



PATIENT SAFETY

March 2020 | Vol. 2, No.1

I Am the Zebra

*One woman's five-year
quest for the truth*

Associated risks with
IV vancomycin

2020 I AM Patient
Safety awards

Ensuring
accurate weight
documentation

LETTER

From the Editor



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

You may have looked at this issue's cover and asked yourself what in the world zebras have to do with patient safety. Join Missy Adams and her husband, Solomon, on her journey to the correct diagnosis. (Hint: Sometimes it really is the zebra and not the horse.) These stories from patients are so informative and critical to keep patient safety moving in the right direction. If you are a patient or caregiver and have a story to share, send us your manuscript. Manuscripts may describe an event or events that didn't go well but they may also describe the things that go right. We learn from both.

March is the month that we celebrate patient safety. It is a time to renew our spirit and sharpen our focus. In this issue we celebrate those healthcare workers who day in and day out demonstrate a powerful commitment to making care safe for all. When you live in the world of patient safety it is so easy to only see the wrong. The team at the Patient Safety Authority (PSA) reviews every account of unanticipated patient death and permanent harm that happens across the Commonwealth of Pennsylvania. The collective review of event after event can be more than depressing. Yet, I love my job. I love my job because we are constantly learning from those events to make improvements AND because for every bad event that happens, I know there are thousands that go right. There are doctors and nurses and techs and support staff that go to work every day to make a positive difference—and they do. The

winners of our 2020 I AM Patient Safety Awards are proof of that and serve as an inspiration.

Also in this issue: Medication errors related to weight discrepancies are a longstanding issue identified by organizations such as the Institute for Safe Medication Practices and the PSA. In 2018, the PSA issued formal recommendations to weigh all patients using metric units. Sonali Muzumdar's practice improvement paper highlights one organization's strategies to decrease errors in patient weights. Raj Ratwani and co-authors discuss their exploration of vancomycin-related events and share a new safety self-assessment tool to support risk identification and organizational learning. Mary Ellen Mannix tells the harrowing journey of her son James' short life and her call to advocacy that followed.

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

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.

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Together we save lives

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NEONATAL MEDICAL ERROR

“I Am the Zebra”

One woman's five-year quest for the truth



Missy A. Adams, MS &
Solomon M. Adams, PharmD, PhD

How many times do you think you could tell people a story about your life before eventually feeling as if you're making it up? You know it's true, yet you have this out-of-body experience where you hear yourself telling the story and wonder, "Is that *really* how it happened?" Add in that no one else was around to experience this event and, well, you're left hoping your mind isn't tricking you.

I entered that cycle of self-doubt after explaining to the sixth doctor how terrible my life was due to some symptoms I had been having for years. I can't even say exactly when or how they started. I only know that after about a year of near-daily stomachaches, I had had enough. At that time (around 2013), I was a single mother to a 4-year-old boy and working as an evaluator clinician in one of the busiest psychiatric emergency rooms in the country. Debilitating stomachaches were just not convenient in my schedule.

I started with my primary care physician's office, as I'm sure most people would. I spoke with a physician assistant (PA), who prescribed some anti-heartburn medications and sent me on my way. When those didn't work, I went back to the physician, who ordered testing. This testing then led me to a gastroenterologist who looked me in the eyes and said, "Well, maybe it's your gallbladder, let's take it out. If you don't feel better, we at least know that's not what was causing it." (Spoiler alert: It wasn't my gallbladder.)

Fast-forward a couple years and I had seen two more physicians and gone through a slew of differ-

ent tests, including blood work, two endoscopies, a stomach emptying test, and several biopsies. All the while, telling that same story over and over again, trying not to succumb to feeling like a fraud. One physician even told me I was probably just anxious and a mental health disorder was causing all of my symptoms. His recommendation? A psychiatrist.

I was defeated. By then, my symptoms had been worsening over the course of nearly five years. I was having daily stomachaches, along with a myriad of other issues. Every evening I spent hours in the fetal position, crying and begging for the pain to go away. I had severe diarrhea and vomiting, night sweats, and pain that was becoming more and more decentralized. No dieting, food journaling, fasting, or attempts to correlate the symptoms with my daily routines helped me understand *why* this was happening to me. I even purposefully lost almost a hundred pounds, thinking if I became a healthier version of myself, maybe it would all stop. After following the "correct" pathway from general practitioners to specialists and being dismissed, I felt completely overtaken by this mystery ailment.

In 2018 I married Solomon, a pharmacist who was finishing a PhD in pharmaceutical science. He had been to appointments with me and shared my frustration and periodic hopelessness. Between us, we had significant expertise in healthcare, yet we were stumped. We had seen excellent gastroenterologists, had all of the recommended testing. The best-guess diagnosis I had received was "You might have something rare, but we might never find out what it is."



Missy waiting to undergo lobectomy

**They said it
was probably
just in my
head.**

It was cancer.



The Adams family in fall 2018



*Missy exploring the hospital a couple days
after surgery, chest tubes in tow*

Solomon connected to a physician colleague with expertise in chronic pancreatitis who suggested that my symptoms *might* be related to my pancreas, and that it would help to at least rule out pancreatitis. He gave me a referral to a pancreatologist at the University of Virginia who might be able to tell us if this was a possibility. And so, I once again told my story and once again received a list of tests that needed to be run. This time, a CT scan of my abdomen was ordered, and the physician was surprised that it wasn't already in my arsenal of prior medical tests.

A few weeks later, which was much longer than I expected to wait for results, I received a phone call. This was now September 2018 and more than five years after first telling my story. The physician himself was on the other line and finally gave me some definitive news as to what was causing my symptoms: *a tumor*. Specifically, they had found a solid tumor in the right lower lobe of my lungs, which just so happened to show up on the very tippy top of the abdominal CT scan. It was as if I was a living version of *Where's Waldo?*—if Waldo was a tumor. He said it was probably cancer, and with that the proverbial wheels were in motion. *I have cancer.*

The next few weeks are a complete blur. I wish I didn't have to use that stereotypical explanation, but it's truly all I have. I saw a pulmonologist. I had a PET scan. I had a respiratory function test. I saw a surgeon. Each time I read the word “cancer” on these papers I thought to myself that it wasn't real. My doctors told me they didn't even want to biopsy; it was almost definitely cancer and a biopsy would waste time. Suddenly there was a sense of urgency after I had been shuffled from specialist to specialist for years.

This transition period between diagnosis and treatment is when the medical community let me down the most. Continuity of care was nonexistent. The type of cancer was rare, and my care team was simultaneously confident that they were going to cure me while also ignorant to what I should expect in the short- and long-term. In cases like these patients are warned not to use “Dr. Google.” In most cases, that's probably right. But in my case? It probably saved my life.

It took three months from diagnosis to major surgery. I had a video-assisted thoracoscopic (VATS) lobectomy of my right lower lung lobe in November 2018. Recovery was rough, to say the least, but I made

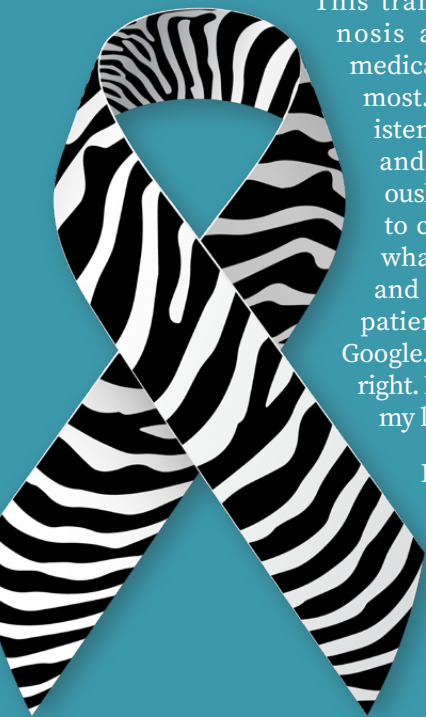
it through and quickly started to adapt to my new life. Pathology confirmed that I had neuroendocrine tumor (NET) cancer (previously called a carcinoid tumor). More specifically, I had a low-grade typical carcinoid of the lung with no spread to my lymph nodes. This was the best-case scenario. I should be happy, right? My surgeon and her PA told me I was “cured” and that I had the “best kind of cancer.” It was the “best” because it had an excellent five-year survival rate, and most people didn't see a reoccurrence for 10–30 years.¹ But hello? I was 32 years old. In 20 years, I would be 52. It wasn't comforting to hear that I would most likely be dealing with this again at a time when I hoped to be empty nesting with my husband.

To help deal with what was happening, Solomon and I decided to attend a support group for NET cancer survivors and caregivers. We walked into a roomful of people who had nothing but warm smiles and open ears. As we told our story, we never could have expected what came next: Everyone there wanted to help. And not just help us recover. No, this group wanted to help us *live*. Because what we were told was far from the truth, and it was up to us to correct my path. These people had been through a remarkably similar process and learned through experience that my journey was not done.

I requested another meeting with my surgeon's team. I explained to the PA that I felt like I needed a referral to an oncologist for continued monitoring. I remember actually having to raise my voice as I nearly begged for what I was asking. It was surreal—I was fighting with a medical professional for a referral to an oncologist after being diagnosed with cancer. My head was spinning. In the end, my self-advocacy paid off and I got a referral.

Ironically, even seeing the oncologist didn't do me much good. She listened to my story (which had acquired a few additional chapters) and ordered some more tests to cover all the bases. My favorite part was the time I had both a colonoscopy and an endoscopy in the same day. I'll never forget the nurse who laughed as she told me, “Don't worry, we will do the top part first and then flip you around, not vice versa.” A little humor goes a long way in those situations.

And still, these physicians insisted I was “fine” and didn't need further observation. The oncologist admitted that she didn't know enough about my specific type of cancer to give me any sort of definitive answer of what would lie ahead. I was to go on with my life as if this little blip never happened. And I almost chose to do just that. I was exhausted. I was tired of being poked and prodded. I just wanted my normal life back. But, it was in that moment that I finally realized... *this is my new normal*. And if I wouldn't fight for someone to keep listening to me and tell me truly what I needed to do, then no one would.



My Timeline



Dr. Google and my support group helped Solomon and me choose our next steps. We found a fantastic NET specialist at the University of Pennsylvania and a National Institutes of Health study of rare diseases that would help me even further (not to mention potentially benefit others). The NET specialist didn't tell me much more than I already knew; however, he was the first to validate the need to see me once a year for the rest of my life. Because guess what? NET cancer is never cured. It just goes into hiding. Which is what my most recent scan has shown. And hopefully, it stays hidden for quite a while.

Many rare diseases, including NET cancer, use a zebra stripe ribbon to raise awareness. This is a play on the medical aphorism coined by Dr. Theodore Woodward that “When you hear hoofbeats, think horses, not zebras.” Rare diseases are zebras, and from an epidemiological standpoint, the medical establishment did exactly what is best for a population. The assumption was that my diagnosis was something common and simple. In many ways, my story is an exception to this rule. However, improvements in diagnostics have brought about a drastic increase in the diagnosis of rare diseases.² This has implications in clinical training and emphasizes the critical need for patient advocates.

Until it comes back, or *if* it comes back, I'm going to keep advocating. Not only for myself, but for others. Solomon and I attend the NET support group as often as we can, where we share not only our story with new members, but also our strength and knowledge. Navigating the world of cancer isn't easy, plain and simple. But navigating a world with a rare disease is even more difficult.

You become the quietest voice in the room, even when you're screaming. But that doesn't mean you should give up. It just means you need to find a megaphone and become louder.

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Missy Adams is currently a stay-at-home mom to her three children (Maxwell, 10; Eleanor, 3; and Penny, 2) and is expecting her fourth child this August. She also owns an at-home baking business and travels to Walt Disney World as often as possible.

Solomon Adams is Missy's husband and parent to Maxwell, Eleanor, and Penny. He is an assistant professor of pharmacogenomics at Bernard J. Dunn School of Pharmacy at Shenandoah University, where he teaches and studies genetic components of drug response. He also frequently travels to Walt Disney World.

Self-Directed Death by ESRD Patients

Suicide vs. Voluntary Termination of Hemodialysis

Tony Salvatore [◇]

In the late 1980s, I worked for a large company, which, at the time, operated most of the hemodialysis centers in the United States. My job was with a division that supplied a nutritional therapy to patients during their dialysis sessions. My introduction to the topics discussed in this article occurred during a visit to a dialysis facility in Southern New England in 1989.

I was to meet with some of the clinical staff. When I arrived that morning, several staff members were huddled outside the building. When I entered, the receptionist was wiping away tears. She told me that a patient had died and everyone was upset. She would check on the status of my meeting.

I took a seat in the lobby. Sitting across from me was an older woman. She must have noted my suit and briefcase and asked if I worked for the company. I said yes and she told me she was a new patient. She went on to share that she did not have kidney disease, but her kidneys were severely damaged by a medication that she had taken for a cardiac condition.

She was glad that her meeting was delayed because it gave her more time to think about the decision that she was facing. She was ambivalent about starting hemodialysis, but her family had urged her to discuss her situation with the medical director and social worker at the center. She said, “I’m sure that they give good care here, but after all that I’ve been through, I don’t know if I want to do this for the rest of my life.”

At that point, the nutritionist came and took me to a conference room. She told me that a long-term patient had taken his life at home the night before. She and her colleagues were struggling to come to terms with his death. I offered to reschedule but they wanted to go ahead to get their minds off the situation.

About a week later, I had a conference call with some of the center’s staff. At the close of the call, I asked the social worker about the woman I met on my visit. Of course, she could not discuss a particular patient; however, she did say she had worked with several patients who elected to stop dialysis, as well as a few who opted not to begin it. She said the issue frequently came up at regional meetings of dialysis center social workers.

I asked the medical director of the dialysis division about the incidence of suicides among patients. He told me that they were not common but most centers had the experience. About 10 years later, I began my present post, which involves crisis intervention and suicide prevention. Every morning I pass a dialysis center on my way in and I often think about the patients and staff, and what I learned at that other dialysis center so many years ago.





End-Stage Renal Disease noun

As defined by the Centers for Medicare & Medicaid Services

1. a medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.

End-stage renal disease (ESRD) is an irreversible condition caused by total kidney failure. Poor care of diabetes and hypertension play a significant role in the onset of ESRD, as do diseases affecting kidney functioning. Most ESRD patients are treated by hemodialysis, in which the blood is filtered through a machine to remove toxins. This regimen is lifelong and completely alters a patient's lifestyle. As of December 31, 2018, 18,822 Pennsylvania residents were receiving dialysis services at one of the 318 Medicare-approved dialysis centers in the state.¹

This commentary will discuss the incidence of suicide and the voluntary termination of treatment in ESRD patients on hemodialysis. While ESRD is a terminal condition, suicide is a premature death that harms the well-being of family members, caregivers, and other patients. Though hastening death, the decision to forego hemodialysis appears to be motivated by different factors than suicide, with fewer negative effects on other parties. Contrasting these two outcomes may help clinicians to better understand the end-of-life issues in ESRD.

Suicidal Behavior in ESRD Patients

ESRD patients on hemodialysis have a strong risk for suicidality because of poor prognosis and quality of life. Suicidal behavior includes thoughts of suicide, expressions of intent to commit suicide, developing a specific suicide plan, and making a suicide attempt. At-risk persons living with ESRD may manifest any of these various forms of suicidal behavior.² Suicidal ideation is the most common type of suicidal behavior and is especially prevalent in ESRD patients.³

Suicides have been documented in dialysis patients for at least 50 years.⁴ However, national data on suicides in the ESRD patient population is not available. It is estimated that 5% of hemodialysis patients die by suicide.⁵ An analysis of national data on hemodialysis patients indicated that those most likely to die by suicide are male, white, and 75 years of age or older who report lower quality of life, problems in interpersonal relationships, greater anxiety, and more sleep problems.⁶ The suicide rate in ESRD patients is placed as high as 15 times that of the general population.⁷

Etiology of Suicide in ESRD Patients

The interpersonal-psychological theory of suicidal behavior (IPPT) sees suicide as proceeding thoughts of suicide to suicidal acts. The IPPT posits that three elements are necessary for an individual to make a lethal

suicide attempt: 1) an acquired capability to overcome the natural resistance to self-harm and affect lethal self-injury, 2) a belief that one is a burden on others, and 3) a belief that one is completely disconnected from a valued social group.⁸ This model readily lends itself to understanding some likely sources of suicidal behavior in persons with a severe disability, such as hemodialysis patients.⁹

Chronic pain is prevalent in ESRD. Patients may become habituated to it and more tolerant of it. They may thereby acquire the ability for lethal self-harm through becoming less fearful of death. According to the IPPT, the capability for suicide may also be a byproduct of self-injury or exposure to abuse, violence, or other types of trauma. ESRD patients may endure these experiences before or after their illness sets in.

ESRD patients may come to see themselves as a burden in those they care about in a number of ways. Reliance on dialysis affects self-worth by diminishing the ability to provide financial or emotional support to others. At the same time, it increasingly fosters dependence on others, which may cause patients to perceive themselves as a burden on others that would be lifted if they were dead. These feelings would be amplified by household budgets already impacted by the loss of a wage earner further strained by uncovered and ever-rising costs of care.

Opportunities for social interaction and connectiveness decline with the demands of treatment. ESRD severely stresses social ties and changes patients' place in their social environment. It creates a sense of isolation, a perception that one is completely alone. A patient's life is lived around three lengthy hemodialysis sessions weekly, and paratransit travel between home and dialysis center and frequent medical appointments.

Voluntary Termination of Hemodialysis

The objective of hemodialysis is to support the quality of life of ESRD patients. Withdrawal from treatment arises as an option when this is no longer feasible.¹⁰ ESRD patients who stop hemodialysis die within several days to a few weeks. The percentage of U.S. dialysis patients reported as having discontinued treatments before death ranged from 19% in 2000 to 23% in 2015.¹¹ Almost 1 in 4 ESRD patient deaths is associated with withdrawal from treatment.¹¹

The decision to decline dialysis is a matter of patient autonomy and self-determination. The National Kidney Foundation offers information for patients thinking about going off dialysis.¹² Electing to cease dialysis is seen as appropriate if the benefits of care are outweighed by the burdens imposed by the care.¹³ Most patients opting to end dialysis are elderly, very dependent, and have significant morbidity and pain.¹⁴ Some feel that patients with poor prospects because of advanced age and other factors should be counseled to forego dialysis.¹⁵

How Suicide and Treatment Termination Differ

Suicide is a death caused by injuring oneself with the intent to die. Explicit intent to die is what sets suicide apart as a self-directed form of death in ESRD patients. Suicide also differs from treatment termination in that common suicide risk factors such as depression and suicidal ideation do not play a role in the decision to end dialysis to the same extent.¹⁶ Some part of the suicide mortality in ESRD patients may actually be cases of treatment noncompliance that did not involve intent to die.¹⁷ These findings aside, all patients expressing an interest in ending treatment must be screened for depression and suicidal ideation, and counseled on-site or referred to a mental health provider.

Suicide and deliberate treatment noncompliance differ from life-ending treatment termination in that patients and their family and provider support systems collaborate in the decision-making process.¹⁸ Ending dialysis is seldom a unilateral act. Families, as well as providers, are often engaged in the discussion. Ending dialysis is a “good death” because it is pain-free and occurs in a context of palliative care and other support.¹⁹

Suicide is a traumatic loss that is usually unexpected and often violent. Treatment termination is an informed and planned process. It spares family members from the debilitating features of a “sudden death.”²⁰ When dialysis ends voluntarily, the death is anticipated and comprehensible. Survivors do not feel guilty and helpless because they “did nothing.” They do not blame or attribute their loss to providers or others. They also do not endure the stigma still adhering to suicide.

Voluntary termination of hemodialysis differs from so-called “assisted suicide,” which is another form of nonsuicidal self-directed death for those with terminal conditions. Assisted suicide (or “assisted dying”) involves a physician providing a patient with means or information to hasten death. With hemodialysis termination, the physician role is limited to advising the patient about the consequence of the decision to end treatment. Legislation legalizing assisted suicide has no bearing on patient choice to stop dialysis.

Concluding Remarks

Patients with chronic kidney disease are among the “groups with increased risk of suicide” referenced in the *National Strategy for Suicide Prevention*.²¹ However, little advice has been offered on mitigating this risk beyond improving assessment measures and support resources in dialysis facilities.²² These steps could readily be complemented by making patients and families more aware of suicide risk through educational programs and incorporating personal suicide prevention safety plans into treatment.

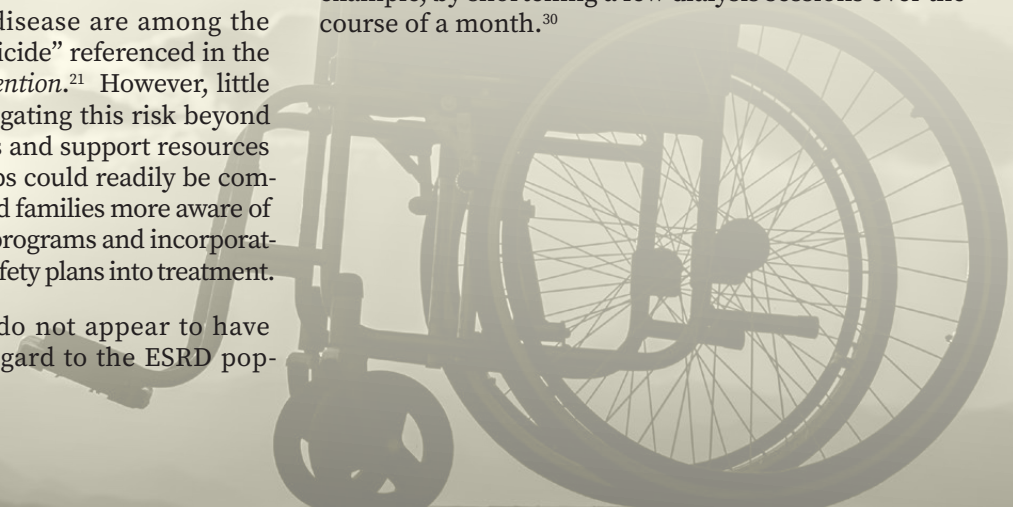
Protective factors for suicide do not appear to have been given any attention in regard to the ESRD pop-

ulation. It is known that depression and suicide risk correlate strongly with hemodialysis patients’ dissatisfaction with their quality of life.²³ Factors enhancing quality of life may lessen suicide risk. This can be done by promoting a full understanding of the disease and its treatment, assuring good relationships with the dialysis treatment team, and encouraging strong support from their family and overall social environment.²⁴ These measures are likely buffers to suicide risk.

The terminal nature of ESRD drives hopelessness and futility in hemodialysis patients. These can trigger the emergence of suicide risk, particularly in patients with a history of self-injury or suicidal behavior, serious mental illness, abuse, or trauma. When present, these experiences constitute a “pre-motivational phase” for the possible onset of progressively worsening suicidal behavior.²⁵ All patients should be screened for suicide risk at admission. Patients with known risk backgrounds should receive a comprehensive psychiatric evaluation and be reassessed periodically over the course of their treatment.

There is some support that motivational interviewing techniques can enhance overall treatment adherence in adults undergoing hemodialysis.²⁶ Motivational interviewing has also been used effectively with predialysis patients to reduce anxiety and depression levels and increase health-related quality of life.²⁷ The benefit of this technique with patients with preexisting risk factors or its long-term value are not known. Nonetheless, motivational interviewing appears to be useful in lessening suicide risk and assuring that decisions about treatment are as informed as possible.

In closing, note should be made of a common self-harming behavior in hemodialysis patients that may be parasuicidal in nature. Non-adherence to the prescribed dialysis schedule or other elements of treatment is highly prevalent and occurs in at least half of the patients.²⁸ Nonadherence is seen as a maladaptive coping strategy used by patients to exert some control over their situations.²⁹ In ESRD, nonadherence can have life-threatening consequences. It may foster the capability for suicide. This may be countered by returning some control to patients. This could be done, for example, by shortening a few dialysis sessions over the course of a month.³⁰



Resources for ESRD Patients and Families



The National Kidney Foundation
www.kidney.org
NKF Cares Help Line
1-855-NKF-CARES (1-855-653-2273)

The Renal Support Network
Hopeline Peer Support Phone Line
www.rsnhope.org
1-800-579-1970



National Kidney Foundation/Eastern
Pennsylvania & New Jersey
1-800-697-7007

The Kidney Foundation of
Central Pennsylvania
www.kfcp.org
1-800-762-6202

National Kidney Foundation/
Western Pennsylvania/Alleghenies
1-800-261-4115

Quality Insight Renal Network 4
www.qirn4.org
1-800-548-9205



National Suicide Prevention Lifeline
1-800-273-TALK (8255)

About the Author

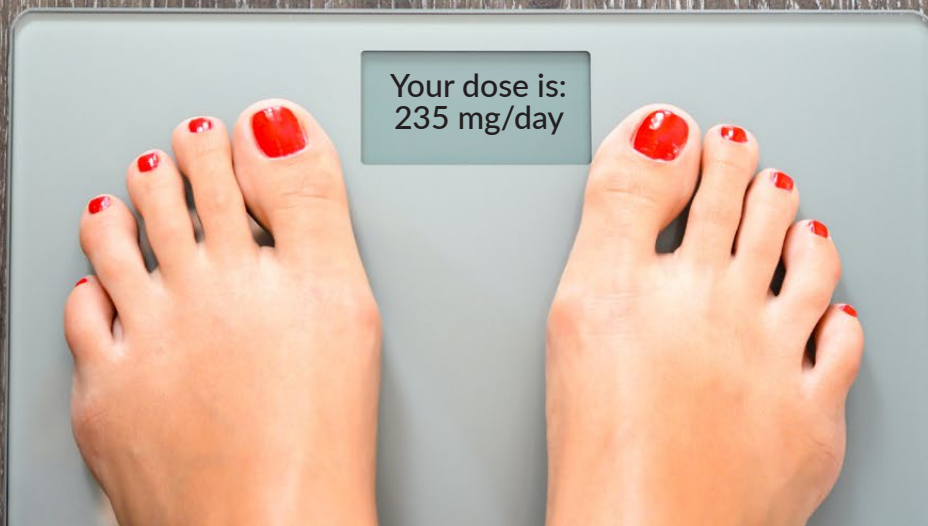
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ACCURATE WEIGHT DOCUMENTATION: HOW TO ADHERE TO BEST PRACTICES

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A patient arrived for his dipyridamole stress test in the outpatient stress lab. He was relatively healthy but had recently experienced some chest pain. His last admission to the hospital was approximately five years before when he had pneumonia. The nurse entered a dipyridamole stress test order per medical staff-approved protocol in the electronic health record (EHR). The dipyridamole dose was entered as 0.57mg/kg IVPB x 1. The pharmacist verified the order with a calculated final dose of 32.5mg (0.57mg/kg x 57kg). The dipyridamole was infused without error; however, it was later realized that there was a dosing error. During disposal of the completed medication, the nurse noticed that the IV label listed the patient's weight as 57kg, which was less than what the nurse believed the patient weighed. Upon investigation, it was discovered that the patient's actual weight was 75kg. The weight of 57kg, which was documented in the EHR, was from the previous admission five years ago. This lack of an updated weight resulted in a suboptimal dose of dipyridamole, thus requiring the patient to schedule another dipyridamole stress test. This case example highlights the numerous system failures related to weight-based errors that are common to any healthcare organization. Weight documentation errors can result in medication errors. Health systems should be aware of current processes and have preventive measures in place.

From December 2008 to November 2015, the Patient Safety Authority (PSA) received 1,291 reports related to patient weight. Of these errors, almost 75% reached the patient.¹ An inaccurate weight in the EHR is a patient safety issue because of its effect on ensuring accurate medication dosing.

