

PATIENT SAFETY

December 2020 | Vol. 2, No.4

Sepsis in the time of COVID-19

How to overcome racial disparities in healthcare: An interview with Queen Quet

Same names. Same birthdates. Both. Making a **wrong-patient error** is easier than you think.

DECEMBER 2020

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
		1	Anthony: wrong-site surgery	2	3	4
6	Ethel: wrong-side surgery	7	8	9	John: wrong-procedure	10
13	14	Emily: wrong patient	15	16	17	18
20	Edward: wrong-site surgery	21	22	23	24	William: wrong-procedure
27	28	Philip: wrong-side surgery	29	Vera: wrong-patient	30	31

New year's resolution: No more wrong-site surgeries.

How can we make sure this never event **NEVER** happens?

JANUARY 2021

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
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LETTER

From the Editor



Regina Hoffman,
Editor-in-Chief
Patient Safety

We enter the winter holiday season amidst the worst health crisis most of us have ever known. It is so difficult to think about anything other than masks and vaccines and how to eradicate an invisible enemy. In fact, it can be all-consuming. However, an additional challenge is how to keep our heads out of the sand in relation to all the other issues that affect patients and their loved ones daily. One of our goals at *Patient Safety* throughout this pandemic has been to continue to shine light on the ongoing patient safety crisis that plagues our healthcare system day in and day out.

Wrong-site surgery (WSS) is one of those things that is never supposed to happen. I experienced a WSS myself, as a former patient safety officer who was working for the Patient Safety Authority (PSA) at the time. I assure you, if it can happen to me, it can happen to you. While this may be an old topic in patient safety, it is still very real and still happens—daily across the globe and 1.42 times weekly in Pennsylvania! Take a look at the various ways PSA staff Robert Yonash and Matthew Taylor broke down and analyzed this data to help give us the clearest picture of these events to date. Our collective challenge is how to make significant improvement in this area. The guidelines are out there. Why are we not following them?

I had the privilege and honor of sitting down (virtually) with Queen Quet, chieftess and head-of-state for the Gullah/Geechee Nation, to discuss some of the unspoken challenges we face in healthcare. Patient safety isn't always about what goes right or wrong in the healthcare setting. It is also about those patients who never reach our doors for various reasons. Patient safety and quality of care starts in our communities. I invite you to learn a little history about a nation within our nation and how we can start to meet the needs of all our communities right now. Adding to the dialogue about ongoing patient safety issues, Cait Allen, our managing editor, spoke with Dr. David F. Gaieski, director of Emergency Critical Care at Jefferson Health, to talk about sepsis, its interplay with COVID-19, and why it's a big deal.

Additional articles include a unique perspective related to health IT and wrong-patient errors; events related

to prone positioning, a common body position for treating patients with acute respiratory distress syndrome; a patient perspective from someone who lived through childhood polio, underscoring the importance of vaccinations; and several others.

Finally, we at *Patient Safety* and the PSA **thank** healthcare workers and **all** essential employees for your dedication and sacrifices through these most trying times. We wish you a very **safe** holiday season!

A handwritten signature in black ink that reads "Regina".

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 inform and advise clinicians, administrators, and patients on preventing harm and improving safety, by providing evidence-based, original research; editorials addressing current and sometimes controversial topics; and analyses from one of the world's largest adverse event reporting databases.

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

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ACKNOWLEDGMENTS

A special thanks to our reviewers:

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

Together we save lives

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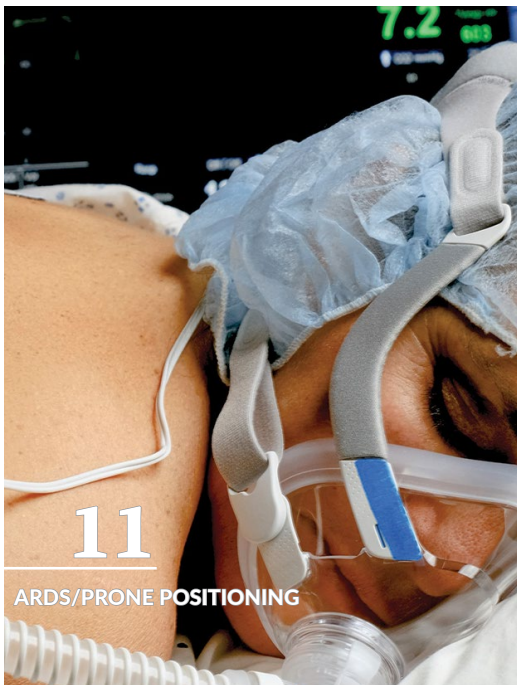
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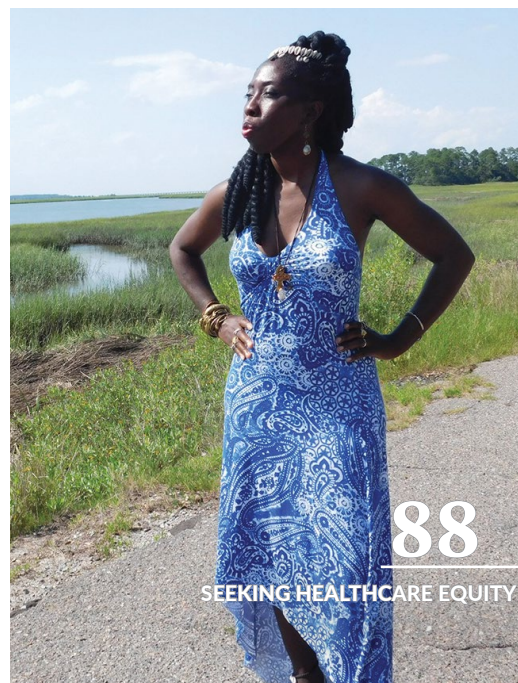
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SEEKING HEALTHCARE EQUITY

“I Never Had a Choice: My Lifelong Struggle With Polio”

By Cathy Casares Reynolds

In 1921 on Campobello Island, Franklin D. Roosevelt began his legacy, not as the 32nd president of the United States nor as the man who would lead the Allied nations to victory over Nazi Germany, but as the most famous survivor of polio.

While on vacation at his family's home in New Brunswick, Canada, FDR's legs became progressively weaker, and by the third day, they could no longer support his weight. After several misdiagnoses, he eventually discovered he had contracted infantile paralysis, i.e., polio. As the name suggests, the disease typically presents during infancy, and most children develop immunity before they turn 5; however, for those who are afflicted, polio can cause lifelong paralysis or death.¹

Long before COVID-19, polio was the most feared disease in the world. In 1952 alone, before a polio vaccine was available, almost 60,000 American children were infected, thousands were paralyzed, and more than 3,000 perished.² Three years later, the United States began widespread inoculation for polio, and by 1979, it had been eradicated across the country.

Since then, the vaccine has been so effective, some have begun to question its necessity. Few people today know someone personally who has been stricken with this horrific disease. No longer is polio what took the life of a loved one or left a neighbor unable to walk. Polio is now a theoretical concept, and the hundreds of thousands of lives taken or disabled have been distilled to “why FDR was in a wheelchair.”

I had polio. We need the vaccine.





Bulbar Polio



Much of what I know about contracting the virus is what I was told by my mother, as I was only 2 years old at the time. In 1954, my parents noticed I was stumbling occasionally, had difficulty going up steps, and was dragging my right leg. We were on an Air Force base in Alaska when I developed a dangerously high fever (>105 degrees Fahrenheit) and was taken to the base hospital, where I was diagnosed with poliomyelitis. The high fever lasted several days, and there was concern if it persisted much longer I would have brain damage. Thankfully, the fever broke. I was flown to Valley Forge General Hospital, a former Army hospital, to continue my treatment. Once discharged home, I vaguely remember my mother doing therapy exercises with me in a highchair, swinging my leg with a weight attached to it, and needing a leg brace. Around this time, the government began administering the new polio vaccine, but I did not receive it since I had just contracted the virus. Once considered “recovered,” from about 3 years old until I was 8 I did not need to wear braces, but I dragged my right leg when walking and my right foot rotated outward. In 1961, polio vaccines were administered in schools as part of a broad prevention campaign, but again I did not receive one, because the doctors my mother spoke to were worried my case was recent enough to reactivate the virus.

At 8 years old, on Langley Air Force base in Hampton, Virginia, I had an operation called a Jones procedure to address my dragging foot. A tendon from my right big toe was transplanted to my right instep, and all my toes on my right foot were fused to restore minimal heel-to-toe movement for walking.

In my teens and adulthood, I learned to live with general discomfort in mainly the right leg, but as I aged, the pain became more severe. My right knee began to bow in, as did my ankle, affecting my gait. I worked as a nurse at a nursing home, and I used to cry after my shifts walking back to my car from the pain of being on my feet.

I saw several orthopedic doctors for answers about the change, but it was an orthopedic resident in an emergency room one night who suggested I go and see Dr. Mary Ann Keenan, an orthopedic surgeon in Philadelphia and a leading expert in this area. Dr. Keenan knew immediately what was happening, and it was then I learned about post-polio syndrome (PPS), a condition that presents as muscle weakness and pain 40 to 50 years post-onset of disease. It can be difficult to diagnose PPS since the symptoms mimic changes that often come with aging.

When I was a child and they felt I had “recovered,” I was told I did not need to wear leg braces anymore. Dr. Keenan explained that we now know those damaged muscles should be supported long-term with braces or other devices, because years of overusing



▲▲ After recovering from acute polio illness circa 1954, Cathy Reynolds' right leg showed signs of muscle damage and weakness.
▲ Since being diagnosed with post-polio syndrome in adulthood, Cathy has needed to wear bilateral, below-the-knee braces on both legs.

Bulbar polio refers to infection of the bulbar region of the brain, consisting of the cerebellum, medulla, and pons.^{4,5} This area is responsible for many key processes necessary for life, such as respiratory function, chewing, and swallowing.⁴

Iron lungs were used to assist polio patients with breathing. During the height of polio epidemics, it was not unusual for hospital wards to be filled with these machines.⁶



▲ Cathy, about 3 years old, using a wheelchair with a brace on her right leg



▲ “Natural changes with aging, combined with the effect of polio as a child, bring new challenges, but the more I learn about my condition, the better I can care for myself.”

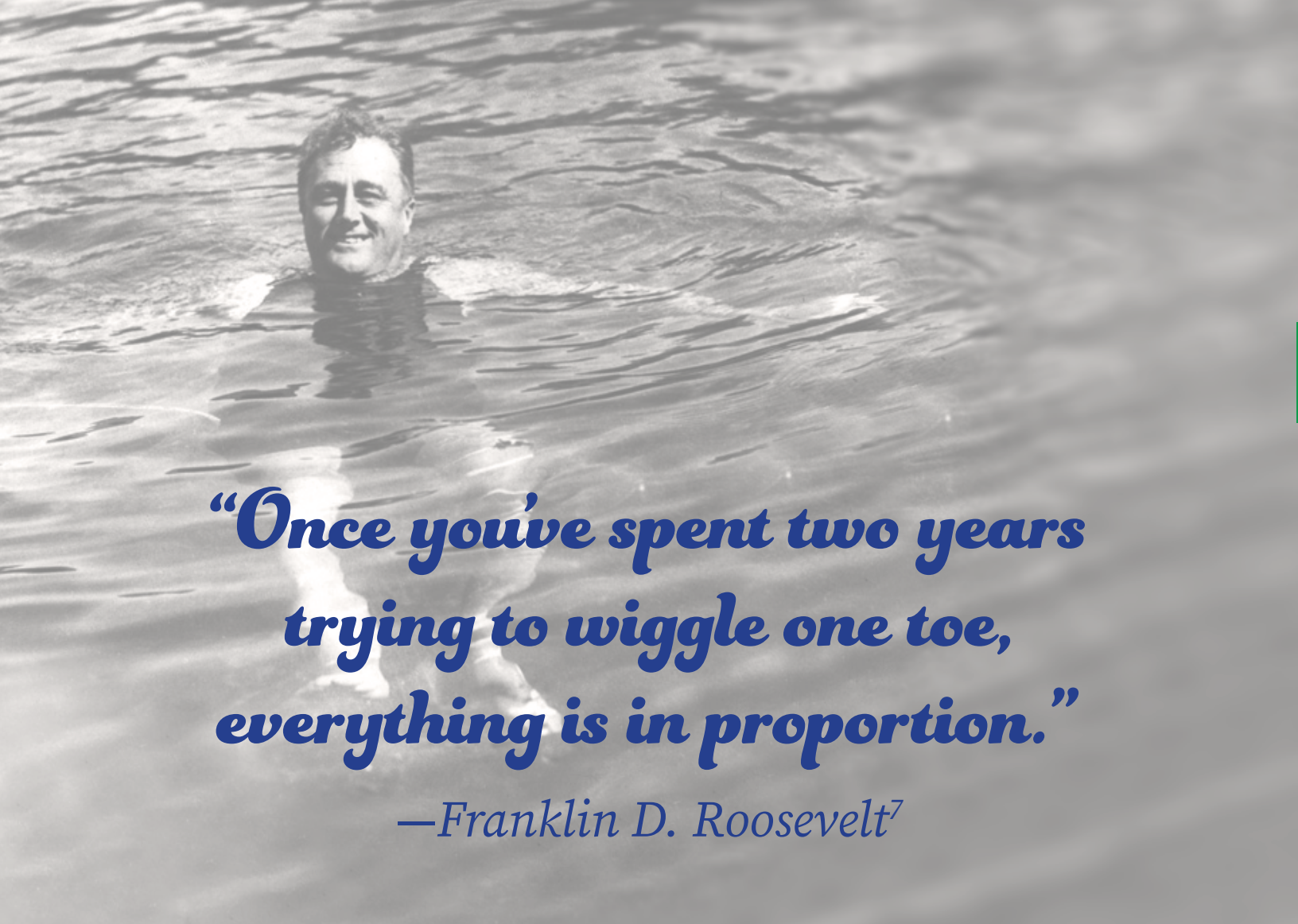
other muscles to compensate for the ones damaged by polio will cause them to give out. So, in middle age, I had another surgery: right triple arthrodesis (right ankle fusing) and iliotibial band lengthening to put my knee back in alignment. Another surgery, another long, painful recovery, and another leg brace. But this time it went up to my thigh, and I had to wear it for so long, it became a member of the family—“Alice.” Six months later Alice and I parted ways, and I transitioned to a below-the-knee brace on my right leg. Unfortunately, the muscles on my right leg were still weak and my left leg continued to have to overcompensate. Eventually, the left leg muscles began to give out too, and I since have had two wear braces on both legs.

Today, I live with chronic discomfort and am unsteady on my feet, so falling is a concern. I have general weakness and learned that muscle pain is your body saying you are doing too much; you need to rest. If I have an active day, the next day I really need to take it easy. I have to listen to my body. I need to conserve what muscle I do have, because I will never be able to rebuild what was damaged. I was lucky to not have bulbar polio, which affected the breathing muscles of victims who wound up in iron lung machines. I have lived with the effects of this disease through nearly every stage of my life. It is all I have known, but others can escape my fate and not suffer like I have.

Before the pandemic, the vaccination rate for polio was only 92%,³ and for months the news has been flooded with stories about the decline in vaccine rates for parents afraid to visit the pediatrician. But don't let the fear of one disease keep you from preventing another. Everyone just wants to protect their kids, but there was no polio vaccine when I was a child. I wish my parents had the choice to protect me.



“
Everyone just wants to protect their kids, but there was no polio vaccine when I was a child. I wish my parents had the choice to protect me.”

A black and white photograph of Franklin D. Roosevelt swimming in the ocean. He is smiling and looking towards the camera. The water is choppy with small waves.

***“Once you’ve spent two years
trying to wiggle one toe,
everything is in proportion.”***

—Franklin D. Roosevelt⁷

Photo courtesy of the Franklin D. Roosevelt Library archives

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Prone Positioning in Patients With Acute Respiratory Distress Syndrome and Other Respiratory Conditions:

Challenges, Complications, and Solutions

By **Lea Anne Gardner, PhD, RN**◇
DOI: 10.33940/data/2020.12.1



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

Acute respiratory distress syndrome (ARDS) and respiratory failure are characterized by hypoxemia (i.e., low levels of blood oxygen). Infections such as influenza and COVID-19 can lead to ARDS or respiratory failure. Treatment is through supportive measures. In severe cases, patients receive oxygen through a ventilator and, when appropriate, are placed in a prone position for an extended period. A retrospective review of events submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) identified 98 prone position-related events in patients with ARDS, respiratory failure, distress, and pneumonia from January 1, 2010, through June 30, 2020; 30 events were associated with COVID-19. Skin integrity injuries accounted for 83.7% (82 of 98) of the events. The remaining events, 16.3% (16 of 98), involved unplanned extubations, cardiac arrests, displaced lines, enteral feedings, medication errors, a dental issue, and posterior ischemic optic neuropathy.

Keywords: *patient safety, prone, proning, acute respiratory distress syndrome, ARDS, respiratory failure, pneumonia*

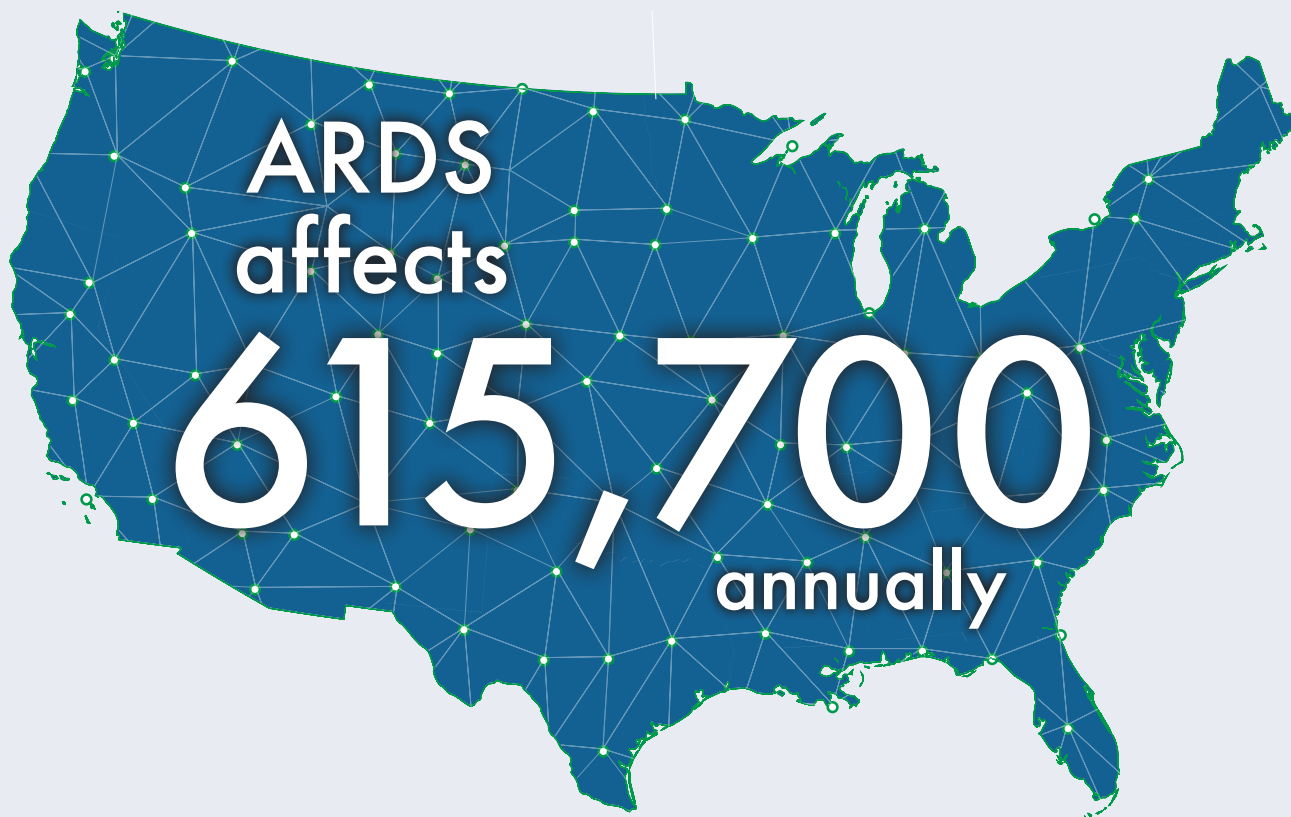
Introduction

Acute respiratory distress syndrome (ARDS) and respiratory failure are serious respiratory conditions characterized by severe shortness of breath, labored and unusually rapid breathing, possible low blood pressure, confusion, and extreme tiredness.^{1,2} ARDS is estimated to affect approximately 615,700 people in the United States annually, based on a 2014 incidence rate of 193.4 per

100,000 population, resulting in nearly 192,000 deaths.³ Patients diagnosed with ARDS are assessed and grouped into one of three categories based on severity of hypoxemia: mild, moderate, and severe. Seventy percent of cases are classified as moderate or severe.⁴ Mortality rates for patients with mild, moderate, and severe hypoxemia are 27%, 32%, and 45%, respectively.⁵ Another metric used to evaluate this syndrome is a survival measure that evaluates the length of mechanical ventilation. Median mechanical ventilation in survivors was 5 days (IQR 2–11 days) for patients with mild ARDS, 7 days (IQR 4–14 days) for moderate ARDS, and 9 days (IQR 5–17 days) for severe ARDS.⁵ See **Box 1**.

In 2017, there was an estimated 1.14 million discharges from U.S. hospitals with a diagnosis of respiratory failure and mechanical ventilation.⁷ Between 2002 and 2017 the incidence (i.e., new cases) increased from 249 to 455 cases per 100,000 adults and hospital mortality decreased from 34% to 23%.⁷

Both conditions can result from inflammation and edema in the lungs that reduce the amount of oxygen getting into the blood and body's organs leading to hypoxemia, i.e., low blood oxygen levels.^{3,8-14} Sepsis, pneumonia, and shock are the most common ARDS risk factors.^{3,15} COVID-19 is an infection that can lead to hypoxemia, pneumonia, and ARDS.¹⁶ Patients with COVID-19 that develop ARDS are difficult to diagnose since their symptoms can fall outside the seven-day onset criteria. Li and Ma (2020) identified an onset time of COVID-19 ARDS between 8–12 days.¹⁷ The Centers for Disease Control and Prevention (CDC) noted this ARDS timeframe for COVID patients.⁶



Box 1. Berlin Criteria for Identifying Patients With ARDS⁵

- **Time Frame** – symptoms will appear within seven days of known clinical insult or new or worsening respiratory symptoms*

- **Identified three ARDS hypoxemia categories:**
 - *Mild, formerly identified as acute lung injury*
 - *Moderate*
 - *Severe*

- **Hypoxemia categories are based on PaO₂ (partial pressure of oxygen)/FiO₂ (fraction of inspired oxygen) ratios**
 - *Mild: 200 mmHg < PaO₂/FiO₂ ≤ 300 mmHg*
 - *Moderate: 100mmHg < PaO₂/FiO₂ ≤ 200 mmHg*
 - *Severe: PaO₂/FiO₂ ≤ 100 mmHg*

- **Oxygenation**
 - *Mild – Positive-end expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) ≥ 5 cm H₂O*
 - *Moderate or Severe PEEP ≥ 5 cm H₂O*

- **Chest Radiography** – bilateral opacities—not fully explained by effusions, labor or lung collapse, or nodules

- **Respiratory failure not fully explained by cardiac failure or fluid overload**

The Berlin definition removed pulmonary capillary wedge pressure (cardiac hemodynamic) monitoring and the phrase “acute lung injury” from the American European Consensus Conference (AECC) definition.⁵

*Median time to ARDS in COVID-19-positive patients ranges from eight to 12 days.⁶

Supplemental oxygen is provided to patients with hypoxemia. Patients with moderate or severe hypoxemia usually require mechanical ventilation to provide additional oxygen to the lungs. In some cases, additional oxygen alone does not increase oxygen levels. One therapy showing improvement in oxygenation with mechanical ventilation is prone positioning, i.e., placing patients facedown, for an extended period of 12 or more hours.^{10,11,18}

Placing patients in a prone position redistributes lung tissue which is suspended from the back chest wall and reduces compression of the lungs by the heart and abdominal organs.⁹⁻¹² Better lung ventilation and perfusion are anticipated to influence better gas exchange.^{9-12,18} See **Box 2** for more information on ARDS and respiratory failure.

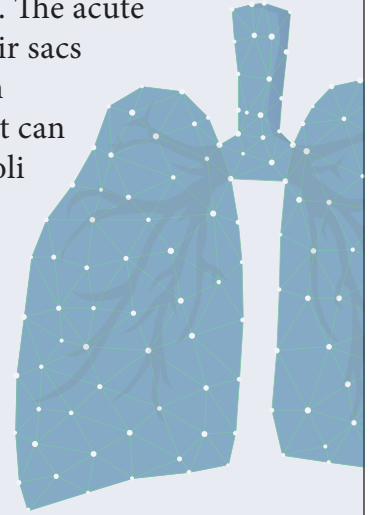
Prone positioning received a strong recommendation for use in adult patients with severe ARDS. Guidelines identify using this position for more than 12 hours a day.^{22,23-25} Extended time periods in prone position may create the potential for patient safety issues, such as pressure-related injuries, unplanned extubations, and disconnected catheters. Prone positioning has also been suggested for shorter periods of time in conscious COVID-19 patients requiring basic respiratory support.²⁶

To learn more about the challenges and complications associated with prone positioning within Pennsylvania hospitals, a retrospective mixed methods study was conducted.

Box 2. ARDS Pathophysiology and Respiratory Failure Definition

A brief review of ARDS may explain the reasoning behind prone positioning. The acute phase of ARDS is characterized by diffuse alveolar damage. Alveoli are tiny air sacs where blood exchange of oxygen and carbon dioxide happens. Inflammation accompanied with fluid and protein buildup causes damage to the alveoli that can lead to atelectasis, i.e., partial or complete collapse of the lung when the alveoli become deflated or filled with fluid.¹⁰ This situation is usually found in the lower, dependent part of the lungs.

When patients with ARDS lie in a supine position, the fluid collects in the lower part of the lung, making it harder for oxygen to enter the blood stream.^{9,10} Decreased amounts of oxygen in the blood stream leads to hypoxemia.^{10,11} In addition to the fluid buildup, the weight of the heart and abdominal organs compresses the lungs, restricting their movement.⁹⁻¹¹



Respiratory failure is a serious breathing condition that arises when oxygen cannot get into the blood or carbon dioxide builds up, resulting in damage to tissue and organs.² Respiratory failure can be acute or chronic. Acute respiratory failure is defined by one of the following:

1. A pulse oximetry (SpO₂) < 91% breathing room air or a partial pressure oxygen (pO₂) < 60 mmHg; OR
2. A partial pressure of carbon dioxide (pCO₂) > 50 mmHg with a pH < 7.35.
3. A pO₂/FiO₂ ratio < 300 mmHg
4. PO₂ decrease or pCO₂ increase by 10 mmHg from baseline¹⁹

Conditions such as pneumonia, opioid overdose, or strokes can lead to acute respiratory failure.² Patients with this condition may need oxygen through tubes or being intubated and placed on a ventilator.²⁰ Not all respiratory failure, pneumonia, or ARDS patients are intubated.^{19,21}

Methods

A query of the Pennsylvania Patient Safety Reporting System (PA-PSRS)* database was performed. The events were searched to identify prone positioning-related events between January 1, 2010, through June 24, 2020. The free-text fields within the event reports were searched using keywords “prone,” “proning,” “acute respiratory distress syndrome,” “ARDS,” “respiratory failure,” and “pneumonia.”

A three-step process was performed on the initial data set to identify events involving patients placed in a prone position due to respiratory conditions. The phrases “prone position” and “prone positioning” throughout the remainder of this article refer only to patients placed in this position as part of treatment for a respiratory condition.

- A random sample of events from the initial data query were reviewed to find out the type of words used to describe these events. This information helped identify keywords for a search of the queried event reports to separate out prone position-related events.
- This search used the following keywords: “ARDS”, “respiratory failure”, “surgery”, “pressure”, “ulcer”, “DTI (deep tissue injury)”, “blister”, “sore”, “wound”, “dental”, “eye”, “skin integrity”, “stage 2 (pressure ulcer)”, and “bed”. Events containing these keywords were read to confirm prone positioning-related events occurred.
- A manual review of the remaining events was performed to confirm no additional prone positioning-related events were missed.

*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).¹³ All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Table 1. Respiratory Conditions Identified in PA-PSRS Prone Position Event Reports, n=98

Respiratory Conditions		Number of Patients	Subset of Patients With Positive COVID-19 Test*
Acute Respiratory Distress	Syndrome	42	3
	Syndrome Not Specified	2	2
Respiratory Condition Not Specified		26	21
Acute Respiratory Failure		19	3
Pneumonia		9	1
Total		98	30

* This subset represents patients diagnosed with COVID-19 between March and June 2020.

Events excluded from this analysis were surgical; radiological procedures; falls; non-prone positioning-related skin integrity events; errors related to treatment; complications where the patient was placed or found in the prone position; references to patients with a history of prone positioning; and events where the word “prone” was used to describe a circumstance or situation, such as the patient is “prone to fall” or the patient completed their “prone exercises.”

Demographic analyses of patient age, gender, and number of hospitals submitting reports were performed. Qualitative analyses focused on the types, location, and number of complications, and equipment and medication challenges.

Skin integrity complications were counted using two different methodologies. The first method was to count the number of events identified in the event description. The second method involved a change in 2018 regarding the reporting of skin integrity events in PA-PSRS. In 2017, the Patient Safety Authority (PSA) and the Pennsylvania Department of Health released *Final Guidance for Acute Health Care Facility Determinations of Reporting Requirements for Pressure Injuries Under the Medical Care Availability and Reduction of Error (MCARE) Act*.²⁷ The guidance outlines principles on the concept of harm, the definition of pressure injuries, and what type of pressure injuries are reportable. PA-PSRS was enhanced to include these principles in the form of additional mandatory questions, including reporting the total number of pressure injuries in a single report. The new reporting capabilities began in January 2018.

To provide a context of the extent of prone positioning-related skin injuries, the location and number were identified. Reported number of pressure-related injuries beginning in January 2018 was used in the analysis. Pressure-related injuries reported in the PA-PSRS “Other” event category† does not require responses to

the mandatory reporting questions. All skin integrity events reported prior to January 2018 and skin integrity events reported in the “Other” category were identified, counted, and included in the analysis based on event text descriptions. Two events identified “several” deep tissue injuries occurred. To address the missing information, the average number of multiple skin injuries per patient was calculated to be 3 injuries. This number was inputted where missing information or general statements such as the word “several” described the number of skin integrity events.

Results

Demographic Analysis

The initial data query identified 192 event reports. Review and analysis of these events narrowed the final data set to 98 event reports from 44 different hospitals across Pennsylvania. COVID-19-related events accounted for 30.6% (30 of 98) of the event reports. Respiratory conditions reported in the event descriptions were grouped by similar conditions. Patients with COVID-19 were categorized based on the type of respiratory condition reported. When there was no respiratory condition noted in patients diagnosed with COVID-19, they were grouped separately. See **Table 1**.

Patients’ ages ranged from a newborn to a 109-year old patient. The median patient age was 60 years (interquartile range = 49 to 71 years). Males accounted for 61.2% (60 of 98) of prone positioning patient safety events while females made up 38.8% (38 of 98) of the population.

An analysis revealed 24.5% (24 of 98) of the event reports identified the use of electric proning beds. The remaining event reports, 75.5% (74 of 98), did not identify the type of bed used, electric versus manual.

†PA-PSRS has an event description category labeled “Other” where miscellaneous adverse events or events determined not to meet the predefined categories are reported.

Qualitative Analysis

Event Categories

Event reports were classified into four categories based on combining information from the PA-PSRS event types and the qualitative analysis: skin integrity, complications of treatment, errors related to treatment, and equipment-related issues. Skin integrity was the predominant event category, 83.7% (82 of 98). Next were complications of treatment, 8.2% (8 of 98); errors related to treatment, 4.1% (4 of 98); and equipment-related issues, 4.1% (4 of 98).*

Skin Integrity Injuries

This analysis focused on all skin integrity issues, i.e., pressure injuries, blisters, and skin tears. Blisters and skin tears were identified in 14 and 3 event reports, respectively. In 42.9% of patients with blisters, 6 reported the appearance of only a single blister; the remaining events identified blisters with pressure injuries. Two of the 3 skin tear reports identified a single skin tear; the third report identified a skin tear and pressure injuries. All other skin integrity event reports were combinations of pressure injuries.

Many patients had more than one skin injury. Over half of these reports, 54.9% (45 of 82), identified instances where 2 or more skin-related injuries occurred per patient. The total number of skin injuries reported was 175. Five patients had 5 or more pressure injuries. See **Figure 1**.

Body Locations

Face and head injuries accounted for half of the skin injuries, 50.9% (89 of 175). Legs and feet accounted for 19.4% (34 of 175). See **Figure 2** for the distribution of injuries.

A closer examination of the face and head injuries reveals cheeks accounting for 29.2% (26 of 89); the remaining injuries by order of frequency are lip, nose, chin/throat, face, ear, forehead/head, and eye. See **Figure 3**.

