(12):1393-400.
22. Lakhani O, Kumar S, Tripathi S, Desai M, Seth C. Comparison of Two Protocols in the Management of Glucocorticoid-Induced Hyperglycemia Among Hospitalized Patients. *Indian J Endocrinol Metab*. 2017;21(6):836.

## About the Authors

**Sara Kolc Brown** (Sara.Brown@meijer.com) graduated with her Doctor of Pharmacy from the Ferris State University College of Pharmacy in 2018. She completed a postgraduate, community-based pharmacy practice residency with Meijer Pharmacy and Wayne State University in Detroit, Michigan, in 2019. Brown is currently a staff pharmacist with Meijer Outpatient Pharmacy located inside of Spectrum Health Butterworth Hospital in Grand Rapids, Michigan. She is an active member of the Wayne

County Pharmacists Association (WCPA), Michigan Pharmacists Association (MPA), MPA Political Action Council Board, American Pharmacists Association, and the Lambda Kappa Sigma (LKS) professional women's pharmacy fraternity. She serves on the board for WCPA, is the current president of the LKS Alpha Iota alumni chapter, and is on various national LKS committees.

**Jacob Peterson** (Jacob.Peterson@spectrumhealth.org) is a graduate of the Ferris State University College of Pharmacy class of 2018 and recently completed a postgraduate pharmacy practice residency at Spectrum Health. Currently he is a clinical pharmacist at Spectrum Health Butterworth Hospital; his work is involved closely with adult acute care service lines, including general medicine, intensive care, and cardiology, at Butterworth Hospital and the Fred and Lena Meijer Heart Center. Peterson is also a member of the American Society of Health-System Pharmacists and the Western Michigan Society of Health-System Pharmacists.

**Shayne Harris Schiedel** has been involved in community pharmacy for 10 years. She dual-enrolled at Ferris State University in order to complete her PharmD and a Master of Business Administration in 2018. Schiedel was an active member of the National Community Pharmacists Association and served as secretary of her chapter while in school. She began her pharmacist career as a relief and staff pharmacist with Meijer Pharmacy after graduation, and is currently in a management role as pharmacy team leader with Meijer Pharmacy in Three Rivers, Michigan.

**Kari Vavra Janes** is an associate professor of pharmacy practice at Ferris State University and practices in adult general medicine at Spectrum Health-Grand Rapids. She has held this position for nine years. Janes has completed a pharmacy practice residency and is board certified in pharmacotherapy. Additionally, she has served on numerous local, regional, and state professional organizations. She has an interest in internal medicine, health-system pharmacy, and academia.

## Acknowledgements

Margo Bowman, PharmD, MS, and Amy Pouillon, PharmD, are acknowledged for helping to develop the project.

Laura McKeown, PharmD, and Daniel Chung, PharmD, are acknowledged for assisting with the calculations of the morphine milligram equivalents of the naloxone patients.



# Incidence and Impact of Reported Infectious Endophthalmitis Events Following Cataract Surgery in Pennsylvania Ambulatory Surgery Centers

By Lynette Hathaway<sup>◇</sup>, MSN, RN,  
Shawn Kepner<sup>◇</sup>, MS & Rebecca Jones<sup>◆◇</sup>, MBA, RN

DOI: 10.33940/infection/2019.12.3

---

<sup>◆</sup>Corresponding author

<sup>◇</sup>Patient Safety Authority

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







## Abstract

Infectious endophthalmitis is a severe eye infection that can occur following cataract surgery. In this study, we sought to explore post-cataract infectious endophthalmitis events reported by ambulatory surgery centers (ASCs) in Pennsylvania. We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for post-cataract endophthalmitis events that occurred between 2009 and 2018. In the 10 calendar years analyzed, we identified 174 reports of post-cataract endophthalmitis, with rates per 1000 cataract procedures ranging from 0.05 in 2009 to 0.19 in 2018. The vast majority of these events were classified as serious (93%; n = 162 of 174), reflecting harm to patients, with one resulting in enucleation (the need to remove the affected eye). Healthcare staff and all involved stakeholders should act now by identifying sources of potential perioperative contamination, adhering to evidence-based infection prevention practices, and prioritizing areas of opportunity for improvement.

**Keywords:** *infectious endophthalmitis, eye infection, cataract surgery, postoperative endophthalmitis, healthcare-associated infection*

## Introduction

Endophthalmitis is a serious eye infection that can lead to permanent harm, including blindness.<sup>1</sup> There are two types of endophthalmitis: endogenous (bloodborne), which may occur from a number of systemic risk factors that spread bacteria or fungi from the primary source of infection into the eye,<sup>2,3</sup> and exogenous, which may occur after ocular trauma, following a corneal infection, or after eye surgery—particularly cataract surgery.<sup>4-7</sup> Cataracts impact the vision of more than 24 million Americans age 40 and older. By age 75, approximately half of all Americans will have visually significant cataracts.<sup>8</sup> By the year 2050, the number of people in the United States with cataracts is expected to double from 24.2 million to about 50 million.<sup>9</sup> Aging is the most common cause of cataracts, as the normal proteins in the lens of the

eye begin to break down and cause clouding.<sup>10</sup> As the elderly population in Pennsylvania continues to grow,<sup>11</sup> cataract surgeries are also on the rise.<sup>12</sup> Given that most cataract surgeries are performed in ambulatory surgery centers (ASCs) and outpatient departments<sup>3</sup> it is no surprise that more than one million cataract procedures were performed in Pennsylvania ASCs between 2009 and 2018.<sup>12</sup>

### endogenous (bloodborne) endophthalmitis noun

en-dog-e-nous en-doph-thal-mi-tis

<sup>1</sup> “may occur from a number of systemic risk factors that spread bacteria or fungi from the primary source of infection into the eye.”<sup>2,3</sup>

### exogenous endophthalmitis noun

ex-og-e-nous en-doph-thal-mi-tis

<sup>1</sup> “may occur after ocular trauma, following a corneal infection, or after eye surgery—particularly cataract surgery.”<sup>4-7</sup>

Cataract surgery is one of the most common ocular surgical procedures in medicine<sup>13,14</sup> and one of the most frequent surgical procedures performed by ophthalmic surgeons in the United States.<sup>15</sup>

While cataract surgery is usually successful and safe,<sup>6</sup> it is not without risk.

Infectious endophthalmitis is a rare yet significant complication of cataract surgery.<sup>3,4</sup> Defined as an infection of the intraocular fluids (aqueous and/or vitreous) and cavities,<sup>3</sup> infectious endophthalmitis is accompanied by complaints of decreased vision, eye pain, and redness in the operative eye. It typically occurs within days of surgery, but may not cause symptoms until weeks post-procedure, depending on the causative microorganism.<sup>1</sup> A diagnosis of endophthalmitis following cataract surgery is usually based on clinical presentation thought to be related to infection, with cultures of vitreous and/or aqueous fluids.<sup>1,5,16</sup> Although the exact manner of development for infectious endophthalmitis is unknown, potential sources of contamination during cataract surgery include intraocular instruments and the intraoperative suite,<sup>17</sup> as well as unsterile solutions/material or the patient’s eyelid skin flora.<sup>1,18</sup> Recognizing the lack of data surrounding infectious endophthalmitis in the ASC setting in Pennsylvania, we sought to identify the rate of infectious endophthalmitis events following cataract surgery reported by Pennsylvania’s ASCs, explore key aspects of the identified cases, and identify strategies to reduce the risk of this harmful complication.

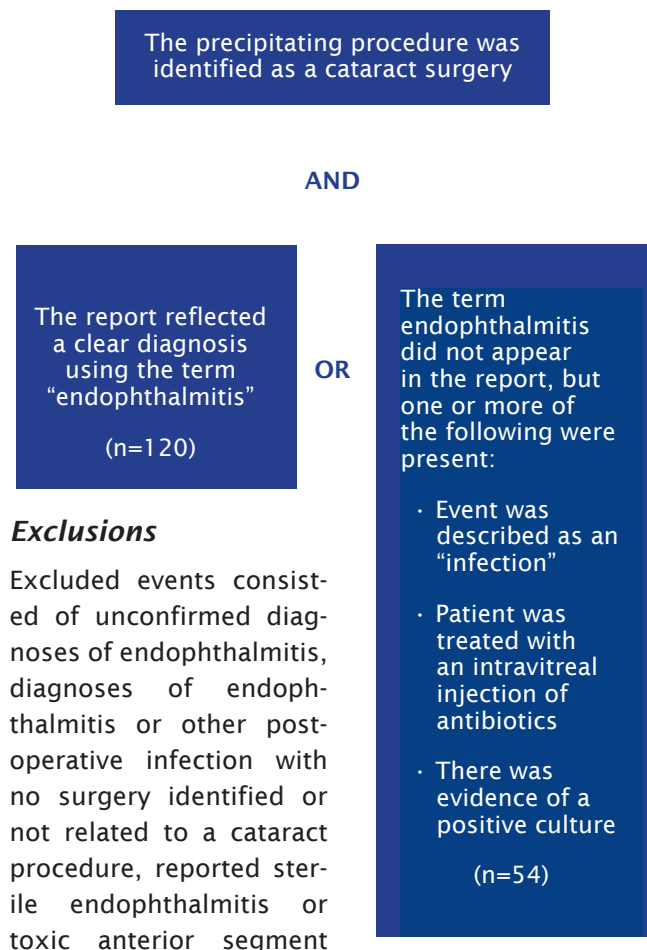
## Methods

We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS)\* database for events that occurred between January 1, 2009, and December 31,

2018, to identify and analyze reports of infectious endophthalmitis following cataract surgery (“post-cataract endophthalmitis”). Key search terms included “endophthalmitis,” as well as a combination of the terms “infection” and “eye,” and “infection” and “cataract.” Our initial search yielded 349 reports which the first two authors independently reviewed and analyzed to determine whether they represented post-cataract endophthalmitis cases. We then compared our findings and resolved discrepancies through joint review and consensus. A subject matter medical expert was also consulted to confirm validity.

### Inclusion Criteria

Reports meeting the following inclusion criteria were classified as post-cataract endophthalmitis events:



### Exclusions

Excluded events consisted of unconfirmed diagnoses of endophthalmitis, diagnoses of endophthalmitis or other post-operative infection with no surgery identified or not related to a cataract procedure, reported sterile endophthalmitis or toxic anterior segment

syndrome (TASS) with or without identified surgical procedures, postoperative complications following a cataract procedure not identified as endophthalmitis, postponed or cancelled procedures, and other unrelated events (e.g., break in sterile technique, drug recall, policy not followed).

## Results

### Rate

We identified 174 reports of post-cataract endophthalmitis over a 10-year period between 2009 and 2018. We then obtained current procedure terminology (CPT) codes from the Pennsylvania Health Care Cost Containment Council (PHC4) to calculate the rate of post-cataract endophthalmitis events reported by Pennsylvania ASCs each year during the study period. As seen in **Figure 1**, rates ranged from 0.05 to 0.19 per 1000 cataract procedures. In the 10 calendar years analyzed, we noted what could be an increase in rates of post-cataract endophthalmitis events, however the increase was not statistically significant ( $P = 0.2530 > 0.05$ ).

### Age/Gender

Patient age was approximately symmetric about the mean value of 73 years with a skewness statistic of -0.18 ( $N = 174$ ). The median and mode were also 73. As seen in **Figure 2**, a very small number of reports were related to patients younger than 50 years of age. Of the 174 events identified, females accounted for 53.45% of the reports, which is not significantly different than the estimated PA population comprised of 51.06% females ( $P = 0.5286 > 0.05$ ).

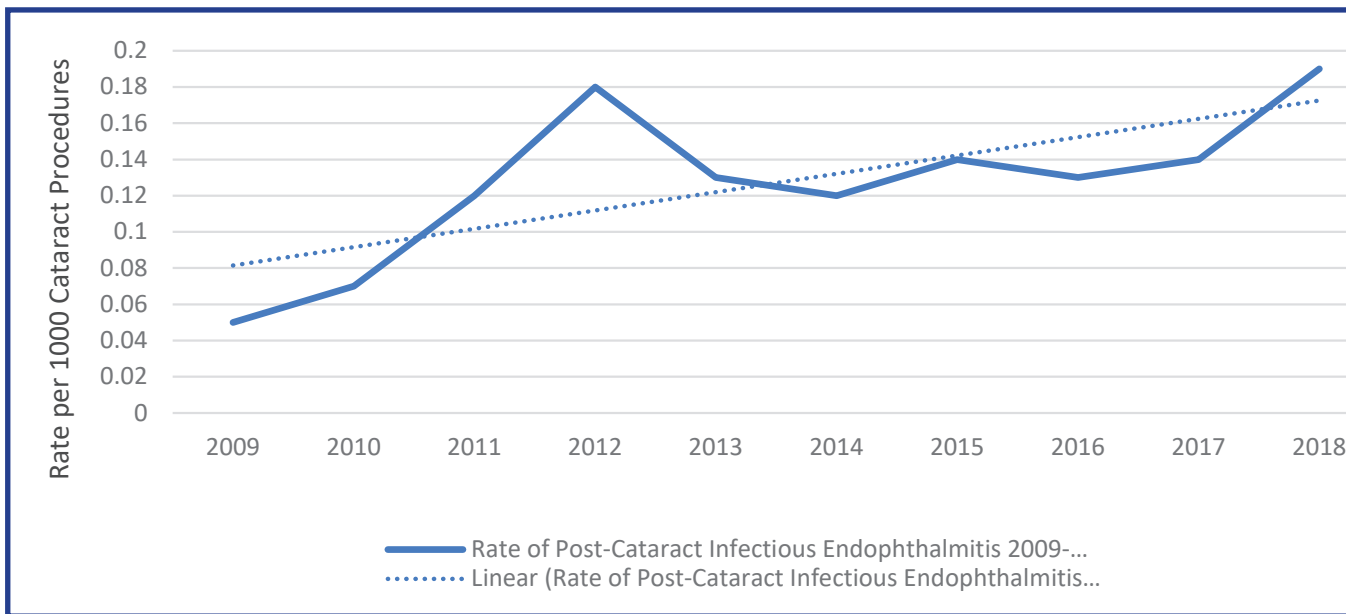
### Harm Score

The vast majority (93%;  $n = 162$  of 174) of post-cataract endophthalmitis events were reported as Serious Events, reflecting harm to patients. Most were reported under harm score “E,” indicating temporary harm that required treatment or intervention. Based on the information reported, four of the events resulted in permanent harm, one of which required enucleation (the need to remove the affected eye). See **Table 1**.

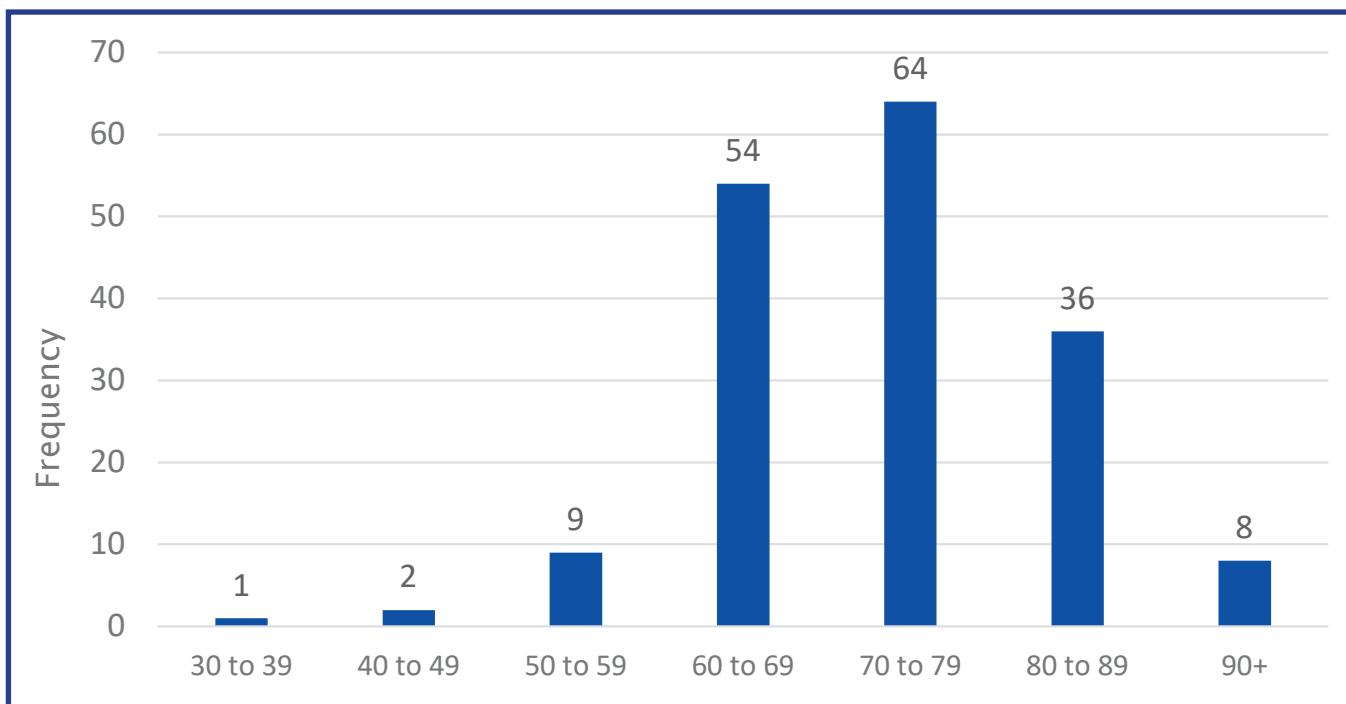
\*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety--related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability 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.



**Figure 1: Rate of Reports of Post-Cataract Endophthalmitis Events by Year**



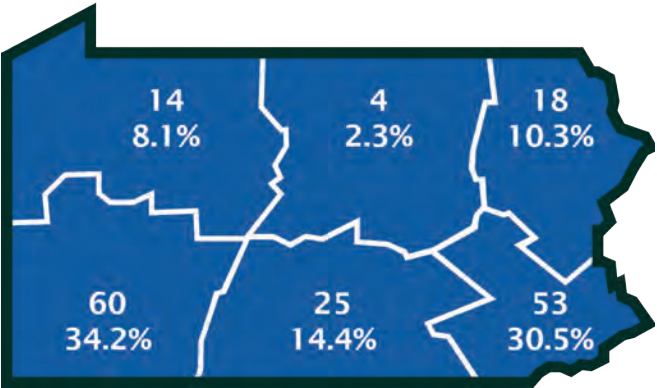
**Figure 2: Frequency by Age Group in Reports of Post-Cataract Endophthalmitis Events (N = 174)**



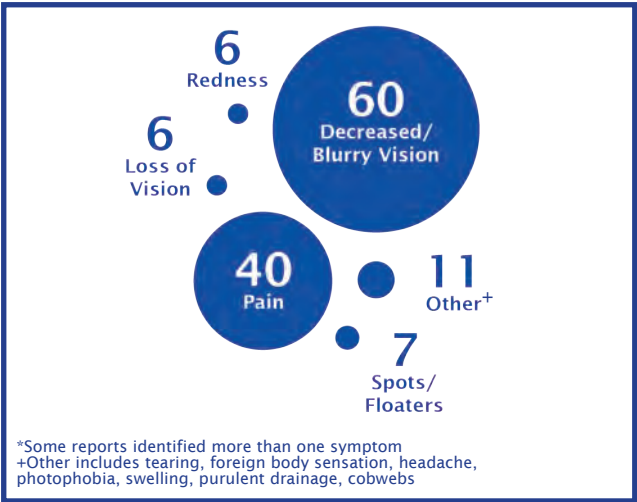
<sup>†</sup>The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of healthcare, and increasing access to healthcare for all citizens regardless of ability to pay. PHC4 has provided 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 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 authors. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

<sup>‡</sup>A “Serious Event” is 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.

**Figure 3:** Regional Distribution in Reports of Post-Cataract Endophthalmitis Events (N = 174)



**Figure 4:** Symptoms Identified in Reports of Post-Cataract Endophthalmitis Events (n = 82)\*



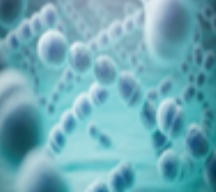
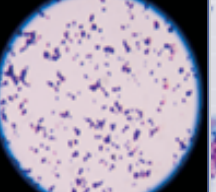

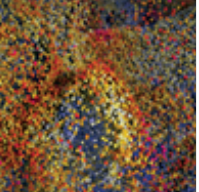


**Table 1:** Harm Score in Reports of Post-Cataract Endophthalmitis Events (N= 174)

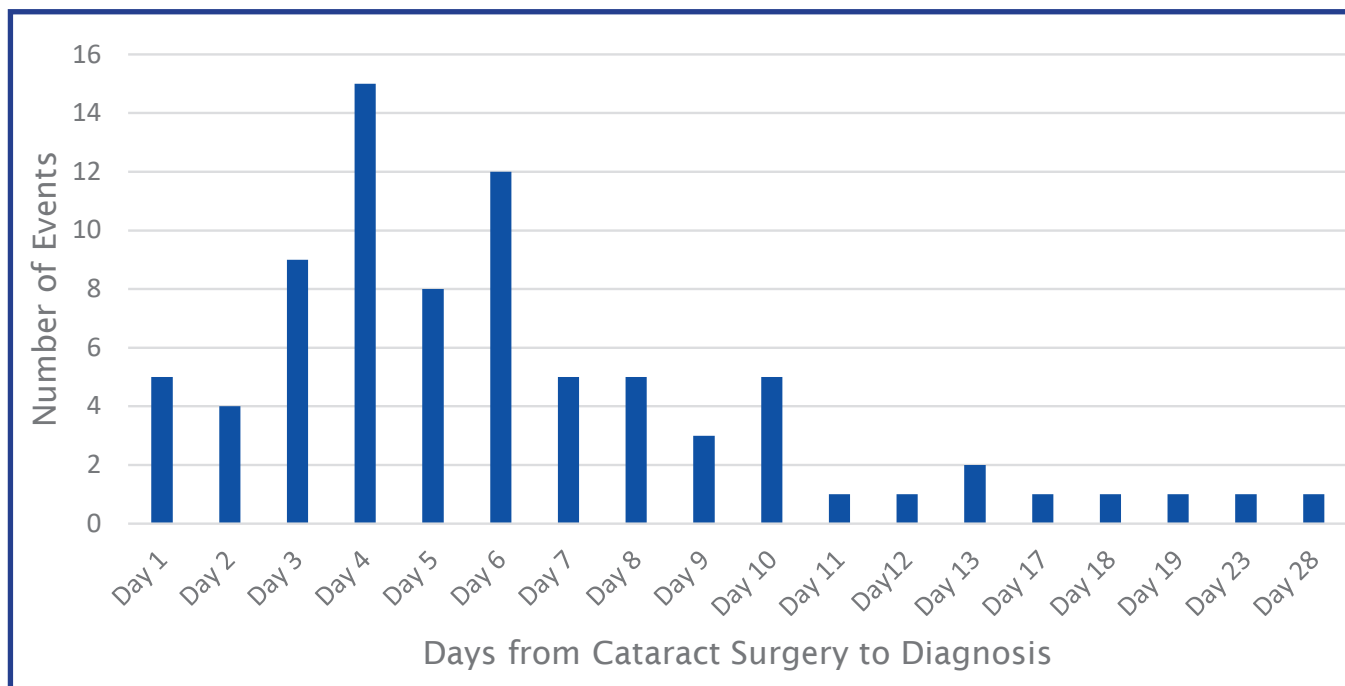
Harm Score	
D	An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.
E	An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.
F	An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.
G	An event occurred that contributed to or resulted in permanent harm.

A donut chart showing the distribution of harm scores in reports of post-cataract endophthalmitis events. The scores and their percentages are: E (154, 89%), D (12, 7%), F (4, 2%), and G (4, 2%).

**Table 2:** Pathogens Identified in Reports of Post-Cataract Endophthalmitis Events (n = 37)

					
Coagulase-negative staphylococci (including <i>Staphylococcus lugdunensis</i> )	<i>Staphylococcus</i> species (including methicillin-resistant <i>Staphylococcus aureus</i> /MRSA)	<i>Streptococcus</i> species (including <i>beta</i> , <i>pneumococcus</i> and <i>viridans</i> )	Gram-positive cocci	<i>Candida</i> species (fungal)	Polymicrobial <i>Streptococcus</i> and <i>Staphylococcus</i>
16	10	6	2	2	1

**Figure 5:** Postoperative Days from Cataract Surgery to Diagnosis in Reports of Post-Cataract Endophthalmitis Events (n = 80)



### Regional Distribution

After controlling for a few outlier facilities, we determined the distribution of reports across the six regions of Pennsylvania was close to what was expected given the general distribution of acute care events in PA-PSRS. **Figure 3** displays the regional distribution of the 174 reported events.

### Symptoms

Almost half (47%;  $n = 82$  of 174) of the post-cataract endophthalmitis event reports included details regarding patient symptoms. Consistent with other studies of postoperative endophthalmitis,<sup>1,7,19</sup> of the reports that included one or more symptoms, decreased/blurry vision (73%;  $n = 60$  of 82) and pain (49%;  $n = 40$  of 82) were noted most frequently. Other symptoms included floaters or spots, redness, and acute loss of vision. **Figure 4** illustrates the frequency of symptoms identified in the post-cataract endophthalmitis events.

We also analyzed the most frequently reported symptoms (decreased/blurry vision and pain) in relation to age and gender, but did not identify any relevant associations. The other symptom categories had too few positive indications to include in the analysis.

### Pathogens

Only 32% ( $n = 55$  of 174) of the post-cataract

endophthalmitis events included information about a culture or the pathogen involved. Of the events that contained this detail, one-third (33%;  $n = 18$  of 55) reflected negative results. The other two-thirds (67%;  $n = 37$  of 55) reported positive cultures, with 95% ( $n = 35$  of 37) involving gram-positive pathogens. This is consistent with other literature, which suggests that most cases of post-cataract endophthalmitis are caused by gram-positive bacteria.<sup>3,5,20-22</sup> **Table 2** displays additional detail regarding the pathogens identified in these 37 cases.

