PATIENT SAFETY

2025 | Vol. 7, No. 1

Wrong-Site Surgery

Oxygen Disruption

Broken Drill Bits

2024

PSA HIGHLIGHTS

LETTER
From the Editor

Regina Hoffman,
Editor-in-Chief
Patient Safety

Happy New Year! I'm thrilled to share the latest *Patient Safety* highlights issue with several of our most-read articles from 2024. You may have noticed that the aesthetics look a little different this time around to mirror the branding refresh for the Patient Safety Authority's website, patientsafety.pa.gov.

We completely overhauled the site to improve the user experience and make it easier to find the information you need faster, and we added new content—all while giving the site a more modern vibe. Check it out if you haven't already.

I also wanted to share a recent personal encounter that led to one of my New Year's resolutions: Celebrate the wins but be cautious of news that's too good to be true.

A relative was diagnosed with cancer last year. I've been attending their appointments with them as the resident family clinician and am familiar with how things are progressing. During an oncology appointment in December, the physician shared the latest test results, and the results were good. Really good. Too good.

Where there had consistently been a mass, there was nothing. It was almost as if they were now in remission, seemingly overnight.

The easiest—and most tempting—option was to accept these results as they were presented to us. Celebrate the win of such good news.

However, the voice in the back of my head, the one who has been a nurse for decades, began screaming that no matter how much we wanted this to be true, it really likely wasn't.

We pressed the care team until they reread the scan and, ultimately, repeated it. And sure enough, these results were more aligned with what we were expecting. We are now able to move on with the appropriate treatment plan.

This is all because I spoke up and chose not to accept something just because it's what we all wanted to hear.

So, for this year, of course, celebrate the wins. The milestones. The steps towards recovery. But be mindful that if news seems too good to be true, it likely is. And most importantly, it can interfere with developing an accurate course of treatment that will actually lead to a well-deserved celebration.

Cheers!

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.

 The current issue is available at patientsafetyj.com.

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

Articles are published online on a rolling basis throughout the year. Selected articles are published in a special print issue and online each January.

Articles accepted for publication do not necessarily reflect practices or opinions endorsed by the Patient Safety Authority.

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Shirley Dominick

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100 **Mpox: An Update on the New Public Health Emergency**

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More isn't always better, especially when dealing with medication. Sublingual nitroglycerin (a tablet under the tongue) is to treat chest pain in patients with coronary artery disease. A single dose is only 0.4 mg (one tablet), but since it comes in multidose bottles with 25 tablets, patients have mistakenly been administered the entire bottle (10 mg) and required resuscitation and additional treatment.

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Even as we strive toward a goal of zero harm, it is also essential to recognize when things go right in hospitals and facilities. The IAPS contest is an opportunity to celebrate and share those stories, that they may inform and inspire others in their work.

Long-Term Care Healthcare-Associated Infections in 2023:

An Analysis of 23,970 Reports

Keywords: long-term care, nursing homes, annual report, healthcare-associated infections, HAI, infection rates, resident days

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By **Shawn Kepner**, MS*[1], **Amanda Bennett**, MPH, MLS(ASCP)CM[1] & **Rebecca Jones**, MBA, RN[1]

Abstract

Background: The Pennsylvania Patient Safety Reporting System (PA-PSRS) is the largest database of patient safety event reports in the United States. In addition to over 4.7 million acute care reports, the PA-PSRS database contains more than 420,000 long-term care (LTC) healthcare-associated infection (HAI) reports.

Methods: LTC HAI data from PA-PSRS were extracted on March 1, 2024. Infection counts were calculated based on report submission date and rates were calculated based on infection confirmation date. Reports submitted by LTC facilities and specific care areas were included for infection rates each month if resident and device days were also entered in PA-PSRS for the facility and care area.

Results: A total of 23,970 infection reports were submitted by Pennsylvania's LTC facilities in 2023, representing an 18.6% increase from 2022. The overall infection rate increased by 11.4%, from 0.88 in 2022 to 0.98 in 2023, and all six regions of the state had an increase in infection rate. The Northeast region had the highest rate, with 1.28 reports per 1,000 resident days, and the Southeast region had the lowest rate, at 0.72. The overall rate increase was driven by rates of urinary tract infection (UTI) and skin and soft tissue infection (SSTI), which increased by 20.1% and 17.4%, respectively. Within the UTI infection type, symptomatic urinary tract infection (SUTI) rates increased by 21.1% and catheter-associated urinary tract infection (CAUTI) rates increased by 11.8%.

Conclusion: There was an increase in the total number and rate of infections reported to PA-PSRS in 2023.

Introduction

The Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] is the largest repository of patient safety data in the United States. In addition to over 4.7 million acute care records, PA-PSRS has collected more than 420,000 long-term care (LTC) healthcare-associated infection (HAI) reports since 2009.

Methods

The LTC data from PA-PSRS were extracted on March 1, 2024, to allow additional time for rate calculations based on resident and device utilization days. Report counts for infections are based on the report submission date. Overall rates are based on the infection confirmation date and calculated per 1,000 resident days. Infection rates related to urinary catheters or central lines are calculated per 1,000 urinary catheters or 1,000 central line days, respectively. Reports submitted by LTC facilities and specific care areas were included in rate calculations if resident and device days were entered in PA-PSRS for the corresponding month.