Complications of Treatment

Repositioning

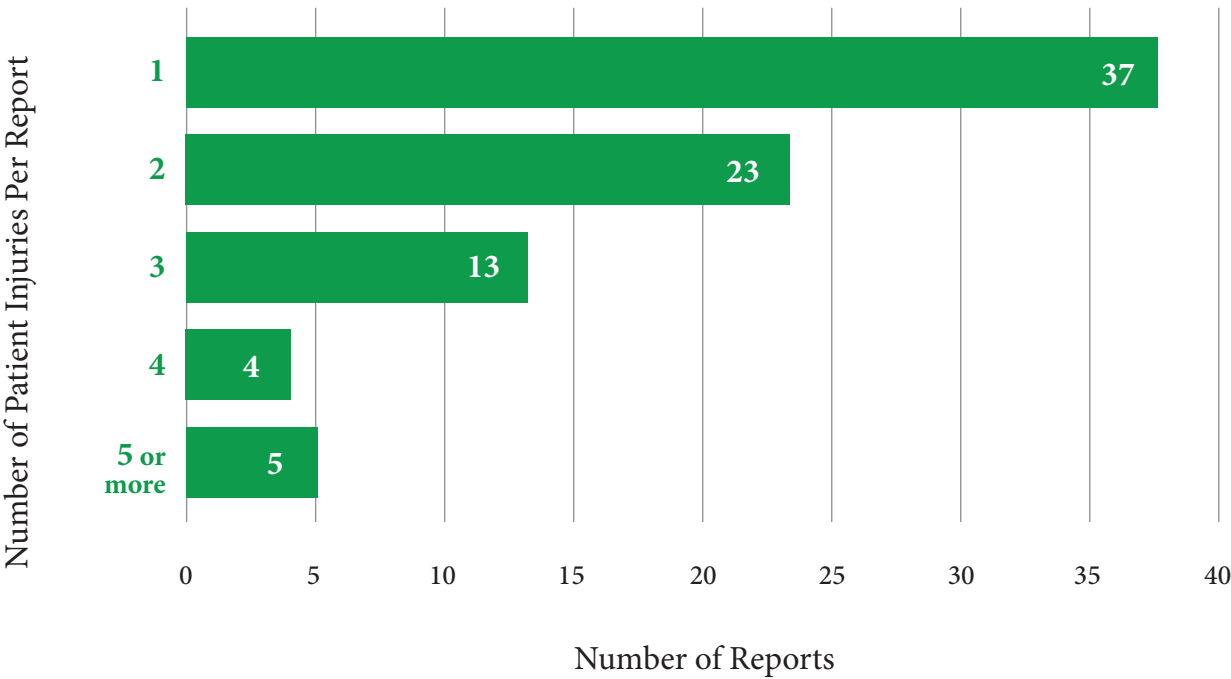
Three complications occurred when repositioning patients.

A patient being turned from prone to supine position went into cardiac arrest and was intubated and transferred to a higher level of care.

A patient being turned from supine to prone position went into cardiac arrest shortly afterward. The patient was unsuccessfully resuscitated.

When turning and repositioning a patient to the prone position their central lines were caught on the bed rails and inadvertently pulled out. Peripheral lines were placed.

Figure 1. Number of Skin-Related Injuries Per PA-PSRS Report, n=82



*These numbers do not total 100% due to rounding.

Figure 2. Number of PA-PSRS Skin-Related Injuries by Anatomical Location, n=175

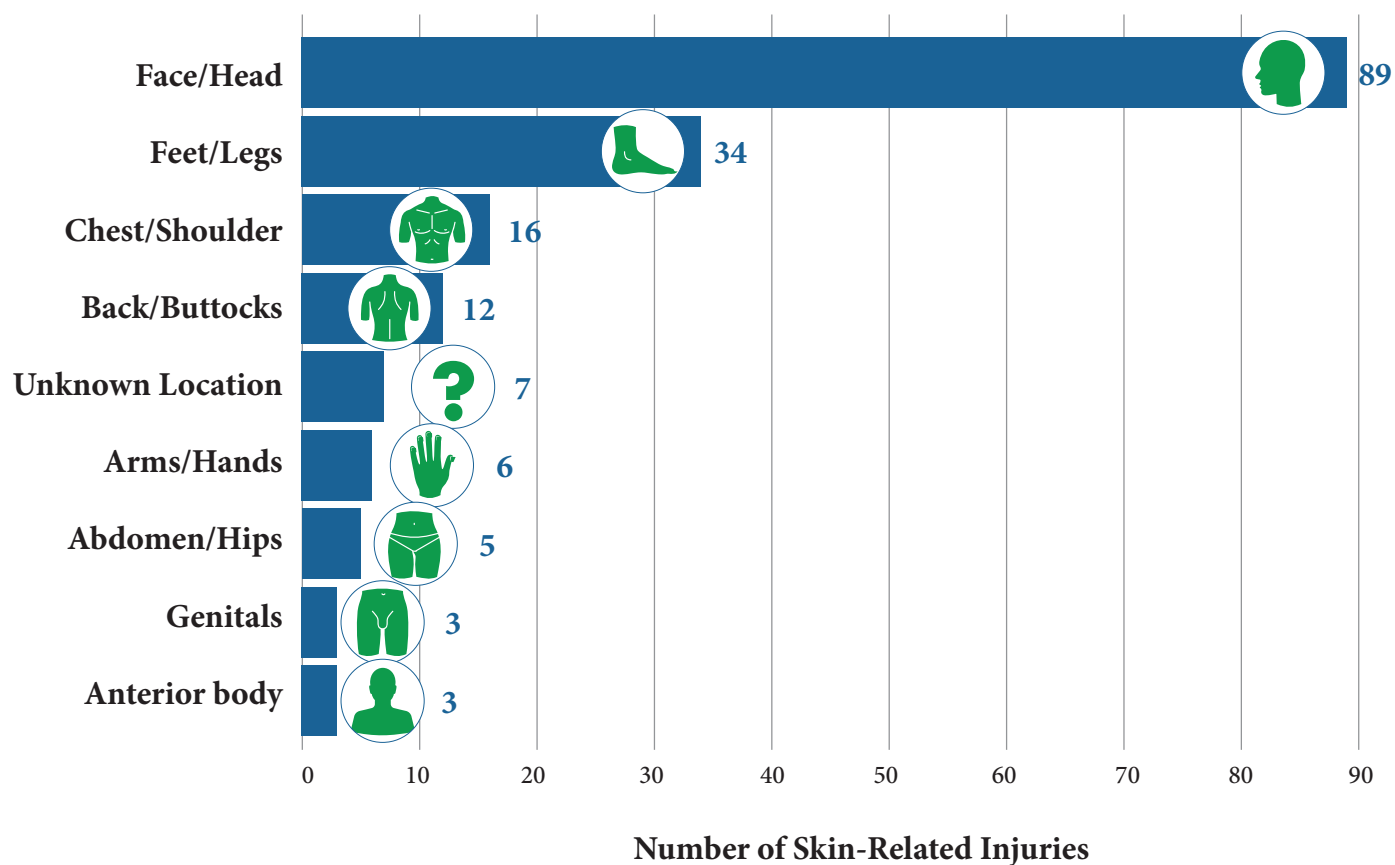
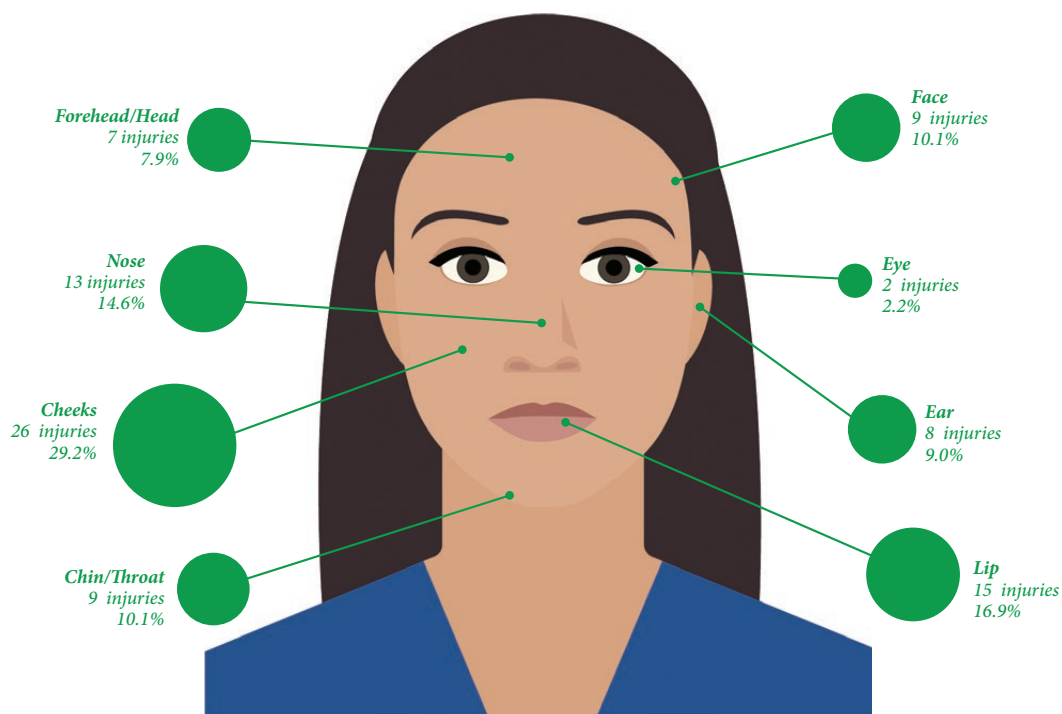


Figure 3. PA-PSRS Facial and Head Skin-Related Injuries, n=89



Unplanned Extubations

Three respiratory events involved unplanned extubations.

An infant's alarm sounded for bradycardia when staff noticed the endotracheal tube [ETT] was no longer in place.

While repositioning the patient's head and arms, staff heard breathing sounds and the patient began to desaturate [i.e., lose oxygen].

A soft ETT holder was used to maintain the patient's skin integrity when proning. The respiratory therapist and nurse assessed the position of the tube regularly. The next day, while staff was repositioning the patient, the ETT slid out of the holder due to the adhesive being soaked with secretions.

All three patients were reintubated without any reported sequelae.

Other

Two events identified dental and ophthalmologic complications.

A patient [in prone position] had a chest X-ray that noted a foreign body. A tooth was found and removed in the OR.

A patient placed in prone position [for extended period] developed posterior ischemic optic neuropathy and lost their vision permanently.

Errors Related to Treatment

Medication Errors

Three medication errors were identified surrounding the use of neuromuscular paralytic agents and sedation. One event involved an increase in the patient's analgesic instead of the sedative. No patient harm was noted. A second error involved a wrong drug administered instead of a neuromuscular blocking agent. The third event involved an inadequate amount of sedation for a patient receiving a neuromuscular blocking agent:

Patient with COVID-19 was intubated, paralyzed, and placed in prone position. The patient developed new onset of hypertension, particularly in response to stimuli. Concern for inadequate sedation while paralyzed. Investigation found that [sedation] was not actually infusing into the patient. Line was reprimed and restarted.

Enteral Feeding Issues

There was 1 event reported where the enteral feeding was not restarted:

Patient was placed in prone position during his treatment. The dietician noted the patient's enteral nutrition was being held during proning due to risk of aspiration. Dietician researched current guidelines, which recommend start feeding patients within the first 24–48 hours if medically appropriate. Dietician collaborated with medical team and new protocols/guidelines were established.

Equipment Issues

The 4 equipment events were related to availability of electric proning beds.

Discussion

Patient Selection and Preparation

Prone positioning is not appropriate for all patients with severe respiratory conditions. Candidates for prone positioning are assessed to confirm there are no contraindications. The list of contraindications is based on current medical literature and is a general, not comprehensive, list of conditions.

Preparation requires having protocols in place; trained healthcare professionals,^{30,32} including a physician present in case the ETT becomes dislodged and reintubation is needed; a checklist of necessary equipment, such as padding for body and head;^{29,33} extra electrocardiogram (EKG) leads;^{29,33} dressings to prevent pressure injuries;³³ equipment to monitor the patient's oxygen levels; and, when appropriate, medications such as neuromuscular blocking agents (NMBAs)^{23,25,34} and sedation.^{22,31}

Skin Integrity Injuries

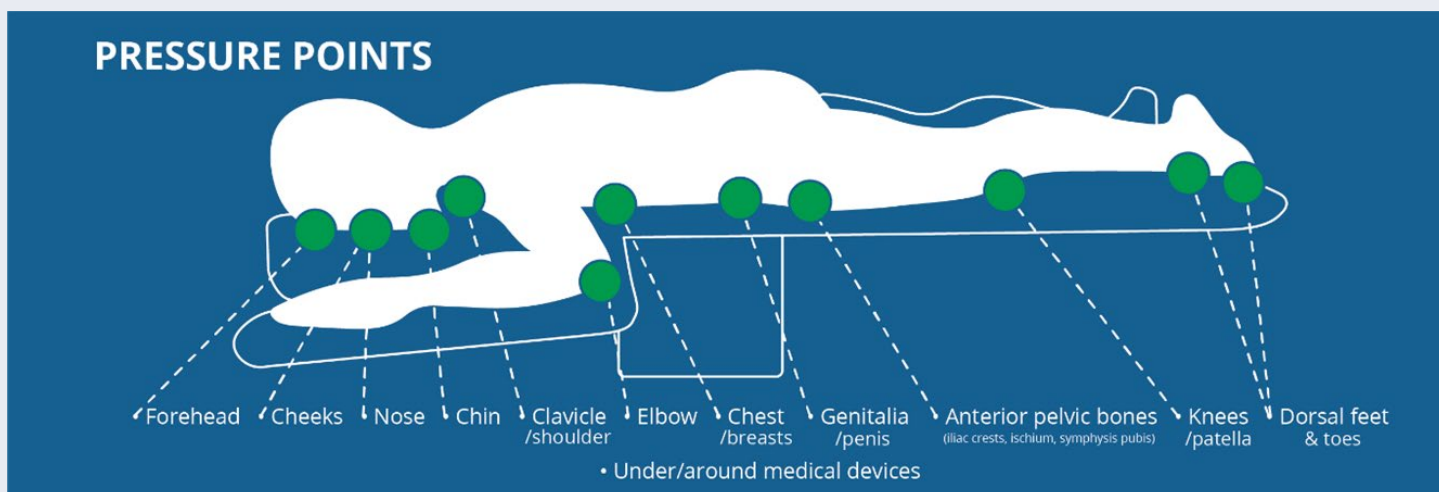
Skin injuries are a recognized major complication of proning that may result from patients lying for extended periods of time (i.e., 12 or more hours) in a facedown position coupled with the potential use of NMBAs and sedation.³⁵

Even though all skin integrity issues were included, most events are pressure injuries. A pressure injury is localized damage to the skin and/or underlying soft tissue, usually over a bony prominence or related to a medical or other device.³⁶ It can present as intact skin or an open ulcer and may be painful. Injury occurs because of intense and/or prolonged pressure, or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, comorbidities, and condition of the soft tissue.^{36,37}

The following are evidence-based recommendations to address and mitigate pressure-related injuries:

- With manual proning, change positions every two hours, placing alternating patient limbs following swimmer's position. The head is turned with the arm extended up along the side that the patient's face is pointed. The opposite arm is placed at the side of the patient.^{28-31,33}
- Place patient at 30 degrees reverse Trendelenburg.^{28,31}
- Assess pressure points frequently for nonblanchable redness or breakdown.^{28,31}
- C-letter shaped pads can be used to prevent facial skin injuries; repositioning of the face is with every pronation or when redness is observed.³⁵
- Apply soft silicone multilayered prophylactic dressings to pressure points on the face.^{29,33}
- Head is placed on prone pillow extending above the mattress.^{28,35}
- Check that the ETT is not pressed against the corner of the mouth/lips.³¹

Figure 4. Pressure Points Associated With Prone Positioning



**Used with permission from the National Pressure Injury Advisory Panel (NPIAP). Copyright 2020 NPIAP*

- Routinely check the position of tubes and lines; look for signs of injury due to the tube's location.^{28,31}
- Manage moisture: suction secretions, use liquid skin protectants and sealants on face. Place cloths under the mouth to capture any liquid that is draining from the patient's mouth.^{29,30,33}
- Mouth care: Make sure the tongue is inside the mouth. May use a small bite block.^{33,38}
- Remove anterior EKG lead and relocate EKG leads to the patient's back to continue monitoring the patient's cardiac status without creating pressure points.^{28,29,31}
- Confirm no tubes such as urinary catheters and IV lines or unsecured devices, including EKG leads, are not under the patient where they can create pressure points.^{28,30,31,33}
- Empty any drains or ostomies²⁸⁻³⁰ and pad around stoma site³³
- Position pillows under the patients upper and lower torso to alleviate as much pressure as possible on bony prominences and organs.^{30,31,38}
- With male patients make sure the penis is hanging between the legs with the catheter secured.³¹

Complications of Treatment

Repositioning: Central and Intravenous Line Disconnections

During preparation to turn a patient, the following activities can reduce the chance of dislodged lines.

- Ensure all lines are secure, not kinked, and long enough for the turn.^{29,31,39}

- Check lines to confirm they are free of equipment.
- Disconnect arterial line from the pressure bag. Cap the arterial line at the T-piece.²⁹

Unplanned Extubations

Unplanned extubations create a life-threatening situation. Evidence-based recommendations to mitigate harm include:

- Protect and secure the patient's airway and ETT.³⁰
- Have a physician present in case any issue arises with the ETT.³¹
- Manage moisture: suction secretions, use liquid skin protectants and sealants on the face. Place cloths under the mouth to capture any liquid that is draining from the patient's mouth.^{29,30,33}
- Routine checks on the equipment holding the ETT in place to confirm it is dry and secure.

Ophthalmologic Issues

Lying face down for extended periods of time can lead to facial and ocular edema. Intraocular pressure has been shown to increase within 10 minutes of placing a patient in the prone position and to persist even at 30 minutes after a proning session ended.⁴⁰ Ophthalmologic complications can include conjunctivitis, corneal abrasions, anterior ischemic optic neuropathy, and posterior optic neuropathy.⁴⁰ Evidence-based recommendations include:

- Eye care: use ophthalmic lubricant and tape eyelid shut horizontally to prevent corneal abrasions.^{29-31,33,38}
- No direct pressure on eyes.^{28,31}

Prone Positioning Contraindications*

Conditions leading to increased intracranial pressure^{13,28-30}



Spinal instability³¹



Facial trauma or surgery in the last 15 days^{30,31}



Cardiac pacemaker implantation in the last two days^{13,22,30}



Unstable fractures of spine, femur, rib cage, pelvis^{13,29,31}



Burns $\geq 20\%$ of body surface^{22,30}



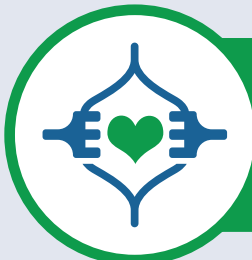
Other underlying disease, with a life expectancy of less than a year^{22,30}



Conditions with massive hemoptysis needing urgent surgical or radiological treatment^{13,22,28}



Tracheal or thoracic surgery in the last 15 days^{13,22,28}



Deep venous thrombosis or pulmonary embolism treated in the last two days^{13,30}



Severe hemodynamic instability, recent cardiac arrest^{13,22}



Pregnancy^{13,22}



Increased intraocular pressure or recent ophthalmic surgery^{13,22,30,31}



*This list is not comprehensive

Errors Related to Treatment

Medication Errors

Neuromuscular blocking agents and sedation are used in the management of ARDS.³⁴ To confirm the right medications and dosages are being delivered, routine monitoring is necessary. The 3 events did not provide specific information about potential contributing factors for the medication errors.

A previous study on distraction using PA-PSRS data identified medication errors accounting for 59.6% of distraction-related events.⁴¹ This study identified medication errors where something “wrong” happened, e.g., wrong drug, wrong rate, and wrong route accounted for 34% of errors in two years’ time.⁴¹ Given the severity of the patient’s illness and location, it is possible that distraction may have played a role in the errors, but no conclusions can be drawn.

Enteral Feeding Issues

Trophic or full nutrition enteral feedings are recommended to begin within 24–48 hours in critically ill patients.^{42,43} To protect patients with enteral feedings from aspirating, recommendations are to hold enteral feedings starting one hour prior to turning the patient.^{42,43} Not all patients have enteral feedings; however, here are patient safety recommendations when feedings are ordered:

- Turn off enteral feedings one hour before proning to reduce chance of aspiration. Resume after proning as ordered.^{29-31,33,42,43}
- Restart enteral feedings, if medically appropriate.⁴²⁻⁴⁴
- Place the patient’s head of bed in reverse Trendelenburg, 25-degree elevation, if enteral feedings are restarted.⁴⁵

Equipment-Related Issues

One-quarter of the events reviewed identified the use of an electric proning bed. The rest of the events do not indicate the type of bed (i.e., electric or manual) used so it was not possible to determine whether electric or manual proning was used in most events. What was identified was electronic proning bed availability accounted for the equipment-related events.

The choice of an electric versus a manual bed to prone a patient is not in question. Decisions about the type of bed used should be based on factors such as patient safety, staff readiness and experience, and cost. For example, turning a patient to a prone position when intubated requires at least five to six staff, including a physician and respiratory therapist.^{28,29,31,35,38}

There is a paucity of information about items to consider when deciding on the type of proning beds to use. One organization shared its process in making a decision, including the pros and cons of the two methods.³⁸ Easy access to assess a patient, improved safety, and lower cost were identified when proning patients manually.³⁸

Limitations

Event reports submitted to the PSA are self-reported. There are no requirements about reporting specific information on this topic, so condition-specific information is unavailable. For example, the identification of medical conditions is based on event report descriptions. PA-PSRS data does not have ICD-10 (International Statistical Classification of Diseases and Related Health Problems revision 10) codes.

The occurrence of complication(s) based on whether it was the first time proning or a subsequent time; duration (e.g., time prone); ARDS severity (i.e., mild, moderate, severe); and method of proning (i.e., electric or manual) were not identified in every event. Potential differences in skin integrity issues between patients with and without a diagnosis of COVID-19 is unknown. The lack of this information and information about similar patients who were prone without a complication prevents calculating complication rates.

Lastly, prone positioning complications that may have occurred could have been missed if the word “prone” was not included in the event description.

Conclusion

ARDS and respiratory failure treatment is supportive and based on the underlying injury. Prone positioning therapy can be used in conjunction with mechanical ventilation to increase oxygen levels in patients with severe ARDS. This analysis identified prone positioning patient safety events in patients with ARDS, respiratory failure, respiratory distress, COVID-19, and pneumonia. The challenges and complications associated with prone positioning identified in this analysis have evidence-based recommendations. They offer ways to mitigate skin pressure and ocular injuries and reduce unplanned extubations, feeding tube aspirations, line displacements, and medication errors. Mitigating the risk of prone positioning-related injuries requires preparation, planning, and teamwork. Suggestions for future research on prone positioning includes enteral feedings; electric versus manual proning beds; mitigating ophthalmologic and skin integrity injuries; and head-of-bed positioning (i.e., flat versus reverse Trendelenburg).

Notes

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

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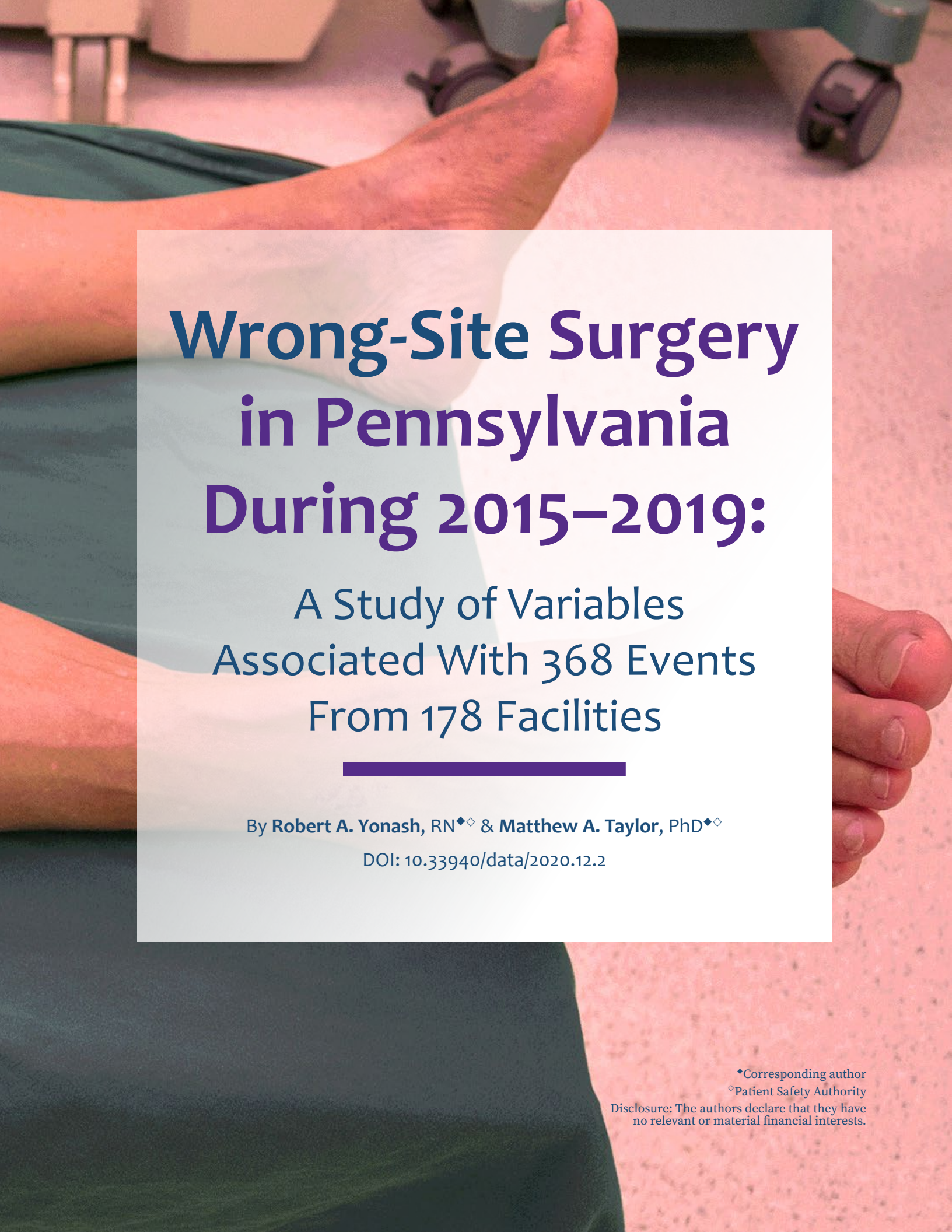
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About the Author

Lea Anne Gardner (leagardner@pa.gov) is a patient safety analyst with the Patient Safety Authority. She has more than 30 years of research experience in patient safety, performance improvement, cardiology, and behavioral health, and a diversified work experience, including roles as a national director of quality improvement and population health and institutional review board administrative director, a coronary intensive care nurse, a clinical research nurse, and a nurse research/leadership preceptor.



A photograph of a patient's leg resting on a hospital gurney. The leg is positioned diagonally across the frame. A large, semi-transparent white rectangular box is overlaid on the center of the image, containing the title and subtitle of the study. The background shows the green fabric of the gurney and the light-colored floor.

Wrong-Site Surgery in Pennsylvania During 2015–2019:

A Study of Variables
Associated With 368 Events
From 178 Facilities

By Robert A. Yonash, RN^{◆◇} & Matthew A. Taylor, PhD^{◆◇}

DOI: 10.33940/data/2020.12.2

◆Corresponding author

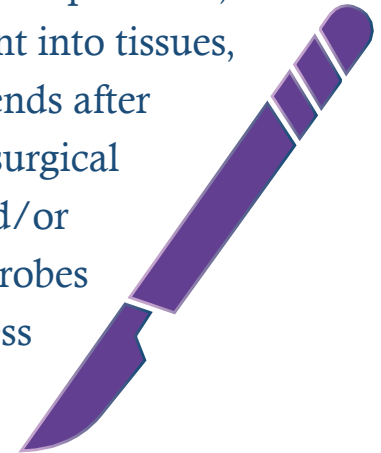
◇Patient Safety Authority

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

Wrong-site surgery (WSS) is a well-known type of medical error that may cause a high degree of patient harm. In Pennsylvania, healthcare facilities are mandated to report WSS events, among other patient safety concerns, to the Pennsylvania Patient Safety Reporting System (PA-PSRS) database. In the study we identified instances of WSS events (not including near misses) that occurred during 2015–2019 and were reported to PA-PSRS. During the five-year period, we found that 178 healthcare facilities reported a total of 368 WSS events, which was an average of 1.42 WSS events per week in Pennsylvania. Also, we revealed that 76% (278 of 368) of the WSS events contributed to or resulted in temporary harm or permanent harm to the patient. Overall, the study shows that the frequency of WSS varied according to a range of variables, including error type (e.g., wrong side, wrong site, wrong procedure, wrong patient); year; facility type; hospital bed size; hospital procedure location; procedure; body region; body part; and clinician specialty. Our findings are aligned with some of the previous research on WSS; however, the current study also addresses many gaps in the literature. We encourage readers to use the visuals in the manuscript and appendices to gain new insight into the relation among the variables associated with WSS. Ultimately, the findings reported in the current study help to convey a more complete account of the variables associated with WSS, which can be used to assist staff in making informed decisions about allocating resources to mitigate risk.

Keywords: *wrong-site surgery, wrong patient, wrong procedure, wrong side, surgical error, interventional radiology, clinician specialty, surgical procedure, WSPE*

The National Quality Forum (NQF) defines surgery as “an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. Surgery begins, regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs. Surgery ends after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting.”³



Introduction

Both ambulatory (i.e., outpatient) and inpatient surgeries are prevalent in the United States. For example, a recent study estimated that 48.3 million ambulatory surgical procedures were performed in the United States during 2010.¹ In a different study, the researchers reported that 30.2 million inpatient surgical procedures were conducted during the same year.²

Fortunately, the healthcare community within the United States has observed a high rate of surgical success, as indicated by a relatively low rate of complications and death.^{4–6} Nevertheless, the National Quality Forum (NQF), The Joint Commission, World Health Organization (WHO), Agency for Healthcare Research and Quality (AHRQ), American College of Surgeons, American Academy of Orthopaedic Surgeons, and North American Spine Society have all identified wrong-site surgery (WSS) as a concerning and preventable type of error.^{7–13}

WSS (e.g., wrong anatomical side, wrong site, wrong procedure, wrong patient) is a

well-known type of medical error that may cause a high degree of patient harm and may result in substantial monetary costs due to malpractice claims.^{14–19} In an effort to prevent WSS, many clinicians, healthcare facilities, and organizations (e.g., professional societies, government agencies) continue to develop interventions and put resources toward reducing the likelihood of WSS.^{8,19–23} Despite the attention given to this topic, there is a dearth of reliable data on the prevalence or frequency of WSS.^{7,24–27} The inability to reliably collect data and monitor trends in WSS is often attributed to a lack of infrastructure and mandates that require reporting of WSS and other medical errors.^{18,26,28–35}

Pennsylvania is among a relatively small number of large governments or entities that legally mandates the healthcare community to report all near misses and serious events, and has a single database where all events are reported.^{26,28,29,31–33,36–41} In Pennsylvania, healthcare facilities report WSS, among other patient safety events, to the Pennsylvania

Patient Safety Reporting System (PA-PSRS)* database, which was established in 2004. With a well-established reporting system and relatively mature reporting culture, the WSS events documented in Pennsylvania are a consistent and robust source of data that should be leveraged to generate safety-related insights.

The purpose of our descriptive study was to use the PA-PSRS database to identify instances of WSS that reached the patient (excluding near miss events) during 2015–2019. We explored the data set for patterns and trends across the events to learn more about the variables associated with WSS, such as error type, facility type, procedure location, procedure performed, body region, clinician specialty, and demographics of patients involved. Overall, we believe that the data from this study can be used to help the healthcare community better understand current challenges with WSS and reveal variables that may influence the likelihood of WSS.

Methods

Data Source and Sample

Data in this study were derived from event reports that were composed by individuals working in healthcare facilities and submitted to the acute care PA-PSRS database. Each event report consists of responses to many structured fields (e.g., event date, patient age, patient gender, care area, facility type) and several free-text narrative fields, which are used by event reporters to describe the event. Given the unstructured nature of free-text narrative fields, the quantity and quality of the information varies from one report to another.

Readers should note that responses within the free-text fields of some reports are concise and none of the reports include access to patients’ medical records or other sources of information. Nevertheless, in many reports the information is sufficient to understand and identify the safety-related variables of interest.

The WSS events included in the study occurred between January 1, 2015, and December 31, 2019. We conducted a two-phase process to select and identify WSS events for inclusion in the study (note: near misses were excluded from the study). The first phase consisted of a database query, where events were extracted if they met one or more of the following inclusion criteria:

- Based on the PA-PSRS taxonomy, events were classified by reporters as “wrong site,” “wrong side,” “wrong procedure,” “wrong patient,” or “preparation inadequate/wrong.”
- Based on the PA-PSRS taxonomy, events were classified by reporters as “surgery/invasive procedure problem” and at least one of the free-text narrative fields contained the words “incision” and “excision” or “left” and “right.”

*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.

Table 1. Definition of Wrong-Site Surgery (WSS) and Examples by Error Type

Wrong-Site Surgery: Defined as a surgical or other invasive procedure performed on the wrong side, site, or patient, or an incorrect procedure performed on the patient. ^{17,43-45}	
Error Type	Examples
Wrong Side	• Ureteral stent erroneously placed in left ureter, rather than right ureter • Regional block performed on the left knee, as opposed to the right knee • Patient admitted for surgical arthroscopy of the right knee; the patient’s left knee was mistakenly draped and prepped, and an incision was performed
Wrong Site	• Anesthetic block performed on wrong finger of the same hand • Osteotomy erroneously performed on second metatarsal rather than third metatarsal • Spinal procedure on unintended spinal level
Wrong Procedure	• Carpel tunnel performed instead of trigger finger release • Patient had a dialysis catheter placed in error (unnecessary procedure, which was a procedure that was not scheduled, consented, or intended) • Patient scheduled for a tonsillectomy, but instead the adenoids were removed
Wrong Patient	• Peripherally inserted central catheter (PICC) line converted to midline on patient A instead of patient B • Circumcision erroneously performed on patient A rather than patient B

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

- Within PA-PSRS, events classified under the “surgical services” care area (including anesthesia care) and at least one of the free-text narrative fields contained any of the following phrases: “wrong site,” “wrong side,” “wrong level,” “time out,” “incorrect side,” “incorrect site,” “block,” or “mark.”

In the second phase, one person manually reviewed each report to identify all events that met the definition of WSS (see **Table 1** for a definition of WSS and examples by error type). Based on the aforementioned query criteria and manual review of event reports, a total of 368 events were included in the study.

Variables Coded

In this study, we explored two sets of variables. The first set was coded by the event reporter (i.e., facility-assigned personnel who submitted the event report to PA-PSRS) and consisted of demographic and clinical variables (e.g., patient age and gender, event date, event harm, facility type, bed size). The second set of variables were coded by a researcher, based on manual review of the event reports. While reviewing the events, the researcher coded the events for the following variables: error type (4 categories), clinician specialty (17 categories), procedure group (11 categories), specific procedure (34 categories, as shown in **Appendix A**), body region (12 categories), and body part (41 categories, as shown in **Appendix C**). Each variable was coded to reflect what occurred in the event, as opposed to what was intended. For example, the researcher coded the events for the procedure performed and body region impacted by the event, which may have been different from the intended procedure or body region.