Several units of measure include weight as a basis for dosing med-

ications, such as mg/kg, mcg/kg/min, mg/m², etc. An Institute for Safe Medication Practices (ISMP) best practice recommends that providers order medications in weight-based units and pharmacists review the weight-based units prior to dispensing for pediatrics, excepting topical agents.² High-alert medications, such as some forms of chemotherapy, are based on body surface area, which is calculated according to a patient's weight. The wrong weight can place the patient at a higher risk of side effects or poor outcomes due to an ineffective dose. Some cardiac medications are titrated to response and can be dosed based on the patient's weight (mcg/kg/min). The wrong weight can delay a patient's response or overshoot the target goal. Anticoagulants like heparin have a narrow therapeutic window to be effective. Heparin can be titrated by units/kg/hour until the activated partial thromboplastin time (aPTT) has reached the target range. If the target goal is exceeded for too long, this can place the patient at a higher risk of bleeding. When patients have declining or improving renal function, some medications need to be adjusted for this change. The Cockcroft-Gault equation is used to estimate a patient's creatinine clearance, which correlates to a patient's renal function. An accurate weight is needed for this calculation. Dosing adjustment errors can compound the differences in dosage.

In addition to prescribing errors, administration errors with the wrong weight can occur. When nurses are administering continuous weight-based IV drips, they enter the patient's weight into the IV pump, which controls the rate of infusion. If the nurse changes the weight in the infusion pump, there is a risk that the infusion rate will change, which can increase the risk of an adverse outcome. If patients are at goal and there is a signifi-

Abstract

Background: The Institute for Safe Medication Practices (ISMP) has recommended that health systems implement preventive measures to decrease weight-based dosing errors.

Problem: Despite a process improvement project that was implemented to meet ISMP's goals, weight documentation discrepancies continue to occur.

Methods: The weight documentation process was reviewed and safety gaps were identified. Pharmacists were notified when patients had greater than 15% weight documentation discrepancy. Notifications were tracked before, during, and after process improvements within the electronic health record (EHR).

Interventions: Streamlining of weight documentation fields within nursing assessments, locking of bed scales, setting an expiration date for the weight documentation field, including a minimum and maximum on height and weight fields, real-time alert for nursing staff upon documentation, and staff education were part of the process improvement plan.

Results: Average monthly weight documentation errors decreased from 115 to 60 per month over the process improvement period.

Conclusion: Human factor errors can result in weight documentation discrepancies despite implementing ISMP's targeted safety goals around weight documentation. A real-time pharmacy notification of weight documentation discrepancies should be required for hospital pharmacists to prevent weight-based dosing errors.

cant weight change, the IV drip rate needs to be back-calculated so the infusion rate stays the same but the units/kg/hour or mcg/kg/hour are dose-adjusted to the new corrected weight.

The PSA has identified multiple causes for weight documentation errors. Documenting a patient's weight in imperial units (pounds) can lead to dosing errors because weight-based medications use the metric system. This can occur if a patient verbally tells the provider their weight in pounds and the conversion is not calculated, or if the patient is weighed on a scale that displays pounds. Estimating a patient's weight due to lack of a scale or the patient being seriously ill is another source of error. An estimated weight can be significantly different from the patient's actual weight. This scenario can occur most often in the emergency department or critical care unit. Transposing numbers when documenting weight in the EHR may also lead to significant dosing errors.¹

ISMP has listed weight documentation as a Targeted Best Medication Safety Practice for the past six years. They recommend that providers weigh patients during every encounter and avoid the use of a "patient's stated weight." They also discourage using a weight from a

previous visit, since this could significantly differ from the patient's current weight. Some bed scales can display values in both pounds and kilograms (one after the other), which can be misread as the wrong value. ISMP recommends a hospitalwide assessment with each hospital's engineering department to determine whether scales can be locked in kilograms. The EHR, infusion pumps, and preprinted order forms should all use metric units for ordering, dispensing, and charting.³ **Table 1** summarizes ISMP's recommendations for reducing weight documentation errors. Even though ISMP established weight documentation as a best practice goal in December 2013, hospitals still had low adoption rates of documenting weights in metric units (47% fully compliant) and weighing a patient with each admission (44% fully compliant) as of July 2017.⁴

At our institution, pharmacists provide daily assessments of anticoagulants and antibiotics. As unexpected labs resulted, they noticed an increase in weight documentation discrepancies. Due to these discrepancies, an internal department alert system for our pharmacists was created so they could be aware of weight documentation differences during order verification. The pharmacist received a notification if there

was a weight discrepancy greater than 15% among any of the weight documentation fields. At the time, there was no literature supporting a specific weight documentation discrepancy that would require a pharmacist's intervention; thus, 15% was our starting point, and adjustment would be considered if we noticed any trends. This notification would enable the pharmacist to adopt a proactive approach to correcting any medication dosing errors. When a weight documentation discrepancy notification fired, the pharmacist would clarify the weight with the nurse, review the patient's medication list, calculate the patient's creatinine clearance for renally adjusted medications, and update the medication orders accordingly. Due to the large volume of notifications that were triggered for the pharmacists to evaluate and the amount of time to address these tasks, this issue was escalated to our medication safety team. In 2013, the pharmacists were evaluating over 100 weight documentation discrepancies per month, as illustrated in **Figure 1**.

Methods

A medication safety team mapped weight documentation workflows and completed a proactive safety assessment using ISMP's

Table 1: Summary of ISMP's Recommendations to Decrease Weight Documentation Errors³ by Hazard



Scales

If scales can measure in both pounds and kilograms/grams, modify the scale to lock out the ability to weigh in pounds.

If purchasing or replacing scales, buy new scales that measure in, or can be locked to measure in, metric units only.



Unit Conversion

Have conversion charts that convert from kilograms (or grams for pediatrics) to pounds available near all scales, so that patients/guardians can be told the weight in pounds, if requested.

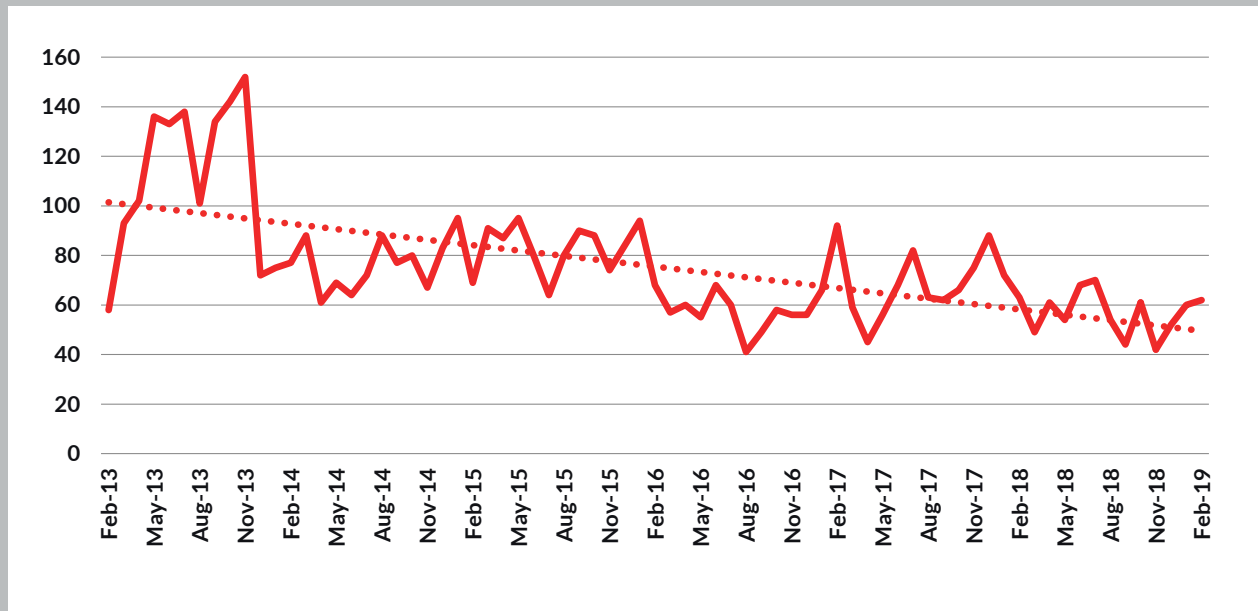


Documentation

Ensure that computer information system screens, medication device screens (e.g., infusion pumps), printouts, and preprinted order forms list or prompt for the patient's weight in metric units only.

In all electronic and written formats, document the patient's weight in metric units only.

Figure 1: Pharmacy Weight Discrepancy Notifications



recommendations. Several documentation forms with multiple weight fields were a source of confusion for both nurses and certified nursing assistants (CNAs), who sometimes felt unsure about which weight field to document. There were also multiple orders for weight documentation within our nursing admission order set.

The informatics team tackled the large task of streamlining our nursing admission assessment forms (Figure 2), which included three weight documentation fields: measured weight, clinical weight, and estimated weight. The measured weight field was used when the patient was physically weighed. Upon admission, this value was copied over to the clinical weight field, which was used by default in the dosing calculator when a weight-based drug was ordered; this field was also used to calculate weight-based continuous IV infusions. The clinical weight and measured weight fields should be the same value in most patients. The estimated weight field was designated for use by the emergency

department when staff were unable to physically weigh the patient. The emergency department nursing staff member would then copy this value into the clinical weight field when a weight-based drug was ordered. These three fields were displayed on various documentation forms throughout the EHR. The clinical weight field was available on over 27 different inpatient assessment forms. If a provider ordered a daily weight for a congestive heart failure patient whose weight can fluctuate due to fluid gain or loss, these three fields displayed for the nurse and CNA. This allowed for the clinical weight field to be easily changed and subsequently affect medication dosing. The goals of this modification were to display the clinical weight field on the patient admission forms and estimated weight field for the emergency department.

During a patient's admission process, a nursing admission order set was ordered, which included three orders for weights, each linked to three different forms—resulting in nine weight documentation fields. Every

weight order that fired an increased the chance for documentation errors. This created unnecessary work for the nurse and CNA. Removing the two additional weight orders streamlined documentation.

Upon reviewing ISMP's recommendations, the medication safety team identified that the bed scales needed to be locked and contacted our engineering department. Engineering had to develop their own process to track and lock the bed scales and implement a check to lock new bed scales. Since this took time and resources to implement this fix, locking of the bed scales was included in their maintenance schedule of the beds.

An EHR risk point was identified where the clinical weight field was crossing encounters. We resolved this issue by setting the clinical weight field to expire after 28 days. This would decrease the risk of an old weight being used for a new weight-based order.

Additional ways to decrease weight documentation errors have been

identified at pediatric hospitals, including developing custom decision support for weight documentation so that the EHR alerts the provider if the documentation is greater than 10% of the normal range based on the patient's age.⁵ At our institution, we do not have a pediatric ward, but the informatics team implemented a minimum and maximum for height and weight fields on our documentation forms along with a real-time alert if the patient's new documented weight changed by 10%. Our nurses and CNAs document most of the patients' weights, so they would be alerted at the time of documentation if there was a typographical error.

During a medication safety discussion, a process gap was identified regarding who would zero out the bed scales prior to a new admission or patient transfer. The bed scale should be tared before a patient is weighed and no equipment should be on the bed when weighing a patient. Education was provided to the nurses and CNAs on the correct process to ensure beds are tared prior to admissions.

The process of streamlining the documentation forms, locking bed scales, adding safety alerts, and educating staff on weight documentation was an almost two-year project. Other disciplines, including dietary and ambulatory services, were involved because they also had weight fields embedded within their documentation forms. As such, changes to these fields would have affected their workflow. Weight field changes would also impact other fields such as body mass index, Cockcroft-Gault creatinine clearance, and body surface area. It took significant time to discuss workflows with these different key stakeholders, secure approval to change the forms, and test workflow once the changes were introduced.

Figure 2: Nursing Adult Admission Orders and Forms

Component	Order Details
Patient Care	
<input checked="" type="checkbox"/> Basic Admission Information	Once, On admission.
<input checked="" type="checkbox"/> Admission History Adult	Once
<input checked="" type="checkbox"/> Admission Assessment Adult	Once
<input checked="" type="checkbox"/> Ongoing Assessment Adult (Adult Ongoing Assessment)	qSHIFT
<input checked="" type="checkbox"/> Activities of Daily Living Adult	qSHIFT, PRN, Per Protocol
<input checked="" type="checkbox"/> Order Entry Details	Daily
<input checked="" type="checkbox"/> Hourly Rounds	PRN, Per Protocol
<input type="checkbox"/> Intake and Output	qSHIFT, PRN, Per Protocol
<input checked="" type="checkbox"/> Morse Fall Risk Assessment	Daily, PRN, Per Protocol
<input type="checkbox"/> Safety First Patient First	qSHIFT, Constant Order, PRN, Per Protocol
<input type="checkbox"/> Infectious Disease Screening	
<input type="checkbox"/> Cardiac Monitoring	q2hrs
<input type="checkbox"/> Cardiac Monitoring	q4hrs
<input type="checkbox"/> Cardiac Monitoring (Telemetry)	q8hrs
Vital Signs	
<input checked="" type="checkbox"/> Weight	T;N, Once, On admission.
<input type="checkbox"/> Weight	T;N, Daily
<input checked="" type="checkbox"/> Height and Weight	
<input type="checkbox"/> Vital Signs	T;N, Constant order, Per unit protocol.

Figure 2a: Form for Basic Admission Information Order

Figure 2b: Form for Weight Order

Figure 2c: Form for Height and Weight Order

Figure 3: Nursing Weight Order/Admission 2013–2014



Results

Implementation of our interventions with the documentation process and safety enhancements to our EHR decreased the number of weight documentation errors, as seen in **Figure 1**. Data collection took place before and after our process improvement period. During this time, the pharmacists were notified to evaluate patients with a weight documentation discrepancy greater than 15%. A report was generated for the pharmacist weight notification from our electronic health record. Prior to any safety enhancements and documentation cleanup, the pharmacy had received its peak weight discrepancy notification of almost 150 notifications, with an average of 115 notifications per month in 2013. In 2014, we started to work on improving our documentation process. In 2015 and 2016, we implemented safety enhancements in our EHR as mentioned above. Weight discrepancy notifications trended down and by 2018 were averaging 60 notifications per month. Streamlining

the number of weight orders within the nursing admission order set reduced the number of weight orders per admission from 3.77 in February 2013 to 1 in December 2014, as seen in **Figure 3**.

Discussion

Despite implementing the above fixes, weight documentation errors can occur due to human factors. For example, a staff member might document a patient's weight on the wrong patient's chart due to a lack of bedside computers or portable scanning devices. A user could also weigh the patient in the room, proceed into the hallway where a computer is available, and document the patient's weight on the wrong chart. Other human factor errors include transposing numbers incorrectly during electronic documentation (e.g., typing 57 kg instead of 75 kg), documenting a patient's weight based on the patient's word (e.g., stated weight) and not physically weighing the patient, and typing the patient's

height in the weight field (and vice versa).⁶ Because documentation remains susceptible to human error, implementing a redundancy such as the pharmacist notification can be an effective strategy.

Human factor errors such as transcribing errors, having the incorrect chart open in the EHR, and not zeroing out the bed scale are potential causes of weight documentation discrepancies. The weight documentation discrepancies did trend down after our improvements, but they were not eliminated.

Despite efforts to implement these best practices, hospitals continue to struggle with weight documentation errors due to human factors. There are three categories of human errors: knowledge-based, rule-based, and skill-based. Knowledge-based errors occur when a person does not have enough experience or knowledge to handle a task.⁷ An error can occur when they try to "guess" what the answer would be based on their current knowledge

base. Rule-based errors occur when rules are misapplied or not followed.⁷ One example seen was weighing a patient one after another and writing their results on a piece of paper which was then later entered into the computer. This would be considered using a shortcut to perform a task rather than following the standard process. Skill-based errors are errors that occur when a routine task is performed without much thought.⁷ An example of this would be not taring the bed or weighing the patient with equipment.

Poor design of systems, equipment, and tools can contribute to human factor errors. At our institution, an enhancement to our EHR could have contributed to a skill-based error. When a medication is ordered with a weight-based dose (e.g., 10mg/kg), a dosing calculator window displays for the provider where they can view the weight-based dose, patient's weight, and final dose in the calculation and then click the mouse to close the screen. The enhancement to the EHR performs the calculation in the background without another window opening for the provider. This saves the provider an extra mouse click and screen in the process of placing an order; however, the provider does not see the weight that is pulled into the calculation window (10mg/kg x 75kg = 750mg). This removes a potential source for an intervention in cases where there is an erroneous weight.

Whenever possible, human factors engineering should be incorporated into the EHR documentation workflow. This discipline reviews employees' work environments and the available technology. The goal is to improve performance and decrease hazards. When a system has elements that increase the likelihood of error or injury, this is considered a hazard.⁸ The design of the weight documentation field was a human factors risk point for our

EHR because, as stated above, staff may experience confusion about the correct place to document weight when multiple weight fields were available on a nursing assessment form. If hospitals do not have access to a human factors engineer, a human factors assessment should be performed to proactively identify high risk points. ISMP has listed some hazards and performance measures that should be included in the weight documentation process (see Table 1).

Conclusion

In conclusion, health systems should have processes in place to decrease weight documentation errors. During this process improvement, it was key to educate multiple disciplines on the repercussions of incorrect weight documentation. It is important to put sustainable processes in place, rather than just applying a temporary fix to this issue. Despite the implementation of recommended practices, however, human factors errors can still occur. As new employees are hired, new beds are purchased for the hospital, or new electronic forms are built, it is important to have a process in place to prevent operational errors from occurring (e.g., orientation, training, and locking of new beds) and system design checks in place to prevent the use of unnecessary data entries in the EHR. The goal is to minimize human factors errors even though they are sometimes unavoidable. A process should be implemented to provide pharmacists with real-time weight documentation discrepancies in order to correct any current medication dosing errors and prevent future errors as a safety check.

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About the Author

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Unplanned Extubation

A Common and Costly Complication of Airway Management

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Endotracheal intubation and extubation are procedures routinely performed by clinicians who manage the airway of critically ill or injured patients (e.g., emergency physicians, anesthesiologists, and intensive care physicians) and patients undergoing general anesthesia (i.e., anesthesiologists and other anesthesia providers). Most of the time, extubation is a planned, intentional, and controlled event and in these circumstances the rate of complications related to extubation has been reported in the literature to be as high as 12%. The unplanned, unintentional, and uncontrolled removal of the endotracheal tube (ETT) can be either due to actions of the patient removing their own tube, defined as self-extubation, or due to an external force applied to the ETT during nursing care or movement of the patient that causes the dislodgement of the tube, defined as accidental extubation. Unplanned extubation is associated with significant complications, including aspiration pneumonia, hypoxemia, arrhythmias, vocal cord injury, brain damage, and death.

Keywords: *extubation, complications, airway management*

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Drew was a teenager who loved skateboarding. He fell one day and sustained a head injury. The local emergency room elected to intubate Drew for transport to a tertiary care center. Enroute, his life-sustaining breathing tube became dislodged. The ambulance team reintubated Drew but did not recognize the tube had been placed in his esophagus. He quickly became hypoxic, his heart rate slowed, and he went into cardiopulmonary arrest. Therefore, the ambulance was diverted to the nearest ER. However, upon arrival the ER physician noted that Drew had sustained irreversible brain ischemia and Drew was pronounced dead. Although Drew's death was tragic it is not an isolated example of complications that can occur from the unintentional and uncontrolled removal of a patient's life-sustaining breathing tube.

Airway management is routinely performed by anesthesiologists, intensivists, emergency physicians, and other trained airway providers such as nurses, anesthesia assistants, respiratory therapists, and paramedics. Airway management includes placing a life-sustaining breathing tube into the trachea (intubation) and eventual removal of the tube when the patient no longer requires the airway support (extubation). Most of the time, removal of the endotracheal tube (ETT) occurs in a planned, intentional, and controlled fashion. Yet even when extubation occurs as part of a planned and controlled situation, it is associated with complications, with rates reported in the literature as high as 12%.^{1,2} When removal of the endotracheal tube is unplanned, unintentional, and uncontrolled, it is typically referred to simply as an unplanned extubation (UE). UE can occur when the patient dislodges their tube by pulling on it (self-extubation) or when an external force is applied to the tube during movement of the patient or other nursing care (accidental extubation).³⁻⁵ UE can occur in any setting where intubated patients are cared for, including the operating room, intensive care unit, the emergency department, diagnostic imaging suites,

and procedural areas such as the GI or CV labs. It also can occur during transport between any of these areas.

Many publications in the literature address the challenge of predicting and managing the difficult intubation, but the problems that occur during extubation, including unplanned extubation, are much less widely studied. This is especially true in the intensive care unit (ICU), where airway complications associated with extubation are higher.^{4,7}

Incidence and Risk Factors

The incidence of unplanned extubation, as reported in the literature, ranges widely, from 0.5–35.8% in adults and as high as 80.8% in neonates.^{4, 8-14} The majority of studies on the incidence of UE were conducted in the intensive care unit. Unplanned extubation in the neonatal ICU (NICU) is the fourth-most commonly reported adverse event.^{14-17.}

In the United States, an average of 1.65 million adult patients are intubated and mechanically ventilated in intensive care settings each year.¹⁸⁻¹⁹ The median reported annual unplanned extubation rate in the ICU is 7.3%, which extrapolates to more than 120,000 adult patients who experience an unplanned, unintentional, uncontrolled extubation every year in the ICU.⁴ In the NICU, the median reported annual unplanned extubation rate is even higher at 18.2%.¹⁶ On average 80,000 patients are intubated and mechanically ventilated in the NICU, resulting in more than 14,500 neonatal patients in the NICU experiencing an unplanned extubation each year. The rate of occurrence of UE outside the ICU setting is unknown, as very few published studies exist.

While less common in the operating room setting, certain conditions can still lead to accidental or self-extubation in the OR. Most patients receive general anesthesia with muscle relaxation, which reduces the risk of patient movement and accidental extubation. Self-extubation during emergence from anesthesia is rare but does occur. Many patients do not require reintubation, but vocal cord injury is a risk if the ETT cuff was not deflated before tube removal. More serious are the rarer events of accidental extubation that occur during the operative procedure. These events can occur during procedures in or proximal to the airway, or during lateral or prone positioning of the patient. Several case reports exist describing accidental extubation during prone spine surgery.¹⁸⁻²⁰ One case report describes an extubation that occurred during a wakeup test to perform a neurological exam. This case was successfully rescued with the placement of a supraglottic airway device.²⁰ Another case report describes an extubation that occurred with the patient in the prone position and

Annual Number of Unplanned Extubations and Associated Cost



the head flexed and secured with surgical pins. This patient's airway was rescued using fiberoptic intubation.²¹ Some surgical procedures require the head of the patient to be positioned 180 degrees away from the anesthesia machine, restricting visualization as well as monitoring of the endotracheal tube. Dislodgement of the endotracheal tube, as well as a delay in recognition that extubation occurred, is possible in these cases.

In comparison to the operating room, accidental extubation is much more common in the intensive care environment. Unlike in the operating room environment, general anesthesia and muscle relaxation often are not employed, potentially increasing the risk of patient movement and tube dislodgement.

Self-extubation is the most common cause of UE in adults and has been the cause in 62–90% of reported incidents.^{22,23} Other causes include accidental extubation while moving the patient, manipulating the endotracheal tube, or performing suctioning maneuvers. Accidental extubation can also occur while the patient is being turned or repositioned. Intubated patients often need to travel outside the ICU setting for diagnostic scans such as CT or MRI, or for interventional procedures (e.g., endoscopy, cardiac catheterization) and may need to be moved several times during which accidental extubation may occur.

Several risk factors can increase the possibility of extubation due to either patient action or accident (**Table 1**).^{4,8,11,24-28}

Inadequate securement of the tube can increase the risk for removal or dislodgement. Additional factors that can increase the risk of dislodgement or removal include lack of physical restraints, inadequate patient sedation, or patient agitation or restlessness in the setting of an inadequately secured ETT.^{4,8,11} Use of physical restraints or oversedation can also potentially lead to agitation and increased risk of extubation.⁴ Emergency surgery, delirium or confusion, congestive heart failure, or the presence of nosocomial infection have also been linked as risk factors for unplanned extubation in the ICU.²⁵⁻²⁷ Lack

of a clear plan for extubation can also increase risk.

The lack of standardized procedures for weaning and extubation has also been associated with increased risk of UE.^{4,8,24} Human factors in the ICU can also play a role in increasing risk and have been linked to unplanned or accidental intubation, including fatigue, level of nursing experience, and inadequate staffing patterns.^{4,25} Other human factors such as high nursing workload and higher nurse-to-patient staffing ratios have been linked as contributing factors for UE, and it is not surprising that unplanned extubations occur more frequently during evening and night shifts.^{23,28,29}

A study by Danielis et al. surveyed nurses in the ICU to identify precipitating factors for unplanned or accidental extubation.²⁸ The results of the survey identified several key factors: a chaotic working environment, poor nurse-to-patient ratios, lack of communication among providers, and barriers to direct observation of the patient. Many institutions utilize continuous sedation with sedation vacations, and UE has been known to occur when the sedation vacation is instituted but not clearly communicated to the entire care team.²⁸

Complications

In the operating room setting, reported airway-related complications are higher during extubation than during intubation; 12% of all airway claims collected by the American Society of Anesthesiologists' closed claims database occurred during extubation.^{1,30} Another report from the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society found that one-third of reported claims were due to respiratory complications associated with emergence and extubation.³¹ In both studies, airway-related complications that occurred outside the operating room setting, under uncontrolled conditions, were even higher.

UE can lead to a large variety of complications (**Table 2**).^{22,23,31,32}

Table 1.
Risk Factors for
Unplanned Extubation

- Inadequate Securement of the Endotracheal Tube
- Inadequate Sedation
- Lack of Physical Restraints
- Restlessness or Agitation
- Delirium or Confusion
- Unclear or Lack of an Extubation Plan

Table 2.
Complications
Associated With
Unplanned Extubation



Clinical

- Hypoxemia
- Hemodynamic Instability
- Vocal Cord Injury
- Aspiration Pneumonia
- Respiratory Failure
- Brain Damage
- Cardiac Arrest
- Death



Other

- Increased:
 - ICU Length of Stay
 - Hospital Length of Stay
 - Hospital Costs
 - ICU Mortality Rate

Table 3.
Average Yearly Costs
Associated With Unplanned
Extubation in the Adult ICU

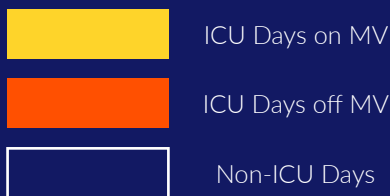
Day	Non-UE	UE
1	\$10,794	\$ 10,794
2	\$ 4,796	\$ 4,796
3	\$ 3,968	\$ 3,968
4	\$ 3,968	\$ 3,968
5	\$ 3,968	\$ 3,968
6	\$ 3,968	\$ 3,968
7	\$ 3,968	\$ 3,968
8	\$ 3,968	\$ 3,968
9	\$ 3,968	\$ 3,968
10	\$ 1,760	\$ 3,968
11	\$ 1,760	\$ 3,968
12	\$ 1,760	\$ 3,968
13	\$ 1,760	\$ 3,968
14	\$ 1,760	\$ 3,968
15	\$ 1,760	\$ 3,968
16	\$ 1,760	\$ 3,968
17	\$ 1,760	\$ 3,968
18	\$ 1,760	\$ 3,968
19		\$ 1,760
20		\$ 1,760
21		\$ 1,760
22		\$ 1,760
23		\$ 1,760
24		\$ 1,760
25		\$ 1,760
26		\$ 1,760
27		\$ 1,760
28		\$ 1,760
29		\$ 1,760
30		\$ 1,760
	\$59,206	\$100,198

Average Cost of UE \$40,992
Avg. Yearly # of UE 121,000



Yearly Cost of
Unplanned Extubations

\$4,960,032,000



When an endotracheal tube is accidentally removed before the tracheal cuff is deflated, injury can occur to the vocal cords or trachea. Intubated patients with large secretion burdens can potentially aspirate these secretions during an unplanned extubation and this can lead to aspiration pneumonia. Unplanned extubation can result in hypoxia if oxygenation or ventilation is inadequate after the tube is removed, and this hypoxia can progress to hemodynamic instability and hypotension, arrhythmias, brain damage, cardiac arrest, and even death if not successfully treated.