Results

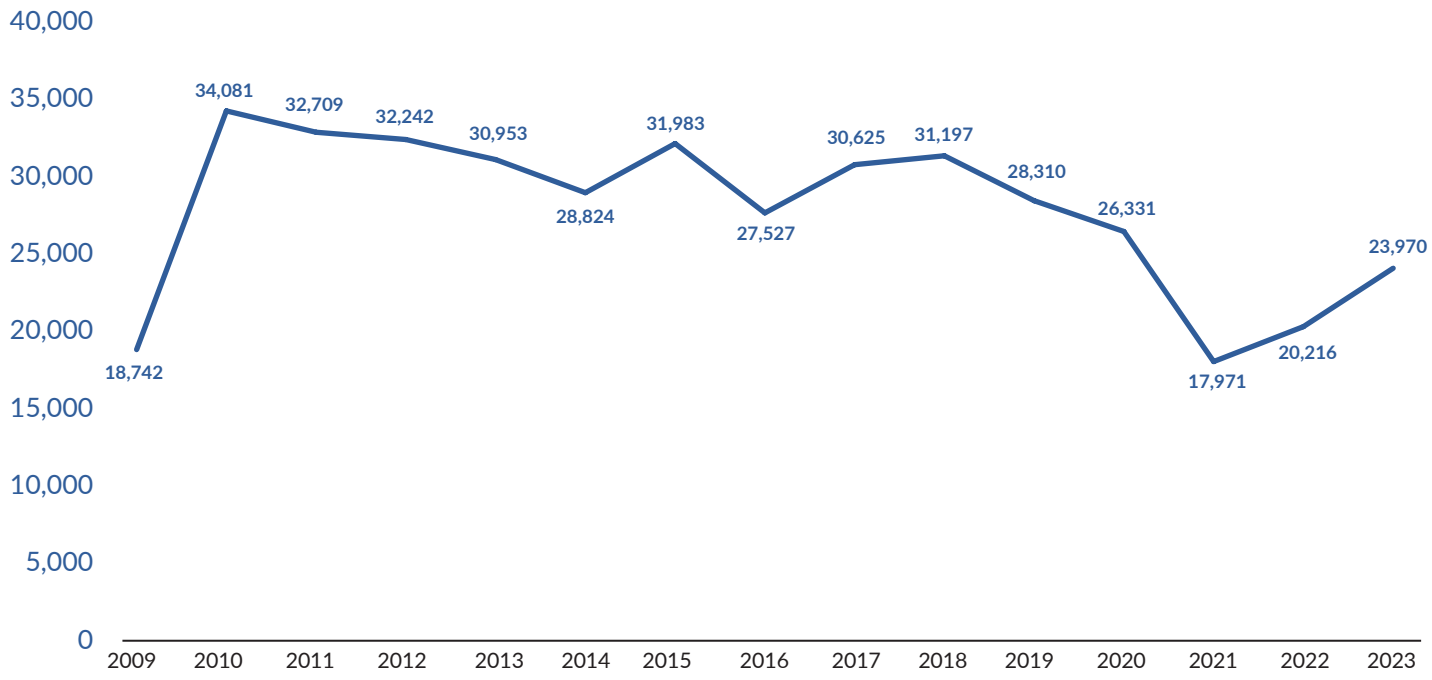
Pennsylvania's LTC facilities submitted 23,970 infection reports to PA-PSRS in 2023, which is an 18.6% increase over the prior year (see **Figure 1**). As shown in **Figure 2**, the overall infection rate in 2023 was 0.98 infections per 1,000 resident days, representing an 11.4% increase from 2022.

Figure 3, which displays infection rates by region, shows that all six regions of the state had an increase in infection rate from 2022 to 2023. The Northeast region had the highest infection rate in 2023, with 1.28 reports per 1,000 resident days, and the Southeast region had the lowest rate, at 0.72. The distribution of LTC infection reports and infection rates by region are shown in **Table 1**.

LTC Healthcare-Associated Infections

Reports submitted by LTC facilities to PA-PSRS are classified into five main infection types (see **Figure 4**). In 2020, respiratory tract infections (RTI) were the most frequently reported infection type. For the last three years, skin and soft tissue infections (SSTI) were the most frequently reported, followed by urinary tract infections (UTI) and RTI. The number of reports submitted for all three of these infection types increased in 2023, with the top two showing large increases of 23.1% and 26.6%, respectively.

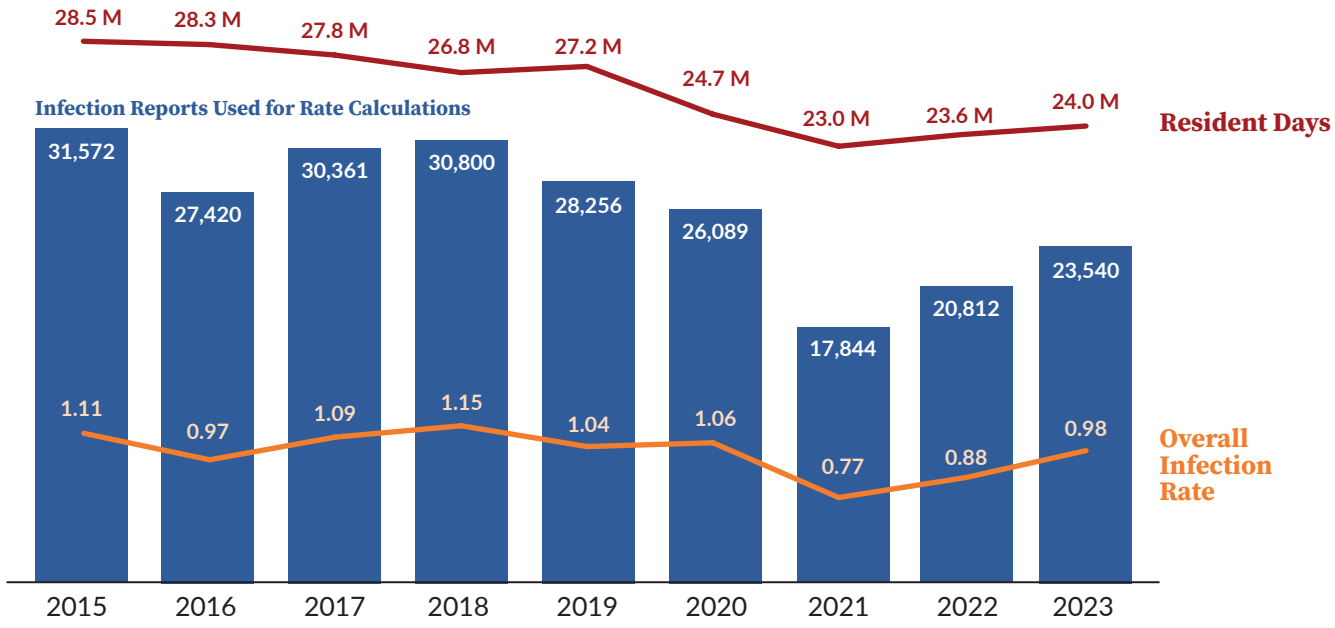
Figure 1. LTC Infection Reports Submitted to PA-PSRS by Year



Note: Numbers shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

[a]PA-PSRS is a secure, web-based system through which Pennsylvania long-term care facilities submit reports of healthcare-associated infections in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 52 of 2007).1 All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Figure 2. PA-PSRS LTC Infection Reports, Resident Days, and Overall Infection Rates per 1,000 Resident Days by Year



Note: The number of infection reports shown for each year is based on infection confirmation date, rather than report submission date, to ensure consistency with the time frame in which the resident days occurred. Reports were excluded from the rate calculation if a facility did not report resident days for the corresponding month. Numbers and rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