### Postoperative Days from Surgery to Diagnosis

Nearly half (46%;  $n = 80$  of 174) of the event narratives contained information regarding the number of postoperative days from cataract surgery to diagnosis of endophthalmitis or infection. Days ranged from post-op Day 1 to post-op Day 28. Post-op Day 4 was noted most frequently (19%;  $n = 15$  of 80), followed by post-op Day 6 (15%;  $n = 12$  of 80). **Figure 5** illustrates the range of postoperative days from surgery to diagnosis. Given that more than half of the reports did not include sufficient information to determine the number of postoperative days from surgery to diagnosis, we were unable to evaluate any possible associations between the time of surgery and diagnosis of post-cataract endophthalmitis or other factors analyzed.



## Discussion

This study is, to our knowledge, the first to evaluate both the rates of and key details regarding post-cataract endophthalmitis events based on patient safety reports by ASCs. In the 10 calendar years analyzed, we noted what could be an increase in the rate of reported post-cataract endophthalmitis, however the increase was not statistically significant ( $P = 0.2530 > 0.05$ ). Our findings, including common symptoms and pathogens most often involved in cases of post-cataract endophthalmitis, were generally consistent with those identified in the literature.<sup>1,3,5,7,19-21</sup> Our findings revealed varying degrees of patient harm, with most cases requiring additional ophthalmology specialist consults, intraocular antibiotic injections, or vitreous procedures, all of which add to the patient's direct medical costs.<sup>5,23</sup>

### **Toxic Anterior Segment Syndrome**

It can be challenging to accurately diagnose a patient who presents with acute inflammation of the operative eye following cataract surgery. Postoperative *noninfectious* endophthalmitis, sometimes described as toxic anterior segment syndrome (TASS), is a sterile anterior segment inflammation<sup>3</sup> reported with symptoms similar to infectious endophthalmitis. Diagnosing TASS against postoperative infectious endophthalmitis can be difficult;<sup>24-26</sup> given the potential damage that can result from bacterial endophthalmitis, most cases of inflammation following cataract surgery are viewed as infectious endophthalmitis until otherwise confirmed.<sup>24,26</sup> Noninfectious reactions in the operative eye following cataract surgery may also be referred to as postoperative anterior segment inflammation, sterile endophthalmitis, and noninfectious endophthalmitis.<sup>3</sup>

### **Risk Factors Associated With Post-Cataract Endophthalmitis**

Infectious endophthalmitis is a rare but real risk of cataract surgery. Some of the most common factors that increase the risk include advanced age, impaired immune system secondary to systemic diseases, intraocular exposure to the patient's own ocular flora, septic periorbital conditions, intraoperative posterior capsular break, and wound leak.<sup>27,28</sup> Other risk factors cited that may contribute to the development of healthcare-associated post-cataract endophthalmitis include surgical face masks not

worn during surgery, breaks in sterility, conjunctival disinfection without povidone-iodine, and not placing a patch or eye shield after surgery.<sup>6,13</sup>

### **Risk Reduction Strategies**

Ophthalmologists may use a combination of antiseptics and antibiotics as measures to prevent post-cataract complications. There is general agreement in the preoperative use of povidone-iodine in the conjunctival cul-de-sac;<sup>6, 27</sup> however, there is no general consensus as to the type and route of antibiotic treatment nor the use of intraocular injection after an uncomplicated cataract procedure.<sup>27,29</sup> While intracameral antibiotic therapy has been associated with a reduction in acute endophthalmitis,<sup>6,27</sup> the potential complications associated with prophylactic antibiotics—including toxicity—should be considered.<sup>27,29,30</sup> Currently there is no Food and Drug Administration–approved product available for intracameral therapy,<sup>29</sup> providers will need to weigh the risk and benefits of therapy.<sup>29</sup> As new research in the management and treatment of post-cataract endophthalmitis emerges, physicians should remain current to better guide their treatment options.

Surgical personnel's awareness of potential sources of contamination that may enter the eye during cataract surgery is imperative in the prevention of post-cataract endophthalmitis.<sup>17</sup> Healthcare-associated infections may be avoided by observing the practices recommended by the American Academy of Ophthalmology, the Association of periOperative Registered Nurses, the American Society of Cataract and Refractive Surgery, and the American Society of Ophthalmic Registered Nurses.<sup>3</sup> Basic infection prevention measures include hand hygiene, standard precautions, and adherence to disinfection and sterilization protocols.<sup>3,31</sup>

**Table 3** provides perioperative risk reduction strategies aimed specifically at reducing sources of contamination.

## Limitations

This article is based on cases of post-cataract endophthalmitis reported to the PA-PSRS database by Pennsylvania ASCs and does not quantify post-cataract endophthalmitis rates across the entire state of Pennsylvania. Despite mandatory reporting laws, this data is subject to the limitations of self-reporting and the complexities of the reporting system and structure. Thus, our ability to substantiate the diagnosis of post-cataract endophthalmitis was

**Table 3: Strategies for Healthcare Providers to Reduce the Risk of Contamination**

Preoperative risk reduction strategies	
	<ul style="list-style-type: none"><li>• Adhere to proper disinfection and manufacturer recommended sterilization protocols.<sup>3,13,32</sup></li><li>• Prepare medication just prior to the procedure. Do not draw up multiple patients' medications for the day.<sup>31</sup></li><li>• Never store or carry medications in personal clothing or pockets.<sup>31</sup></li></ul>
Intraoperative risk reduction strategies	
	<ul style="list-style-type: none"><li>• Use povidone-iodine in the conjunctival cul-de-sac.<sup>27</sup></li><li>• Drape the patient's eyelid and lashes precisely to prevent the patient's skin flora from contaminating the field.<sup>28,33</sup></li><li>• Facemasks should be worn by the surgeon and scrubbed personnel. Facemasks should cover the nose, mouth, and chin completely, and should not be hung around the neck.<sup>33</sup></li><li>• Prior to administering ophthalmic drops, carefully remove the top of the bottle and place it in a clean, protected area. If the inside of the bottle top becomes contaminated, discard it immediately.<sup>34</sup></li><li>• The eye drop tip must never come in contact with the patient's eyelid, eyelashes, or surface of the eye.<sup>31,34</sup></li><li>• Surgical cataract instruments and handpieces may be placed in a sterile water bath immediately after use to avoid drying of debris until cleaning takes place.<sup>13,35</sup> Instrument cleaning involves the removal of soil and debris before the disinfection and sterilization process.<sup>35</sup> All cleaned instruments must be thoroughly rinsed and dried prior to disinfection and sterilization.<sup>13,31</sup></li></ul>
Postoperative risk reduction strategies	
	<ul style="list-style-type: none"><li>• Customize discharge instructions and remind patients not to wear eye makeup until the surgeon approves.</li><li>• Evaluate patient comprehension regarding discharge instructions, including wearing the postoperative eye shield as directed, avoiding eye rubbing, and following postoperative eye drop regimen.</li><li>• Consider education and return-demonstration in properly instilling eye drops.</li></ul>
Environmental risk reduction strategies	
	<ul style="list-style-type: none"><li>• Clean the surgical environment between patients. Microorganisms can live in the environment on an uncleaned surface for hours to months, depending on the organism and contamination present.<sup>17,31</sup></li><li>• Regular maintenance of the ventilation filter system is recommended in the surgical suite to avoid potential environmental sources of contamination.<sup>17</sup></li></ul>

dependent upon the taxonomies and free-text event detail narratives, which may limit the degree to which ASC reporting is both accurate and complete.

Many reports referenced endophthalmitis following elective eye surgery but did not specify the procedure.

Cataract surgery is the most common elective eye surgery linked to endophthalmitis;<sup>3</sup> however, we did not include reports in our analysis if we were unable to definitively identify the procedure. Therefore, it is likely the actual rate of endophthalmitis events is higher than is reported in this study.

## Conclusion

The results of this study provide areas of interest for further investigation into the incidence and impact of post-cataract endophthalmitis. Though cataract surgery is a customary surgical eye procedure, complications such as infectious endophthalmitis can lead to significant and sometimes permanent harm. Recognizing the risks of developing post-cataract endophthalmitis, perioperative staff and all concerned stakeholders have a duty to work together to prevent this acute postoperative condition.

## Notes

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

## References

1. Durand ML. Bacterial and Fungal Endophthalmitis. *Clinical Microbiology Reviews*. 2017.
2. Sadiq MA, Hassan M, Agarwal A, Sarwar S, Toufeeq S, Soliman MK, et al. Endogenous Endophthalmitis: Diagnosis, Management, and Prognosis. *J Ophthalmic Inflamm Infect*. 2015;5(1):32. Epub 2015/11/04. doi: 10.1186/s12348-015-0063-y. PubMed PMID: 26525563; PubMed Central PMCID: PMC4630262.
3. Miller D. Ophthalmology Services. In: Boston KC, APIC Text Online, editor. APIC Text of Infection Control and Epidemiology Online. Arlington, VA: APIC; 2014.
4. Durand ML. Endophthalmitis. *Clin Microbiol Infect*. 2013;19(3):227-34. Epub 2013/02/27. doi: 10.1111/1469-0691.12118. PubMed PMID: 23438028; PubMed Central PMCID: PMC3638360.
5. Hashemian H, Mirshahi R, Khodaparast M, Jabbarvand M. Post-Cataract Surgery Endophthalmitis: Brief Literature Review. *J Curr Ophthalmol*. 2016;28(3):101-5. Epub 2016/09/01. doi: 10.1016/j.joco.2016.05.002. PubMed PMID: 27579452; PubMed Central PMCID: PMC4992095.
6. Cao H, Zhang L, Li L, Lo S. Risk Factors for Acute Endophthalmitis Following Cataract Surgery: a Systematic Review and Meta-Analysis. *PLoS One*. 2013;8(8):e71731. Epub 2013/08/31. doi: 10.1371/journal.pone.0071731. PubMed PMID: 23990980; PubMed Central PMCID: PMC3753305.
7. Vaziri K, Schwartz SG, Kishor K, Flynn HW, Jr. Endophthalmitis: State of the Art. *Clin Ophthalmol*. 2015;9:95-108. Epub 2015/01/23. doi: 10.2147/OPTH.S76406. PubMed PMID: 25609911; PubMed Central PMCID: PMC4293922.
8. Eye Health Statistics. American Academy of Ophthalmology. 2015.
9. Cataracts Defined. National Eye Institute. 2010.
10. Boyd K. What Are Cataracts? American Academy of Ophthalmology. 2018.
11. Center PSD. Population Characteristics And Change: 2010 to 2017. PennState Harrisburg. 2018.
12. Pennsylvania Health Care Cost Containment Council. Hospital Performance Report. Central & Northeastern Pennsylvania : ... Common Medical Procedures and Treatments. Harrisburg, PA: Pennsylvania Health Care Cost Containment Council. p. v.
13. *Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments*. American Academy of Ophthalmology. 2018.
14. Jabbarvand M, Hashemian H, Khodaparast M, Jouhari M, Tabatabaei A, Rezaei S. Endophthalmitis Occurring after Cataract Surgery: Outcomes of More Than 480 000 Cataract Surgeries, Epidemiologic Features, and Risk Factors. *Ophthalmology*. 2016;123(2):295-301. Epub 2015/12/26. doi: 10.1016/j.ophtha.2015.08.023. PubMed PMID: 26704882.
15. *Facts About Cataract*. National Eye Institute. 2015.
16. Endophthalmitis Study Group ESOC, Refractive S. Prophylaxis of Postoperative Endophthalmitis Following Cataract Surgery: Results of the ESCRS Multicenter Study and Identification of Risk Factors. *J Cataract Refract Surg*. 2007;33(6):978-88. Epub 2007/05/29. doi: 10.1016/j.jcrs.2007.02.032. PubMed PMID: 17531690.
17. Kelkar A, Kelkar J, Amuaku W, Kelkar U, Shaikh A. How to Prevent Endophthalmitis in Cataract Surgeries? *Indian Journal of Ophthalmology*. 2008;56(5):403-7. PubMed Central PMCID: PMC2636140.
18. Pandya H. Postoperative Endophthalmitis. Medscape. 2019.
19. Kernt M, Kampik A. Endophthalmitis: Pathogenesis, Clinical Presentation, Management, and Perspectives. *Clin Ophthalmol*. 2010;4:121-35. Epub 2010/04/15. doi: 10.2147/ophth.s6461. PubMed PMID: 20390032; PubMed Central PMCID: PMC2850824.
20. Fintelmann RE, Naseri A. Prophylaxis of Postoperative Endophthalmitis Following Cataract Surgery: Current Status and Future Directions. *Drugs*. 2010;70(11):1395-409. Epub 2010/07/10. doi: 10.2165/11537950-000000000-00000. PubMed PMID: 20614947.
21. Horster S, Bader L, Seybold U, Eschler I, Riedel KG, Bogner JR. Stenotrophomonas maltophilia Induced Post-Cataract-Surgery Endophthalmitis: Outbreak Investigation and Clinical Courses of 26 Patients. *Infection*. 2009;37(2):117-22. Epub 2009/01/17. doi: 10.1007/s15010-008-8150-8. PubMed PMID: 19148575.
22. Shivaramaiah HS, Relhan N, Pathengay A, Mohan N, Flynn HW, Jr. Endophthalmitis Caused by Gram-Positive Bacteria Resistant to Vancomycin: Clinical Settings, Causative Organisms, Antimicrobial Susceptibilities, and Treatment Outcomes. *Am J Ophthalmol Case Rep*. 2018;10:211-4. Epub 2018/03/20. doi: 10.1016/j.ajoc.2018.02.030. PubMed PMID: 29552670; PubMed Central PMCID: PMC5854869.
23. Schmier JK, Hulme-Lowe CK, Covert DW, Lau EC. An Updated Estimate of Costs of Endophthalmitis Following Cataract Surgery Among Medicare Patients: 2010-2014. *Clin Ophthalmol*. 2016;10:2121-7. Epub 2016/11/09. doi: 10.2147/OPTH.S117958. PubMed PMID: 27822008; PubMed Central PMCID: PMC45087791.
24. Lipuma L. Presentation Spotlight Distinguishing TASS From Endophthalmitis. EyeWorld. 2018.
25. Deschênes J. Toxic Anterior Segment Syndrome (TASS) Clinical Presentation. Medscape. 2017.
26. Park CY, Lee JK, Chuck RS. Toxic Anterior Segment Syndrome-An Updated Review. *BMC Ophthalmol*. 2018;18(1):276. Epub 2018/10/26. doi: 10.1186/s12886-018-0939-3. PubMed PMID: 30359246; PubMed Central PMCID: PMC6203205.
27. Garg P, Roy A, Sharma S. Endophthalmitis After Cataract Surgery: Epidemiology, Risk Factors, and Evidence on Protection. *Curr Opin Ophthalmol*. 2017;28(1):67-72. Epub 2016/09/24. doi: 10.1097/ICU.0000000000000326. PubMed PMID: 27661662.
28. Packer M, Chang DF, Dewey SH, Little BC, Mamalis N, Oetting TA, et al. Prevention, Diagnosis, and Management of Acute Postoperative Bacterial Endophthalmitis. *J Cataract Refract Surg*. 2011;37(9):1699-714. Epub 2011/07/26. doi: 10.1016/j.jcrs.2011.06.018. PubMed PMID: 21782382.
29. George N, Stewart M. The Routine Use of Intracameral Antibiotics to Prevent Endophthalmitis After Cataract Surgery: How Good is the Evidence?. *Ophthalmol Ther*. 2018;7(2):233-45.
30. Kamjoo S, Palestine A, Lim J, Hossain K, Tripathy K, et al. Endophthalmitis. American Academy of Ophthalmology EyeWiki. 2019.
31. Infection Prevention in Eye Care Services and Operating Areas and Operating Rooms American Academy of Ophthalmology. 2012.
32. Galor A, Goldhardt R, Wellik SR, Gregori NZ, Flynn HW. Management Strategies to Reduce Risk of Postoperative Infections. *Curr Ophthalmol Rep*. 2013;1(4). Epub 2013/12/10. doi: 10.1007/s40135-013-0021-5. PubMed PMID: 24319649; PubMed Central PMCID: PMC3851038.



33. Niyadurupola N, Astbury N. Endophthalmitis: Controlling Infection Before and After Cataract Surgery. *Community Eye Health*. 2008;21(65):9-10. Epub 2008/05/28. PubMed PMID: 18504468; PubMed Central PMCID: PMC2377381.

34. Directors ABo. American Society of Ophthalmic Registered Nurses. Recommended Practice for Registered Nurses – Use of Multi-dose Medications. 2013(San Francisco, CA: American Society of Ophthalmic Registered Nurses).

35. *Standards of Practice for the Decontamination of Surgical Instruments*. Association of Surgical Technologists. 2009.

36. Verma L, Chakravarti, A. Prevention and Management of Postoperative Endophthalmitis: A Case-Based Approach. *Indian Journal of Ophthalmology*. 2017;65(12):1396-402.

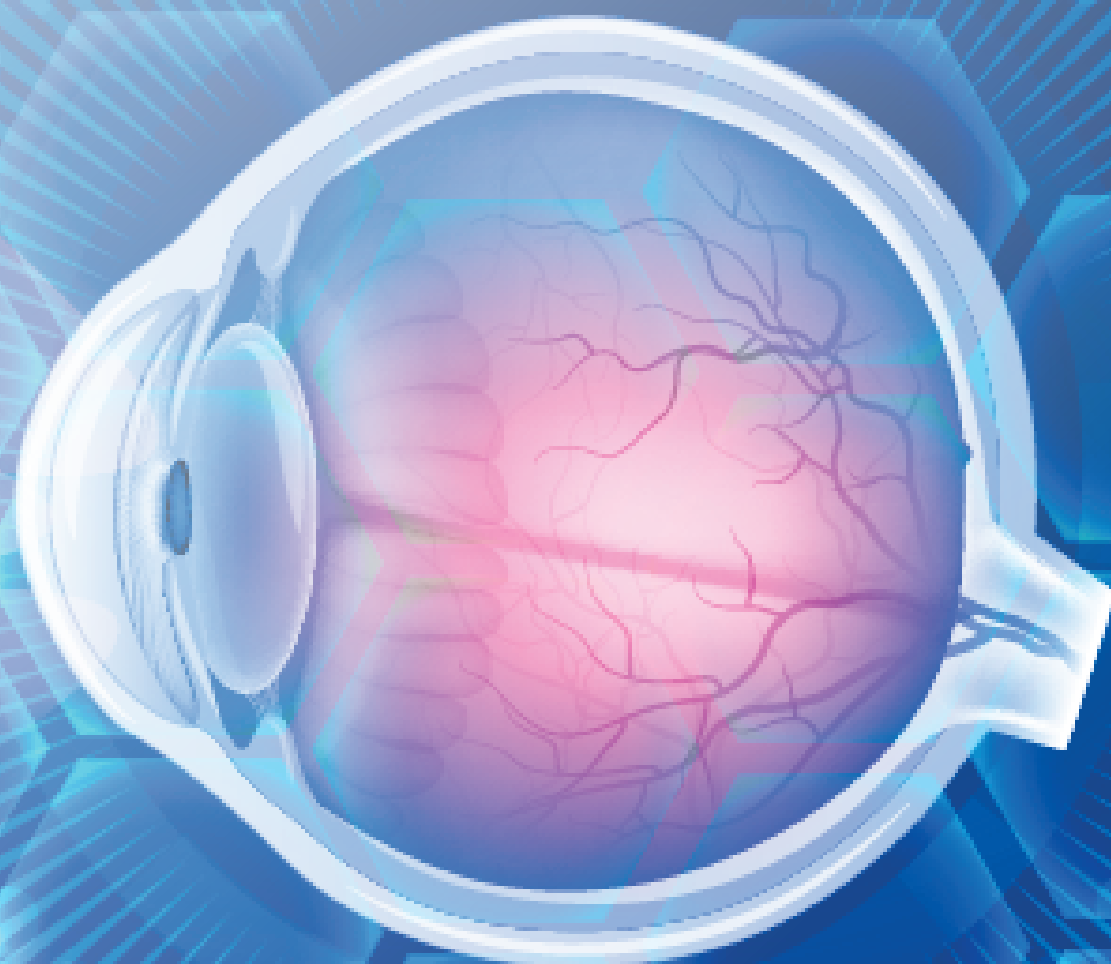
director of the Center of Excellence for Improving Diagnosis. Her previous roles at the PSA include director of Innovation and Strategic Partnerships, and regional patient safety liaison. Before joining the PSA, Jones served in various roles leading patient safety efforts and proactively managing risk 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.

## About the Authors

**Lynette Hathaway** is an infection prevention analyst for the Patient Safety Authority, where she assists with the improvement of patient safety by initiating, developing, implementing, and monitoring new and existing infection prevention initiatives throughout Pennsylvania. Her diverse nursing experience includes cardiovascular and medical-surgical nursing, gastroenterology, utilization review, long-term care, nursing education, and infection prevention and control. Prior to joining the PSA, Hathaway was manager of Infection Prevention and Control at a 156-bed acute care facility. She is board-certified in infection control and epidemiology, and an active member of the Three Rivers Chapter of the Association for Professionals in Infection Control and Epidemiology.

**Shawn Kepner** is a data analyst for the Patient Safety Authority, providing actionable insights using data science techniques, working with staff to focus resources and research for maximum benefit to patient safety, and helping assess the quality and validity of statistical methodologies for research and publications. Before joining the PSA, Kepner was a contractor with the Pennsylvania Department of Health, where he served as the data manager for a new community health initiative. His prior positions include decision support consultant and manager of informatics for Novitas Solutions, bureau director for program support with the Pennsylvania Department of Public Welfare (DPW), and program manager with Xerox Corporation. He also has been an adjunct mathematics instructor at Harrisburg Area Community College and a presenter on statistics to the DPW's Leadership Development Institute.

**Rebecca Jones** (rebejones@pa.gov) is director of Data Science and Research at the Patient Safety Authority, where she also founded and serves as





# A Brief Analysis of Telemetry– Related Events

---

Elizabeth Kukiela<sup>\*,◇</sup>, PharmD, MA, RPh,  
Kelly R. Gipson<sup>◇</sup>, BSN, RN & Rebecca Jones<sup>◇</sup>, MBA, RN

DOI: 10.33940/biomed/2019.12.4

## Abstract

Successful telemetry monitoring relies on timely clinician response to potentially life-threatening cardiac rhythm abnormalities. Breakdowns in the processes and procedures associated with telemetry monitoring, as well as improperly functioning telemetry monitoring equipment, may lead to events that compromise patient safety. An analysis of reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) from January 2014 through December 2018 identified 558 events specifically involving interruptions or failures associated with telemetry monitoring equipment or with the healthcare providers responsible for setting up and maintaining proper functioning of that equipment. The analysis highlighted a steady increase in the quantity of event reports associated with telemetry

monitoring submitted to PA-PSRS. User errors accounted for nearly half (47.1%, 263 of 558) of events in the analysis. The most common event subtypes included: errors involving batteries in telemetry monitoring equipment (14.0%); errors in which patients were not connected to telemetry monitoring equipment as ordered (12.9%); errors involving broken, damaged, or malfunctioning telemetry monitoring equipment (10.9%); and errors in which patients were connected to the wrong telemetry monitoring equipment (9.0%).

**Keywords:** *telemetry, cardiac monitoring, patient safety, alarm management, cardiac arrhythmias, communication, equipment malfunction, monitor technician*

---

\*Corresponding author

◇Patient Safety Authority

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



001 ???

X1 Monitor

Recorder out of Paper

ECG



120  
50  
**89**

✗ **0**  
PVCs

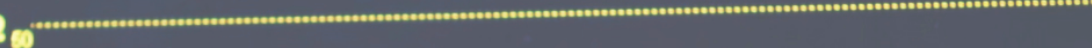
ST OFF



SpO2  
%

100  
90  
**99**

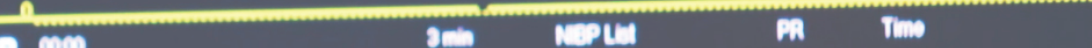
Source SpO2  
✗ **105**  
PR



CO2  
mmHg

✗ **0**

swPR **0**  
PR **0**



00:00

3 min

NIBP List

PR

Time

160  
90

--- / ---  
---

Gas

N2O %

O2 %

AA %

MAC

**0**

**21**

---

**0.0**

**0**

**21**

---

Please Wait

patient in the MPM and patient monitor is different.

Patient Setup

NIBP Measure

Stop All

Screens

Volume Setup

Manual Event

Standby

Alarm Setup

Review

Main

Silence

Alarm Pause

Freeze

Record

NIBP

Menu

## Introduction

Continuous cardiac monitoring of a patient outside the setting of the intensive care unit (ICU) is usually achieved via portable telemetry monitoring equipment (hereafter referred to in some instances as “equipment”) connected to a patient that transmits vital data, such as heart rate and rhythm, to a telemetry monitoring station that may be located on the nursing unit or to a remote centralized telemetry monitoring unit located away from the nursing unit.<sup>1</sup> Successful telemetry monitoring relies on timely clinician response to potentially life-threatening cardiac rhythm abnormalities identified through the use of this healthcare technology. Breakdowns in the processes and procedures associated with telemetry monitoring, as well as improperly functioning equipment, may lead to events that compromise patient safety.

Following review of several event reports submitted to the Pennsylvania Patient Safety Reporting System\* (PA-PSRS) involving telemetry monitoring that resulted in serious harm, we decided to investigate the full spectrum of events in PA-PSRS involving interruptions or failures related to telemetry monitoring. In addition to our analysis, we also share relevant examples of telemetry monitoring events to promote awareness of areas in which actionable changes within healthcare facilities are possible, as well as a summary of lessons learned from these events.