In this study, the procedure group variable was comprised of three categories independent of clinician specialty and anatomical area, and seven categories that were dependent on specialty and/or anatomical area. The three independent categories were biopsy, excision, and injection procedures. During the coding process, if the procedure performed during the WSS event was among either of the three independent categories, then it was coded as one of those categories. However, if the

WSS event was not associated with either of the three independent categories, then it was subsequently coded as being among one of the seven clinician specialty and/or anatomical area dependent categories (e.g., ophthalmic, urological, vascular). If the procedure was not aligned with either of the 10 independent or dependent categories, then we coded the event under the other category. During the coding process, each of the WSS events were coded as being associated with one category of the procedure group variable; therefore, the categories are mutually exclusive to each other.

The body region variable consisted of three categories of systems and eight categories of anatomical areas, which included numerous body parts. During the coding for the body region variable, if a WSS event occurred in the digestive, reproductive, or urinary system, then we coded the event as occurring within one of those three systems. However, if the WSS event did not occur within either of those systems, then the WSS event was coded as occurring within one of the eight anatomical areas. If the event report did not identify the body region impacted by the WSS event, then we coded the event under the unspecified category. In this study, the categories within the body region variable are mutually exclusive to each other.

Descriptive Data Analysis

The variables were measured by frequency of occurrence and were subjected to a descriptive analysis. A descriptive analy-

sis is an approach where phenomena are identified and patterns are explored to better understand and explain the conditions in which the phenomena occur.⁴² This type of analysis is not used to identify causal relations; rather, it is used to characterize the context of the phenomena, point toward possible causal mechanisms, and generating hypotheses. With a descriptive analysis, data are presented in a manner favoring simplicity with minimal statistical adjustments, as opposed to complex statistical modeling or an unnecessarily complex presentation of the data, to help a broader audience readily comprehend the findings. This type of analysis is often achieved with graphs and tables of the data that will allow a triangulation among various combinations of variables. Overall, our goal with this approach is to analyze and present the data in a manner that is most useful for readers.

Results

Patient Age and Gender

Based on all 368 event reports, patient age was an average of 56 years and a median of 58 years (range of 0 to 99 years). Also, 57% (209 of 368) of patients were reported as female and 43% (159 of 368) were reported as male.[†]

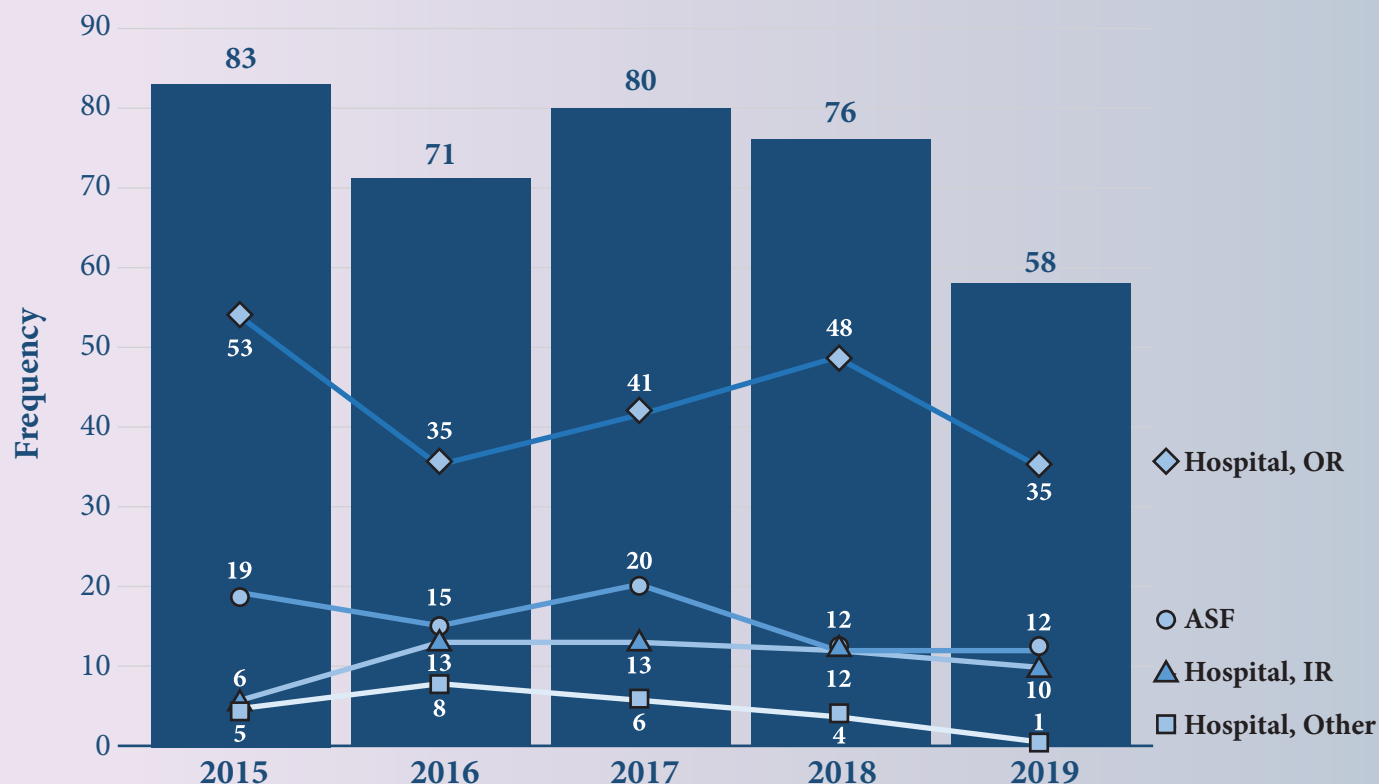
Event Harm

For each event, the reporter identified the degree of patient harm, which was defined by the 10 categories of harm scores used

In Pennsylvania, during the period of 2015–2019 there was an average of 1.42 wrong-site surgeries reported each week (368 WSS events during a period of 260 weeks).

[†]Within the PA-PSRS database, reporting patient gender is a mandatory field, yet response options are binary and only include Male and Female. It is unclear if the reported patient gender matches each patient's self-identified gender.

Figure 1. Wrong-Site Surgery by Year, Facility Type, and Hospital Procedure Location



Note: The bars represent the total frequency per year, across facility type and hospital procedure location. Each line represents a specific combination of facility type and/or hospital procedure location. OR represents operating room, IR represents interventional radiology, and ASF represents ambulatory surgical facilities that were individually licensed.

in PA-PSRS. Based on the harm scores, we found that 76% (278 of 368) of the WSS events contributed to or resulted in temporary harm or permanent harm to the patients and required treatment/intervention or initial/prolonged hospitalization.

Wrong-Site Surgery by Facility Type, Hospital Procedure Location, and Hospital Bed Size

Wrong-site surgeries occurred at individually licensed acute care hospitals and ambulatory surgical facilities (ASF).[‡]

Figure 1 presents the frequency of WSS over a five-year period by facility type and hospital procedure location. The figure shows that the total frequency of WSS was up and down from year to year, with a high of 83 events in 2015 to a low of 58 events in 2019. A closer look at the figure reveals that a majority of WSS events were associated with hospitals, as opposed to ASFs, and were distributed across the following procedure locations: operating room (OR),[§] interventional radiology (IR), and other.[¶] The frequency of WSS was consistently greater in the hospital OR than IR; nevertheless, IR

experienced a range of 6 to 13 WSS events per year, over the five-year period. Finally, **Figure 1** also shows that ASFs reported WSS events each year during that five-year period, with a high of 20 events in 2017 and a low of 12 events in both 2018 and 2019.

As shown in **Table 2**, we explored the frequency of WSS by year, facility type, and hospital bed size. The table shows that hospitals account for 79% (290 of 368) of all WSS events and those with more than 300 beds account for 43% (157 of 368) of all WSS events. Also, we found that ASFs

[‡]The Health Care Facilities Act of Jul. 19, 1979, P.L. 130, No. 48 defines ambulatory surgical facility (ASF) as “a facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. Ambulatory surgical facility does not include individual or group practice offices of private physicians or dentists, unless such offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. For the purposes of this provision, outpatient surgical treatment means surgical treatment to patients who do not require hospitalization, but who require constant medical supervision following the surgical procedure performed.”

[§]The category of hospital procedure location labeled operating room (OR) was comprised of events that occurred in the operating room, preoperative area, postoperative care unit, and procedure room (endoscopy/gastrointestinal laboratory, laser room, or dedicated anesthesia block room).

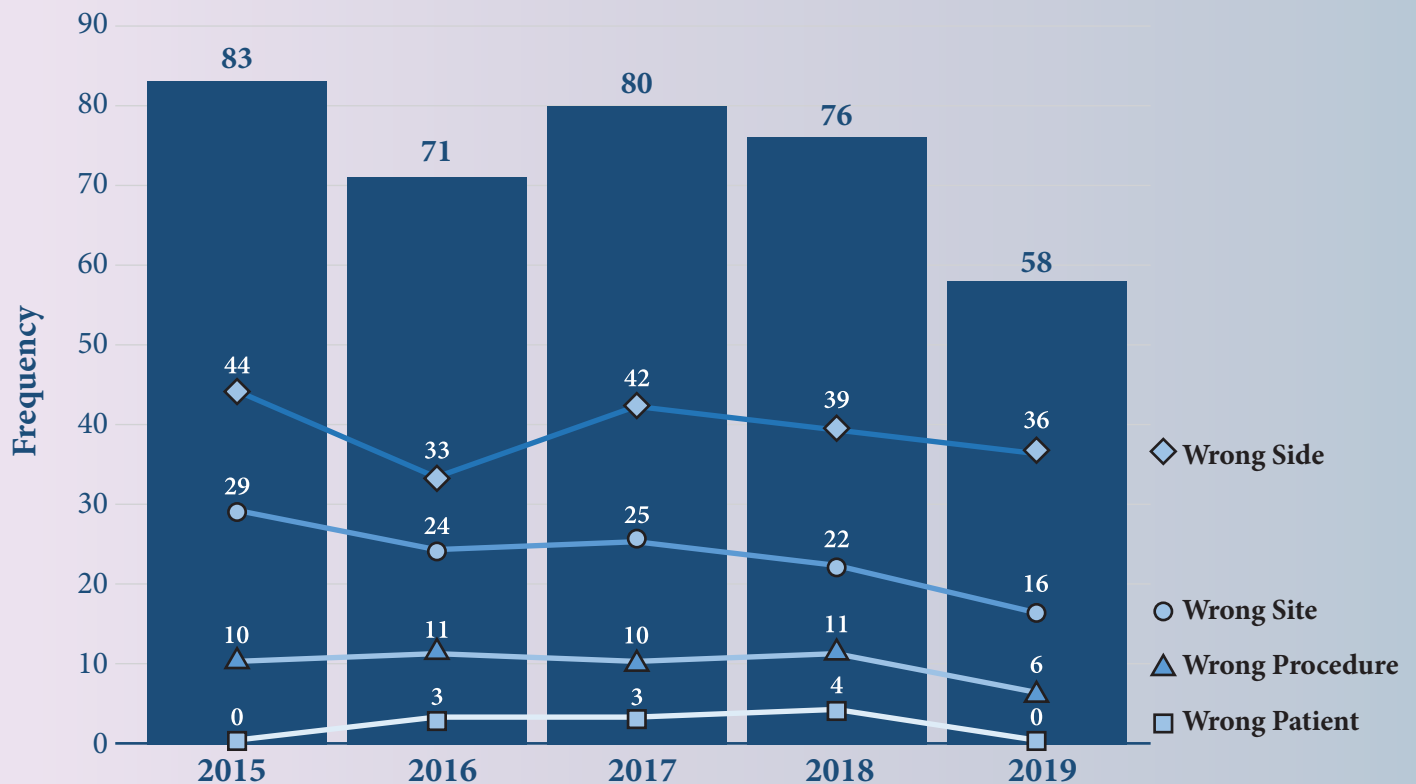
[¶]The category of hospital procedure location labeled other consisted of events that occurred in radiation oncology, rehabilitation unit, short stay unit, invasive cardiology, emergency department, electrophysiology laboratory, intensive care unit, newborn nursery, and nursing care unit (medical/surgical, neurology, medical oncology).

Table 2. Frequency of Wrong-Site Surgery by Year, Facility Type, and Hospital Bed Size

Facility Type	Unique Facilities	2015	2016	2017	2018	2019	Grand Total
ASF	62	19	15	20	12	12	78
Hospital	116	64	56	60	64	46	290
Acute Care Hospitals - 1 to 100 beds	29	13	7	11	10	2	43
Acute Care Hospitals - 101 to 200 beds	28	4	10	10	12	9	45
Acute Care Hospitals - 201 to 300 beds	26	8	5	11	11	10	45
Acute Care Hospitals - over 300 beds	33	39	34	28	31	25	157
Grand Total	178	83	71	80	76	58	368

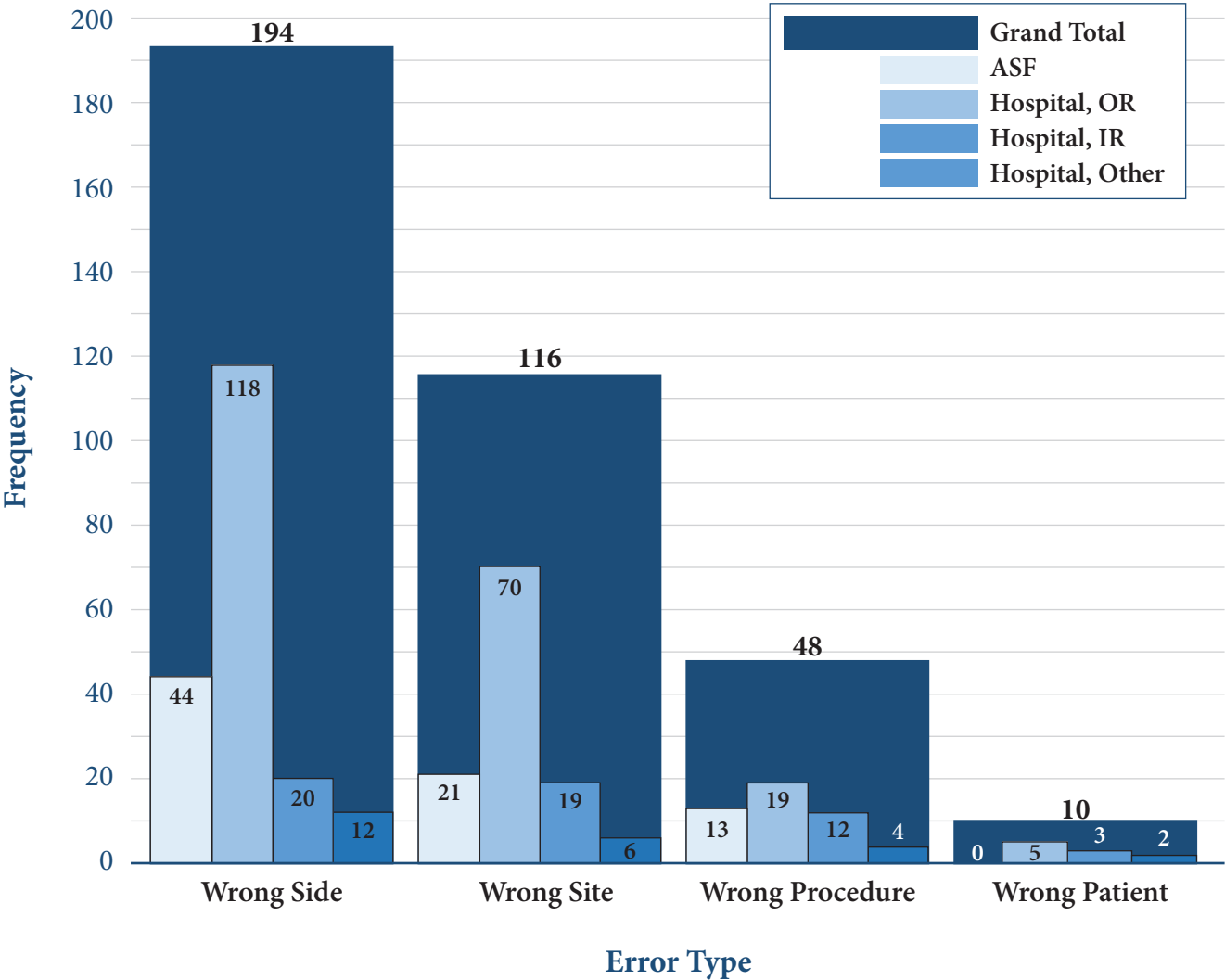
Note: The category of acute care hospitals includes children hospitals, critical access hospitals, and long-term acute care hospitals. All ASFs were individually licensed ambulatory surgical facilities. The numbers under the Unique Facilities column represents the count of individually licensed facilities that had at least one WSS during the five-year period.

Figure 2. Wrong-Site Surgery by Year and Error Type



Note: The bars represent the total frequency per year, across all error types. Each line represents the frequency per error type.

Figure 3. Wrong-Site Surgery by Error Type, Facility Type, and Hospital Procedure Location



Note: The figure shows the frequency of WSS across a five-year period (2015–2019). The primary bar per error type represents the grand total of events across the four sub-categories of bars. OR represents operating room, IR represents interventional radiology, and ASF represents ambulatory surgical facilities that were individually licensed.

were associated with 21% (78 of 368) of all WSS events, which is a greater portion of the sample than hospitals with a bed size of 1–100 (12%, 43 of 368), 101–200 (12%, 45 of 368), or 201–300 (12%, 45 of 368).

We also explored the frequency of unique facilities that reported at least one WSS event during 2015–2019. We found that a total of 62 ASFs and 116 acute care hospitals reported at least one occurrence of WSS during that five-year period. Across the 62 ASFs that reported a WSS event, there was a range of 1–3 events reported per facility (mean of 1.26, median of 1, and only one fa-

cility reported 3 WSS events). Across all 116 acute care hospitals that reported a WSS event, the range of reports per facility was 1–16 throughout the five-year period (mean of 2.5, median of 1, and 39 facilities reported having 3 or more WSS events). For the count of unique facilities with at least one WSS event by hospital bed size, see **Table 2**.

Wrong-Site Surgery by Error Type and Related Variables

Figure 2 shows the frequency of WSS by error type and year. Wrong-side errors were the most common type of error,

when compared with the other error types (wrong site, wrong procedure, and wrong patient). The figure reveals that the frequency of wrong-side, wrong-procedure, and wrong-patient errors were variable and without a clear trend over the five-year period. In contrast, the frequency of wrong-site errors decreased from 29 events in 2015 to 16 events in 2019.

Figure 3 conveys the frequency of WSS by error type, facility type, and hospital procedure location over the entire five-year period (2015–2019). This figure shows that there were some observable differences in

Table 3. Frequency of Wrong-Site Surgery by Error Type and Procedure Group during 2015–2019

Procedure Group	Wrong Side	Wrong Site	Wrong Procedure	Wrong Patient	Grand Total
Biopsy	8	16	3		27 (7%)
Excision	2	10	1		13 (4%)
Injection	96	16	3	1	116 (32%)
Ophthalmic	11	1	2		14 (4%)
Orthopedic, Upper Extremity		12	5		17 (5%)
Orthopedic/Podiatry, Lower Extremity	13	2			15 (4%)
Other	14	14	13	4	45 (12%)
Spinal	4	36	1		41 (11%)
Thoracic	11	2	2		15 (4%)
Urological	28		2	1	31 (8%)
Vascular	7	7	16	4	34 (9%)
Grand Total	194	116	48	10	368

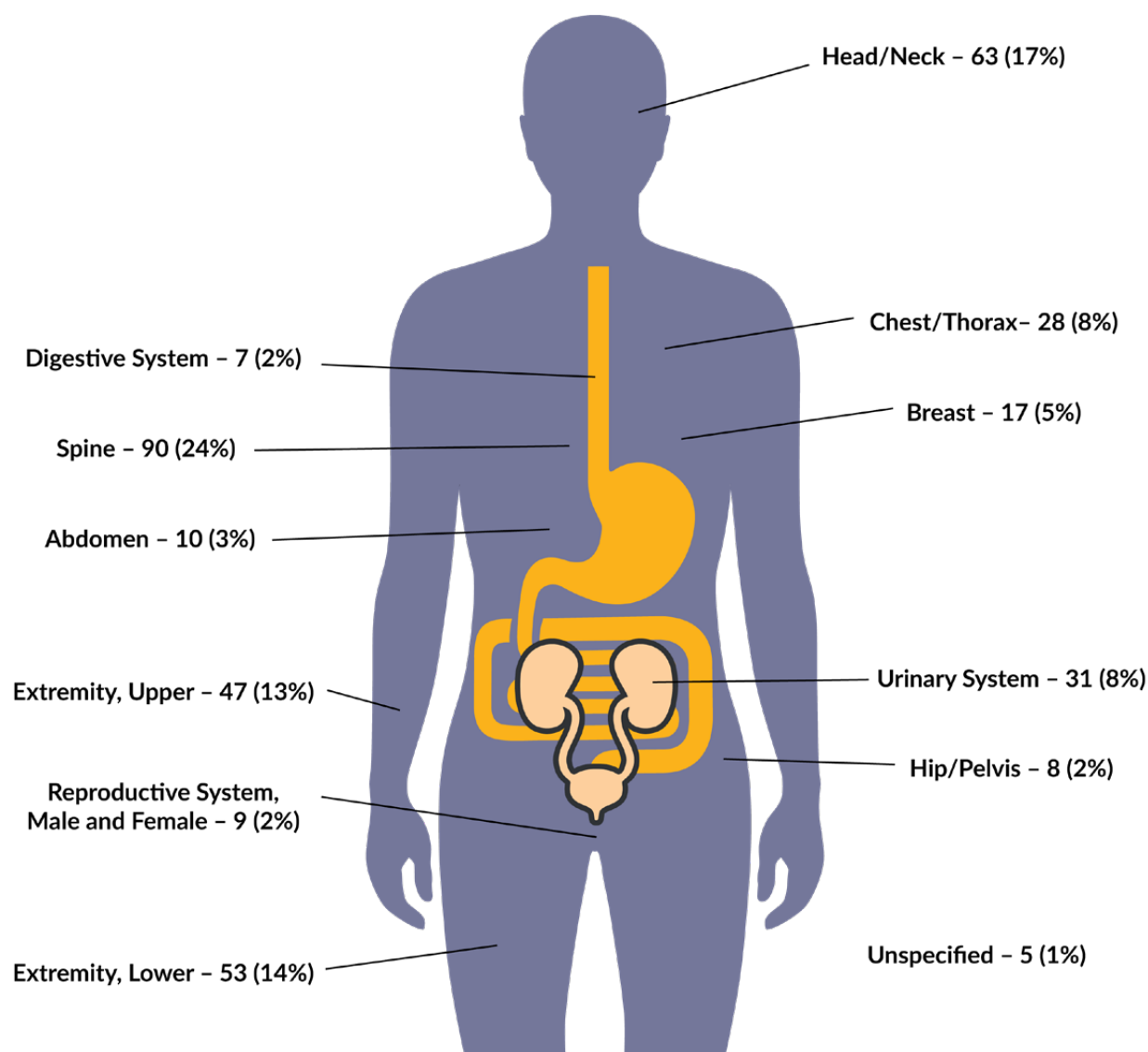
Note: The data reflect the procedure performed, which may have been different from the intended procedure. The “Other” category under Procedure Group consisted of 29 specific procedures, which were each associated with 4 or fewer WSS events. Within each variable, the frequency of events per category are mutually exclusive to other categories. For example, the frequency of events related with the Injection category exclude events associated with the Ophthalmic category and vice versa. Blank cells represent a zero frequency per combination of categories.

Table 4. Frequency of Wrong-Site Surgery by Error Type and Body Region during 2015–2019

Body Region	Wrong Side	Wrong Site	Wrong Procedure	Wrong Patient	Grand Total
Abdomen	3	2	4	1	10 (3%)
Breast	2	14	1		17 (5%)
Chest/Thorax	17	5	6		28 (8%)
Digestive System		2	4	1	7 (2%)
Extremity, Lower	43	6	4		53 (14%)
Extremity, Upper	12	23	9	3	47 (13%)
Head/Neck	39	12	12		63 (17%)
Hip/Pelvis	6	1	1		8 (2%)
Reproductive System, Male and Female	2	1	3	3	9 (2%)
Spine	39	48	2	1	90 (24%)
Unspecified	3	2			5 (1%)
Urinary System	28		2	1	31 (8%)
Grand Total	194	116	48	10	368

Note: The data reflect the body region involved in the WSS events, which may have been different from the intended body region. The “unspecified” category of body region represents the WSS events where the report did not identify the body region. Within each variable, the frequency of events per category are mutually exclusive to other categories. For example, the frequency of events related with the Urinary System category exclude events associated with the Abdomen category and vice versa. Blank cells represent a zero frequency per combination of categories.

Figure 4. Frequency of Wrong-Site Surgery by Body Region During 2015–2019



the distribution of WSS across facility types and hospital procedure locations from one error type to another. For example, although events were most frequent in the hospital OR, relative to the other locations, the proportion represented by the hospital OR varied from one error type to another. Within the wrong side type of error, the hospital OR represents 61% (118 of 194) of the events and within the wrong procedure type of error, the hospital OR accounts for 40% (19 of 48) of the events. As another example, hospital IR was associated with 10% (20 of 194) of the wrong-side errors and 25% (12 of 48) of the wrong-procedure errors. Overall, these two examples indicate that the type of error might be more or less

likely depending on the facility type and hospital procedure location.

Table 3 provides insight into the relation between error types and procedure groups. Overall, we found that the following procedure groups were most frequently associated with WSS: injection (32%, 116 of 368), spinal (11%, 41 of 368), and vascular (9%, 34 of 368). Injections cited in this study include blocks (anesthetic/pain), steroids, and radiation (tracer/therapy). The table reveals that some procedure groups were associated with several types of errors while others were predominantly related with a single type of error. For example, vascular procedures were associated with

all four types of errors. In contrast, almost all urological procedures were associated with a single type of error (wrong side). Additionally, the table indicates that certain procedure groups might be more prone to certain error types than other types. For example, orthopedic/podiatry lower extremity procedures were largely associated with wrong-side errors and orthopedic upper extremity procedures were primarily associated with wrong-site errors. Last, the table shows that wrong procedure errors and wrong patient errors were the most infrequent among the four types of errors. Interestingly, we found that 33% (16 of 48) of the wrong procedure errors and 40% (4 of 10) of the wrong patient errors were as-

sociated with vascular procedures, which is the procedure group most frequently associated with those two error types.

To gain further insight into the WSS events associated with each of the procedure groups, we tabulated the frequency of specific procedures (unique), which are summarized in **Appendix A**. Across all 368 event reports, we found that 10 reports did not provide adequate information to identify the specific procedure performed (i.e., unspecified). Among the 358 event reports that identified the specific procedure, we found that there were a total of 97 different procedures associated with the WSS events. Within the four procedure groups most frequently associated with WSS, we found that there was one category of specific procedure within each that was associated with at least a quarter of the WSS events. For example, urological endoscopy with a stent was related with 58% (18 of 31) of the urological WSS events. The findings indicate that some procedures might be more prone to a WSS event than other procedures.

Table 4 shows the frequency of WSS by error type and body region. The table reveals that the spine (24%, 90 of 368), head/neck (17%, 63 of 368), lower extremity (14%, 53 of 368), and upper extremity (13%, 47 of 368) were the body regions most frequently related with WSS events. Additionally, the data indicate that certain body regions might be prone to multiple types of error, while others are primarily related with a single type of error. For example, the spine is frequently associated with both wrong-side and wrong-site (including wrong spinal level) errors. In contrast, the breast region is mostly related with wrong-site errors. See **Figure 4** for an illustration of the frequency of WSS per body region.

Readers should note that the frequency of WSS per category of procedure group (**Table 3**) might be less than the frequency reported in the corresponding category of body region (**Table 4**). Any difference in frequency across corresponding categories between **Table 3** and **Table 4** reflects our use of procedure group categories that are independent of specialty and/or anatomical area. For example, **Table 4** shows that a total of 90 WSS events were associated with the spine body region and **Table 3** shows

that there were 41 WSS events associated with the spinal procedure group. This difference in frequency is due to 49 WSS events occurring in the spine body region, but were associated with a biopsy, excision, injection, or other procedure. For a cross-tabulation of WSS events by procedure group and body region, see **Appendix B**.

To better understand the nature of WSS, we also identified the frequency of WSS by body part within each of the body regions, which are presented in **Appendix C**. Across all 368 event reports, there were 28 reports where the body part was unspecified. Within the 340 reports where the body part was identified, we found that a total of 51 different body parts were impacted by the WSS events. In each of the four body regions most frequently associated with WSS, there was at least one body part in each region that was associated with roughly a third to half of the WSS events. For example, within the lower extremity region, the knee was related with 45% (24 of 53) of the WSS events. As another example, the eye represented 35% (22 of 63) of the WSS events among the head/neck region. Overall, the results suggest that certain body parts might be more likely to be associated with a WSS event than other body parts.

Table 5 presents the frequency of WSS by error type and clinician specialty. The table shows that the following clinician specialties were the most frequently related with a WSS event: pain management (15%, 54 of 368), interventional radiology (14%, 52 of 368), and orthopedics (12%, 44 of 368). The table also reveals that some clinician specialties primarily experience one type of error while other clinician specialties are associated with several error types. For example, pain management is primarily associated with wrong side errors while interventional radiology has a notable relation with several types of error: wrong side (37%, 19 of 52), wrong site (37%, 19 of 52), and wrong procedure (23%, 12 of 52).

In addition to the aforementioned **Appendices A, B, and C**, see **Appendices D–G** for various cross tabulations of variables related to WSS (**Appendix D**, clinician specialty by procedure group; **Appendix E**, clinician specialty by body region;

Appendix F, procedure group by facility type by hospital procedure location; **Appendix G**, body region by facility type by hospital procedure location).

The appendices serve the function of providing greater insight into the WSS events. We believe the various combinations of visuals allow patient safety professionals, healthcare leaders, frontline providers, and other concerned stakeholders to better understand the nature of WSS by triangulating this complex and multifaceted issue. With the information, readers can better gauge the degree to which certain variables are impacting the frequency of WSS. Ultimately, the findings reported in the current study help to convey a more complete account of the variables associated with WSS.

Discussion

Many clinicians, patient safety professionals, and organizations take the position that WSS events are preventable and should never occur.^{9,11-13,28,43,46,47} For those reasons, the topic of WSS has received considerable attention and many studies have been conducted to monitor and shed light on the occurrences of WSS. Previous research on WSS events used a variety of data sources, including government agencies, hospital systems, accrediting organizations, malpractice claims with insurance companies, and survey of clinicians.^{18,24,28,44-46,48-52} There are benefits to using different data sources and taking different approaches to studying a topic; unfortunately, the differences likely impact the findings and create challenges in making valid comparisons that are free of confounding variables. For example, among the studies we identified during our literature review, we found study design differences across the following variables: time period; geography; reporting culture; definitions of surgery and WSS; inclusion or exclusion of near misses; and selective inclusion of categories within clinician specialty, procedure performed, procedure location, and facility type. While there is value in nearly all studies of WSS, the lack of consistency in study design and manner of reporting results (e.g., frequency of WSS vs rate) makes it difficult to directly compare our findings with much of the previous research.

Table 5. Frequency of Wrong-Site Surgery by Error Type and Clinician Specialty during 2015-2019

Clinician Specialty	Wrong Side	Wrong Site	Wrong Procedure	Wrong Patient	Grand Total
Anesthesia	29	1	4		34 (9%)
Dermatology	1	8			9 (2%)
Ear, Nose, and Throat	4	1	2		7 (2%)
Foot/Ankle	4	2			6 (2%)
Gastroenterology		1	2	1	4 (1%)
General Surgery	9	11	11	1	32 (9%)
Gynecology	1		1	2	4 (1%)
Interventional Radiology	19	19	12	2	52 (14%)
Neurosurgery	3	1			4 (1%)
Ophthalmology	19	1	2		22 (6%)
Orthopedics	17	22	5		44 (12%)
Other	8	3	2	2	15 (4%)
Pain Management	43	9	1	1	54 (15%)
Spinal Surgery		33	1		34 (9%)
Thoracic Surgery	5	1	1		7 (2%)
Urology	28		2	1	31 (8%)
Vascular	4	3	2		9 (2%)
Grand Total	194	116	48	10	368

Note: The “Other” category consisted of 10 different clinician specialties, which were each associated with two or fewer WSS events. Within each variable, the frequency of events per category are mutually exclusive to other categories. For example, the frequency of events related with the Anesthesia category exclude events associated with the Pain Management category and vice versa. Readers should note that many of the WSS injections were administered by anesthesiologists and pain management specialists. Anesthesiologists tend to care for the patient during the perioperative period whereas the pain management specialists (many of whom are anesthesiologists) treat a patient’s pain both in the surgical setting as well as ancillary departments and outpatient care. These two points were the basis upon which the events were classified as either an anesthesia event or a pain management event. Blank cells represent a zero frequency per combination of categories.

Wrong-Site Surgery By Year

The current study showed that WSS events continue to occur, which is consistent with an abundance of published research,^{24,28,44,46} including previous studies conducted by the Patient Safety Authority (PSA).^{36,53,54} Previous PSA research targeted the frequency of WSS events that occurred in hospital ORs and/or ASFs, and excluded procedure locations of hospital IR and hospital “other” (e.g., radiation oncology,

rehabilitation unit, invasive cardiology, emergency department, newborn nursery). In order to monitor the status of WSS events over an extended period of time, we compared data from a previous PSA study⁵³ that reported WSS events during 2005-2014[#] and our data from 2015-2019 (only Hospital OR and ASF procedure locations). Based on those parameters, we found an average of 58.27 WSS events per calendar year during that 15-year period

(median of 57, low of 38 in 2012, and a high of 80 in 2008). When comparing our findings with the previous study, the mean frequency of WSS events per calendar year was 65.8, 51, and 58 during the five-year periods of 2005-2009, 2010-2014, and 2015-2019, respectively. The findings indicate that WSS continues to be a challenge in Pennsylvania and that healthcare facilities should continue allocating resources and putting effort into preventing WSS.