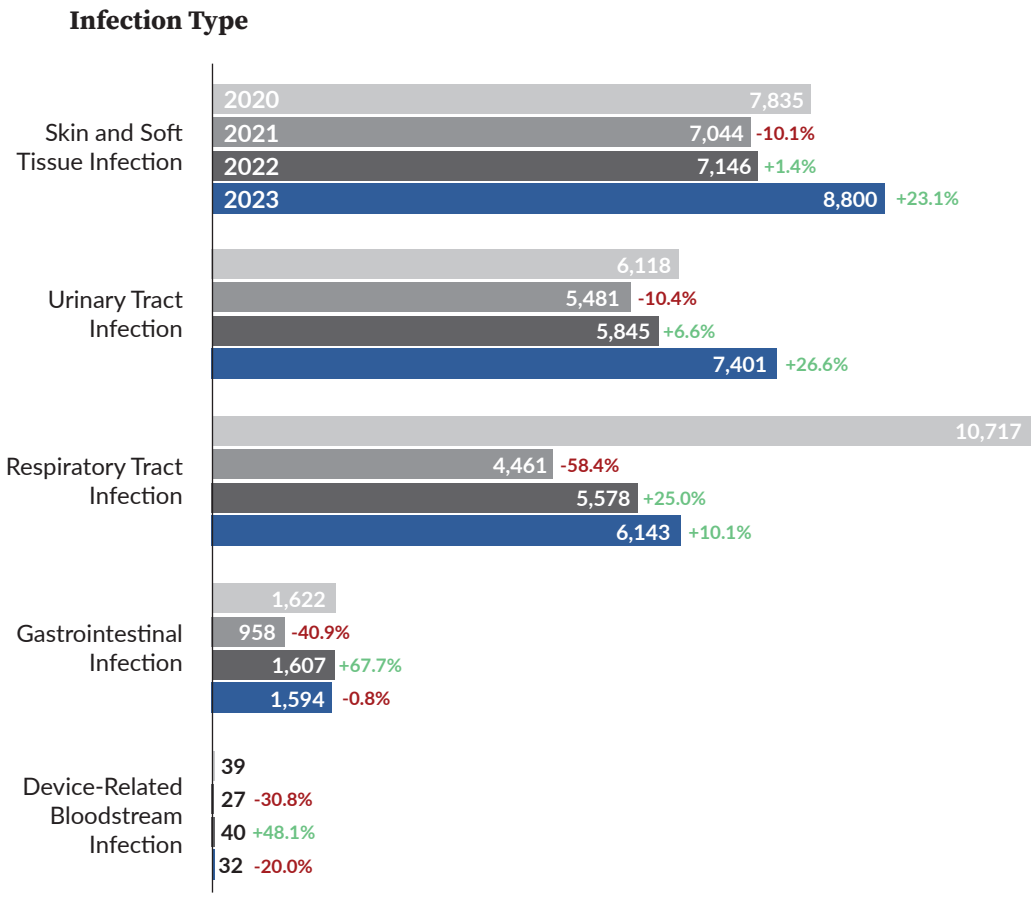
Figure 3. PA-PSRS LTC Infection Rates per 1,000 Resident Days by Region—2022 Versus 2023

Table 1. PA-PSRS LTC Infection Reports and Infection Rates per 1,000 Resident Days by Region

Region	2022 Infection Reports	2022 Rate per 1,000 Resident Days	2023 Infection Reports	2023 Rate per 1,000 Resident Days
North Central	1,653	1.15	1,850	1.23
Northeast	3,452	1.12	4,026	1.28
Northwest	1,963	0.94	2,265	1.08
South Central	3,123	1.01	3,481	1.10
Southeast	6,213	0.66	6,807	0.72
Southwest	4,408	0.97	5,111	1.11
Total	**20,812**	**0.88**	23,540	0.98

Note: The number of infection reports shown for each year is based on infection confirmation date, rather than report submission date, to ensure consistency with the time frame in which the resident days occurred. Reports were excluded from the rate calculation if a facility did not report resident days for the corresponding month. Numbers and rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

Figure 4. LTC Infection Reports Submitted to PA-PSRS by Infection Type and Year



Note: Numbers shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

LTC Healthcare-Associated Infection Subtypes

Table 2 shows the number of reports submitted for all infection subtypes for the past four years. The most frequently reported subtype in 2023 was cellulitis, soft tissue, or wound infection, followed by symptomatic urinary tract infection (SUTI) and pneumonia, which is the same top-three subtype ordering as the prior two years. Of the 14 infection subtypes, nine had an increase in number of reports submitted in 2023 compared to 2022, with SUTI showing the largest increase of 1,228 reports. Influenza-like illness had the largest percentage increase of 179.7%, going from 64 reported infections in 2022 to 179 in 2023. Of the five subtypes that decreased in number, influenza had the largest decrease, dropping by 449 reports from 2022 to 2023.

Care Area

Table 3 shows the distribution of 2023 reports by infection type and care area. Skilled nursing/short-term rehabilitation units accounted for the largest proportion of infections (34.1%; 8,162 of 23,970). In 2023, SSTI were reported more than any other infection type in all care areas except ventilator-dependent units, in which RTIs were reported most frequently. **Table 4** shows the 2023 distribution of infection reports by infection subtype and care area. As was the case in 2022, the largest concentration of reports in 2023 was seen with SUTI in skilled nursing/short-term rehabilitation units.

LTC Healthcare-Associated Infection Rates

Figure 5 shows rates per 1,000 resident days for the five main infection types for 2020 through 2023. The increase in overall rate in 2023 was driven by increases in the UTI and SSTI rates, which increased by 20.1% and 17.4%, respectively.

In **Figure 6** and **Table 5**, rates are shown for each infection subtype for 2020 through 2023. As mentioned above, the UTI rate was a driver of the increase in the overall rate for 2023. Within the UTI infection type, there were notable increases in SUTI and catheter-associated urinary tract infection (CAUTI) rates, with SUTI increasing by 21.1% and CAUTI by 11.8%. Looking further into the circumstances around CAUTI, the past three years have seen a steady increase in the percentage of resident days that coincided with catheter usage. In the 10 years prior to 2021, this percentage varied from 4.5% to 4.8%; in 2021, 2022, and 2023, the percentage was 4.9%, 5.1%, and 5.3%, respectively.

In **Table 6**, the infection rates are displayed by year based on care area and infection subtype. The largest percentage increases in rate from 2022 to 2023 occurred with influenza-like illness in dementia units (+528.6%), asymptomatic bacteremic urinary tract infection (ABUTI) in dementia units (+128.6%), and norovirus in mixed units (+108.1%). Influenza rates had the largest percentage decrease of all infection subtypes in three of the five care areas (mixed, nursing, and ventilator-dependent units).

Figure 7 and **Table 7** display infection rates for influenza, influenza-like illness, pneumonia, lower RTI (LRTI), and norovirus by quarter for 2020 through 2023. These rates are calculated as the number of infections by quarter per 1,000 resident days. With the exception of 2021, norovirus rates have peaked in Q1 of each year. The influenza rate rose to 0.04 in Q4 2023 after having been on a decline for three quarters following its peak in Q4 2022.