Successful reintubation after unplanned extubation can be quite challenging, especially if hypoxia or airway edema is present. The reported reintubation rate after unplanned extubation varies in the literature but may be as high as 89%.^{4,34,35} A study by Mort assessing the need for reintubation after unplanned extubation found that 89% of patients needed reintubation within two hours, and 66% required reintubation within 30 minutes after accidental extubation.³⁵ The need for reintubation after accidental extubation is higher and carries a poorer prognosis compared to reintubation after patient self-extubation.³⁶ A study by de Lassence et al. reported an overall reintubation rate of 77% after unplanned extubation. The majority of the patients in this study who required reintubation experienced accidental extubation, and 37% of patients who self-extubated did not require re-intubation.²³

Prolonged mechanical ventilation increases the risk of ventilator-associated pneumonia (VAP), a condition associated with longer ICU and hospital lengths of stay (LOS).^{37,38} Unplanned extubation has been associated with increased VAP rates, as well as increased ICU and hospital length of stay and increases in mortality rates.^{23,37-42} However, conflicting studies have found no increases in mortality in intubated patients who experienced unplanned extubation.^{8,34} De Lassence et al. found that both ICU and hospital length of stay were longer (18 vs.

9 days for ICU LOS and 30 vs. 18 days for hospital LOS) in intubated patients who experienced unplanned extubation.²³ Similar results have been reported in pediatric and neonatal patients with UE.⁴³⁻⁴⁵

Other, more severe complications have also been reported after unplanned extubation. In a study by Klugman, cardiovascular collapse occurred following 20% of unplanned extubations, and neonatal patients were found to be at higher risk.⁴⁶ Increased mortality rate and worse prognosis have been reported in multiple studies examining complications after unplanned extubation.^{34,41,46}

Costs

Complications associated with UE, especially if they increase hospital or ICU length of stay, can significantly increase hospital costs.⁴⁷⁻⁴⁹ The need for mechanical ventilation in the ICU, even in the absence of complications, adds to hospital costs (Table 3). According to Dasta et al., mechanical ventilation adds an average of \$1,522 to hospital costs per day.⁴⁸ The average cost for an ICU stay for a mechanically ventilated patient without an unplanned extubation is \$59,206. Due to an increased ICU length of stay (18 vs. 9 days) for patients who experience an unplanned extubation, the average cost of an ICU stay and complications for a patient who experiences an unplanned extubation is \$100,198. Therefore, due to the increased length of stay and complications that occur due to an unplanned extubation, the additional cost per unplanned extubation is \$40,992.^{48,49} A study by Roddy factored in complications such as nosocomial infection and increased LOS in pediatric patients who experienced unplanned extubation in the ICU and found that costs increased by \$36,692 per UE incident.⁴⁵ In the United States, the overall cost burden in the ICU from unplanned extubations totals near \$5 billion.^{23,47,49} If incidents of unplanned extubation in the NICU are included, this adds an additional \$500 million in hospital costs.⁴⁹

Figure 1. Society for Airway Management Collaborative



Prevention

The literature clearly shows that UE is both common and costly. Yet, the gravity of this very serious problem remains underrecognized in many hospitals and commonly is not acknowledged as a valid problem. Many hospitals still do not track unplanned extubation rates as a quality metric, and most electronic health record (EHR) systems do not include data sets to track accidental or self-extubation. An informal survey of EHR companies conducted by the Airway Safety Movement found that none surveyed had a data field for UE. A major first step in prevention is to increase awareness of the problem. There are several strategies that can be employed to reduce the risk of UE.

Increased Awareness of Risk Factors

An important first step to increase awareness of the problem is staff education for providers caring for intubated patients about the risk factors and how to monitor for patients at risk. Vats et al. created an airway risk assessment scoring tool that can stratify pediatric patients and identify patients at risk for unplanned intubation.⁵⁰ This tool assigns points for several risk factors, with a score of 5 or higher indicating high risk for UE. The study found a high correlation between the scoring tool and the incidence of unplanned extubation.

Several hospitals have introduced quality improvement initiatives using multidisciplinary interventions to prevent unplanned extubation and improve outcomes. Chao et al. used a multidisciplinary approach of stan-

dardized procedures, revised sedation and weaning protocols, improved restraint and securement methods, and improved communication, and found a significant reduction in UE rates from 3.19 to 0.95 per 100 patients.⁵¹ Chao's strategy also used team resource management and a no-blame culture, and created a task force to identify high-risk patients. Similar quality improvement strategies have demonstrated a reduction in unplanned extubation rates in the pediatric and neonatal ICUs.^{53,54} Kandil et al. demonstrated a reduced rate of UE by 75% (1.2 to 0.3 UE per 100 ventilator days) using quality improvement methods.⁵⁷ Galote et al. reduced unintended extubations in their Level IV NICU by 61% using quality improvement methods.⁵⁶

Strategies to Reduce the Incidence of Unplanned Extubation

Individual strategies can also reduce the incidence of UE. Standardization of protocols as well as the creation of bundles and checklists in the ICU setting has been shown to reduce VAP and improve outcomes.^{57,58} Standardization of tube restraint methods as well as patient restraint and sedation protocols could have a similar benefit.^{51,55,56}

Kandil identified several strategies that should be deployed during high-risk situations to decrease the incidence of unplanned extubation.⁵⁵ High-risk situations include repositioning the ETT, moving the patient during nursing procedures, and situations that require transport of the patient from one unit to another. One of the strategies is to require two caregivers to participate in any high-risk situation, with one of the caregivers being solely

Table 4. Attributes of an Optimal Endotracheal Tube Securement Device

Ease of placement, use, and maintenance
Prevents incremental tube movement that can lead to eventual malpositioning
Adequate stabilization against external forces that may dislodge tube
Facilitates suctioning but is not compromised by secretions
Allows tube movement for oral care
Requires infrequent adjustment or change
Cost-effective
Enhances patient comfort and minimizes skin pressure
Avoids adhesives that could irritate skin

responsible for protection of the tube. The caregiver who is responsible for the protection of the ETT performs a verbal call-out of the ETT depth position prior to movement of the patient (e.g., “ETT 23cm at upper incisors”) and upon completion of movement of the patient (e.g., “ETT at 23 cm... No change”). The same caregiver directs a verbal call-out of when to begin coordinated movement of the patient (e.g., “move on-three... 1... 2... 3”).

Improving and optimizing securement of the ETT can prevent UE. Many different methods and securement devices exist to maintain an indwelling ETT. Although no single method or device has been proven superior, there are several recommended attributes for an optimal securement method (**Table 4**).⁵⁹⁻⁶¹

Human and Environmental Factors

Human factors that impact the incidence of UE, such as staffing ratios, teamwork, and communication, should be optimized to reduce risk. The use of simulation has been shown to be very effective for teaching and practicing teamwork and communication outside of the clinical setting.^{62,63} A survey of nurses in the ICU identified several organizational and environmental factors that could be modified to reduce UE risk, such as communication failures, environmental chaos and barriers to direct surveillance of the patient, and poor nurse-to-patient ratios.²⁸

Operating Room Strategies

Briefings, or time-outs, are often used in the operating room to discuss extubation risks and strategies for prevention and management in high-risk cases, similar to the concerns often discussed for cases at risk for airway fire.^{20,21} Cases at risk for airway fire are often also at risk for accidental extubation due to the nature of the procedure. Since the airway is often inaccessible during these

procedures, careful securement of the endotracheal tube is important to reduce extubation risk. In high-risk cases, it is recommended to have alternate airway devices immediately available for reintubation, such as video laryngoscopes, flexible bronchoscopes, and supraglottic airway devices.^{20,21}

Strategies to Prevent Reintubation After Unplanned Extubation

Strategies to maximize oxygenation and ventilation can be employed after unplanned extubation to avoid reintubation, or at least to prevent an urgent need for intervention. Several newer methods of high-flow oxygenation via the nasal route can potentially prevent or delay reintubation.^{64,65} Some of these methods also provide continuous positive airway pressure (CPAP), which can be especially useful in obese patients or individuals with obstructive sleep apnea.^{66,67} A study by Lin et al. used noninvasive positive pressure ventilation as a strategy after unplanned extubation, and found that it significantly reduced the rate of reintubation.³⁴ Conversion to tracheostomy or early extubation are other strategies that can potentially reduce risk for unplanned extubation.

Conclusion and Future Directions

UE is a common and costly problem in the perioperative and intensive care environments, with a large impact on outcomes and hospital costs, yet it remains an under-recognized problem. Increased awareness and prevention are critical. Better tracking and the implementation of quality improvement initiatives can potentially address the problem. Prevention requires commitment from not only clinical care providers but also leadership to implement strategies and protocols to standardize care. The Patient Safety Movement Foundation (PSMF) has identified that a hospitalwide culture of safety is important in reducing UE.⁶⁸ Rates of UE should be identified and tracked, ideally within an EHR system.

The Society for Airway Management, a global multidisciplinary society devoted to improving airway safety, created a special projects committee to address unplanned extubation. This committee formed a collaborative with over 20 other medical societies and safety organizations to increase awareness of the magnitude of the problem. The collaborative has published over 20 articles on UE and developed a toolkit consisting of checklists, core data sets, and Actionable Patient Safety Solutions (developed by PSMF) that hospitals can use to track unplanned extubation.⁶⁸ These resources can be downloaded from AirwaySafetyMovement.org or PatientSafetyMovement.org completely free of charge.

The Children’s Hospitals’ Solutions for Patient Safety Network (SPS Network), consisting of 135+ Children’s Hospitals collaborating to eliminate serious harm in the children being cared for in their facilities, has been very successful in bringing together institutions, sharing

proven best-practice quality improvement methods for UE, instituting those best practices, and publishing their results in peer-reviewed publications. Patterned after this model, a similar network is being formed for adult acute care hospitals. The Adult Hospitals' Solutions for Airway Safety Network will also work together to determine if the quality improvement methods already proven by the SPS Network to reduce UE in the NICU and PICU can be effectively applied to the adult ICU environment. Through research and publication, the Adult Hospitals' network hopes to demonstrate that a proven best-practice quality improvement bundle will decrease the incidence of UE from the literature benchmark of 7.3% and thereby decrease the associated complications and associated costs of nearly \$5 billion. For more information on the Adult Hospitals' Solutions for Airway Safety Network contact akanowitz@airwaysafetymovement.org.

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Identifying Safety Hazards Associated With Intravenous Vancomycin Through the Analysis of Patient Safety Event Reports

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Abstract

Intravenous (IV) vancomycin is one of the most commonly used antibiotics in U.S. hospitals. There are several complexities associated with IV vancomycin use, including the need to have an accurate patient weight for dosing, to provide close monitoring to ensure appropriate drug levels, to monitor renal function, and to continue delivery of the medication at prescribed intervals. There are numerous healthcare system factors, including workflow processes, policies, health information technology, and clinical knowledge that impact the safe use of IV vancomycin. Past literature has identified several safety hazards associated with IV vancomycin use and there are some proposed solutions. Despite this literature, IV vancomycin-related safety issues persist. We analyzed patient safety event reports describing IV vancomycin-related issues in order to identify where in the medication process these issues were appearing, the type of medication error associated with each report, and general contributing factor themes. Our results demonstrate that recent safety reports are aligned with the issues already identified in the literature, suggesting that improvements discussed in the literature have not translated to clinical practice. Based on our analysis and current literature, we have developed a shareable infographic to improve clinician awareness of the complications and safety hazards associated with IV vancomycin and a self-assessment tool to support identification of opportunities to improve patient safety during IV vancomycin therapy. We also recommend development of clear guidelines to optimize health information technology systems to better support safe IV vancomycin use.

Keywords: *patient safety event, medication safety, vancomycin, human factors*

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V

Vancomycin is one of the most commonly used broad-spectrum antibiotics prescribed to treat many different types of infections. For example, from 2006 to 2012, vancomycin use in U.S. hospitals increased by 32%, with intravenous (IV) vancomycin being the most common administration route.¹ While this drug can be effective when prescribed for the appropriate clinical conditions and administered properly, there are unique complexities to using IV vancomycin. If these complexities are not well understood and appropriate processes are not implemented, there can be serious patient safety consequences that result in patient harm or death. Understanding the complexity of delivering treatments like IV vancomycin, including healthcare system factors such as the clinicians involved in the care process, technology, and workflow processes and policies, is critical to improve patient safety.

Physicians, nurses, pharmacists, phlebotomists, dialysis technicians, and laboratory technicians all have important roles in the delivery of IV vancomycin, whether for a critically ill patient, routine preoperative prophylaxis, or scheduling therapy around dialysis.² IV vancomycin therapy requires an accurate patient weight for dosing, monitoring of drug levels, attention to renal function, and the ongoing delivery of doses at scheduled intervals. Most IV vancomycin doses are initially calculated from a patient's total body weight and kidney function. Once an initial dose of vancomycin is administered to a patient, clinicians must continuously monitor vancomycin levels in the patient's

blood. This is typically called a trough and is done by measuring serum concentrations.^{2,3} The trough level is obtained by drawing blood 30 minutes prior to a patient's third or fourth dose of vancomycin, once the medication has reached a steady state.⁴ The trough is the best current method we have to monitor and guide adjustment of vancomycin dosing.

These complexities create opportunities for numerous patient safety hazards. In this paper we (1) identify many of these hazards and proposed solutions developed to mitigate some of the risks from previous literature, (2) analyze recent patient safety event (PSE) reports in the context of this existing literature to determine where gaps between research and clinical practice exist, and (3) propose and develop solutions to address some of these gaps in the form of a safety assessment tool (**Appendix A**).

Recognized Safety Hazards Associated with IV Vancomycin and Current Improvement Efforts

Dosing. Challenges with vancomycin dosing are a well-recognized safety issue. Several case studies described unintentional overdoses of vancomycin and the use of hemodialysis to quickly remove excess drug.^{5,6} At the other extreme, groups

with the highest frequency of sub-therapeutic drug levels included critically ill patients and patients receiving hemodialysis.^{7,8} To address these issues, some hospitals have implemented therapeutic drug monitoring (TDM) programs. These programs are managed by clinical pharmacists and have demonstrated improvement in effective vancomycin therapy.⁹⁻¹¹

Monitoring. Monitoring the circulating concentration of vancomycin and kidney function is essential for effective treatment and prevention of renal complications. An individual's severity of illness and comorbid conditions affect the metabolism of IV vancomycin. Therefore, a vancomycin trough is necessary to measure the remaining serum concentration of vancomycin after an individual metabolizes several doses of the drug. Trough levels guide adjustments of future doses to prevent under or overdosing. Underdosing may not effectively treat the target infection while overdosing may impair renal function. Monitoring of serum creatinine trends provides an indication of renal response to therapy. Processes that support the timely collection, processing, and reporting of both the trough level and serum creatinine have been the focus of improvement efforts. Pharmacist participation in physician rounds has been found to reduce preventable adverse drug events by up to 78% and computer physician order entry (CPOE) with guided order sets has significantly increased appropriate vancomycin dosing and monitoring.^{12,13} TDM assigns therapy oversight to the clinical pharmacist, who monitors administration and compliance with timely trough collection, and adjusts the dose accordingly, thus preventing the need to place doses on hold and risk delayed or omitted doses.¹⁶ This method of monitoring commonly involves communication between the lead provider, the pharmacist, and nurses who are involved

While IV vancomycin can be effective when prescribed and administered appropriately, this drug has unique complexities.

with direct patient interactions.^{2,3} Technological tools assist with the implementation of TDM, offering new and efficient ways of developing safe medication administration practices.¹⁴ Conditions for acceptance of electronic TDM programs are unique at each clinical site and thus mandate local modifications.¹⁴ While TDM is very helpful, it does not replace clinical judgement.

IV administration. Administration issues are related to IV access, rate, timing, and concomitant administration. Infiltration of caustic medications such as vancomycin can lead to extravasations and necrosis of surrounding tissues when they escape the vascular pathway.¹⁵ Peripheral IV access is an acceptable practice for short-term vancomycin administration, while midline and peripherally inserted central catheter (PICC) access methods are preferred for severely ill patients and long-term infusions.¹⁵⁻¹⁸ Hyaluronidase, such as vitrase, has been used to reduce the effect of vancomycin infiltration and extravasations.

The most common adverse effects related to vancomycin administration, excluding IV infiltration, are hypotension, chills, fever, and red man syndrome (RMS). These reactions are often associated with a rate of administration in excess of 1 gram over 60 minutes. For many patients, administering the dose over a longer period and premedication with diphenhydramine reduces this response. Vancomycin administration tables and “smart” IV pumps with embedded clinical decision support have been implemented to reduce the frequency of rapid administration errors.^{2,3,19-21,22}

As with other drugs, in order to maintain therapeutic levels of vancomycin and have effective treatment, it is essential that the drug be given at consistent intervals. Case studies describing organizational barriers to schedule adherence include the missed delivery of a dose

from pharmacy, delay in collecting and reporting of predose trough levels, and patients being off their unit for testing or treatment.^{23,24}

Patients are frequently treated with vancomycin in combination with other antibiotics.^{25,26} Evidence suggests that the antibiotics piperacillin/tazobactam, when co-administered with vancomycin, can induce greater kidney injury.²⁷⁻²⁹ Also, other potentially nephrotoxic medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs), can increase the risk of acute kidney injury. Kidney injury may be mild, but some severe cases may require temporary or permanent hemodialysis. Some antibiotics from the β -lactam class cannot be administered concurrently in the same IV line as vancomycin.²³ Consultation with a clinical pharmacist and accessibility of intranet-based compatibility software have reduced errors related to medication co-administration.³⁰

Workflow and communication issues. Transitions in care between facilities, hospital departments, and shifts have been extensively studied as factors that increase risk for adverse events.^{31,32} Additionally, dialysis-dependent patients, as well as patients with significant decline in renal function, require different dosing, administration, and monitoring protocols. Some patients need to go off a unit to receive dialysis, leading to an opportunity for missed or incorrect doses of vancomycin. Orders for vancomycin dosing during or after dialysis are often not visible to dialysis nurses using some electronic health records (EHRs). This lack of situation awareness has contributed to both under and overdosing.³³ In a similar fashion, prophylactic vancomycin dosing before surgery may be ordered to be given “on call” to the operating room (OR); however, breakdowns

in communication between surgical floors and OR scheduling are frequent and have contributed to both missed and extra doses.³³ Patients treated with vancomycin in the emergency department (ED) are often seriously ill and may receive a loading dose in order to quickly initiate therapy. One study noted that nearly 12% of patients admitted to the hospital from the ED have a medication discrepancy and that 36% of these discrepancies result in omitted drug doses.³³ Differences in EHR views between inpatient units and EDs, as well as multiple hand-offs by both nursing and provider teams, have resulted in medication errors.^{31,32} Health information technology (IT) solutions have been explored to improve situation awareness.

Study Focus

Despite the literature recognizing safety issues associated with IV vancomycin use and the existence of some proposed solutions to address these recognized issues, IV vancomycin-related safety issues persist. In this study, we analyzed recent IV vancomycin-related PSE reports to identify current safety issues associated with IV vancomycin use, with a focus on healthcare system factors that may be contributing to these types of events. Our analysis of PSE reports focused on identifying where in the medication-use process issues were arising, the types of medication errors associated with the reports, and identification of themes that characterize the contributing factors from each report. Comparing the results of our analysis of recent safety event reports with the recognized safety hazards and proposed solutions from the literature, we identified important next steps to improve IV vancomycin patient safety in clinical practice and developed an infographic and self-assessment tool to begin to address safety hazards.

Figure 1. Event Data Review Process



Methods

A nurse and pharmacist identified and analyzed IV vancomycin-related PSE reports with input from human factors experts throughout the process. They performed a rigorous thematic analysis to identify common safety issues across the event reports. The analysis was focused on reports that resulted in patient harm.

Data Source and Selection

Data were comprised of 68,277 acute care PSE reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)* between April 1, 2019, and June 30, 2019. To identify IV vancomycin-related reports, we searched the free-text event details and other relevant fields of each report for

- Reports containing the characters “vanc” or “vanco”. A space character was included after the term “vanc” to eliminate false positives such as matching on a report that describes an “advancement.”
- Reports that ended with the string “vanc”.

This resulted in 974 event reports. Reports with harm scores of A (unsafe condition) and B (event, no harm) were excluded given that these events did not reach the patient. Ten percent of the reports with a harm score of C (event, no harm, reached the patient) were screened to determine whether they were qualitatively different from the remaining reports.

They were not different and were also excluded since they were less severe and did not add any insight. This resulted in 411 reports. Clinicians manually reviewed these reports to ensure they were IV vancomycin-related as opposed to a report describing an unrelated occurrence that contained the word vancomycin. This further excluded 32 events, resulting in 379 reports. Since our analysis focused on identifying healthcare system factors contributing to IV vancomycin safety hazards, we removed events where system factors could not be identified. One hundred forty-nine IV infiltration events were removed since they did not include enough detail to identify system contributing factors. Seventy-nine adverse drug events were also removed since they were newly diagnosed drug allergies with no contributing system factors described. Finally, eight reports did not have enough information to identify the contributing system factors and were removed from analysis. This resulted in a total of 143 reports for descriptive and thematic analysis. The data review filtering process is shown in **Figure 1**.

Analysis Methods

The 143 IV vancomycin reports were first analyzed with a focus on descriptive statistics and were then qualitatively analyzed.

Descriptive Analysis. Descriptive analysis of the 143 events included the event type, harm score, and patient age as reported by healthcare facilities to PA-PSRS.

Qualitative Analysis. Using a grounded theory approach, two clinicians, pharmacist AK and nurse EF, manually coded all the reports for medication-use process, medication error type, and contributing factor emerging themes. To establish inter-rater reliability, 51 reports (35.7%) were dually coded by AK and EF. Differences were reconciled through joint discussion. After establishing inter-rater reliability, the remaining reports were split between the two coders and individually reviewed. Inter-rater reliability was calculated using Cohen’s kappa, which resulted in 0.74 for medication-use process, 0.77 for medication error type, and 0.81 for contributing factor emerging themes.

Coding of Vancomycin Reports. The 143 reports were coded to understand medication-use process stage, medication error type, and contributing factor emerging themes, as described in the codebook in **Appendix C**. The medication-use process stages were modeled after the American Society of Hospital Pharmacists (ASHP) medication use categories.³⁵ The medication error type was adopted from the National Coordinating Council for Medication Error Reporting

*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.

and Prevention taxonomy.³⁶ Contributing factor emerging themes (e.g., care coordination and information exchange) and subthemes (e.g., incomplete information flow, handoff) were identified through an iterative process of reviewing vancomycin-related reports.³⁴ The free-text narrative served as the foundation for coding. Each report was assigned a single medication-use process stage, if one could be identified from the report, and a single medication error type if identifiable from the report. However, a single report could be assigned more than one contributing factor theme.

Results

We first report on the descriptive analysis of the vancomycin reports to provide general context followed by the results from the expert review.

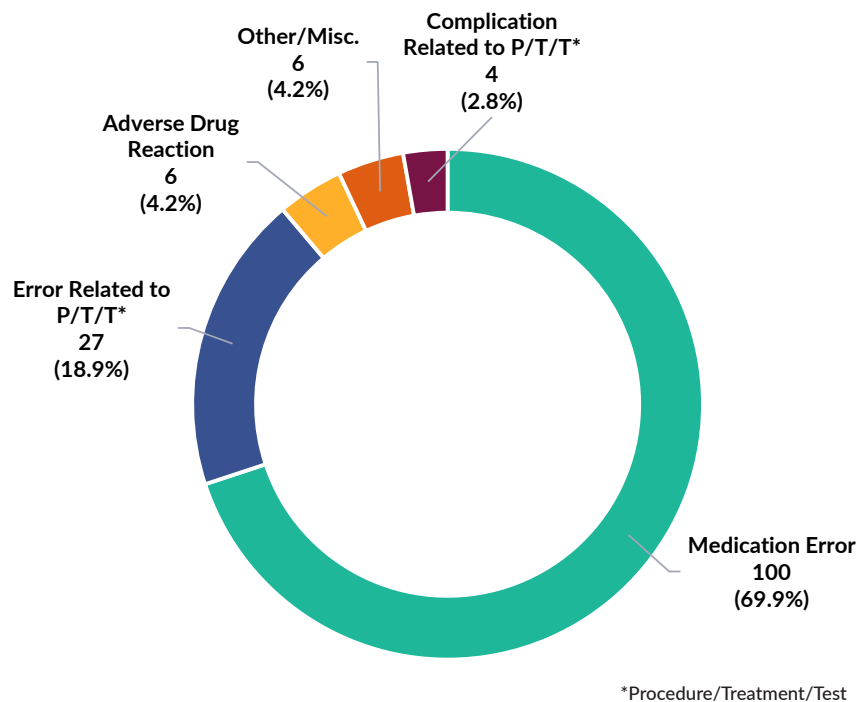
Descriptive Analyses

Event Type. We first analyzed the general event type categories assigned by the event reporter to each report in PA-PSRS. The reported event type category of *Medication Error* (n=100 of 143, 69.9%) had the highest frequency of vancomycin events, as expected. The event type *Error Related to Procedure, Treatment, or Test* (n=27 of 143, 18.9%) was the second-most frequent category for vancomycin cases (**Figure 2**).

Harm Score. Of the 143 reports analyzed, nearly all events were reported as harm score *D* (n=141 of 143, 98.6%). One event was reported as harm score *E* (0.7%) and one event was reported as harm score *F* (0.7%).

Patient Age. Over half of all vancomycin reports reviewed were related to the adult population (ages 18–69) (n=92 of 143, 64.3%). Older adults (ages 70+) contributed to nearly one-third of all reports

Figure 2. Event Type Category and Frequency



(n=45 of 143, 31.5%) and the pediatric population accounted for 6 reports (4.2%).

Qualitative Analyses

Medication-Use Process. Of the 143 reports analyzed, the medication-use process stage was associated with reported safety issues in 139 of the 143 reports, with 4 reports not containing enough information to identify this stage. Events were most commonly associated with Administration (n=55 of 143, 38.5%), followed by Monitoring (n=39 of 143, 27.3%), and then Ordering/Reviewing (n=28 of 143, 19.6%), as shown in **Figure 3**.

Medication Error Type. Of the 143 reports analyzed, the medication error type was identified in 135 of the 143 reports, with 8 reports not containing enough information to identify the medication error type. The most frequent errors identified were Dose Omission/Delay or Receipt of Partial Dose (n=59 of 135,

41.3%), Improper Dose (n=42 of 135, 29.4%), and Monitoring Errors (n=26 of 135, 18.2%), as shown in **Figure 4**.

Contributing Factor Emerging Theme. The contributing factor thematic analysis revealed that Appropriate Therapy Management was associated with most event reports (n=104 of 143, 72.7%), followed by issues with Care Coordination and Information Exchange (n=61 of 143, 42.7%), Documentation (n=21 of 143, 14.7%) and Workflow (n=19 of 143, 13.3%), as shown in **Table 1**. The contributing factor emerging themes were also evaluated in the context of the medication process stage (**Table 2**) and the type of medication error (**Table 3**).

Within the theme of Appropriate Therapy Management (n = 104), issues with Timing were the most prevalent (n = 70 of 104, 67.3%), followed by Monitoring (n = 53 of 104, 51.0%). Looking at where these issues occurred within the medica-

Figure 3. Medication process stage associated with vancomycin reports³⁴



tion-use process stage, they often occurred during Administration (n = 41 of 104, 39.4%) and Monitoring (n = 39 of 104, 37.5%), followed by the Ordering/Reviewing (n = 16 of 104, 15.4%), **Table 2**. These issues often resulted in Dose Omission/Delay or Receipt of a Partial Dose errors (n = 43 of 104, 41.3%), followed by Improper Dose (n = 26 of 104, 25%) and Monitoring errors (n = 26 of 104, 25%), **Table 3**.