[#]Note that previous PSA studies reported WSS events by academic year as opposed to calendar year.

Wrong-Site Surgery By Error Type And Other Variables

The current study shows that the frequency of WSS events vary by error type and numerous other variables (e.g., facility type, procedure location, procedure group, body region, and clinician specialty). During 2015–2019 the frequency of WSS events per error type were without a clear trend, except for what appeared to be a decreasing trend of wrong-site errors. Taking a closer look at previous PSA studies, we found only two studies that systematically explored the relation between WSS events and error type; however, each of those studies had a relatively narrow focus on events related to orthopedic surgery or ASFs.^{54,55} In the study of events at ASFs, the distribution of WSS by error type was similar to what was reported by ASFs in our current study. Overall, the findings in the present study expand upon previous PSA studies by including a broader scope of variables and subcategories that help to provide further insight into distribution of WSS by error type.

During our literature search we identified several other studies that explored error type among WSS events.^{44,45,49,51} For example, two studies from the Veterans Health Administration (VHA) evaluated WSS events as a function of error type, clinician specialty, and body region variables.^{44,45} Between the two VHA studies and the current study, the distribution across all four error types were similar, except for wrong patient errors. In the two VHA studies, wrong patient errors were among the most common and represented at least 27% of the total errors. In contrast, our study found that wrong patient errors were the least common and consisted of fewer than 3% of all errors (10 of 368). Overall, the findings appear to indicate that clinicians within Pennsylvania are relatively effective in preventing wrong patient errors; nevertheless, we would still argue that an average of two wrong patient errors per year is too many.

Further comparison between the two VHA studies^{44,45} and our current study revealed some similarities and differences in the distribution of WSS events by clinician specialty. The findings were similar by revealing that interventional radiology, orthopedics, urology, and ophthalmology specialties

were associated with the highest frequencies of WSS. The current study also found a notable frequency of WSS events associated with anesthesia and pain management; yet, the VHA studies did not report any events related with those specialties, despite defining injections as a type of WSS. We speculate that this contrast in findings indicates a design difference between studies, as opposed to the VHA's lack of WSS events associated with injections. Finally, the current study revealed a relatively high frequency of WSS events associated with the spinal surgery specialty, which is consistent with previous research.^{50,52} In the end, the findings show that each of the 17 categories of clinician specialty have a history of WSS; consequently, many clinicians and healthcare facilities should be concerned with the risk of WSS.

Our WSS findings across the 11 categories of procedure groups were difficult to compare with much of the previous research, including previous PSA studies.^{53,56–59} For example, some of the previous studies either targeted only a small number of procedures that were relatively specific (ureteral stents as opposed to all urological procedures or eye blocks by surgeons as opposed to ophthalmic procedures) or the variable parameters were unclear due to lack of information. Regardless, it appears that our findings are consistent with some of the previous PSA studies that reported a high frequency of WSS associated with anesthetic blocks and spinal surgery.^{53,57–59}

Our study also showed that the frequency of WSS varied by body region, which is consistent with previous research.^{45,54} For example, a VHA study reported that across nine body regions, the eye, upper extremities, and lower extremities were most frequently associated with WSS and the least frequent were abdomen, spine, and head/neck. A portion of their findings are aligned with our results, but in our study the spine was the most frequent body region and the eye was in the bottom 50% of the distribution associated with WSS, which is a notable contrast from the VHA study. A previous PSA study focused on the relation between WSS and seven body parts within the upper and lower extremity regions.⁵⁴ The study reported that hand, knee, and foot were most frequently associated with WSS, which is similar to our findings. Nevertheless, the previous

PSA study was relatively narrow in scope by only studying events that involved orthopedic surgery and the extremities. Our current study expanded upon previous PSA research by exploring the distribution of WSS across 12 body regions (including body parts, as shown in **Appendix C**) and other relevant variables (e.g., error type, clinician specialty, procedure group, specific procedure, facility type, and procedure location).

Overall, some of our findings are consistent and some are inconsistent with previous literature, which should be expected in part due to the differences in design across the studies. The current study systematically evaluated the frequency of WSS according to 14 different combinations of variables, and this comprehensive approach allows for greater depth of analysis into the complex and multifaceted topic of WSS.

Strategies to Reduce the Likelihood of Wrong-Site Surgery

Based on our study, it is apparent that WSS continues to be a challenge for patient safety and the spectrum of surgical and procedural services. As a result, clinicians and healthcare facilities should continue to review their existing processes and revise their approach as necessary to reduce the likelihood of WSS. The prevention of WSS events is a team effort that encompasses all staff members, starting at the point of procedure scheduling to the successful completion of the consented procedure. Strategies should be employed throughout the perioperative process, which should include preoperative verification and reconciliation, site marking, and timeout and intraoperative verification. Clinicians and healthcare facilities should conduct a gap analysis of their existing processes relative to the 14 risk mitigation strategies described in **Appendix H**.

For further information about various strategies and tools to prevent WSS events, please see the many resources available at the PSA website, patientsafety.pa.gov. Resources include educational posters, self-assessment checklist, sample scheduling forms, observational monitoring tools, and error analysis forms (e.g., wrong spinal level and wrong ureter).

Limitations

We urge readers to avoid interpreting the findings as being representative of the absolute frequency of WSS events across Pennsylvania, as it is possible that some events may go unreported. In particular, certain types of procedures (e.g., injection) might be systematically underreported due to the misperception that those procedures were harmless mistakes. The findings in the present study were reported as a frequency and are consistent with previous studies conducted by PSA; however, without reporting a normalized rate (ratio of WSS events per number of surgical procedures performed) it is difficult for the healthcare community to gauge the risk of WSS as a function of one variable versus another.

Conclusion

The results show that WSS continues to be a challenge throughout Pennsylvania, as evidenced by 368 WSS events reported by 178 healthcare facilities during 2015–2019 and an average of 1.42 WSS events reported each week. Overall, the present study addresses many gaps in the literature and shows that the frequency of WSS varied according to a range of variables, including error type (e.g., wrong side vs wrong patient), year, facility type, hospital bed size, hospital procedure location, procedure, body region, body part, and clinician specialty. We encourage readers to gain insights into the relation among the variables associated with WSS by using various combinations of visuals in the manuscript and appendices. We believe the visuals allow patient safety professionals, healthcare leaders, frontline providers, and other stakeholders to better understand the nature of WSS by triangulating the complex and multifaceted issue. With the information, readers can better gauge the degree to which certain variables are impacting the frequency of WSS. Ultimately, the findings reported in the current study help to convey a more complete account of the variables associated with WSS, which can be used to assist staff in making informed decisions about allocating resources to mitigate risk.

To access the appendices,
visit patientsafetyj.com.

Notes

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

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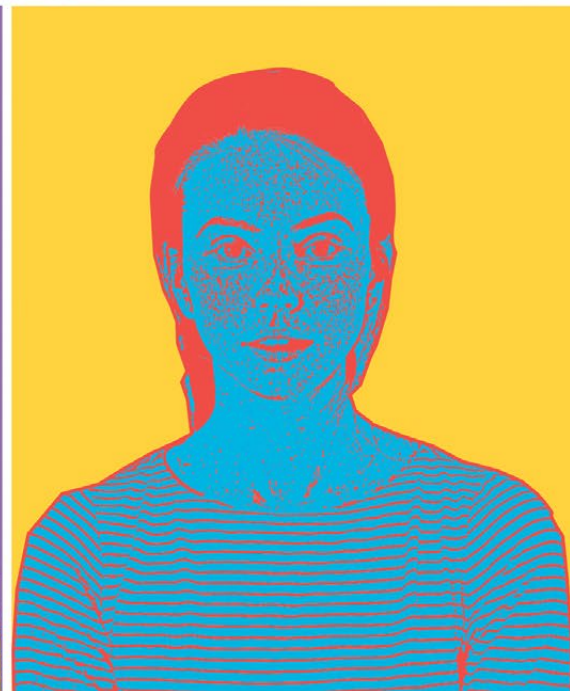
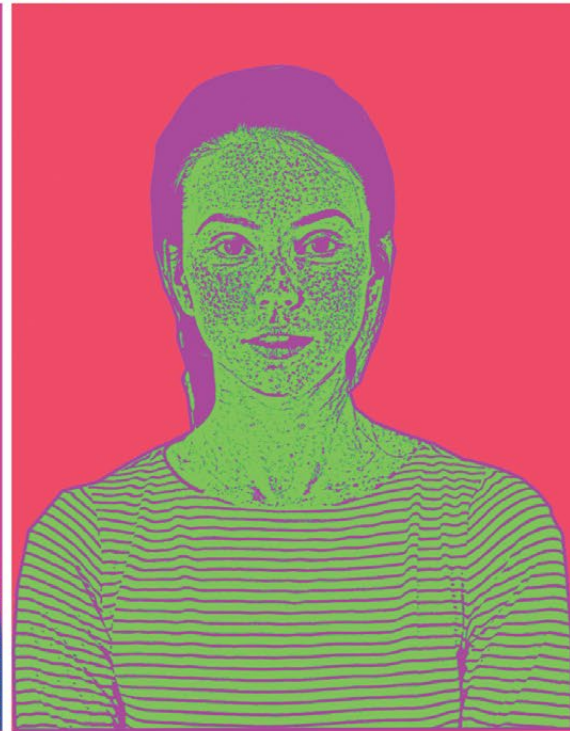
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About the Authors

Robert A. Yonash (ryonash@pa.gov), a registered nurse, has been with the Patient Safety Authority (PSA) since 2009 as the patient safety liaison for the Southwest region of Pennsylvania. He works with medical facilities to eliminate medical errors and has undertaken several projects, including a joint initiative with the Pennsylvania Society of Anesthesiologists on wrong-site blocks and serving as a Core Team Lead for the PSA's Center of Excellence for Improving Diagnosis. Yonash is a member of the American Society of Professionals in Patient Safety and has attained certification as a Certified Professional in Patient Safety (CPPS) and a Lean Six Sigma Healthcare Green Belt. He is also a master trainer in TeamSTEPPS.

Matthew A. Taylor (MattTaylor@pa.gov) is a patient safety analyst for the Patient Safety Authority (PSA), where he conducts research; uses data to identify patient safety concerns and trends; and develops solutions to prevent recurrence, as well as tools and materials to help facilities and clinicians improve patient safety. Prior to joining the PSA, Taylor was a scientific writer and research specialist at the University of Pittsburgh School of Pharmacy, and he has served fellowships at the Centers for

Disease Control and Prevention (CDC) and the VA Pittsburgh Healthcare System. His expertise in data analysis and research covers a range of topics, including patient safety, public health, employee training, process efficiency, human factors, workplace culture/climate, behavior change interventions, and organizational management.





Health Information Technology– Related Wrong- Patient Errors:



Context is Critical

Tracy C. Kim, BA[♦], **Jessica L. Howe**, MA[◇],
Ella S. Franklin, MSN[◇], **Seth Krevat**, MD[◇],
Rebecca Jones, MBA, RN[†], **Katharine T. Adams**, BA[◇],
Allan Fong, MS[◇], **Jessica Oaks**, MIT[†]
& **Raj M. Ratwani**, PhD^{◇‡}

DOI: 10.33940/data/2020.12.3



[♦]Corresponding author

[◇]MedStar Health National Center for Human Factors in Healthcare, Washington, DC

[†]Patient Safety Authority, Harrisburg, PA

[‡]Georgetown University School of Medicine, Washington, DC

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

Health information technology (HIT) provides many benefits, but also facilitates certain types of errors, such as wrong-patient errors in which one patient is mistaken for another. These errors can have serious patient safety consequences and there has been significant effort to mitigate the risk of these errors through national patient safety goals, in-depth research, and the development of safety toolkits. Nonetheless, these errors persist. We analyzed 1,189 patient safety event reports using a safety science and resilience engineering approach, which focuses on identifying processes to discover errors before they reach the patient so these processes can be expanded. We analyzed the general care processes in which wrong-patient errors occurred, the clinical process step during which the error occurred and was discovered, and whether the error reached the patient. For those errors that reached the patient, we analyzed the impact on the patient, and for those that did not reach the patient, we analyzed how the error was caught. Our results demonstrate that errors occurred across multiple general care process areas, with 24.4% of wrong-patient error events reaching the patient. Analysis of clinical process steps indicated that most errors occurred during ordering/prescribing (n=498; 41.9%) and most errors were discovered during review of information (n=286; 24.1%). Patients were primarily impacted by inappropriate medication administration (n=110; 37.9%) and the wrong test or procedure being performed (n=65; 22.4%). When errors were caught before reaching the patient, this was primarily because of nurses, technicians, or other healthcare staff (n=303; 60.5%). The differences between the general care processes can inform wrong-patient error risk mitigation strategies. Based on these analyses and the broader literature, this study offers recommendations for addressing wrong-patient errors using safety science and resilience engineering, and it provides a unique lens for evaluating HIT wrong-patient errors.

Keywords: *wrong-patient, health information technology, patient safety*

Introduction

Electronic health records (EHRs) and other health information technology (HIT) provide numerous benefits, including better provider and patient accessibility to health information, and more efficient and effective care delivery.^{1,2} However, there are also unintended consequences of HIT use, including the technology facilitating certain types of errors.^{3,4} Wrong-patient errors, which occur when one patient is mistaken for another, is one type of HIT-facilitated error that includes situations like ordering a medication for the wrong patient, documenting in the wrong record, and uploading an X-ray to the wrong record. The occurrence of wrong-patient errors may not be immediately known, and these errors can lead to significant patient harm.

Recognizing the risks associated with wrong-patient errors, The Joint Commission's accreditation standards require the verification of patient identification before providing care, treatment, or services, and that two patient identifiers be used in the verification process.⁵ The Joint Commission's National Patient Safety Goals for hospitals and ambulatory care sites include patient identification. Further, there has been extensive research on HIT-facilitated wrong-patient errors that have provided insight for standards, safety goals, and the development of toolkits to mitigate the risk of these errors.⁶⁻¹¹ Despite these, HIT wrong-patient errors persist.^{10,12} For example, one recent study of physician interactions with computerized provider order entry (CPOE) found that 37.6% of the time, physicians did not verify patient identification information when placing orders in a simulated setting.¹⁰

Previous research, and resulting improvement efforts, are largely based on the analysis of instances where wrong-patient errors occurred and reached the patient, with a focus on the actions that

led to the error. While there are clear benefits to this approach, there are also benefits to analyzing instances where wrong-patient errors occurred and were discovered *before* they reached the patient to determine the specific people, processes, and/or technology that prevented the error from reaching the patient.

An analytic focus on instances where errors are caught before they reach the patient is based in two scientific areas. First, industrial safety science stresses that errors are going to occur in complex domains, like healthcare, and that while humans can be

HIT-facilitated errors include situations like ordering a medication for the wrong patient, documenting in the wrong record, and uploading an X-ray to the wrong record



a contributing factor to adverse safety events, they also play a crucial role as a “line of defense” against errors reaching patients.¹³ Humans can detect and correct errors that may stem from technology, organizational processes, or policies before patients are harmed. Second, resilience engineering is an approach that focuses on safety in complex domains, with a focus on how behaviors emerge and adapt. Humans are a critical part of the healthcare system and can rapidly adapt to perform their work and deliver care. When studying the behaviors that give rise to patient outcomes, it is important not only to focus on the behaviors that contribute to adverse outcomes, but also to focus on the behaviors that serve to prevent adverse outcomes.^{14,15} Safety science and resilience engineering provide a different lens on wrong-patient errors that could lead to additional recommendations for how to improve healthcare safety by expanding the application of processes discovered as working well.

In this paper, we first sought to better understand the pervasiveness of wrong-patient errors across care processes. We then focused on the context of wrong-patient errors, including identification of the people, specific processes, and/or technology that contributed to the errors that reached the patient, and how errors were discovered before they reached patients.

Previous Wrong-Patient Error Research and Proposed Solutions

Previous research has found that HIT-related wrong-patient errors often occurred during a patient’s clinical encounter, compared to before (e.g., registration, scheduling) or after (e.g., referrals, patient portals) the patient’s encounter. For example, a study of patient safety reports submitted by 181 healthcare organizations identified that 72.3% occurred during a clinical encounter, with several reports related to diagnostic procedures (e.g., laboratory tests, imaging; 36.5%) and treatment (e.g., medications, procedures; 22.1%). Most wrong-patient errors are considered near misses that do not reach the patient, and past research on HIT-related wrong-patient errors mostly has been focused on the ordering process and medication administration.^{6,16}

Wrong-Patient Errors During Ordering

Within the clinical encounter, wrong-patient errors during ordering of diagnostic images, labs, and medications have been a central focus of research efforts, given the prevalence of these errors. CPOE systems can facilitate wrong-patient errors due to poor usability, fragmented displays, and limited functionalities. For example, one study examining wrong-patient errors in radiology found that 50% of safety reports were related to order entry, and another study analyzing laboratory wrong-patient errors found that errors during order entry were the most frequent compared to other parts of the care process.^{16,17} Wrong-patient errors during medication ordering also have received considerable attention given the potential for significant patient harm if a patient receives the wrong medication or does not receive a medication that was intended for him/her.¹⁸

Several improvement efforts have focused on enhancing CPOE systems to reduce the occurrence of incorrect order entry. Numerous studies implemented a HIT verification alert pop-up requiring prescribers to confirm a patient’s identity prior to signing off on an order, which was found to reduce the number

One recent study of physician interactions with computerized provider order entry (CPOE) found that

37.6%

of the time, physicians did not verify patient identification information when placing orders in a simulated setting¹⁰

of wrong-patient errors.¹⁹⁻²² However, this intervention can also increase user frustration. Clinical decision support systems integrated within CPOE systems have also been tested, though not all studies resulted in a decrease in wrong-patient errors.²³⁻²⁵ Other improvement efforts have involved limiting the number of patient charts open concurrently in the EHR to reduce the likelihood of selecting the wrong patient’s record. While this solution showed early promise, recent studies have found that limiting the number of open charts made no significant difference in the number of wrong-patient orders.²⁶⁻²⁸

Prior studies have also identified HIT enhancements to improve identification of wrong-patient errors in radiology. One study implemented radiopaque patient identification stickers as an additional check to ensure the patients’ conditions correlated with their imaging, and a second study involved capturing photographs of patients’ faces simultaneously with portable chest radiographs.^{29,30}

Wrong-Patient Errors During Medication Administration

Wrong-patient errors during medication administration have also been a prominent area of research given the frequency of errors and potential for significant patient harm. For example, one study reviewing safety reports from two hospitals found 10% of medication administration errors were related to wrong-patient errors.³¹ Similar to wrong-patient errors and CPOE systems, shortcomings in the design and implementation of barcode medication administration (BCMA) systems have been recognized as a challenge by some researchers.^{32,33} One study found 15 types of workarounds (steps performed out of sequence and unauthorized BCMA process steps) performed by nurses as a result of technology-related issues (e.g., connectivity, multiple scans needed to read barcode), all of which had wrong-patient errors listed as a possible negative outcome.³² Additionally, previous literature investigating BCMA’s role in reducing wrong-patient medication administration errors have been inconsistent in terms of significance of results.^{33,34}

Study Focus

With the extensive research on HIT-related wrong-patient errors and recognition that these errors persist, we analyzed patient safety event (PSE) reports with a focus on the contextual details of each report. We analyzed the general care process and clinical process step during which HIT wrong-patient errors occurred and were discovered, whether the error reached the patient, and the impact on the patient or how the error was caught. Importantly, we compared the clinical process steps involved for errors that reached the patient and those that were caught before reaching the patient. This approach affords the opportunity to identify the people, processes, or technology that may effectively enable the identification of wrong-patient errors before reaching the patient. With this knowledge, those specific processes can be shared and may serve to inform performance optimization within healthcare facilities.

Methods

Data Source and Selection

Data were comprised of all safety reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)* between January 1 and December 31, 2019, which comprised 293,400 reports from 595 facilities. To identify possible HIT- and wrong-patient-related reports, we used a three-pronged retrieval process that included reports in which the:

- Reporter assigned a subevent type category of “wrong patient” or similar subevent type (e.g., “wrong patient requested,” or “wrong patient transfused” in the Transfusion event type category), or
- Reporter categorized the issue as HIT-related and the description contained a keyword (e.g., “wrong-person”) indicating it may be wrong-patient-related, or
- Report was identified as HIT-related from a machine learning algorithm, which was previously developed to identify HIT-related reports based on the free-text description in patient safety event reports, and contained a keyword indicating it may be wrong-patient-related.³⁵

This search returned 3,114 reports, which were manually reviewed to determine if they were HIT-related; 1,433 reports met this criterion. After reviewing the 1,433 reports to determine if they were wrong-patient-related, 244 were excluded. In total, 1,189 reports were verified to be both HIT- and wrong-patient-related, and thus were included in the descriptive and qualitative analyses. The data selection process is outlined in **Figure 1**.

Analysis Methods

A descriptive analysis of the 1,189 HIT wrong-patient reports included harm score and facility type as reported by healthcare facilities to

PA-PSRS. Harm scores were categorized as an unsafe condition, an event with no harm, or an event with harm.

For the qualitative analysis, a grounded theory approach was used.³⁶ The free-text narratives of each report served as the foundation for coding. The codebook, including definitions and examples, is described in **Tables 1** and **2**. Two human factors experts manually coded all reports for general care process, clinical process step during which HIT wrong-patient errors occurred and were discovered, and if the HIT wrong-patient error reached the patient. First, each report was categorized into one of six general care processes in which the error primarily occurred (i.e., administrative, general, laboratory, medication, procedure, radiology). The reports were then categorized by the clinical process step during which the wrong-patient error occurred and the step during which the error was discovered. Each report was also coded for whether the error reached the patient, the error did not reach the patient, or there was insufficient information to make the determination. Reports were coded as reaching the patient if the error resulted in the patient’s care being altered in any way, such as a delay in care or the wrong procedure being performed, or a patient receiving the wrong information, such as test results or discharge instructions, as a result of a HIT wrong-patient error. For those errors that reached the patient, the immediate impact on the patient was categorized into one of five categories, shown in **Table 2**. For those errors that did not reach the patient, the person or technology (i.e., HIT system) that caught the error was categorized into one of five categories, shown in **Table 2**.

Fifteen percent of the reports were dually coded. Inter-rater reliability was calculated using Cohen’s kappa (.9 for general care process, .8 for clinical process step, and .8 for reached patient).

Results

From the 293,400 reports submitted in calendar year 2019, 3,114 (1.1%) were initially identified as potentially HIT wrong-patient errors and 1,189 (0.4%) were confirmed through expert review. We first present the descriptive analysis with harm score and facility type followed by the qualitative analysis of general care process, clinical process step during which HIT wrong-patient errors occurred and were discovered, and whether the error reached the patient, with descriptions of the impact on the patient or how the error was caught.

Descriptive Analyses

Harm Score. Of the 1,189 PSE reports analyzed, nearly all reports were either unsafe conditions or events with no harm (n=1,188; 99.9%). There was 1 event with harm (0.1%).

Facility Type. Of the 1,189 PSE reports analyzed, the majority were from hospitals (n=1,186; 99.7%), with 3 reports from ambulatory surgical facilities (0.3%).

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

Figure 1. HIT Wrong-Patient Data Selection Process from PA-PSRS (Calendar Year 2019)



Qualitative Analyses

We report the general care process involved, the clinical process steps during which the HIT wrong-patient error occurred and was discovered, and whether errors reached the patient. Following these analyses, we focus on the four general care processes in which errors were most frequently involved to determine the most common clinical process steps during which the error occurred and how they were discovered.

General Care Process. The prominent general care processes in which HIT wrong-patient errors occurred were radiology (n=295; 24.8%), medication, (n=283; 23.8%), laboratory (n=241; 20.3%), and procedures (n=224; 18.8%), followed by administrative (n=95; 8.0%) and general (n=51; 4.3%).

Clinical Process Steps During Which HIT Wrong-Patient Errors Occurred and Were Discovered. Analyzing where the errors occurred, most were during prescribing/ordering (n=498; 41.9%), followed by registration (n=110; 9.3%), and before or during imaging (n=96; 8.1%).

Analyzing where the errors were discovered, approximately one-quarter of errors were discovered when reviewing information (n=286; 24.1%) followed by review of results (n=119; 10.0%). For nearly half of the reports, there was insufficient information to identify where the error was discovered (n=524; 44.1%). All frequency counts and percentages for clinical process steps during which errors occurred and where the errors were discovered are displayed in **Table 1**.

Table 1: Frequency Counts, Percentages, Definitions, and Examples of Categories for General Care Process and Clinical Process Step

	Frequency Count (%)	Definition	Example
General Care Process, N=1,189			
Administrative	95 (8.0%)	Reports related to registration, scheduling, admission, consent processing, billing, referrals, consults, scanning, faxing, and uploading documents.	The wrong patient's document was scanned into a patient's electronic chart.
General	51 (4.3%)	Reports that contain general language of HIT wrong-patient errors and do not identify whether an error was related to administrative, laboratory, medication, procedure, radiology, or other care processes.	A nurse documented a patient's weight in the incorrect electronic chart.
Laboratory	241 (20.3%)	Reports related to the ordering, labelling, collection, processing, and/or documentation of results of a clinical specimen or other laboratory procedures. Includes reports related to a specimen or blood test that does not specify whether it is a point of care test.	A nurse drew labs on a patient that were ordered for another patient.
Medication	283 (23.8%)	Reports related to the ordering and labeling, and/or the prescribing, retrieval, administration and documentation of a medication. Includes reports related to the electronic medication administration record (eMAR) and the selection of medications or wrong patients in an automated dispensing system.	A medication was ordered for a different patient than the one for whom it was intended.
Procedure	224 (18.8%)	Reports related to the ordering, processing, interruption, and/or documentation of results for procedures. Includes reports related to preop procedures, surgery, dialysis, point of care tests (e.g., iSTAT, urine dip), biopsies, transfusions, telemetry strips, and EKG/ECG.	The point-of-care urine analyzer was run under the wrong patient identification number.
Radiology	295 (24.8%)	Reports related to the ordering, processing, interpretation, and/or documentation of results for imaging. Includes reports related to CT scans, ultrasounds, and MRIs.	A patient's ultrasound was performed under the incorrect patient name.

Table 1 (continued): Frequency Counts, Percentages, Definitions, and Examples of Categories for General Care Process and Clinical Process Step

	Error Occurred	Error Discovered	Definition	Example
Clinical Process Step, N=1,189				
Before or during imaging	96 (8.1%)	91 (7.7%)	Report states HIT wrong-patient error occurred or was discovered before or during imaging. Includes errors related to patient verification and scanning or entering wrong patient information into a HIT system before a medical imaging procedure, as well as those identified immediately after obtaining an image but before it was sent or uploaded for interpretation.	Outpatient MRI done on correct patient but under incorrect name on scanner.
Before or during labs	37 (3.1%)	15 (1.3%)	Report states HIT wrong-patient error occurred or was discovered before or during laboratory specimen analysis. Includes errors related to the collection of specimens, patient verification and scanning, or entering wrong patient information into a HIT system before analyzing specimen, as well as those identified immediately after analyzing specimen but prior to inputting results into a HIT system.	The operator entered the incorrect patient identifier into the analyzer.
Before or during medication administration	24 (2.0%)	40 (3.4%)	Report states HIT wrong-patient error occurred or was discovered before or during medication administration. Includes errors related to patient verification, scanning patient barcodes or medications when an automated dispensing system was not mentioned, and opening up the wrong patient chart during administration.	Patient was started on respiratory treatment that was ordered for a different patient.
Before or during procedure	83 (7.0%)	19 (1.6%)	Report states HIT wrong-patient error occurred or was discovered before or during a procedure. Includes errors related to patient verification and scanning patient barcodes or entering patient identifiers into test equipment.	The incorrect patient identification number was entered into the point-of-care testing machine and utilized to perform and result the patient test.
Dispensing medication	35 (2.9%)	1 (0.1%)	Report states HIT wrong-patient error occurred or was discovered during the process of a clinician dispensing medication from a HIT system (e.g., automatic dispensing system).	Medication found to have been pulled from Pyxis on wrong patient but administered to correct patient.
Documentation	94 (7.9%)	25 (2.1%)	Report states HIT wrong-patient error occurred or was discovered during clinician or staff documentation within a HIT system. Includes errors related to dictating, charting on the wrong-patient, and e-messages containing wrong-patient information or being sent for the wrong-patient.	Charted under the wrong patient in the electronic health record.
Inputting results	74 (6.2%)	2 (0.2%)	Report states HIT wrong-patient error occurred or was discovered related to incorrectly inputting results into a HIT system for a wrong-patient. Includes errors related to inputting lab or imaging results into a patient's records with no explicit mention of whether the error was related to entering wrong-patient information before or during a procedure, lab or imaging.	Wrong patient results were entered into another patient's chart.
Labeling	21 (1.8%)	2 (0.2%)	Report states HIT wrong-patient error occurred or was discovered during the labeling process and that resulted from mislabeled documents, specimen, equipment or printed images. Excludes reports describing errors related to staff generating, handwriting, or retrieving labels to perform a test when "mislabeled" or "labeled" are not included in the narrative.	Specimen was mislabeled and now the results are in the incorrect patient chart.
Other	10 (0.8%)	NA	Report states HIT wrong-patient error that occurred outside of the clinical process codes or as a result of a HIT system error (not user-error). Includes errors related to discharge.	Technician reported that there had been a system issue and the wrong patient images were in the wrong chart.

	Error Occurred	Error Discovered	Definition	Example
Clinical Process Step, N=1,189				
Patient engagement	NA	32 (2.7%)	Report states HIT wrong-patient error that was discovered by a patient at any point of care. Includes errors discovered prior to a patient's arrival to a facility, during admission or an appointment, and after leaving a medical facility that were discovered in-person, from a follow-up call or from a patient portal.	Error found upon discharge when patient verified information.
Prescribing/ ordering	498 (41.9%)	19 (1.6%)	Report states HIT wrong-patient error that occurred or was discovered during the ordering or prescription of medications, images, referrals, or other care procedures. Includes errors related to consult or physician requests, discharge, and orders for a wrong patient scanned into a HIT system.	Lab orders ordered under wrong patient.
Registration	110 (9.3%)	9 (0.8%)	Report states HIT wrong-patient error occurred or was discovered during the process of patient registration or admission.	Patient was admitted under an incorrect medical record number (MRN) belonging to a different patient.
Review of results	1 (0.1%)	119 (10.0%)	Report states HIT wrong-patient error occurred or was discovered from a clinician reviewing test results in a HIT system.	Patient given 400 mg levetiracetam seven hours earlier than planned because EEG thought to show 15-second seizure. EEG was actually of a different patient.
Reviewing information	2 (0.2%)	286 (24.1%)	Report states HIT wrong-patient error occurred or was discovered when reviewing information related to patient care from a HIT system. Includes clinicians (e.g., pharmacy) reviewing orders and calling for verification.	Nurse opened incorrect patient chart and read order for oral contrast.
Scanning documents	66 (5.6%)	3 (0.3%)	Report states HIT wrong-patient error occurred or was discovered during the process of scanning care-related documents into a HIT system. Excludes orders scanned into a HIT system.	Auditing charts and found another patient's paperwork scanned into wrong record.
Scheduling	20 (1.7%)	2 (0.2%)	Report states HIT wrong-patient error occurred or was discovered during the process of scheduling a patient appointment, outpatient exam, or any other care process.	This patient was scheduled for an abdominal ultrasound but it was the wrong patient.
Insufficient information	18 (1.5%)	524 (44.1%)	Report does not explicitly state how or at what point of care the HIT wrong-patient error occurred or was discovered.	The wrong patient information was found on patient's chart.

Analysis of Whether the Report Reached Patient. Distinct from the severity level entered by the reporter, as part of our analysis, we identified whether the error described by the reporter reached the patient. Of the 1,189 errors, 290 (24.4%) reached the patient, 501 (42.1%) did not reach the patient, and for 398 reports (33.5%) there was insufficient information to determine if the error reached the patient.

Of the 290 errors that reached the patient, over one-third of reports resulted in inaccurate medication administration (n=110; 37.9%); followed by wrong test or procedure performed (n=65; 22.4%); and retest, redraw, or reimage due to results going to the wrong patient (n=56; 19.3%), shown in **Table 2**.

Of the 501 HIT wrong-patient errors that did not reach the patient, errors were frequently caught by a nurse, technician, or other healthcare staff (n=303; 60.5%). There was insufficient information in 161 (32.1%) HIT wrong-patient reports that did not reach the patient to determine how the error was caught. Very few errors were reported as being caught by a physician or advanced practice provider (n=16; 3.2%); HIT system (n=12; 2.4%); or patient, caregiver, or family member (n=9; 1.8%). All frequency counts and percentages for categories related to impact on the patient and how the errors were caught are displayed in **Table 2**, and frequency counts and percentages of whether a HIT wrong-patient error reached the patient, by the clinical process step during which it occurred and was discovered, are shown in **Table 3**.

Focused Analysis on Prominent General Care Processes. Reports categorized as radiology, medication, laboratory, or procedures, which were the general care processes with the highest frequency of reports, were further analyzed to identify the clinical process steps that were associated with errors that reached the patient and did not reach the patient. When comparing the clinical process steps, we focused on the highest frequency categories, excluding the category of insufficient information, since this category does not provide information on an identifiable clinical process step.

Radiology-Specific Reports. Of the 295 radiology related reports, 71 (24.1%) reached the patient, 159 (53.9%) did not reach the patient, and for the remaining 65 reports (22.0%) there was insufficient information to determine whether the error reached the patient.

Of the 71 radiology-related errors that reached the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=36; 50.7%), and before or during imaging (n=22; 31.1%). The most frequent identifiable clinical process steps during which errors were *discovered* included before or during imaging (n=17; 23.9%) and review of results (n=12; 16.9%).

Of the 159 radiology-related errors that did not reach the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=94; 59.1%) and before or during imaging (n=48; 30.2%), similar to errors that reached the patient. The most frequent identifiable clinical process steps during which errors were *discovered* included before or during imaging (n=69; 43.4%) and, different from errors that reached the patient, reviewing information (n=27; 17.0%). Additional details regarding errors involving radiology clinical process steps are in **Table 4**.