Table 2. LTC Infection Reports Submitted to PA-PSRS and Percentage Distribution by Infection Subtype and Year

Infection Type	Infection Subtype	Number of Reports				% of Total				Change in Reports 2022 to 2023	
		2020	2021	2022	2023	2020	2021	2022	2023	Number	Percent
Skin and Soft Tissue Infection	Cellulitis/Soft Tissue/ Wound Infection	5,180	4,951	5,081	6,212	19.7%	27.5%	25.1%	25.9%	1,131	22.3%
	Conjunctivitis	2,528	1,957	1,937	2,483	9.6%	10.9%	9.6%	10.4%	546	28.2%
	Scabies	127	136	128	105	0.5%	0.8%	0.6%	0.4%	-23	-18.0%
Urinary Tract Infection	SUTI	4,715	4,288	4,589	5,817	17.9%	23.9%	22.7%	24.3%	1,228	26.8%
	CAUTI	1,251	1,052	1,087	1,363	4.8%	5.9%	5.4%	5.7%	276	25.4%
	ABUTI	152	141	169	221	0.6%	0.8%	0.8%	0.9%	52	30.8%
Respiratory Tract Infection	Pneumonia	4,862	3,004	3,005	3,747	18.5%	16.7%	14.9%	15.6%	742	24.7%
	LRTI	3,769	1,216	1,451	1,608	14.3%	6.8%	7.2%	6.7%	157	10.8%
	Influenza	1,432	201	1,058	609	5.4%	1.1%	5.2%	2.5%	-449	-42.4%
	Influenza-Like Illness	654	40	64	179	2.5%	0.2%	0.3%	0.7%	115	179.7%
Gastro-intestinal Infection	*C. diff*	961	883	854	872	3.6%	4.9%	4.2%	3.6%	18	2.1%
	Norovirus	647	70	730	707	2.5%	0.4%	3.6%	2.9%	-23	-3.2%
	Bacteriologic Gastroenteritis	14	5	23	15	0.1%	0.0%	0.1%	0.1%	-8	-34.8%
Device-Related Bloodstream Infection	CLABSI	39	27	40	32	0.1%	0.2%	0.2%	0.1%	-8	-20.0%
Totals		**26,331**	**17,971**	**20,216**	**23,970**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**3,754**	**18.6%**

Note: Numbers shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

SUTI = Symptomatic Urinary Tract Infection
CAUTI = Catheter-Associated Urinary Tract Infection
ABUTI = Asymptomatic Bacteremic Urinary Tract Infection
LRTI = Lower Respiratory Tract Infection
CLABSI = Central Line–Associated Blood Stream Infection

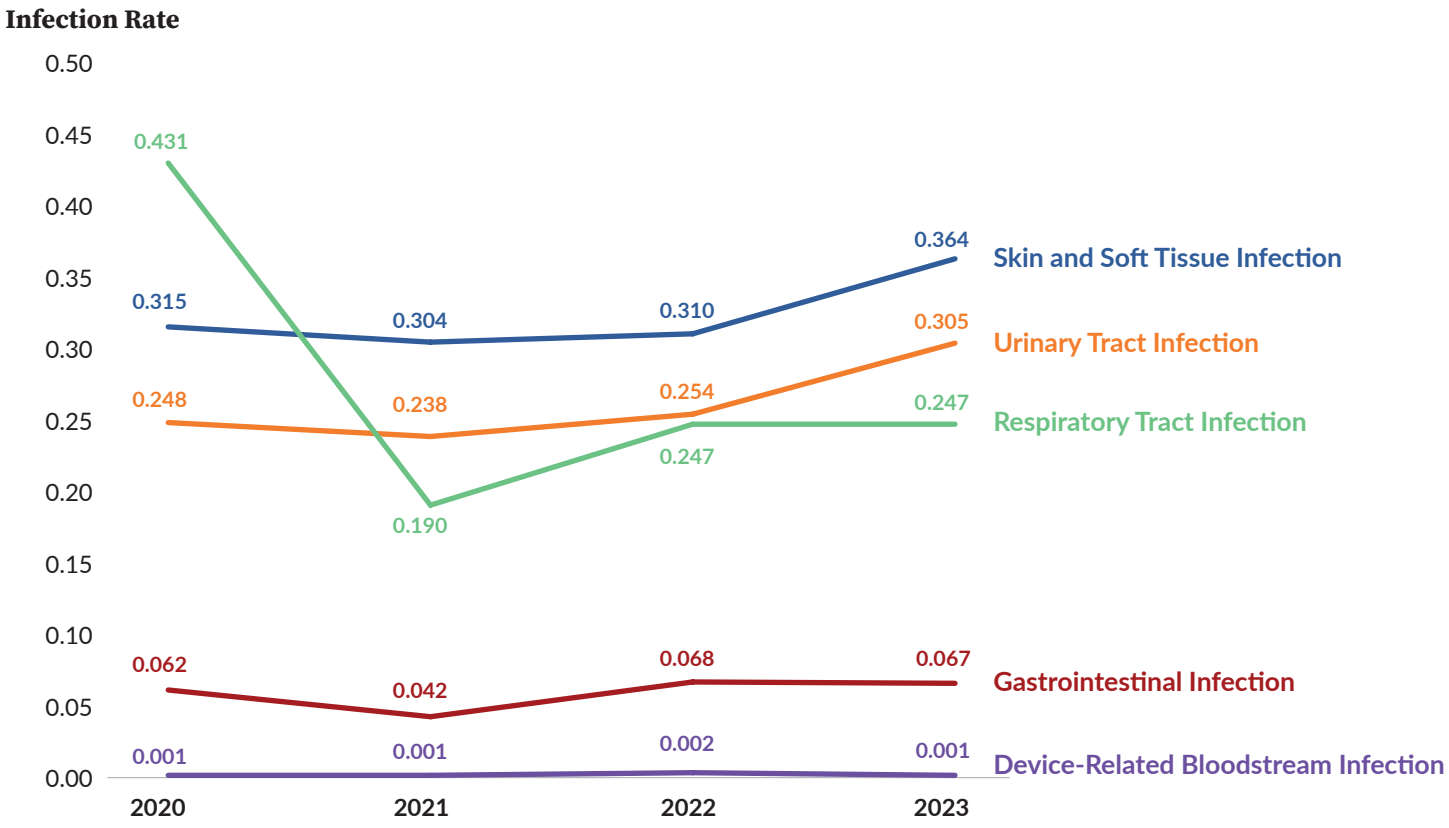
Table 3. LTC Infection Reports Submitted to PA-PSRS in 2023 by Infection Type and Care Area