## Methods

We queried PA-PSRS for events submitted from January 1, 2014 through December 31, 2018. We identified events for analysis if one of the free text fields contained either “telemetry” or “tele” (excluding “telephone” and “telemed”) and one of the following: “off”, “alarm”, “batter”, “disconnect”, “expire”, or “transmi”. An analyst manually reviewed all event reports to identify events that involved interruptions or failures associated with equipment or with the healthcare providers responsible for setting up and maintaining proper functioning of that equipment. Events related to telemetry monitoring were categorized according to whether they resulted from user errors, communication breakdowns between healthcare providers, device malfunctions, or alarm issues, and were then further subcategorized within each of these categories.

## Results

The query returned 1,494 event reports submitted to PA-PSRS during the five-year study period. An analyst manually reviewed all events and determined that 812 events specifically involved interruptions or failures related to telemetry monitoring. The remaining 682 events were excluded from the analysis because they did not involve interruptions or failures related to telemetry monitoring; many of these events simply mentioned that the patient was on telemetry monitoring. Of the 812 events involving

interruptions or failures related to telemetry monitoring, 558 events were included in the analysis because they were related to issues with the equipment or with the healthcare providers responsible for setting up and maintaining proper functioning of that equipment (e.g., a patient who became disconnected from equipment during transfer from one unit to another); 254 events were excluded from the analysis because they were considered to be outside the control of the hospital staff and unrelated to the function of equipment (e.g., a patient who became disconnected from telemetry following a fall).

**Figure 1: Number of Telemetry Monitoring Events Submitted by Year, N=558**

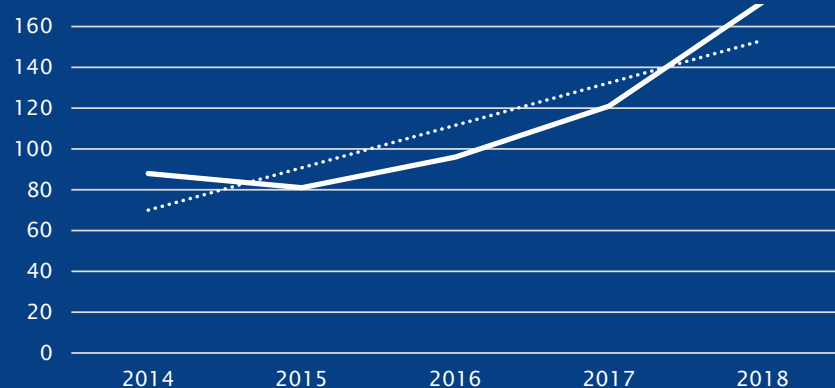
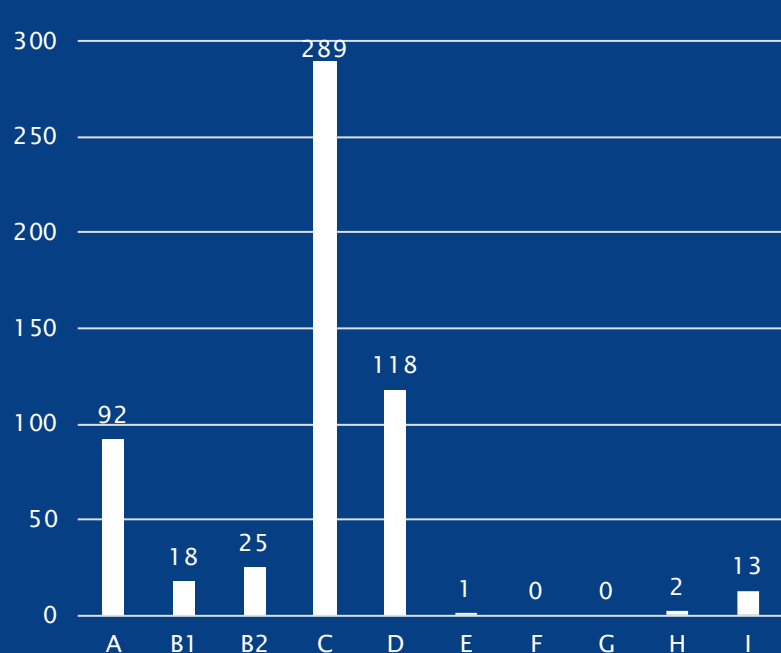


Figure 2: Telemetry Monitoring Events by Harm Score, N=558



A - Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)  
 B1 - An event occurred but it did not reach the individual ("near miss" or "close call") because of chance alone  
 B2 - An event occurred but it did not reach the individual ("near miss" or "close call") 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 (an error of omission such as a missed medication dose does reach the individual)  
 D - An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm  
 E - An event occurred that contributed to/resulted in temporary harm and required treatment or intervention  
 F - An event occurred that contributed to/resulted in temporary harm and required initial or prolonged hospitalization  
 G - An event occurred that contributed to/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/resulted in death

Figure 3: Telemetry Monitoring Events by Category and Subcategory, N=558





**Table: Telemetry Event Subcategories**

Subcategory	Definition
Patient not connected to telemetry monitoring equipment as ordered	Patient had verbal or written orders for continuous telemetry monitoring, but monitoring was delayed or not initiated
Patient transferred or transported without telemetry monitoring	Patient had orders for continuous telemetry monitoring, but patient was transferred from one unit to another unit without proper monitoring during transit
Patient off unit without telemetry monitoring	Patient had orders for continuous telemetry monitoring but was not properly monitored while off the unit (such as while receiving dialysis or imaging)
Patient not reconnected to telemetry monitoring equipment upon return to unit	Patient had orders for continuous telemetry monitoring but was permitted to be off the unit without telemetry monitoring for a procedure or test; however, upon return to the unit, the patient was not reconnected to the telemetry monitoring equipment in a timely fashion and was therefore unmonitored for some period of time
Patient connected to wrong telemetry monitoring equipment	Patient was connected to telemetry monitoring equipment under the wrong name or another identifier, or two or more patients had their telemetry monitoring equipment switched, resulting in incorrect information appearing on the telemetry technician's central monitor for the patients in question
Telemetry monitoring on standby	Telemetry monitoring was placed on standby at some point and was not activated or reactivated at the appropriate time
Leads off or leads failed	Patient's leads were either not connected to telemetry monitoring equipment, or they were connected but not transmitting for an unknown reason
Poor handoff	Patient was transferred from one unit to another without a proper handoff (i.e., patient was brought to the unit by staff from another unit and left without any communication between the staff members)
Telemetry monitoring technician unable to notify nursing unit of alarm conditions and/or delayed response on nursing unit	Telemetry monitoring staff were unsuccessful at contacting nursing staff to notify them of potentially life-threatening changes in rhythm, or nursing unit staff were notified but delayed in responding
Miscommunication between telemetry monitoring unit and nursing unit	Telemetry monitoring unit was not made aware of patient transfer between rooms or units, or monitoring was discontinued in error
Telemetry monitoring unit failed to notify nursing unit of alarm conditions	Review of patient's telemetry monitoring history revealed an alarm condition that was not communicated to nursing staff or other clinicians
Telemetry monitoring equipment broken, damaged, or malfunctioning	Telemetry monitoring equipment was physically damaged or was not functioning properly
Battery issues	Telemetry transmitter's batteries were dead, damaged in some way, or improperly inserted
Alarm issues	Alarm was turned off, alarm volume was turned down, or alarm settings were changed

**Figure 1** shows the number of events submitted each year from 2014 through 2018. The majority (97.1%, 542 of 558) of telemetry monitoring events were categorized as incidents<sup>†</sup>; the remaining 16 events were categorized as serious events<sup>‡</sup>. Harm scores were identified by healthcare facilities at the time of their reporting. **Figure 2** summarizes the frequency of each harm score and includes definitions of each harm score. Most serious events (harm scores E-I) resulted in death (13 of 16).

Telemetry monitoring events were categorized according to whether events resulted from user errors, communication breakdowns between healthcare providers, device malfunctions, or alarm issues. User errors accounted for nearly half (47.1%, 263 of 558) of the events. Events were further subcategorized based on common details among reports, and these categories are defined in the **Table**. The distribution of each event category and subcategory is summarized in **Figure 3**. The most common event subtypes included: errors involving batteries in equipment (14.0%); errors in which patients were not connected to equipment as ordered (12.9%); errors involving broken, damaged, or malfunctioning equipment (10.9%); and errors in which patients were connected to the wrong equipment (9.0%).

Incidents and serious events were distributed similarly across the various event subcategories. For this reason, it is our position that the level of harm associated with telemetry monitoring events may depend largely on chance (i.e., the level of harm is not linked to certain subcategories of contributing factors, but rather to the patient's underlying condition). Therefore, an analysis of all events—regardless of harm level—will contribute a considerable amount of information to the current knowledge base.

## Case Vignettes

The following are examples of each subcategory of telemetry monitoring event. These examples are

\*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.

†“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.<sup>2</sup>

‡“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.<sup>2</sup>

based on actual reports submitted to PA-PSRS, but none of these examples represents an individual event report, and event details were modified to ensure confidentiality.

### Equipment Malfunctions

#### Telemetry Monitoring Equipment Broken, Damaged, or Malfunctioning

The telemetry monitoring technician called to notify the nurse on the medical/surgical unit that GP's cardiac tracing had not been displayed on the technician's central monitor for about 10 minutes, and that he was now displaying in atrial fibrillation with a rapid ventricular rate. The nurse attempted to rectify the situation by changing the leads connected to the patient as well as the batteries in the telemetry transmitter, but GP yet again did not display on the technician's central monitor. A biomedical technician tested the equipment and identified an equipment failure. They replaced the telemetry transmitter with a new unit, and GP's cardiac tracing immediately began displaying on the central monitor. GP had gone unmonitored for about 45 minutes. The nurse contacted the physician after the event to notify them about GP's abnormal rhythm so that appropriate treatment could be ordered for GP, but the monitor malfunction delayed the notification.

#### Battery Issues

VH is a 72-year-old female with history of obesity, end-stage renal disease with dialysis three times per week, high blood pressure, atrial fibrillation, right-sided heart failure, and asthma. After a trip and fall at home, VH arrived at the emergency department complaining of severe left hip pain, and an MRI revealed a fracture. She was admitted and was ordered continuous telemetry monitoring. The nurse caring for VH in the emergency department connected the equipment prior to transferring VH to the inpatient unit. On the second day following admission, while VH was resting comfortably in her room after dinner, her nurse checked her vital signs at 6 p.m. They were unremarkable except for a slightly elevated heart rate of 105 beats per minute. VH reported to the nurse that she was feeling fine. Later that evening, the nurse entered the room and found VH slumped over in her bed without a pulse. A code was called, but VH could not be resuscitated and was pronounced dead at 8:45 p.m. After the event, it was discovered that the batteries in the telemetry monitoring transmitter had died; the last reading was taken at 7:10 p.m., so VH's heart rhythm prior to the event was unknown.



*Harm associated with telemetry monitoring is rare but potentially catastrophic, with death being the most frequent outcome among serious events.*

### User Errors

#### Patient Not Connected to Telemetry Monitoring Equipment as Ordered

CM, a 62-year-old male with a history of diabetes and congestive heart failure, came to the emergency department with complaints of diarrhea for the past three days and a feeling of general weakness. The physician assistant who examined him determined that he was dehydrated. CM was admitted and was ordered continuous telemetry monitoring. The nurse in the emergency department signed off on the telemetry order but did not connect the equipment to CM. Two additional nurses did not notice the order for telemetry monitoring and did not connect the equipment to CM. On the day following admission, CM was found in his room on the medical/surgical unit without a pulse. A code was called, and CM was successfully resuscitated and transferred to the ICU. The order for telemetry monitoring was later found in CM's chart; he had been unmonitored for about 18 hours, so his rhythm prior to the event was unknown.

#### Patient Off Unit Without Telemetry Monitoring

CV, a 75-year-old female with a history of atrial fibrillation, hypertension, and angina, was receiving a continuous infusion of diltiazem and heparin and had orders for continuous telemetry monitoring. Her physician ordered an MRI, and when the technician arrived to transport CV for testing, he disconnected her telemetry monitoring equipment and did not notify the nurse. Soon after, the nurse discovered that CV was off the nursing unit without telemetry monitoring. The nurse immediately went

**Figure 4: Key Takeaways From Telemetry Monitoring Events**



Harm associated with telemetry monitoring is rare but potentially catastrophic, with death being the most frequent outcome among serious events.



Battery issues were one of the most common contributing factors identified in telemetry monitoring events.



Communication breakdowns among clinicians, technicians, and units are another common contributing factor related to telemetry monitoring events.



Improper alarm settings, including volume being turned down or alerts being changed, also contributed to telemetry monitoring events.



Failures to follow orders, procedures, or protocols among hospital staff members were a factor in many telemetry monitoring events.

to the testing area with the necessary equipment, reconnected CV to telemetry monitoring, and remained with her until her test was complete. The nurse then accompanied CV back to the nursing unit. CV was off the monitor for about 20 minutes.

#### **Patient Connected to Wrong Telemetry Monitoring Equipment**

LM, a 58-year-old female with a history of ventricular fibrillation, and GR, a 35-year-old female with a history of supraventricular tachycardia, were both on continuous telemetry monitoring and hospitalized in the same room. At some point, their equipment was disconnected and mixed up before being reconnected. GR was experiencing a rapid heart rate, but LM's tracing reflected the rapid rate because of the mix-up. In response to the change in rhythm, LM's physician ordered a diltiazem infusion, but the equipment mix-up was discovered before the infusion was started. Because both patients had been improperly monitored for several hours, the nurse for each patient went back over the alarms for the preceding hours. The monitor mix-up was reported to the physician, who decided to keep both patients overnight for observation.

#### **Telemetry Monitoring Equipment on Standby**

MK, an 81-year-old female, was admitted to the hospital with complaints of shortness of breath. A cardiac catheterization was ordered. Prior to the procedure, MK's telemetry monitoring was put on standby mode. She returned to her room following the procedure, but the equipment was not taken off standby. Several hours later, the nurse found MK unresponsive on the floor next to the bed. A code was called, and MK was successfully resuscitated and transferred to the ICU. After the event, the nurse discovered that the telemetry monitoring equipment had remained on standby when MK returned to the unit after her procedure.

### **Communication Breakdowns**

#### **Poor Handoff**

RS, a 22-year-old female suspected of having Wolff-Parkinson-White syndrome, was admitted through the emergency department for a full cardiac workup with orders for continuous telemetry monitoring, which was initiated in the emergency department. RS was transported from the emergency department to the medical/surgical unit by a technician. After being notified that RS would be arriving, the nurse on the medical/surgical unit registered telemetry monitoring equipment for RS and placed it on the counter in the room. Not seeing anyone immediately available for a handoff upon arrival to the unit, the technician brought RS directly to her room and removed the emergency department's equipment. The technician did not connect the new equipment and did not notify the nurse that RS had arrived on the unit. When walking by, the nurse noticed RS in the room. RS informed the nurse that she had been waiting there for about 25 minutes. The nurse then placed RS on telemetry monitoring and found her heart rate to be elevated at 135 beats per minute.

#### **Telemetry Monitoring Technician Unable to Notify Nursing Unit of Alarm Conditions and/or Delayed Response on Nursing Unit**

A telemetry monitoring technician observed that HR, a 65-year-old male with a history of right-sided heart failure, was disconnected from his telemetry monitoring equipment. The technician attempted to page HR's nurse four times, but a nurse was not signed in to receive pages for HR. The technician then contacted the charge nurse to inform them that HR had been unmonitored for an hour and a half. The charge nurse assured the technician that someone would check on HR to ensure that his leads were attached. After another hour, the patient was still unmonitored, so the technician reached out again and was



finally able to speak with HR's nurse, who checked on HR and reconnected his telemetry leads. In all, HR had been unmonitored for over three hours.

### **Miscommunication Between Telemetry Monitoring Unit and Nursing Unit**

KM, a 55-year-old patient with a history of hypertension and high cholesterol, was admitted to the hospital following a heart attack. She was ordered continuous telemetry monitoring, which was initiated in the emergency department. After her arrival on the telemetry unit, KM was initially placed in room 1254, but after a fall from her bed, KM was moved to room 1220 so she could be closer to the nurses' station to prevent another fall. The move was not reported to the telemetry monitoring unit when it took place. The telemetry monitoring technician observed that KM's cardiac rhythm was not visible on the monitor, so they called to notify KM's nurse. The nurse informed the technician that KM had been transferred to a different room and was bathing. The technician then updated the patient's location in the telemetry monitoring system.

### **Alarm Issues**

JR, a 76-year-old patient with a history of hypertension, high cholesterol, and atrial fibrillation, presented to the emergency department with a chief complaint of palpitations and dizziness for the past two days. JR was admitted to the hospital and was ordered continuous telemetry monitoring. The oncoming nurse reviewed JR's alarm log and discovered that he had experienced a 21-beat run of ventricular tachycardia and a run of atrial flutter during the previous shift, despite being told that the patient had no episodes of irregular rhythms. Upon further investigation, it was found that the alarm volume on the telemetry monitor at the nurse's station had been turned completely down, therefore no one had heard the alert.

### **Discussion**

Several important lessons can be learned from our analysis, which are summarized in **Figure 4**. Although telemetry monitoring events do not frequently result in patient harm, the events that do cause harm may be catastrophic, typically leading to patient death. The most commonly reported causes of telemetry monitoring errors were problems with dead or improperly inserted batteries in the telemetry transmitter. In addition, many reports described alarm settings being

modified, leading to situations in which clinicians were unaware of heart rhythm changes. Communication breakdowns among clinicians were also widespread among reports, from poor or nonexistent handoffs to failures in communicating changes in patient location or status between units.

Overall, facilities may benefit from clear processes and training on the proper use of equipment for all health-care providers who may encounter telemetry monitoring as a regular part of their job, to ensure that all patients are monitored safely and that no medical device takes the place of clinical care, observation, and judgment. A closed-loop communication protocol that outlines specific escalation strategies should be written and reviewed with all staff, especially when clinicians and monitoring staff are in different locations.<sup>1</sup> In addition, facilities should follow the most up-to-date practice standards on continuous cardiac monitoring in the hospital setting to ensure this technology is not overused, as this has been tied to alarm fatigue among healthcare providers.<sup>3</sup>

### **Limitations**

Despite mandatory event-reporting laws in Pennsylvania, our data are subject to the limitations of self-reporting. The annual number of telemetry monitoring event reports submitted to PA-PSRS increased from 2014 through 2018, but this upward trend may simply highlight a growing use of telemetry monitoring or an increased awareness and reporting of telemetry monitoring events in Pennsylvania healthcare facilities.

Because a standard taxonomy for reporting telemetry monitoring events does not exist, it is possible that relevant event reports were missed with our query. In addition, equipment and practices vary greatly from one facility to another, and event details often referred broadly to telemetry without specifying a particular device, component, or practice. For this reason, we used the label "telemetry monitoring equipment" (or "equipment" for brevity) to include devices, monitors, electrodes, leads, wires, and monitors.

### **Conclusion**

This analysis revealed that, although patient safety events associated with telemetry monitoring do not often result in harm, those events that do lead to harm most often result in death. Both incidents and serious events were distributed across the various event subcategories. In addition, the reporting of

patient safety events associated with telemetry monitoring increased from 2014 to 2018.

The most common telemetry monitoring events were related to user errors, including patients not being connected to monitoring as ordered and patients being connected to the wrong monitor, and to equipment malfunctions, including damaged or broken monitors or monitors with dead batteries. It may be prudent for healthcare facilities to focus their attention on policies and processes surrounding initiation of continuous telemetry monitoring and daily care of equipment, including timely replacement of leads, patches, and batteries.

In addition, biomedical and clinical engineering staff play a critical role in ensuring proper maintenance of monitoring equipment. Any staff member who encounters or works with patients on telemetry could benefit from training on the steps necessary to initiate or maintain appropriate monitoring. In addition, lines of communication between clinicians on the frontline and technicians responsible for remote telemetry monitoring should always be kept open to ensure patients receive safe care throughout their hospital stay.

## Notes

---

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

## References

---

1. Sandau KE, Funk M. What Happened on Telemetry? Patient Safety Network. 2019.
2. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002).
3. Sandau KE, Funk M, Auerbach A, Barsness GW, Blum K, Cvach M, et al. Update to Practice Standards for Electrocardiographic Monitoring in Hospital Settings: A Scientific Statement From the American Heart Association. *Circulation*. 2017;136(19):e273-e344. Epub 2017/10/05 doi: 10.1161/CIR.0000000000000527. PubMed PMID: 28974521.

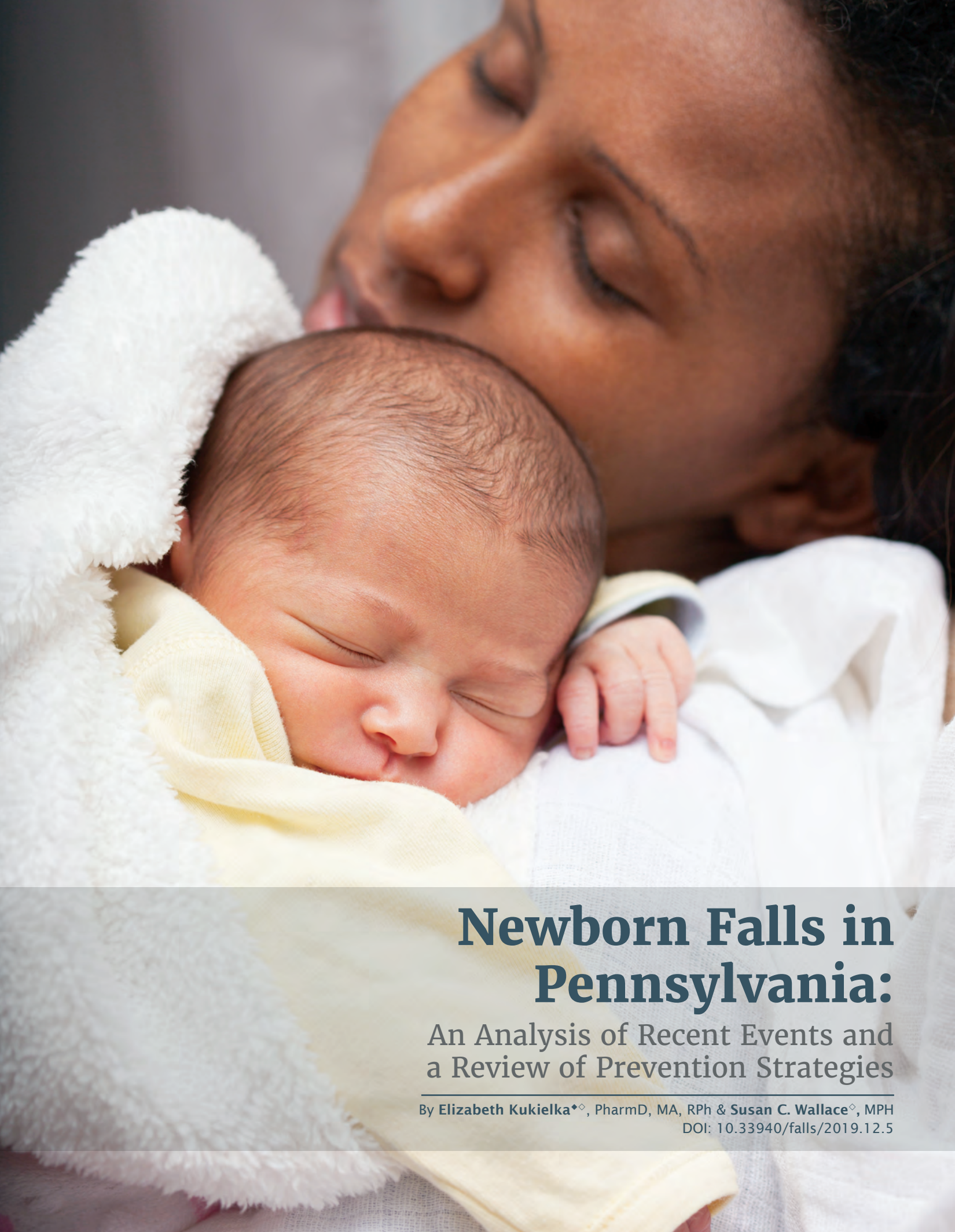
## About the Authors

---

**Elizabeth Kukiela** (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*. Kukiela 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.

**Kelly R. Gipson** is a project manager at the Patient Safety Authority. She started with the PSA as a patient safety liaison for the South Central region of Pennsylvania. Prior to joining the PSA, she worked as the associate patient safety officer at WellSpan York Hospital in York, Pennsylvania. Her clinical background includes experience in medical/surgical, critical care, and recovery room settings, as well as on multiple hospitalwide shared decision-making committees.

**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.



# Newborn Falls in Pennsylvania:

An Analysis of Recent Events and  
a Review of Prevention Strategies

---

By Elizabeth Kukielka<sup>♦◇</sup>, PharmD, MA, RPh & Susan C. Wallace<sup>◇</sup>, MPH  
DOI: 10.33940/falls/2019.12.5





Connor Donnelly as an infant and at 5 years old.



*I was afraid that I was going to get a social worker call... I think hospitals need to not only provide education to parents and caregivers, but also show some care and concern for the parents who experience a fall accident.*

- Annie Donnelly

## Abstract

Despite increasing recognition of the potential risks associated with in-hospital newborn falls among health professionals, new parents are frequently unaware of the possibility of dropping their newborn, especially in the hospital. Although most newborn falls do not result in lasting harm to the newborn, they may necessitate additional healthcare services and cause stress to all involved parties. An analysis of reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) from January 2014 through December 2018 identified 318 events specifically related to newborn falls in the hospital following birth. An increase in the number and rate of serious newborn fall events reported to PA-PSRS was observed compared with a previous analysis by Wallace. Newborn falls were most commonly associated with a caregiver falling asleep (168 events, or 52.8%) and with newborn feeding (72 events, or 22.6%). Strategies to prevent newborn falls in the hospital include focusing efforts on providing support for exhausted parents during the critical time following the birth, offering periods of rest for new parents whenever they are tired, increasing the frequency of rounding when new mothers are breastfeeding, and promoting a midday break in visiting hours.