Medication-Specific Reports. Of the 283 medication related reports, 113 (39.9%) reached the patient, 134 (47.3%) did not reach the patient, and for the remaining 36 reports (12.7%) there was insufficient information to determine whether the error reached the patient.

Of the 113 medication-related errors that reached the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=66; 58.4%) and before or during medication administration (n=21; 18.6%). The most frequent identifiable clinical process steps during which errors were *discovered* included before or during medication administration (n=28; 24.8%) and reviewing information (n=17; 15.0%).

Of the 134 medication-related errors that did not reach the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=114; 85.1%) and, different from errors that reached the patient, dispensing medication (n=9; 6.7%). The most frequent identifiable clinical process steps during which errors were *discovered* included reviewing information (n=98; 73.0%) and before or during medication administration (n=7; 5.2%), similar to when the error reached the patient. Additional details regarding errors involving medication clinical process steps are in **Table 5**.

Laboratory-Specific Reports. Of the 241 laboratory-related reports, 61 (25.3%) reached the patient, 66 (27.4%) reports did not reach the patient, and for the remaining 114 reports (47.3%) there was insufficient information to determine whether the error reached the patient.

Of the 61 laboratory-related errors that reached the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=31; 50.8%) and before or during labs (n=11; 18.0%). The most frequent identifiable clinical process steps during which errors were *discovered* included review of results (n=20; 32.8%) and reviewing information (n=8; 13.1%).

Of the 66 laboratory-related errors that did not reach the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=29; 43.9%) and before or during labs (n=11; 16.7%), similar to errors that reached the patient. The most frequent identifiable clinical process steps during which the error was *discovered* included review of results (n=18; 27.3%) and reviewing information (n=14; 21.2%), also similar to errors that reached the patient. Additional details regarding errors involving laboratory clinical process steps are in **Table 6**.

Procedure-Specific Reports. Of the 224 procedure-related reports, 23 (10.3%) reached the patient, 76 reports (33.9%) did not reach the patient, and for the remaining 125 reports (55.8%) there was insufficient information to determine whether the error reached the patient.

Of the 23 procedure-related errors that reached the patient, the most frequent identifiable clinical process steps during which errors *occurred* included before or during procedure (n=9; 39.1%), prescribing/ordering (n=3; 13.0%), and registration (n=3; 13.0%). The most frequent identifiable clinical process steps during which errors were *discovered* included patient engagement (n=4; 17.4%) and reviewing information (n=3; 13.0%).

Of the 76 procedure-related errors that did not reach the patient, the most frequent identifiable clinical process steps during which errors *occurred* included prescribing/ordering (n=25; 32.9%) and before or during procedure (n=21; 27.6%), similar to errors that reached the patient. The most frequent identifiable clinical process steps during which errors were *discovered* included reviewing information (n=34; 44.7%) and, different from errors that reached the patient, before or during a procedure (n=14; 18.4%). Additional details regarding errors involving procedure clinical process steps are in **Table 7**.

Discussion

While there are national patient safety goals, extensive research, and specific safety improvement tools focused on reducing HIT-related wrong-patient errors, our descriptive and qualitative analyses of thousands of reports from over 500 healthcare facilities show that HIT-related wrong-patient errors persist. Of the 293,400 reports submitted to PA-PSRS in calendar year 2019, 3,114 (1.1%) were initially identified as potential HIT wrong-patient

Table 2: Frequency Counts, Percentages, Definitions, and Examples of Categories for Impact on the Patient and How the Error was Caught

Impact on the Patient (coded when the error reached the patient), N=290			
Delay in care	26 (9.0%)	A patient's care is delayed due to: • Results going to the wrong patient but can be transferred back to the correct patient (retest, redraw, reimage not needed) • The wrong patient's results are in the record • A registration error • An order, consult, or appointment on the wrong patient	A patient's X-ray was uploaded to a different patient's record. The X-ray was moved back to the right patient with technical support that took time and resulted in a delay in care.
Inaccurate medication administration	110 (37.9%)	A patient received a medication intended for another patient, or received the correct medication administered at a time, dose, or route that was intended for another patient.	Heparin was ordered and given to the wrong patient.
Other	33 (11.4%)	A wrong-patient error results in the patient receiving information that was not intended for them, including: • Prescriptions • Patient portal messages/results • Lab orders • Appointments	Patient received patient portal message of dietary recommendations and medication information from physician intended for another patient.
Retest, redraw, or reimage due to results going to the wrong patient	56 (19.3%)	A patient had the correct test, sample, or image collected, but results were entered on the wrong patient and required a retest, redraw, or reimage.	The tech performed an EKG and uploaded the results to the wrong patient record requiring the need to retest.
Wrong test or procedure performed	65 (22.4%)	A patient had a lab, imaging, or other procedure or test performed that was intended for another patient, including specimen collection.	The CT scan was performed on the wrong patient.
How the Error was Caught (coded when the error did not reach the patient), N=501			
HIT system	12 (2.4%)	Reports related to an error being identified by a HIT system (e.g., alert) prior to reaching a patient.	Upon entering a patient's weight in the wrong patient's chart, the weight alert fired.
Nurse, technician, or healthcare staff	303 (60.5%)	Reports related to an error being identified by a nurse, technician, or healthcare staff person prior to reaching the patient.	The technician questioned the physician about the order for the patient and it was discovered it was placed on the wrong patient.
Patient, caregiver, or family member	9 (1.8%)	Reports related to an error being identified by a patient, caregiver, or family member prior to reaching the patient.	When nurse described the need to be transported for an X-ray, the patient questioned the need for an X-ray and it was discovered this was for a different patient.
Physician or advanced practice provider	16 (3.2%)	Reports related to an error being identified by a provider (including attending, fellow, and resident physicians; physician assistants; and nurse practitioners).	Medication ordered for the wrong patient and identified immediately by the physician.
Insufficient information	161 (32.1%)	Reports that contain general information related to an error being identified or not reaching a patient (e.g., near miss) but do not include more specification regarding how it was identified.	Near miss, did not reach the patient.

errors using a three-pronged retrieval process and 1,189 (0.4%) were confirmed through expert review. Findings from the qualitative analysis revealed that nearly 90% of the wrong-patient errors were associated with radiology (24.8%), medication (23.8%),

laboratory (20.3%), or procedure (18.8%) general care processes, shown in **Table 1**. While most of the HIT wrong-patient related error reports reviewed described errors that did not reach the patient, 24.4% of the reports described errors that did. When the

errors reached the patient, our analyses show that the impact on the patient was frequently inaccurate medication administration (37.9% of errors reaching the patient) or the wrong test or procedure performed on the patient (22.4% of errors reaching the patient), both of which are issues that have the potential for significant patient harm. (See **Table 2.**)

Healthcare worker (e.g., nurse, technician, or other healthcare staff) workflow processes and verbal communication practices with patients, family members, and other staff often caught errors before they reached and potentially harmed the patient. These findings underscore the role of humans as a safety “line of defense” in complex healthcare environments. Within the reports, there were few instances of physicians and advanced practice providers; HIT systems, such as alerts; or patient, caregiver, or family members catching errors, which may be due to the underreporting of those details or events.³⁷

Focusing on Processes Associated With Catching Errors

Unique to our HIT wrong-patient error analysis is the focus on where the error occurred and where it was discovered. Across all 1,189 general care processes, most errors occurred during prescribing/ordering (n=498; 41.9%) replicating previous research.^{6,8,11} When it could be determined how errors were discovered, it was primarily through reviewing information (n=286; 24.1%).

Looking at the prominent general care processes individually and analyzing where the error occurred and where it was discovered for reports that reached the patient and those that did not, reveals important differences that are not appreciated when findings are collapsed across general care processes. Where there are patterns of clinical process steps that are serving to discover errors before reaching the patient, a safety science and resilience engineering approach of learning from these instances and expanding these practices can be used. Our analyses identified several interesting patterns.

- For radiology-related wrong-patient errors, nearly 50% of errors occurred during the ordering process, and when these errors were caught before reaching the patient, it was just before or during imaging as well as when reviewing information. These clinical process steps served to catch over 60% of the errors that did not reach the patient.
- For medication-related wrong-patient errors, over 70% of errors occurred during prescribing or ordering, and when these errors were discovered, before reaching the patient, over 70% of the time it was when reviewing information.
- For laboratory-related wrong-patient errors, nearly 40% of the errors occurred during the ordering process, and when these errors were discovered, before reaching the patient, it was during the review of results, review of information, and before or during labs.
- For procedure-related wrong-patient errors, over a third of the errors occurred before or during the procedure, and when these errors were caught, before reaching the patient, over 70% of the time it was when reviewing information or just before or during the procedure.

Reviewing information was a critical process step for catching errors before they reached the patient in all four general care pro-

cesses, confirming the importance of taking time to deliberately review patient identifiers. For three of the four general care processes, the time just before or during the clinical activity was also important for catching errors before they reached the patient, suggesting that time-outs and other deliberate actions to pause activity may be important for catching errors.

Recommendations for Reducing Wrong-Patient Errors

Based on our analyses, previous literature, and recommendations from other organizations, we highlight the following:

- As this study and previous studies have found, wrong-patient errors often occur during the ordering process. We recommend reviewing provider workflow processes to ensure it includes checking at least two patient identifiers.^{6,7} Additionally, EHR ordering screens may be cluttered, making it difficult to find patient identifiers, and these identifiers may not always be consistently displayed across different screens.¹⁰ Therefore, using existing toolkits to optimize HIT and workflow processes may be beneficial.⁸
- Task interruptions have been identified as a potential cause of wrong-patient errors during the ordering process.^{19,20,26} As a result, we recommend ordering providers develop strategies to manage interruptions, including:³⁸
- Placing orders in an environment that is not prone to interruptions.
- When interrupted, attempt to complete the task or place a reminder for where to resume work, such as a Post-it note or the mouse cursor. This will support accurate resumption of the interrupted task since you can look back at this reminder.
- When interrupted, ask the person interrupting you to wait for a few minutes while you complete the task of placing the order.
- We recommend that healthcare facilities review their safety reports related to wrong-patient errors to determine where existing issues reside. Interview providers and other staff to determine where they believe hazards are. Ask providers and staff about clinical process steps that they believe serve to discover errors before they reach patients, as well as where gaps exist. Once successful processes are identified, the application of these processes should be expanded.
- Across the four prominent general processes of radiology, medication, laboratory, and procedure, reviewing information was important for catching errors before they reached patients. Reiterating this importance of reviewing information and rewarding staff when these behaviors are observed will serve to reinforce this practice.
- Reviewing of information just before or during the clinical activity was also important for discovering errors before reaching the patient. Healthcare facilities should reinforce the importance of identity verification before and during clinical activities and determine whether specific time-outs or other deliberate pauses would be beneficial.

Table 3: Total Frequency Counts and Percentages for Whether a HIT Wrong-Patient Error Did or Did Not Reach the Patient by the Clinical Process Step in Which It Occurred and Was Discovered

	Total			
	All	Reached Patient	Did Not Reach Patient	Insufficient Information
Error Occurred				
Before or during imaging	96 (8.1%)	22 (7.7%)	48 (9.5%)	26 (6.5%)
Before or during labs	37 (3.1%)	11 (3.8%)	11 (2.2%)	15 (3.8%)
Before or during medication administration	24 (2.0%)	21 (7.2%)	2 (0.4%)	1 (0.3%)
Before or during procedure	83 (7.0%)	9 (3.1%)	21 (4.2%)	53 (13.3%)
Dispensing medication	35 (2.9%)	20 (6.9%)	9 (1.8%)	6 (1.5%)
Documentation	94 (7.9%)	8 (2.8%)	50 (10.0%)	36 (9.0%)
Inputting results	74 (6.2%)	13 (4.5%)	17 (3.4%)	44 (11.1%)
Labeling	21 (1.8%)	7 (2.4%)	10 (2.0%)	4 (1.0%)
Other	10 (0.8%)	1 (0.3%)	5 (1.0%)	4 (1.0%)
Patient engagement	--	--	--	--
Prescribing/ordering	498 (41.9%)	141 (48.6%)	267 (53.3%)	90 (22.6%)
Registration	110 (9.3%)	22 (7.7%)	21 (4.2%)	67 (16.8%)
Review of results	1 (0.1%)	1 (0.3%)	--	--
Reviewing information	2 (0.2%)	1 (0.3%)	1 (0.2%)	--
Scanning documents	66 (5.6%)	5 (1.7%)	22 (4.4%)	39 (9.8%)
Scheduling	20 (1.7%)	3 (1.0%)	10 (2.0%)	7 (1.8%)
Insufficient information	18 (1.5%)	5 (1.7%)	7 (1.4%)	6 (1.5%)
Total	1,189 (100%)	290 (100%)	501 (100%)	398 (100%)
Error Discovered				
Before or during imaging	91 (7.7%)	17 (5.9%)	69 (13.8%)	5 (1.2%)
Before or during labs	15 (1.3%)	3 (1.0%)	9 (1.8%)	3 (0.8%)
Before or during medication administration	40 (3.4%)	28 (9.8%)	7 (1.4%)	5 (1.2%)
Before or during procedure	19 (1.6%)	2 (0.7%)	14 (2.8%)	3 (0.8%)
Dispensing medication	1 (0.1%)	--	1 (0.2%)	--
Documentation	25 (2.1%)	1 (0.3%)	21 (4.2%)	3 (0.8%)
Inputting results	2 (0.2%)	--	2 (0.4%)	--
Labeling	2 (0.2%)	--	2 (0.4%)	--
Other	--	--	--	--
Patient engagement	32 (2.7%)	23 (7.9%)	6 (1.2%)	3 (0.8%)
Prescribing/ordering	19 (1.6%)	5 (1.7%)	12 (2.4%)	2 (0.5%)
Registration	9 (0.8%)	2 (0.7%)	5 (1.0%)	2 (0.5%)
Review of results	119 (10.0%)	34 (11.7%)	36 (7.2%)	49 (12.3%)
Reviewing information	286 (24.1%)	38 (13.1%)	199 (39.7%)	49 (12.3%)
Scanning documents	3 (0.3%)	--	2 (0.4%)	1 (0.3%)
Scheduling	2 (0.2%)	--	2 (0.4%)	--
Insufficient information	524 (44.1%)	137 (47.2%)	114 (22.7%)	273 (68.5%)
Total	1,189 (100%)	290 (100%)	501 (100%)	398 (100%)

Table 4: Radiology Frequency Counts and Percentages for Whether a HIT Wrong-Patient Error Did or Did not Reach the Patient by the Clinical Process Step in Which It Occurred and Was Discovered

	Radiology			
	All	Reached Patient	Did Not Reach Patient	Insufficient Information
Error Occurred				
Before or during imaging	96 (32.5%)	22 (31.1%)	48 (30.2%)	26 (40.0%)
Before or during labs	--	--	--	--
Before or during medication administration	--	--	--	--
Before or during procedure	--	--	--	--
Dispensing medication	--	--	--	--
Documentation	1 (0.3%)	--	--	1 (1.5%)
Inputting results	17 (5.8%)	5 (7.0%)	6 (3.8%)	6 (9.3%)
Labeling	1 (0.3%)	--	--	1 (1.5%)
Other	2 (0.7%)	--	1 (0.6%)	1 (1.5%)
Patient engagement	--	--	--	--
Prescribing/ordering	147 (49.8%)	36 (50.7%)	94 (59.1%)	17 (26.2%)
Registration	20 (6.8%)	5 (7.0%)	6 (3.8%)	9 (13.9%)
Review of results	--	--	--	--
Reviewing information	--	--	--	--
Scanning documents	2 (0.7%)	--	2 (1.3%)	--
Scheduling	4 (1.4%)	--	1 (0.6%)	3 (4.6%)
Insufficient information	5 (1.7%)	3 (4.2%)	1 (0.6%)	1 (1.5%)
Total	295 (100%)	71 (100%)	159 (100%)	65 (100%)
Error Discovered				
Before or during imaging	91 (30.8%)	17 (23.9%)	69 (43.4%)	5 (7.7%)
Before or during labs	--	--	--	--
Before or during medication administration	--	--	--	--
Before or during procedure	--	--	--	--
Dispensing medication	--	--	--	--
Documentation	--	--	--	--
Inputting results	1 (0.3%)	--	1 (0.6%)	--
Labeling	--	--	--	--
Other	--	--	--	--
Patient engagement	4 (1.4%)	2 (2.8%)	1 (0.6%)	1 (1.5%)
Prescribing/ordering	1 (0.3%)	--	1 (0.6%)	--
Registration	1 (0.3%)	--	1 (0.6%)	--
Review of results	35 (11.9%)	12 (16.9%)	13 (8.2%)	10 (15.4%)
Reviewing information	38 (12.9%)	6 (8.5%)	27 (17.0%)	5 (7.7%)
Scanning documents	--	--	--	--
Scheduling	--	--	--	--
Insufficient information	124 (42.2%)	34 (47.9%)	46 (29.0%)	44 (67.7%)
Total	295 (100%)	71 (100%)	159 (100%)	65 (100%)

Table 5: Medication Frequency Counts and Percentages for Whether a HIT Wrong-Patient Error Did or Did not Reach the Patient by the Clinical Process Step in Which It Occurred and Was Discovered

	Medication			
	All	Reached Patient	Did Not Reach Patient	Insufficient Information
Error Occurred				
Before or during imaging	--	--	--	--
Before or during labs	--	--	--	--
Before or during medication administration	24 (8.5%)	21 (18.6%)	2 (1.5%)	1 (2.8%)
Before or during procedure	--	--	--	--
Dispensing medication	35 (12.4%)	20 (17.7%)	9 (6.7%)	6 (16.7%)
Documentation	12 (4.2%)	3 (2.6%)	6 (4.4%)	3 (8.3%)
Inputting results	--	--	--	--
Labeling	4 (1.4%)	2 (1.8%)	2 (1.5%)	--
Other	--	--	--	--
Patient engagement	--	--	--	--
Prescribing/ordering	206 (72.8%)	66 (58.4%)	114 (85.1%)	26 (72.2%)
Registration	--	--	--	--
Review of results	--	--	--	--
Reviewing information	1 (0.4%)	1 (0.9%)	--	--
Scanning documents	--	--	--	--
Scheduling	--	--	--	--
Insufficient information	1 (0.4%)	--	1 (0.8%)	--
Total	283 (100%)	113 (100%)	134 (100%)	36 (100%)
Error Discovered				
Before or during imaging	--	--	--	--
Before or during labs	--	--	--	--
Before or during medication administration	40 (14.1%)	28 (24.8%)	7 (5.2%)	5 (13.9%)
Before or during procedure	--	--	--	--
Dispensing medication	1 (0.4%)	--	1 (0.8%)	--
Documentation	1 (0.4%)	1 (0.9%)	--	--
Inputting results	--	--	--	--
Labeling	--	--	--	--
Other	--	--	--	--
Patient engagement	4 (1.4%)	2 (1.8%)	2 (1.5%)	--
Prescribing/ordering	10 (3.5%)	4 (3.5%)	5 (3.7%)	1 (2.8%)
Registration	--	--	--	--
Review of results	--	--	--	--
Reviewing information	121 (42.8%)	17 (15.0%)	98 (73.0%)	6 (16.6%)
Scanning documents	1 (0.4%)	--	1 (0.8%)	--
Scheduling	--	--	--	--
Insufficient information	105 (37.1%)	61 (54.0%)	20 (15.0%)	24 (66.7%)
Total	283 (100%)	113 (100%)	134 (100%)	36 (100%)

Table 6: Laboratory Frequency Counts and Percentages for Whether a HIT Wrong-Patient Error Did or Did not Reach the Patient by the Clinical Process Step in Which It Occurred and Was Discovered

	Laboratory			
	All	Reached Patient	Did Not Reach Patient	Insufficient Information
Error Occurred				
Before or during imaging	--	--	--	--
Before or during labs	37 (15.4%)	11 (18.0%)	11 (16.7%)	15 (13.1%)
Before or during medication administration	--	--	--	--
Before or during procedure	--	--	--	--
Dispensing medication	--	--	--	--
Documentation	5 (2.1%)	1 (1.7%)	2 (3.0%)	2 (1.8%)
Inputting results	40 (16.6%)	6 (9.8%)	7 (10.6%)	27 (23.7%)
Labeling	8 (3.3%)	3 (4.9%)	4 (6.1%)	1 (0.9%)
Other	--	--	--	--
Patient engagement	--	--	--	--
Prescribing/ordering	94 (39.0%)	31 (50.8%)	29 (43.9%)	34 (29.8%)
Registration	43 (17.8%)	8 (13.1%)	7 (10.6%)	28 (24.5%)
Review of results	--	--	--	--
Reviewing information	1 (0.4%)		1 (1.5%)	--
Scanning documents	7 (2.9%)	1 (1.7%)	2 (3.0%)	4 (3.5%)
Scheduling	1 (0.4%)			1 (0.9%)
Insufficient information	5 (2.1%)		3 (4.6%)	2 (1.8%)
Total	241 (100%)	61 (100%)	66 (100%)	114 (100%)
Error Discovered				
Before or during imaging	--	--	--	--
Before or during labs	15 (6.2%)	3 (4.9%)	9 (13.7%)	3 (2.6%)
Before or during medication administration	--	--	--	--
Before or during procedure	--	--	--	--
Dispensing medication	--	--	--	--
Documentation	1 (0.4%)	--	1 (1.5%)	--
Inputting results	1 (0.4%)	--	1 (1.5%)	--
Labeling	2 (0.8%)	--	2 (3.0%)	--
Other	--	--	--	--
Patient engagement	9 (3.7%)	6 (9.8%)	3 (4.6%)	--
Prescribing/ordering	4 (1.7%)	1 (1.7%)	2 (3.0%)	1 (0.9%)
Registration			--	
Review of results	64 (26.6%)	20 (32.8%)	18 (27.3%)	26 (22.8%)
Reviewing information	30 (12.4%)	8 (13.1%)	14 (21.2%)	8 (7.0%)
Scanning documents	1 (0.4%)	--	--	1 (0.9%)
Scheduling	--	--	--	--
Insufficient information	114 (47.3%)	23 (37.7%)	16 (24.2%)	75 (65.8%)
Total	241 (100%)	61 (100%)	66 (100%)	114 (100%)

Table 7: Procedure Frequency Counts and Percentages for Whether a HIT Wrong-Patient Error Did or Did not Reach the Patient by the Clinical Process Step in Which It Occurred and Was Discovered

	Procedure			
	All	Reached Patient	Did Not Reach Patient	Insufficient Information
Error Occurred				
Before or during imaging	--	--	--	--
Before or during labs	--	--	--	--
Before or during medication administration	--	--	--	--
Before or during procedure	82 (36.6%)	9 (39.1%)	21 (27.6%)	52 (41.6%)
Dispensing medication	--	--	--	--
Documentation	17 (7.6%)	--	6 (7.9%)	11 (8.8%)
Inputting results	17 (7.6%)	2 (8.7%)	4 (5.3%)	11 (8.8%)
Labeling	5 (2.2%)	2 (8.7%)	2 (2.6%)	1 (0.8%)
Other	2 (0.9%)	--	1 (1.3%)	1 (0.8%)
Patient engagement	--	--	--	--
Prescribing/ordering	38 (17.0%)	3 (13.0%)	25 (32.9%)	10 (8.0%)
Registration	16 (7.1%)	3 (13.0%)	3 (4.0%)	10 (8.0%)
Review of results	1 (0.4%)	1 (4.4%)	--	--
Reviewing information	--	--	--	--
Scanning documents	34 (15.2%)	1 (4.4%)	9 (11.8%)	24 (19.2%)
Scheduling	8 (3.6%)	2 (8.7%)	4 (5.3%)	2 (1.6%)
Insufficient information	4 (1.8%)	--	1 (1.3%)	3 (2.4%)
Total	224 (100%)	23 (100%)	76 (100%)	125 (100%)
Error Discovered				
Before or during imaging	--	--	--	--
Before or during labs	--	--	--	--
Before or during medication administration	--	--	--	--
Before or during procedure	19 (8.5%)	2 (8.7%)	14 (18.4%)	3 (2.4%)
Dispensing medication	--	--	--	--
Documentation	3 (1.3%)	--	2 (2.6%)	1 (0.8%)
Inputting results	--	--	--	--
Labeling	--	--	--	--
Other	--	--	--	--
Patient engagement	5 (2.2%)	4 (17.4%)	--	1 (0.8%)
Prescribing/ordering	3 (1.3%)	--	3 (4.0%)	--
Registration	3 (1.3%)	--	3 (4.0%)	--
Review of results	20 (8.9%)	2 (8.7%)	5 (6.6%)	13 (10.4%)
Reviewing information	60 (26.8%)	3 (13.0%)	34 (44.7%)	23 (18.4%)
Scanning documents	--	--	--	--
Scheduling	--	--	--	--
Insufficient information	111 (49.6%)	12 (52.2%)	15 (19.7%)	84 (67.2%)
Total	224 (100%)	23 (100%)	76 (100%)	125 (100%)

Improving HIT to Reduce Wrong-Patient Errors

In addition to improving clinical processes to reduce wrong-patient errors, there is also an opportunity to improve the design of HIT systems. Additional applied research is needed to identify effective solutions and we recommend the following areas for further exploration:

- Previous research has found HIT safeguards alerting clinicians of potential wrong-patient errors during the ordering process can assist with discovering these errors before reaching the patient.²³ Thus, we recommend further exploring such protection measures to integrate into other workflow processes, such as selecting a patient from a worklist prior to performing a procedure.
- Factors related to clinical working environments, such as lighting, noise, and time pressures, are also important to consider in the context of wrong-patient errors.³⁹ For example, poor lighting, inadequate space, and high noise levels have been associated with medication errors in previous literature.^{40,41} Taking these factors into consideration when designing HIT may reduce the occurrence of wrong-patient errors.
- Several studies have shown that design interventions of HIT, such as making patient facial photographs visible to a provider during the ordering process, have been found to be effective in reducing the occurrence of these errors.^{18,22,29} We recommend incorporating such designs in combination with other strategies, including improvements to the working environment and verbal communication.

Limitations

PSE reports provide one lens for examining the safety hazards in healthcare facilities and are recognized as being underreported. Reporting is influenced by an organization's event reporting culture and ease of reporting, as well as other factors. It is likely that not all HIT wrong-patient events that occurred were reported.⁴² Additionally, when entering reports, the reporter is not required to specify clinical process steps in which an error occurred, was discovered, or how it was caught, resulting in only a subset of reports having this information. It is also worth noting that while the descriptive analysis showed there was only one report with harm, this may underrepresent the actual number of reports that resulted in harm; the reporter may not have known the severity of the event at the time the report was entered.

Conclusion

HIT wrong-patient errors continue to occur across different general care processes and can have serious patient safety consequences. Identifying clinical process steps that are serving to catch errors before they reach the patient can provide additional insight into ways to prevent these errors from harming patients.

Institutional Review Board: This study was approved by the MedStar Health Research Institute institutional review board.

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About the Authors

Tracy Kim (tracy.c.kim@medstar.net) is a research and program coordinator at the MedStar Health National Center for Human Factors in Healthcare.

Jessica Howe is a research scientist and system safety specialist at the MedStar Health National Center for Human Factors in Healthcare.

Ella Franklin is the nursing director at the MedStar Health National Center for Human Factors in Healthcare.

Seth Krevat is assistant vice president for Safety at MedStar Health and a faculty associate at the MedStar Health National Center for Human Factors in Healthcare.

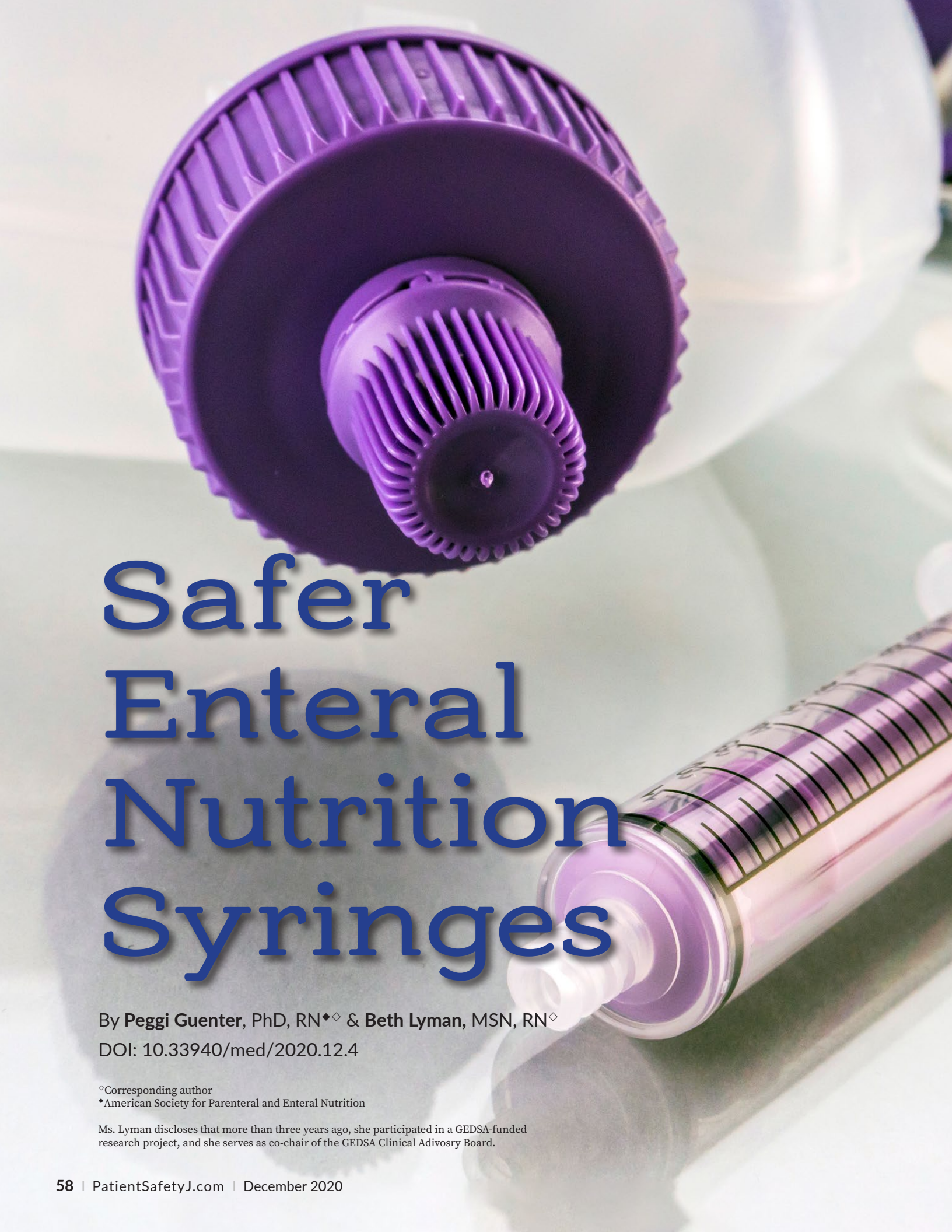
Rebecca Jones is director of Data Science and Research at the Patient Safety Authority (PSA) and founder and director of the PSA's Center of Excellence for Improving Diagnosis.

Katharine Adams is a data scientist with the MedStar Health National Center for Human Factors in Healthcare.

Allan Fong is a senior research scientist with the MedStar Health National Center for Human Factors in Healthcare.

Jessica Oaks is a program manager at the Patient Safety Authority.

Raj Ratwani is the director of the MedStar Health National Center for Human Factors in Healthcare, vice president of Scientific Affairs at the MedStar Health Research Institute, and an associate professor at Georgetown University School of Medicine.



Safer Enteral Nutrition Syringes

By Peggi Guenter, PhD, RN^{◆◇} & Beth Lyman, MSN, RN[◇]

DOI: 10.33940/med/2020.12.4

[◇]Corresponding author

[◆]American Society for Parenteral and Enteral Nutrition

Ms. Lyman discloses that more than three years ago, she participated in a GEDSA-funded research project, and she serves as co-chair of the GEDSA Clinical Advisory Board.



Hundreds of thousands of patients receive enteral nutrition (EN) or tube feeding each year in U.S. hospitals, and many more in long-term care and home settings.¹ In addition, these patients receive medications and or supplemental fluids, most often through that feeding tube, using syringes to deliver the medication or fluids. With each of those many medications, usually administered several times a day, a syringe is used and an enteral connection is made between the syringe and the enteral access device. With each connection is the potential for a misconnection or wrong route error.

An enteral misconnection is defined as an inadvertent connection between an enteral feeding system and a non-enteral system such as an intravenous (IV) line, peritoneal dialysis catheter, tracheostomy tube cuff, or medical gas tubing.² More than 116 instances of enteral misconnections were reported in a large review, spanning 1972–2010.³ The severity of this type of error was high and resulted in death in 18% of the patients due to ensuing embolus or sepsis.³ While this review reports many misconnections, like many other adverse events, enteral misconnections may be greatly underreported.

In a report that included 24 cases of enteral misconnection errors, these events were classified by type. The report found 33% of the errors were sentinel events, which result in permanent injury, a life-threatening situation, and/or death.² These misconnections were related to use of IV syringe pumps for EN, preparing enteral medications using IV syringes, and administering ready-to-hang enteral formula with IV tubing.² In this report, 13 cases were enteral medications administered intravenously using an IV syringe. This resulted in a 23% rate of life-threatening or fatal outcomes.²

In 2013, another report cited 20 cases of inadvertent IV administration of oral medications between 2004 and 2012. In this paper from the Patient Safety Authority (PSA), all the events reached the patient and 20% (n=4) resulted in patient harm, including one death. In many of these cases, oral drugs were administered using an IV syringe.⁴

In a data set provided to these authors by Dr. Mike Cohen of the Institute for Safe Medication Practices (ISMP), as reported to the Medication Errors Reporting Program (MERP), 8 incidents were noted between 2000 and 2019. In each of these cases, medication or fluid not intended for IV administration was given intravenously. Since 2012, after all the above reports, an additional 3 incidents occurred with this same scenario, where the nurse administered a non-IV medication using a parenteral syringe, with one of the three patients expiring.