Infection Type	Skilled Nursing/ Short-Term Rehabilitation Unit	Mixed Unit	Nursing Unit	Dementia Unit	Ventilator-Dependent Unit	Total
Skin and Soft Tissue Infection	2,786	2,612	2,735	589	78	**8,800**
Urinary Tract Infection	2,742	2,236	2,099	303	21	**7,401**
Respiratory Tract Infection	2,000	1,782	1,757	404	200	**6,143**
Gastrointestinal Infection	625	444	397	112	16	**1,594**
Device-Related Bloodstream Infection	9	17	6	0	0	**32**
Total	**8,162**	**7,091**	**6,994**	**1,408**	**315**	**23,970**

Table 4. LTC Infection Reports Submitted to PA-PSRS in 2023 by Infection Subtype and Care Area

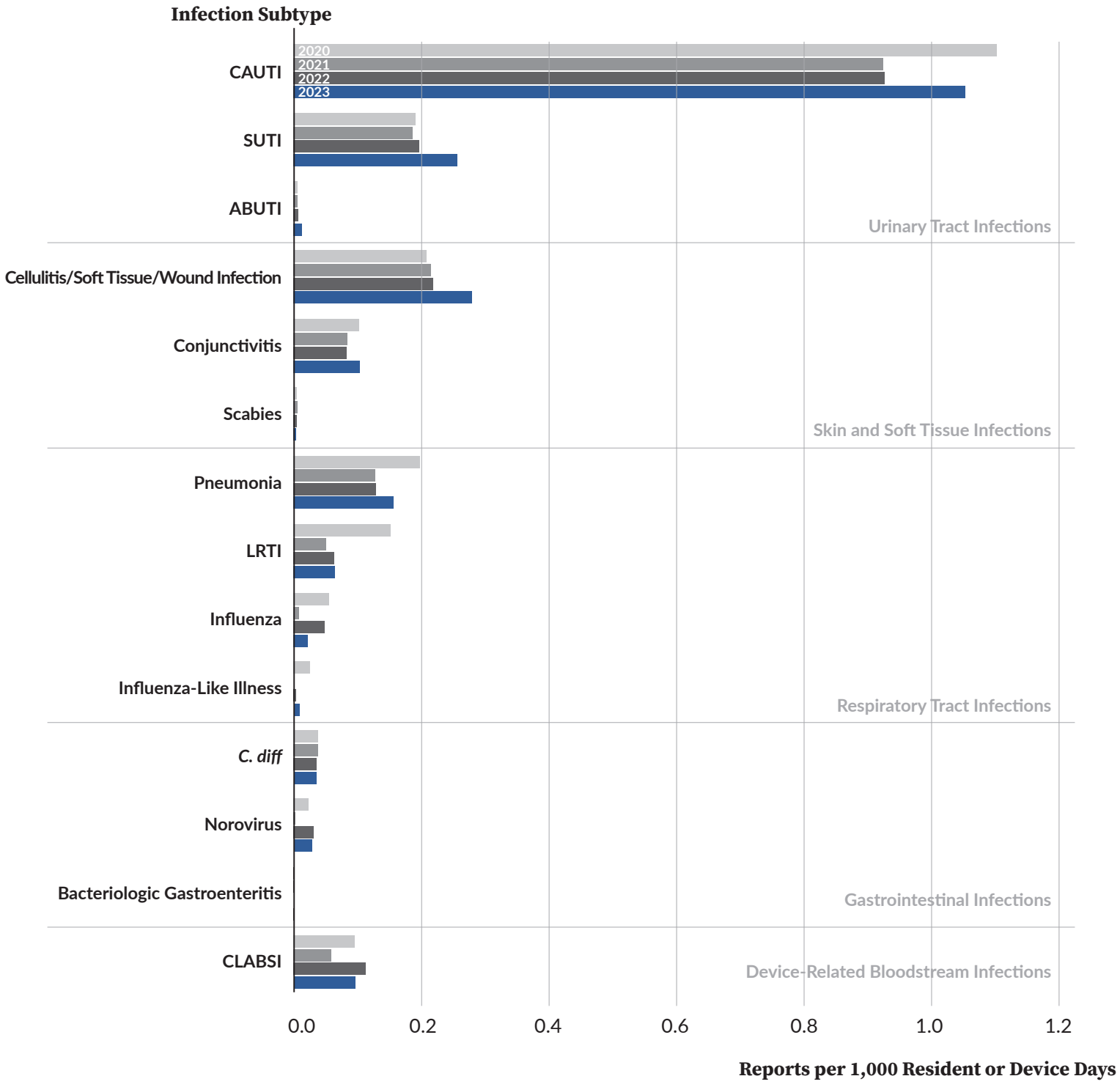
Infection Subtype	Skilled Nursing/ Short-Term Rehabilitation Unit	Mixed Unit	Nursing Unit	Dementia Unit	Ventilator-Dependent Unit	Total
Cellulitis/Soft Tissue/Wound Infection	1,948	1,860	2,045	313	46	**6,212**
SUTI	2,156	1,713	1,688	249	11	**5,817**
Pneumonia	1,181	1,092	1,121	198	155	**3,747**
Conjunctivitis	784	727	674	266	32	**2,483**
LRTI	536	440	451	136	45	**1,608**
CAUTI	522	429	360	44	8	**1,363**
Influenza	362	257	201	36	16	**872**
C. diff	258	183	191	75	0	**707**
Norovirus	220	192	154	43	0	**609**
ABUTI	64	94	51	10	2	**221**
Scabies	63	58	31	27	0	**179**
Influenza-Like Illness	54	25	16	10	0	**105**
CLABSI	9	17	6	0	0	**32**
Bacteriologic Gastroenteritis	5	4	5	1	0	**15**
Total	**8,162**	**7,091**	**6,994**	**1,408**	**315**	**23,970**

Figure 5. PA-PSRS LTC Infection Rates per 1,000 Resident Days by Infection Type



Note: Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

Figure 6. PA-PSRS LTC Infection Rates per 1,000 Resident or Device Days by Infection Subtype and Year



Note: Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

Table 5. PA-PSRS LTC Infection Rates per 1,000 Resident or Device Days by Infection Subtype and Year in Descending Order by 2023 Rates

	Rates			
Infection Subtype	**2020**	**2021**	**2022**	**2023**
CAUTI	1.098	0.921	0.938	**1.049**
Cellulitis/Soft Tissue/Wound Infection	0.208	0.215	0.221	**0.256**
SUTI	0.191	0.186	0.199	**0.241**
Pneumonia	0.197	0.128	0.130	**0.154**
Conjunctivitis	0.102	0.084	0.083	**0.104**
CLABSI	0.095	0.059	0.112	**0.093**
LRTI	0.152	0.051	0.064	**0.065**
C. diff	0.038	0.038	0.036	**0.036**
Norovirus	0.023	0.003	0.031	**0.030**
Influenza	0.055	0.009	0.049	**0.022**
ABUTI	0.006	0.006	0.007	**0.009**
Influenza-Like Illness	0.026	0.002	0.004	**0.006**
Scabies	0.005	0.006	0.005	**0.004**
Bacteriologic Gastroenteritis	0.001	<0.0005	0.001	**0.001**

Note: Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications. If <0.0005 appears in a cell, it means that the rate is greater than zero but would otherwise be shown as 0.000 due to rounding to three decimal places.