Looking specifically at the Appropriate Therapy Management theme and the administration medication-use process stage together, common challenges occurred when (1) there were delays in receiving the first dose or in continuation after the first dose, (2) vancomycin was combined with the administration of Zosyn, and

(3) a patient was transferred while there was an active order for vancomycin. There were instances where the dose of vancomycin was available (explicitly stated in the report) and not administered. Of the 41 Administration medication-use process stage issues related to Appropriate Therapy Management, more than half (n=24 of 41, 58.5%) resulted in Dose Omission/Delay or Receipt of a Partial Dose errors. Next, looking at the Appropriate Therapy Management theme and the Monitoring medication-use process stage together nearly all challenges were centered around timing of troughs. Difficulties were noted when doses and/or timing needed to be adjusted, including starting, restarting, and stopping IV vancomycin. Of the 39 events occurring during the Monitoring

medication-use process stage related to Appropriate Therapy Management, nearly two-thirds (n=25 of 39, 64.1%) resulted in Monitoring medication errors.

The theme of Care Coordination and Information Exchange (n = 61) was the second-most common theme associated with the vancomycin events. Incomplete Information Flow was the most common contributing factor within this theme (n = 35 of 61, 57.4%). The Administration medication-use process stage was associated with most of these issues (n = 28 of 61, 45.9%), followed by the Ordering/Reviewing stage (n = 13 of 61, 21.3%) and Monitoring stage (n = 12 of 61, 19.7%), **Table 4**. Dose Omission/Delay or Receipt of a Partial Dose errors (n = 27 of 61, 44.3%) and Improper Dose errors (n = 20 of 61, 32.8%) were the most frequent type of medication errors associated with the Care Coordination and Information Exchange theme, **Table 3**.

Looking specifically at the Care Coordination and Information Exchange theme and the Administration medication-use process stage together, common challenges included workflow issues of handoffs and transfers. More specifically, we noted issues within the ED and OR. In these settings, vulnerabilities were associated with one-time preoperative prophylaxis or with ED loading doses of vancomycin. Incomplete Information Flow between the OR or ED and the receiving patient units precipitated errors in the medication-use process stages of Administration and Monitoring.

Figure 4. Medication error type associated with vancomycin reports

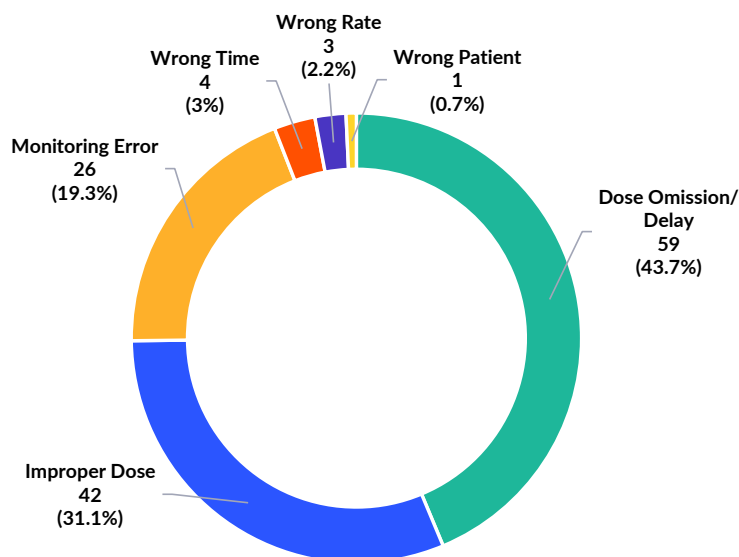


Table 1. Contributing factor emerging themes associated with vancomycin reports

Contributing Factor Emerging Theme	Frequency	%
Appropriate Therapy Management	104	72.7% (of 143 total reports)
Timing	70	67.3% (of 104 reports)
Monitoring	53	51.0% (of 104 reports)
IV Access	8	7.7% (of 104 reports)
Care Coordination and Information Exchange	61	42.7% (of 143 total reports)
Incomplete Information Flow	35	57.4% (of 61 reports)
Handoff	17	27.9% (of 61 reports)
Renal Function	14	23.0% (of 61 reports)
Documentation	21	14.7% (of 143 total reports)
Workflow	19	13.3% (of 143 total reports)
OR System	11	57.9% (of 19 reports)
ED System	9	47.4% (of 19 reports)

Table 2. Vancomycin reports by medication process stage and contributing factor themes

<i>Medication Process Stage</i>	Appropriate Therapy Management	Care Coordination & Information Exchange	Documentation	Workflow
Admission	2 (1.9%)	3 (4.9%)	9 (42.9%)	2 (10.5%)
Ordering/Reviewing	16 (15.4%)	13 (21.3%)	4 (19.0%)	6 (31.6%)
Dispensing	4 (3.8%)	2 (3.3%)	2 (9.5%)	0 (0.0%)
Administration	41 (39.4%)	28 (45.9%)	4 (19.0%)	11 (57.9%)
Monitoring	39 (37.5%)	12 (19.7%)	1 (4.8%)	0 (0.0%)
Discharge	1 (1.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)
Not Enough Info to Determine	1 (1.0%)	2 (3.3%)	1 (4.8%)	0 (0.0%)
TOTAL REPORTS	104	61	21	19

Table 3. Vancomycin reports by medication error type and contributing factor themes

<i>Medication Error Type</i>	Appropriate Therapy Management	Care Coordination & Information Exchange	Documentation	Workflow
Dose Omission/Delay or Receipt of a Partial Dose	43 (41.3%)	27 (44.3%)	7 (33.3%)	11 (57.9%)
Improper Dose	26 (25.0%)	20 (32.8%)	9 (42.9%)	2 (10.5)
Monitoring Error	26 (25.0%)	6 (9.8%)	1 (4.8%)	6 (31.6%)
Not Enough Info to Determine	4 (3.8%)	5 (8.2%)	2 (9.5%)	0 (0.0%)
Wrong Time	3 (2.9%)	1 (1.6%)	1 (4.8%)	0 (0.0%)
Wrong Rate	2 (1.9%)	1 (1.6%)	1 (4.8%)	0 (0.0%)
Wrong Patient	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)
TOTAL REPORTS	104	61	21	19

Order sets within the EHR were noted to be confusing and further complicated by the use of paper, fax, and verbal communication to order and review vancomycin effectively. Nearly all the challenges in the Care Coordination and Information Exchange theme that were also in the Monitoring medication-use process stage were centered around troughs. More specifically, there was a lack of awareness of (1) the trough being ordered but not drawn, (2) trough results not transmitted/received, and (3) trough results not being acted upon appropriately in a timely manner. Of the 12 medication-use process stage Monitoring issues related to Care Coordination and Information Exchange, half of the events resulted in monitoring medication errors.

The theme of Documentation was associated with 21 events. These events were mostly associated with the Admission (n = 9 of 21, 42.9%) medication-use process stage, followed by Ordering/Reviewing (n = 4 of 21, 19.0%) and Administration (n = 4 of 21, 19.0%). The most common medication error types were Improper Dose (n = 9 of 21, 42.9%) and Dose Omission/Delay or Receipt of a Partial Dose (n = 7 of 21, 33.3%).

The theme of Workflow was associated with 19 events. Within this theme two more events were associated with OR workflows (n = 11) than ED workflows (n = 9). These issues were most frequently associated with the Administration (n = 11 of 19, 57.9%) and Ordering/Reviewing (n = 6 of 19, 31.6%) medication-use process stages. The most frequent medication error types were Dose Omission/Delay or Receipt of a Partial Dose (n = 11 of 19, 57.9%) and Monitoring Errors (n = 6 of 19, 31.6%).

Discussion

The descriptive analysis shows that most events involving vancomycin are reported under the event type *Medication Error*, followed by *Error*

Related to Procedure, Treatment or Test. Most of the reports are associated with adults between the ages of 18 and 69. The coding of event reports into the medication-use process stage showed that most reports are associated with Administration (38.5%), Monitoring (27.3%) and Ordering/Reviewing (19.6%). The coding of event reports into the medication error types revealed that most reports were related to Dose Omission/Delay or Receipt of Partial dose (41.3%), followed by Improper Dose (29.4%), and Monitoring Errors (18.2%). The thematic analysis of event reports revealed that issues with Appropriate Therapy Management and Care Coordination and Information Exchange were the most prevalent, indicating an opportunity for focused efforts to improve these issues.

In many ways, the overall results from this analysis of IV vancomycin-related PSE reports are not surprising, since other researchers have identified many of these issues. However, the fact that these issues persist given this existing literature highlights the gap between patient safety research and improvements to actual clinical practice. To close this gap with a specific focus on IV vancomycin safety, we believe several actions should be taken.

First, it is important to raise clinician awareness of the complexities and risks associated with vancomycin. Although it is recognized that clinician awareness and training initiatives are generally ineffective as long-term solutions to identified patient safety hazards, they can temporarily begin to address recognized risks. For example, nursing may reinforce the practice of reviewing vancomycin trough levels prior to dosing as they do for lab values associated with safe insulin and anticoagulant administration. To increase awareness, we have created a single page infographic that can be displayed in healthcare

facilities either electronically (e.g., as a screensaver) or in paper format posted in high visibility areas (e.g., nurse's station or break room); see **Appendix B**.

Second, given the nuances in clinical workflows, policies, health IT, and processes across different healthcare facilities, we have developed a self-assessment tool that provides a framework for healthcare facilities to identify specific IV vancomycin-related hazards within their institution; see **Appendix C**. This self-assessment tool brings knowledge from the literature to frontline practice in a format that allows application to specific clinical environments.

Finally, with pervasive use of health IT for medication ordering, administration, and monitoring, these technology systems should be a central focus of safety improvement efforts. Recent research has highlighted some effective health IT solutions to address IV vancomycin-related safety issues, specifically to support ordering and monitoring, which were prevalent in our event report analysis. Using a weight-based vancomycin EHR order set, specifically in ED settings, resulted in a 20% increase in appropriate dosing.³⁷ Evidence-based guidelines informing the structure and design of order sets should be more effectively disseminated to healthcare facilities for inclusion in their implemented EHR products. One study created an EHR process to address monitoring such that when a new vancomycin order was placed, a trough was automatically ordered 30 minutes before the fourth dose.³⁸ Further, an alert was included in the nurse's barcode administration system to prevent administration of vancomycin if no trough level had been drawn. This resulted in nearly a 20% increase in trough levels being drawn between the third and fourth dose. This research demonstrates that health IT solutions can be implemented to

address vancomycin-related safety issues. The clinical guidelines from these previous studies should be shared with healthcare facilities and health IT vendors to expand dissemination of these best practices into implemented products.

Conclusion

The complexities associated with IV vancomycin introduce the potential for patient safety hazards. While the literature has identified many of these hazards and there are some proposed solutions, a recent analysis of PSE reports demonstrates that these safety hazards persist. By increasing awareness of the risks associated with vancomycin, identifying local hazards, and utilizing clinical decision support, healthcare facility leaders and frontline providers can improve medication safety.

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Appendix A—IV Vancomycin Safety Assessment Tool

IV Vancomycin Safety Assessment Tool

Purpose: This self-assessment tool is designed to increase awareness of *known* IV vancomycin patient safety risk factors, determine how your facility may or may not be addressing these risks, and identify areas of opportunity to improve patient safety. It is intended to support intrafacility risk identification and organizational learning. The assessment tool is based on current literature and a recent analysis of patient safety event reports.¹⁻⁴

Assessment Organization: The tool is organized around three factors that have been identified as important to IV vancomycin safety: practitioner and organizational knowledge, workflow processes and tasks, and health information technology. Under each factor, items that promote the safe use of IV vancomycin are described. These items are organized under phases of the medication process: medication ordering, medication administration, and medication monitoring and maintenance.

How to use this Assessment Tool:

1. Form a multidisciplinary team that may include nurses, pharmacists, physicians, patient safety analysts, laboratory services, and informatics or information services.
2. Review all assessment items prior to beginning the assessment.
3. Complete the assessment by indicating “yes,” “no,” or “not applicable (N/A)” for whether a safety strategy is used in your organization. For certain items, indicate frequency of use by marking “never,” “sometimes,” “always,” or “not applicable (N/A).” Where frequency of use is not relevant, the row is grayed out indicating it need not be completed.
4. Review the items with a focus on those marked “no” as well as those marked as “yes” that are “never” or “sometimes” used. Create an action plan to address the gaps and identify which stakeholders need to be engaged to make the improvements.

This assessment tool provides one method to identify IV vancomycin-related safety hazards in your organization. By using this tool, certain safety hazards can be mitigated, resulting in improved patient safety.

19	Clinicians (including nursing, pharmacy, and ordering providers) can describe the actions they need to perform after vancomycin trough results become available.							
20	Clinicians (including nursing, pharmacy, and ordering providers) can describe their specific role in monitoring and responding to evidence of diminishing renal function for patients receiving vancomycin.							
21	There is a process for reporting and reviewing vancomycin monitoring errors.							
22	There is a process for providing feedback to clinical staff about vancomycin monitoring errors.							

Factor 2: Workflow Processes and Tasks

Rationale: Having a complete understanding of the detailed workflow and tasks associated with IV vancomycin therapy will enable care teams to mitigate risk.

		Safety Strategy Used?			Frequency of Use			
		Y	N	N/A	Never	Sometimes	Always	N/A
Medication Ordering								
1	Equipment to obtain weights for patients of all sizes and mobility levels is consistently available within the organization.							
2	Scales are routinely calibrated as specified by manufacturer's operational instructions.							
3	On each admission, a patient's weight is measured in metric units (g/kg) and the value is readily accessible by all clinicians.							
4	When a provider orders an initial or stat dose of vancomycin, there is a mechanism for pharmacy to be notified of the urgency of the order.							
5	When a provider orders an initial or stat dose of vancomycin, there is a mechanism for nursing to be notified of the urgency of the order.							
Medication Administration								
6	Timing of scheduled vancomycin doses is specifically communicated during handoffs, especially high-risk handoffs from the ED to inpatient and transfers from unit to unit.							
7	There is a standard process for communicating perioperative antibiotic dosing during handoffs from floor to OR and OR to PACU/floor.							
8	Dialysis nurses have access to electronic medication administration records (eMAR) and have a process for ensuring their patients on vancomycin do not miss or do not have delayed administration of vancomycin doses.							
9	Dialysis nurses have a standard process for obtaining peridialysis vancomycin doses from inpatient units or from the pharmacy.							
10	Your organization has a policy addressing venous access site selection for the administration of caustic medications.							
11	Nurses have resources for obtaining adequate IV access prior to vancomycin administration at all hours.							
12	Pharmacy maintains a stock of extravasation antidote medications (e.g., hyaluronidase).							

Medication Administration						
15	Nurses receive an automated reminder through barcode medication administration software, where available, to hold a specified dose until a vancomycin trough is obtained and results are reviewed.					
16	Smart IV pumps are programmed for safe vancomycin administration.					
17	There is a reliable process for updating and maintaining current drug libraries within smart pumps.					
Medication Monitoring and Maintenance						
18	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) if an ordered trough level is outside of therapeutic parameters.					
19	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) if an ordered serum creatinine is outside of therapeutic parameters.					
20	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) of a scheduled vancomycin dose delayed more than two hours.					

Assessment Tool References

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VANCOMYCIN

We use it all the time, but are we managing it optimally?

STARTER DOSE



New Order Awareness

Ensure nurses and pharmacists are aware of new orders that should be started right away through standardized notification methods such as verbal channels and automated alerts.

Delays in vancomycin will increase mortality risk.



Accurate Weight

Ensure patients are weighed as soon as possible on admission and weight is accurately documented.

Inaccurate weight may lead to dangerously inaccurate dose calculations.

MAINTENANCE DOSE



Handoff

When handing off patient to another nurse or another service, inform receiver of patient's vancomycin status including next scheduled dose and pending and/or next related labs which may include vancomycin trough or BUN/Cr.

Poor handoffs lead to missed or extra doses.



IV Infiltrate

Aim for large gauge IV in a larger vein when possible.

Vancomycin is irritating to the vein and infiltration can lead to necrosis of surrounding tissue.

MONITORING



Timing Is Important

Trough levels are typically drawn 30 minutes before the dose they are preceding. Patients with renal insufficiency and/or requiring dialysis may require a customized monitoring schedule.

Inaccurate trough timing can lead to inaccurate dose adjustment.



Renal Function

Monitor for changes in serum creatinine, which indicates a need for closer vancomycin monitoring.

Renal response to vancomycin is not always predictable.

START, MAINTAIN, MONITOR

Appendix C. Codebook with Categorization Label, Definition, and Example

Categorization Label	Definition	Example
Medication-Use Process		
Admission	The primary error occurred in the admission phase, including documentation of patient weight or documentation of current vancomycin therapy in home or a subacute care setting.	“During admission process, nurse incorrectly documented patient’s weight in electronic health record as 131 kilograms instead of 131 pounds.”
Ordering/Reviewing	The primary error occurred in the provider ordering or pharmacy reviewing phase.	“a second dose of Vancomycin was inadvertently ordered and administered to the patient 6 hours after the first dose.”
Dispensing	The primary error or delay occurred in the pharmacy dispensing stage.	“IV vancomycin was ordered for sepsis prevention at 11:10 but was not available for administration until 13:30.”
Administration	The primary error occurred in the administration phase.	“Nurse noted that the 10:00 dose of vancomycin was not signed off as being given by the nurse from the previous shift. Nurse confirmed that the medication was inadvertently omitted”
Monitoring	The primary error occurred in the monitoring of drug levels or of renal function.	“Vanc trough level ordered for 15:00 was not drawn until 17:30”
Discharge	The primary error occurred in the discharge phase.	“Patient was discharged with an order for 8 weeks of IV vancomycin via PICC. But, later learned that patient was not able to fill prescription and home health was not established.”
Medication Error Types		
Improper Dose	Ordering, dispensing, or administering an improper dose, which may result in an overdose, underdose, or extra dose.	“Patient was on 1g of vancomycin Q24h which resulted in a trough of 11.4. As a result, dose was increased to 1500 mg Q24h. After receiving one dose of 1500 mg, order was erroneously changed to 2000 mg Q8h.”
Dose Omission/Delay or Receipt of Partial Dose	An intended dose was not ordered, dispensed, or administered, or it was delayed or only partially infused.	“Additional 1g dose of vancomycin was ordered for 1030, for a total 2g dose. Additional dose was not administered.”
Monitoring Error	Inadequate monitoring of therapy response, which may include monitoring delays or failing to monitor.	“Vancomycin level scheduled for 1600 was never drawn”
Wrong Rate	The wrong rate was ordered, dispensed, or administered (e.g., too fast or too slow).	“Vancomycin infusion was administered over 30 minutes instead of one hour. The bag was labeled as 500 mL but actually contained 250 mL.”
Wrong Time	Medication administered outside of the clinically appropriate time window.	“Vancomycin was ordered to be given in EP lab but was administered while patient was still on the nursing unit.”
Wrong Patient	Medication was ordered, dispensed, or administered to a different patient than was intended.	“Day shift nurse noticed that the vancomycin bag was labeled with another patient’s name, birth date, and room number.”

Categorization Label	Definition	Example
Contributing Factor Emerging Themes		
Care Coordination and Information Exchange		
Incomplete information flow	Report suggests necessary information was not effectively communicated to appropriate caregivers verbally or by other means, contributing to a breakdown in vancomycin therapy.	“Night shift nurse advised that no information regarding the vancomycin order was passed on from day shift”
Handoff	Report suggests challenge related to patient care handoff between different individuals or teams (e.g., OR, ED, shift change, transfer of unit, transfer from other hospital, etc.).	“Patient was received as a transfer from an outside hospital. Receiving hospital was not informed that vancomycin loading dose was ordered and administered prior to transfer.”
Renal Function	Report suggests challenges related to adjusting vancomycin therapy for patients with renal impairment. This includes patients on dialysis and with acute or chronic kidney injury.	“After receiving dialysis treatment, it was discovered that patient was on vancomycin therapy.”
Workflow		
Operating Room (OR) System	Report suggests challenge related to OR processes such as unanticipated adjustment in OR schedule affecting timing of prophylactic (preop) vancomycin.	“Nurse called the OR and confirmed that dose of Vancomycin, sent with patient, would be hung immediately following surgery.”
Emergency Department (ED) System	Report suggests challenges related to ED processes such as standalone health information technology systems that don’t integrate with inpatient computer physician order entry.	“Vancomycin dose ordered and administered in ED. Following admission, hospitalist service was unaware of prior dose and ordered an additional dose, which was administered, resulting in an extra dose to the patient”
Documentation		
Documentation	Report suggests challenges relating to documentation, such as patient weight error, progress note not matching medication orders, etc.	“Nurse inadvertently documented vancomycin administration in wrong patient’s chart.”
Appropriate Therapy Management		
Timing	Report suggests error relating to a time-sensitive process of vancomycin therapy.	“Vancomycin trough was ordered for 1730, prior to the 1800 dose. However, the lab was not drawn prior to administration.”
Monitoring	Report suggests challenge related to monitoring of vancomycin blood levels.	“Vancomycin trough was drawn one hour before the next dose was due. Trough came back elevated, but vancomycin was already hung.”
Intravenous (IV) Access	Report suggests challenge related to IV access that affects vancomycin therapy.	“IV access lost in the middle of vancomycin infusion. IV access was not able to be re-established until 4 hours later.”



20

130

135

140

km/h

How Safety Is Compromised When Hospital Equipment Is a Poor Fit for Patients Who Are Obese

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DOI: 10.33940/data/2020.3.4

Obesity is common, serious, and costly, and according to recent data, its prevalence is on the rise in the United States. Event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) indicate that some healthcare facilities do not have the necessary equipment to monitor and care for some individuals in this patient population, leading to embarrassment for patients, delays in care, and injuries to patients. An analysis of 107 events related to monitoring and patient care for patients who are obese submitted to PA-PSRS from 2009 through 2018 showed that imaging equipment, especially MRI and CT scanners, was most often implicated in event reports (49.5%; 53 events); other equipment included stretchers (24.3%; 26 events) and wheelchairs (11.2%; 12 events). Events most often occurred in an imaging department (30.8%; 33 events) or a medical/surgical unit (21.5%; 23 events). Analysts determined that 80 events (74.8%) resulted in a delay in care and that 44 events (41.1%) resulted in temporary harm to the patient, including skin tears and abrasions. Healthcare providers may not be able to prevent delays in care resulting from the unavailability of adequate equipment for patients who are obese, but they may be able to prevent harm and embarrassment for patients through proactive assessment.

Keywords: *obesity, abdominal girth, BMI, patient safety, imaging, equipment, hospital infrastructure*

[◇]Patient Safety Authority
Disclosure: The author declares that they have no relevant or material financial interests.

According to the Centers for Disease Control and Prevention (CDC), obesity is common, serious, and costly.¹ Obesity is defined as a body mass index (BMI) equal to or greater than 30 kilograms per meter squared.² Obesity is most common among middle-aged adults (age 40 to 59), and recent statistics indicate that nearly 40% of the adult population (93.3 million individuals) in the United States is considered obese, with prevalence on the rise.^{1,2}

A study of Medicare patients published in 2016 revealed that patients who were obese were more likely to suffer from chronic conditions affecting cardiovascular, metabolic, and psychological health and to utilize healthcare services compared to patients who were not obese.^{1,3} An earlier study that examined patient utilization of healthcare services demonstrated that patients who were obese had higher numbers of both primary care and specialty care visits, as well as use of diagnostic services, than patients who were not obese.⁴

If patients who are obese have higher rates of utilization of various healthcare services, it stands to reason that healthcare facilities must provide access to equipment that will meet the needs of this patient population. A review of event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[†] indicates that some healthcare facilities do not have the necessary equipment to monitor and care for this patient population, which may lead to embarrassment for patients, delays in care, and injuries to patients. In this article, we report an analysis of events submitted to PA-PSRS related to monitoring and patient care for patients who are obese. Our dual objectives were to identify trends in the data and to share best practices for preventing future events.

Methods

We queried PA-PSRS for events that took place from January 1, 2009, through December 31, 2018. We searched the event detail for the keywords “fit” OR “fits” AND at least one of the following keywords: “girth,” “habitus,” “bariatric,” “size,” “too large,” “too small,” “obese,” “obesity,” “too heavy,” “weight,” “BMI,” “too tight,” “scan,” “MRI,” “bed,” “stretcher,” and “wheelchair.” We reviewed each event to determine if the event was related to a patient

being unable to undergo an ordered test or receive care due to the patient’s weight, size, or abdominal girth. We specifically looked for details indicating that a patient was scheduled to undergo a test that was delayed or cancelled due to the patient’s weight or size, or for other information that suggested that patient safety was compromised by use of equipment that was too small for the patient or too big to be moved from one location to another (e.g., a stretcher that would not fit through a door or into an ambulance). Events were only included in the analysis if they were determined to be the result of the patient being too large; patients who were unable to undergo an ordered test or receive care due to the patient being too small were excluded.

We classified events that met the inclusion criteria according to the type of equipment involved: imaging equipment (such as an MRI or CT scanner), a stretcher or bed, a wheelchair, or another type of equipment or clothing (which included anything that did not fit into the first three categories). We also reviewed the details of each event and assessed whether the patient experienced a delay in care and/or an injury. We performed additional analyses to identify trends in event type and subtype, care area, facility size, and patient age and gender. Two analysts independently performed all assessments and then compared those assessments to agree on classification of each event.

Results

The query returned 502 event reports. After an initial independent review of each event report by two analysts, agreement was reached about the inclusion or exclusion of 466 events; a discussion of the remaining 36 events resulted in agreement about the inclusion or exclusion of those remaining events. Ultimately, 165 unique events were selected for inclusion in the analysis, including two event reports that described a single event.

Of the 165 events selected for inclusion, 58 events were reported by a

$$\text{BMI} = \frac{\text{kg}}{\text{m}^2}$$

BMI is calculated by dividing weight in kilograms by height in meters squared.²

49.5%

of events involved imaging equipment

30.8%

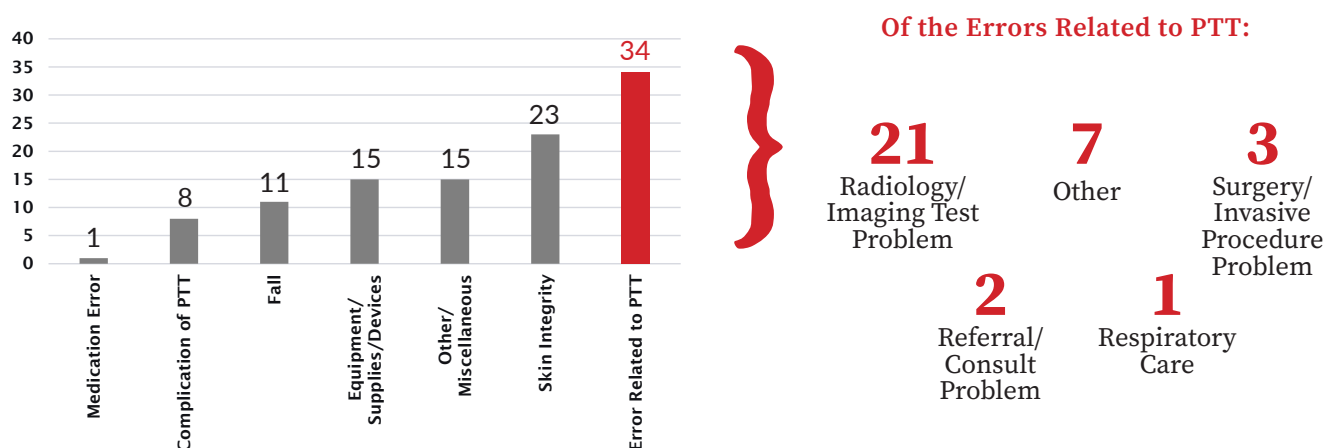
of reports occurred on an imaging unit

21.5%

of reports occurred on a med/surg unit

[†]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).⁵ All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Figure 1. Event Type for All Events and Event Subtype for Errors Related to Procedure, Treatment, or Test (PTT), Assigned by Reporting Facility, N=107



single facility. These event reports all involved an MRI scanner that was too small to accommodate patients beyond a certain weight or size limit. (This limit was not specifically stated in the event reports.) After reaching out to this facility, we learned that they had acquired a new MRI scanner with a much higher weight limit. Following that acquisition, this facility did not report any additional events related to patients who were too large for the MRI scanner. We decided to exclude these events from our analysis because this subset of data had the potential to skew the larger dataset. As a result, our final analysis included only the remaining 107 events.