Adding a patient-level perspective to these sentinel events greatly reinforces the need for change. Here is one such unfortunate event:

A 24-year-old woman was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready-to-hang enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, which the woman had received on previous admissions, pulled regular intravenous tubing from floor stock, spiked the bag, and started the infusion of tube feeding through the patient's peripherally inserted central catheter line. The fetus died—and then the mother, after several hours of excruciating pain.²

While this incident did not involve a syringe, it involved enteral connectors of which have been changed to a safer design.

Enteral delivery systems include the feeding tube or access device, an administration set or bag, a feeding pump, and/or an enteral syringe. This system can have many connections, again, each with a chance of a misconnection. In response to reported misconnections, the International Organization for Standardization (ISO) created and published the ISO 80369 standard for small-bore connectors in 2010.⁵ The first clinical platform of this new connector standard was ISO 80369-3 for enteral feeding.^{6,7} The first connectors on the U.S. market were launched on enteral administration sets in 2014. As seen in the drawing in **Figure 1**, the ENFit connector is no longer a tapered end but requires a twisting motion to connect the two ends, with the feeding tube end being the male end and the delivery set or syringe being the female end. This is called “design incompatibility,” because these connectors do not work with any non-enteral medical devices.

New ISO 80369-3 compliant connector (known as ENFit) enteral syringes with volumes ranging from 1 mL to 100 mL are now available to “force function”—meaning the clinician can only deliver the medication via another ENFit-compatible connection, such as a feeding tube, and not an IV catheter. A concern early on with the new ENFit syringe was dosing accuracy of small-volume medications due to the reverse orientation of the entire enteral system,

Figure 1. ENFit® Connector



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Figure 2. ENFit® Low Dose Tip Syringe



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Since the transition to these connectors, there have been zero wrong route medication errors associated with these connectors in the United Kingdom.

as the dead space volume was deemed to be significant. To mitigate this problem, a low dose tip (LDT) syringe was developed and tested and has been shown to be accurate.⁸ As seen in **Figure 2**, there is an internal stem in the LDT syringe to mitigate the dead space concern.

While most of the United Kingdom and Europe has already transitioned to ENFit, progress is slow in North America. Since the transition to these connectors, there have been zero wrong route medication errors associated with these connectors in the U.K., indicating this is a successful patient safety initiative.⁹ Overall, this transition involves changing approximately 200 products and requires education of staff and patients, making it a mega change in practice for most institutions. However, the Global Enteral Device Supplier Association (GEDSA) has many resources on their website (www.stayconnected.org) to assist with the planning and implementation of the transition. In addition, GEDSA has a multidisciplinary Clinical Advisory Board of clinicians who have successfully transitioned to ENFit connectors and serve as resources for institutions seeking assistance.

There are several reasons why this transition may be slower in the United States as compared to the global market. These include, first, that the conversion is not mandatory as regulated by the U.S. Food and Drug Administration (FDA), The Joint Commission, and any payers. Second, the United States has a decentralized healthcare system that does not lend itself to concerted action across the country. Third, healthcare systems have had competing priorities over the past few years, such as implementing electronic health records systems and now the COVID-19 pandemic, which has paused conversion efforts to focus on the priority of the virus; hospitals are reporting that the transition was not a priority and, in addition, manufacturers’ representatives cannot get into the hospitals to help with the conversions. Finally, some facilities remain unconvinced of the need for conversion or its benefits.

In order to stop ongoing misconnections with medication delivery, it is imperative that the proper syringes are available and used for all medication preparation and administration, particularly enteral medications. This is especially important during this transition period in the United States, where ENFit enteral syring-

es are slowly replacing legacy syringes for enteral use in hospitals. Suggested practices to prevent this ongoing risk of wrong route error include the following steps:

1. Be sure providers order medications with specific route noted (via nasogastric tube versus oral)
2. Communicate specific medication route with pharmacy in as many ways as possible
3. Have pharmacy prepare medications and deliver to patient care area in enteral syringes
4. Have enteral syringes of all needed sizes available at the nurses' medication preparation areas
5. Prepare an injectable medication to be administered enterally with an ENFit blunt tip needle and ENFit syringe.
6. Send a zip-close bag of ENFit supplies home with patients to allow them to give medications at home. (Some institutions send home adapters to allow for legacy syringes to be used with ENFit feeding tubes, but workarounds should be time-limited)
7. Avoid workarounds like adapters that allow ENFit syringes to become legacy or vice versa.
8. Amend durable medical equipment orders to include ENFit syringes so these companies can provide ongoing supplies to patients.
9. Educate families and staff about this change prior to, during, and after the transition, with opportunities for hands-on practice with the new supplies.
10. Encourage retail pharmacies to stock enteral syringes for over-the-counter purchase by home EN families. (These syringes are now available on Amazon and other internet sources.)
11. Prepare medications using the steps outlined in the medication delivery infographs for inpatient and home settings.^{10,11}

Use of appropriate enteral syringes can prevent misconnections such as those incidents illustrated in the case reports outlined in this paper. This important global patient safety initiative to prevent enteral misconnections is just the first of many connector changes to come, with neuraxial connectors changing next. The lessons learned from this first transition experience will be a template for how the next connector transitions can be implemented. Patient safety builds one step at a time, but the momentum depends on the work of individual institutions and clinicians dedicated to making the healthcare system a safer environment.

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About the Authors

Peggi Guenter (peggi@nutritioncare.org) is senior director of Clinical Practice, Quality, and Advocacy at the American Society for Parenteral and Enteral Nutrition.

Beth Lyman (lymanb2054@gmail.com) is a nutrition support nurse consultant.

An Analysis of Patient Safety Events Submitted by Abortion Facilities in Pennsylvania 2017–2019

By **Elizabeth Kukielka**, PharmD, MA, RPh[◇]
DOI: 10.33940/data/2020.12.5

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



Induced abortion, also called elective abortion, therapeutic abortion, and termination of pregnancy, is widely considered a safe procedure, but complications are known to occur. In Pennsylvania, an induced abortion may be performed at an abortion facility as an outpatient procedure, and these facilities are required to report patient safety events to the Pennsylvania Patient Safety Reporting System (PA-PSRS). We extracted 736 events submitted to PA-PSRS by abortion facilities from 2017 through 2019 and analyzed these events in order to better understand patient safety concerns at abortion facilities in particular. All patients were female, and they ranged in age from 14 to 47 years, with a median patient age of 27 years (interquartile range = 23 to 31 years). Complications related to an induced abortion comprised the majority of events (71.6%; n=527), followed by unplanned transfers to the emergency department or acute visits to a healthcare facility following an induced abortion (13.9%; n=102). The most common complication associated with induced abortion was an incomplete abortion (i.e., retained pregnancy tissue; n=343); other complications included failed abortions (i.e., a continuing intrauterine pregnancy following an abortion; n=101), infections (e.g., endometritis and pelvic inflammatory disease [PID]; n=45), and surgical complications (e.g., hematometra, uterine perforation, and cervical lacerations; n=66). The remainder of events (14.5%; n=107) described other patient safety events that occurred at abortion facilities, such as documentation failures and medication-related events.

Keywords: *abortion complication, incomplete abortion, failed abortion, hematometra, endometritis, uterine perforation, patient safety*

Introduction

Induced abortion, also called elective abortion, therapeutic abortion, and termination of pregnancy, is the removal of pregnancy tissue (i.e., an embryo or fetus) from the uterus.¹ Induced abortion is accomplished through the use of medication (termed medical abortion or medication abortion) or surgical techniques (termed surgical abortion), or some combination of the two.¹ Medical abortions are offered up to 10 weeks estimated gestational age (EGA); surgical abortions are more common for abortions at nine weeks EGA and beyond.¹ In the United States, the most common medication regimen utilized for medical abortion is a combination of mifepristone 200 mg followed 24 to 48 hours later by misoprostol 800 mcg (typically administered vaginally or buccally).^{2,3} The most common surgical abortion procedures are vacuum aspiration, dilation and curettage (D&C), and dilation and evacuation (D&E).¹

Although induced abortion is widely considered a safe procedure, complications are known to occur.^{4,5} Many patients having a medical abortion will experience pain and bleeding during or after the process as the pregnancy passes; pain is also common for patients undergoing surgical abortion.⁴ The most common complication associated with induced abortion is an incomplete abortion; other complications include failed abortion, infections (e.g., endometritis and pelvic inflammatory disease [PID]), and surgical complications (e.g., hematometra, uterine perforation, and cervical lacerations).⁴ Medications, procedures, and potential complications related to induced abortion are detailed in **Table 1**.¹⁻¹⁴

In Pennsylvania, abortions may be performed at licensed abortion facilities, and any abortion facility that performs more than 100 abortions per calendar year is required to report patient safety events to the Pennsylvania Patient Safety Reporting System (PA-PSRS)*.¹⁵ The Pennsylvania Department of Health (PA DOH) has been

monitoring and reporting data related to abortions since 1975, but the patient safety reports submitted to PA-PSRS are typically more detailed than the information included in the annual reports published yearly by the PA DOH and may therefore provide greater insight into abortion complications and other patient safety events that occur at abortion facilities. For this reason, we performed an analysis of all patient safety events submitted to PA-PSRS by abortion facilities over a three-year period to better understand associated patient safety concerns that arise at abortion facilities.

Methods

We extracted all event reports submitted to PA-PSRS by abortion facilities from January 1, 2017, through December 31, 2019. All event reports extracted were included in this analysis.

A descriptive analysis was performed to evaluate trends among information specified by the reporting facility, including patient age, event classification and harm score, and event type and subtype(s). An in-depth qualitative analysis of free-text fields (i.e., event detail, event comments, event recommendation, and event type sub other†) was performed to collect pertinent information (if specified) that would allow better characterization of patient safety events. For event reports that included details about an abortion complication, the following information was coded (if specified):

- Abortion type (i.e., medical or surgical)
- Estimated gestational age (EGA)
- Abortion complication(s)
- Treatment modalities, including medications, used to manage abortion complication(s)

Relationships between key variables, such as abortion complication, abortion type, and treatment modalities, were also explored.

*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).¹⁵ All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

†The field “event type sub other” provides a space for facilities to add details for events that are classified as other.

Table 1a: Induced Abortion: Medications and Procedures^{1-3,5,6,9,10}

Most Common Medications Used for Medical Abortion ^{1-3, 5, 6}	
mifepristone (Mifeprex) (previously known as RU-486)	• Dosage form: tablet • Route of administration: oral • Mechanism of action: counters the effects of progesterone, a hormone that is necessary to sustain pregnancy • Common adverse effects: nausea, vomiting, vaginal bleeding (may be serious), and pelvic pain • Other: most effective when used in combination with another medication, such as misoprostol
misoprostol (Cytotec)	• Dosage form: tablet • Route of administration: oral, buccal, sublingual, vaginal, or rectal (bold indicates most effective route) • Mechanism of action: causes uterine contractions and cervical dilation • Common adverse effects: bleeding, cramping, diarrhea, nausea, and vomiting • Other: typically used in combination with mifepristone for a medical abortion; may be used to dilate the cervix prior to a surgical abortion
methotrexate (Trexall)	• Dosage form: tablet, powder for injection • Route of administration: oral, intramuscular injection • Mechanism of action: blocks the production of reduced folate, which is necessary for cell reproduction and DNA synthesis • Common adverse effects: diarrhea, nausea, and vomiting • Other: typically reserved for women who are allergic to mifepristone or when mifepristone is unavailable; should not be used beyond seven weeks EGA; also used to treat ectopic pregnancy
Most Common Procedures for Surgical Abortion ^{1, 5, 9, 10}	
vacuum aspiration	• Duration: about 15 minutes • Procedure: cervix is dilated; a small, flexible tube is inserted into the uterus through the cervix; a suction device, either handheld (manual vacuum aspiration [MVA]) or electric (electric vacuum aspiration [EVA]), is used to suction out pregnancy tissue • Typical uses: pregnancy termination; removal of retained pregnancy or pregnancy tissue after a failed or incomplete abortion
dilation and curettage (D&C)	• Duration: 5–15 minutes • Procedure: cervix is dilated; sharp instruments known as curettes are used to remove the pregnancy tissue; often used in combination with suctioning (MVA or EVA) to ensure the procedure is complete • Typical uses: pregnancy termination; removal of a retained pregnancy or pregnancy tissue after a failed or incomplete abortion
dilation and evacuation (D&E)	• Duration: procedure itself takes 10–25 minutes, but cervical dilation requires advance preparation over one to three days • Procedure: cervix is dilated (with medication, mechanical dilators, or osmotic dilators) in advance of the surgery; suctioning is used along with larger instruments (e.g., forceps) to ensure all the pregnancy tissue is removed • Typical uses: pregnancy termination between 14 and 26 weeks EGA; removal of a retained pregnancy or pregnancy tissue after a failed or incomplete abortion

Table 1b: Induced Abortion: Complications^{1,4,7,8,11-14}

Potential Complications of Induced Abortion ^{1, 4, 7, 8, 11-14}		
Retained pregnancy or pregnancy tissue	failed abortion	• Complication that results when an induced abortion fails to terminate the pregnancy and an ongoing pregnancy is identified in the uterus • More common with early EGA • When misoprostol was administered as part of the procedure, the primary safety concern is the possibility of birth defects
	incomplete abortion	• Pregnancy tissue remaining in the uterus following an induced abortion • May also be termed retained pregnancy tissue, retained products of conception (RPOC), or intrauterine debris
Infection	endometritis	• Inflammation and infection of the endometrium (i.e., the uterine lining) that results from introduction of bacteria into the uterus • First and most common symptom is fever; other symptoms include abdominal and/or pelvic pain and vaginal bleeding or discharge
	pelvic inflammatory disease (PID)	• A clinical syndrome that encompasses inflammation and infection of the organs of female upper genital tract, including the uterine lining (endometritis), the connective tissue surrounding the uterus (parametritis), the ovaries (oophoritis), the fallopian tubes (salpingitis), and the surrounding peritoneal space (peritonitis) • Symptoms are similar to endometritis but may be more diffuse
Surgical complications	hematometra	• Blood retained within the uterine cavity in the postoperative period
	uterine perforation	• Tear or cut in the uterus that may result from a surgical abortion
	cervical laceration	• Tear or cut in the cervix that may result from a surgical abortion
	broad ligament hematoma	• Hematoma (a collection of blood) that forms in the broad ligament, which is a peritoneal fold that attaches the uterus, fallopian tubes, and ovaries to the pelvis • Typically results from a tear or laceration of the cervix, uterus, or vagina
	ovarian vein thrombosis	• Thrombosis (clot) that forms in an ovarian vein (typically on the right) and obstructs blood flow • Radiographic imaging is necessary for diagnosis
	uterine rupture	• Catastrophic tear of the uterus into the abdominal cavity occurs • Tear often originates along a cesarean scar
	vaginal laceration	• Tear or cut in the vagina that may result from a surgical abortion
	vasovagal reaction	• A type of reflex syncope that results from a failure of blood pressure autoregulation • In the setting of surgical abortion, this may be caused by the use of osmotic dilators for cervical dilation

Results

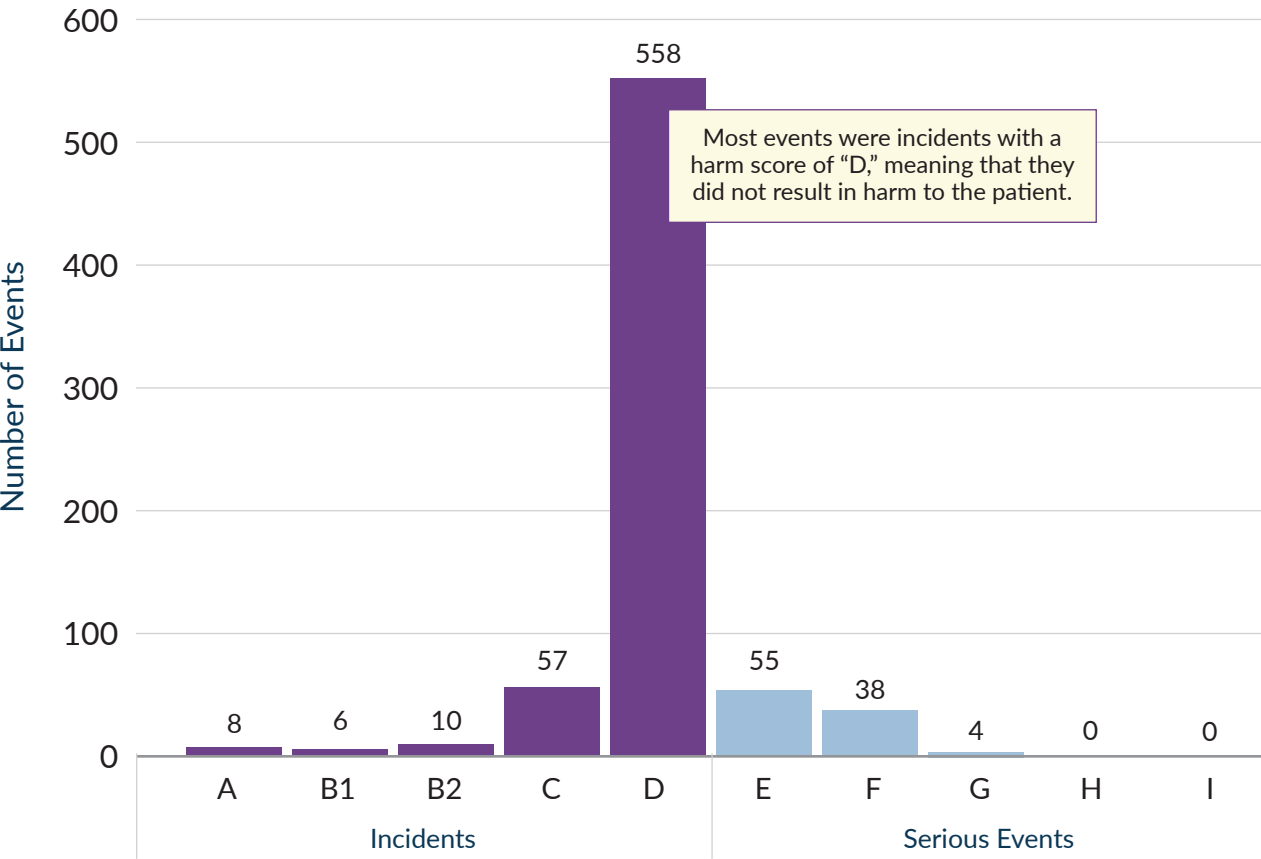
Descriptive Analysis

We analyzed 736 events submitted by abortion facilities in Pennsylvania from January 1, 2017, through December 31, 2019. Most events were classified by the reporting facility as a complication of a

procedure, treatment, or test (84.2%; 620 of 736); within this category, events were most often specified as “other complication following surgery or invasive procedure” (59.3%; 344 of 620) or simply as “other” (36.1%; 224 of 620). Event classification (incident[‡] versus serious event[§]) and harm score for all events are detailed

in **Figure 1**; the vast majority of events were classified as incidents (86.8%; 639 of 736) with an assigned harm score of D[¶] (75.8%; 558 of 736), which indicates that the patient did not sustain harm as a result of the event. No events resulted in patient death. All patients were female, and they ranged in age from 14 to

Figure 1: Event Classification and Harm Scores, Assigned by Facilities, N=736



Harm Scores¹⁵

- A – Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)
- B1 – An event occurred but it did not reach the individual (“near miss” or “close call”) because of chance alone
- B2 – An event occurred but it did not reach the individual (“near miss” or “close call”) because of active recovery efforts by caregivers
- C – An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission such as a missed medication dose that does reach the individual)
- D – An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm
- E – An event occurred that contributed to or resulted in temporary harm and required treatment or intervention
- F – An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization
- G – An event occurred that contributed to or resulted in permanent harm
- H – An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life)
- I – An event occurred that contributed to or resulted in death

[‡]An “incident” is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.¹⁵

[§]A “serious event” is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.¹⁵

[¶]A harm score of “D” indicates that an event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.

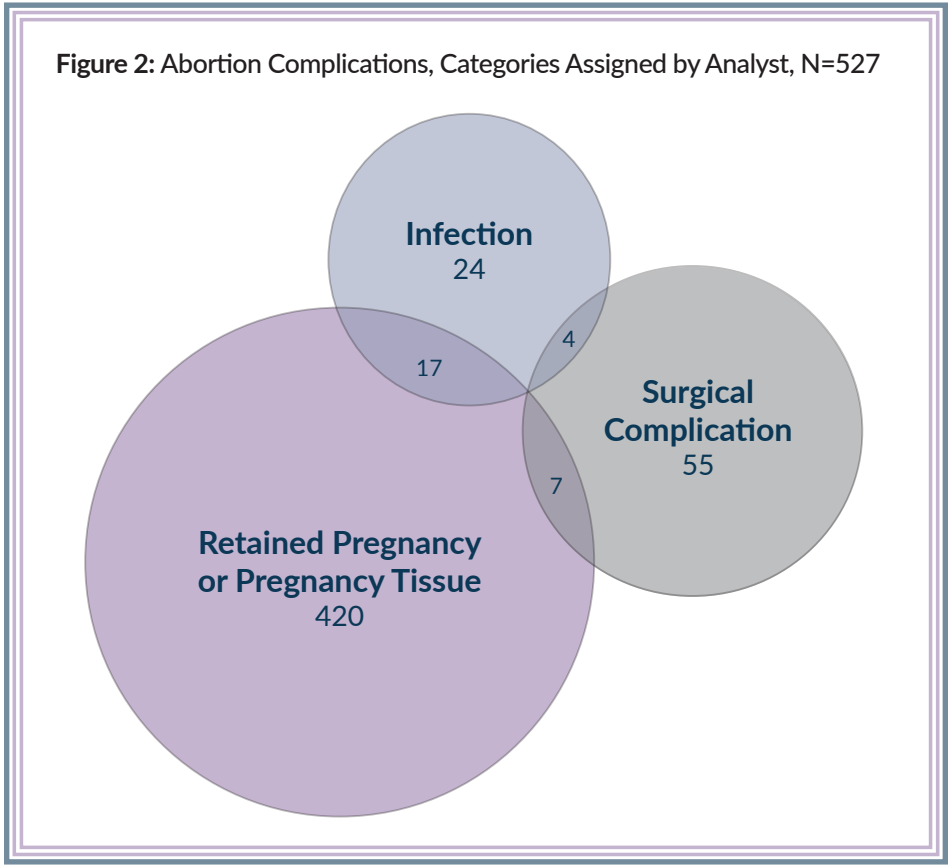
47 years, with a median patient age of 27 years (interquartile range=23 to 31 years).

All events except 1 were in some way related to an induced abortion (either stated directly or implied); the 1 remaining event described an expelled contraceptive implant. About three-quarters (71.7%; 527 of 736) of events described a patient who experienced one or more complications related to an abortion, and 102 events (13.9%) described a patient who had an immediate unplanned transfer to the emergency department (ED) following an induced abortion, or later unplanned acute visit to the abortion facility or an ED following an induced abortion. The remaining 106 events (14.4%) were unrelated to an abortion complication and described procedural or administrative issues surrounding an induced abortion performed at the abortion facility, such as documentation failures or medication-related events.

In-Depth Qualitative Analysis of Abortion Complications

Among 527 events that described at least one abortion complication, patients more often had undergone a medical abortion (69.1%; n=364) than a surgical abortion (30.4%; n=160); 3 events did not specify the type of abortion. EGA was specified for 380 of these events and ranged from 4 to 23 weeks.

Events were categorized into three groups of abortion complications: retained pregnancy or pregnancy tissue (84.3%; 444 of 527), surgical complications (12.5%; 66 of 527), and infections (8.5%; 45 of 527). Complication groups were not mutually exclusive, and 28 patients experienced complications in two of the three groups,



e.g., a surgical complication and an infection (see **Figure 2**). Abortion complications categorized by complication type and year are summarized in **Table 2**.

Retained Pregnancy or Pregnancy Tissue

Among 444 events involving a retained pregnancy or pregnancy tissue, incomplete abortions (77.3%; n=343) were far more common than failed abortions (22.7%; n=101). Overall, among 426 events that specified one or more treatments for a failed or

incomplete abortion, the most common treatment was a D&C; treatments for failed and incomplete abortions grouped by abortion type are detailed in **Table 3**.

Among 350 events in which a patient was diagnosed with a failed or incomplete medical abortion, the patient received an additional dose of misoprostol as second-line treatment in 94 events (26.9%). In nearly one-third (33.0%; 31 of 94) of those events the patient required third-line treatment, and the most common third-line treatment was a D&C (87%; 27 of 31).

Table 2: Abortion Complications by Year of Occurrence, N=527

Year	Retained Pregnancy or Pregnancy Tissue		Infection		Surgical Complication			Total
	Failed Abortion	Incomplete Abortion	Endometritis or PID	Other	Hematometra	Uterine Perforation	Other	
2017	32	83	13	4	14	9	5	160
2018	36	100	7	6	5	6	9	169
2019	33	160	10	5	7	8	3	226

Note: PID indicates pelvic inflammatory disease.

Table 3: Treatments for Incomplete and Failed Abortions by Abortion Type, N=426

	Surgical Abortion		Medical Abortion	
	Failed Abortion	Incomplete Abortion	Failed Abortion	Incomplete Abortion
Dilation and Curettage	1	41	52	111
Misoprostol	1	19	5	89
Aspiration	1	11	5	21
Expectant Management	0	4	0	18
Dilation and Evacuation	2	6	9	13
Unspecified Surgical Procedure	3	0	12	0
Other	1	6	1	1

Note: "Other" includes sutures, hysterectomy, salpingectomy, and laparoscopy.

Infections

Infections[#] were observed more often following a medical abortion (55.6%; 25 of 45) than a surgical abortion (42.2%; 19 of 45); the abortion type was not specified in 1 event that involved an infectious complication. The most common infections were endometritis/PID** (66.7%; 30 of 45) and urinary tract infections (15.6%; 7 of 45); other infectious complications included sepsis and group B streptococcal infection. Endometritis/PID occurred with roughly the same frequency following a medical abortion (53.3%; 16 of 30) or a surgical abortion (46.7%; 14 of 30).

Among 45 events involving an infectious complication, 42 events (93.3%) specified that the patient received antibiotic therapy, and 13 events indicated that the patient received a combination of antibiotics. Among 16 patients diagnosed with endometritis/PID for whom the prescribed antibiotic(s) were specified, a combination of ceftriaxone, doxycycline, and metronidazole was prescribed most often (n=5). For the 1 event in which a patient was diagnosed with sepsis, the patient had undergone a medical abortion, and she received a combination of ceftriaxone, doxycycline, and vancomycin to treat the infection.

Surgical Complications

The most common surgical complications following a surgical abortion were hematometra (n=26), uterine perforation (n=23), cervical lacerations (n=7), and uterine atony (n=4); other surgical complications included a serious vasovagal reaction, vaginal perforation, ovarian vein thrombosis, broad ligament hematoma, and uterine rupture secondary to placenta increta^{††}. Among 26 patients who were diagnosed with hematometra, 10 patients were treated with a D&C, and 8 patients were treated with MVA. Among 23 patients who experienced a uterine perforation, 6 patients underwent laparoscopy to confirm and/or repair the perforation, and 3 patients required a hysterectomy.

Other Unplanned Transfer or Acute Visit Following Induced Abortion

Following an abortion procedure, 102 events (13.9%; N=736) involved an unplanned transfer or acute visit; among events that specified the type of abortion procedure, patients had more often undergone a medical abortion (n=64) than a surgical abortion (n=32). Eight patients were immediately transferred to an ED for evaluation of a possible complication (e.g., uterine perforation, elevated blood

pressure, or excessive bleeding); these patients were treated and released following confirmation that a complication had not occurred, or the details of their visit were not specified or not known.

An additional 94 patients had an unplanned visit to a healthcare facility (i.e., the abortion facility, an urgent care clinic, or an ED) at some time after their procedure for evaluation of symptoms. Apart from bleeding, which we analyzed across all events (see below, **Other Trends**), the most common presenting symptoms overall were pain or cramping (n=46), dizziness or fainting (n=12), and nausea or vomiting (n=9); other complaints included fever, flu-like symptoms, dehydration, hypertension, shortness of breath, chest pain, and weakness. Among 46 patients that reported pain or cramping, 27 patients received analgesic medications, which included acetaminophen, nonsteroidal anti-inflammatory drugs, and opioids.

Brief Analysis of Other Patient Safety Events Unrelated to an Abortion Complication

The remaining 106 events (14.4%; N=736) that were not related to an abortion complication or an unplanned transfer

[#]Diagnosis of infection is a complex process that goes beyond the scope of this analysis, as the Patient Safety Authority does not have access to patient-specific clinical data related to event reports. Events were coded as infections if the facility reported them as such.

^{**}Endometritis and PID were grouped together because endometritis is a diagnosis that falls under the umbrella of PID, and treatment of the two infections is similar.⁸

^{††}Placenta increta is a complication of pregnancy in which placental tissue invades the myometrium.¹⁶

or acute visit following an induced abortion are summarized in **Figure 3**. Over one-quarter (27.4%; 29 of 106) of events involved documentation errors (e.g., patient or provider did not sign consent or provider did not document procedure or monitoring), and another one-quarter (24.5%; 26 of 106) of events involved medication (e.g., patient left the facility without her prescription, patient was not given RhoGAM^{**} as indicated, or patient was dispensed the wrong medication). The other half of events (47.2%; 50 of 106) fell into one of five groups: (1) patient nonadherence (e.g., patient signed out against medical advice prior to the completion of the observation period or patient used an illicit substance prior to the procedure); (2) change in procedure from surgical abortion to medical abortion or vice versa, often related to an incorrect EGA or complicated patient anatomy; (3) patient experienced an adverse reaction following procedure while still at the facility (e.g., fall or heavy bleeding); (4) patient had a preexisting condition that precluded continuing with the induced abortion or required additional treatment following the procedure (e.g., ectopic pregnancy, tumor, or tortuous blood vessel); or (5) another procedural complication (e.g., problems with dilators for a surgical abortion or lost specimen following a procedure).

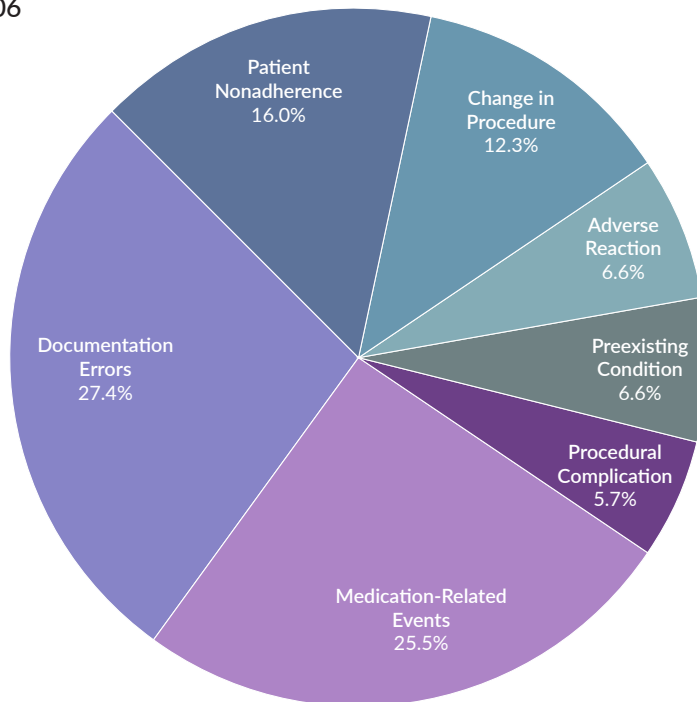
Other Trends

There were some trends observed across all reported events. The patient experienced concerns surrounding bleeding following an induced abortion in 221 events (30.0%; N=736). Among these bleeding events, the patient was diagnosed with anemia in 32 events, and the patient received a blood transfusion in 34 events; these were not mutually exclusive. Patient adherence was a concern in 59 events (8.0%; N=736) that specifically indicated the patient was “not compliant” with some aspect of an induced abortion or its follow-up.

Discussion

To our knowledge, our analysis is the first to examine patient safety reports related to induced abortions and com-

Figure 3: Patient Safety Events Unrelated to an Abortion Complication, N=106



plications submitted solely by abortion facilities. In addition, the information available in the reports submitted to PA-PSRS is more detailed than what is available in state or national abortion surveillance reports, and so our analysis is able to provide a unique perspective on the topic of abortion complications.

Recent annual reports of abortion statistics published by the PA DOH indicate that women more frequently undergo surgical abortions than medical abortions, with surgical abortions accounting for roughly 60% of procedures performed in 2017 and 2018.^{17,18} However, complications were observed more often following medical abortions in both our analysis and in annual reports of abortion statistics in Pennsylvania, and the most common complication we observed with medical abortion was a failed or incomplete abortion.^{17,18} This finding is not surprising given that studies have found that medical abortion fails more often than surgical abortion, with success rates of 94.1% and 97.7%, respectively.¹⁹

We observed an increase in the number of incomplete abortions reported from 2017 to 2019. At the time of publication of this article, abortion data across the United States is available only through 2016 and within Pennsylvania only through 2018, so we cannot draw any conclusions about the relationship between this observed shift and the number and type of induced abortions performed each year. It should also be noted that overall patient safety event reporting increased across Pennsylvania during this same timeframe, so we cannot determine whether there were more actual events or if the increase is solely due an increase in reporting efforts.