Table 6. PA-PSRS LTC Infection Rates per 1,000 Resident or Device Days by Care Area, Infection Subtype, and Year in Descending Order by Percentage Increase From 2022 to 2023 Within Each Care Area

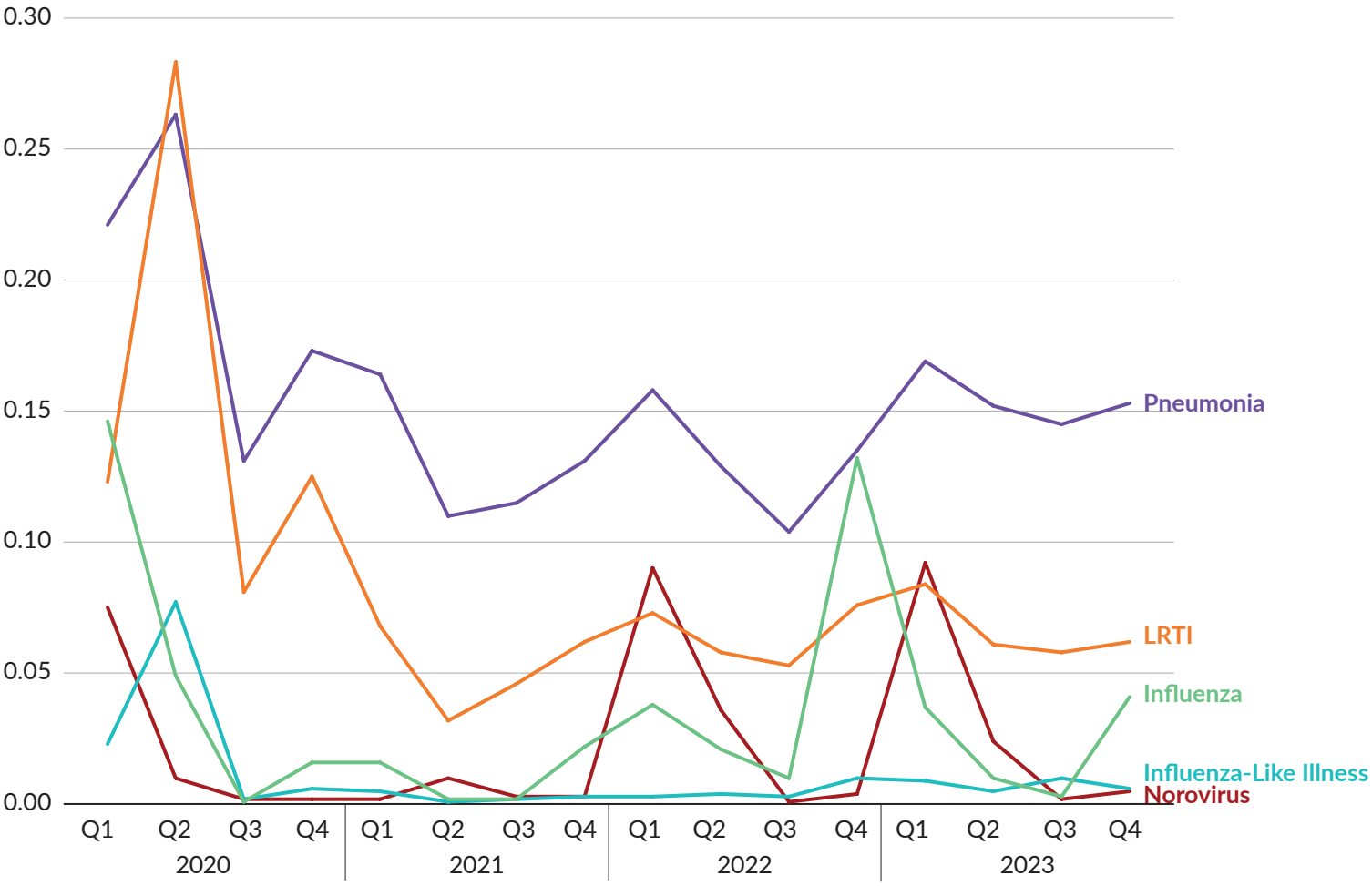
Care Area	Infection Subtype	2020	2021	2022	2023	2020 to 2021	2021 to 2022	2022 to 2023
Dementia Unit	Influenza-Like Illness	0.032	0.001	0.002	0.013	-96.6%	90.9%	528.6%
	ABUTI	0.005	0.004	0.002	0.005	-14.0%	-51.2%	128.6%
	Conjunctivitis	0.107	0.090	0.084	0.141	-15.8%	-6.6%	67.1%
	C. diff	0.016	0.012	0.012	0.019	-20.6%	-1.6%	52.9%
	Scabies	0.006	0.014	0.005	0.006	152.7%	-66.2%	23.4%
	Pneumonia	0.147	0.085	0.088	0.102	-42.2%	3.5%	15.6%
	LRTI	0.136	0.027	0.061	0.067	-80.0%	124.6%	9.3%
	Cellulitis, Soft Tissue, or Wound Infection	0.149	0.151	0.156	0.167	1.4%	3.2%	7.0%
	CAUTI	1.105	0.451	0.975	0.996	-59.2%	116.1%	2.2%
	SUTI	0.122	0.107	0.130	0.132	-11.8%	20.7%	2.2%
	Influenza	0.044	0.002	0.023	0.018	-95.3%	1004.8%	-22.4%
	Norovirus	0.045	-	0.066	0.039	-100.0%	-	-41.3%
	Bacteriologic Gastroenteritis	<0.0005	-	-	<0.0005	-100.0%	-	-
	CLABSI	-	-	-	-	-	-	-
Mixed Unit	Norovirus	0.016	0.003	0.014	0.028	-82.8%	400.0%	108.1%
	ABUTI	0.007	0.006	0.008	0.014	-13.6%	35.1%	85.7%
	Influenza-Like Illness	0.022	<0.0005	0.004	0.007	-98.7%	1233.3%	72.5%
	CLABSI	0.062	0.052	0.100	0.163	-17.5%	94.8%	62.0%
	Scabies	0.002	0.006	0.003	0.004	250.0%	-58.7%	46.2%
	CAUTI	1.256	0.954	0.955	1.216	-24.0%	0.1%	27.3%
	Conjunctivitis	0.109	0.088	0.087	0.110	-18.7%	-1.6%	26.4%
	SUTI	0.204	0.209	0.205	0.259	2.5%	-2.0%	26.3%
	Cellulitis, Soft Tissue, or Wound Infection	0.215	0.228	0.231	0.282	6.1%	1.7%	21.7%
	Pneumonia	0.200	0.123	0.136	0.162	-38.4%	10.6%	19.2%
	LRTI	0.144	0.040	0.054	0.064	-72.3%	35.7%	17.6%
	C. diff	0.043	0.040	0.042	0.040	-8.8%	6.8%	-5.5%
	Bacteriologic Gastroenteritis	<0.0005	<0.0005	0.001	<0.0005	-66.7%	450.0%	-45.5%
	Influenza	0.041	0.011	0.053	0.020	-73.2%	373.9%	-61.8%
Nursing Unit	Pneumonia	0.164	0.109	0.107	0.138	-33.8%	-2.0%	29.9%
	Conjunctivitis	0.093	0.071	0.072	0.086	-23.0%	0.8%	19.2%
	Cellulitis, Soft Tissue, or Wound Infection	0.183	0.198	0.221	0.252	8.2%	11.7%	13.9%
	SUTI	0.164	0.162	0.187	0.206	-1.4%	15.4%	10.3%
	LRTI	0.139	0.042	0.055	0.056	-69.9%	30.3%	2.4%
	ABUTI	0.005	0.007	0.007	0.007	43.8%	0.0%	1.4%
	C. diff	0.026	0.028	0.025	0.025	9.4%	-10.4%	0.4%
	Bacteriologic Gastroenteritis	<0.0005	-	<0.0005	<0.0005	-100.0%	-	0.0%
	CLABSI	0.151	0.014	0.081	0.081	-90.9%	494.2%	-0.4%
	CAUTI	0.943	0.855	0.959	0.850	-9.4%	12.2%	-11.4%
	Norovirus	0.033	0.006	0.035	0.024	-82.0%	494.9%	-30.8%
	Influenza-Like Illness	0.023	0.002	0.004	0.002	-89.7%	45.8%	-37.1%
	Scabies	0.006	0.005	0.004	0.002	-12.7%	-27.1%	-40.0%
	Influenza	0.057	0.005	0.051	0.021	-90.4%	837.0%	-59.3%