**Keywords:** *newborn fall, newborn drop, infant fall, maternal fatigue, breastfeeding, fall prevention*

## Introduction

Several years ago, Annie and Brad Donnelly experienced a newborn fall during their hospital stay after the delivery of their first child, Connor. Annie recently spoke with one of the authors about her experience, in the hope of preventing other families from going through a similar situation. She described the fall:

*"The night before we were leaving, I was so tired that Brad told me to switch positions and try to sleep on the pullout chair instead of in the bed. He said that he would watch Connor. By that point, neither one of us had really had time to close our eyes. While Brad was holding Connor in the bed, he became so comfortable that he accidentally fell asleep. The railing was up on one side but not the other, and that's where Connor slipped out of Brad's hands and received a contusion on the left side of his head. It happened very fast."*

Annie shared that Connor was transferred to the neonatal intensive care unit (NICU) for a short period following his fall, but he did not sustain any permanent injuries. The emotional repercussions of the fall experienced by Annie and Brad were more significant. She explained:

*"When the nurse came in, I was explaining what had happened. Nobody said, 'This was an accident.' I was afraid that I was going to get a social worker call. Nobody was saying, 'Accidents happen. It's not uncommon.' Nobody was consoling. Brad was completely mute, and he was just crying in the corner. Absolutely horrible. No one, not a counselor or a nurse, was with us from the time that they took Connor down to CT to the time that they came and told us his update. I paced the hallway. I called my aunt to come. I didn't know what was going on. I think hospitals need to not only provide education to parents and caregivers, but also show some care and concern for the parents who experience a fall accident."*

A newborn fall or drop may be defined as an unplanned or unintentional event that occurs when a newborn descends from a raised surface, such as a bed or couch, or is dropped from the arms of a caregiver, and comes to rest on the floor or another surface with or without injury to the newborn.<sup>1</sup> Recognition of the

♦Corresponding author

◇Patient Safety Authority

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

potential risks associated with in-hospital newborn falls has been increasing among health professionals and within hospitals and health systems. In the last five years alone, numerous reports and analyses have been published on the subject of newborn falls. On the other hand, new parents are frequently unaware of the possibility of dropping their newborn in the hours and days following childbirth. Although most newborn falls do not result in lasting harm to the newborn, they may necessitate additional healthcare services for the newborn. In addition, any caregivers involved in a newborn fall, including parents, other family members, and hospital staff (often collectively referred to as second victims), may experience distress following a newborn fall.<sup>1</sup>

In Pennsylvania, patient safety events, including reports of in-hospital newborn falls, are collected through the Pennsylvania Patient Safety Reporting System\* (PA-PSRS). In 2014, Wallace published an article that analyzed newborn fall events submitted to PA-PSRS from 2004 through 2013.<sup>2</sup> In order to provide an update on newborn falls in Pennsylvania, the present article analyzes newborn fall events submitted to PA-PSRS from 2014 through 2018. In addition, recommendations for best practices for the prevention of newborn falls are also shared.

## Methods

We queried the PA-PSRS database for events submitted from January 1, 2014, through December 31, 2018. We identified events for analysis if the event type was classified as “Falls” or “Other” and contained one of the following keywords in the event detail: “fall,” “fell,” “drop,” “sleep,” “slip,” or “unrespon.” To limit the search to newborns, we specified patient age for events as 30 days or less. Each event report retrieved by this query was individually reviewed to ensure that it was specifically related to a newborn fall.

We calculated annual newborn falls rates in Pennsylvania. Newborn fall events were also classified according to:

- time of day when the fall occurred
- time since birth when the fall occurred
- primary circumstance leading to the fall

- factors potentially contributing to the fall
- primary caregiver involved in the fall

The full range of events were identified and analyzed, from near-miss events to events with varying levels of harm. For this analysis, a near-miss event was defined as a circumstance that had the potential to cause a newborn fall but did not result in a fall. Near-miss events were identified by manual review. Serious newborn fall events, which are events that caused harm to the patient that required additional healthcare services, were identified based on harm scores assigned by the reporting facility.

## Results

The query returned 994 records reported during the five-year study period. An initial review of all events revealed that many of the records were related to adult falls, possibly because the patient age in days was recorded as 0 in PA-PSRS in numerous events submitted via the interface. An analyst reviewed each individual event and identified 332 events related to potential or actual newborn falls. Of these, 318 unique events were related to an actual newborn fall, and 14 events were identified as near misses. In one instance, a single newborn fall event was reported twice, first after the initial fall, and subsequently after the newborn experienced a change in vital signs and was transferred to a higher level of care; because these events pertained to the same event, they were merged and treated as a single event.

### Annual Rate of Newborn Falls

The annual rate of newborn falls was reported per 10,000 live births, which is the standard across other newborn falls studies. To calculate this rate, we used the number of newborn fall events reported to PA-PSRS each year and the number of live births reported by the Pennsylvania Health Care Cost Containment Council (PHC4) each year.<sup>†</sup> Annual rates of newborn falls ranged from 3.7 to 5.9 falls per 10,000 live births from 2014 to 2018, with an average annual rate of newborn falls of 4.8 falls per 10,000 live births over the five-year study period. Annual rates of newborn falls are found in **Figure 1**.

\*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.

<sup>†</sup>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 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 authors. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

<sup>‡</sup>The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

## Timing of Newborn Falls

More than two-thirds of newborn fall events reported to PA-PSRS from 2014 through 2018 occurred within the first 72 hours following birth. Among the 332 newborn fall events analyzed (including near misses), a total of 230 events (69.3%) occurred within the first 72 hours, and 300 events (90.4%) occurred within the first seven days. Notably, nearly one-third of newborn fall events (30.7%; 102 of 332 events) occurred on the second day following birth, between 24 and 48 hours after birth.

Newborn fall events in this study were also analyzed to determine the time of day when events occurred, with falls broken down by hour of occurrence in **Figure 2**. The time of the fall was unspecified in 12 reports. Newborn fall events occurred most frequently from 4 a.m. to 5 a.m., with 33 of 320 newborn falls (10.3%) reported to have occurred during this timeframe.

## Primary Circumstance Leading to the Newborn Fall

The primary circumstance contributing to each newborn fall event is summarized in **Figure 3**. Of the 318 newborn fall events reviewed (excluding near misses), 168 events (52.8%) took place after the caregiver fell asleep (166 events) or lost consciousness following a seizure (2 events). The following are examples<sup>†</sup> of newborn falls that occurred following a caregiver falling asleep or losing consciousness:

*Father sitting on side of bed holding newborn and fell asleep. Newborn fell to floor. Father uncertain if newborn hit head.*

*Mother had a seizure while holding infant. Mother fell to the floor, subsequently dropping the newborn.*

Other primary circumstances contributing to newborn fall events included: caregiver dropped newborn while in motion (19.8%; 63 of 318 events), caregiver dropped newborn while stationary (12.6%; 40 of 318 events), and newborn fell from another surface, such as a bed or couch (5.7%; 18 of 318 events). The following are examples of events associated with each of these primary circumstances:

*Mother attempted to get out of bed while holding newborn and dropped newborn from her arms onto the floor.*

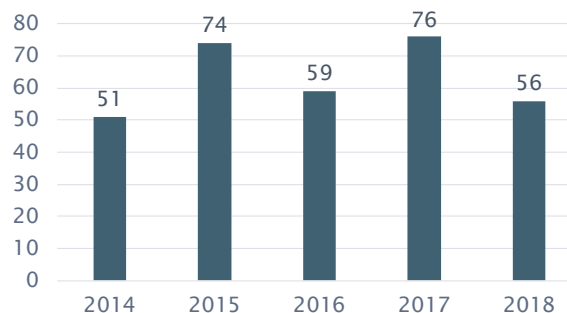
*Father told nurse he dropped the newborn while sitting in a chair and the newborn hit her head.*

*Mother stated she placed newborn on top of a pillow on the bed and the newborn fell off the bed.*

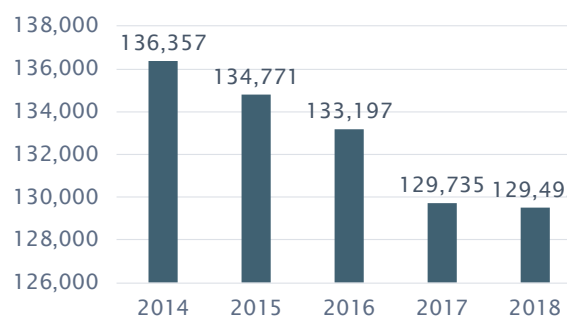
In 5 events (1.6%), the newborn fall occurred following a precipitous delivery. There was insufficient detail included in 24 events (7.5%) to determine the primary circumstance leading to those events.

**Figure 1. Annual Rates of Newborn<sup>a</sup> Falls in Pennsylvania**

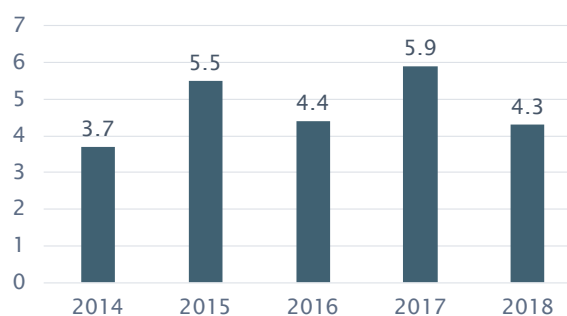
**Number of Newborn Fall Event Reports<sup>b</sup>, N=316**



**Number of Live Births<sup>c</sup>**



**Rate of Newborn Falls Per 10,000 Live Births<sup>b,c</sup>**



<sup>a</sup>Patients ≤ 30 days old.

<sup>b</sup>Reports submitted to PA-PSRS.

<sup>c</sup>Data obtained from PHC4.

## neonatal abstinence syndrome noun

neo-na-tal ab-sti-nence syn-drome

As defined by the American Academy of Pediatrics

“a collection of signs and symptoms occurring in a newborn following delivery as a result of abrupt withdrawal from substances used or abused by the mother during pregnancy, including opioids.”<sup>3</sup>

## serious event noun

se-ri-ous e-vent

As defined by Act 13 of 2002 of Pennsylvania

§ “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.”<sup>4</sup>



## Potential Contributing Factors

Our analysis also identified potential contributing factors that newborn fall events shared in common. Here, we report contributing factors that were described in at least 1% of events (>3 events). The most frequently reported contributing factor was feeding of the newborn, which was mentioned in 72 of 318 events (22.6%); breastfeeding was specifically identified in 45 of these 72 events (62.5%). Burping was also listed as a contributing factor in 14 of 318 events (4.4%). Both feeding and burping were listed as a contributing factor in 5 of 318 events (1.6%).

The following are examples of events associated with feeding and/or burping:

*While burping the newborn in a seated position, newborn pushed back on father's supporting hand. Father was unable to catch him and he fell to the floor.*

*After breastfeeding, while mother was repositioning, the newborn fell out of her hands onto the floor.*

Bedding, such as sheets, pillows, and blankets, was described as a contributing factor in 18 of 318 events (5.2%). Equipment was listed as a contributing factor in 4 of 318 events (1.3%). The following are examples of events associated with bedding or equipment:

*Mother propped newborn on bedlinens and pillow in center of bed. When mother shifted her weight and then got off of the bed, her newborn rolled onto the floor.*

*Father tripped over cords and fell with the newborn in his arms.*

In 6 of 318 events (1.9%), the mother attributed the newborn fall, at least in part, to her hand or arm falling asleep or going numb. In 7 of 318 events (2.2%), monitoring and/or treatment for neonatal abstinence syndrome<sup>ae</sup> were mentioned.

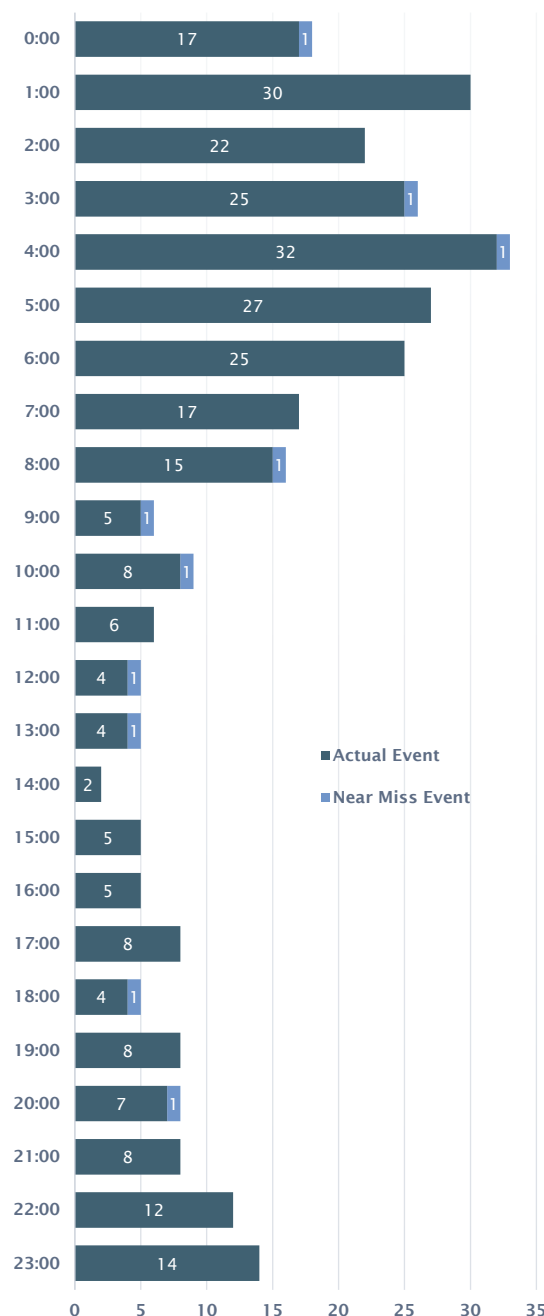
## Primary Caregiver Involved in the Newborn Fall

Among 311 events that specified the primary caregiver involved in the newborn falls event (excluding precipitous deliveries and near misses), 263 events (84.6%) involved the mother, 32 events (10.3%) involved the father, 9 events (2.9%) involved another family member (most often a grandparent), 6 events (1.9%) involved a member of the hospital staff (most often a nurse), and 1 event involved an unspecified visitor.

## Imaging Studies Following Newborn Falls

Among 72 events that indicated the newborn underwent one or more imaging studies following a fall, 55 newborns underwent a CT scan, 25 newborns underwent an x-ray, and 8 newborns underwent an ultrasound (including 1 who underwent a

Figure 2. Time of Day of Newborn Fall Events, N=320<sup>a</sup>

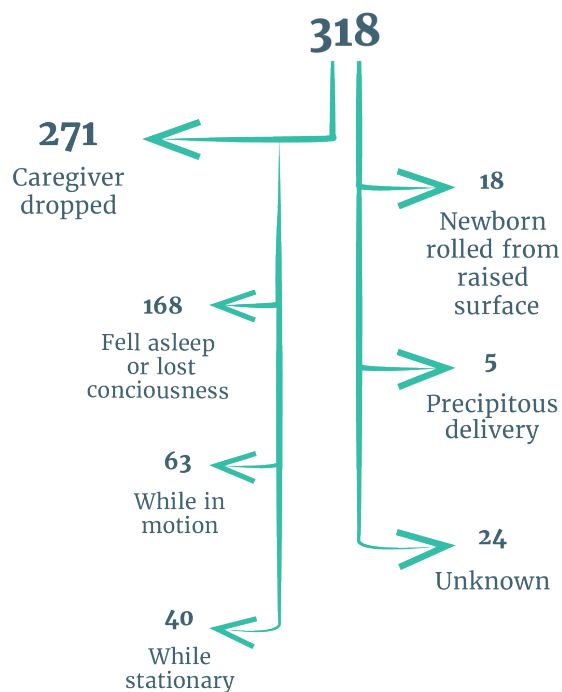


<sup>a</sup>Includes actual events and near misses for which time of fall was specified in the report.



**181 falls  
(56.6%)  
occurred  
between  
midnight  
and 7 a.m.**

**Figure 3. Primary Circumstance Leading to Newborn Fall, N=318**



neurosonogram). Notably, none of the events involving a hospital staff member indicated that the newborn underwent any kind of imaging study following the fall.

### Harm Resulting From Newborn Falls

Each event in PA-PSRS includes a harm score that describes the level of injury to the patient. Of the 318 newborn fall events reported to PA-PSRS from 2014 through 2018, 33 events (10.4%) were classified as Serious Events.<sup>5</sup> None of the events resulted in permanent harm or death. In 21 of the 33 Serious Events (63.6%) reported, the newborn experienced temporary harm that required treatment or intervention; in the remaining 12 Serious Events (36.4%), the newborn experienced temporary harm that required initial or prolonged hospitalization. In several of these Serious Events, the newborn was transferred to another facility for a higher level of care, and the final outcome was not reported. Examples of temporary harm experienced by newborns who fell include bumps, bruises, swelling, hematomas, hemorrhages, and fractures. Fractures were reported in 25 of the 33 serious events (75.8%). The following is an example of a serious newborn fall event:

*Mother fell asleep with the newborn laying on top of her and newborn fell to the floor. A CT scan showed a mildly displaced skull fracture with hemorrhage. Newborn was transferred to an outside children's hospital for further evaluation and was subsequently discharged.*

### Near-Miss Newborn Falls

As previously mentioned, 14 near-miss newborn fall events were reported to PA-PSRS from 2014 through 2018. All but one near-miss newborn falls event (92.9%; 13 of 14 events) involved the mother as the primary caregiver, and 11 of these events involved hospital staff finding the mother asleep with a newborn; in these cases, hospital staff intervened to prevent a newborn fall. A single event described a hospital staff member circumcising a newborn over a bed tray table, which the reporter felt had the potential to lead to a newborn fall.

## Discussion

### Annual Rates of Newborn Falls

Despite an increasing awareness of in-hospital newborn falls in recent years, experts on the subject have suggested that newborn fall events are underrecognized and underreported.<sup>5-7</sup> Reasons for underreporting among family members may include embarrassment or the belief that the fall did not result in any apparent harm; among hospital staff members, underreporting has been attributed to fear of disciplinary action.<sup>6-8</sup> Rates of in-hospital newborn falls in the literature vary considerably. In many early studies of newborn fall events, falls were relatively rare, and annual rates of 1.6 falls, 4.1 falls, 4.6 falls, and 5.9 falls, each per 10,000 live births, were reported.<sup>9-12</sup> In 2019, a health system consisting of five hospitals reported relatively higher, variable annual fall rates ranging from 6.03 to 12.58 falls per 10,000 live births systemwide over a five-year period.<sup>8</sup> In 2016, a single hospital reported a rate of 21.2 falls per 10,000 births over a seven-month period.<sup>13</sup>

The analysis of newborn fall events published in 2014 by Wallace included estimates of annual rates of newborn falls in Pennsylvania that ranged from 0.4 to 3.8 events per 10,000 live births.<sup>2</sup> The present analysis showed an increase in reports of newborn fall events through PA-PSRS, with annual rates ranging from 4.0 to 5.9 events per 10,000 live births.

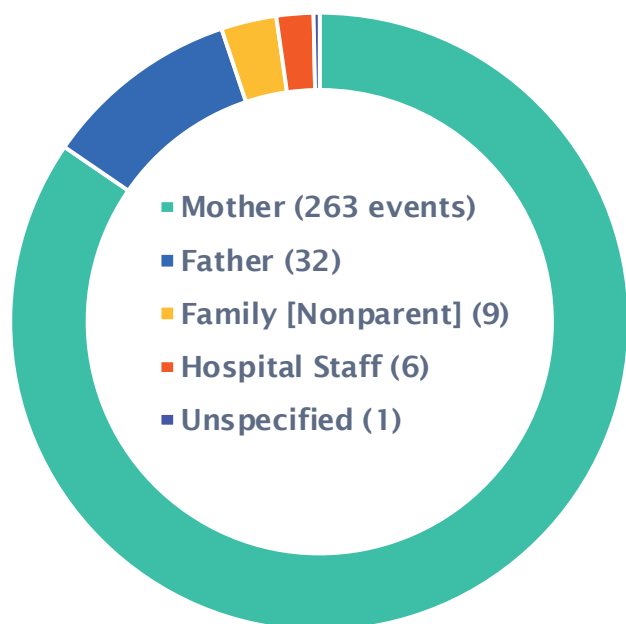
### Increase in Reports of Serious Newborn Falls

An increase in the number and rate of serious newborn fall events reported to PA-PSRS was observed. Of the 272 newborn fall events (no near misses were identified) reported to PA-PSRS from 2004 through 2013, 23 events (8.5%) were classified as Serious Events.<sup>2</sup> Of the 318 newborn fall events (excluding near misses) reported to PA-PSRS from 2014 through 2018, 33 events (10.3%) were classified as Serious Events.

### Breastfeeding and Maternal Sleep

More than half (52.8%) of the newborn fall events in

**Figure 4. Primary Caregiver Involved, N=311**



this study occurred when a caregiver, most often the mother, fell asleep with the baby in her arms or bed, and nearly one-fourth (22.6%) of events were associated with infant feeding, especially breastfeeding. There is substantial crossover between these groups; of the 72 events in which feeding was mentioned as a potential contributing factor to the newborn fall, 50 events (69.4%) identified the caregiver falling asleep as the primary contributing factor (**Figure 5**).

Many hospitals strongly encourage mothers to keep newborns in bassinets in their hospital rooms to promote bonding and breastfeeding in the immediate postpartum period. While the benefits of breastfeeding for both mother and baby are many, some recent commentaries and studies have suggested that this well-intentioned push for mothers to breastfeed exclusively around the clock may have unforeseen consequences for newborn safety. Mothers may experience fatigue, which may in turn lead to co-sleeping, putting the newborn at risk of a fall and suffocation.<sup>14,15</sup>

Data from a recent study of maternal sleepiness in the postpartum period demonstrated that mothers slept on average only 3.7 hours per day and that only about 6.9% of mothers (7 of 101) were getting the recommended eight hours of sleep while in the hospital after childbirth.<sup>16</sup> The relationship between breastfeeding and maternal sleep is complex. Another study looked at maternal sleep patterns among first-time mothers during the first 48 hours following delivery, and data from this study showed that mothers who breastfed slept on average 2.6

hours longer than mothers who bottle-fed ( $P=.042$ ).<sup>17</sup> However, a causal relationship between breastfeeding and maternal sleep cannot be established based on this limited data.

While newborn falls have been reported around the clock, numerous studies have identified the overnight hours as the peak time for in-hospital newborn falls to occur, and our analysis supports that finding.<sup>13,18,19</sup> In our analysis of newborn fall events published in 2014, 58.0% of newborn falls (140 of 257) were reported to have occurred between midnight and 7 a.m.<sup>2</sup> Similarly, 56.6% of newborn fall events (181 of 320) in the present study were reported to have occurred during that same time period. The cluster of events during hours when parents or caregivers would otherwise be sleeping suggests that maternal sleep in the immediate postpartum period should be a focal point in newborn fall prevention strategies.

### Newborn Fall Prevention Strategies

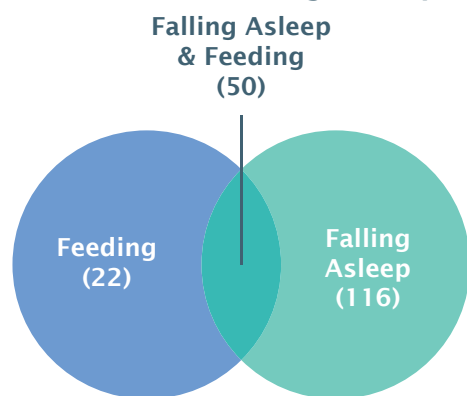
An analysis of near-miss newborn fall events has provided a window into awareness and prevention strategies already in place. Following a review of near-miss newborn fall events submitted to PA-PSRS from 2014 through 2018, we were able to identify a healthcare facility that has made great strides towards eliminating newborn falls: Penn Highlands Elk, a critical access hospital located in St. Marys, Pennsylvania, which is part of Penn Highlands Healthcare System. Nearly half of the 14 near-miss newborn fall events reported during the five-year study period were submitted by this single facility.

We reached out to Susan Dixon, RN, who is the patient safety/grievance officer and case management supervisor at Penn Highlands Elk. Dixon shared with us that following a newborn fall that occurred several years ago at her facility, she and members of her team conducted a root cause analysis and developed strategies to prevent future newborn falls.

Their team recognized parental fatigue as one important factor that may have contributed to the newborn fall at their facility. In order to educate new parents on potential safety issues, Dixon explained, “The first thing that we did as far as the action plan goes is that we changed the education that we give to parents.” New parents are given a welcome letter that includes information on newborn safety and safe sleep and discourages co-sleeping. Parents are also encouraged to give their baby to nursing staff to take to the nursery if they are feeling tired or just need a break. While not mandatory, parents are strongly encouraged to have a break in visiting hours from 2 p.m. to 4 p.m. each day to give them the opportunity



**Figure 5. Falls While Feeding & Sleeping**



to rest. This practice has been implemented at all facilities across the health system.

Their team identified breastfeeding as another contributing factor. Nurses were already rounding every hour on the maternity ward, so this was increased to every 15 minutes as an added precaution when mothers are breastfeeding. To support the nurses in this practice, the director of the maternity unit purchased handheld timers as a reminder. This is also something that became a systemwide initiative across the health system.

Overall, awareness and education among hospital staff about newborn safety and safe sleep was also increased at their facility. Staff receive specific training to prevent newborn falls, and they also learn how to lock hospital beds in the lowest position to reduce the likelihood of injury if a newborn were to fall from the bed. The American Academy of Pediatrics publishes and regularly updates recommendations for safe sleep practices to prevent sleep-related deaths among infants.<sup>20</sup> Several safe sleep practices that should be implemented in the hospital following birth include placing newborns on their back to sleep; using a firm sleep surface; and removal of all soft objects, including bedding, from the newborn's sleep area.