Classification of Events

Events were assigned an event type and subtype(s) by the reporting facility at the time the report was submitted to PA-PSRS. Event types are summarized in **Figure 1**. The most common event type was an error related to procedure, treatment, or test (31.8%; 34 of 107 events). The most common subtype among errors related to procedure, treatment, or test was a radiology or imaging test problem (19.6%; 21 of 107 events), and the most common subtypes within this subgroup were test not completed (8.4%; 9 of 107 events) and test ordered but not performed (6.5%; 7 of 107 events).

We classified events according to the type of equipment involved. We subclassified imaging events as involving an MRI scanner, a CT scanner, or another type of imaging. **Figure 2** summarizes our classification of events based on equipment type. We also determined that 80 events (74.8%) resulted in a delay in care for the patient.

The following are examples[‡] of imaging events:

Patient taken for abdominal CT scan. Due to her weight and abdominal girth, patient was unable to fit completely into the bore of the gantry, even with her arms above her head. Attempt was made to perform the scan, but table motion was impeded by the distribution of patient's body habitus on the table. Ultimately, the table became stuck and the scan was aborted. The ordering physician was notified.

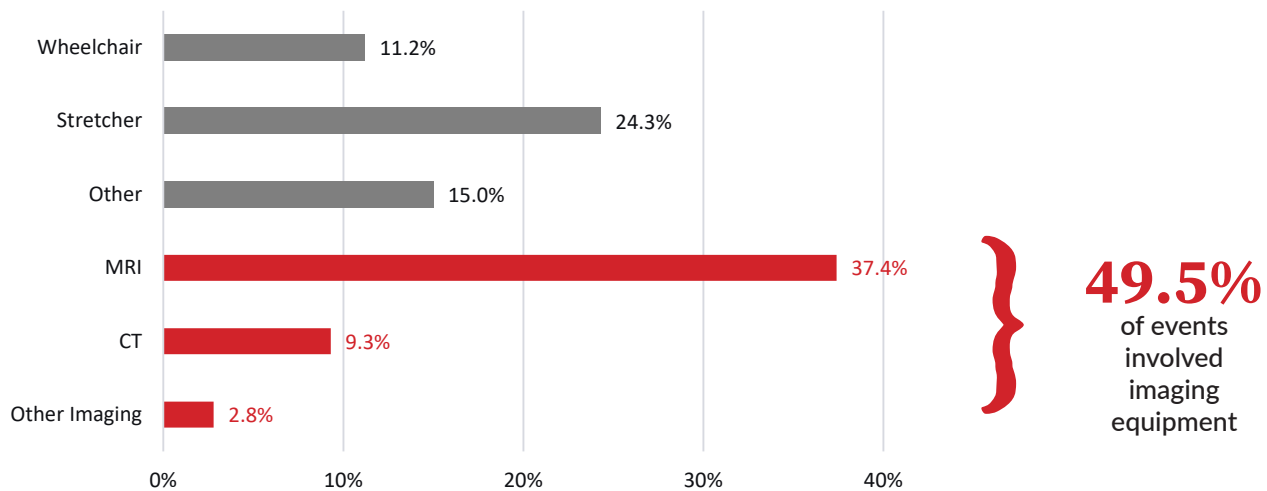
Patient came for MRI scan of spine, and he was sedated for the exam. Patient was placed on the table, which was then sent into the scanner. Patient was only able to be moved partially into the scanner, to the level of his upper arms, at which point the table stopped and could not be moved further. A second attempt was made after repositioning patient's arms, but this attempt was also unsuccessful. Patient was brought out of the scanner and scan was aborted. Explained to patient that he would have to be rescheduled at another facility with a larger MRI scanner.

The following are examples of events associated with other equipment, including a stretcher, a wheelchair, and a lift:

Patient was transported to the operating room on a bariatric bed. Upon arrival, staff determined that the bariatric bed did not fit through the operating room door. An alternate room and table were prepared for the procedure. The patient did not fit on this table because of the patient's body habitus, so the provider decided to perform procedure on the bariatric bed instead.

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

Figure 2. Classification of Events by Equipment Type, Assigned by Analysts, N=107



During physical therapy, patient who weighed 209 kg (460 lb) tried to sit in bariatric wheelchair, but patient did not fit comfortably in the chair due to her abdominal girth. Patient squeezed herself onto chair and sustained skin tears on both sides of abdomen. Wounds were treated appropriately.

Patient was being transferred from the operating table to a stretcher via lift due to his weight. The legs of the lift were too large to fit properly under the stretcher. As the transfer was attempted, the patient was dropped down onto the stretcher when the lift fell. Patient came to rest directly on stretcher, he did not sustain any injuries.

Harm or Injury Associated With Events

Nearly all events (97.2%; 104 of 107 events) were classified as incidents⁵ by the reporting facilities. Event harm scores assigned by the reporting facilities at the time of reporting are based on whether the event led to temporary or permanent harm and required additional healthcare services, and none of the events in this analysis resulted in permanent harm to the patient. Because we were also interested in whether patients experienced even temporary injuries, we reviewed each event report to determine whether the patient sustained a minor injury as a result of equipment being too small for the patient. We determined that the patient sustained a minor injury in about two-fifths of events (41.1%; 44 of 107 events). Some of the injuries sustained by patients included falls, drops, pressure ulcers, burns, cuts, skin tears, abrasions, and bruises. The most serious injury mentioned in an event report was a second-degree burn that required a visit to the emergency department.

The following is an example of an event in which the patient experienced temporary harm:

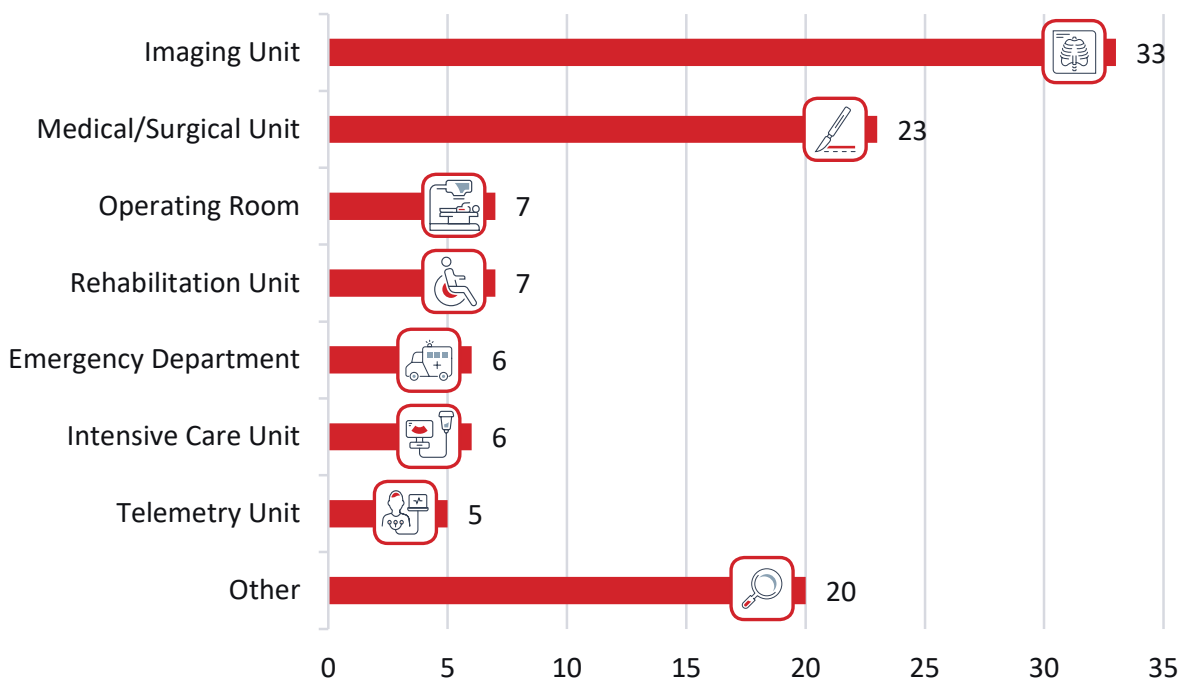
Patient was received in imaging department for an MRI of the shoulder. Patient was a tight fit in the MRI scanner because of his body habitus, so he was covered by a blanket for protection. Scan was started and technician checked with the patient midway through the study, and he reported no complaints. When the patient was removed from the bore, he reported a hot feeling on his left arm. Redness on his upper arm was observed after removal of the blanket. The patient was discharged following completion of the study. Later that day, the patient was seen in the emergency department, where a provider determined that he had suffered a second-degree thermal burn as a result of the close proximity of his arm to the MRI scanner. Patient was treated and released.

Other Findings

The majority of events (92.5%; 99 of 107 events) occurred at an acute care facility, and the remaining events occurred at a children's hospital, a long-term acute care facility, or a rehabilitation hospital. Facilities ranged in size from fewer than 25 beds to over 1000 beds. The most common care areas in which events took place are reported in **Figure 3**. Events were split fairly evenly between males (47.7%; 51 of 107 events) and females (52.3%; 56 of 107 events). Patients ranged in age from 10 to 90 years old, and the median patient age was 57 years.

⁵An "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.⁵

Figure 3. Number of Events by Care Area in Which Event Occurred, Assigned by Reporting Facility, N=107



Note: Other units included anesthesia, endoscopy/GI unit, orthopedic unit, pediatric intermediate unit, and psychiatric unit.

Among events involving a stretcher or bed (24.3%; 26 of 107 events), we determined that the stretcher was too small for the patient in 17 of 107 events (15.9%) and too big to fit through a door or into a room or transport vehicle in 9 of 107 events (8.4%). Among events involving a wheelchair (11.2%; 12 of 107 events), we determined that the wheelchair was too small for the patient in 7 of 107 events (6.5%) and too big to fit through a door or into a transport vehicle in 5 of 107 events (4.7%).

Sixteen of 107 events (15.0%) were classified as involving equipment other than a stretcher or bed, a wheelchair, or a scanner or other apparatus for imaging. Equipment implicated in these other events included a bedside commode (2.8%; 3 of 107 events), a lift (1.9%; 2 of 107 events), a boot (1.9%; 2 of 107 events), an immobilizer, a restraint vest, a sequential compression device, a blood pressure cuff, a chair, briefs, mittens, or stirrups.

We reviewed each event report to identify other commonalities. We found that 20 of 107 events (18.7%) involved some type of transfer or transport of the patient (either within a facility or between two facilities).

Discussion

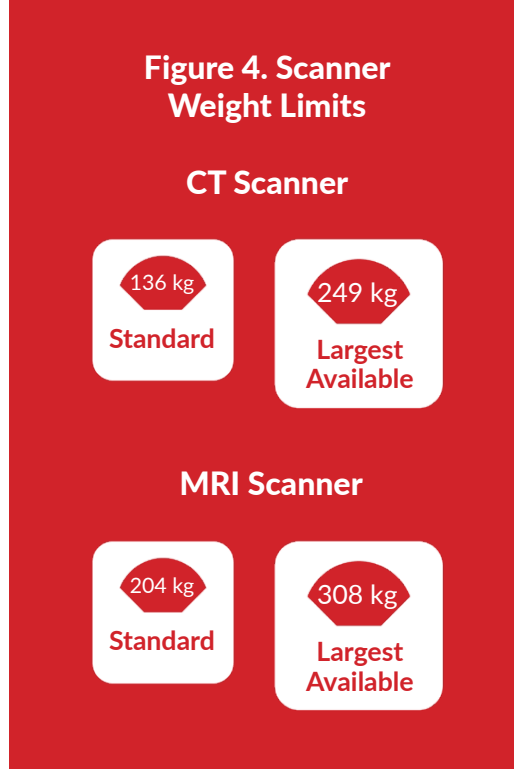
Beyond identifying safety events related to patient care and monitoring among patients who are obese, we also wanted to provide strategies to reduce these events

in the future. Unfortunately, our literature review did not identify any studies that provided support for best practices. What we did find in the literature were several reviews that shared best practices in use at other healthcare facilities. We blended this information with the findings from our own analysis and present this information here.

Imaging

Imaging studies are a regular component of diagnosing and treating patients with a host of medical conditions. A patient's weight, abdominal girth, and distribution of fatty tissue must be taken into account when assessing whether a particular scanner or other type of imaging equipment can accommodate that patient.⁶⁻⁸ Our analysis revealed that there are facilities in Pennsylvania that are not able to accommodate some patients due to their large size or weight. Reviewing the event details drew our attention to the fact that some patients were brought to an imaging department for a study without first being measured or with only their weight being measured. For example, in one event report, the technician stated that "they only go by the weight of the patient [and there is] no premeasurement of girth... to determine if the patient will fit [in the scanner]." In these instances, we learned that some staff members then attempted to force the patient's body into a scanner that was too small, which at a minimum caused embarrassment for the patient, but also frequently

Figure 4. Scanner Weight Limits



wasted time and occasionally led to patient injury. Our observations were similar to what has been observed in these events in the literature.^{6, 7} Attempting to scan a patient with a weight in excess of a scanner's limit has the potential to cause damage to the scanner itself, though there were no reports of this in the events in our analysis.⁶⁻⁸

The majority of imaging events included in our analysis involved either a CT or an MRI scanner. CT scanners typically can accommodate larger patients than MRI scanners. See **Figure 4** for scanner weight limits. The weight limit on a standard MRI scanner is 158.7 kg (350 lb), while the weight limit on the largest commercially available MRI scanner is 249.5 kg (550 lb).^{6, 7} The weight limit on a standard CT scanner is 204.1 kg (450 lb), while the weight limit on the largest commercially available CT scanner is 308.4 kg (680 lb).^{6, 7} The diameter of the opening of a CT or MRI scanner is often the limiting factor in whether a patient will fit into the scanner.^{6, 7} Open MRI scanners have been suggested as a potential solution for accommodating larger patients, but in some cases they actually have a smaller diameter than a closed MRI scanner.⁶ When open MRI scanners do have a larger diameter, the image produced may be of inferior quality compared to an image produced by a closed MRI scanner.⁷

In our review of the literature, we identified recommendations for best practices to alleviate some of the downstream problems (e.g., embarrassment, injuries, and delays) related to a patient being too large to fit in a CT or an MRI scanner. Before sending a patient for an imaging study, measuring both the patient's weight and abdominal girth can help the practitioner determine whether a patient will fit in the scanner prior to transporting the patient for the study.⁷ An alternative to measuring abdominal girth in all patients is to measure abdominal girth only when the patient's BMI indicates that they are obese.⁷ Because abdominal girth may shift in response to the patient's movement and position, another idea suggested in the literature is to order a custom hula hoop that reflects the maximum circumference that a CT or an MRI scanner can accommodate; patients can then simply try the hoop on to ensure they will fit in the scanner prior to transport.⁷ In addition to taking measurements and assessing size, it may be beneficial for facilities to post or make readily available the weight and size limits for all available imaging scanners in the facility, and, if possible, incor-

porate alerts into computerized order entry to notify healthcare providers to take certain patient measurements when imaging tests are ordered.⁷

Other Equipment

Other medical equipment routinely used to care for patients in healthcare facilities includes stretchers and beds, wheelchairs, bedside commodes, lifts, blood pressure cuffs, and clothing such as briefs or mittens. While some of this equipment is generally available in a single size (e.g., one-size-fits-all or one-size-fits-most), patients who are obese may require larger equipment to ensure both

safe care for them and a safe working environment for any providers responsible for caring for them. In our analysis, we identified issues with these other types of equipment, and these could generally be categorized into one of two groups: events in which the patient was too big for the equipment and events in which equipment was too large to be moved around a facility or into a transport vehicle. Both event types have the potential to cause humiliation or distress for patients, injuries, and delays in care.

Beyond the availability of equipment necessary for care and monitoring of patients who are obese, staff sometimes lacked knowledge about how to proceed when larger equipment was needed. For example, one reporter said that the team "received no guidance on how to find" equipment large enough for the patient. Another reporter explained that "the staff was not aware of the BMI early enough to find" appropriately sized equipment. A tertiary care facility in Canada shared some of their best practices for addressing these knowledge gaps among staff at their facility.⁹ To support the care of patients who weigh more than 160 kg (350 pounds) or who have a BMI over 49 kg per m², the facility has focused on educating staff when they are hired and providing access to policies, procedures, algorithms, and assessments.⁹ Promotion of education and awareness and development of these kinds of resources may improve the ability of staff to quickly identify solutions for these patients and improve their overall care.

Hospital Infrastructure

Our analysis identified gaps in both the knowledge and availability of equipment necessary to provide safe care for all patients, including patients who are

obese, throughout our reporting facilities, suggesting that the problem is much larger than a single piece of equipment or a single department within a facility. To address problems within a hospital's infrastructure, administrators should be informed of deficiencies within their facilities so that all patients who enter can receive safe and dignified care. When decisions are being made about equipment purchases intended for use in a new or existing facility, measurements and assessments should be made in advance to ensure the equipment, especially bariatric equipment, will fit in patient rooms, through doorways, and on elevators throughout the facility.

Limitations

Despite mandatory event-reporting laws in Pennsylvania, our data are subject to the limitations of self-reporting. In addition, because PA-PSRS only collects reports of patient safety events from hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities, our analysis was unable to capture events that occurred at outpatient facilities (e.g., outpatient radiology facilities not under a hospital license). Therefore, the generalizability of our findings beyond our reporting facilities may be limited.

It is difficult to ascertain the long-term consequences of these events because our knowledge is limited to the details shared in the event report by the reporting facility. Although we know that many patients experienced delays in care or minor injuries, we do not know whether the patients mentioned in these reports followed up to receive the ordered studies at another facility or to seek further care for their injuries.

PA-PSRS only collects reports from facilities and not from individual patients, so our analysis relied on details shared by the reporting facility to assess whether patients experienced any emotional distress as a result of hospital equipment that was inadequate for patients who were too big. Some event reports did include very specific details about a patient's reaction to an event, or even direct quotes from a patient, but this information was both too rare and specific to share without potentially compromising confidentiality of a patient or facility.

Patient weight is not a mandatory field in PA-PSRS, so we were only able to indirectly determine whether events were related to patient weight or size by analyzing free-text fields. In addition, a standard taxonomy for reporting events related to monitoring and patient care for patients who are obese does not exist, so the author acknowledges that it is possible that relevant event reports were missed with our query. In addition, including more keywords in the query may have resulted in the retrieval of more events, but we felt that

the keywords selected provided an adequate sample. A situation at a facility that did not involve a specific patient may have been reported through PA-PSRS as an infrastructure failure; these event reports are received by the Pennsylvania Department of Health and were not included in this analysis.

Conclusion

Obesity is increasingly common among adults in the United States, and patients who are obese are more likely to utilize healthcare services, so healthcare facilities should have the capability to provide safe care for this patient population. An analysis of events submitted to PA-PSRS from 2009 through 2018 revealed that there are some facilities in Pennsylvania that do not have the necessary equipment to monitor and care for all patients who are obese, and that staff at some facilities may not be aware of the appropriate next steps when the required equipment is unavailable. Events in our analysis most often involved imaging equipment, especially MRI and CT scanners. In some cases, staff may not be able to prevent events related to imaging scanner size, but they can ensure that patients are not embarrassed or harmed, and facilitate development of an action plan by clearly marking all scanners with their limits—and even making that information available on any unit that may send patients for imaging. Patients who are suspected of not being able to fit in an imaging scanner should be measured prior to transport to an imaging department. With regard to other types of equipment, the provision of education and the development of guidance documents may facilitate a more effective response on the part of staff when they are caring for patients who are obese. Ultimately, hospital administrators may have the most power to effect change in this area by ensuring the availability of equipment necessary for the safety and care of all patients. These best practices are summarized in **Figure 5**.

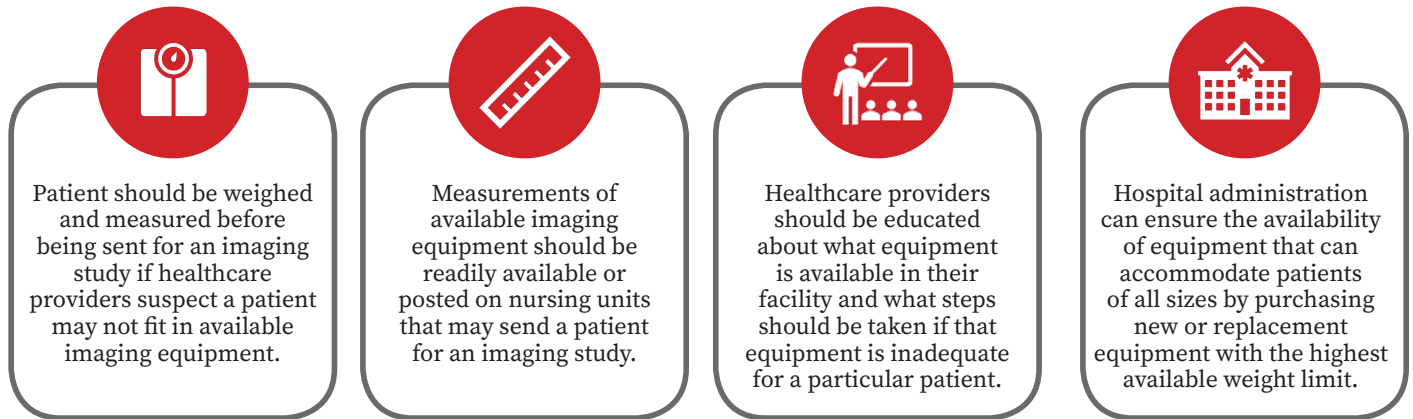
Acknowledgments

The author would like to thank Lynette Hathaway, MSN, RN, former infection prevention analyst at the Patient Safety Authority, for her collaboration in performing the data analysis for this study, which contributed significantly to the information that was able to be gleaned on this topic.

Notes

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

Figure 5. Best Practices for Imaging of Patients Who Are Obese



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Create a Safe Night

*An Interdisciplinary Approach to
Risk Identification and Mitigation
for Hospitalized Patients*



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



Abstract

Background: The ultimate goal and purpose of healthcare is to improve health while preventing morbidity and mortality. The optimal approach to this is through teamwork using a reliability framework. Upon review of our institution's 2012 patient safety culture survey data, we noted that the teamwork domain of the Agency for Healthcare Research and Quality (AHRQ) assessment was in the lowest decile. Our institution implemented the Crimson Analytics tool in 2013, and an analysis of inpatient mortality data revealed higher than expected mortality statistics.

Objective: Hospital systems and team-based care are more developed during daytime hours, leaving patients more vulnerable to adverse events (morbidity and mortality) during the overnight period. Our objective was to develop optimal transitions of care and proactive risk identification/mitigation through an interprofessional team-based approach, with resultant decrease in patient harm and improvement in safety culture.

Methods: In a community hospital, standardize transitions to identify "at risk" patients for nurses, physicians, and respiratory techs with subsequent interprofessional review of care plans/patient status in a centralized midevening standup briefing, subsequent proactive

rounding on "at risk" patients, use of error prevention behaviors aimed to mitigate cognitive bias, and end-of-shift reflection process.

Results: Inpatient mortality rates fell from a baseline level of 2.08% in April 2013–March 2015 to 1.56% during the intervention period from April 2015–March 2018. The observed/expected mortality ratio fell from 1.04 to 0.76. AHRQ safety culture data improved in the teamwork domain from 81% to 83%. A custom survey for this intervention was developed and found significant improvements in risk awareness and mitigation response, teamwork, efficiency, and—potentially—joy at work.

Conclusion: An interprofessional approach to high-quality transitions in care, risk identification, and mitigation, along with structured huddles and proactive rounding, can improve patient safety at night while simultaneously improving staff satisfaction, joy, and safety culture.

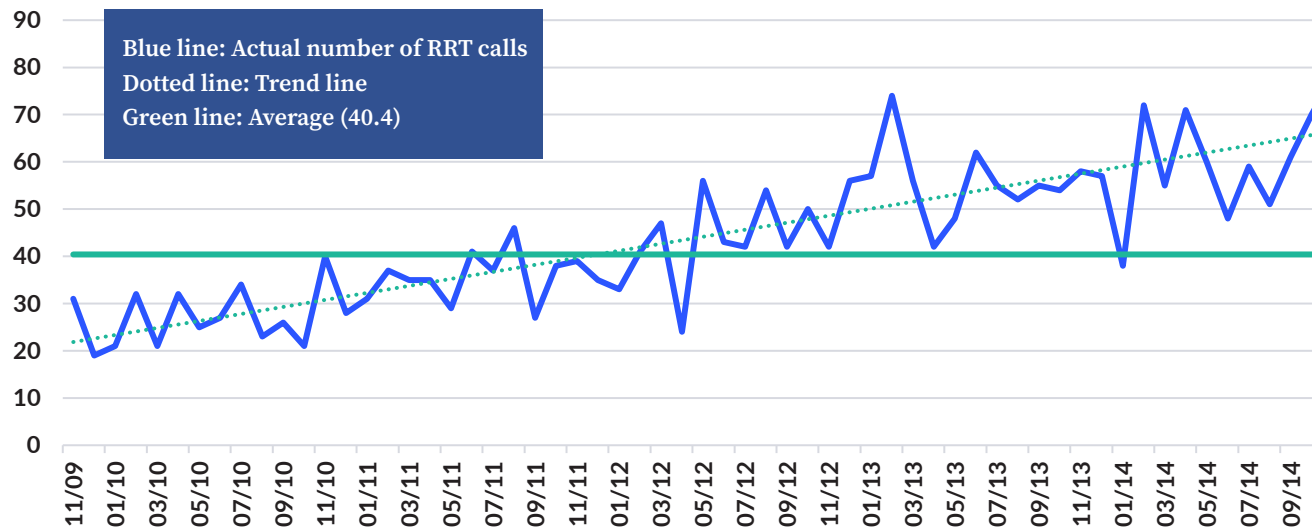
Keywords: *high reliability, transitions in care, night time, teamwork, proactive risk mitigation, interdisciplinary*

Introduction

The ultimate goal and purpose of healthcare is to improve health while preventing morbidity and mortality. The optimal approach to this is through teamwork using a reliability framework. Upon review of our institution's 2012 Surveys on Patient Safety Culture (SOPS) data,¹ we noted that the teamwork domain of the Agency for Healthcare Research and Quality (AHRQ) assessment was in the lowest decile.² Our institution implemented the Crimson Analytics tool in 2013³ and an analysis of inpatient mortality data revealed higher than expected mortality statistics. Baseline inpatient mortality rates (April 2013–March 2015) were 2.08% (compared to the Crimson national cohort average of 1.79% and top quartile of 1.65%). Our baseline observed/expected mortality ratio was 1.04.

Expected mortality rates were determined from Crimson comparator of risk-adjusted "like cases" in the database of over 1000 hospitals. Increased mortality occurred despite Rapid Response Team (RRT) data (**Figure 1**) that revealed continued month-over-month growth in activations since its inception in 2009 and during our baseline period for the Create a Safe Night Program (CSNP) intervention (April 2013–March 2015).⁴ Additionally, multiple published articles of early warning

Figure 1. Number of Rapid Response Team (RRT) calls per month from November 2009 to March 2015 at Abington Hospital



scoring tools such as the Modified Early Warning Score (MEWS) demonstrated relatively low sensitivity and specificity for ability to identify patients at risk for clinical decline.⁵ Finally we increasingly became aware of the tenets of high reliability. Becoming “highly reliable” will require organizations to move towards higher functioning interprofessional teams that are situationally aware of risk and are able to anticipate and mitigate potential harm before it occurs.⁶

With this as context, we set out to create an approach to impact interprofessional team dynamics and performance with an ultimate goal of reduction of inpatient mortality—with a particular focus on the unmet need of patient safety and risk during the overnight period.