Table 6. (continued.)

Care Area	Infection Subtype	2020	2021	2022	2023	2020 to 2021	2021 to 2022	2022 to 2023
Skilled Nursing/ Short-Term Rehabilitation Unit	Influenza-Like Illness	0.030	0.002	0.005	0.008	-92.4%	113.0%	69.4%
	SUTI	0.225	0.214	0.225	0.291	-5.2%	5.1%	29.4%
	Conjunctivitis	0.100	0.083	0.084	0.105	-16.3%	0.4%	25.1%
	CAUTI	1.054	0.950	0.910	1.137	-9.9%	-4.2%	24.9%
	Cellulitis, Soft Tissue, or Wound Infection	0.239	0.233	0.226	0.259	-2.5%	-2.9%	14.4%
	Pneumonia	0.226	0.145	0.143	0.158	-36.1%	-1.4%	10.7%
	ABUTI	0.007	0.006	0.008	0.009	-16.2%	43.9%	6.1%
	C. diff	0.050	0.052	0.047	0.048	2.8%	-9.5%	2.6%
	Norovirus	0.014	0.002	0.034	0.035	-86.6%	1684.2%	1.8%
	LRTI	0.169	0.061	0.074	0.072	-64.3%	22.0%	-2.7%
	Scabies	0.008	0.005	0.010	0.007	-41.0%	119.6%	-28.7%
	Influenza	0.070	0.014	0.053	0.026	-80.1%	280.6%	-51.8%
	Bacteriologic Gastroenteritis	<0.0005	<0.0005	0.002	<0.0005	0.0%	200.0%	-53.3%
	CLABSI	0.095	0.091	0.136	0.062	-4.2%	49.5%	-54.1%
Ventilator-Dependent Unit	Pneumonia	0.892	1.037	1.062	1.105	16.3%	2.4%	4.1%
	Cellulitis, Soft Tissue, or Wound Infection	0.340	0.361	0.363	0.354	6.1%	0.6%	-2.5%
	C. diff	0.141	0.190	0.151	0.113	34.9%	-20.8%	-24.8%
	LRTI	0.449	0.774	0.507	0.319	72.4%	-34.5%	-37.1%
	Conjunctivitis	0.289	0.407	0.452	0.220	40.9%	11.1%	-51.4%
	SUTI	0.109	0.105	0.164	0.071	-3.8%	56.6%	-56.9%
	CAUTI	1.785	1.440	0.828	0.276	-19.3%	-42.5%	-66.7%
	CLABSI	-	-	0.165	-	-	-	-100.0%
	Influenza	0.019	-	0.007	-	-100.0%	-	-100.0%
	ABUTI	0.006	0.026	-	0.014	309.4%	-100.0%	-
	Bacteriologic Gastroenteritis	-	-	-	-	-	-	-
	Influenza-Like Illness	0.006	-	-	-	-100.0%	-	-
	Norovirus	-	-	-	-	-	-	-
	Scabies	-	-	-	-	-	-	-

Note: When a dash "-" appears in a cell within the table, it means that the rate is zero. If <0.0005 appears in a cell, it means that the rate is greater than zero but would otherwise be shown as 0.000 due to rounding to three decimal places. When -100.0% appears in a cell, it means that the year to which that percentage reduction applies had a zero rate and the prior year had a nonzero rate. Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

Figure 7. PA-PSRS LTC Infection Rates per 1,000 Resident Days Trending for Seasonal Infection Subtypes by Quarter



Note: Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications.

Table 7. PA-PSRS LTC Infection Rates per 1,000 Resident Days for Seasonal Infection Subtypes by Quarter

	Influenza	Influenza-Like Illness	LRTI	Norovirus	Pneumonia
2020 Q1	0.145	0.022	0.122	0.074	0.220
Q2	0.048	0.076	0.282	0.009	0.262
Q3	<0.0005	0.001	0.080	0.001	0.130
Q4	0.015	0.005	0.124	0.001	0.172
2021 Q1	0.015	0.004	0.067	0.001	0.163
Q2	0.001	<0.0005	0.031	0.009	0.109
Q3	0.001	0.001	0.045	0.002	0.114
Q4	0.021	0.002	0.061	0.002	0.130
2022 Q1	0.037	0.002	0.072	0.089	0.157
Q2	0.020	0.003	0.057	0.035	0.128
Q3	0.009	0.002	0.052	<0.0005	0.103
Q4	0.131	0.009	0.075	0.003	0.134
2023 Q1	**0.036**	**0.008**	**0.083**	**0.091**	**0.168**
Q2	**0.009**	**0.004**	**0.060**	**0.023**	**0.151**
Q3	**0.002**	**0.009**	**0.057**	**0.001**	**0.144**
Q4	**0.040**	**0.005**	**0.061**	**0.004**	**0.152**

Note: Rates shown for prior years may differ from previously published information due to receipt of data or changes to reports made by reporting facilities after the data cutoff date for prior publications. If <0.0005 appears in a cell, it means that the rate is greater than zero but would otherwise be shown as 0.000 due to rounding to three decimal places.