Dixon said that all staff on the maternity unit, including nurses and physicians, are conscientious about intervening when they see an unsafe situation. Within their hospital, staff on the maternity unit have received recognition for good catches to prevent newborn falls. Dixon shared that her facility has not experienced any newborn falls since implementation of these newborn fall prevention strategies, which are summarized in **Figure 6**.

### Risk Assessment

A safety advisory published by The Joint Commission (TJC) suggests that facilities develop an assessment

tool to identify those mothers and babies who are at highest risk of experiencing a newborn fall.<sup>1</sup> While most literature endorses a policy of educating all parents about the potential risks of newborn falls, TJC advises facilities to provide more education and support for parents and newborns who are at the highest risk, rather than taking a one-size-fits-all approach. High-risk situations that have been identified by reviewing newborn fall incidents include delivery (especially when the mother has lost a significant amount of blood) and transport (when a caregiver has the potential to trip and fall), as well as more broadly during the postpartum period (when parental fatigue is at its peak).<sup>7</sup> Additional research is needed to develop reliable assessment tools to prevent newborn falls in the future.

### Limitations

Despite mandatory event-reporting laws in Pennsylvania, PA-PSRS data are subject to the limitations of self-reporting; it is not possible to draw conclusions about changes in the actual rates of newborn falls. Reports have increased compared to our previous analysis, both in the raw numbers and the percentage of Serious Events among all newborn fall events in Pennsylvania. Upward trends in the data may simply highlight an increasing awareness about the risk of newborn falls in facilities across our state.

### Conclusion

Based on events reported to PA-PSRS from 2014 to 2018, it is evident that newborn falls continue to occur in healthcare facilities across Pennsylvania despite increased awareness of the issue in recent years. To reduce the possibility of newborn falls, recognition of the potential for these events should be increased in maternity units, and education should target both new parents and hospital staff alike. Because the primary contributing factor cited in more than half of newborn fall events reports in PA-PSRS is a caregiver falling asleep, facilities should focus their efforts on providing support for exhausted new mothers and fathers during the critical hours and days following the birth of a child, by offering periods of rest for new parents whenever they are tired, by increasing the frequency of rounding when new mothers are breastfeeding, and by promoting a break in visiting hours midday. In cases where a newborn fall event does occur, facilities should provide support to both injured newborns and any caregivers involved. In many cases, parents and other caregivers may benefit from counseling to help them better navigate the emotional turmoil that often follows these events.

## Figure 6. Newborn Fall Prevention Strategies



### Improve Education on Newborn Safety and Safe Sleep

- Welcome letter for new parents
- Training for hospital staff, including nurses and physicians
- More signage throughout maternity ward



### Support Rest Time for Parents, Especially Mothers

- Nurses offer to take baby to nursery whenever parents need a break
- Encourage a break in visiting hours from 2 p.m. to 4 p.m.



### Promote Vigilance Among Hospital Staff to Monitor for Potential Hazards to Newborn Safety

- Round every 15 minutes when mother is breastfeeding
- Always keep bed locked at lowest position

## Notes

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

## References

1. The Joint Commission. Preventing Newborn Falls and Drops. *Quick Saf*. 2018;40:1-2.
2. Wallace S. Balancing Family Bonding With Newborn Safety. *Pa Patient Saf Advis*. 2014;11(3):102-8.
3. Kocherlakota P. Neonatal Abstinence Syndrome. *Pediatrics*. 2014;134(2):e547-61. Epub 2014/07/30. doi: 10.1542/peds.2013-3524. PubMed PMID: 25070299.
4. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002).
5. Matteson T, Henderson-Williams A, Nelson J. Preventing In-hospital Newborn Falls: A Literature Review. *MCN Am J Matern Child Nurs*. 2013;38(6):359-66; quiz 67-8. Epub 2013/09/10. doi: 10.1097/NMC.0b013e3182a1fb91. PubMed PMID: 24013477.
6. Hodges KT, Gilbert JH. Rising Above Risk: Eliminating Infant Falls. *Nurs Manage*. 2015;46(12):28-32. Epub 2015/11/20. doi: 10.1097/01.NUMA.0000473504.41357.f5. PubMed PMID: 26583337.
7. Teuten P, Bolger S, Paul SP. Need For Improved Recognition of In-hospital Newborn Falls. *Aust Nurs Midwifery J*. 2015;23(1):28-31. Epub 2015/08/01. PubMed PMID: 26226814.
8. Carr H, Crotto J, Demirel S, Fisher S, Logue L, Marcott M, et al. A System-Wide Approach to Prevention of In-Hospital Newborn Falls. *MCN Am J Matern Child Nurs*. 2019;44(2):100-7. Epub 2019/02/27. doi: 10.1097/NMC.0000000000000516. PubMed PMID: 30807327.
9. Monson SA, Henry E, Lambert DK, Schmutz N, Christensen RD. In-hospital Falls of Newborn Infants: Data From a Multihospital Health Care System. *Pediatrics*. 2008;122(2):e277-80. Epub 2008/08/05. doi: 10.1542/peds.2007-3811. PubMed PMID: 18676512.
10. Helsley L, McDonald JV, Stewart VT. Addressing In-hospital "Falls" of Newborn Infants. *Jt Comm J Qual Patient Saf*. 2010;36(7):327-33. Epub 2011/01/14. PubMed PMID: 21226386.
11. Loyal J, Pettker CM, Raab CA, O'Mara E, Lipkind HS. Newborn Falls in a Large Tertiary Academic Center Over 13 Years. *Hosp Pediatr*. 2018;8(9):509-14. Epub 2018/08/03. doi: 10.1542/hpeds.2018-0021. PubMed PMID: 30068526.
12. Kahn DJ, Fisher PD, Hertzler DA, 2nd. Variation in Management of In-hospital Newborn Falls: A Single-Center Experience. *J Neurosurg Pediatr*. 2017;20(2):176-82. Epub 2017/05/20. doi: 10.3171/2017.3.PEDS16651. PubMed PMID: 28524786.
13. Ainsworth RM, Summerlin-Long S, Mog C. A Comprehensive Initiative to Prevent Falls Among Newborns. *Nurs Womens Health*. 2016;20(3):247-57. Epub 2016/06/12. doi: 10.1016/j.nwh.2016.04.025. PubMed PMID: 27287351.
14. Bass JL, Gartley T, Kleinman R. Unintended Consequences of Current Breastfeeding Initiatives. *JAMA Pediatr*. 2016;170(10):923-4. Epub 2016/08/23. doi: 10.1001/jamapediatrics.2016.1529. PubMed PMID: 27548387.
15. Hughes Driscoll CA, Pereira N, Lichenstein R. In-hospital Neonatal Falls: An Unintended Consequence of Efforts to Improve Breastfeeding. *Pediatrics*. 2019;143(1). Epub 2018/12/30. doi: 10.1542/peds.2018-2488. PubMed PMID: 30593451.
16. Bittle MD, Knapp H, Polomano RC, Giordano NA, Brown J, Stringer M. Maternal Sleepiness and Risk of Infant Drops in the Postpartum Period. *Jt Comm J Qual Patient Saf*. 2019;45(5):337-47. Epub 2019/05/20. doi: 10.1016/j.jcjq.2018.12.001. PubMed PMID: 31103475.
17. Hughes O, Mohamad MM, Doyle P, Burke G. The Significance of Breastfeeding on Sleep Patterns During the First 48 Hours Postpartum for First Time Mothers. *J Obstet Gynaecol*. 2018;38(3):316-20. Epub 2017/10/13. doi: 10.1080/01443615.2017.1353594. PubMed PMID: 29022404.
18. Torino VV, Tsunehiro MA, Santos AU, Aragaki I, Shimoda GT. Newborn Falls in Rooming-In Care. *Cogitare Enferm*. 2016;21(4):1-8.
19. Lipke B, Gilbert G, Shimer H, Consenstein L, Aris C, Ponto L, et al. Newborn Safety Bundle to Prevent Falls and Promote Safe Sleep. *MCN Am J Matern Child Nurs*. 2018;43(1):32-7. Epub 2017/10/19. doi: 10.1097/NMC.0000000000000402. PubMed PMID: 29045245.
20. Moon RY. SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*. 2016;138(5). Epub 2016/12/13. doi: 10.1542/peds.2016-2940. PubMed PMID: 27940805.

## About the Authors

**Elizabeth Kukiella** (ekukiella@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*. Kukiella 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.

**Susan C. Wallace** is a senior patient safety liaison with the Patient Safety Authority for the South Central region of Pennsylvania, as well as a Core Team Lead for the PSA's Center of Excellence for Improving Diagnosis. Prior to her current role, Wallace worked as a director of risk management, patient safety officer, and safety analyst.





# faces of falls

Susan Wallace♦♦, MPH  
Caitlyn Allen♦, MPH

DOI: 10.33940/falls/2019.12.6

**One in 56 patients fall every year in  
Pennsylvania hospitals. See the breakdown  
by age, harm score, and patient days.**





\*Corresponding author  
\*Patient Safety Authority  
Disclosure: The authors declare that they have no  
relevant or material financial interests.  
\*Not actual patients



# Pennsylvania Fall Rates

Falls are a common and often devastating health threat for hospitalized patients, as they can cause serious injuries such as a hip fracture, and even lead to death.<sup>1</sup> Falls in Pennsylvania continue to be one of the biggest contributors to patient harm and the fourth-most frequently reported event.<sup>2</sup> An estimated 1 out of every 56 inpatients will fall in a Pennsylvania hospital.

## Methods

We queried the Pennsylvania Patient Safety Reporting System\* (PA-PSRS) database for inpatient event reports submitted January 1, 2013, through December 31, 2018, by acute care, behavioral health, children's, critical access, long-term acute care, and rehabilitation hospitals. Events categorized as event type "Falls" or "Other/Miscellaneous" that contained the terms "fall" or "fell" were included. Records were excluded if they contained the phrases "did not fall," "fall risk," "fall wristband," "falls at home," "fall at home," "for a fall," "fallen asleep," "fear of fall," "fell at home," and "fell asleep."

"Other" reports were included if they met the definition of a fall, as outlined in the *Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act*.<sup>3</sup>

- a. Patient falls are to be reported as either Serious Events<sup>†</sup> or Incidents.<sup>‡</sup>

- b. A fall is defined as any unplanned descent to the floor (or other horizontal surface such as a chair or table), with or without injury to the patient. The definition of falls includes: 1) assisted falls in which a caregiver sees a patient about to fall and intervenes, lowering them to a bed or floor; 2) falls during physical or occupational therapy, in which a caregiver is present specifically to catch the patient in case of fall; 3) physiologic falls in which a patient falls as a result of seizure or syncope.
- c. The definition excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position.
- d. Falls with harm: Any fall that requires more than first aid care. Treatment beyond first aid care includes a laceration that requires medical intervention (e.g., sutures), more serious injury (e.g., fracture) or death.
- e. Note: The Patient Safety Authority (PSA) believes the criteria for falls as outlined here are consistent with the definitions and criteria used by the National Database of Nursing Quality Indicators (NDNQI). One notable exception is that NDNQI only counts falls occurring on nursing units and excludes other care settings (e.g., physical therapy). MCARE reporting requirements apply to the entire facility.

\*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.

†Event harms are defined by PA-PSRS taxonomy and are assigned to events by healthcare facilities at the time of report submission.

‡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.<sup>4</sup>

§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.<sup>4</sup>

Reports were stratified by harm score: “No harm” incidents that reached the patient are harm score C through D, and Serious Events are harm score E through I, which indicate temporary or significant harm and death.<sup>5</sup> Data on 2013–18 inpatient hospital days and discharges by patient age were obtained from the Pennsylvania Healthcare Cost Containment Council (PHC4).<sup>6</sup>

## Results

The query returned a total of 177,031 reports (175,095 reports categorized as “Fall” and 1,936 reports categorized as “Other”). Of the 1,936 events reported as “Other,” 203 were a fall, bringing the total number of reported falls to 175,298.

### Falls per 1,000 Patient Days

The fall rate per 1,000 patient days was calculated by using the total number of falls reported into PA-PSRS and the number of inpatient hospital days reported by PHC4. Annual fall rates ranged from 3.09–3.33 falls per 1,000 patient days, with an average annual rate of 3.21 falls per 1,000 patient days. Annual rates of falls per 1,000 patient days are in **Figure 1**.

### Falls with Harm per 1,000 Patient Days

The falls with harm rate per 1,000 patient days was calculated by using the total number of falls with harm reported into PA-PSRS and the number of inpatient hospital days reported by PHC4. Annual falls with harm rates ranged from 0.084–0.087 falls with harm

### Rate calculation methods included

- Rates of total falls and falls with no harm:  $\text{number of total patient falls} \times 1,000 / \text{number of patient days}$
- Rates of falls with harm:  $\text{number of patient falls} \times 1,000 / \text{number of patient days}$
- Number of inpatients who will fall annually:  $(29,215 \text{ average falls per year} / 1,641,886 \text{ average discharges per year}) = 0.0178$ 
  - $0.0178 = 1 / (\text{number of patients who will fall})$  is 1 out of 56 inpatients

per 1,000 patient days, with an average annual rate of 0.086 falls with harm per 1,000 patient days. Annual rates of falls with harm per 1,000 patient days are in **Figure 2**.

### Falls by Harm Level

More than 9 out of 10 of the 175,298 falls reported to PA-PSRS were No Harm events (170,598 to 4,694), with an average rate of 97.3% from 2013–18. The annual number of falls by harm level are in **Table 1**.

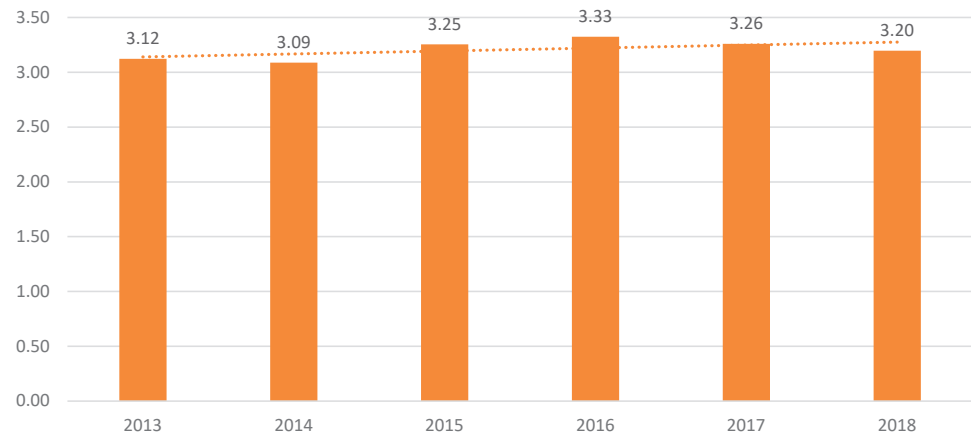
**Table 1. Annual Falls by Harm Level**

Year	Patient Days	Discharges	Total	No Harm	Serious
2013	9,659,562	1,686,343	30,170	29,341	829
2014	9,232,808	1,654,739	28,513	27,734	779
2015	9,041,883	1,648,769	29,427	28,643	784
2016	8,955,573	1,637,974	29,780	29,015	765
2017	8,903,601	1,621,387	29,018	28,244	774
2018	8,882,928	1,602,104	28,390	27,625	765
<b>Average</b>	<b>9,112,726</b>	<b>1,641,886</b>	<b>29,215</b>	<b>28,433</b>	<b>782</b>

Note: Number of falls reported by Pennsylvania hospitals (i.e., acute care, behavioral health, children’s, critical access, long-term acute care, rehabilitation) through the Pennsylvania Patient Safety Reporting System PA-PSRS, January 1, 2013–December 31, 2018. Patient days and discharges were provided by PHC4.

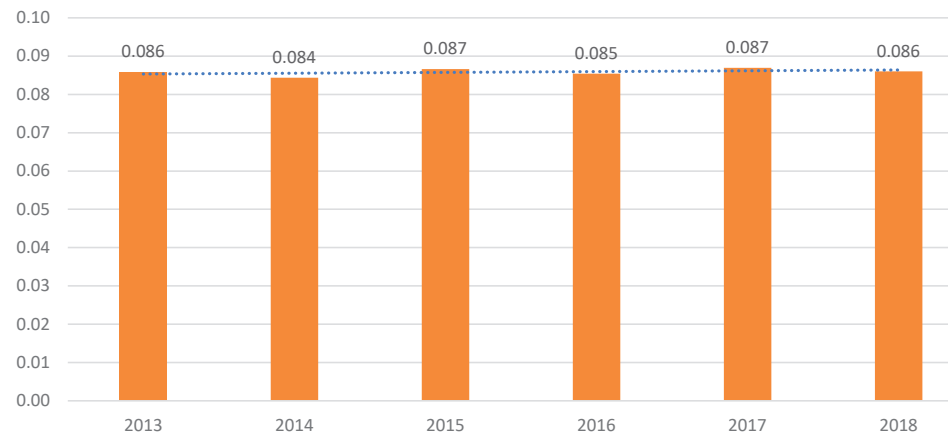


**Figure 1. Annual Falls per 1,000 Patient Days**



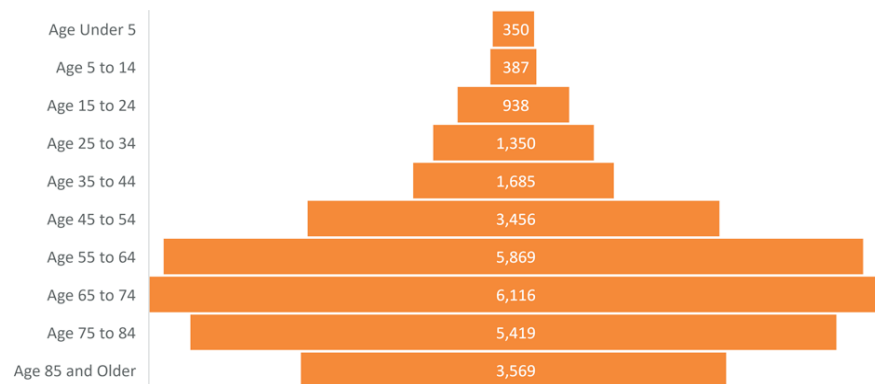
Note: Fall rates of Pennsylvania hospitals (i.e., acute care, behavioral health, children's, critical access, long-term acute care, rehabilitation) reported through PA-PSRS, January 1, 2013–December 31, 2018.

**Figure 2. Annual Falls With Harm per 1,000 Patient Days**



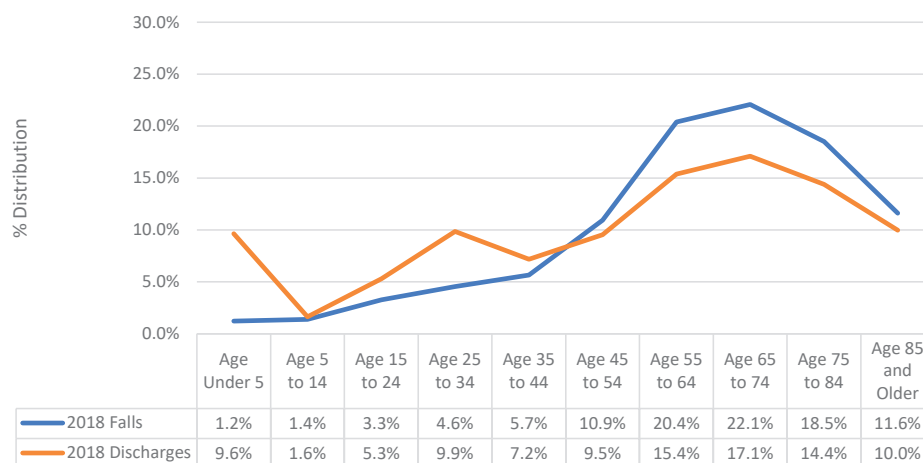
Note: Fall rates of Pennsylvania hospitals (i.e., acute care, behavioral health, children's, critical access, long-term acute care, rehabilitation) reported through PA-PSRS, January 1, 2013–December 31, 2018.

**Figure 3. Falls by Age Group**



Note: Average annual number of falls in Pennsylvania hospitals (i.e., acute care, behavioral health, children's, critical access, long-term acute care, rehabilitation) reported through PA-PSRS, January 1, 2013–December 31, 2018. Not every report included a patient age.

**Figure 4. 2018 Percentage of Total Inpatient Discharges and Falls by Age**



### Falls by Patient Age

Eighty-four percent of all reported falls occurred in patients aged 45 or older, with 65 to 74 being the most commonly reported age group. The annual fall rates by age are in **Figure 3**. **Figure 4** displays the distribution of inpatient discharges and falls by age in 2018.

### Limitations

PA-PSRS data contains only information submitted by facilities required to submit reports to the PSA. Although the data fields in PA-PSRS are standard for all reporting facilities, the type and amount of information recorded in those fields—including the event description field—varies among reports.

### Note

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

### References

1. Moyer VA U.S. Preventative Services Task Force. Prevention of falls in community-dwelling older adults; U.S. Preventative Services Task Force recommendation statement. *Ann Intern Med*. 2012;157:197-204.
2. Patient Safety Authority. Annual Report 2018 [online]. 2019 May 22 [cited 2019 Jun 6]. Available from internet: <http://patientsafety.pa.gov/PatientSafetyAuthority/Documents/2018%20PSA%20Annual%20Report.pdf>.
3. Doering, M., & Wolf, M. Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements Under the Medical Care Availability and Reduction of Error (MCARE) Act (n.d.). Harrisburg, PA.
4. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002).
5. Patient Safety Authority harm score taxonomy. Harrisburg (PA): Patient Safety Authority; 2015. 1 p. Also available: [http://patientsafety.pa.gov/ADVISORIES/Documents/Tool%20PDFs/201503\\_taxonomy.pdf](http://patientsafety.pa.gov/ADVISORIES/Documents/Tool%20PDFs/201503_taxonomy.pdf).
6. Pennsylvania Health Care Cost Containment Council (PHC4) [website]. [cited 2019 Dec 19]. Harrisburg (PA): PHC4. <http://www.phc4.org>

### Author Bios

**Susan C. Wallace** ([suwallace@pa.gov](mailto:suwallace@pa.gov)) is a senior patient safety liaison with the Patient Safety Authority for the South Central region of Pennsylvania, as well as a Core Team Lead for the PSA's Center of Excellence for Improving Diagnosis. Prior to her current role, Wallace worked as a director of risk management, patient safety officer, and safety analyst.

**Caitlyn Allen** is director of Engagement for the Patient Safety Authority and managing editor for *Patient Safety*, the PSA's peer-reviewed journal. Before joining the PSA, she was the project manager for Patient Safety at Jefferson Health, where she also was the only non-physician elected to serve on the House Staff Quality and Safety Leadership Council. Previously, Allen also was a project manager and patient safety officer for Wills Eye Hospital.





# Risk of Medication Errors With Infusion Pumps

A Study of 1,004 Events From 132 Hospitals Across Pennsylvania

Matthew Taylor, PhD<sup>♦◇</sup> & Rebecca Jones, MBA, RN<sup>◇</sup>

DOI: 10.33940/biomed/2019.12.7

The risk of medication errors with infusion pumps is well established, yet a better understanding is needed of the scenarios and factors associated with the errors. Our study explored the frequency of medication errors with infusion pumps, based on events reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS) during calendar year 2018. Our study identified a total of 1,004 events involving a medication error and use of an infusion pump, which occurred at 132 different hospitals in Pennsylvania. Fortunately, a majority of medication errors did not cause patient harm or death; however, we did find that 22% of events involved a high-alert medication. Our study shows that the frequency of events varies widely across the stages of medication process and types of medication error. In a subset of our data, we manually reviewed a free-text narrative field in each event report to better understand the nature of errors. For example, we found that a majority of wrong rate errors led to medication being infused at a faster rate than intended, and user programming was the most common contributing factor. Overall, results from our study can help providers identify areas to target for risk mitigation related to medication errors and the use of infusion pumps.

**Keywords:** *infusion pump, IV pump, smart pump, medication error, risk factors, adverse events, patient safety, Pennsylvania, high-alert medication, medical device*

<sup>♦</sup>Corresponding author

<sup>◇</sup>Patient Safety Authority

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

# 1,004

Events

# 132

Hospitals Reporting  
an Event

# 19%

of Events Had  
a Rate Error

# 85%

of Events  
Reached the  
Patient

# 22%

Events Involving  
a High-Alert Drug

Infusion pumps are essential for administering fluid, nutrients, and medications intravenously (IV) to patients; however, the use of infusion pumps is also associated with a high frequency of adverse events.<sup>1</sup> Previous research has noted the need for studies that capture the prevalence and context of errors associated with infusion pumps, as such knowledge is necessary to better understand scenarios and factors associated with greater risk.<sup>2-7</sup> Unfortunately, few studies have assessed medication errors with infusion pumps across more than 10 hospitals, during an extended period of time, and across multiple factors (e.g., stage of medication process, type of medication error, and contributing factor).

## Study Methods and Results

In this study, we explored the Pennsylvania Patient Safety Reporting System (PA-PSRS)\* database for events reported as a medication error that included the use of an infusion pump. Our database query included a total of 39 unique keywords that were paired with the term “pump.” The 39 unique keywords consisted of “infusion,” “IV,” “smart,” and 36 company names. We selected only names of companies who submitted a 510(k) premarket notification† to the U.S. Food and Drug Administration (FDA) during years 2000–2018. In addition to using a keyword filter during our query

\* 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.

† According to the FDA, “medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected.”<sup>8</sup>

‡ “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.<sup>9</sup>

# “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.<sup>9</sup>

\*\* High-alert medications are defined as drugs that bear a heightened risk of causing significant patient harm when they are used in error.<sup>10</sup>

of PA-PSRS, we also narrowed our search to events that occurred at hospitals and were submitted to PA-PSRS between January 1 and December 31, 2018.