Although the choice of induced abortion is dictated in part by the EGA, patients often do have clear preferences for one procedure type over another that may include considerations other than success rates.^{10,20} In a study of women's preferences regarding induced abortion, women who were eligible for either a medical or surgical abortion based on EGA underwent a medical abortion 68% of the time.²⁰ Medical abortion offers a

^{**}Rh^o(D) immune globulin (RhoGAM) is an injection administered after spontaneous or induced abortion to women who are Rh negative to prevent a reaction against fetal blood that is Rh positive.¹

less invasive option that may be completed in the privacy of the patient's home, and more recently, telemedicine may allow for patients who would otherwise have limited access to induced abortion to safely receive a medical abortion remotely.²¹ Alternatively, some women prefer surgical abortion because of the low rate of complications and completion within an expected time frame.¹⁰

Bleeding is an anticipated complication of any induced abortion¹ and was frequently reported in our study across all events; however, bleeding severe enough to require a blood transfusion was rare. Post-abortion bleeding is generally only considered to be a serious complication when it is heavy for longer than 12 hours or when bleeding persists beyond 21 days.²² Bleeding as a serious complication may result from uterine atony, uterine perforation, cervical lacerations, incomplete abortion, or an underlying coagulopathy.¹³ Absence of bleeding following a medical abortion may be a signal that the procedure has failed and further intervention may be required.¹

Worldwide, infectious complications are a serious cause of morbidity and mortality following induced abortion, especially in areas where access is limited or induced abortions are illegal.²³ In the United States, infections following induced abortion are rare, and we observed infectious complications in only 8.5% of events involving abortion complications.^{23, 24} Retained pregnancy tissue following induced abortion may provide an ideal spot for an infection to germinate, and surgical instruments introduced into the uterus during an induced abortion are believed to increase the risk for an infection.²⁴

Information was sparse in the medical literature regarding endometritis following induced abortion, and this is likely due to the rarity of this complication in the United States. In contrast, endometritis is one of the most common postpartum complications following cesarean delivery, occurring in up to a quarter of cases.²⁴ Endometritis is a clinical diagnosis, and the most common signs of this infection include retained pregnancy tissue, fever, vaginal discharge, and heavy bleeding.²⁴ Cultures may be obtained to confirm the diagnosis and inform choice of antibiotics, which may be given orally

or intravenously depending on disease severity.^{7,24} Broad-spectrum antibiotic coverage is desirable because of the diverse pathogens that may cause an infection following an induced abortion, and we observed that nearly one-third of patients diagnosed with endometritis received two or more antibiotics.²³ In addition to antibiotic treatment, retained pregnancy tissue should also be evacuated from the uterus to eliminate the source of the infection.²³

Surgical complications following induced abortion occur more often and are more severe as EGA increases.¹³ Hematometra was the most common surgical complication observed in our study, and although it is associated with severe pain and cramping, prompt diagnosis and treatment typically allow for resolution without further issues.¹³ Uterine perforation was the second most common surgical complication observed in our study, and variation in treatment ranged from expectant management to hysterectomy. Uterine perforation in the first trimester tends to be low-risk and may be managed with conservative observation.¹³ In contrast, perforation following a D&E may result in more extensive injuries (e.g., bowel injuries) and may require more invasive exploration and intervention (e.g., laparoscopy, laparotomy, or hysterectomy).¹³ Notably, uterine perforation is the most common complication of a surgical abortion that necessitates a hysterectomy.¹³

Limitations

Although it may be desirable to assess the safety of induced abortions by calculating rates of abortion complications in the state of Pennsylvania, this is beyond the scope of our study. Although the PA DOH publishes an annual report of abortion statistics, they do not specify where procedures were performed.^{17,18} For our study, we only extracted patient safety events submitted to PA-PSRS by abortion facilities, as our objective was to broadly assess patient safety at this specific subset of facilities rather than to focus on the complications associated with induced abortion at all types of facilities. In addition, we may have missed events submitted by hospitals and physician practices as well as events that may have taken place at abortion facilities that

provide fewer than 100 abortions per year, and this may also limit the generalizability of our findings to these other clinical settings.

Despite mandatory event-reporting laws in Pennsylvania, our data are subject to the limitations of self-reporting. Because the details included in each event report are left up to the discretion of the reporter, some information was missing or incomplete for some events, such as EGA, abortion type, and infection type. Standard criteria for what constitutes an abortion complication have not been established, and the definitions we found were varied, so we attempted to design a framework for classification based on our available data and the most recent literature, which may also limit comparison of our findings with other studies.

Conclusion

Current data and research regarding induced abortions in the United States have demonstrated their safety. In our study, we observed that the vast majority of patient safety events reported by abortion facilities in Pennsylvania did not result in patient harm, although some patients did require interventions to ensure a successful outcome. Incomplete abortion was the most common complication observed in our study and in the literature, and these were observed more often following medical abortions. The most common infectious complication of an induced abortion was endometritis/PID, which was typically treated with antibiotics. The most common surgical complications were hematometra and uterine perforation/rupture, the latter of which involved more serious and invasive treatments, up to and including hysterectomy. In the future, it may be beneficial to investigate abortion complications prospectively in order to collect specific data that may allow researchers to more definitively connect patient-specific factors, such as patient age and EGA, with specific induced abortions and associated complications.

Notes

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

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About the Author

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



▲ Randall Fleming, certified environmental services technician, in the operating room at Geisinger Wyoming Valley Medical Center

Not All Heroes Wear Stethoscopes

Honoring the Essential Role of Nonclinical Staff

Catherine M. Reynolds, DL,MJ,RN

DOI: 10.33940/culture/2020.12.6

Raymond Cipollini, a long-time employee (recently retired) of the maintenance department at Einstein Medical Center Montgomery in East Norriton, Pennsylvania, used to visit patients during his shifts. His fellow staff noted that he would respond to call lights, asking how he could help, with a cheerful demeanor. Raymond often intervened if a patient was restless and pulling at IV lines or needed nurse assistance to get out of bed—potentially preventing falls. The Patient Safety Authority (PSA) named him the winner of its 2017 I AM Patient Safety Award in the category Individual Impact; he was nominated by his colleagues, who had frequently noted lively conversations coming from patient rooms, where he bonded with his “friends” over sports or other shared interests. It is lonely sometimes in those rooms, especially for patients who do not have visitors. “When I stop in, I hope I take their mind off their troubles and make them smile,” he said. These connections attend to patient’s physical safety and emotional well-being. Raymond brought his own perspective to his job and felt empowered to act for the benefit of patients and strengthened the fabric of the organizational culture.

Nonclinical staff in healthcare environments serve an invaluable role in the overall culture of the organization and individual units. Staff in roles such as en-

vironmental services, patient transport, dietary services, and maintenance spend a majority of their time on patient care units and interact with patients, families, and caregivers daily. We all bring a unique lens to our work formed by our training and experience. I have been a registered nurse in Pennsylvania for more than twenty years, with clinical experience in critical and emergency care. When I was a patient safety officer in a Philadelphia hospital, I was aware that my default view was through the lens of a nurse. It was imperative to pull in staff in diverse roles when investigating adverse events and looking for opportunities to prevent harm. I had many experiences seeing the value in doing just that, but one story remains close.

I was planning a kickoff meeting of a newly formed, unit-based, patient safety team and program in the medical intensive care unit. Having diverse input on patient safety risks from staff in various roles was a guiding principle of this new team. Several environmental services (EVS) staff persons were a regular presence on the unit during different shifts. As an integral part of the team in this busy city trauma center, they maintained environmental hygiene and cleaned rooms quickly to keep pace with the heavy patient flow. We needed to have their voices at the table as we discussed opportunities to make care safer in the unit. “You want me to come to your meeting?” was

a common initial response when I invited them. “I usually do not go to the nurse and doctor meetings.” I said this was different and we absolutely need their input, and I explained how I would obtain approval from their department leadership. As the team coach, I prepared them for what to expect in the meeting and encouraged them to share ideas of how to prevent harm to patients in the unit. I saw apprehension in their face and body language.

During the kickoff meeting, discussion ensued as expected, with clinical staff sharing ideas and opportunities to prevent harm from their perspective. I looked over at the EVS team members, hoping to encourage any of them to share. One woman raised her hand and described watching an ICU team transporting a patient in a bed through a back hallway that sometimes held additional equipment. “When I see the person squeezing the bag [valve mask to manually breathe for a ventilated patient] have to stop to move around the bed to fit down the hall as they move, that should not happen. So, we are going to make sure that hallway is clear and clean all the time.”

With all the discussion in the meeting, no one else had spoken about patient safety risks from unkempt and crowded spaces except our EVS teammates, who saw that hallway and the challenge of the clinical team through their own lens. Had they not been invited to the discussion, had leaders not actively included them, we would not have heard that perspective.

Diverse Teams Strengthen Safety Culture

Teamwork and communication are integral components of an organizational culture that promotes consistent patient safety practices. The shared attitudes and beliefs of staff are influenced by behaviors that are visibly rewarded and encouraged. Raymond Cippolini’s initiative to attend to patient’s needs, outside of his job duties, speaks to a culture where staff feel empowered by leadership to act in a patient-centered model.

I recently spoke with some nonclinical team members in Pennsylvania hospitals about their role in patient safety. A common sense of purpose was evident among them, and staff members like Randall Fleming shared their views. Randall is an environmental services team member in the operating room at Geisinger Wyoming Valley Medical Center in Wilkes-Barre. “My main target for my job is to prevent infection. To stop the spread of any germs or bacteria in the room and to stop spreading them throughout the hospital, to anyone—nurses, visitors, and patients.” With additional training, he obtained certification for his role and brings that knowledge as an integral member of the team. He says the team “depends on us to give information back if we see something that’s not supposed to be, and they want us to speak up. I do feel like my input is valued.”

Harley Woodring has worked for UPMC Williamsport for seven years, initially in environmental services and currently as a food services host. She and her colleagues assist patients with receiving their food trays and selecting their menu choices for upcoming meals. “This position allows me to inform nurses if feel like something is happening with a pa-

tient. If I notice a diet is not right, we can notify the dietary office.” For example, “A patient was on a dysphagia [difficulty swallowing] diet, so they required pureed food. It was missed so they got regular food and luckily enough we caught it, and they didn’t eat it and possibly choke.” Harley shared that she feels like part of the team and is comfortable speaking up. I asked what made her feel so included and invited to give input, and she said, “That they know my name, they approach me and encourage me to approach them.”

Shannon Silvis, a 20-year employee at UPMC Williamsport Divine Providence Campus, is a team lead in the environmental services department. As a leader, she creates time and space for her team to discuss safety in morning huddles and safety checks throughout the day and encourages them to speak up. “I think they are very important, keeping the floor not slippery and sticky, watching out for trip hazards. Their eyes are everywhere so they will see something that maybe someone else wouldn’t see.” Speaking up is not always easy and as a leader, Shannon supports her staff when needed. “I encourage them to speak up when they see something they know is not right. If they are not comfortable bringing it up in the area they work, they bring it to us and we will get it addressed for them.”

Patient safety-focused work and activities, such as committees and workgroups, are often comprised of clinical staff and those in leadership roles. Nonclinical staff spend time interacting with patients and those interactions allow them to notice changes and offer valuable input to the clinical care team. Creating space and removing barriers for diverse roles to participate enhances your patient safety efforts. Ensuring trust and psychological safety is necessary for fear of being blamed or incivility,¹ but the benefit far outweighs the burden.

Comfort and Humanity in Dark Times

The COVID-19 pandemic has challenged healthcare organizations from so many angles. Frontline healthcare workers have been rightfully recognized as heroes, with clinical staff more readily recognized. In service of preventing spread of this virus, hospital visitation from families and caregivers has been halted. Likely the most painful stories many of us have heard were of sick and sometimes dying patients, unable to have their loved ones present at their bedside. This crisis has shown us that human touch, compassion, and familiarity are as vital to well-being as our evolving high-tech industry.²

Environmental cleaning, delivery of food, or transport to necessary tests may be what brings patients and nonclinical staff together, but it is unlikely to be what the patient will remember most. A familiar, warm face becomes a touchstone for ill patients. Samantha Persun, a food and nutrition host at UPMC Williamsport since December 2019 shared, “I lost my mom almost 20 years ago and before I lost her, I helped take care of her. I told myself when I came to work for the hospital that I was going to do anything I could to put a smile on a patient’s face. Even a smile on a patient’s face makes them feel better. So, if I cannot do anything else, at least maybe I can make them smile.” That sense of purpose, connected to the organizational mission, can be a powerful driver and should be recognized and rewarded.



“

If I were a patient in the hospital, I would want somebody to take care of me the way that I feel I've taken care of the patients. I would want them to take care of me 100% like I was their parent, their brother, or their sister. So, I do the same thing with the patients.

– Samantha Persun,
Food and Nutrition Host,
UPMC Williamsport Hospital

▲▲ Samantha Persun, food and nutrition host, in the Food Services department at UPMC Williamsport, where team members review patient information and prepare meals for delivery to clinical areas

▲ Shannon Silvis, Environmental Services lead at UPMC Williamsport Divine Providence Campus, discusses the plan for the shift with a team member.

◀ Harley Woodring, food and nutrition host at UPMC Williamsport, prepares her cart to deliver patient meals to the clinical unit.

“

We needed to have their voices at the table as we discussed opportunities to make care safer in the unit.

– Catherine M. Reynolds on the importance of engaging nonclinical staff in patient safety



Leadership commitment to a safety culture includes

1. Establishing a learning organization model of operation that spans all departments and service lines
2. Supporting workers who speak up for safety—even when it creates conflict with revenue generators
3. Investing in employee safety
4. Normalizing transparency with patients, families, and staff
5. Modeling expected behavior

– Regina Hoffman, Executive Director, Patient Safety Authority



▲ Raymond Cipollini, retired employee of the Maintenance Department of Einstein Medical Center Montgomery and a 2017 winner of the Patient Safety Authority's 1 AM Patient Safety annual contest

► Ashley Sanders, supervisor of Patient Services at Gettysburg Hospital, reviewing patient transport requests from clinical units and directing her team

Ashley Sanders is the supervisor of patient transporting services at WellSpan Gettysburg Hospital. This is a very new team that was established in December 2019, yet Ashley has worked at the facility for 15 years, starting in environmental services. In her time, she saw the need for a dedicated patient transport team and utilized quality and process improvement tools to demonstrate the need to obtain approval. The COVID-19 pandemic challenged facilities to navigate uncertain times, but these essential healthcare workers pulled together to care for patients' needs, physical and emotional. "Everybody really pulled together during this pandemic," she said. "We are not just a community hospital; we are a family. When our transport calls dropped, we would go and help housekeeping. We would do extra cleaning of wheelchairs, go around to elevators for more cleaning, and we still continue to help as able."

I am often struck by how these essential workers describe their actions unassumingly as "just doing my job" or "this is just what we do." Harley Woodring said, "Since visitors are limited and hours more strict, I had a patient remark that I was the first person they've actually had a conversation with, since their family couldn't be in. I was just going in to do my job, but I took the extra time to talk to them, and I was glad I could brighten their day."

Per Ashley Sanders, transporting patients provides an ideal opportunity to be a sounding board, someone to listen, for patients unable to have their usual support with them. "It is kind of nice when you transport patients and in that very short time it is just you and that patient. They often use that time to vent to you. It is hard not being able to have family near. It gives them that time to get something off their chest, and if they want someone to help them, we can reach out and get them what they need." I believe in time, when recovered patients hospitalized in 2020 begin to share their stories more readily, we will learn how absolutely vital that brave human connection brought to what it means to care for and heal patients.

The 2020 Reset

The ongoing COVID-19 pandemic has only highlighted the essential role that our nonclinical team members play. Like many people, I have found this unusual year a time to take a deep look and reevaluate things important to me and my work. I highly recommend you also pause and take a hard look at your organization. When it comes to optimizing your efforts to prevent patient harm, who are you inviting to the table? Organizations can continue to build an optimum patient safety culture by engaging participation from all levels of staff. Leaders can facilitate taking some core actions:

- Ensure there is opportunity for teams to discuss patient safety in the workflow such as huddles, unit-based patient safety meetings, and rounding.
- Actively invite and remove barriers for all levels of staff to have their voices represented in patient safety discussions. Coordinate coverage for a team member to attend a hospital patient safety meeting or training on behalf of the department. This is also time spent in service of caring for patients.

- Provide education for all staff on the basic principles of the science of patient safety. Stress the importance of speaking-up and reporting adverse events.
- Openly recognize and reward behavior you want to see repeated.

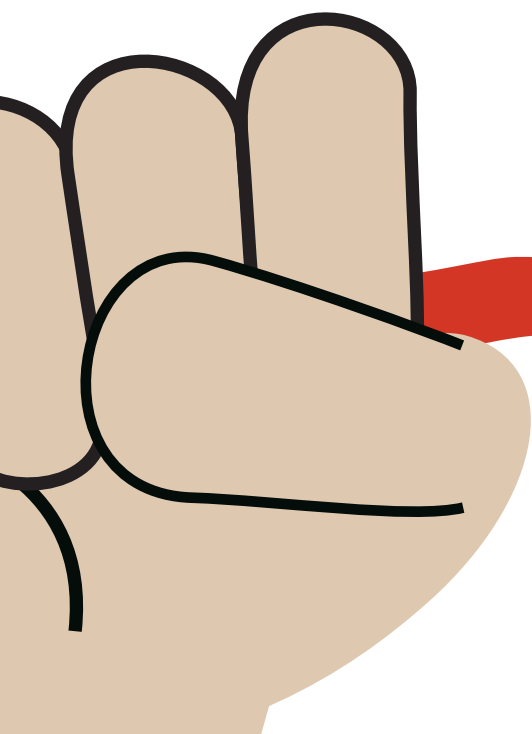
The PSA continues to support Pennsylvania healthcare facilities and can provide patient safety education adapted to any department on request.

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About the Author

Catherine M. Reynolds (catreynold@pa.gov) is a patient safety liaison with the Patient Safety Authority, working directly with more than 80 healthcare facilities in the Southeast region of Pennsylvania to improve patient safety through consulting, education, and collaboration. She is an accomplished healthcare and patient safety professional, specializing in the analysis of adverse events and facilitywide implementation of patient safety plans. With more than 20 years of experience in healthcare, she has served as a registered nurse and quality improvement coordinator in Philadelphia-area hospitals, including as patient safety manager for the Einstein Healthcare Network. She has been published in *Patient Education and Counseling* and *The Joint Commission Journal on Quality and Patient Safety*.



Oral Care for Non-Ventilator Associated Hospital-Acquired Pneumonia Prophylaxis:

Optimizing Clinical Outcomes and Organizational Effectiveness

Olivia Lounsbury[♦] & Shannon Munro, PhD, APRN[†]

DOI: 10.33940/med/2020.12.7

Non-ventilator-associated hospital-acquired pneumonia (NV-HAP) is a largely preventable illness. Quality improvement efforts including prevention measures, such as oral care, are incorporated into most standard clinical workflows but may be performed in an inconsistent manner. Oral care can have a profound impact on rates of pneumonia when performed in a systematic manner for all hospitalized patients, regardless of “traditional” risk factors. Furthermore, oral care can be performed by patients themselves in many cases, thereby relieving frontline staff of this task. Introducing patient education for sustained oral care efforts postdischarge and encouraging healthy habits to aid in achievement of their recovery goals is essential.

The prevention of even 100 cases of NV-HAP is associated with a cost savings of \$400 million and a decrease of 700–900 hospital days.¹

The need for consistent oral care is compelling upon analysis of its impact on the incidence rate of NV-HAP and ventilator-associated pneumonia (VAP). Hospital-acquired pneumonia represents 25% of hospital-acquired infections (HAI) in a given year in the United States, with 60% of those cases occurring among non-ventilated patients.² Outcomes of prevention programs for ventilated patients, which typically include oral care, reduced VAP prevalence from 10.4 incidents to 3.9 incidents per 1,000 ventilator days.³ These promising results ignited the implementation of similar oral care for non-ventilated patient initiatives in hospitals around the country. As a result of the success of VAP reduction efforts, NV-HAP is now viewed as a greater threat to patient safety.^{2,4}

[♦]Corresponding author

[◇]Patient Safety Movement Foundation

[†]U.S. Department of Veterans Affairs

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



When oral care is performed consistently and sustainably, hospitals can expect to see greater patient satisfaction, reduced cases of pneumonia, a decrease in cost, and recognition within the healthcare community for leading efforts in NV-HAP prevention.

Risk factors for NV-HAP are universal. For example, the risk of NV-HAP is not exclusive to typical high-risk patients and includes young and seemingly healthy people. Aspects of hospitalization, such as increases in medication and limited mobility, expand the pool of susceptible populations even further. Polypharmacy is common in hospitalized patients and even more common in hospitalized older adults. Because the side effects of a number of medications include xerostomia (dry mouth), the oral cavity is depleted of its normal salivary mechanisms, and therefore the patient is at higher risk for aspiration pneumonia.⁵ Early mobilization protocols and respiratory physiotherapy are associated with a decrease in pneumonia incidence but are often performed in a fragmented manner.^{6,7} Among all of these risk factors, oral care has proven to be one of the most fundamental and overlooked interventions in pneumonia prophylaxis.⁸

While pneumonia risk can be significantly minimized, researchers have found that these basic prevention measures were not consistently followed, with 58.6% of patients diagnosed with NV-HAP not receiving oral care during their hospital stay.⁸ This is due, in part, to the lack of knowledge about the relationship between oral care and improved outcomes, poor emphasis on the patient's capacity to be involved in their own care, and the perception that oral care is a comfort measure rather than clinical necessity.

Frontline clinicians can:

1) **Recognize the potential for patients to perform their own oral care and support patient efforts when appropriate.** Oral care is one prevention measure that patients can perform on their own in many circumstances. Not only would this alleviate nursing responsibility and ensure their time is available elsewhere, but the patient-initiated and patient-owned behavior would facilitate sustained oral care after discharge to prevent readmission. By giving patients a “job” while they are hospitalized, it includes them as core members of the care team, with a responsibility to which they are held accountable. Finally, this assignment is likely to rechannel patient and family member anxiety into a productive task they can be proud of.

2) **Bundle oral care with other patient care activities.** Standardization of oral care delivery ensures consistency and sustainability. Watch for opportunities to perform oral care in tandem with other activities, such as changing the bed linens or assisting the patient with breakfast. If the patient can perform their own oral care, these encouraging conversations can occur within the existing workflow, for example, when checking the patient's vital signs or administering medications.

Senior leaders can:

1) **Evaluate the current clinical workflow to investigate root causes of gaps in oral care performance.** A holistic review of the clinical process is necessary to identify discrepancies between current and ideal oral care performance. Observe variations in practice among clinicians and availability and proximity of oral care equipment.

2) **Devise ongoing and engaging educational activities.** Educational activities for frontline staff can underline the importance of oral care for patient satisfaction and safety, and clinical and financial outcomes. Deliverables should be engaging, multimodal, and pragmatic. Additionally, these educational activities also apply to conversations between the frontline clinicians, patients, and family members. Observe discussions and note opportunities for patients to ask questions, seek resolution of barriers,

and support dialogue as it relates to realistic goal setting and planning.

3) **Track oral care performance and related clinical outcomes.**

Purposefully track data with the intention that the data will be analyzed, evaluated, and applied to improve patient safety and care quality. Use metrics to align and optimize oral care practice to remove redundant efforts across the continuum of care.

When oral care is performed consistently and sustainably, hospitals can expect to see greater patient satisfaction, reduced cases of pneumonia, a decrease in cost, and recognition within the healthcare community for leading efforts in NV-HAP prevention.⁹⁻¹¹ While many healthcare organizations have the tools and resources necessary to provide consistent oral care assistance for all patients, priority has not been given to standardization of practice and protocols organizationwide. An impactful and sustainable oral care initiative requires a comprehensive strategy for integration of a consistent oral care message across the continuum of care. This requires evidence-based research, standardized, organizationwide policies, and facilitation in implementation efforts.

In 2020, the VHA Innovation Ecosystem, a unit within the U.S. Department of Veterans Affairs (VA), introduced a three-pronged approach aimed at a comprehensive strategy for oral care sustainment, with roles and responsibilities tailored by discipline. The trajectory and aims of the group were articulated after extensive collaboration with experts in the field, including, but not limited to, bedside clinicians, dentists, academics, policymakers, insurers, hospital administrators and leaders, and implementation scientists.

This interdisciplinary group facilitated by VA leadership consists of representatives from the Centers for Disease Control and Prevention; The Joint Commission; the Centers for Medicare & Medicaid Services; the American Dental Association; Health Resources and Services Administration; the VA QUERI Center for Evaluation and Implementation Resources; the Patient Safety Movement Foundation; Aetna; United Healthcare; Oral Health Nursing Education and Practice (OHNEP) program; Teaching Oral-Systemic Health (TOSH) initiative at NYU Rory Meyers College

of Nursing; University of Utah Health; University of Massachusetts Amherst; California State University, Sacramento; Brigham and Women's Hospital, Harvard Medical School; University at Buffalo; Amplifire; and Johnson & Johnson. These experts in the field have come together to form the National Organization for NV-HAP Prevention (NOHAP).

NOHAP was stratified into policy, implementation, and research workstreams, with significant overlap between the groups to ensure consistency, synergy, and reduction of duplicative efforts to optimize efficiency and effectiveness. The groups are described from a broad perspective:

1) **The Research Workstream** focuses on developing an understanding of the pathogenesis, surveillance, prevention, and impact of NV-HAP; identifying the gaps in NV-HAP research; and developing a national research agenda, including a white paper on NV-HAP.

2) **The Implementation Workstream** translates the research findings into pragmatic, best practice applications in the clinical setting. The group emphasizes the need for rapid deployment of NV-HAP prevention initiatives within and outside of the VA and focuses on marketing, communication, and patient empowerment to bolster accountability. The final focal point is engagement with electronic medical record vendors to standardize data collection points, which would optimize tracking and subsequently inform course adjustments needed throughout the NV-HAP prevention journey.

3) The **Policy Workstream** supports these efforts by releasing a joint policy statement including national oral care guidance, leveraging incentives for oral care performance in health systems, and integrating NV-HAP prevention into clinical education curriculum modules.

Outcomes and Anticipated Trajectory

The VA healthcare system is leading the way in adoption of NV-HAP monitoring and prevention measures in acute and long-term care units across its 146 facilities. VA pilot testing of the new NV-HAP measure is underway, and it is slated for release by January 2021. A Joint Position Statement from NOHAP is forthcoming, which encourages other healthcare systems to conduct active NV-HAP surveil-

For more information: www.va.gov/INNOVATIONECOSYSTEM/views/solutions/happen.html

VAHAPPEN@va.gov

lance and adopt prevention measures for NV-HAP in addition to providing education on NV-HAP prevention to nurses, nursing assistants, medical students, and other clinicians in prelicensure and professional development programs. The NOHAP team is working together to make proven educational resources and training publicly available to the benefit of all Americans, institute repeatable mechanisms for tracking NV-HAP, and foster positive incentives for the adoption of effective preventive measures.

Note

The findings and conclusions in this article are those of the authors and do not necessarily reflect those of the U.S. Government or any of its agencies. Dr. Munro and her team's work is supported by the VA Quality Enhancement Research Initiative (QUERI) program of the VHA Health Services Research and Development Service and the Diffusion of Excellence Initiative.

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About the Authors

Olivia Lounsbury (olivia.lounsbury@patientsafetymovement.org) is a clinical research coordinator for the Patient Safety Movement Foundation.

Dr. **Shannon Munro** is an advanced practice nurse and the national implementation lead for HAPPEN (Hospital-Acquired Pneumonia Prevention by Engaging Nurses) for the U.S. Department of Veterans Affairs Diffusion of Excellence Initiative.



SEPSIS IN THE TIME OF COVID-19

By Cait Allen, MPH

DOI: [10.33940/sepsis/2020.12.8](https://doi.org/10.33940/sepsis/2020.12.8)

This year, almost 2 million adults will contract this condition, and 270,000 will die as a result. Not COVID-19, sepsis. I sat down with Dr. David F. Gaieski, emergency medicine physician and director of Emergency Critical Care at Jefferson Health, to understand what sepsis is, its relationship with COVID-19, and how we can—and must—prevent both.

Cait Allen: What is sepsis?

Dr. David Gaieski: Sepsis is a reaction of the body to an infectious stimulus, which can be a virus, a fungus, a parasite, or most commonly bacteria. The body is mounting an immune response to try to fight off the infection. Sepsis as it's defined now is a dysregulation of that immune response: a dysregulated inflammatory response where the body is injuring itself, causing acute organ dysfunction, through its attempts to get rid of the pathogen that's causing an infection.

Why is this something that we should care about?

Because it's common. There are at least a million cases a year in the United States, probably significantly more than that. And the mortality from sepsis cases is somewhere in the 20% range; when patients also have shock—inadequate oxygen delivery to meet the metabolic needs of the cells—the mortality goes up over 30%. It affects all age groups. Young kids can get sepsis, adults can get sepsis, geriatric patients can get sepsis. It's also important because the more we know about it both as a lay public and as physicians and other healthcare workers, the better we can take care of it. People need to know the warning signs of sepsis, and they need to know how to get proper care when they are starting to develop sepsis.

What are some of those warning signs?

That's part of the problem, because sepsis isn't like a heart attack or a stroke, where you typically know exactly when things started or have a good idea of when things started because the person was normal, and now, for example, they're slurring their speech and they can't move one side of their body. But sepsis grows slowly in a lot of cases, and the initial symptoms are not unlike the symptoms of a cold or a mild case of the flu. It's a continuum. You can have sepsis from the flu, and the easiest way to think about the difference is that a lot of people who get the flu may feel achy and have some nausea and a stuffy nose and a fever. But their heart keeps working right, their oxygen level doesn't drop, their kidneys keep working right.

But some people get really sick with the flu, most commonly by having hypoxia—a low oxygen level in their blood. The problem is that sometimes it's hard to know when you just have the flu that you can treat at home with fluids and Tylenol, versus the flu that you need to go into the hospital for. A lot of the symptoms of sepsis are the same as the symptoms of less severe infections: fever, aches, nausea, decreased appetite. The concerning signs are when people start to feel confused, really weak, or short of breath like “I can't get enough air in” and they have a sense of air hunger, or have severe pain, or their urine output drops. Those are all things that can be pointing to a more severe case of infection and sepsis.

What things do clinicians typically look for to determine whether it's sepsis?

When someone comes into the emergency department, the first thing we ask them is, “Why are you here?” They might say, “I have

a fever. I have a cough. I have belly pain.” Then right off the bat we're going to get a set of vital signs. Is their blood pressure low or is it normal but significantly lower than where they usually are because they have baseline hypertension? What's their temperature? Is it high or low? What's their heart rate? Is it fast? What's their respiratory rate? Is it higher than 20? They're breathing very fast, are they taking really deep respirations? What's their mental status? Are they confused or sluggish or slow to respond?

We use something called the Glasgow Coma Scale, which gives us a 3 to 15 range, with 15 being totally normal. People with sepsis will often be confused and not answer questions appropriately. Then we'll look at their pulse ox, which is where you check the oxygen level in the blood through a sensor that's put on their finger.

We also check the patient's lactate level in most cases of possible sepsis. Our blood flow is all about bringing oxygen to cells so they can run the engines of life. If there's not enough oxygen delivery, then we shift into what's called anaerobic metabolism, where we use up the energy that's already been produced instead of being able to continually produce more energy. When that happens, the lactate level goes up. A normal lactate is typically less than 2 mmol/L. What research has shown is that as the lactate level goes above 2, the mortality starts to increase in sepsis, and it heads upward in a stepwise fashion, depending upon the lactate level. We check that early to help us risk stratify patients, to start therapy earlier, and it's considered an organ dysfunction by the different committees that have tried to codify what sepsis is and make uniform definitions.

What can make sepsis so difficult to diagnose?

It's not always obvious where the infection is, or even if there is an infection. It's not hard to diagnose sepsis when someone comes in with a cough and say “I think I have pneumonia” and you get a chest X-ray, and they have an obvious pneumonia on their chest X-ray. Or they come in and they say, “I have pain in my back, and I've been urinating a lot.” Then you get a urine sample and they have an obvious kidney infection. Or if they have cellulitis and they have a big area of redness on their arm. But it can be much harder to diagnose in people who present confused and don't have something obvious on their physical exam, or in people who primarily have bacteremia. The bacteria have gotten into their blood and it's circulating around, but you don't know exactly where it came from. You don't have an obvious source.

There's also a lot of overlap with other diseases. For example, we often go down the pathway of, is this pneumonia, or is this a pulmonary embolism? Is this a kidney stone or is this diverticulitis? There are things that look like each other, some of which are infectious and some of which aren't. The speed with which you need to diagnose sepsis in general is faster than some other disease entities.

People can know that something's going on, but it can be harder for us to find. That's a lot of the reason. Then some of it too is that we don't have the optimal systems in a lot of emergency departments to take someone who has some screening criteria that raise a concern for possible sepsis, put them in a treatment space, and systematically work them up until we've ruled in or ruled out sepsis. If they're fairly stable, they may float around the ED and have a circuitous path to their diagnosis. But 25 years from now, maybe we'll be able to do bedside immunologic panels and tailor therapy to the way people respond to their infection.

Could there be a genetic predisposition to sepsis?

It's certainly being looked into. I'm not an immunologist, but there are known conditions in patients, for example those with meningococemia and meningococcal sepsis, where they have certain genetic polymorphisms, which put them at a higher risk. Some of the overwhelming cases of meningococcal sepsis that you see will be in people who have a genetic defect in one of the factors that would help them to fight off infection.

Would it be better to take a more aggressive approach for treating sepsis, for instance, assuming that any patient could be or could become septic and ruling out sepsis as part of the standard differential?

Sure. The standard of care in most emergency departments when you see most patients is that you're evaluating them for exactly that and systematically ruling sepsis in or out. It might be as simple as you go to see someone who sprained their ankle and you say, "Tell me what happened." Big difference when it's a 25-year-old kid who says, "I was playing basketball and I stepped on someone's foot and I rolled my ankle," versus some older person who says, "I don't know really what happened. I went into the bathroom and I just twisted my ankle." Then the next question I always ask is, "How were you feeling when you went into the bathroom?" If they say, "Doc, I was feeling great." You say, "Have you been sick at all?" "No." So then you assume they probably just sprained their ankle.

But if they say, "I'm just feeling run down and not feeling great," then your suspicion that it could be something else goes up a little bit. You start to think maybe I need to figure out why they fell or why they sprained their ankle. I think we do this in all patients we see, it's just a question of whether we do it as systematically and as thoroughly as possible.

Is there any national registry for sepsis like what exists for cancer patients? Is this something that you think would be worthwhile?

There is no national registry, but I think it would be great to have one. If we were able to have a better sense of how many cases of sepsis there are a year, we would maybe be able to dedicate more resources to treating it and have, epidemiologically, a lot more sense of the syndrome and who it's affecting, and where and when it occurs most frequently, and stuff like that.

The Sepsis Alliance has been proposing to have a national sepsis registry. I don't know where they are in the process of that, but they were meeting with some government officials to try and talk

through how to build one. That would be a heavy lift to get an actual registry where say 90% of the sepsis cases were tracked; you'd need a lot of resources dedicated to it.