Methods

Our institution realized that the structures and processes for teamwork and response to patient decline were significantly more advanced and developed during

daytime hours. A goal was set to bring additional order and structure to the evening/night hours with an ultimate goal of reduction of harm at night.^{7,8} Several focus groups and brainstorming sessions with night shift leadership were held to inform the development of the program. The CSNP was launched in April 2015 after a significant educational effort that included live, in-person didactic information sessions, memos, and distribution of PowerPoint presentations to all involved stakeholders and leaders (nursing, residents, attending physicians).

The CSNP has multiple components. Daily it begins with the identification of patients that are at risk for clinical decline in the overnight period. Borrowing from the Patient Safety Institute’s I-PASS program,⁹ we used the word “watcher” to identify these patients. Resident physicians were trained to identify watchers using clinical judgment by asking, “Which patients on my service are at most risk of having a clinical

decline overnight?” Attending physicians were trained to supervise the process, and watchers were systematically signed out to covering night float interns/residents. Watcher patients were clearly noted in a column in the electronic medical record (EMR) that allowed transparency for all staff to see the identified patients. Similarly, nurses were trained to identify watcher patients on their units who they believed had risk for clinical decline.¹⁰

A 9:30 p.m. huddle was implemented to bring covering intern night floats, nursing representatives from each floor, respiratory technicians, and the evening nurse coordinators together. During these 15–20 minute sessions, the status of each watcher was ascertained, care plans were reviewed, and contingencies were developed for each patient. Critically, this function served as an opportunity for interdisciplinary collaboration in the development of optimal care plans.¹¹

Our institution has long had error prevention behaviors similar to those found in TeamSTEPPS.¹² These have traditionally focused on optimizing team function by creating standardized language and expectations through the use of tools such as SBAR (Situation-Background-Assessment-Recommendation) and CUS (I am Concerned! I am Uncomfortable! This is a Safety Issue!). As part of our evolution and in response to the Institute of Medicine’s report on diagnostic error, we developed and deployed new behaviors called “Talk Out Loud” and “What Else Can It Be.”¹³ These strategies were based on recent literature of cognitive bias.¹³ Use of these tools was encouraged during the 9:30 p.m. huddle, during proactive rounding at the bedside, and during emergent responses to evolving situations.

Between 11 p.m. and 1 a.m. interns proactively went to their assigned nursing units accompanied by nursing supervisors and had another briefing with unit-based staff to identify any new issues of concern. After this brief huddle, the watcher patients were seen in their rooms to ensure another medical assessment for further refinement of their care plan. To ensure collaboration, nurses were encouraged to be at the bedside

during these proactive rounds as well as for emergent calls.¹⁴

Nighttime unit-based nursing leaders submitted nightly electronic reports of intern participation in the unit-based huddles and the proactive rounding. Reports of attendance and participation were automatically forwarded to medical and nursing leadership on a daily basis to enable rapid course correction and resetting of expectations as necessary.

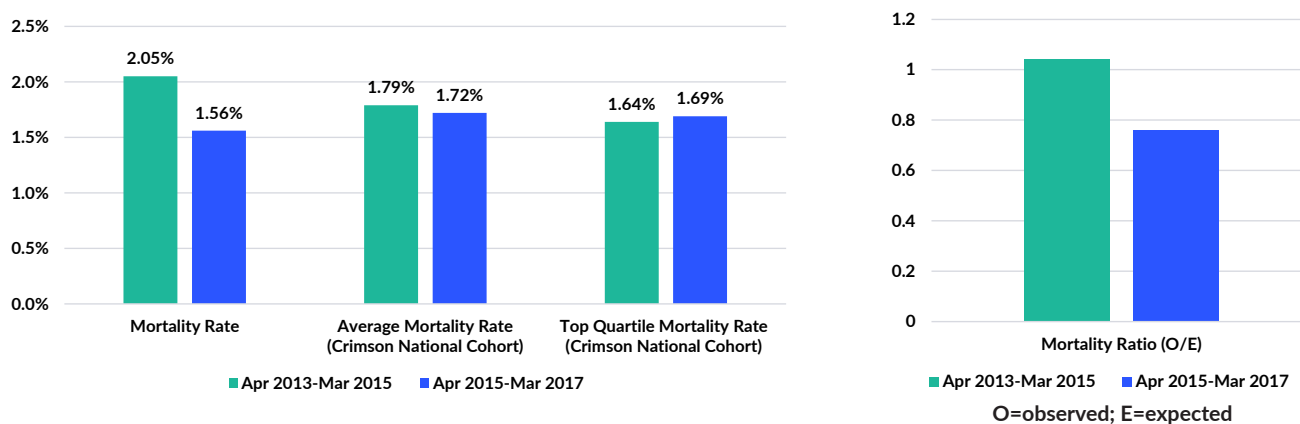
In the morning, at the end of their shift, the night float interns were asked to reflect on the sign-out they received as well as the course of the events of the evening. They were asked to enter an end-of-shift electronic report form. The process of form completion and reflection allowed for the development of a feedback loop to the day teams with the intent of improving the sign-out process. As an example: If the night floats encountered situations that had been evolving during the day but the patient was not identified as a watcher, they would note that in the form and discuss it with the daytime primary service/team.

It was recognized that despite the above efforts, there were patients that had clinical declines in the overnight period that were not

identified as watchers at end-of-day sign-out. In order to provide additional cycles of learning and reflection any non-watcher patient that had a critical event or an unplanned transfer to a higher level of care was identified and a “reflection form” was sent to the primary team to guide them through the process of learning and refining their approach to future watcher patient identification. The intent was to allow the day teams to ponder if there could have been different decisions made during the previous day that could have prevented the patient’s decline. The form used open-ended questions but also contained prompted options such as a proactive upgrade in level of care, the ordering of additional labs, obtaining specialty consultation, etc.

In order to better understand the impact of the CSNP, an electronic survey was developed and distributed via email on May 5, 2017, and remained open for completion until June 1, 2017. Observed/expected mortality ratios were obtained from the Advisory Board’s Crimson Continuum of Care national cohort and are based on All Patient Refined Diagnostic Related Groups (APR-DRG) methodology which uses age, severity of illness, and risk of mortality-based case matching.

Figure 2. Mortality data for Abington Hospital before (April 2013–March 2015) and after (April 2015–March 2017) the initiation of the Create a Safe Night Program



Results

Baseline inpatient mortality rate from April 2013–March 2015 was 2.08% (compared to the Crimson national cohort average of 1.79% and top quartile of 1.65%) (**Figure 2**). Baseline observed/expected mortality ratio was 1.04. The CSNP was initiated in April 2015 and mortality rates from April 2015–March 2017 fell to 1.56% (compared to Crimson average of 1.72% and top quartile of 1.69%). The observed/expected mortality ratio fell to 0.76 during this same period.

AHRQ SOPS data improved in the teamwork domain from a pre-baseline (2012) level of 78% to baseline (2015) of 81% to 83% after the intervention period (2017). This improvement represented movement from the lowest decile against the AHRQ benchmark in the 2012 survey to the 25th percentile at baseline in 2015 to the 50th percentile in the 2017 survey.

Process measures were used to ensure accountability and to develop ongoing learning and feedback systems. For example, unit-based nursing night leadership completed “end of evening” electronic data capture to verify the presence and participation of the rounding intern/resident in the evening. Since the launch of the program a total of 2,640 opportunities were present for intern/nursing staff proactive rounding on WATCHER patients. A total of 1,920 interactions occurred for a rate of 72.7%.

A total of 41 critical events that occurred at night (codes, RRT activation) in patients that were not proactively identified as watchers were analyzed by the primary teams using the structured reflection form (this process commenced in October 2016). Twelve of the 16 teams that cover the general medicine patients completed at least one reflection form for these patients, thus demonstrating feasibility of this approach. Of the 41 patients, 1

patient had a cardiac arrest, 28 had unplanned transfers to a higher level of care, and 12 had RRTs but remained in the room. Many insights were had on the part of the day teams. A few examples of learnings and reflections included the need for earlier consultation of specialists, more attention to changes in daytime vital signs, need for more aggressive medical management, different triage decisions regarding level of care from emergency trauma center, and more aggressive use of blood products.

A convenience sample of 105 staff members was surveyed using an electronic survey capture tool. The majority of the survey respondents were nurses and intern/resident physicians (82.8%) (**Figure 3**). As indicated by the survey results (**Table 1**) the overall program was extremely well received. The 9:30 p.m. interdisciplinary huddle was shown to be positive in improving situational awareness (67% somewhat or completely agreed) and in allowing the development

of appropriate action planning for risk mitigation. (66.9% somewhat or completely agreed.)

Through its use of structured process and standard language the CSNP has dramatically improved the organization’s ability to be proactive in identifying risk; 67.6% somewhat or completely agreed that it helped reduce risks for unanticipated clinical decline and 84.7% somewhat or completely agreed the watcher created clarity and focus for priority setting (**Table 1**). The CSNP has led to improved interactions (72.4% somewhat or completely agreed) and collaboration and communication between disciplines at night (71.4% somewhat or completely agreed), while simultaneously impacting efficiencies (52.3% somewhat or completely agreed) and “joy at work” (37.2% somewhat or completely agreed) (**Table 1**).

Figure 3. Clinical Role of Survey Respondents (N=105)

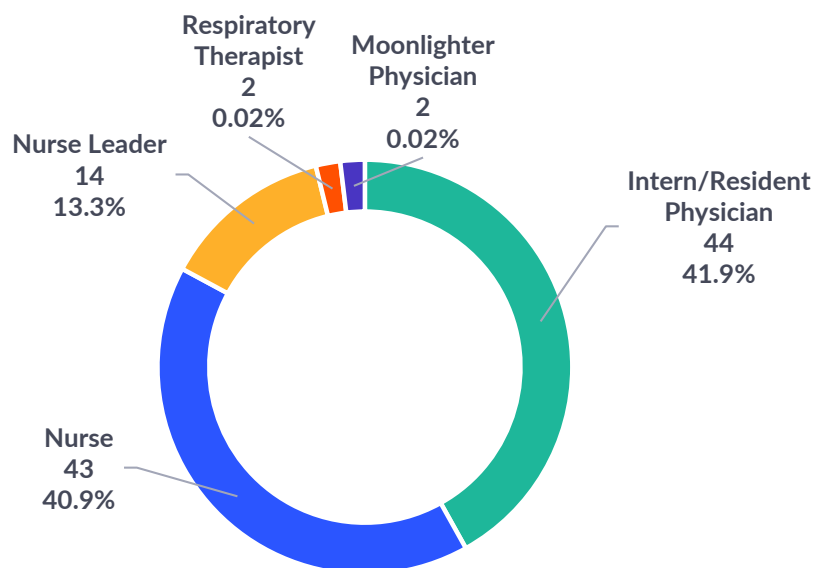


Table 1. Create a Safe Night Program (CSNP) Post-Intervention Survey Results

Survey Question	Completely Disagree (N/%)	Somewhat Disagree (N/%)	Neutral (N/%)	Somewhat Agree (N/%)	Completely Agree (N/%)	Not Applicable (N/%)
The 9:30 p.m. huddle in the flow center was useful in creating situational awareness of risk at the unit and organizational level	6/88 (6.8)	3/88 (3.4)	20/88 (22.7)	24/88 (27.3)	35/88 (39.8)	17 (Did not participate)
The 9:30 p.m. huddle helped the organization prioritize the application of resources in the evening to mitigate the risk of patient decline	4/88 (4.5)	5/88 (5.6)	19/88 (21.5)	35/88 (39.7)	25/88 (28.42)	17 (Did not participate)
The CSNP has been helpful in reducing risks for unanticipated clinical decline (codes, upgrades to critical care, etc.) for our patients	6 (5.7)	7 (6.7)	21 (20.0)	39 (37.1)	32 (30.5)	
The use of the word “watcher” created clarity and focus for priority setting that was easily recognizable across disciplines	1 (1.0)	4 (3.8)	11 (10.5)	31 (29.5)	58 (55.2)	
The CSNP has been helpful to foster positive interdisciplinary team-based interactions	5 (4.8)	7 (6.7)	17 (16.2)	38 (36.2)	38 (36.2)	
The CSNP has improved communication between the disciplines at night	8 (7.6)	7 (6.7)	15 (14.3)	41 (39.0)	34 (32.4)	
The CSNP has been helpful to create order and structure thereby reducing overall work burden. (i.e., it improved our ability to get the job done efficiently)	11 (10.5)	13 (12.4)	26 (24.8)	37 (35.2)	18 (17.1)	
The CSNP has allowed me to feel better about my role at night and has improved my “joy at work”	15 (14.3)	11 (10.5)	40 (38.1)	28 (26.7)	11 (10.5)	

Discussion

We believe that the CSNP has contributed to patient safety, enhanced our culture, and possibly improved joy of work for involved staff. Acknowledged, however, is the fact that the intervention took place in a non-static environment with concurrent staff turnover and other improvement activities. Hence a direct causal link between the CSNP and the outcomes presented and studied cannot be scientifically proven without a randomized control trial of hospitals.

Given the face validity of the results and the fact that interventions naturally are born from and are aligned to safety and high-reliability science, the program has merit to be replicated at other facilities. The initiative can be replicated in other facilities given its ability to be modified to any hospital's structures. The program simply needs to have a coordinated approach between physicians who cover patients during the evening and their nursing counterparts. While physician staff in our initiative took

the form of interns in training and moonlighters, other facilities can vary the program dependent on their coverage model (e.g., fellows, nocturnists, hospitalists, intensivists, etc.). Nursing departments are all organized slightly differently but all have unit-based staff and leadership as well as a senior nurse who is operationally “in charge” in the evening. Other types of providers (e.g., respiratory technicians, pharmacists, laboratory professionals, etc.) can be brought in as necessary and able.

Sustainability of any new initiative or tactic is key for long-term improvement. The CSNP is likely to be sustainable given its positive impact on teamwork, culture, and efficiency. Considering the staff's support of the structural and process changes that have occurred, the fabric and culture of the institution at night has been altered—these processes are the new normal and the new “habit” of the evening. Should drift occur, frontline staff will likely demand its return. Additionally, this initiative is highly likely to be sustained, given the integration of the process into other core daily activities where a high degree of accountability exists. These include structured and supervised physician sign-outs, hospitalwide safety calls during the day where patients are now also being discussed, as well as the aforementioned ability to collect real-time performance data that can be fed back to leadership should drift emerge.

Our study demonstrated that 37.2% of providers experienced more joy at work through this initiative. With burnout rates of healthcare providers climbing year over year, any intervention that may increase joy at work should be critically evaluated and supported.

Many lessons have been learned through this project. Through the lens of the reliability framework we needed to carefully follow the formula of: 1) set expectations, 2) educate, and only then, 3) hold accountable. We found that we needed to be very clear regarding the expectations. Expectations of standard work needed to be distributed repeatedly and regularly in writing to staff that rotated at night. For staff that may be present for only a few shifts a month, just-in-time teaching was developed. Moonlighters who may work only a few sessions a month and interns who rotated on weekly schedules benefited from this just-in-time

approach. This degree of coordinated expectation setting required tremendous support from leadership from each discipline. The establishment of electronic feedback loops back to leadership was developed early on to ensure all parties were aware of drift.

Technology will continue to evolve and predictive tools (e.g., MEWS) will improve over time. The CSNP creates the cultural and structural foundation to manage and mitigate risk before events occur. At the end of the day, technology is important, but people working collaboratively in teams are necessary to achieve the outcomes our patients deserve.

Conclusion

An interprofessional approach to high-quality transitions in care, risk identification, and mitigation, along with structured huddles and proactive rounding, can improve patient safety at night while simultaneously improving staff satisfaction, joy, and safety culture. This approach is possible without the application of additional resources and may be replicable at most hospitals.

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Safe Healthcare *For All Patients*

Voices of the LGBTQ Community Seeking Safe and Inclusive Care

Catherine M. Reynolds[◇], DL, MJ, RN

Keywords: *LGBTQ, stigma, inclusive, safe, misgendered, marginalization, community, transgender*

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The acronym LGBTQ is often used as an umbrella term for the community. As language evolves, more inclusive acronyms may be used, such as LGBTQIA, to also reference intersex and asexual identities, or LGBTQ+ to include the queer community.



to access in serving local communities—extended visitor hours, expanded interpreter services, and patient navigators are examples. Members of the LGBTQ community continue to experience disparities from years of stigma and lack of education of providers and healthcare organizations. LGBTQ individuals shared that after negative experiences while accessing healthcare, they have been less open to providing current and past health history and often delay having health issues addressed. Such delays could contribute to poor patient outcomes.

Providing safe healthcare for all patients requires an understanding of the unique needs of members of a community and a visible commitment to providing a safe, inclusive space.

Abstract

Members of the lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) community have long described experiencing stigma and lack awareness and education about their needs in healthcare environments. These experiences often lead to anxiety and avoidance to seek further healthcare when needed. Delay or lack of treatment for medical and psychiatric symptoms is a patient safety issue that can lead to poor patient outcomes.

Growth and shifting of attitudes can come with open listening and seeking to gain perspective on how LGBTQ individuals view safe and inclusive care. The Patient Safety Authority (PSA) captured some of these voices in asking participants at the 2019 Philadelphia Trans Wellness Conference to share experiences they have had seeking healthcare. We share them here to broaden an ongoing dialogue and discuss initial steps healthcare facilities could take to improve the patient experience for LGBTQ individuals.

The Impact of Mistrust

“I went to my local ER for a chronic condition flare and they treated me horribly. Misgendered me every time someone spoke to me. Now I only go to the hospital further away from me and I need to be driven because it is far, but it is safe.”
(See Page 68 for more voices of the community.)

Pennsylvania healthcare facilities have made strides to provide welcoming environments and bridge gaps

The Impact of History

The LGBTQ community includes distinct groups, each of which may have unique needs but collectively have experienced marginalization in many environments, including healthcare.¹ Despite evolving social acceptance, anti-LGBTQ bias in healthcare continues to affect the experiences of those seeking care.² Only as recently as 1973, homosexuality was listed as a mental disorder in the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*. The Institute of Medicine’s 2011 report *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* states, “LGBT people face barriers to equitable health care that profoundly affect their overall well-being. Understanding outcome disparities, provider attitudes and education, ways in which the care environment can be improved, and the experiences of LGBT individuals seeking care would provide a base from which to address these inequities.”¹

These inequities affect LGBTQ individuals across their lifespan and include:¹

- LGBTQ youth are at increased risk to attempt suicide and experience homelessness
- Lesbian and bisexual women are less likely to use recommended preventative health services
- Gay black and Latino men are disproportionately affected by HIV/AIDS
- LGBTQ seniors are less likely than heterosexual peers to have adult children as caregivers
- Less available data for transgender individuals represents a public health need

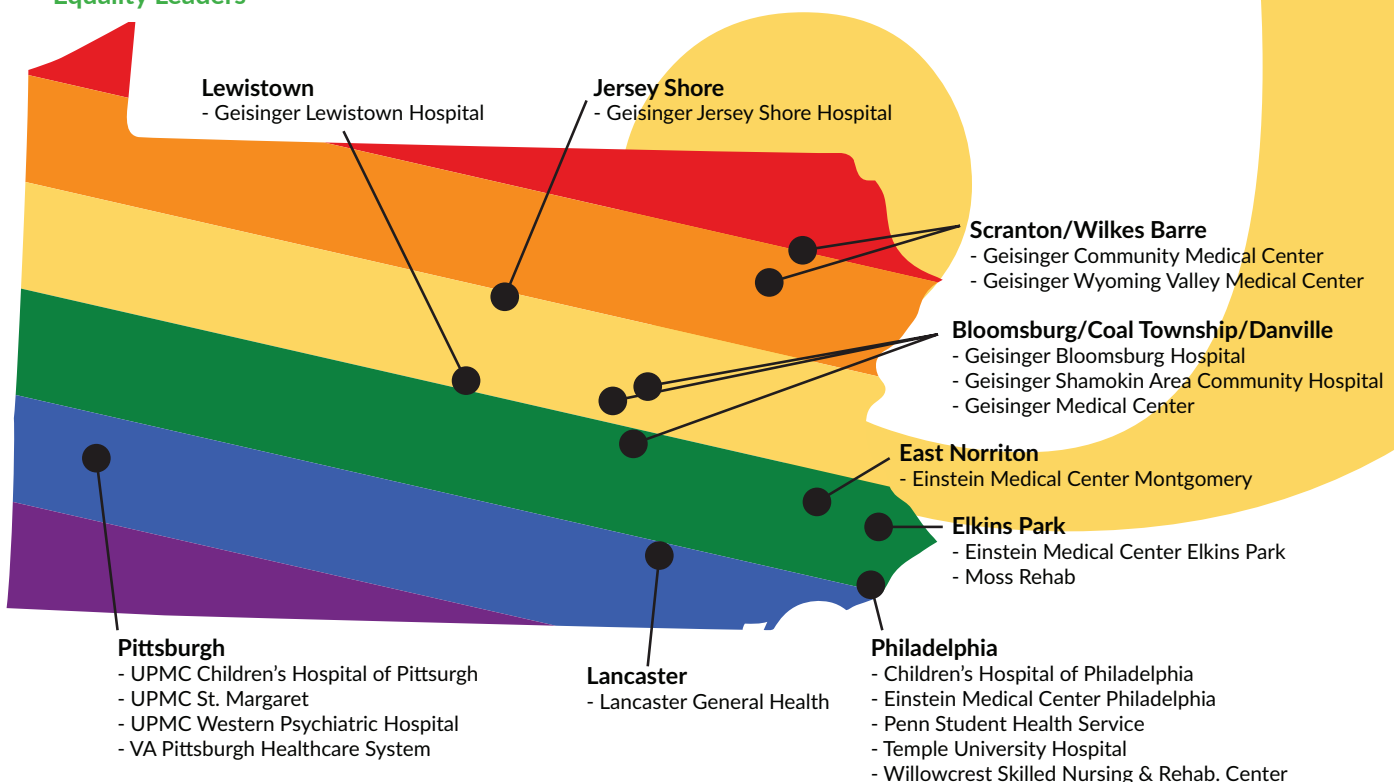
While important research continues, LGBTQ individuals are living in all communities and sharing varied experiences with the healthcare system, both positive and negative. Engaging and truly listening to those voices allows healthcare providers and organizations to gain new perspective on how they engage this community and how they can improve care delivery.

Creating a Safe and Inclusive Experience: Start Where You Are and Build

In 2019, 20 Pennsylvania healthcare facilities (see **Figure 1**) have attained the Leader in LGBTQ Healthcare Equality designation by scoring 100 on the Human Rights Campaign (HRC) Healthcare Equality Index (HEI). This tool scores facilities on having policies and practices to ensure inclusion and equitable treatment of the LGBTQ community.³ These organizations are to be commended for their efforts. Most other facilities, large and small, can follow some key steps that provide a good and achievable starting point to improve the experience for LGBTQ patients.

The Joint Commission field guide *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBTQ) Community* offers four key recommendations and strategies for healthcare organizations to improve provision of care to the LGBTQ community.⁴ We add one more to include providing staff and provider education to build comfort and competence in caring for the community. The Top 5 Strategies (adapted from The Joint Commission guide) provides a foundation for a facility to begin or build on changes to provide a safe and inclusive care environment.

Figure 1. 2019 Pennsylvania LGBTQ Healthcare Equality Leaders⁵



Top 5 Strategies for Creating a More LGBTQ-Inclusive Experience in Your Healthcare Facility

1. Creating a welcoming and inclusive environment
 - Have materials and brochures in the waiting room and visibility of LGBTQ-friendly symbols (e.g., rainbow flag, pink triangle, safe zone symbol)
 - Having unisex or single stall bathrooms
2. Don't make assumptions of sexual orientation or gender identity
 - Don't rely on external appearances to assume gender
 - Allow information about sexual orientation and gender identity to come from the patient
 - Ask "How would you like to be addressed?" or "What name would you like to be called?"
3. Create a safe context to facilitate disclosure of important health information about sexual identity or gender identity
 - Have gender neutral and inclusive language on forms that allow patients and families to self-identify
 - Use gender neutral and inclusive language in interviews
4. Provide information and guidance for specific health concerns of the community
 - Have providers remain knowledgeable about LGBTQ-related health topics
 - Have knowledge of available online resources and connect patients and families to them⁴
5. Staff and provider education
 - Educating staff and providers to build competence and comfort in caring for members of the LGBTQ community

Amplifying Voices of the Community

The Philadelphia Trans Wellness Conference (PTWC) was held over three days in July 2019. The mission of PTWC is to educate and empower trans individuals on issues of health and well-being; educate and inform allies and health service providers; and facilitate networking, community-building, and systemic change.³ With a vision of Safe Healthcare for All Patients, the Patient Safety Authority (PSA) was there to invite attendees to share an experience they have had accessing or receiving healthcare and how that experience impacted them. Here is what we heard in their voices:

People at the front desk not respecting my pronouns and name. Being called by my birth name in the waiting room. Feeling as if I have to actually educate my doctor on trans healthcare, especially regarding hormone therapy. It makes me feel incredibly dysphoric and also like I am not being seen. As if I am an afterthought for healthcare professionals even if they advertise themselves as #1 in LGBT care.