Based on our query of PA-PSRS, we identified a total of 1,004 events, from which we selected a random sample of 30% (n = 300 of 1,004) for manual review. One author manually reviewed the sample of 300 events and confirmed that the free-text narrative field in all event reports (100%; n = 300 of 300) described a medication error with use of an infusion pump. This finding indicates a high degree of confidence in the results of our database query, 95% CI [98.8%–100%; Clopper-Pearson exact method], so we proceeded to include the full data set of 1,004 events in our analysis.

Our study revealed that the 1,004 events were concentrated at 132 of the hospitals in Pennsylvania. Among the 132 hospitals with an event, we found that the median was 3 events per hospital and a mean of 7.61 (SD: 14.79) per hospital.

Based on information provided by event reporters, 99% (n = 996 of 1,004) of the events were identified as Incidents<sup>‡</sup> and 1% (n = 8 of 1,004) as Serious Events.<sup>#</sup> Also, 85% (n = 856 of 1,004) of all medication errors reached the patient and high-alert medications<sup>\*\*</sup> were involved in 22% (n = 217 of 1,004) of the events. **Table 1** shows a cross tabulation of the 1,004 events. The data show that the frequency of events varies widely across the stages of the medication process and types of medication error. In particular, the data reveal that 59% (n = 595 of 1,004) of events were categorized as PA-PSRS medication error taxonomy type “Wrong.” This type of medication error is further categorized into 11 different subtypes (see **Figure 1**).

In **Figure 1**, we focused on the subtypes of wrong medication error and found that 19% (n = 187 of 1,004) of the events were categorized as having a Rate error. Based on this finding, we manually reviewed the free-text narrative field for all 187 event reports with a Rate error to better understand the nature of the events.

We independently classified each of the 187 events to determine how the rate of medication differed from what was

**Table 1. Frequency of Events During 2018 With a Medication Error and Use of an Infusion Pump**

Types of Med Error	Total Events <sup>1</sup>	Stages of Medication Process					
		Prescribing	Transcription	Preparation	Administration	Monitoring	Other
Dose omission	126	0	0	2	114	6	7
Extra dose	16	2	0	0	12	1	3
Wrong*	595	34	23	39	468	50	58
Prescription/refill delayed	13	6	0	3	4	0	1
Medication list incorrect	2	1	1	1	0	0	1
Monitoring error	32	1	1	2	19	9	3
Unauthorized drug	7	1	0	1	4	1	1
Inadequate pain management	2	0	0	0	2	0	0
Other	211	18	9	20	129	27	37
<b>Total Events</b>	<b>1,004</b>	<b>63</b>	<b>34</b>	<b>68</b>	<b>752</b>	<b>94</b>	<b>111</b>

<sup>1</sup>Events may have involved more than one stage of medication process.

\*"Wrong" is a term used in the PA-PSRS taxonomy to describe a type of medication error. Wrong is defined by 11 subtypes, which are listed in Figure 1.

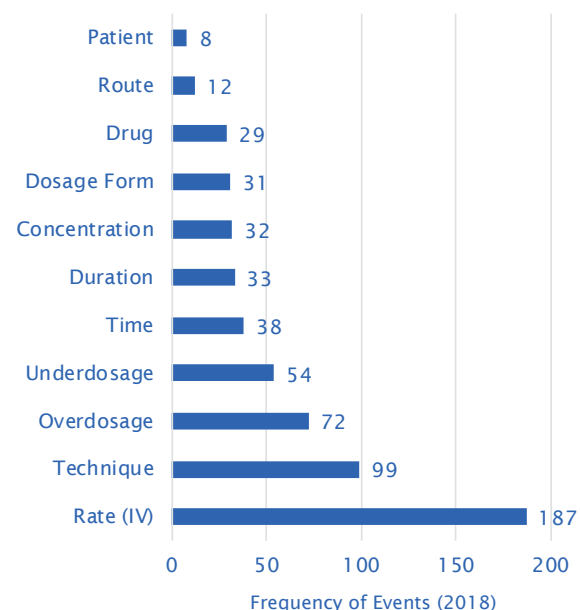
intended (e.g., faster or slower). To assess inter-rater reliability of our classification, we used the kappa statistic,<sup>11</sup> which indicates that we had a substantial level of agreement ( $K = 0.812$ ).<sup>12</sup> During our initial review we agreed on Rate classification in 88% ( $n = 165$  of 187) of events. Thereafter, we reviewed all 22 disagreements and came to consensus on the appropriate Rate classification per event, which ultimately yielded 100% agreement and increased the accuracy of our results.

Results from our classification revealed that 85% ( $n = 158$  of 187) of event reports provided sufficient information to determine how the medication rate differed from what was intended. Based on events with sufficient information, we found that 64% ( $n = 101$  of 158) of events involved medication infusion at a faster rate than intended, 32% ( $n = 50$  of 158) infused at a slower rate, and 4% ( $n = 7$  of 158) had both a faster and slower rate (e.g., single event included two medications and were swapped on pump channels).

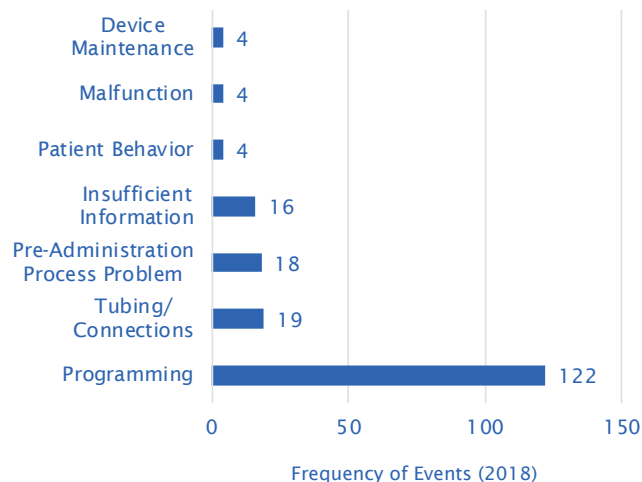
While reviewing the 187 events with a Rate error, we attempted to identify the key contributing factor for each event, based on information provided in the free-text narrative field. We independently applied a categorization system that consisted of seven contributing factors, which are defined in Table 2. We evaluated our inter-rater reliability of event classification with the Kappa statistic,<sup>11</sup> which revealed that we had a substantial level of agreement ( $K = 0.730$ ).<sup>12</sup> We agreed on Rate classification in 84% ( $n = 157$  of 187) of events during our initial review. To increase the accuracy of our results, we reviewed all 30 disagreements and came to consensus on the appropriate contributing factor classification for each event, which then resulted in 100% classification agreement.

Results from our classification of Rate errors showed that 91% ( $n = 171$  of 187) of events had sufficient information to identify a key contributing factor. Based on events with sufficient information,

**Figure 1. Subtypes of "Wrong" Medication Errors**



**Figure 2. Factors Contributing to Rate Error**





**Table 2. Factors Contributing to a Medication Rate Error With an Infusion Pump**

Contributing Factor	Definition and Sample Event
<b>Programming</b>	<p><b>Definition:</b> Entered incorrect setting or value into infusion pump interface. Provider may have entered incorrect information for a range of reasons, such as miscalculation due to incorrect patient weight or chose incorrect units of measure when calculating rate (e.g., ml/hr vs. mg/kg/hr), failure to adjust rate post-bolus, entered too few or too many digits (e.g., entered 0.2 instead of 0.02 or 488 instead of 48), entered a value into the rate field that was intended for dose or Volume To Be Infused field (i.e., field swap), failed to choose correct medication in drug library or instead entered as custom concentration, entered drug information into incorrect pump channel (i.e., pump channel swap), or failed to start pump after entering information.</p> <p><b>1) Sample Event:</b> A 61 year-old male was taken to the Emergency Dept after being found unresponsive at home. On arrival, his blood sugar was 1,594. An insulin bolus and drip were ordered. After verification by two nurses, the 10-unit bolus was administered and the drip (100mL bag with 100 units of insulin) was started. Just a few minutes later, the IV pump alarmed and the nurse discovered that the entire 100mL bag had infused due to erroneous pump programming. Treatment was administered, but the patient soon became short of breath with an irregular heart rhythm and a Code Blue was called. The patient was resuscitated and admitted to the ICU.</p> <p><b>2) Sample Event:</b> When the oncoming nurse checked the PCA pump to verify the patient's HYDROMORPHONE rates, he noticed that the pump was programmed incorrectly. The basal rate ordered for 0.6mg/hr was running at 0.3mg/hr and the PCA dose ordered for 0.3mg was set at 0.6mg. The rates were corrected and the patient was closely monitored.</p> <p><b>3) Sample Event:</b> While hanging IV fluids to run with an anesthetic drug, the nurse set the pump at 999mL/hr to clear the air in the tubing. The rate was not subsequently changed to the actual rate ordered for the fluids (10mL/hr) and the patient received a significant bolus of fluid as a result. The physician was notified and the patient's vital signs were checked more frequently overnight.</p> <p><b>4) Sample Event:</b> Patient with a history of red man syndrome asked nurse to infuse his vancomycin slower than usual. Vancomycin was ordered to infuse over 1 hour and nurse intended to program the pump to infuse the medication over 2 hours. However, the nurse inadvertently programmed the pump to infuse over 15 minutes instead of over 2 hours. The patient subsequently developed hives and extreme itching. The physician was notified and Benadryl was administered.</p> <p><b>5) Sample Event:</b> Oncoming nurse noticed that the infusion pump was programmed to infuse epinephrine to the patient based on a weight of 76kg. However, patient's weight listed in medical record as 176kg. Nurse verified correct weight was 176kg and adjusted the pump settings accordingly.</p>
<b>Pre-Administration Process Problem</b>	<p><b>Definition:</b> Incorrect order, transcription, or preparation of medication. For example, medication order may have had incorrect or conflicting rate or dose information, transcription of medication order was misinterpreted, erroneous laboratory test result led to wrong rate, medication prepared as a volume greater or lesser than ordered.</p> <p><b>1) Sample Event:</b> Nurse noticed that patient's dosing weight for Heparin was listed as 58 kg, but the order was written using a weight of 64kg and the pump was set for 64kg. Nurse contacted physician and Heparin rate was decreased to match appropriate dosing weight of 58kg.</p> <p><b>2) Sample Event:</b> Handwritten orders in patient's chart contained conflicting information regarding the rate of infusion for chemotherapy drug (1 hour vs. 2 hours). Pharmacy profiled the medication to be infused over 1 hour and it was administered accordingly. After the infusion was complete, it was determined the rate was too fast for the patient and the medication should have been infused over 2 hours.</p>

<u>Contributing Factor</u>	<u>Definition and Sample Event</u>
<b>Tubing/Connections</b>	<p><b>Definition:</b> Failure to correctly connect or clamp IV tubing. For example, the provider may have erroneously administered medication as gravity flow instead of via the pump, connected IV tubing to the incorrect access port, connected tubing meant for another medication into wrong bag, or failed to close or open the tubing clamp.</p> <p><b>1) Sample Event:</b> 25 year-old female patient ordered to receive an immunosuppressant drug to be infused over 4 hours. While hanging the medication, the nurse became distracted and inadvertently hung the medication by gravity instead of loading it into the pump. This resulted in the medication being infused over 5 minutes instead of over 4 hours as ordered. The patient immediately complained of chest pain. She was placed on increased monitoring and an EKG and other testing was ordered. All tests came back within normal limits.</p> <p><b>2) Sample Event:</b> 80 year old male patient was ordered to receive Protonix 80mg/100mL at a rate of 10 ml/hr continuously, along with IV fluids at a rate of 80mL/hr continuously. Within minutes of starting the Protonix infusion, the nurse heard the pump alarming and realized the Protonix bag was spiked using the tubing meant for the IV fluids and the entire 80mg dose had infused over less than 10 minutes.</p>
<b>Malfunction</b>	<p><b>Definition:</b> Despite correct programming and set-up, the pump or tubing valve did not function properly.</p> <p><b>Sample Event:</b> As a result of a pump malfunction, the patient's diuretic medication was delivered at a faster rate than programmed. Patient was ordered to receive 5mL/hr—and pump was accurately programmed at 5mL/hr—but drip rate was observed for one minute and noted to be much greater than 5mL/hr. The pump was taken out of service and sent to the biomedical department for evaluation.</p>
<b>Device Maintenance</b>	<p><b>Definition:</b> Device was not maintained properly, which prevented it from functioning as intended. For example, the drug library was not set-up properly or multiple pumps had the same barcode.</p> <p><b>Sample Event:</b> When attempting to program IV pump, the incorrect rate was showing for the IV fluids she was intending to administer. After investigating the problem, it was discovered that two different pumps had the same barcode assigned to Line A. Both pumps were removed from service.</p>
<b>Patient Behavior</b>	<p><b>Definition:</b> Patient intentionally or unintentionally adjusted programming of the pump.</p> <p><b>Sample Event:</b> While assessing the patient, the nurse noticed the IV fluids were set at a rate of 700mL/hr instead of 100mL/hr as ordered. The patient told the nurse he pushed some buttons on the pump and must have changed the rate. The nurse corrected the rate to 100mL and locked the pump.</p>
<b>Insufficient Information</b>	<p><b>Definition:</b> Inadequate information that prevented us from confidently identifying the contributing factor.</p> <p>The event report provided little information beyond stating that the medication was infused too quickly or too slowly.</p>

**Figure 2** shows that 71% (n = 122 of 171) of Rate errors were related to programming of the infusion pump, 11% (n = 19 of 171) were related to tubing/connections, and 11% (n = 18 of 171) were related to preadministration process problems. As indicated by the definition of “programming” in **Table 2**, the factor is broad and includes a range of elements. We would have preferred to present the data according to more specific categories of contributing factors, such as miscalculations and human factors; however, most of the event narratives did not include adequate information to make such a determination.

### Limitations

Although our study is based on reports from 132 hospitals, our findings only reflect reports that matched our query. It is possible that some reports of medication errors involving infusion pumps from other hospitals were not included in the results based on the event type selection and language used to report them in PA-PSRS. In addition, although hospitals are mandated to report all Incidents and Serious Events, it is possible that some underreporting may have occurred. Therefore, we caution against using our findings as an estimate of the absolute number of events across Pennsylvania. Instead, we encourage focusing on the information gleaned from the reports discussed in this study.

### Safety Strategies

Our findings shown in the figures and tables are a testament to event reporters at 132 of the hospitals in Pennsylvania. By studying the event reports we are able to collectively learn from the events, better understand the nature of the events, and subsequently devise strategies to mitigate risk. Our findings suggest that the conditions associated with programming create the greatest risk for patient harm. As indicated in **Table 2**, a breadth of conditions contribute to the events with erroneous programming. Due to the myriad of variables that contribute to erroneous pump programming, hospital staff should consider an array of strategies for minimizing risk of errors. Based on our findings and various references, we outlined several strategies that may help providers and hospitals decrease the risk of infusion pump programming errors.

**1. Ensure appropriate setup, maintenance, and integration of smart pumps.** Modern infusion pumps, often referred to as smart pumps, incorporate numerous design features that are intended to prevent various types of use errors.<sup>1</sup> For example, many models of infusion pumps now include the capability for upload-

ing a drug library with preset limits specific to each drug. This technology can help prevent wrong dose, wrong rate, and various other setting errors.<sup>13,14</sup> Despite the potential benefits of this technology, when compared to traditional infusion pump models, many of the advantages are dependent on the setup and maintenance of the pump.<sup>13,15</sup>

**Enhanced safety associated with smart pumps is dependent on the setup and maintenance of the device.**

For example, studies have reported that use of a comprehensive drug library that is regularly maintained/updated is associated with a reduction in use errors.<sup>16,17</sup> With an incomplete and outdated drug library, users are more likely to enter custom concentrations and identify workarounds that nullify the potential benefits of the “smart” technology.<sup>13,18</sup> Furthermore, studies have shown that use of “soft limit” settings, rather than “hard limit” settings, has little impact on the reduction of use errors.<sup>15,19</sup> With the use of soft limits, staff are able to bypass the warning and administer a potentially unsafe drug dose or

rate.<sup>14</sup> In contrast, if the infusion pump is set up with “hard limits”, then studies have shown a significantly lower rate of errors when compared to traditional infusion pumps.<sup>13,15,19</sup> Additionally, a study reported observing fewer wrong patient errors with a smart pump that included a barcode reader.<sup>19</sup>

The Institute for Safe Medication Practices (ISMP) recommends using a system that includes an infusion pump with a barcode reader to facilitate bidirectional interoperability with electronic health records.<sup>20</sup> Successful implementation of this type of system would dramatically reduce the need for providers to manually enter information and instead increase the use of autoprogramming. Greater use of autoprogramming likely will reduce errors across the various stages of the medication process. Although greater use of autoprogramming should be the goal, facilities should note that successful implementation and maintenance of a bidirectional interoperable system is dependent on many variables and a rather complex process. As a result, ISMP recommends using a multidisciplinary team that includes stakeholders from 12 different groups to develop and maintain the system.

Despite the many potential benefits of “smart” infusion pumps, staff should keep in mind that the technology will not prevent all use errors and the degree of reduction in use errors is heavily dependent on the staff’s adoption of the safety-related features that are designed to reduce risk.<sup>14</sup> Overall, hospitals should continue to adopt smart infusion pumps and put forth significant effort to ensure that pumps are set up and maintained properly, and that the safety-related features are adopted by staff.<sup>16,21,22</sup>



**2. Apply a multidisciplinary approach when evaluating and procuring infusion pump.** Given the implications for patient safety and cost associated with a large procurement of infusion pumps, it is very important that all relevant parties are involved in the decision-making process.<sup>23-25</sup> In particular, it is important that frontline staff (e.g., nurses) are able to view a demonstration of the device and ideally have an opportunity for a hands-on experience with each device that is being considered for procurement.<sup>25,26</sup> This experience allows a representative of frontline staff, who will be the regular user of the pump, to consider how the pump design and safety-related features will impact usability.

Previous studies have recommended that frontline staff formally review and evaluate the pumps in a systematic manner, in an effort to increase uniformity and reduce bias in the decision-making process.<sup>25,26</sup> In addition to frontline staff, it is important that representatives from pharmacy and biomedical engineering teams also are given an opportunity to evaluate the pump and drug library software for set up and maintenance.<sup>23</sup>

Last, we recommend that a human factors scientist be involved, if possible, to conduct a formal evaluation to identify any potential design problems with each infusion pump. A human factors scientist's evaluation may range in complexity and depth from a heuristic assessment to full-scale usability testing.<sup>27</sup> The heuristic assessment is a popular approach because it is considered an efficient and low-cost method for identifying usability problems, which are often associated with the occurrence of medical errors.<sup>28,29</sup>

As demonstrated by Zhang et al.,<sup>28</sup> a heuristic assessment can be applied to evaluate the usability of infusion pumps. In their study, they used 14 heuristics (i.e., empirically guided principles) to evaluate the design of two models of infusion pumps and found that one pump had 89 usability problems and the other pump had 52 usability problems.

In addition to a heuristic assessment, a facility may also consider hiring a human factors scientist to conduct full-scale usability testing in a simulated clinical environment with frontline staff.<sup>26,30</sup> The information gathered from this type of testing may help to elucidate and confirm hypotheses generated from a heuristic assessment.<sup>23,31</sup> Overall, input from a knowledgeable human factors scientist likely will generate highly valuable information that will help to inform the procurement of a well-designed infusion pump and mitigate risk of an adverse event.<sup>25</sup>

In the procurement process, personnel should also factor in which models of pumps are already used at the

facility. Greater standardization or uniformity among the inventory of pumps could decrease maintenance errors and use errors.<sup>16,32</sup> For example, if the entire inventory of pumps within a unit is uniform, then personnel are less likely to have a problem operating the pumps.

Furthermore, if pumps are uniform across units, then personnel likely will have fewer challenges when transferring patients from one unit to another. Additionally, personnel who work in various units (e.g., float nurses) would be less likely to have a problem operating the pumps if all units use the same model of infusion pump. In contrast, when personnel use multiple models of a medical device, then the variability in design across models may increase the likelihood for misinterpretation of a device interface and induce a use error.<sup>33-35</sup> As a result, facilities should consider using a uniform inventory of infusion pumps, which may reduce the likelihood of erroneous pump programming.

**3. Develop a process to regularly collect safety-related data, review the data, and create solutions to address pump-related concerns.** Given the complexity of this recommendation, we urge facilities to develop a multidisciplinary team and apply a continuous quality-improvement process.<sup>20</sup> This type of process has been shown to produce a range of improvements in healthcare facilities, including those related to the use of infusion pumps.<sup>18,32</sup> One of the primary components of this process is collecting information, which will inform the choice of solution(s).

Fortunately, healthcare facilities encourage and often mandate that employees report patient safety-related events to their in-house reporting system.<sup>36-39</sup> In the interest of preventing Serious Events, we strongly encourage staff and leadership to place a high degree of value in the information gathered from "near miss" events. Near misses are particularly important because they are a warning signal of the potential for a Serious Event. As a result, we recommend that healthcare facilities develop a robust system for collecting reports of actual and near miss patient safety events.

We also encourage facilities to leverage data from infusion pump event logs (i.e., onboard memory), which are often overlooked. Event logs from infusion pumps, much like black boxes in aviation, can be used to provide insight about how staff are using the device.<sup>5,20</sup> For example, the event logs can be used

to assess staff's compliance with alerts by level and type, and compliance with the dose error reduction system (DERS) by care area and medication.<sup>20</sup> The insights gathered from event logs are low effort and efficient, when compared to direct observation of

**Leverage event log data from pumps to gain additional insight.**

users engaging with the device. Furthermore, the event log data are often considered to be objective and reliable, which may enhance confidence in the process of developing solutions to address concerns with infusion pumps.

With quality data, a team could apply a continuous quality improvement process to analyze the data, investigate the concerns, and develop robust solutions to improve patient safety. Given the complexity of a healthcare environment and the many groups involved in ensuring patient safety during use of infusion pumps, there are many possible solutions to mitigate risk.<sup>20</sup> For example, depending on the nature of the concerns, the multidisciplinary team may recommend replacing the problem pump with a better designed pump. Alternatively, the team may reveal that a simple adjustment of a setting on the device could significantly reduce the likelihood of a use error (e.g., use of hard limits rather than soft limits).<sup>21,30,40</sup> As another possible solution, the team may recommend developing a staffwide training program with concrete strategies to reduce the likelihood of a specific use error.<sup>30,38,41-43</sup> Although training can be effective, engineering controls or design-oriented strategies are often more reliable in preventing a use error.<sup>13</sup> Nevertheless, we recognize that facilities often have no options other than training the staff to avoid specific use errors.

When developing a training program with the goal of helping staff prevent notable patient harm, we strongly recommend using a well-qualified team to develop the training content. As demonstrated by previous research, the effectiveness of a training program can vary widely and depend on many variables, such as quality of feedback, complexity of the target behavior (e.g., recognition vs. kinesthetic repertoire), correspondence between the trained behavior and the desired behavior in a clinical context, similarity and distinction among stimulus properties in the training environment and the target clinical environment, and rigor of the skill assessment.<sup>44-46</sup> Regardless of the solution selected to mitigate risk, the effectiveness of a safety program is heavily dependent on a culture of reporting near misses.

## Conclusion

Despite recent advances in infusion pump technology, hospitals continue to experience medication errors while using infusion pumps. The current study provides insight into the frequency of events by stages of the medication process, types of medication errors, and contributing factors. Based on a subset of our data, the findings show that pump programming, tubing/connections, and preadministration process problems are the primary factors contributing to medication errors with infusion pumps. In an effort to mitigate risk of safety-related events, we urge personnel at healthcare facilities to foster a strong culture of

event reporting, including near miss events. With that information, a safety program can proactively identify problems and subsequently develop solutions. As we have highlighted, there are many potential solutions to mitigating risk of medication errors with infusion pumps. Personnel should carefully consider all possible solutions, which will range from acquiring better-designed pumps, adjusting settings on the pumps, or developing a robust error reporting and training program to address use errors.

## Notes

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

## References

1. U.S. Food and Drug Administration. White Paper: Infusion Pump Improvement Initiative. 2010.
2. Schnock KO, Dykes PC, Albert J, Ariosto D, Call R, Cameron C, et al. The Frequency Of Intravenous Medication Administration Errors Related to Smart Infusion Pumps: A Multihospital Observational Study. *BMJ Qual Saf.* 2017;26(2):131-40.
3. Blandford A, Furniss D, Lyons I, Chumbley G, Iacovides I, Wei L, et al. Exploring the Current Landscape of Intravenous Infusion Practices and Errors (ECLIPSE): Protocol for a Mixed-Methods Observational Study. *BMJ Open.* 2016;6(3):e009777.
4. Husch M, Sullivan C, Rooney D, Barnard C, Fotis M, Clarke J, et al. Insights From the Sharp End of Intravenous Medication Errors: Implications for Infusion Pump Technology. *BMJ Qual Saf.* 2005;14(2):80-6.
5. Lee PT, Thompson F, Thimbleby H. Analysis Of Infusion Pump Error Logs and Their Significance for Health Care. *British Journal of Nursing.* 2012;21(Sup8):S12-S20.
6. Lyons I, Furniss D, Blandford A, Chumbley G, Iacovides I, Wei L, et al. Errors and Discrepancies in the Administration of Intravenous Infusions: A Mixed Methods Multihospital Observational Study. *BMJ Qual Saf.* 2018;27(11):892-901.
7. Schnock KO, Dykes PC, Albert J, Ariosto D, Cameron C, Carroll DL, et al. A Multi-Hospital Before-After Observational Study Using a Point-Prevalence Approach With an Infusion Safety Intervention Bundle to Reduce Intravenous Medication Administration Errors. *Drug Safety.* 2018;41(6):591-602.
8. 510(k) Premarket Notification. Medical Device Databases: U.S. Food and Drug Administration; 2019 [October 16, 2019]. Available from: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>.
9. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002).
10. Institute for Safe Medication Practices. High-Alert Medications in Acute Care Settings. August, 2018 [9/26/2019]. Available from: <https://www.ismp.org/recommendations/high-alert-medications-acute-list>
11. IBM SPSS Statistics for Macintosh. Version 26.0. Released 2019. Armonk, NY: IBM Corp.
12. Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;159-74. PubMed Central PMCID: PMC843571.
13. Pinkney S, Trbovich P, Fan M, Rothwell S, Cafazzo JA, Easty A. Do Smart Pumps Actually Reduce Medication Errors? *Human Factors Horizons.* 2010. 2010;44(s1):64-9.
14. Ohashi K, Dalleur O, Dykes PC, Bates DW. Benefits and Risks of Using Smart Pumps to Reduce Medication Error Rates: A Systematic Review. *Drug Safety.* 2014;37(12):1011-20.
15. Trbovich P, Jeon J, Easty A. Smart Medication Delivery Systems: Infusion Pumps. Healthcare Human Factors Group; 2009.