But it would be great to have a registry. I'm not going to hold my breath because there isn't even a national cardiac arrest registry in America. Many countries in Europe and Asia have national cardiac arrest registries.

For example, in Japan, they know within a dozen patients a year probably how many cardiac arrests there are, because by law they have to enter them into a database within 24 hours of the cardiac arrest occurring, and the EMS [emergency medical services] providers do just that. In the U.S., we don't have anything like that. We just guess that there's 350,000 out-of-hospital cardiac arrests a year. But in Japan they know there's 109,452—I am making this number up but it is close to their real number—because they have it worked out as an epidemiologic tool. But I think it would be very helpful to have one, I would love to see it come along.

What are some of the long-term effects of sepsis?

When someone's hospitalized, they are often focused on recovery from that episode and going home. I think the longer-term effects are less appreciated. With sepsis, there's a lot of overlap with many other critical illnesses, something called post-intensive care syndrome. That has some well-defined things that happen to people, and bad sepsis cases have a lot of the same things. People have more depression afterwards. They have accelerated dementia if they already had it. They have earlier onset of other kinds of aging-related neurologic conditions. They're physically deconditioned. People who had a bad episode of sepsis fall more often, break hips more often, end up getting subdural hematomas. They may also get sepsis again.

A significant percentage of patients who had bad sepsis get readmitted within 30 days. Sometimes it's for another sepsis event that's related to the one they had, because they didn't get rid of it. But oftentimes it's just another event of sepsis that's different, because their immune system is not working well, and they're more at risk of infection in general for a period of time. The repercussions of sepsis are huge. Some places even have multidisciplinary sepsis follow-up clinics with PT/OT [physical therapy/occupational therapy], nutrition, and things like that. Some places do neuro-cognitive functioning tests down the road to see how people are doing after sepsis.

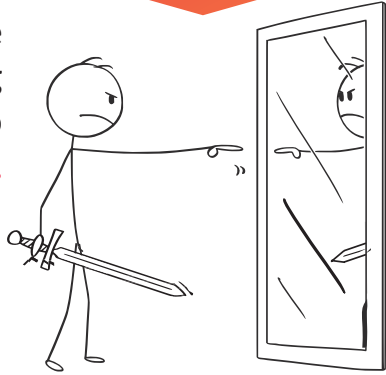
This just reinforces why everyone should care about this. Not only is sepsis challenging, but so is everything that happens afterwards. What can people do to prevent sepsis?

Wear their masks, so that they don't get COVID and then viral sepsis. They can wash their hands. They can get their vaccines, that's probably the most important thing if you're in a high risk category, or if you're old enough to be in a high risk category, you should be getting your strep pneumonia vaccine. You should get your flu vaccine, even if the flu vaccine for that year isn't a great vaccine as far as its match. Because in general if you've had your flu vaccine and you do get flu, you're going to get a less severe case of flu. Basic stuff like that. Basic first aid, you cut yourself you clean it off, and you pull out a splinter if it's there, and things like that. Most of it is common sense, but right now, the number one way to prevent sepsis is social distancing and wearing a mask.

Right now, the number one way to prevent sepsis is social distancing and wearing a mask.

Sepsis Fast Facts

Sepsis is when the body starts attacking itself when trying to **fight an infection.**



Long-term effects:

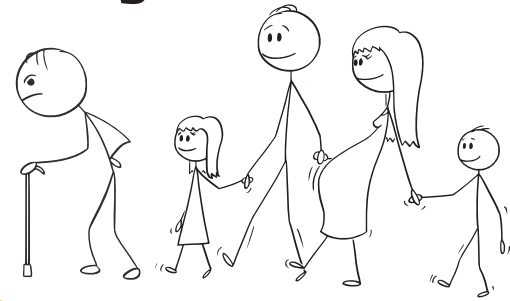
Early onset of age-related diseases like dementia

Depression

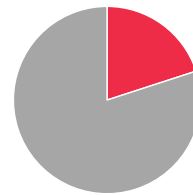
Increased risk of falls and infections

1 million+
Americans get sepsis every year.

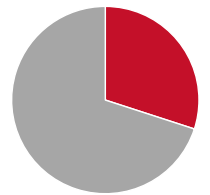
Anyone can get sepsis.



Sepsis must be treated in a **medical facility.**



20%
of people with sepsis die.

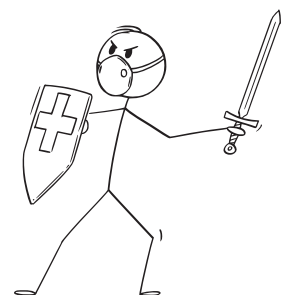
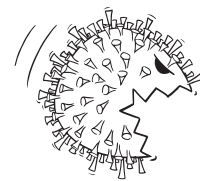


30%
of people with septic shock die.

Symptoms include:

- Aches
- Fever/chills
- Nausea/decreased appetite
- Shortness of breath
- Feeling weak

The best way to prevent sepsis is to **prevent infection.**



You mentioned that sepsis can stem from any kind of infection. Over the course of your career what have been some of the more surprising sources of infection that you've seen?

One interesting case I had was a young person who had acute HIV, seroconversion to HIV, and was diagnosed when we took care of him in the hospital. He presented with classic sepsis, a markedly elevated lactate level, and hypotension that required a lot of fluids, and then a vasopressor, and had kidney injury and liver injury as well. Every other diagnostic test was negative in him. The only thing that we found was that he did have acute HIV. The infectious disease doctors that saw him thought that's what was causing his sepsis syndrome.

Then things like septic foreign bodies, septic miscarriages. A young woman, who had just moved to the U.S. from a malaria-prone part of Africa, had falciparum malaria, which is the most dangerous kind of malaria. She was in septic shock with that. There are a lot of questions about how you should resuscitate people with malaria because of some of the issues with brain swelling. It was interesting to treat someone with that as their cause of septic shock and think through how to best manage her care.

How do sepsis and COVID relate to each other? Are you more likely to contract COVID following sepsis or vice versa?

Some people would debate this, but there's general consensus that bad COVID is sepsis. Because if you look at the body's response toward COVID and what COVID does to different organs in the body—kidneys, heart, and especially the lungs—it's clear that there's an inflammatory response to COVID. The body's trying to get rid of it, and that is, in part, what damages the tissues and organs. But some people don't agree with that.

If someone is hypoxic or hypotensive, or someone has acute kidney injury, and they have sepsis, we need to try to recover the acutely damaged organs and treat the person with systematic supportive care, and try to make sure nothing else goes wrong for them. The same is true for critically ill COVID patients.

I think people get into big debates about whether COVID is sepsis, because there isn't the same antibiotic therapy. Remdesivir helps a bit in the sicker patients. But there isn't the whole array of broad-spectrum antibiotics to target to the patient's specific source of infection and which should be administered as soon as possible. Regardless, the basic principles of management of patients are very similar with any kind of viral sepsis.

As far as whether after you have sepsis you're at more risk for COVID, if you have had a lower respiratory infection like pneumonia, you're probably a little more at risk for being exposed and then contracting a virus. Your immune system's not as good for a period of time after you've been sick, and your mucosal barriers where you're going to get exposed to COVID aren't going to be intact in the same way. After sepsis, you're probably a little more at risk for getting COVID, because you're a little more immunocompromised.

Then after you have COVID, are you at risk of getting sepsis? I would say similar things. We haven't seen that much co-infection with bacteria and COVID at the same time. We've seen co-infections with COVID and other viruses more frequently. But after any major episode of critical illness you're at increased risk for another infection. That's one of the things people get readmitted with after they have COVID—a urinary tract infection or a bed sore that gets infected or

pneumonia. All these things are related to what state the immune system is in and your ability to fight off another infection.

How difficult is it to distinguish between sepsis, COVID, and the flu? What should clinicians look for, and what can patients do to help get an accurate diagnosis?

They can be very hard to tell apart. The level of hypoxia that we see with COVID when people otherwise look pretty good suggests that it's not a bacterial pneumonia, for example. When you have bacterial pneumonia and your oxygen level is only 70% on room air, people look horrible, they feel horrible. We saw it more at the beginning of the COVID pandemic then we're seeing now, but when patients come in with COVID with pulse oxes of 60, 70, 72%, they often say, "No, I don't feel short of breath. I feel fine." There's a lot of theories about why that is. There's some neuro input from the lungs to the brain, and then the damage that COVID does to the olfactory area. There are some thoughts that this is all linked together, that our brain's perception of hypoxia is altered by COVID the same way our sense of smell is and this is what produces "happy hypoxia."

I'm not sure that's correct, but I saw one presentation on it that was very convincing to me. If I go climb Mount Kilimanjaro and I'm at 20,000 feet on Kilimanjaro, I'm going to have a pulse ox of 70% or 75% or so if I'm not using any supplemental oxygen. I'm going to know that I'm short of breath. I'm not going to be saying I feel perfectly fine. I might still be able to climb up the mountain, but I will have a sense of hypoxia and shortness of breath. These people coming in who aren't nearly in as good shape as your average person climbing Kilimanjaro don't even know that they're hypoxic.

It's interesting. But there's a ton of overlap and that's one thing people are really concerned about, the overlap in symptomatology between the flu and COVID and bacterial pneumonia.

Now, are we going to get people who don't know whether they have the flu or COVID, and they don't know whether they should come in or not? Or are they going to come in with both infections and then they're going to be sicker than they would have if they had one or the other? That's what we'll find out when flu season comes.

Sepsis versus those is different than with a localized infection. If I have a septic knee, my knee hurts. If I have cellulitis, my arm hurts where the cellulitis is. If I have an infected kidney stone or gallbladder, things are localized there, at least in the beginning. There's a lot more overlap between bacterial pneumonia and COVID or bacterial pneumonia and influenza than there is between some of those other bacterial causes of sepsis.

What should you do if you think you have sepsis? Can you treat it yourself or should you seek medical attention?

For most infections you need to get medical attention. Essentially, with the definition of sepsis now being infection and acute organ dysfunction, what we used to call severe sepsis, no one should be taking care of that on their own at home. Most of the time you need some IV fluid. Most cases require antibiotics unless it's caused by a viral source or a fungus or something, and many of those still require an antiviral or antifungal drug. Most of the time you need to be monitored and watched in a hospital setting. Sometimes it's only for a day or two to get the antibiotics going and make sure the person's stable and responding.

But it's not something you should manage on your own. The problem is many things that we feel like are "just a virus" or "just feeling run down" could be sepsis. People that are postoperative who start to feel flu-like symptoms, have a fever, achiness, etc., should be concerned about those symptoms. They should call their surgeon or go to the ED for evaluation. Odds-wise it's more likely that nothing serious is going on, but there's a decent chance that it's a complication of their surgery and that should be evaluated. Then the warning signs we talked about earlier, trying to really sort through, "Do I just have strep throat or an ear infection? Or do I have something more serious?" People need to have some medical literacy so they can sort through some of those things on their own and know what to go to the emergency department for versus what to go to an urgent care for versus what to call their doctors about the next day.

What can someone do to gain that medical literacy?

For patients at home trying to figure out what they should do, it is important that they know concerning symptoms. "I feel short of breath, I have pain in my rib cage when I take a deep breath and I've been coughing a lot. My urine output has dropped off, I feel fuzzy-headed and cannot think clear. Am I running a fever?" I think every person is capable of counting their pulse, counting their respiratory rate. People should know what normal vital signs are and people should really think about doing that—checking their vital signs when they don't feel good. Just look at a clock with a second hand, know where your radial pulse is and count your heart rate. If you feel like you're fighting off an infection and you are tachycardic that's a different scenario from if your heart rate is normal. No one of these things is definitive, but people can get some more medical literacy and really think through the question, "Do I need to be seen or not?"

A 30-year-old woman who's had three bladder infections can call her primary care doctor or go on to a video visit and describe her symptoms, and say, "My heart rate's 62 and I don't have a fever, and I feel fine, but I feel like I can't empty my bladder, like I have to urinate again as soon as I just went, and no I don't have any kidney pain. No, I haven't had chills or anything." That person can be treated with an antibiotic prescription over the phone or over the video connection. Being able to differentiate that from, "I have flank pain and I feel like I'm not peeing as much as I normally do, and my temperature's 102 and my heart rate's 110," is crucially important.

With that information, you can tell them to go to the emergency department so someone can check their vital signs there, lay a stethoscope on them and figure out what's going on, and get a urine sample and probably some lab work to further evaluate the situation. That's the kind of literacy people can have to help them know whether they should go in to the ED or not.

David F. Gaieski, MD, is a professor, vice chair for Resuscitation Services, and director of Emergency Critical Care in the Department of Emergency Medicine at the Sidney Kimmel Medical College of Thomas Jefferson University. His clinical and research expertise focuses on cardiopulmonary resuscitation, post-cardiac arrest syndrome (PCAS), extracorporeal CPR, and protocolized care for severe sepsis and septic shock. Dr. Gaieski has lectured and published extensively on the optimal clinical management of patients with PCAS and severe sepsis. In addition, he has used large national and international databases to study cardiac arrest and sepsis incidence and mortality.

Be Your Own Advocate: How to Measure Your Heart Rate

60 to 100
beats per minute:
normal resting
heart rate for adults

To measure your heart rate, start by checking your pulse. Place two fingers between the bone and the tendon over your radial artery — which is located on the thumb side of your wrist. Or place your index and middle fingers on your neck to the side of your windpipe.



When you feel your pulse, count the number of beats in 15 seconds. Multiply this number by four to calculate your beats per minute.

x4
=BPM

Uncharted

How one woman became the first elected official of a centuries-old people and how their future will impact us all

By **Regina Hoffman**, MBA, RN
DOI: 10.33940/interview/2020.12.9

Waters

Meet Queen Quet Marquettea L. Goodwine

—computer scientist turned head-of-state. Since 2000, she has led the Gullah/Geechee Nation, a group of more than 1 million inhabitants on the southeastern shores of the United States. She sat down with Editor-in-Chief Regina Hoffman to discuss life on the Sea Islands, strategies to improve care for minority patients, and how one Gullah/Geechee native launched a national movement to defend workers' rights—and why you have never heard about it.





▲ Queen Quet, chieftess of the Gullah/Geechee Nation, takes in the Sea Islands air as she looks at her beloved St. Helena Island.
Photographer: Kumar L. Goodwine-Kennedy

Regina Hoffman: You lead the Gullah/Geechee Nation, which is one of the largest subcultures within the United States, though many Americans are probably unfamiliar with it. How would you describe it?

Queen Quet: Well, a lot of people ain eba yeddi we da crack we teet likka disya an ain kno bout who webe as Gullah/Geechee. So, a lot of people have never heard of Gullah or Geechee until they hear us speaking our language, which you just heard. I like to say that we are the African and Indigenous descendants that live between Jacksonville, North Carolina, and Jacksonville, Florida, on islands in the Atlantic Ocean—called the Sea Islands—and then 30 to 35 miles in-land to the mainland to the St. Johns River.

We are an indigenous group in the sense that Gullah/Geechee culture began on this coastline and survived since the 1500s and the 1600s, and many of our descendants were the ones that were kidnapped and enslaved here.

We created our own unique language, food, traditions, healing practices, and music. We have our own cultural heritage and our own cultural community, and what many in historic preservation call a cultural landscape.

How integrated are the people of the Gullah/Geechee Nation with the other residents in those areas? Do you have separate schools for your children, separate hospitals?

Well, it's interesting. A lot of people integrated themselves into our communities, but their integration is what started assimilation and annihilation of the culture. Many Gullah/Geechee children go to schools that have teachers that are not native Gullah/Geechee, who have never heard of Gullah/Geechee. We've had people try to destroy our language and our traditions because they weren't aware of them. Also, we have a lot of disparities in terms of jobs. People can't get certain jobs when new companies come to the region because of the way some of us may speak; the people hiring don't understand it.

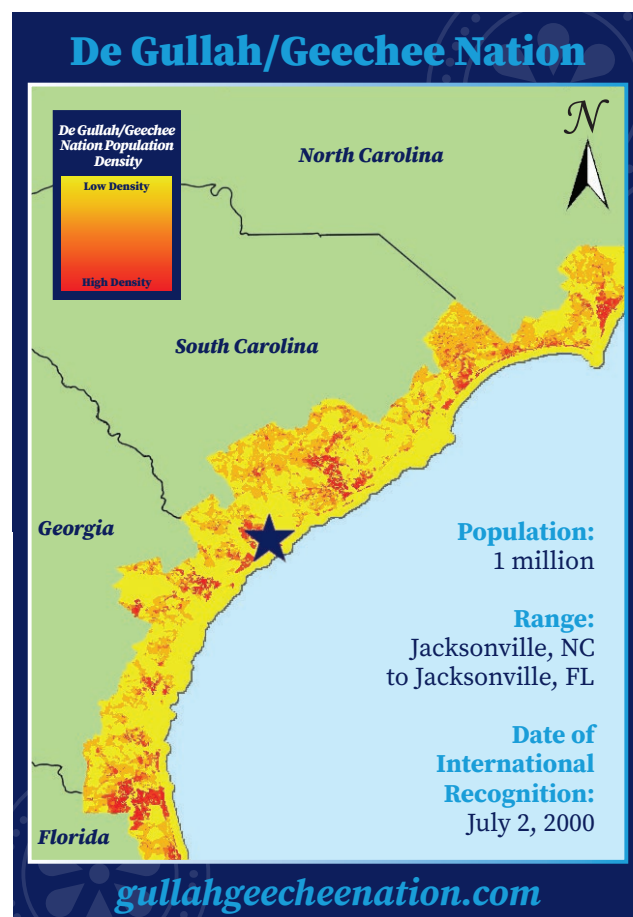
In terms of medical care, sometimes doctors don't clearly understand what the person is trying to convey, because a lot of people in our community are still somewhat isolated away from mainland culture and traditions.

So, even though it appears like it's a very integrated community now along our coast, in some ways it's not. There are entire families or people who don't go out to mainland areas or don't come out to public functions. You literally would have to find them out in some of the most rural points of the Sea Islands, still practicing our cultural traditions, somewhat away from most of the western world.

In cases like my home, St. Helena Island, there's a clinic and a library. Their children or grandchildren now take them to these new spaces, and then they may interact a bit with some of the people who moved here, but there is still what we call de cumya. Those of us who are de binya, we don't often interact with the others, and when we do, we found it not to always be to our benefit unfortunately.

You mentioned you were born on St. Helena Island in South Carolina and are now the chieftess of the Gullah/Geechee Nation. Can you tell me more about yourself and that journey?

People always want to know how I became the queen mother and the head of state, or as we say, Head pun de Bodee of the Gullah/Geechee Nation. That is not something I aspired to do; I am a computer scientist, a mathematician. There was no queen prior to me. I am the first one in world history to ever hold this elected position. That came about in 1999 when I became the first native Gullah/Geechee to ever take our human rights before the



United Nations Commission on Human Rights in Geneva, Switzerland, all the way to July 2, 2000, when my election was confirmed. Instead of a one-day election, there was a one-year election done by natives of the Gullah/Geechee Nation from the Carolinas all the way to Florida that voted me in so they would have a voice.

That was two decades ago, and I'm sure a lot has changed during that time. How has the Gullah/Geechee Nation evolved, and what do you hope for its future?

This is my third seven-year term as de Head pun de Bodee. In two decades, we have seen a lot of progress of people globally recognizing our nation and wanting to support our efforts here to keep our cultural heritage alive and to sustain our communities. Unfortunately, we've also seen overbuilding on the coast that has not just displaced our people but also had a negative environmental impact on our coast, our seafood, the land, the water quality, and what's happening to us.

One of our major focal points now as leaders of the Gullah/Geechee Nation is to really address climate change issues, especially sea level rise and ocean acidification. We also address the overbuilding that caused a lot of the pollutants in our waterways.

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Africans were not illiterate—literacy started in Africa. They brought it with them, but because they could read and fight back for their own human rights, it became, “Well, we’re going to stop them from reading and writing to try and keep enslavement going.”

There is constant work being done against that which would destroy our community. There are folks that collaborate with us; we formed the Gullah/Geechee Sustainability Think Tank that involves scientists, doctors, and Gullah/Geechee native people who want to hold on to this unique culture. We even have a federal law that recognizes us and wants us to be sustained for the future. The value is always in the people. We weren't called Black Gold for nothing. If we keep the people rich and keep our environment rich, we'll be able to continue to be here in the future, as we say, "We da binya and ain gwine nowhey!"

Where did the term "Gullah/Geechee" originate?

The first Africans that were kidnapped directly from the continent and brought to be enslaved on the Sea Islands were the Angolans. When the Angolans were sold at auctions, there would be listings and posters that would say, "We have a cargo of Gullah for sale." So, the first use of the term "Gullah" came into existence because of our Angolan ancestors who were kidnapped largely for their blacksmithing abilities.

When you're trying to clear down all a disya wha dey pun de island fa make it into plantations, you would need people who have the scientific knowledge base to do that. So, they found that the Angolans brought a very high price on auction blocks. But the Angolans were blacksmiths for warrior class people, so they tended to lead uprisings over and over in this region.

That led to a ban on the importation of Angolans, and later, the Europeans started kidnapping people from the Wind-ward Coast and Rice Coast regions. They kidnapped a group of people named Gola, G-O-L-A, a group of people named Gidzi, G-I-D-Z-I, or the group Kisse, K-I-S-S-E-E, from which people get the word "Geechee."

The uprisings continued into 1739 with the Stono Rebellion, which led to the 1740 Slave Code that denied Africans the right to own land, the right to gather three or more without an overseer present, the right to play drums, and to read and write. Africans were not illiterate—literacy started in Africa. They brought it with them, but because they could read and fight back for their own human rights, it became,



▲ Queen Quet Marquetta L. Goodwine leads the ancestral tribute libation ceremony at the Gullah/Geechee Nation International Music & Movement Festival (gullahgeechenation.com). Photographer: Kumar L. Goodwine-Kennedy

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For someone with the energy and spirit and who wants to focus on [medicine], they shouldn't have to be denied access because the school doesn't have computers, technical equipment, or chemistry laboratories.

“Well, we're going to stop them from reading and writing to try and keep enslavement going.”

Over the years, we have started spelling Gullah phonetically. We spell Gullah here, G-U-L-L-A-H, and Geechee is spelled, G-E-E-C-H-E-E, even though the ancestry of those words came from the Motherland.

Last year marked the 50th anniversary of the Charleston Hospital workers' strike, which predominantly involved Black and Gullah/Geechee women seeking better compensation and working conditions. Tell me more about that and why it's important for everyone, including patients, that healthcare workers are treated fairly.

▼ Queen Quet and South Carolina General Assembly Member Wendell Gilliard stand with Mary Moultrie and family at the unveiling of a marker at the Medical University of South Carolina in honor of the Charleston Hospital workers' strike. Photo Credit: De Gullah/ Geechee Alkebulan Archive (gullahgeecheenation.com)



Even though we commemorated the 50th anniversary of the Charleston Hospital workers' strike, many people throughout South Carolina, and throughout the United States, have no idea it ever took place because of the lack of coverage of movements led by African people, and Gullah/Geechees.

Someone that I was blessed to get to know in the latter years of her life, Mary Moultrie, was a leader in the Charleston Hospital workers' strike. She and I both received awards from ASALH, which is the Association for the Study of African American Life and History. They are the founders of Black History Month and dubbed us “living legends” at a major ceremony in Washington, D.C, along with Dr. Najmah Thomas, who is also a native of St. Helena Island.

Mary Moultrie got the workers to strike, and all they were asking for is to have equal benefits and equal pay and to be treated with respect. As a woman doing this, and a Black woman doing this, and a Gullah/Geechee native woman doing this, she set a precedent when she had people walking through the streets of Charleston against the Medical University of South Carolina (MUSC) demanding Black workers be paid the same as their white colleagues or not be subjected to racial slurs at work.

It is unfortunate that schools have not taught about the hospital workers' strike, but it is important that we tell people about it, because it plays a part in why there are still medical disparities today, especially in the city of Charleston.

But I was blessed to be there with Mary Moultrie and her family the day that they unveiled the marker in front of MUSC to finally honor her leadership and honor that hospital workers' strike. It was important to recognize the Black people and Gullah/Geechee people, who were leading the Civil Rights Movement here in South Carolina. Back then, the state papers didn't cover it, because they said they didn't want outsiders coming in to help.

▼ Queen Quet proudly stands for the Sea Island environment. "De wata bring we and de wata gwine tek we bak." Photo Credit: De Gullah/Geechee Alkebulan Archive (gullahgeecheenation.com)





Not even fame, fortune, or 23 Grand Slam singles titles is enough to protect against harm. **Serena Williams**, formerly the top-rated female tennis player in the world, discovered this unfortunate truth after giving birth to her daughter in 2017.

Six years earlier, Williams, who is prone to blood clots, **nearly died from a pulmonary embolism**. The day after delivering her daughter by emergency cesarean section—which required her to stop taking her usual daily anticoagulants—she had trouble breathing and worried she had another clot in her lungs.

Williams requested a CT scan and anticoagulant heparin drip but was told she likely was just experiencing side effects from the pain medication. **She persisted**, and after an ultrasound on her legs was inconclusive for deep-vein thrombosis, she finally underwent a CT scan.



As Williams had predicted, the scan revealed several small blood clots in her lungs, for which she was treated with a heparin drip.

People knew about it then, we know about it now, and we have to continue to tell that story because it is one of great importance.

It's been 50 years since the strike, and when you look at the workforce protections, especially for Black people and other minorities, it's easy to say that the playing field is equal, because of laws prohibiting pay disparities because of race or gender. Do you think that progress is largely superficial? Do you think minority employees are treated differently? If so, what can we do to effect actual change?

I had an outstanding opportunity some years ago to present for the APHA, American Public Health Association, and that opportunity no doubt came because we have a Gullah/Geechee Sustainability Think Tank. I also work a great deal with a local healthcare organization, and I'm on a committee that is a Sea Island family's project committee. These things have given me a new lens into medicine, and I can say that when someone writes me in 2019 to say that they just formed an organization for Black medical students and that it was the first one, but yet they didn't have a budget. That tells me that there are disparities.

If you still need to form these organizations for us to have the space for us to dialogue with one another, and to find support for one another, then that tells me that there's a need for it and that need exists usually because the Black workers are not being treated the same as the other workers. They are still not seeing the equity and the equality once they enter the field. These are things that need to change. Going into the field of medicine is also a challenge, it's not that there aren't Black people who want to go into medicine, but if you want to go in, who can afford to go? Many of our communities, our families, are not in the financial position to support that.

Young children in elementary school and middle school are always asked, "What do you want to be when you grow up?" My teachers always said, "You're going to be a doctor." I was like, "I don't think I want to be around sick people."

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A lot of Black women... will tell their whole family all about [their complaint], but then go in a doctor's office and become silent, because they're intimidated by the doctor, because the doctor has been presented as this larger-than-life figure, as opposed to a caring compassionate person.



▲ Queen Quet presents to an audience of 30,000 for the American Public Health Association's national conference at the Georgia World Congress Center in Atlanta, Georgia.
Photo Credit: De Gullah/Geechee Alkebulan Archive (gullahgeecheenation.com)

But for someone with the energy and spirit and who wants to focus on that, they shouldn't have to be denied access because the school doesn't have computers, technical equipment, or chemistry laboratories. First, we must better finance education at a K through 12 level. Then we need peer-to-peer mentoring by allowing children to shadow medical professionals if they are inspired by that field. Seeing other Black professionals and, as women, seeing other female professionals, would help influence what kind of doctors we'll have. We need to address the cost of education so students don't enter the medical community saddled with hundreds of thousands of dollars in debt.

I absolutely agree. I've been a nurse for 25 years. When I look to the future of healthcare, knowing the shortages we have, there's such tremendous opportunity for young people, but how do we reach them where they are? How do we make sure all children have access to these opportunities without coming out of school with loans as large as a mortgage?

I have two other questions that I want to make sure that I get to. Last fall, you gave a presentation at the University of Florida on environmental and cultural sustainability, and one of the points you made was, "Talking is one thing, but are you getting an understanding from the

conversation? If we don't speak the same language, there might be a problem." How do you think this relates to healthcare, particularly for minorities who routinely have lower rates of health literacy and worse health outcomes? For example, we know that Black women who are pregnant have higher maternal morbidity and mortality rates than Caucasian women by about 3% to 4%. Do you see communication between providers and patients as an issue, and how do we begin to bridge that gap?

Yeah, it's a problem. There is a problem in communication, I've seen it for many years now, especially when I think about how I talk to a doctor versus how my mom talks to a doctor, and she's in her 80s. A lot of Black women in particular were taught that the doctors know more than you. As a result, they shy away from actually communicating with the doctor. They go in there, and even if the doctor says, "Well, why are you here today?" They'll give them a one-sentence answer when it needs to be a two-paragraph answer: I have the following conditions, these things are going on, this is happening. They'll tell the whole family all of this and complain about it, but then go in a doctor's office and become silent, because they're intimidated by the doctor, because the doctor has been presented as this larger-than-life figure, as opposed to a caring compassionate person.

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People are believing [COVID-19] is another Tuskegee experiment that's underway and that they're being culled from the population. When I hear these things, I can't immediately say to them, "Just stop that," because unfortunately there's a historical legacy of us being used.

We need to as the gwine bak ta ole landmak, as the phrase goes. Rebrand the doctors. We need to make them more human to people, as opposed to somebody that you fear, because a lot of people in the Black community don't want to have anything to do with the medical field because of medical apartheid. It literally makes my stomach sick the types of things that have happened to Black people in the name of medicine.

Even now, in the COVID pandemic, people are discouraging some people from going to get tested, because they don't believe you need to swab on the inside of someone's nose instead of in the cheek. For AIDS and other things, you do the cheek, so why are you doing the nose for this?

"It's because you're actually implanting chips in the Black community." That's what people are believing. People are believing that it's another Tuskegee experiment that's underway and that they're being culled from the population. When I hear these things, I can't immediately say to them, "Just stop that," because unfortunately there's a historical legacy of us being used. Even as cadavers, just being dug up and studied for various nefarious reasons over the years, not to the benefit of the Black community, and especially not to the benefit of Black women.

There used to be an organization called the Black Women's Health Crisis that I supported for many, many years. Because that organization, I guess, did not continue to get any funding and was primarily grassroots, I don't see it anymore; I've searched for it several times on the in-

ternet. They were trying to address health disparities for Black women in general, much less the morbidity rates that you're talking about. Look at what happened with the Williams sister. She had the voice and the platform, and she wasn't ashamed to tell people what happened to her—even though she's rich, she was mistreated.

I was blessed because I did not have to go through what my cousins and my sister told me they went through in hospitals in America. My son was born in Canada at a maternity hospital, and everyone was trained to have a beautiful bedside manner and to treat people appropriately. Also, everybody there has health insurance.

A lot of women in the United States are not getting the proper prenatal care because of this conveyor belt system of medicine. And if you're Black, you're further down on the belt, if you get to be put on the belt at all.

We talk about food deserts in a lot of Black communities. People tell me, "Well, I need to eat this, I need to eat that, can I buy it? Is it available to me? Do I have a farm where I can get fresh food?" All that's going to make a difference in terms of the health of the mother and of the baby. These are things that haven't been properly addressed, and they need to be addressed, but it's going to have to be a constant push from groups like the Black Women's Health Care Crisis.

We can't have this deficit because it's a major problem. We all know stressors are a major killer. When you are Black, or female, and you don't have enough money; you don't have the proper medical facilities; you live in a food desert; and you might live in apartment buildings with a whole bunch of other things going on there, how healthy can you be? How healthy might your baby be? What gets

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If you really want to bring about equity and equality, you will put your heart and soul into it. Be active. Be involved. That's the greatest investment you can ever make.

transferred into that womb, and what kind of womb are you gestating in as you grow, or does it stunt your growth?

Those are all major things. When we're talking again about equity and equality, all of this has been built into America. These disparities have been built in, it's generational, and medical apartheid really put a bright light on that, and I think it's crucial that we examine that.

If you were speaking to a group of hospital administrators and they asked you, "Is there one thing that I can start doing tomorrow, individually or as an organization, to improve the health of people of color in my community?" What would you tell them?

My answer as an individual medical practitioner administrator is the same as an entire medical facility. You need to invest in that community starting today, and that investment can take different forms. A lot of times people who make large sums of money, they fought hard to get it, so they don't think about giving any to anybody. They live a lifestyle such that they have so much debt themselves, they don't feel they have enough to give to anybody, but trust me, the hundred dollar or the thousand dollar donation will make a difference in those communities. And often gifts you give as an individual are matched by an organization.

If you really want to bring about equity and equality, you will put your heart and soul into it. Be active. Be involved. That's the greatest investment you can ever make. Your behavior will follow where your heart goes, and if your heart is really going out to Black, Indigenous, people of color's communities, you will then call in your colleagues to do the same with you. Support scholarships for our youth to enter the field of medicine. Now is the time to do more than talk; it is now time to walk the walk.

Doctors took an oath to make people healthy. And if people see them investing in their communities, they will inspire a future of other medical practitioners that truly give safety to the community, because they have so much love and compassion for everybody.

When we think of patient safety, it's typically very categorized—medication errors, patients who fall, or if something goes wrong during a surgery. But one of the pieces we're missing, are these equity issues and the access issues, particularly for our minority populations. It's just as much of a safety issue that you couldn't get access to care to be able to get your surgery in a timely manner, regardless of whether a complication happened. It's still patient safety.

There's more to patient safety than just an error. It's how patients are treated differently and how some people are uncomfortable speaking up because they feel intimidated. Those are all pieces that play into patient safety that we don't always think about.

Absolutely. The last thing that I would add is when we're talking about the safety of patients, we're talking about the safety of people. What about the safety of the communities those people live in? What about the households that they're in? If we can make those households places in which the health and safety are primary concerns, we could revolutionize the medical field. We could empower a whole generation of people to be safe and healthy. We could all create a safer world together and look at all the different cultural components that go into that. If you focus there and invest there, we can have a safer world overall.

About the Author

Regina Hoffman is executive director of Pennsylvania's Patient Safety Authority (PSA), an independent agency charged with taking steps to reduce medical errors by identifying problems and recommending solutions to promote patient safety, and editor-in-chief of *Patient Safety*, PSA's peer-reviewed journal.

Thank you & Happy New Year!

To all the healthcare workers across Pennsylvania,
the United States, and abroad who have been
risking their lives to protect ours: thank you.



PSA | PATIENT
SAFETY