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I find it hard as a person who works in healthcare seeing forms that only have male/female and no inclusivity of gender/orientation identities, and the lack of education of practitioners within healthcare. **I was so worried about explaining my story to my OB/GYN (even knowing him for more than 20 years) that I almost fell apart. He is now on his way to receiving WPATH [World Professional Association for Transgender Health] certification as a healthcare provider. I love him for this!**

I was so worried about explaining my story to my OB/GYN (even knowing him for more than 20 years) that I almost fell apart. He is now on his way to receiving WPATH [World Professional Association for Transgender Health] certification as a healthcare provider. I love him for this! **In March 2019, I went to a provider who has “LGBTQ+ friendly” on her page, but when I was asked about my romantic partners and I said I am with a woman (I’m also a woman), the nurse practitioner did not complete the screening. The provider never came to visit either, so I left. It makes me distrust providers, even those who boast LGBTQ+ competency, and makes me anxious about trying any provider, seeing as I identify as a lesbian.**

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A nurse audibly mocking/laughing at me from outside the door made me not want to go out to a PCP regularly. **The first gynecologist I ever visited (at age 16, shortly after coming out) told me that testosterone would make me infertile and that I was disappointing my mother by not having kids. I didn’t have a really good relationship with my mom at the time, so I felt like I was the worst child in the world. I didn’t tell her about it for years because I was so embarrassed and ashamed.**

The first gynecologist I ever visited (at age 16, shortly after coming out) told me that testosterone would make me infertile and that I was disappointing my mother by not having kids. I didn’t have a really good relationship with my mom at the time, so I felt like I was the worst child in the world. I didn’t tell her about it for years because I was so embarrassed and ashamed. **Having doctors ask about or assume surgery status when it wasn’t relevant and assuming that to be that cause of all medical problems made me feel uncomfortable coming out to physicians, even if it was medically relevant.**

Having doctors ask about or assume surgery status when it wasn’t relevant and assuming that to be that cause of all medical problems made me feel uncomfortable coming out to physicians, even if it was medically relevant. **For the most part my experience has been okay. Though I am a woman, born a woman, I know friends who have been treated unfairly or not respected. It made me feel sad and mad, and made me want to get more educated and to advocate.**

For the most part my experience has been okay. Though I am a woman, born a woman, I know friends who have been treated unfairly or not respected. It made me feel sad and mad, and made me want to get

I'm a trans male and constantly misgendered in the GYN office back in Maryland. My mom has never seen me break down so badly in the bathroom. I'm a trans male and constantly misgendered in the GYN office back in Maryland. My mom has never seen me break down so badly in the bathroom. **I went to my local ER for a chronic condition flareup, and they treated me horribly. Misgendered me every time someone spoke to me. Now I only go to the hospital further away from me and I need to be driven because it is far, but it is safe.** I went to my local ER for a chronic condition flareup, and they treated me horribly. Misgendered me every time someone spoke to me. Now I only go to the hospital further away from me and I need to be driven because it is far, but it is safe. **Being told I'm too "complicated" when sharing my identities/sexual experiences when asked by a medical professional.** Being told I'm too "complicated" when sharing my identities/sexual experiences when asked by a medical professional. **When getting an MRI, the tech had to ask about why I wasn't menstruating (to make sure I wasn't pregnant) and when I explained that I was on testosterone, she asked if I was transitioning and if there was another name she should call me. I felt so taken care of and valid!! The tech was also great with my claustrophobia and checking in during the MRI, and each time she used my correct name. I appreciated it so much.** When getting an MRI, the tech had to ask about why I wasn't menstruating (to make sure I wasn't pregnant) and when I explained that I was on testosterone, she asked if I was transitioning and if there was another name she should call me. I felt so taken care of and valid!! The tech was also great with my claustrophobia and checking in during the MRI, and each time she used my correct name. I appreciated it so much. **I have had a pretty positive experience with healthcare, but I do know people who feel that their sexuality or gender identity has caused providers to shame or treat them as insignificant.** I have had a pretty positive experience with healthcare, but I do know people who feel that their sexuality or gender identity has caused providers to shame or treat them as insignificant. **Nurses violating my HIPAA rights by assuming that I wasn't there for a mammogram and arguing with me in a waiting room full of people gave me much more anxiety about medical visits.** Nurses violating my HIPAA rights by assuming that I wasn't there for a mammogram and arguing with me in a waiting room full of people gave me much more anxiety about medical visits. **At my last ER visit, I expressed my desire to be called my preferred name and they did not have a way to put that in the system, so I kept getting deadnamed and having to request each person to stop. The staff was mostly cooperative, except for my doctor. He insisted on calling me "she" and by my deadname. Makes me afraid of ever going to an ER again.** At my last ER visit, I expressed my desire to be called my preferred name and they did not have a way to put that in the system, so I kept getting deadnamed and having to request each person to stop. The staff was mostly cooperative, except for my doctor. He insisted on calling me "she" and by my deadname. Makes me afraid of ever going to an ER again. **It took a long time to find an accepting PCP and therapist, but once I did I almost became responsible for teaching them instead of the other way around.** It took a long time to find an accepting PCP and therapist, but once I did I almost became responsible for teaching them instead of the other way around. **I went to an out-of-network surgeon with a private OR in his office. The whole space was very trans friendly and the workers were well-trained. Everyone used my correct name and pronouns from the start.** I went to an out-of-network surgeon with a private OR in his office. The whole space was very trans friendly and the workers were well-trained. Everyone used my correct name and pronouns from the start. **Before my legal name change, it was very difficult going to medical appointments presenting as a male with a "typical" female name. The feeling was always uncomfortable trying to explain my situation.** Before my legal name change, it was very difficult going to medical appointments presenting as a male with a "typical" female name. The feeling was always uncomfortable trying to explain my situation. **Even though my fiancé works for a doctor's office and is advocating for me, they still couldn't put my preferred name and pronouns on my chart. So, I would just correct the staff saying it would be fine once I got it legally changed. After I legally changed my name my doctor's office still called my deadname in the waiting room. I didn't get up, just sat there stunned. Since I pass for my gender identity I was scared for my safety.** Even though my fiancé works for a doctor's office and is advocating for me, they still couldn't put my preferred name and pronouns on my chart. So, I would just correct the staff saying it would be fine once I got it legally changed. After I legally changed my name my doctor's office still called my deadname in the waiting room. I didn't get up, just sat there stunned. Since I pass for my gender identity, I was scared for my safety. **Hospitals are not doing enough education about LGBT community with regards to healthcare experiences with doctors and nurses.** Hospitals are not doing enough education about LGBT community with regards to healthcare experiences with doctors and nurses.

Common Terms and Abbreviations Related to Gender Identity and Sexual Orientation

Ally noun

a person who supports and stands up for the rights of LGBT people.

Bisexual adjective

a sexual orientation that describes a person who is emotionally and sexually attracted to people of their own gender and people of other genders.

Gay adjective

a sexual orientation that describes a person who is emotionally and sexually attracted to people of their own gender. It can be used regardless of gender identity but is more commonly used to describe men.

Gender affirming surgery (GAS) noun

surgeries used to modify one's body to be more congruent with one's gender identity. Also referred to as sex reassignment surgery (SRS) or gender confirming surgery (GCS).

Gender binary noun

the idea that there are only two genders, male and female, and that a person must strictly fit into one category or the other.

Gender dysphoria noun

distress experienced by some individuals whose gender identity does not correspond with their assigned sex at birth. Manifests itself as clinically significant distress or impairment in social, occupational, or other important areas of functioning. *The Diagnostic and Statistical Manual of Mental Disorders (DSM-5)* includes gender dysphoria as a diagnosis.

Gender expression noun

the way a person acts, dresses, speaks, and behaves (i.e., feminine, masculine, androgynous). Gender expression does not necessarily correspond to assigned sex at birth or gender identity.

Gender fluid adjective

describes a person whose gender identity is not fixed. A person who is gender fluid may always feel like a mix of the two traditional genders, but may feel more one gender some days, and another gender other days.

Gender identity noun

a person's internal sense of being a man/male, woman/female, both, neither, or another gender.

Gender non-conforming adjective

describes a gender expression that differs from a given society's norms for males and females.

Gender role noun

a set of societal norms dictating what types of behaviors are generally considered acceptable, appropriate or desirable for a person based on their actual or perceived sex.

Lesbian adjective, noun

a sexual orientation that describes a woman who is emotionally and sexually attracted to other women.

Queer adjective

an umbrella term used by some to describe people who think of their sexual orientation or gender identity as outside of societal norms. Some people view the term queer as more fluid and inclusive than traditional categories for sexual orientation and gender identity. Due to its history as a derogatory term, the term queer is not embraced or used by all members of the LGBT community.

Questioning adjective

describes an individual who is unsure about or is exploring their own sexual orientation and/or gender identity.

Sexual orientation noun

how a person characterizes their emotional and sexual attraction to others.

Top surgery noun

colloquial way of describing gender affirming surgery on the chest.

Trans man/transgender man/female-to-male (FTM) noun

a transgender person whose gender identity is male may use these terms to describe themselves. Some will just use the term man.

Trans woman/transgender woman/male-to-female (MTF) noun

a transgender person whose gender identity is female may use these terms to describe themselves. Some will just use the term woman.

Transgender adjective

describes a person whose gender identity and assigned sex at birth do not correspond. Also used as an umbrella term to include gender identities outside of male and female. Sometimes abbreviated as trans.

Transition noun

for transgender people, this refers to the process of coming to recognize, accept, and express one's gender identity. Most often, this refers to the period when a person makes social, legal, and/or medical changes, such as changing their clothing, name, sex designation, and using medical interventions. Sometimes referred to as gender affirmation process.

Transphobia noun

the fear of, discrimination against, or hatred of transgender or gender nonconforming people or those who are perceived as such.

*Adapted from the National LGBT Health Education Center's Glossary of LGBT Terms for Health Care Teams.⁵ This list is not exhaustive and language related to gender identity and sexual orientation is evolving. See links to further resources associated with this article to gain broader understanding.

Conclusion

An individual's interaction with the healthcare system will be shaped by personal factors as well as prior experiences. What provides a sense of safety and inclusion in that space will vary among members of diverse communities. Healthcare facility leadership and staff should develop awareness about the unique needs of the LGBTQ community and build capacity over time in serving their community.

Many facilities have implemented and continue to build on their programs to provide safe care for the LGBTQ community. These facilities can serve as a valuable resource for learning and guidance along with national organizations. The Top 5 recommendations included in this article offer a concise list of interventions for any facility to begin ensuring a safe environment and care delivery for the LGBTQ community they serve.

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Safe and Inclusive Care of the LGBTQ Community Resources

Glossary of Terms

National LGBT Health Education Center
A Program of The Fenway Institute

www.lgbthealtheducation.org/wp-content/uploads/LGBT-Glossary_March2016.pdf

Educational Resources on LGBTQ Aging

SAGE—Advocacy and Services for LGBT Elders

www.sageusa.org/

The National Resource Center on LGBT Aging

www.cdc.gov/lgbthealth/links.htm

Educational Resources

The Fenway Institute

fenwayhealth.org/the-fenway-institute/education/the-national-lgbt-health-education-center/

The Joint Commission—Field Guide

The Joint Commission: *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community: A Field Guide*. Oak Brook, IL, Oct. 2011. LGBTFieldGuide.pdf.

www.jointcommission.org/-/media/enterprise/tjc/imported-resource-assets/documents/lgbtfieldguide_web_linked_verpdf.pdf?db=web&hash=1EC363A65C710BCD1D4E14ED120CB237

The Centers for Disease Control and Prevention (CDC)
Lesbian, Gay, Bisexual, and Transgender Health

www.cdc.gov/lgbthealth/links.htm

Benchmarking Tool

Healthcare Quality Index
Human Rights Campaign (HRC)

www.hrc.org/hei/

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Institute of Medicine 2011. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, DC: The National Academies Press. doi.org/10.17226/13128.

www.nap.edu/read/13128/chapter/1

I A

**I AM Patient Safety - 2020
Annual Achievement Awards**

By Eugene Myers

PS

Executive Director's Choice Award: Tyrone Hospital is the quintessential community hospital: created by the community, for the community. Established with bequests from Tyrone, Pennsylvania, businessman Harvey Gray and his wife, Adda, as well as local donations, it has been serving Northern Blair County residents for 66 years. Now part of the Tyrone Regional Health Network, one of the hospital's core values is "continued improvement and learning," and no one demonstrates this commitment better than its staff, which recently rallied together to improve surgical safety for their patients.

Surgical site infections (SSIs) are a leading cause of morbidity and mortality among all U.S. hospital-acquired infections—and are also among the most preventable. When SSIs occur following arthroplastic (hip and knee) surgeries, the impact can be devastating for patients, including additional surgeries, antibiotics, and rehabilitation that place a heavier physical, emotional, and financial burden on patients and their caregivers.¹

In 2018, the infection rate for total hip arthroplasties at Tyrone was as high as 4.1%, above the national rate of 2.40% (according to the Centers for Disease Control and Prevention National Healthcare Safety Network data for 2010).² So in a spirit of community, members of the OR, infection control, patient safety, housekeeping, and maintenance departments collaborated to address the problem. They posted the infection rate in the OR, held monthly discussions, and analyzed the causes of each SSI. They updated policies and procedures to reflect best practices. And they reached out to the Patient Safety Authority (PSA) for help identifying areas for improvement in their surgical suite. Then they got to work fixing issues with terminal cleaning, broken equipment, and instrument cleaning practices.

Because of a true community effort that involved a multidisciplinary team; full transparency; and buy-in from hospital leadership, physicians, and staff, in just one year Tyrone Hospital reduced SSIs for hip replacement surgery to 0%. For this extraordinary effort and success, the Surgical Infection Reduction Team at Tyrone Hospital is the winner of the PSA's 2020 I



▲ Executive Director's Choice Award winners from Tyrone Hospital

Surgical site infections were reduced to zero

AM Patient Safety (IAPS) Executive Director's Choice Award. They were one of nine groups and individuals to receive awards for their inspiring and life-changing accomplishments in patient safety in the last year, highlighted in the following pages. Judges selected the winners from 156 nominations, received from 79 facilities throughout Pennsylvania. The award winners will be formally recognized at the 3rd Annual Pennsylvania Patient Safety Summit (P2S2) in Lancaster, Pennsylvania, on April 28, 2020.

1. <http://www.ihl.org/Topics/SSIHipKnee/Pages/default.aspx>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5124739/>



Transparency and Safety

Women's Health Division

Pennsylvania Hospital - Penn Medicine

The interdisciplinary leadership team observed a concerning trend from FY16 through FY18: The number of safety events reports was static, yet more events were reaching the patient and resulting in harm. A thorough review of all safety events revealed common themes, including interprofessional communication, handoff communication, and acuity response. TeamSTEPPS, an evidence-based program to enhance team performance and patient safety, supported the development of a team safety structure.

The team provided interdisciplinary education to more than 450 staff, including nursing, providers, respiratory therapy, and anesthesia. An implementation timeline was designed, and components of the program were rolled out strategically through a variety of methods such as raffles, weekly emails, daily data boards, and staff meetings. Stakeholders designed structures to support safety, including standardized safety briefs, a debrief template, and clear guidelines of events that require debriefing.

To effectively build a safety culture, a focus was placed on enculturation of TeamSTEPPS methods and sustainability using escape room activities to engage the team in a creative way. “Drop the mic with SBAR” and “Close the Loop” rounding used a prize patrol approach to reinforce the TeamSTEPPS processes and recognizes achievements regularly. The TeamSTEPPS Summer Olympics keep the skills and tools top of mind, while infusing a little fun. Communication and transparency remain at the center of the program.

Events reaching a patient with a harm score of E or greater has decreased from 12% of all events before implementation of TeamSTEPPS to a low of 3% of all events post-intervention. Additionally, the number of debriefs following unanticipated events has increased significantly, from 2–4 per quarter prior to TeamSTEPPS to 16–24 in the last three quarters. The implementation of a team safety structure has demonstrated that standardized communication, empowering team members in all roles to speak up for safety, and encouraging near miss identification and reporting has had a positive impact on patient safety and team dynamics throughout the division.

Ambulatory Surgery

The staff of Penn Highlands Elk Surgery Center—Molly L. Quesenberry, BSN, RN; Kathy Wortman, BSN, RN; Dr. Brett Karlik; staff of the Elk County Eye Clinic staff; Dr. J. Ryan Rice; and the staff of Penn Highlands Plastic and Reconstructive Surgery

Penn Highlands Elk Surgery Center

Staff at the Penn Highlands Elk Surgery Center launched a performance improvement (PI) project to further decrease the risk of a wrong-site surgery (WSS) by reducing the number of incorrect surgery registrations received by the physicians' practices during the initial pre-procedure verification.

Using data from the Pennsylvania Patient Safety Reporting System (PA-PSRS), the team analyzed event reports from the Center from calendar year 2018 and found that nine near miss events were related to incorrect registrations from four surgeons' offices. For each of these events, the surgeon and/or office manager was

notified when the Center received incorrect registration information and it was reconciled either before patient admission or before the procedure.

In January 2019, the Center's patient safety officer (PSO) reached out to the physicians and offered to provide staff education on WSS prevention. The PSO developed a PowerPoint, "Partnering With the Surgeon's Office to Keep Our Patient's Safe," which includes information on WSS causes and prevention, 2019 Hospital National Patient Safety Goals from The Joint Commission, preop testing requirements for the Center, a newly introduced anticoagulation management form, and information on just culture. PSA handouts with tips to prevent a WSS also were distributed to physicians' practices.

As of December 2019, the data from the PA-PSRS indicated that this education was successful in decreasing the number of incorrect registrations by 75-100% of previous results, further decreasing the risk of a WSS. The goal of this PI project has been met.

Innovation

The Patient Safety and Organizational Learning and Development Departments: Dr. MaryEllen Pfeiffer, Mary Zeigler, Melissa Heath, Melinda Jeffries, Nancy Nicholas, Suzanne Gervase, Karla Heberlig, and Duane Patterson

WellSpan Health

For the annual WellSpan Health Quality Forum, where 500 team members from the integrated health network gather to showcase various quality improvement and patient safety projects, this team created a unique workshop breakout session; a patient safety escape room.

The escape room featured an unfolding narrative of a 66-year-old Hispanic woman, Marina, who suffered from rheumatoid arthritis, diabetes, kidney disease, and anemia. She had fallen down the steps on the front porch and presented to the ED with back pain. She was found to have an acute compression fracture of her lumbar vertebra and a urinary tract infection. She was a fall risk and did not have vascular access, requiring a central venous catheter to be placed for administration of IV antibiotics and pain medicine.

For the exercise, 150 participants were divided into tables of eight. As the timer counted down from 30 minutes, the groups worked through a series of puzzles, guided by a trained facilitator with props and a laptop. These challenges incorporated videos, pictures, and book ciphers. For example, filling out a crossword puzzle to simulate identifying and removing self-harm elements from Marina's ED room, and assembling a 24-piece jigsaw puzzle of a blueprint of the medical unit to find an unoccupied bed close to the nurse station.



▲ Winners for *Ambulatory Surgery*—Penn Highlands Elk Surgery Center

▼ *Innovation* winners from WellSpan Health



After a team completed all the tabletop exercises, they escaped the large conference room into a smaller room where they ran through a high-fidelity simulator showing Marina was unarousable, bradycardic, and barely breathing. The medication administration record uncovered two doses of narcotics in close succession, and naloxone was the antidote that revived the patient.

Eight teams completed all six puzzles. Evaluations showed more than 95% of participants rated the session as excellent or above average. Everyone walked away feeling inspired by the experience and with a new passion for patient safety.



▲ Winners of the *Safety Story* award from Pennsylvania Hospital
▼ The Ligature Risk Team from Einstein Medical Center Montgomery, winners for *Focus on the Patient*



Safety Story

Sara Cohen, MSN, RN; Kelly Milligan, CRNP; Barbara Morrison, MSN, RN

Pennsylvania Hospital - Penn Medicine

When Sara Cohen, MSN, RN, began working at Pennsylvania Hospital supporting the nighttime staff, she recognized that care for patients with diabetes did not follow appropriate practice recommendations. Sliding scale insulin was not being given at bedtime, the timing of insulin administration throughout the day was not within the care guidelines, and there was a general tendency toward permissive hyperglycemia—liberal management of high glucose levels in patients. Staff also had a general gap in knowledge about the actions and timing of insulin, and how sliding scale coverage differs from basal bolus dosing.

Cohen worked closely with Barbara Morrison, outpatient diabetes educator, to better understand the guidelines staff should be following. Over the past two years they audited hundreds of charts; provided shoulder-to-shoulder education to staff; enhanced hospital guidelines around care of patients with diabetes; and created a comprehensive, mandatory, online learning module for all staff covering diabetes, insulin action, and best practices related to caring for these patients. They also created a diabetes task force to elicit participation from staff on all units, share the steps in caring for patients with diabetes, and help with chart audits to track compliance.

Cohen also collaborated with others to develop a daytime and nighttime education grand rounds in November about the new guidelines, the reasons for this initiative, and in-depth information about diabetes and the risks associated with practicing permissive hyperglycemia. The facility's bedtime sliding scale insulin administration compliance is now at 98% (up from 34%), and staff is now tracking charts for improved timing of insulin and blood glucose results, and improved documentation around insulin administration.

This two-year process resulted not only in enhanced knowledge and appropriate practices for staff, but also, most importantly, improved care that so many patients will receive while they are admitted to the hospital.

Focus on the Patient

Ligature Risk Team—Kristy Burkart, Kim Tissue, John Barella, Jimmy Hawkins, Mark Menapace, Tom Cleary, and Aurora Capone-Soll

Einstein Medical Center Montgomery

A multidisciplinary team with staff from Quality, Safety, Facilities, Environmental Services, and Nursing took a close look at care for suicidal patients, with a special

emphasis on ligature risks in the hospital. Team members walked through the patient care areas and noted every item that could be used as a ligature or anchor point. They were amazed by the number of everyday items that could be dangerous to someone wanting to self-harm.

In addition to the standard process of maintaining 1:1 close observation, the hospital adopted a policy of removing ligature risk items from the suicidal patient's environment unless there was a medical necessity to have the item in the room. Staff was educated on this policy, but the team went a step further: They recreated the same eye-opening experience they had by setting up an activity station outside the cafeteria, at which staff were asked to identify the ligature risks in pictures of patient care rooms and bathrooms. This turned out to be a very powerful activity that was more immersive than most training exercises.

Alongside the focus on the safety of the physical environment, the Ligature Risk Team identified improvement opportunities in several other steps of caring for suicidal patients. As a result, the hospital now ensures that all personal items are carefully inventoried and secured by Protective Services in a timely fashion to keep the patient, staff, and visitors safe. The team also worked with Dietary Services to increase safety at mealtime by serving finger foods on disposable trays. Staff was re-educated on the safety considerations for performing 1:1 observation of a suicidal patient.

This team working together with an engaged staff throughout the hospital has led to increased safety for a high-risk population.

Improving Diagnosis

Dept. of Pharmacy and Dept. of Infectious Diseases—James Curtis, PharmD, MHA; Shafinaz Akhter, MD, PhD; Michael Edleman, PharmD; Ricky DiPasquale, PharmD; and Melissa Ilano, PharmD

Chester County Hospital - Penn Medicine

The Department developed a protocol that uses penicillin skin testing (PST) to identify patients who truly have an allergy to penicillin, as a thorough allergy history from the patient isn't always accurate, and an incorrect



▲ Members of the winning team for *Improving Diagnosis* from Chester County Hospital

reporting of hypersensitivity to penicillin may unnecessarily limit the patient's treatment options.

In the new protocol, a clinician identifies patients who would benefit from PST based upon allergy history and may order PST by placing a consult to pharmacy. The pharmacist provides the stewardship ID physician with the patient information, who orders PST once patient consent has been obtained. A pharmacist prepares, administers, and documents the skin test. After completing the test, a progress note is left in the patient's chart explaining the interpretation of the results; the attending physician is notified; and a letter is sent to the patient's primary care provider and primary outpatient pharmacy. The documented penicillin allergy is removed and replaced by either "Penicillin Skin Test Negative" or "Penicillin Skin Test Positive," along with who conducted the test, when, and any details regarding the results.

Since June 2018, 48 patients have received PST. All of them had a negative result, and the allergy was removed from each patient's profile. To assess the impact on patient outcomes, a cohort of patients who received PST was compared to a cohort of patients who were treated with aztreonam for more than 24 hours. There were fewer readmissions in the PST group when compared to the group that did not receive PST (9.1% vs 18%, respectively), suggesting that 12 patients would need to receive PST to prevent a 30-day readmission.

The reduction in readmissions demonstrates that removing or clarifying a penicillin allergy benefits the patient not only for the acute episode, but also for the rest of their lives when antimicrobials may be prescribed.



▲ Individual Impact winner, Char Boyd, from UPMC Hamot
▼ Long-Term Care Facility winners from Windy Hill Village



Long-Term Care

Tara Gregory and Falls Prevention Team

Windy Hill Village (a Presbyterian Senior Living Community)

The falls prevention team at Windy Hill Village, led by nurse aide and unit clerk Tara Gregory, has worked diligently over the past two years to decrease resident falls and improve resident quality of life.

The team has made process changes in the community that involve additional check-ins with the residents that are completed by the nurse aides at the beginning of each shift and 15–30 minutes before the end of each shift. These checks help to better anticipate resident needs, therefore preventing falls. They also allow for extra reviews to ensure care planned interventions are in place.

Through review of resident fall data, the team has identified those residents that are at highest risk for falls in each neighborhood. This information is reviewed regularly, revised as needed, and shared with the interdisciplinary team. Better sharing of information allows all disciplines to be more vigilant of high-risk residents and to make everyone aware that if they cannot meet a resident’s need, they should call for assistance and stay with the resident until nursing staff can meet the need. When working on the unit, all staff (e.g., nursing, dietary, housekeeping, maintenance, laundry, community life, therapy, etc.) must check-in with these residents, increasing visualization and recognition of potential needs.

The team provides ongoing education to all community staff and celebrates goals that are met throughout both the neighborhood and community. These celebrations of success ensure staff are aware of positive outcomes due to their diligence. Decreased numbers of resident falls and improved outcomes have been noted since the inception of this program.

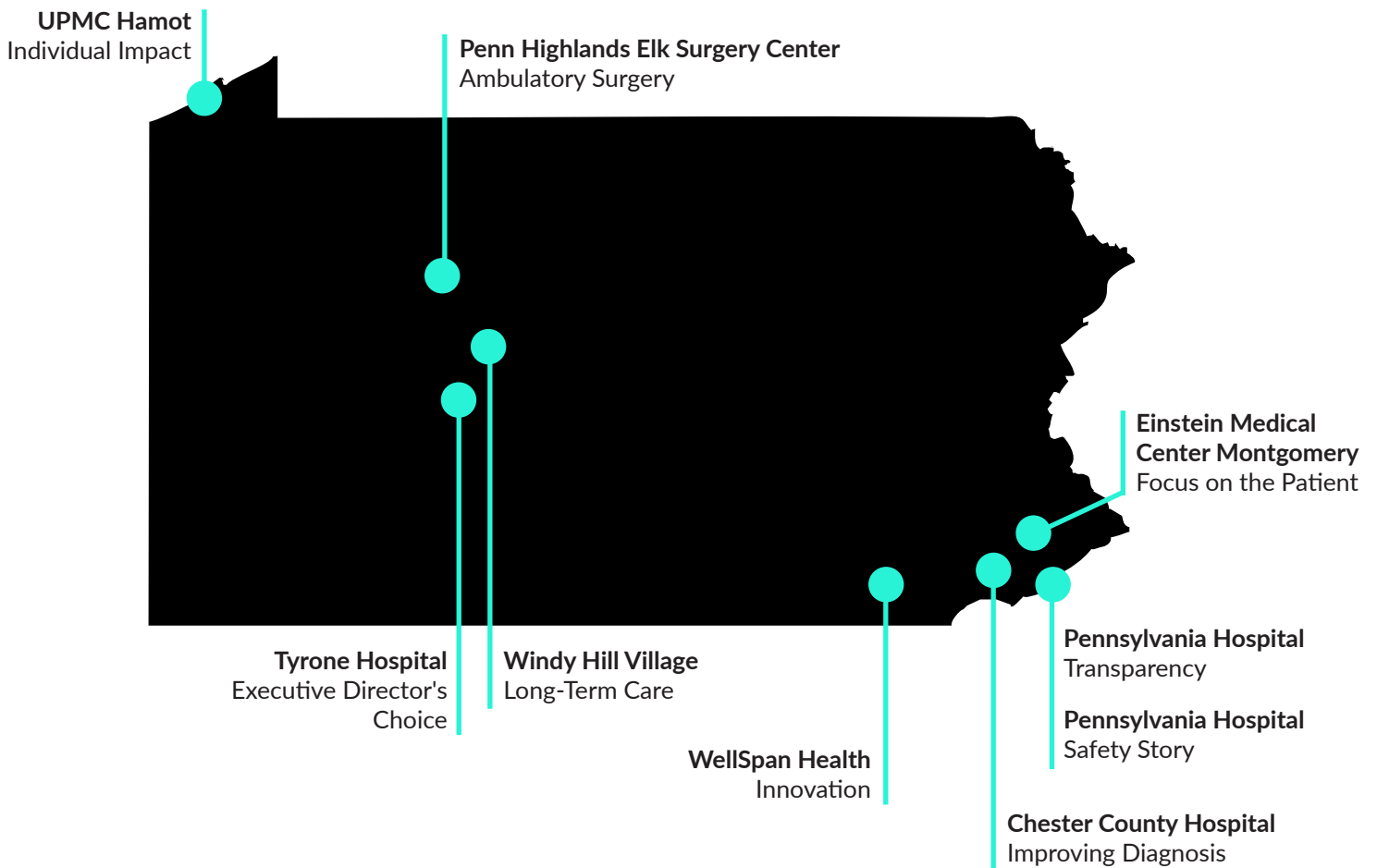
Individual Impact

Char Boyd, BSN, RN UPMC Hamot

In February 2019, a 17-year-old girl* presented to the Emergency Department (ED) requesting a pregnancy test. Triage nurse Char Boyd, RN, noted that she was accompanied by an adult man and woman claiming to be her stepbrother and his girlfriend. When the patient gave a birthdate that differed from what she was registered under, Boyd’s years in the ED and her training as a sexual assault nurse examiner kicked in.

Boyd asked the girl who her companions were, but the patient couldn’t give her “stepbrother’s” name. The girl also didn’t know where they were, stating they had driven from hours away and were only in town for a short while. She seemed nervous and looked to the older couple to answer questions. Thinking quickly, Boyd told the girl she needed to give a urine sample in the restroom behind triage while the man and woman sat in the waiting room. Once she was taken behind triage, the girl asked to leave, saying she didn’t want to wait for testing. Boyd reassured her that she would be well taken care of. She got

*Identifying details have been changed for privacy.



the patient a room and notified the charge nurse, case manager, and the local police about her concerns. The couple left before police arrived. The officers identified the patient as a 13-year-old Connecticut resident listed as a missing and endangered youth with high suspicion of being trafficked.