16. Breland BD. Continuous Quality Improvement Using Intelligent Infusion Pump Data Analysis. *Am J Health-Syst Ph.* 2010;67(17):1446-55.
17. Skledar SJ, Niccolai CS, Schilling D, Costello S, Mininni N, Ervin K, et al. Quality-Improvement Analytics for Intravenous Infusion Pumps. *Am J Health-Syst Ph.* 2013;70(8):680-6.
18. Harding AD. Increasing the Use of "Smart" Pump Drug Libraries By Nurses: A Continuous Quality Improvement Project. *Am J Nurs.* 2012;112(1):26-35.
19. Trbovich P, Pinkney S, Cafazzo J, Easty A. The Impact of Traditional and Smart Pump Infusion Technology on Nurse Medication Administration Performance in a Simulated Inpatient Unit. *BMJ Qual Saf.* 2010;19(5):430-4.
20. Institute for Safe Medication Practices. Draft Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps 2019 [11/8/2019]. Available from: <https://ismp.org/resources/draft-guidelines-optimizing-safe-implementation-and-use-smart-infusion-pumps>.
21. Peterson J, Losek JD. Post-Tonsillectomy Hemorrhage and Pediatric Emergency Care. *Clin Ped.* 2004;43(5):445-8. doi: 10.1177/000992280404300505.
22. Rothschild JM, Keohane CA, Cook EF, Orav EJ, Burdick E, Thompson S, et al. A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients. *Crit Care Med.* 2005;33(3):533-40.
23. Namshirin P, Ibey A, Lamsdale A. Applying a Multidisciplinary Approach to the Selection, Evaluation, and Acquisition of Smart Infusion Pumps. *J Med Biol Eng.* 2011;31(2):93-8.
24. Rosenkoetter MM, Bowcutt M, Khasanshina EV, Chernecky CC, Wall J. Perceptions of the Impact of "Smart Pumps" on Nurses and Nursing Care Provided. *J Assoc Vasc Access.* 2008;13(2):60-9.
25. Keselman A, Patel VL, Johnson TR, Zhang J. Institutional Decision-Making to Select Patient Care Devices: Identifying Venues to Promote Patient Safety. *J Biomed Inf.* 2003;36(1-2):31-44.
26. Cassano AL, editor. Applying Human Factors to the Procurement of Electrosurgical Medical Devices: A Case Study. Proceedings of the Human Factors and Ergonomics Society Annual Meeting; 2003: SAGE Publications Sage CA: Los Angeles, CA.
27. Ginsburg G. Human Factors Engineering: A Tool for Medical Device Evaluation in Hospital Procurement Decision-Making. *J Biomed Inf.* 2005;38(3):213-9.
28. Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using Usability Heuristics to Evaluate Patient Safety of Medical Devices. *J Biomed Inf.* 2003;36(1-2):23-30.
29. Gagnon R, Laberge J, Lamsdale A, Histon J, Hudson C, Davies J, et al., editors. A User-Centered Evaluation of Three Intravenous Infusion Pumps. Proceedings of the Human Factors and Ergonomics Society Annual Meeting; 2004: SAGE Publications Sage CA: Los Angeles, CA.
30. Miller KE, Arnold R, Capan M, Campbell M, Zern SC, Dressler R, et al. Improving Infusion Pump Safety Through Usability Testing. *J Nurs Care Qual.* 2017;32(2):141-9.
31. Lamsdale A, Chisholm S, Gagnon R, Davies J, Caird J, editors. A Usability Evaluation of an Infusion Pump by Nurses Using a Patient Simulator. Proceedings of the Human Factors and Ergonomics Society Annual Meeting; 2005: SAGE Publications Sage CA: Los Angeles, CA.
32. Burdeu G, Crawford R, van de Vreede M, McCann J. Taking Aim at Infusion Confusion. *J Nurs Care Qual.* 2006;21(2):151-9.
33. Taylor MA, Li A, Estock JL, Boudreaux-Kelly MY, Pham IT, Casey MC. Preferred Terms and Icons for Labels on Electrosurgical Units: Survey of VA Nurses. *Biomed Inst Tech.* 2019;53(2):102-9.
34. Pyrek KM. Product Evaluation and Purchasing Advice for Perioperative Nurses and Infection Preventionists. *Inf Control Today.* 2012.
35. Donaldson MS, Corrigan JM, Kohn LT. *To Err Is Human: Building A Safer Health System.* National Academies Press; 2000.
36. Wolf ZR, Hughes RG. Error Reporting and Disclosure. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Agency for Healthcare Research and Quality (US); 2008.
37. Koczmara C, Dueck C, Jelincic V. *To Err Is Human, To Share Is Divine. Dynamics.* 2006;17(3).
38. Polisen J, Gagliardi A, Urbach D, Clifford T, Fiander M. Factors That Influence the Recognition, Reporting and Resolution of Incidents Related to Medical Devices and Other Healthcare Technologies: A Systematic Review. *Syst Rev.* 2015;4(1):37.
39. Polisen J, Gagliardi A, Clifford T. How Can We Improve the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals? A Qualitative Study of Physicians and Registered Nurses. *BMC Health Services Research.* 2015;15(1):220.
40. Estock JL, Pham I-T, Curinga HK, Sprague BJ, Boudreaux-Kelly MY, Acevedo J, et al. Reducing Treatment Errors Through Point-of-Care Glucometer Configuration. *Jt Comm J Qual Patient Saf.* 2018;44(11):683-94.
41. Subramanyam R, Mahmoud M, Buck D, Varughese A. Infusion Medication Error Reduction by Two-Person Verification: A Quality Improvement Initiative. *Ped.* 2016;138(6):e20154413.
42. O'Byrne N, Kozub EI, Fields W. Reducing Continuous Intravenous Medication Errors in an Intensive Care Unit. *J Nurs Care Qual.* 2016;31(1):13-6.
43. Ferguson R, Williams ML, Beard B. Combining Quality Improvement and Staff Development Efforts to Decrease Patient-Controlled Analgesia Pump Errors. *J Nurses Prof Dev.* 2010;26(5):E1-E4.
44. Taylor MA, Wirth O, Olvina M, Alvero AM. Experimental Analysis of Using Examples and Non-Examples in Safety Training. *J Safety Res.* 2016;59:97-104.
45. Burke MJ, Sarpy SA, Smith-Crowe K, Chan-Serafin S, Salvador RO, Islam G. Relative Effectiveness of Worker Safety and Health Training Methods. *Am J Public Health.* 2006;96(2):315-24.
46. Robson L, Stephenson C, Schulte P, Amick B, Chan S, Bielecky A, et al. A Systematic Review of the Effectiveness of Training & Education for The Protection of Workers. Toronto: Institute for Work & Health. 2010:2010-127.

## About the Authors

**Matthew A. Taylor** (MattTaylor@pa.gov) is a patient safety analyst for the Patient Safety Authority, where he conducts research; uses data to identify patient safety concerns and trends; and develops solutions for safety issues, as well as tools and materials to help facilities and clinicians improve patient safety. Prior to joining the PSA, Taylor was a scientific writer and research specialist at the University of Pittsburgh School of Pharmacy, and he has served fellowships at the Centers for Disease Control and Prevention and the VA Pittsburgh Healthcare System. His expertise in data analysis and research covers a range of topics, including patient safety, public health, employee training, process efficiency, human factors, workplace culture/climate, behavior change interventions, and organizational management.

**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.





# INPATIENT SUICIDE PREVENTION



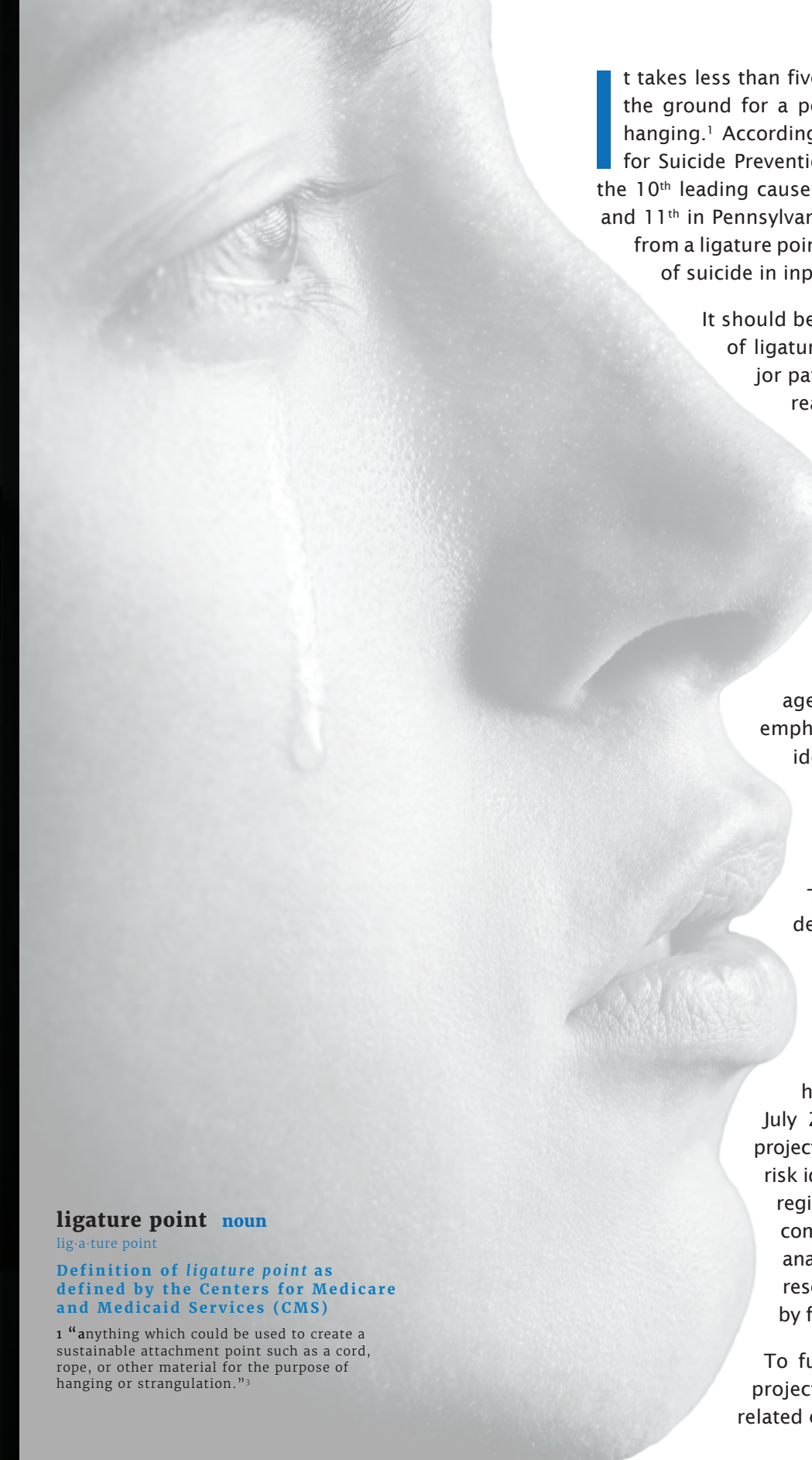
A Review of the Patient Safety Authority's  
Keys to Ligature Risk Assessment Project

Christopher Mamrol<sup>◆</sup>, BSN, RN, Melanie A. Motts<sup>◆</sup>, MEd, BSN, RN & Richard Kundravi<sup>◆</sup>, BS  
DOI: 10.33940/behavhealth/2019.12.8

<sup>◆</sup>Corresponding author  
<sup>◇</sup>Patient Safety Authority

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





It takes less than five minutes and 18 inches from the ground for a person to self-asphyxiate from hanging.<sup>1</sup> According to the American Foundation for Suicide Prevention (AFSP), suicide is currently the 10<sup>th</sup> leading cause of death in the United States and 11<sup>th</sup> in Pennsylvania.<sup>2</sup> Of those deaths, hanging from a ligature point is the most common method of suicide in inpatient healthcare facilities.

It should be no surprise that the plethora of ligature points in hospitals is a major patient safety concern. For these reasons, the Patient Safety Authority (PSA) launched a project in July 2018 with the aim to assist Pennsylvania facilities in identifying and mitigating ligature risks.

The Centers for Medicare and Medicaid Services (CMS) and other regulatory agencies have increased their emphasis on facility efforts to identify and mitigate the risks for harm by hanging.<sup>3,4</sup> This has led to an increased need for facilities to dedicate time and resources to the issue. To address this need, the PSA developed and implemented the Keys to Ligature Risk Assessment project for all acute care, children's, critical access, long-term acute care, rehabilitation, and psychiatric hospitals in Pennsylvania. From July 2018 through June 2019, the project team conducted a ligature risk identification contest, presented regional education programs, completed facility-specific gap analyses, and shared available resources for further engagement by facility staff.

To further refine the goals of the project, the team tracked ligature-related events within the Pennsylvania

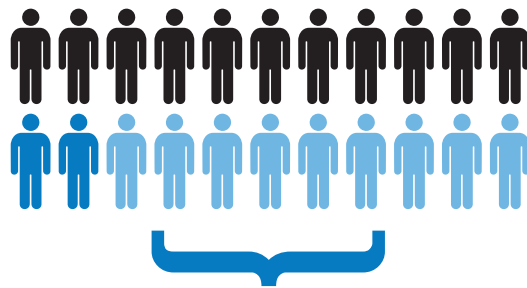
## ligature point **noun**

lig-a-ture point

**Definition of *ligature point* as defined by the Centers for Medicare and Medicaid Services (CMS)**

<sup>1</sup> "anything which could be used to create a sustainable attachment point such as a cord, rope, or other material for the purpose of hanging or strangulation."<sup>3</sup>





9 of the 11 deaths involved hanging. The bathroom door was identified as the most common ligature point.

Of the reports submitted from January 2015 to June 2019, there were 22 suicide deaths, 11 of which occurred on an inpatient unit.

Patient Safety Reporting System (PA-PSRS). Prior to 2015, variations in the reporting data made it difficult to identify and interpret ligature-related events. The 2014 *Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements Under the Medical Care Availability and Reduction of Error (MCARE) Act*, effective as of April 1, 2015, required these events to be reported as Serious Events if they were self-harm or suicide attempts resulting in death or harm to the patient.

Based on a review of the data, the abundance of literature on the topic, and escalating regulatory challenges for facilities, it was clear that ligature risk would continue to be a growing concern among all Pennsylvania hospitals. Of the facilities completing a gap analysis as part of the project, 18.4% had been cited during a survey, most commonly by The Joint Commission or Pennsylvania Department of Health (DOH) on behalf of CMS. Of the specific citations shared, bedroom or bathroom doors and paper towel dispensers were the most-identified risks. Among facilities completing a gap analysis, the rate that had been cited on issues related to ligature risk remained consistent, independent of whether the facility offered behavioral health services. This was also reflected in discussions with facilities, reinforcing that this issue extended beyond dedicated behavioral health facilities and units to more general inpatient settings.

Many of the facilities engaged in the project had real or anticipated costs for renovations to reduce ligature risks in their physical environment and/or staffing patterns. However, facilities expressed that they had difficulty with identifying products that meet

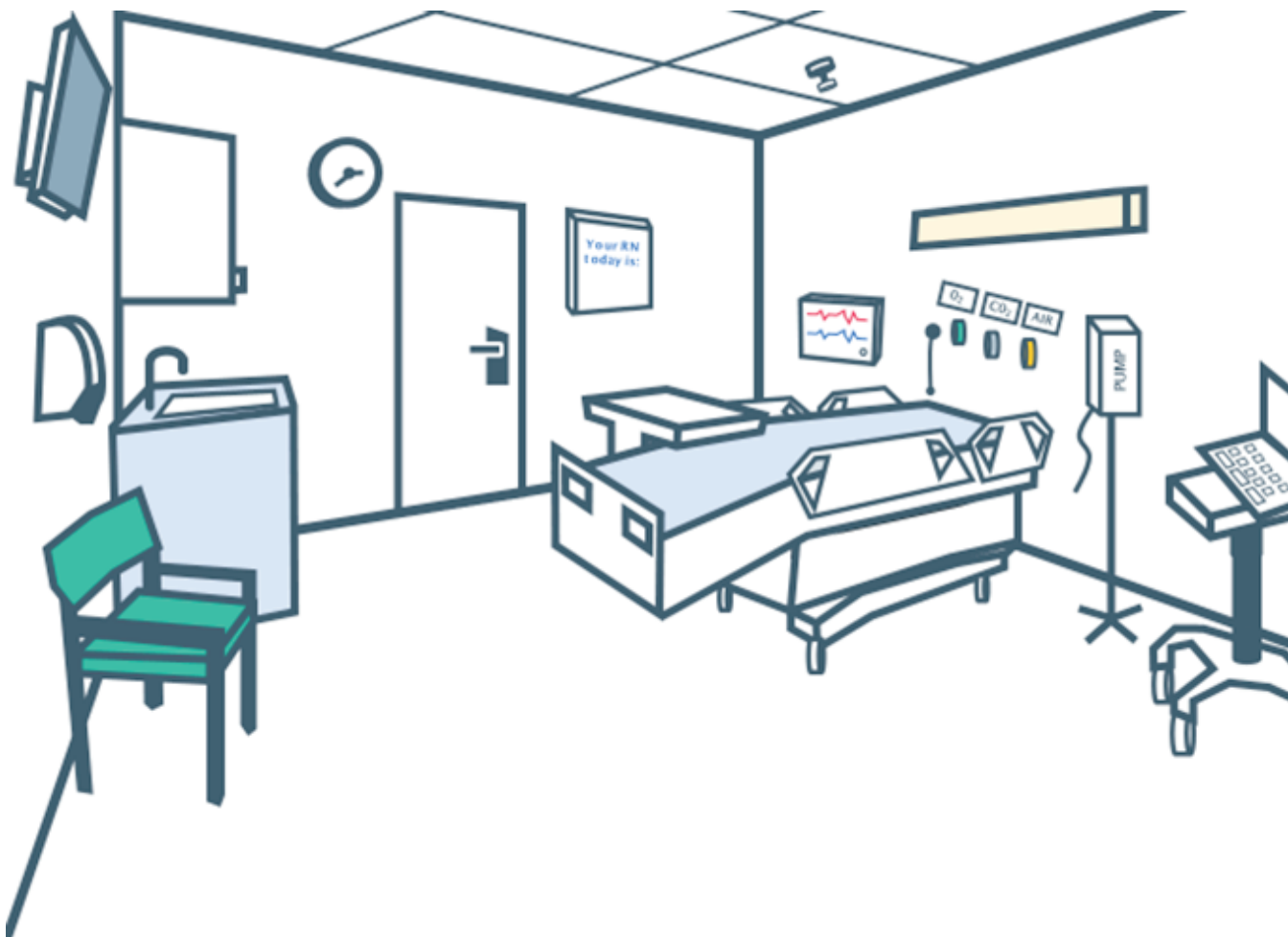
the regulatory interpretations of ligature resistant. Distribution of information to assist facilities with identifying sources of vetted products became a larger priority of the project.

The team kicked off the project with the development of six graphic representations of inpatient care settings: medical-surgical room, emergency room, intensive care room (see **Image 1**), behavioral health room, corridor, and patient bathroom. Four of these graphics were introduced in a contest to promote awareness and interest in the topic. Participants were asked to identify as many potential ligature risks as possible in each graphic. Each of the “Risky Rooms” were released during consecutive weeks of August 2018 and advertised via email, social media, and the

**\$1.3m** Cost of a suicide

**250%** Cost of a suicide compared to renovations and interventions

Many of the facilities engaged in the project had real or anticipated costs for renovations to reduce ligature risks in their physical environment and/or staffing patterns. However, facilities expressed that they had difficulty with identifying products that meet the regulatory interpretations of ligature resistant. Distribution of information to assist facilities with identifying sources of vetted products became a larger priority of the project.<sup>5</sup>



**Image 1:** The Risky Rooms contest asked participants to identify the ligature risks in six different graphics of patient care settings such as this intensive care room.

PSA website. In total, 419 entries were received, and a winner who identified the most ligature risks for each graphic was publicly recognized and awarded with a gift card. Several facilities have since been using the collection of Risky Rooms as a training resource for staff. One Western Pennsylvania hospital referenced the graphics during the renovation of their emergency department, and another integrated the graphics during the design of a new facility. The high number of respondents and ensuing positive reception to the Risky Rooms graphics suggest the PSA could use similar contests in future engagement efforts.

The project team developed a four-hour Proactive Ligature Risk Assessment education program and presented it regionally in September 2018 to 121 attendees across four dates and locations. Attendees

of these programs included Pennsylvania hospital patient safety professionals, leadership, and DOH surveyors and supervisors. The presenters reviewed the general aspects of conducting a proactive risk assessment and explored the identification and mitigation of ligature risks. These sessions also served as the unveiling of all the risks identified in each of the Risky Rooms. In addition to the regional PSA educational programs, adapted versions have been presented to numerous individual facilities and professional organizations, including multiple chapters of the National Association for Healthcare Quality and the Pennsylvania Association for Health Care Risk Management. The PSA continues to provide on-site education on ligature risk assessment to Pennsylvania facilities upon request.

The largest component of the project involved in-person visits to each target facility by their assigned patient safety liaison (PSL). During these visits, the PSL reviewed and discussed ligature-related questions to complete a gap analysis and offered further resources and assistance, which included walking rounds with the facility team to identify and discuss potential ligature points and associated risks, as well as other on-site education. The facilities visited were at different stages of their journey toward a ligature resistant environment. For some, this project was the first step to addressing the issue, while others benefited from the targeted resources and feedback. In all, the gap analyses gave the PSA a snapshot of where Pennsylvania facilities stood pertaining to ligature risk assessment.

During the project period, a gap analysis was completed for a total of 192 facilities, 99 of which did not have a specified behavioral health unit. Each

to either the method of identifying suicide risk within their facilities or the benefits of using a validated tool. To improve in this area, the PSA shared available validated tools and associated resources with facilities. This put Pennsylvania hospitals in a position to not only enhance patient safety but to proactively address upcoming Joint Commission changes regarding the use of validated tools. Over the project year, there was an increase in the number of facilities both discussing ligature risk with their patient safety committees and providing applicable training to their staff, with an additional 21% of facilities expressing interest in arranging future training. This suggests the PSA's project had positive effects.

A summary of the project and the experiences and perspectives of two participating facilities were shared via a webinar conducted in July 2019 to 118 attendees. Shawna Baney-Shaw, risk manager, and

**44%** of facilities either did not use or were unsure if they used a validated suicide risk screening or assessment tool.

completed gap analysis was reviewed, and three communiques were distributed from July 2018 to June 2019 to keep facilities updated. Each communique included a gap analysis data snapshot, a relevant article, and other resources. For facilities that had previously been visited by their PSL and completed a gap analysis, these communiques offered an opportunity to stay informed of additional findings and developments. In July 2019, following the completion of the project, the gap analysis data was aggregated and reviewed for noteworthy findings.

Limited conclusions can be drawn from the data, but there were some interesting points for consideration. Of note was that 44% of facilities either did not use or were unsure if they used a validated suicide risk screening or assessment tool. This identifies a knowledge deficit among patient safety staff related

Tina Kephart, director of Behavioral Health, both from Mount Nittany Medical Center, shared considerations and challenges of a unit wide renovation. Carol VanZile, director of Behavioral Health Regulatory, Compliance and Accreditation, UPMC Western Psychiatric Hospital, discussed the process of performing ligature and suicide risk reviews and developing mitigation plans in various inpatient care settings throughout the UPMC Health System. Additionally, the PSA shared updated resources and forms from participating facilities during the webinar and on the PSA website.

The PSA learned several lessons while engaging Pennsylvania hospitals on the topic of ligature risk assessment. The approach of using a contest for healthcare workers and focused site visits coinciding with regional education was popular and effective



for delivering knowledge and resources. The topic proved to be timely as well; the patient safety information shared with Pennsylvania facilities gave them a foundation to tackle evolving patient needs and impending regulatory requirements. Beyond identifying and mitigating ligature risks, the project highlighted opportunities within Pennsylvania facilities related to general suicide risk assessment and intervention.

For more information on this topic, please visit [patientsafety.pa.gov/pst/Pages/Behavioral\\_Health/hm.aspx#](https://patientsafety.pa.gov/pst/Pages/Behavioral_Health/hm.aspx#).

## References

1. Knoll JL. Inpatient suicide: identifying vulnerability in the hospital setting. *Psychiatric Times*. 2013 May;30(6):36.
2. Suicide Statistics [Internet]. New York: American Foundation for Suicide Prevention; 2018 [cited 2019 Jul 15]. Available from: <https://afsp.org/about-suicide/suicide-statistics/>.
3. Clarification of Ligature Risk Interpretive Guidelines [Internet]. Revisions to State Operations Manual (SOM) Chapter 2 Certification Process and Appendix A Hospitals. Baltimore: Department of Health & Human Services, Centers for Medicare & Medicaid Services; 2019 [cited 2019 Aug 5]. Available from: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-12-Hospitals.pdf>
4. Hunt JM, Sine DM, McMurray KN. [Internet]. Behavioral Health Design Guide. [cited 2019 Aug 5]. Available from: <http://www.bhfcllc.com/wp-content/uploads/2019/06/Design-Guide-8.1-web.pdf>
5. Shepard DS, Gurewich D, Lwin AK, Reed GA Jr, Silverman MM. Suicide and suicidal attempts in the United States: costs and policy implications. *Suicide Life Threat Behav*. 2016 Jun;46(3):352-62.

## About the Authors

**Christopher Mamrol** ([cmamrol@pa.gov](mailto:cmamrol@pa.gov)) is a senior patient safety liaison with the Patient Safety Authority for the Southeast region of Pennsylvania. Prior to joining the PSA, he worked at Montgomery County Emergency Services, Inc., serving in multiple roles, including as a psychiatric technician, registered nurse, risk manager/patient safety officer, performance improvement director, and Safety and Quality Systems director.

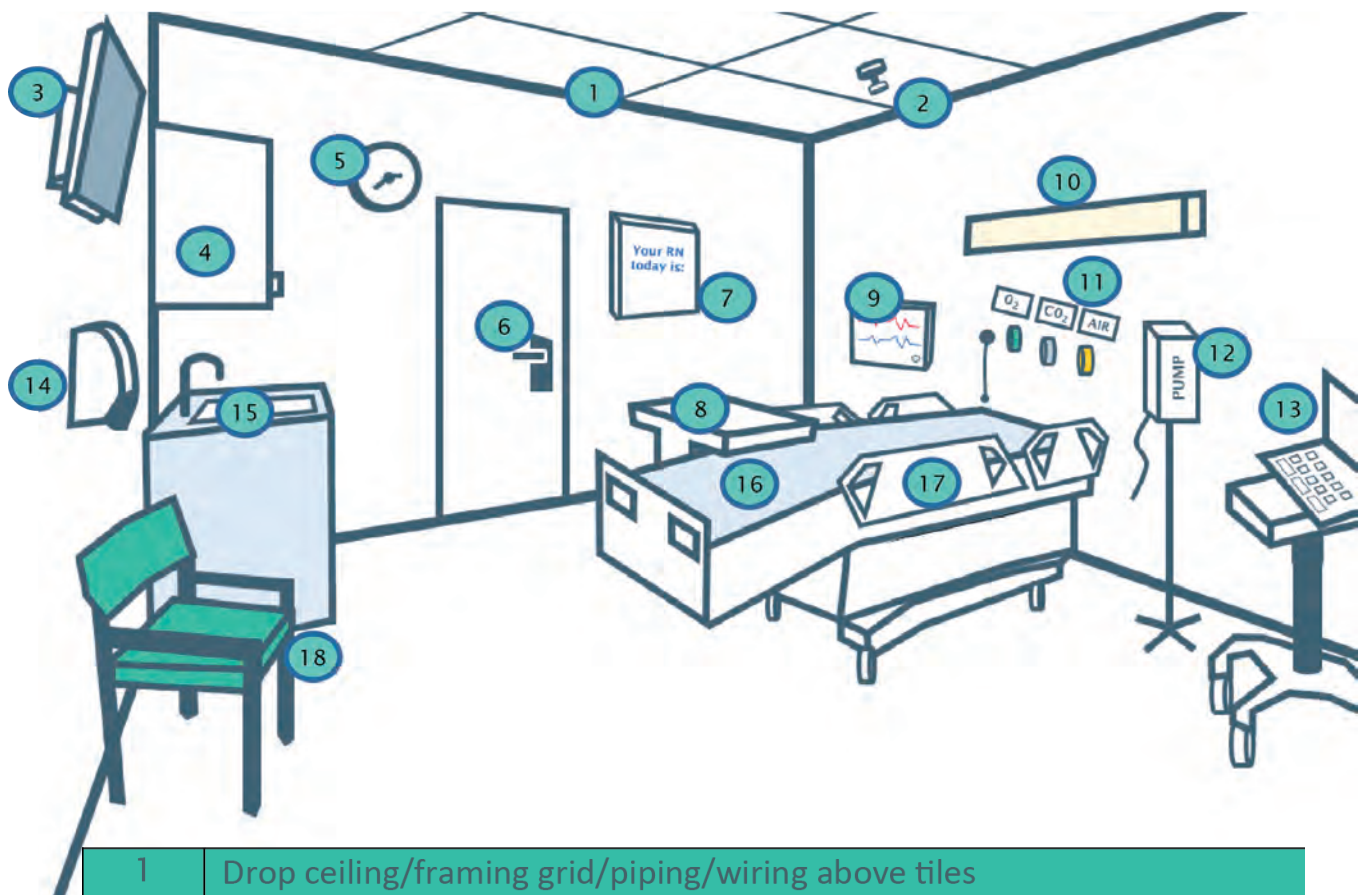
**Melanie A. Motts** is a senior patient safety liaison with the Patient Safety Authority for the Eastern region of Pennsylvania. Previously she worked in outpatient and inpatient settings as a manager, educator, and registered nurse. As director of nursing and a patient safety officer for an acute care hospital in the Lehigh Valley, she led a team of nursing staff, case managers, laboratory staff, and clerical support, which earned the CMS 5-star rating for quality of care provided and patient satisfaction.

**Richard Kundravi** is a patient safety liaison with the Patient Safety Authority for the Northwest region of Pennsylvania. Prior to coming to the PSA, he served as the director of Risk Management and Patient Safety at UPMC McKeesport as well as the facility's corporate compliance officer, privacy officer, director of peer review, and patient representative.

For more information on this topic, please visit [patientsafety.pa.gov/pst/Pages/Behavioral\\_Health/hm.aspx#](https://patientsafety.pa.gov/pst/Pages/Behavioral_Health/hm.aspx#).

To access the webinar on ligature risk, please visit <https://www.youtube.com/watch?v=COGQOtaC7YA&>.

Image 2: Answer Key



1	Drop ceiling/framing grid/piping/wiring above tiles
2	Sprinkler
3	TV/TV Mount/TV wires/electrical outlet
4	Storage cabinet/cabinet handles
5	Clock
6	Door/door handles
7	Daily board
8	Tray table
9	Monitor screen
10	Light fixture/light switch
11	Air port, oxygen port, CO2 port
12	IV pump/IV Tubing
13	Portable computer/computer stand/Workstation on wheels
14	Hand sanitizer/paper towel holder
15	Faucet/sink
16	Mattress/bed
17	Bed rails
18	Chair







# Antibiotic Stewardship

## Long-Term Solutions for Long-Term Care

JoAnn Adkins<sup>◊</sup>, BSN, RN

**A**ntimicrobial resistance is one of the top 10 global health threats identified by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO). Antibiotics are life-saving drugs, but misuse has led to the development of multidrug resistant organisms<sup>1-3</sup> (MRDO), or “superbugs”: bacteria that have developed resistance to several antibiotics.<sup>1,2,4</sup>

Antibiotic resistance—when bacteria are no longer sensitive to drugs that have killed or inhibited their growth in the past<sup>2-4</sup>—occurs when bacteria are exposed to nonlethal doses of antibiotics, causing the bacteria to mutate to become less susceptible to the drug and survive.<sup>2,4-7</sup> Infections caused by MRDO have higher morbidity and mortality, are more difficult to treat, and have higher treatment costs than infections caused by susceptible organisms. Inappropriate antibiotic use contributes to the development of these organisms. Annually, at least two million people in the United States get an antibiotic-resistant infection, and at least 23,000 people die.<sup>3,4</sup> Antibiotics are frequently prescribed in long-term care facilities (LTCF), with approximately 70% of residents receiving at least one course of antibiotics annually.<sup>3</sup>

Implementing an antibiotic stewardship program—a set of evidence-based actions that promote appropriate antibiotic use, decrease the development of antibiotic resistance, improve the treatment of infections, and reduce adverse events caused by antibiotic use—has been shown to significantly improve patient and resident outcomes.<sup>3,5</sup> As of November 2017, the Centers for Medicare and Medicaid Services (CMS) requires all LTCF to have an antibiotic stewardship program, protocols, and monitoring in place.<sup>6</sup>

To help Pennsylvania LTCF adhere to these guidelines, Patient Safety Authority (PSA) staff developed and facilitated a 22-month antibiotic

<sup>◊</sup>Patient Safety Authority

Disclosure: The author declares that they have no relevant or material financial interests.

## Results

# 10% reduction



All urine cultures performed  
**17 out of 24**  
met/exceeded this goal

Urine cultures performed for ASB  
**9 out of 24**

New antibiotics ordered for UTI  
**17 out of 24**

Antibiotic orders for ASB  
**12 out of 24**

Antibiotic treatment for UTIs that  
do not meet clinical criteria  
**11 out of 24**

stewardship collaborative project (seven months for planning and 15 months of active facility participation). The project focused on urinary tract infections (UTIs), the most common healthcare-acquired infection in long-term care residents,<sup>7</sup> and introduced the participating facilities to the evidence-based practices associated with improved antibiotic use. The project provided participants with education; tools to improve practice; and support through monthly one-on-one calls, webinars, and in-person visits.

Thirty-one Pennsylvania LTCF initially enrolled in the collaborative, with 24 facilities completing the project.



*The PSA collaborative really helped with all the resources that they give you. You cannot fail if you follow their recommendations.*

—Mary Pat Frick, Masonic Village

**Project goals:** The project goal was a 10% reduction in all urine cultures performed, urine cultures performed for asymptomatic bacteremia (ASB), new antibiotic orders for UTIs, antibiotic orders for ASB, and antibiotic treatment for UTIs not meeting clinical criteria.

**Resources provided to facilities:** Monthly data was submitted via Checkbox survey and analyzed by PSA infection preventionists. Monthly reports summarized progress made toward meeting project goals and provided strategies for reducing inappropriate antibiotic use. PSA staff also developed an onboarding educational presentation; a facility kickoff celebration; a resource toolkit; and an educational plan for monthly webinars and one-on-one calls with each facility to review monthly data and discuss successes, challenges and opportunities for improvement.

**Lessons learned and/or barriers:** The participating facilities faced several challenges to implementing antibiotic stewardship. Staff turnover in some facilities led to unnecessary culturing and antibiotic ordering until current staff was educated. In many of the participating facilities, the infection preventionist had many concurrent roles including assistant director of nursing, clinical staff educator, and employee health. This made it very difficult for them to devote time to the collaborative, collect

and submit the required data in a timely manner, and attend the monthly educational webinars and one-on-one calls.

Family response to antibiotic stewardship was very difficult for many of the participating facilities. Families would pressure staff and providers to order an antibiotic without appropriate signs and symptoms.

**Notable achievements:** Participation in the collaborative led to facility recognition and corporate participation. One of the participating facilities was recognized by Leading Age and the Pennsylvania Department of Health for the success of their antibiotic stewardship program. Another facility was selected to present on implementing an antibiotic stewardship program at the Peace Conference in King of Prussia. Following the onboarding education, two other participants communicated the value of the collaborative to their senior leadership, who invited a PSA senior infection preventionist to provide education to all of their corporate facilities and implemented the project in all their facilities.

## Tool Kit

[http://patientsafety.pa.gov/pst/Pages/Antimicrobial\\_Resistance/Antimicrobial\\_Resistance.aspx#](http://patientsafety.pa.gov/pst/Pages/Antimicrobial_Resistance/Antimicrobial_Resistance.aspx#)

Urinary Tract Infection Internal Case Review Form

CDC Antibiotic Factsheet – You've Been Prescribed an Antibiotic – Now What?

Antibiotic Stewardship Goals

Antibiotic Timeout Protocol

Ambulatory Surgical Center Infection Control Surveyor Worksheet

Strategies to Turn the Tide Against Inappropriate Antibiotic Utilization

Antibiotic Stewardship Plan



## References

1. World Health Organization. Antimicrobial resistance. <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>. Accessed April 28, 2019.
2. Centers for Disease Control and Prevention. Antibiotic/antimicrobial resistance. <https://www.cdc.gov/drugresistance/>. Accessed April 8, 2019.
3. Centers for Disease Control and Prevention. The core elements of antibiotic stewardship for nursing homes. <https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html>. Accessed April 8, 2019.
4. Ventola, CL. The antibiotic resistance crisis: part 1: causes and threats. *P T*. 2015 Apr;40(4):277-83. PubMed PMID: 25859123; PubMed Central PMCID: PMC4378521.
5. Agency for Healthcare Research and Quality. US Department of Health and Human Services. Nursing home antimicrobial stewardship guide. <https://www.ahrq.gov/nhguide/about/index.html>. Accessed April 8, 2019.
6. Centers for Medicare and Medicaid. US Department of Health and Human Services. CMS regulation §483.80 (a)(3) Infection Control. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>. Accessed May 28, 2019.
7. Montoya A, Mody L. Common infections in nursing homes: a review of current issues and challenges. *Aging Health*. 2011 Dec;7(6):889-899. doi: 10.2217/AHE.11.80. PubMed PMID: 23264804; PubMed Central PMCID: PMC3526889

## About the Author

**JoAnn Adkins** ([joaadkins@pa.gov](mailto: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 and is board-certified in infection control and epidemiology. She is a member of the Association for Professionals in Infection Control and Epidemiology, the Sigma Theta Tau International Honor Society of Nursing, and the Central Pennsylvania Association for Healthcare Quality.



*The bottom line is improved resident care, and it just drives home the fact there is opportunity to continue to learn and to grow and to become better and better and better.*

—Beth McMaster, United Church of Christ Homes







# Kathleen Noonan

DOI: 10.33940/interview/2019.12.1

*Kathleen Noonan is chief executive officer of the Camden Coalition of Healthcare Providers, a nonprofit, multidisciplinary healthcare innovator in Camden, New Jersey. A former corporate lawyer, Noonan previously was co-director of PolicyLab at Children's Hospital of Philadelphia, which she co-founded in 2008 to ensure clinical research was connected to and influencing real-world health policy change. Noonan recently spoke with Cait Allen, MPH, director of Engagement at the Patient Safety Authority, about the Camden Coalition's efforts to improve care for people with complex health and social needs in the city of Camden, regionally, and across the country.*

## Tell us about the Camden Coalition of Healthcare Providers.

The Camden Coalition was founded in 2002 by Jeffrey Brenner, a family physician in Camden. It was really a breakfast meeting of Jeff and other clinicians who were frustrated that their patients, mostly Medicaid and rural patients, were ending up in the hospital again and were using the emergency room (ER) for care. They wondered what this was all about, and so through these conversations, they came together to develop a coalition. One of the ideas that came out of the coalition was that the hospitals and the primary care offices at that time did not provide navigation that could help these patients once they were discharged, figure out how to get stabilized, get connected to a primary care office, stay connected to a primary care office, and then access social services.

We call what we do complex care. Some people use the emergency room because it's the easiest place to go for medical attention. Some people find themselves in a situation where they don't have the medication they need, and they haven't quite figured out how to call a pharmacy to get medication. Some people go to the emergency room because they can get a meal. There are a lot of different reasons why people use the emergency room. What our care team tries to do is figure out what is driving the patient. What will allow them to get stable in their life, and in a way then that could help improve their health situation.

### **Camden is a pretty urban environment. Does any of the work you're doing translate outside the city?**

Absolutely. One similarity between urban and rural areas you wouldn't necessarily realize is the sense of isolation people can feel in both. In urban areas, sometimes we succeed in getting people housing, but they are suddenly housed and become incredibly isolated—as isolated as somebody living in a place that has very few people nearby.

Especially if you're working with a population that's been homeless. A lot of people who are newly housed are used to living with other people. Suddenly now you're saying, "You get your own apartment." Well, that's a very different way of living. Imagine a mom with three kids who's been living in a family shelter with other adults around all the time. Now it's you, in your apartment, with your kids on your own, not having another mom in the shelter to say, "Can you watch my kids for five minutes? I'm going to take a shower." That adjustment can create tremendous feelings of guilt.

So we think about how to keep people connected, how to connect to informal supports, how to connect them to other affinity groups, maybe creating opportunities for them to come together.



*One similarity between urban and rural areas you wouldn't necessarily realize is the sense of isolation people can feel in both.*

### **What are some of the biggest challenges that you face day-to-day?**

In the beginning we thought that it was going to be possible to create what we call a care team, to wrap a nurse and a community health worker around a patient and help them navigate both back to the health system and then to these very fragmented social services. We have found that that is not the solution. We—and when I say we, I don't just mean the Camden Coalition, I mean all of us that care about this issue and care about these patients—really need to think differently about how services are wrapped around people in a much less fragmented way. We are discharging patients who have multiple chronic health conditions, other complexities, and then telling them to basically work across eight to 10

different services or offices to potentially get the care that they need. We believe that there's still a lot to be done in terms of figuring out how we can sort of seamlessly provide care to the patients that we see.

### **What are some of the biggest successes that you have had?**

One of the things that we're very, very proud of is our ability to use data to actually identify who the complex patients are—patients who have both health complexity and social complexity. The health complexity is usually a couple of chronic conditions, and then the social complexity is anything from poverty, homelessness, lack of access around transportation, language barriers, substance use disorders, and behavioral health conditions.

We have what's called a Health Information Exchange. That was developed in 2010—imagine the world before Epic and Cerner and the ability of health systems to share data with each other. At that time,

we knew that we needed to look and see where our patients had been. We also needed to see, was there a provider in the Camden region who they might have a good relationship with, and for some reason, things dropped off? Maybe they no longer had transportation to get to that provider. So we created the Camden Coalition Health Information Exchange with all the health systems in the area, so that we get on a daily basis all of the information from the local hospitals on who's been admitted and who's in the ER.

We use that information in a process that we call triage. Right around the corner from where we're sitting now is my team that's looking at who is currently admitted to the hospital in Camden, who is in the ER, and which of those patients have complex needs in a way that we could help navigate them and help provide care management to them. We've gotten very good at knowing which are the patients that maybe hospitals have programs for already, so they don't need the type of care navigation we have, and which patients are more likely to be able to benefit from that.

One of the things that is amazing about the Camden Coalition and certainly a success is that we are adapting our model to actually address the needs of our patients as they come up. I'll give you an example: Our care team is a nurse and a community health worker. We found that we could help patients navigate back to healthcare, but that many of them had unstable housing or a housing that wasn't healthy; for example, a family living in an apartment that irritates a child's asthma. Figuring out housing became to us the single most important priority, and so we created a Housing First program, got the state to give us vouchers, and housed our first patient in November 2015.

The 7-Day Pledge is another success that came out of our care team's work.

### **Tell me about that.**

As I said, whenever we hit a barrier, we try to say, "Okay. What can we do to address this?" Well, another barrier that we found was that patients with complex needs were being discharged from the hospital, and it was very hard for us to get them appointments with primary care within seven days. We knew that there was already a good evidence base that showed that when patients were connected to primary care



*Patients that were able to get into primary care within seven days actually had reduced admissions and reduced use of the Emergency Room.*





*We are adapting  
our model to  
actually address  
the needs of our  
patients as they  
come up.*



quickly, they were more likely to reduce readmissions and use of the ER.

Because we're a coalition, we can go out and talk to people, and so we talked to primary care providers in the city. We talked to our hospital partners, and we realized that our primary care offices did not have the bandwidth to change their workflows to be able to easily say, "Okay. Sure, we can see five new patients this week who are being discharged from the hospital, even the patients who we're going to need to take more time with because they have medical and social complexity."

So we said, "Well, what if we work with you to change your workflows and we provide the staffing to come in and help your staff to do that?" They said sure.

We all came together and created a citywide campaign called the 7-Day Pledge. Hospitals and providers took the pledge that they would try as hard as they could for any Medicaid patient who was being discharged from a hospital to get them into the primary care office within seven days. Our Clinical Redesign Team was born, which is a team that looks a little bit like

a team you might find in a management consulting firm that goes in and looks at the processes you're using and helps you try to figure out how to change those processes.

Imagine a doctor's offices changing their scheduling to have more availability for sick patient visits. Some of it is spending time with a scheduler and figuring out how to make their life a little bit easier overall, and not just related to these patients. We co-designed by practice, and while there were standard workflows put into place, we were also very attentive to the local needs.

In January of this year we published the results of our 7-Day Pledge evaluation in *JAMA Network Open* that showed in fact the patients that were able to get into primary care within seven days actually had reduced admissions and reduced use of the ER. So it was as successful as we said it was going to be, and so we're really, really proud of that. The nice thing is that many of our partners have now incorporated those changed workflows into what they do on a regular basis.

## If there were a provider or a group of providers who were going to unofficially take the 7-Day Pledge, what advice would you give them on how to get started?

I would definitely tell them that among themselves, they had to choose one of them to be a lead. Or find a little bit of money to have somebody help and be a facilitator across all the practices.. And to keep count, because one of the things that we did was, on a monthly basis, we would go to a practice and show them how they were doing. Are they seeing more patients? Are those patients going back to the ER? They were interested in really using the data to help their practice.

## What are you doing to build the field of complex care?

We are developing competencies about what it means to do complex care, identifying exemplars, identifying what kind of payment methods and models you need to be able to do complex care. At our Putting Care at the Center conference last year, we unveiled the *Blueprint for Complex Care*—a document that we co-authored with the Institute for Healthcare Improvement, the Center for Health Care Strategies, and a large group of advisors from around the country. The *Blueprint* sets forth 11 recommendations for what the field can be and what should be done to develop that field. It includes things like creating cross-sector data infrastructure and fostering peer-to-peer connections.

The *Blueprint* is available on our website. It's available for everybody. It has advice in it right now that health systems or communities can use to get started in thinking about complex care. One of the things that we found is that there are a lot of communities or providers doing complex care, but they don't call it that. So one of the things that the *Blueprint* does is really give us a framework and a shared language to be able to talk about what we're doing.

## What's one piece of advice that you've received that you've continued to follow?

Grace under pressure, always. Grace under pressure. Having a long view of things, a sort of advocate's temperament and advocate's mindset that we must do better but appreciating that it's a long game. I try really hard to live by that. I think it's why I'm able to work in an advocacy organization that is a big tent for a lot of different points of view.

*Visit [Patientsafetyj.com](http://Patientsafetyj.com) to see an extended video interview with Kathleen Noonan.*

## Camden Coalition of Healthcare Providers Highlights

### 7-Day Pledge

The Camden Coalition's practice-facing interventions include partnerships throughout the city of Camden to connect hospitalized patients to their primary care physician within seven days of discharge. Download an overview of this initiative at [camdenhealth.org/resources/7-day-pledge-reducing-hospital-admissions-through-rapid-connections-to-primary-care/](http://camdenhealth.org/resources/7-day-pledge-reducing-hospital-admissions-through-rapid-connections-to-primary-care/).

### Camden Coalition Health Information Exchange

The Coalition uses data-driven "healthcare hotspotting" to identify and engage patients with complex health and social needs—in real-time. Learn more about how they collect and use this data from the Camden Coalition Health Information Exchange to better serve individuals with unmet needs: [camdenhealth.org/connecting-data/](http://camdenhealth.org/connecting-data/).

### Blueprint for Complex Care

Through the National Center for Complex Health and Social Needs, in collaboration with the Institute for Healthcare Improvement, the Coalition has developed a strategic plan for advancing the field of complex care. Read their *Blueprint* at [www.nationalcomplex.care/our-work/Blueprint-for-complex-care/](http://www.nationalcomplex.care/our-work/Blueprint-for-complex-care/).









# Cancer for Christmas

“  
*Your health is  
your responsibility  
and you must ask  
questions and work  
to understand the  
answers.*

— Casey Quinlan

Caitlyn Allen<sup>◇</sup>, MPH

Presents go hand in hand with the holiday season. Whether you receive an item from your wish list or during an office gift exchange, it's hard not to get wrapped up in the tradition. And if that new sweater doesn't quite fit or you end up with a movie you already own, you can just return it with ease.

But that isn't always the case. Five days before Christmas in 2007, Casey Quinlan got something she didn't want nor could send back: breast cancer. Nonetheless, she considered it a gift. Rather than let the news cripple her, Quinlan decided to chronicle her experience—what questions she asked her doctors; their responses; and how she handled surgery, chemotherapy, and radiation—to help others navigate the complex healthcare system.

“It's like a car wash,” Quinlan says. “When you go to a car wash, do you want to be inside the car, or strapped to the hood? Ask questions, make sure you understand the answers—you get to stay inside the

car. Otherwise, you get lots of soap and wax up your nose!”

Quinlan's championing of being an active “healthcare industry customer” began long before her own diagnosis as she watched, and eventually helped, her parents battle their own illnesses.

Her father was diagnosed with Parkinson's disease and pored through every research article he could find. He freely asked questions and joined the Parkinson's Foundation.

Her mother overcame a pituitary tumor, surgery to remove it, and not least of all sexism; after several male physicians had chalked up her symptoms to menopause, she sought another opinion from a female surgeon, who correctly diagnosed her. Her mother's steadfastness and willingness to question saved her life and taught Quinlan a valuable lesson: “Your health is your responsibility and you must ask questions and work to understand the answers.”

Thankfully, today Quinlan is in remission, and continuing her work as a patient advocate. To learn more about Quinlan's work, check out her blog at [www.cancerforchristmas.com](http://www.cancerforchristmas.com).

<sup>◇</sup>Patient Safety Authority  
Disclosure: The author declares that they have no relevant or material financial interests.



## Jacket #160: “Cancer for Christmas”



Quinlan’s parents, Betty and Mike Casey, taught her from an early age the importance of self-advocacy as she watched them battle misdiagnoses, Parkinson’s disease, and a hip replacement. She has leveraged this grit and tenacity in her career as a patient advocate; one of Quinlan’s myriad accomplishments is serving as a charter author for Patients Included™—a movement to engage patients in academic literature and healthcare conferences.



Casey Quinlan/Cancer for Christmas

# P2S2|2020

3<sup>rd</sup> Annual Pennsylvania Patient Safety Summit

## Save the Date!

**Tuesday, April 28, 2020**

**DoubleTree Resort by Hilton Hotel Lancaster  
Lancaster, PA**



333 Market Street - Lobby Level  
Harrisburg, PA 17101  
[patientsafetyj.com](http://patientsafetyj.com)  
[patientsafetyj@pa.gov](mailto:patientsafetyj@pa.gov)  
717.346.0469