The International Labor Organization estimates there are 40.3 million victims of human trafficking globally, with hundreds of thousands in the United States. Eighty-eight percent of rescued victims report accessing healthcare while being trafficked. Sixty-three percent of those victims were treated in an ED while being trafficked. Three quarters of human trafficking victims are women and children.

The statistics are alarming, and yet limited training to identify victims of human trafficking is provided to healthcare workers across the United States. Before this event, Boyd had devoted herself to the hospital's sexual assault nurse examiner team for several years, supported and cared for its most vulnerable patients, and provided education to her peers in identifying victims of abuse. Boyd is nothing less than a hero for helping rescue that 13-year-old girl from trafficking.

Thank you to this year's judges:

- Diane Frndak, PhD *Robert Morris University*
- Candace McMullen, MHA, RN *PADONA*
- Dani Jurgill, RN *Patient Representative*
- Ariana Longley, MPH *Patient Safety Movement Foundation*
- Darryl Jackson, MD *Pennsylvania Department of Military and Veterans Affairs*
- Rob Shipp, PhD, RN *The Hospital and Healthsystem Association of Pennsylvania*

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Pressure Injuries in the Healthcare Setting: Even Superman Is **Not Immune**

Janette Bisbee[◇], MSN, RN-BC
DOI: 10.33940/HAPI/2020.3.6

[◇] The Hospital and Healthsystem Association of Pennsylvania
Disclosure: The author declares that they have no relevant or material financial interests.

In 2004, pressure injuries (then called pressure ulcers) got a lot of publicity when Christopher Reeve, the actor who played Superman in four major motion pictures, died from sepsis caused by an infected pressure injury on his sacrum.

Those of us in healthcare found this case compelling because of the irony that the ventilator-dependent quadriplegic who was synonymous with an impervious superhero could die from something as seemingly mundane as a skin wound. If Reeve, whose wealth enabled him to receive state-of-the-art medical care and round-the-clock nursing, could succumb to a pressure injury, how can healthcare providers prevent pressure injuries in vulnerable patients in the acute care hospital setting?

How big is the problem?

Despite years of research, development of evidence-based practices, and the National Quality Forum's designation as "Never Events,"¹ pressure injuries—sometimes mistakenly called bedsores—continue to affect more than 2.5 million Americans a year. Some 60,000 die from these injuries annually.²

Pressure injuries cause pain and suffering, degrade quality of life, lengthen hospital stays, and burden patients and families financially.³ They also increase already too-high healthcare spending. They cost an average of \$20,900 to \$151,700 to treat per injury, adding up to a whopping \$9.1 to \$11.6 billion annually.²

More than 17,000 lawsuits each year are related to pressure injuries. This diagnosis is the second-most common claim after wrongful death and more common than falls.²

Why haven't we made more progress?

Pressure injuries are common in the hospital intensive care unit. Caregivers in these units are challenged to provide preventative skin care for severely ill and medically compromised patients with multiple comorbidities. Treatment of these patients' multiple illnesses is frequently at odds with preventative skin care in patients who are:⁴

- Confined to bed
- Required to have the head of the bed raised more than 45 degrees
- Too unstable to be turned and repositioned
- Mechanically ventilated
- Being given vasopressors or steroids

Other risk factors include:⁴

- Lack of adequate nutrition and hydration
- Incontinence
- No or limited mobility
- Memory problems or dementia
- Co-morbidities such as diabetes or peripheral vascular disease
- Very high or low body mass index

Very young and elderly patients are at high risk for developing pressure injuries due to their frail skin and lack of adipose tissue.⁴ Patients who use a wheelchair have a higher risk of developing pressure injuries on their buttocks and sacrum.⁵ Even the medical devices that patients need, such as oxygen tubing and masks, tracheostomy tubes, casts, urinary catheters, and cervical collars, can cause pressure injuries without diligent monitoring and removal as soon as that is possible.⁶

Some pressure injuries really are unavoidable

The general consensus from a broad interprofessional group of wound care professionals is that, while most pressure injuries are avoidable, unavoidable pressure injuries do exist.⁷ The majority of unavoidable pressure injuries occur with gravely ill patients and those at end of life, due to multisystem organ failure.⁷

Skin is the largest organ in the body and fails like any other organ system.⁸ Skin failure was first identified in the 1800s by physician Jean-Martin Charcot, who noticed that patients nearing the end of life sometimes developed what he termed decubitus ominusus.^{8,9}

Through the years, this phenomenon has continued to be studied. An array of names have been used for terminal skin failure, including the Kennedy terminal ulcer, Trombley-Brennan terminal tissue injury, and Skin Changes at Life's End (SCALE).⁸

Unfortunately, despite scientific literature to the contrary, government and regulatory agencies continue to refrain from recognizing the existence of unavoidable pressure injuries in the acute care setting.⁴ If skin failure at end of life were acknowledged as frequently unavoidable, despite the consistent and accurate use of preventative interventions suggested by evidence-based best practice, many pressure injuries would lose their distinction as a quality measure and be more accurately recognized as a medical diagnosis.¹⁰

eight

WAYS HOSPITAL ADMINISTRATORS CAN PREVENT PRESSURE INJURIES

1

Make a commitment to the elimination of avoidable hospital-acquired pressure injuries. Recognize that the *prevention* of pressure injuries frees up healthcare staff time, saves money, decreases readmissions, and avoids regulatory problems and poor patient experience scores. Pressure injury prevention is money well spent.¹¹

Develop a multidisciplinary mindset. While often seen as the nurses' responsibility, pressure injury prevention requires an all-hands-on-deck approach. No individual clinician working alone, regardless of how talented, can prevent all pressure injuries. Frontline staff, who provide the majority of direct patient care, should be part of any interdisciplinary team.¹²

2

3

Change the hospital culture. Shift the goal from "our patients will receive the best care possible" to "our patients will receive the best care possible, which includes being free of avoidable hospital-acquired pressure injuries."¹¹

Use data to track improvement. Drill down on incidence and prevalence studies, adverse event reports, and root cause analyses to identify patient characteristics, interventions implemented (or lack thereof), and contributing factors by unit so that targeted interventions can be applied.¹³

4

5

Hire at least one certified wound care nurse to provide advanced practice knowledge and experience, deal with complex wounds, and lead your pressure injury prevention campaign.¹⁴

Educate, and then educate some more. Use competency testing to ensure effective and standardized wound assessment, prevention, and treatment skills. Simulation labs provide real-life scenarios and hands-on practice to enhance skills.¹⁵

6

7

Provide staff education regarding the goals and best practices of documentation. Many a healthcare provider has attended a deposition and attempted to defend care based on a medical record that is inaccurate, that is missing important communication regarding the care the patient received, or that does not meet recognized standards of documentation.¹⁶

Educate patients and families and make them part of the healthcare team by explaining the importance of pressure injury prevention and enlisting their help.¹⁷

8

Pennsylvania providers have a partner ready to help

Mounting the coordinated, multidisciplinary efforts needed to prevent pressure injuries is clearly a daunting undertaking. Fortunately, The Hospital and Healthsystem Association of Pennsylvania (HAP) has been working on this issue for a while.

Since 2012, HAP developed its in-depth understanding of the best, evidence-based ways to prevent pressure injuries through the Hospital Engagement Networks (HEN) and Hospital Improvement Innovation Network (HIIN), collaborative learning networks funded by the Centers for Medicare & Medicaid Services (CMS).

Together with Pennsylvania hospitals, HAP developed and shared resources, tools, and materials to enhance pressure injury prevention efforts, including:

- On-site hospital visits conducted by skin care experts and certified wound care nurses (CWCNs) to help hospitals review current practices and develop action plans for future success
- Data analysts who track and trend data, and provide this information to hospitals in formats that include “live” reviews of these findings using shared computer screens
- E-learning modules designed for staff and patient education which include a menu of strategies, change concepts, and specific actionable items that any hospital may choose to implement based on individual need¹⁸
- One-to-one focused attention, peer networking opportunities, a robust education calendar, and advisory council expert advice and input
- Membership in the pressure injury prevention project focus group provides hospital-specific identification and implementation of best practice interventions¹⁹

Now is your chance to develop your very own superpower: preventing avoidable hospital-acquired pressure injuries.

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264 HOURS

Mary Ellen Mannix

James Matthew Mannix was born on October 2, 2001. By October 13, he was gone. While the country was still reeling from 9/11, Mary Ellen Mannix and her family were struggling with a life-shattering crisis of their own. James was diagnosed with a congenital heart condition, though it was relatively common and treatable. However, his 11 short days in the hospital involved a series of unfortunate events: medical mistakes, miscommunications, and ultimately a death that should never have happened. Although James' story tragically ended after only 264 hours of life, it was just the beginning of his mother's story of discovery and her journey toward patient safety advocacy.



You work in the Head Start program. Can you tell us a little bit about what that is?

Head Start began in the mid-1960s as a federal program, and it continues today. It's one of the best evidence-based programs supporting children's development and their health. Head Start is generally thought of as preschool age, 3 to 5. But I specifically work in the Early Head Start realm, which is 0 to 3. In recent years, most Early Head Start programs are done via a home visiting model. A number of states, including Pennsylvania, were awarded grants to incorporate the Early Head Start model within private childcare partners throughout the state.

I offer coaching to Early Head Start teachers. Basically it's more in-depth training and technical assistance. It's really supporting their professional development, what they would like to get better at, what skills they would like to refine. And in addition to that, statewide, I am the health consultant for the Early Head Start - Child Care Partnership, and that really is pulling in everything health and safety. So from diapering procedures to making sure vaccinations are compliant, to supporting programs in parent education outreach around health specifics. I also facilitate a statewide Health Services Advisory Council made up of stakeholders from the Early Head Start community.

Another big focus of yours is around patient advocacy. How would you define that?

I would start by defining advocacy. Advocacy is speaking for those who can't speak. It may be people; it may be issues or elements. Some people are animal advocates, some people are ocean advocates, earth advocates, some people are child advocates. So in patient advocacy, it's speaking for those in healthcare who cannot or do not know yet that they need to speak up for themselves.

Why is patient advocacy such a personal issue for you?

In 2001, shortly after 9/11, we welcomed James into the world. Before his birth, we learned that he "might" have a medical condition—a **discrete coarctation of the aorta (COA)**—that "might" need some follow-up. To be candid, I had to ask the doctor to spell it. But we took it in stride and trusted the care team to look out for him.

Like most expecting parents in the technology age who've just learned their soon-to-be-born child has a health risk, I did a Google search, and what I found scared the living bejesus out of me. Coarctation of the aorta most often occurs in boys, and children born with any kind of congenital heart defect—which is what a COA is—**generally have a lower birth weight**. James was eight pounds four ounces and was the largest of the four children I delivered, God bless him.

I focused on our blessings. We had health insurance, we were aware of what was happening, both parents were present, and we set things up as we were instructed by my physicians and the healthcare team. Yet, almost anything that could have gone wrong did. We learned through the legal discovery process that James' care involved broken medical equipment, hospital-acquired infections, failure to rescue, care not done in accordance with best practices, etc. But I am jumping ahead.

Right after delivery, James was taken to the NICU [neonatal intensive care unit] as a precaution. At some point tests confirmed the prenatally diagnosed cardiac defect. His care team advised a procedure to correct the discrete coarctation of the aorta. It was not explained nor stated that James would be undergoing open-heart surgery. **Nor were any other clinically appropriate alternatives suggested or discussed.**

We trusted the counsel of the clini-

A congenital condition when the aorta is narrow

Babies with a COA generally have a lower birth weight... James was 8 pounds!

Open heart surgery was NOT the only option!

cians and James was taken for the procedure. A few hours later, we were allowed to visit briefly with our 2-day-old son. He had a scar down the middle (which I had never been told about) and tubes coming out of his chest. The tubes were quite jarring. I didn't even know what they were for. The CICU [Cardiac ICU] staff said everything went as expected though. Evidently the care team always expected open-heart surgery with deep hypothermic circulatory arrest (DHCA). James' dad and I had no idea. We had never even heard of DHCA until well after it was done to our son. During our few minutes visiting the care team, they said, "The next time you visit you can probably feed him." I was shocked.

I looked at the nurse and the critical care anesthesiologist and stated clearly, "Please don't rush him. So long as he is okay, I can wait." Then we were ushered out of the CICU. A few hours later we called back to the CICU and asked if we could see our son. We were told no. Hours passed. Eventually, we were told he had a "sudden and serious event." More hours would pass before we were permitted access, only to see our son hooked up to an endless battery of tubes. Many more than before.

We asked, "What happened?" No one would answer us.

This wall of silence continued for days. James was put on extracorporeal membrane oxygenation (ECMO) and placed in a medically induced coma, breathing through a ventilator. Prior to his birth, I had never been in a CICU before. We did not know what was happening or what had happened between James' arrival and the doctor telling us "coarct babies come home quick" to seeing James "tied" down to a hospital isolate. My sister who is a nurse visited once during James' hospitalization. The nurses talked to her. In turn my sister reported that a nurse practitioner confessed there was an "event" the previous night, and





“Well, could you tell me who will be overseeing his care this weekend?” my husband asked.

“What difference does knowing that make now,” the world-renowned-has-a-procedure-named-after-him-surgeon stated more than asked.

The rest of the story is unnecessarily complex yet brief, just like James’ life. He passed on October 13, 2001. My earlier Google search had informed me that **if a COA is undiagnosed, a person might die in their 40s**. James was 11 days old. He did not die from anything he was born with.

It took years for me to learn everything that I’m telling you now, outside of knowing what his condition was called and how much he weighed. I did give permission for them to take him and potentially do a procedure to widen the aorta, if they needed to. I learned well after 2001 that at that time, the standard of care of treatment for my son’s condition was a **thoracotomy**—not open-heart surgery. I’d never even heard of a thoracotomy until I had to ask lawyers what happened to my son.

So my patient advocacy very much started with the birth of my children, my oldest one now being 30. None of them, none of James’ older three siblings ever had such a serious medical condition that we were in the hospital. I was already advocating in the education system based on my children’s needs at home and in the classrooms where I taught. After my newborn lived and died so quickly, in such a traumatic way, my advocacy shifted to patient safety on a whole new level.

Perhaps being a teacher informed my persistent questioning. I just kept asking, “Well, why? Why did that happen?” I realized that as special as my children are, and as special as James is, he’s just James. If it could happen to him, it could happen to somebody else. And I knew I had children who would grow up, and they might have kids

according to this nurse practitioner “they had lost him” but were able to revive him. None of this had been communicated to us, his parents. But still, though dire, things seemed stable, until a neurologist informed us that James, who was neurologically sound and healthy at delivery, was showing serious signs of brain damage. The neurologist report stated that “sometime between the start of surgery and his examination James had suffered serious insult to his brainstem and cortex.”

Ever the fighter, James appeared to start improving. He was removed from ECMO. He could even have some breast milk. Just as our hopes were returning, we were told that he had been rushed emergently to surgery. Hours passed, but a phone call came letting us know James was back in the CICU, and we could go see him. James was swollen to the size of a 9-month-old and was purple, black, and blue. He was back on ECMO, but the tubes were now coming out of the left side of his chest and his side was open. His little newborn hand was swollen. And black. Black.

We asked to speak with the surgeon but were told he wasn’t available and was “busy.” We needed to speak with the man making decisions in our son’s medical care immediately.

In a daze, as we slumped back to our room, fate intervened, and we crossed paths with James’ surgeon—the same surgeon who did the initial “correction.” He admitted he would not be in the hospital over the weekend.

— If a COA goes undiagnosed, a person might die in their 40s.

— Thoracotomy? Surgery to open your chest... ≠ open heart surgery

— Restorative Practice? Evidence-based peace and community-building strategies to repair harm

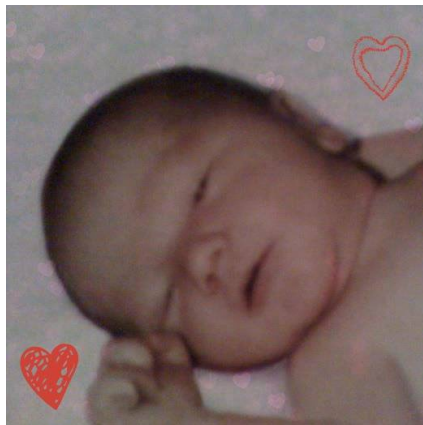
themselves. I didn't want this system to be what they have to endure. They've endured it as young siblings trying to understand why a baby brother didn't come home. I know how painful it is as a parent to bury a child. I didn't want them to endure that as well, especially if it was preventable—like James' death.

If others can benefit, then all the better. So yes, my patient and pediatric advocacy is very much informed by and surrounded in my son James. It came full circle recently.

In 2010, 2011, 2012, I advocated that all infants born in hospitals and birthing centers should be receiving a pulse ox screening to see if they have critical congenital heart disease. It's now the new standard of care that children across the country receive pulse ox screening 24 hours after delivery and before leaving the hospital or birth center. Pulse ox screening not only identifies critical congenital heart disease, it can uncover additional undiagnosed conditions. In September, my first grandchild was born. She had the test, and my daughter and son-in-law know the joy of bringing their baby home.

You mentioned “the lawyers.” In your book, *Split the Baby*, you share about a five-year battle with the legal system to find out what happened, a battle that you never intended to undertake.

I'll preface all of this with saying what I know now without question is there is space and a place for everybody within the healthcare system—physicians; nurses; patients; lawyers; and, hopefully in the future, restorative practice facilitators or restorative justice practitioners. **Restorative practice** is the social science of evidence-based peace and community-building strategies to repair harm(s). For a post-adverse event process to be restorative, all those impacted by a harm voluntarily participate in repairing or addressing it to bring resolution.



▲▲ The Mannix children visiting James in the hospital ▲ Newborn James

When James died, I went home without a child. They gave me a box. There were things in the box that he never wore because he was here so shortly. There was a clip of hair, which has since disintegrated. I knew when I first received that box, my son was gone but I would never forget him.

Before his funeral, I reached out to the hospital and asked for his medical records. I just wanted whatever had his name on it. I figured he's not going to have a birthday cake with his name on it. I thought his medical records were the biggest part of his life, I'd want that. For some reason though, I was not getting any response from the hospital. I offered to donate a rocking chair, but I really didn't hear anything back.

Later that month, in between crying and trying to pack lunches for my kids, I picked up a *Philadelphia* magazine that I believe somebody

actually gave us to read while we were in the hospital with James for those 11 days. My brain couldn't handle reading anything at the time. But that day the story I saw on the front cover, no less, was titled something like, “The Doctor, the Lawyer, and the Little Boy.” When I saw that in November 2001, it was all I could focus on, that literally was my life then—the doctor and the little boy. I started reading and it was about a boy, who at 6 months of age, was treated for coarctation of the aorta with open-heart surgery. He left the hospital severely brain damaged. Different hospital, same surgeon. *Somebody else knows how to live like this.* I didn't know what to do as a postnatal mother with no child. I wanted to talk to the mom.

I called the author, who shared that all the information he had received was through her lawyer. I reached out to the lawyer for her number. It's an amazing thing. Never in a million years would I think I'd be calling some bigwig lawyer; let alone anyone who was mentioned in a magazine; I'm just a preschool teacher.

But when your child dies, the world's a very different place. In the raw and early grief, nothing matters anymore. Names, titles, they're all meaningless. So I picked up the phone, and he answered directly. I told him what I was looking for, and he said he would reach out and see.

The mom was understandably managing her own emotions and trauma at that time, so we were unable to connect. We never did. In reflection, I figured my child actually died. Hers was still here. I have since learned through my experiences, when your child dies, you feel like the angel of death. When you walk in a room with parents, especially parents whose children either have the same condition as yours or went through something similar, you're scary, almost a threat to them. Sometimes it feels like they want to embrace you—and this is my



◀ The Mannix family at their first fundraiser in James' memory benefiting The Make-A-Wish Foundation

Catholic schoolgirl perspective—as an early penance. Like if they're nice to me, if they do a lot in memory of my son and in memory of others, then their child will be okay. It's that they are still on the other side of the bridge where they're still making deals with God, the universe, or whatever or wherever there may be power on their side. The reality is every breath of your child is a gift.

I'm over here on this side of the bridge, I don't have any deals to make with anybody anymore. I just want to cut through the crap (excuse the vernacular) and get to what's actually happening in life. The lawyer reached out again and said he truly was sorry that he wasn't able to make that connection but wanted to help me. Since people in my world were already starting to disappear... The world gets very small and dark, especially in early grief after a child passes. It is a very hard thing for anyone to deal with. Here was somebody volunteering to talk with me, to "walk" with me and my misery. Somebody who would be willing to listen to the story. Therein started a five-year formal relationship with a very bigwig law firm and other lawyers in Philadelphia and elsewhere.

Spending time with the lawyer, I learned he lost a son as an infant as well. And this lawyer was the first one who described for me the best

way to help somebody else understand what it's like to lose a child. And it's only a minuscule bit like it, but it can be like losing a limb. His living son, who also ended up arguing our case, had a son who died as a stillbirth a year after our son died. It was serendipitous in that I wasn't looking for a lawyer. Perhaps later on I might have, I don't know. However, that particular lawyer kind of popped up really from a gift somebody left in our house for us to look at when we had time. Crazy.

The father/son legal team were compassionate and understanding. I don't advocate for people to go through a lawsuit. I advocate actively to try every other mode possible before going that route. Transparent, compassionate communication is key. I'm hopeful that our systems, both legal and medical, will start to meaningfully engage with restorative justice modalities in the adverse health outcomes discussions.

My book is called *Split the Baby: One Child's Journey Through Medicine and Law*. The term "split the baby" was actually argued in court regarding what happened to James. James was pretty much split between medicine and law. They just took him. Medicine, specifically the pediatric cardiology profession took him, did what they wanted with him. Law took him and did what they needed to. But I'm sitting here as the mom

without him saying this isn't the way to heal anybody after there's harm, and whether that harm includes death or not, there is healing that can be done after medical error in our systems. The emotional and financial tolls of iatrogenic injury [relating to illness caused by medical examination or treatment] and death on our systems are heavy and expensive.

The AHRQ [Agency for Healthcare Research and Quality] has introduced a process called CANDOR, Communication and Optimal Resolution, which has the potential to be an effective restorative justice modality in post-error resolution. There's opportunity for those who have been harmed to speak to what they need versus those who did the harm coming in and saying, "This is what you'll need now." Patients and families who have been harmed as a result of medical error should have the opportunity to ANSWER the question, "What would help you now?" That starts the conversation for healing. And that's a whole lot more than what I got, because I got nothing.

Having those who shared in the experience of iatrogenic error meet and share discussion in some way post-event is better than a lawsuit. I do want to make that clear, lawsuits are tough. Lawsuits are also sometimes necessary.

What about the rest of James' care team?

He had a long list of caregivers in his short life as a direct result of the errors in care. There is one for whom I have a certain level of respect, the doctor that offered hope for healing when I did not realize I would need it. This double board-certified neonatologist/pediatric cardiologist is a uniquely compassionate person and talented physician. Despite our wish that the events that led us to meet had never happened, I am grateful for the personal conversations we shared.

He is the doctor that initially informed us of James' "sudden and serious event." During those moments he said he was sorry. He never said what he was sorry for. This was the physician that came back to check on us during the week of trying to repair the errors. He never provided any answers or insights. He did offer us a human and (what I would later come to appreciate as a) courageous expression of empathy for the tragic situation our newborn son was unexpectedly facing.

At the time of filing the lawsuit, I personally requested that this doctor not be named as a defendant. He had expressed sorrow and shown us some kindness. He wasn't involved with the lack of information before and at consent. Nor was he a party to the final operation that was never consented to, yet guaranteed James' death. Unfortunately, this doctor was also victim to the lack of informed consent the surgeon provided. Another victim to a broken and inhumane system. He did end up being named in the lawsuit. We were on opposite sides during the trial. However, post-verdict and post-trial motions, once I guaranteed that I was not seeking any additional legal avenues, he agreed to a discussion with me. We met privately in the lobby of a hospital and talked about what happened to James and what happened since.

We actually ended up serving on the same inaugural board of a nonprofit. While we arrived there in opposing ways, we absolutely had a shared mission—to save babies, and their families and clinicians, from unnecessary harm and death. We were successful, and some new standards of care have been established in the care of newborn infants as a result—specifically the pulse ox screening for critical congenital heart defects that I mentioned earlier.

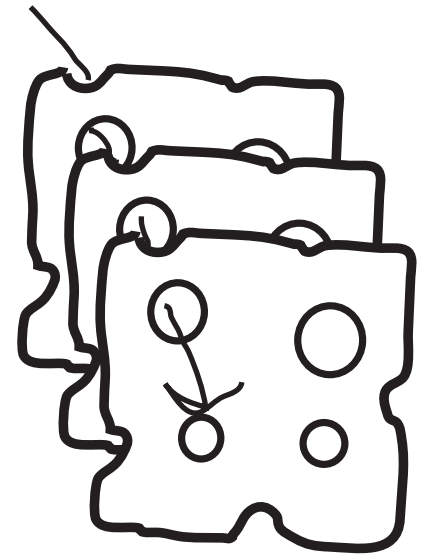
A surprising proclamation by James' surgeon years later was that "informed consent is a complete fallacy"—that patients and their family members can never truly be informed of healthcare procedures and the risks that each procedure holds. What are your thoughts on that?

If you're putting forth an informed consent process that isn't acknowledging in some way that you believe it's a fallacy, then you've created that first hole in that **Swiss cheese theory**, and somebody's going to fall through it—if a lot of your patients aren't falling through it already. Especially in my case where the informed consent process was one page that had three words scrawled on a blank line. There was a lot of empty space and then some signatures at the bottom.

The informed consent process should always be a part of your CQI [continuous quality improvement] plan. I have seen systems improve their informed consent process. I've seen new programs, videos, digital ways of improving this process be developed, tested, and implemented to the benefit of patients, families, and the clinicians caring for them. I'm not saying that's the final answer, but there are additional methods to improving the informed consent process. If you are a healthcare clinician or administrator that is not 100% convinced of the process, it is your responsibility to work to improve it.

And honestly the least of these improvements is asking the patient—it's simple **Teach-back**—"What did you hear, can you tell me?" Instead of asking, "Do you have any other questions?" Which is what I was asked before James was taken away from me and my husband. I didn't even know how to spell coarctation. The question should be, "Can you tell me what you just heard?" You'll get a much better idea if this person is with you—if they're on the same page or if you're in two separate rooms.

Swiss Cheese Theory? When multiple layers of protection are put into place but things are still able to fall through the cracks.



Teach back? Repeat back what you've heard.



◀ The Mannix family in 2019
▼ Mannix speaking at the Society to Improve Diagnosis in Medicine's annual conference

A growing trend in healthcare is to include the “patient perspective.” What advice would you give to somebody who truly wants to do that and not just make a token gesture?

I would start with their biggest challenge, the toughest case. If I were a hospital or healthcare system CEO or VP of Quality or even a risk management professional and I actually wanted the patient perspective, I'd look through all of those lawsuits and find the case that most troubles me. (And maybe it never got to a lawsuit because as we know very few patients and families ever are able to get representation.) I would look for the one (or two or three) that would scare me the most to pick up the phone and call and talk to the person behind that case number. That's where you start.

You start where the biggest problem is. And if you're truly afraid to do it within your own system or you have others who have power to refuse, don't start there. Seek out a sister system, organization, or peer in another part of your state or part of the country who would have that kind of a patient and family available to you to start that discussion. The closer to home you are the better the perspective you will receive. Finally, don't just include the patient “perspective.” The patient must be included in ACTION steps. Let's go beyond trends and employ a new best standard for patient care in the 21st century: care informed by restorative practices.

And be kind. If you're kind, whether it's in the hospital or anywhere, you're probably doing okay.

Mannix was one of the first members of The Walking Gallery—Jacket #32 “Never Enough”!





Split The Baby

Split The Baby

Split The Baby

Mary Ellen

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