Discussion

Pennsylvania's LTC facilities reported 23,970 infections and 24.0 million resident days in PA-PSRS in 2023, with an overall infection rate of 0.98. This represents an 18.6% increase in the total number of infection reports and an 11.4% increase in the rate of reported infections when compared to 2022. The increase in overall infection rate was driven by increases in UTI and SSTI rates, which increased by 20.1% and 17.4%, respectively.

Since the COVID-19 pandemic began, Patient Safety Authority (PSA) infection prevention advisors have noted that LTC facilities are challenged by infection preventionist turnover, creating scenarios with no overlap in on-site infection prevention coverage and a need for education on required reporting. In 2023, PSA identified facilities that did not report any HAIs or that were in the bottom 10th percentile of reporting in the previous year. PSA sent letters to these facilities advising that they may not be meeting reporting requirements. In addition, infection prevention advisors followed up with these facilities to discuss reporting requirements and provide guidance and resources for surveillance and reporting.

Conclusion

In 2023, there were increases in the number of infection reports submitted to PA-PSRS and the overall infection rate for Pennsylvania's LTC facilities. The increase in overall infection rate was driven by UTI and SSTI, with notable increases in CAUTI and SUTI rates.

Note

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

References

1. Pennsylvania Department of Health. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002). DOH website. https://www.health.pa.gov/topics/Documents/Laws%20and%20Regulations/Act%20 13%20of%202002.pdf. Published 2002. Accessed April 12, 2024.

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Patient Safety Trends in 2023:

An Analysis of 287,997 Serious Events and Incidents From the Nation's Largest Event Reporting Database

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Abstract

Background: The Pennsylvania Patient Safety Reporting System (PA-PSRS) is the largest repository of patient safety data in the United States and one of the largest in the world, with over 4.7 million acute care event reports dating back to 2004. In this article, we analyze the patient safety event reports submitted to PA-PSRS in 2023.

Methods: We extracted data from PA-PSRS and obtained data from the Pennsylvania Health Care Cost Containment Council (PHC4). Report counts are based on report submission date, and rates are based on event occurrence date and calculated per 1,000 patient days for hospitals or 1,000 surgical encounters for ambulatory surgical facilities (ASFs).

Results: In 2023, 287,997 reports were submitted to PA-PSRS, which is a considerable increase from 2022 but very close to the 2021 total. Reports of serious and high harm events increased by 20.6% and 25.0%, respectively, representing the largest annual increases historically. Of the 287,997 reports, 96.0% were from hospitals, 3.8% were from ambulatory surgical facilities, and 0.2% were from birthing centers and abortion facilities. The vast majority (95.9%) of the 2023 reports were incidents, with the remaining 4.1% classified as serious events. The reporting rate based on event occurrence date for hospitals in the first half of 2023 was 30.0 reports per 1,000 patient days; for ASFs, the rate was 9.9 reports per 1,000 surgical encounters. For each of the past five years, the most frequently reported event type was Error Related to Procedure/Treatment/Test, which accounted for 33.1% of acute care event reports submitted in 2023. From a distribution perspective, the greatest increase in percent of total reports in 2023 occurred with event type Medication Error, and the greatest increase for serious events was with event type Complication of Procedure/Treatment/Test (P/T/T). Almost half of the increase in Complication of P/T/T was with subtype Complication following surgery or invasive procedure (48.2%; 968 of 2,009), and 54.6% (529 of 968) of reports in this subtype were due to unplanned returns to the operating room.

Conclusion: The number of total reports, serious events, and high harm events, as well as preliminary reporting rates for hospitals and ASFs, all increased in 2023. Patient Safety Authority will continue working with Pennsylvania healthcare facilities to support high-quality reporting and patient safety practices.

Introduction

Pennsylvania is the only state that requires healthcare facilities to report all events that cause harm or have the potential to cause harm to a patient. These patient safety events are reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a], which is the largest repository of patient safety data in the United States and one of the largest in the world, with over 4.7 million acute care event reports dating back to 2004.

This article summarizes data from acute care event reports submitted to PA-PSRS in 2023, along with comparisons and insights that can be used to identify potential areas of focus for patient safety efforts.

Definitions

Terms describing patient safety occurrences, including "serious event," "medical error," "adverse event," "harm," and "incident," are often used interchangeably. However, within the context of this manuscript they have distinct meanings and indications for whether they must be reported to PA-PSRS in accordance with the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002).[1] 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."[1] 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."[1]

Each event report includes a harm score—assigned by the reporting facility—that describes the potential or actual harm to the patient resulting from the event. **Table 1** lists the definition for each harm score, along with harm score groupings for incidents, serious events, and high harm events.

Methods

This analysis was performed using data extracted from PA-PSRS on February 1, 2024, and data from the Pennsylvania Health Care Cost Containment Council (PHC4)[b]. Report counts are based on the date the report was submitted; reporting rates are based on the event occurrence date and calculated per 1,000 patient days for hospitals and per 1,000 surgical encounters for ASFs. Event occurrence date is used for rate calculations to ensure consistency with the time frame in which the patient days or surgical encounters occurred. At the time this analysis was performed, data from PHC4 was available through Q2 2023, which allowed us to calculate 2023 rates using the first two quarters of PA-PSRS data.

Table 1. PA-PSRS Harm Scores

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

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

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

Results

As seen in **Figure 1**, a total of 287,997 reports were submitted by Pennsylvania acute care facilities in 2023, which represents a 12.2% increase (31,324 reports) over the prior year, the largest percentage increase since 2006. Of the 287,997 reports submitted in 2023, 11,750 were serious events, and of those serious events, 610 were classified as high harm. The numbers of serious and high harm events increased from 2022 by 20.6% and 25.0%, respectively, which are the largest annual percentage increases for both categories historically. **Figure 2** shows incidents and serious events as a percentage of total reports. In 2023, 4.1% of reports were serious events, which represents the highest percentage since the first full year of PA-PSRS reporting in 2005.

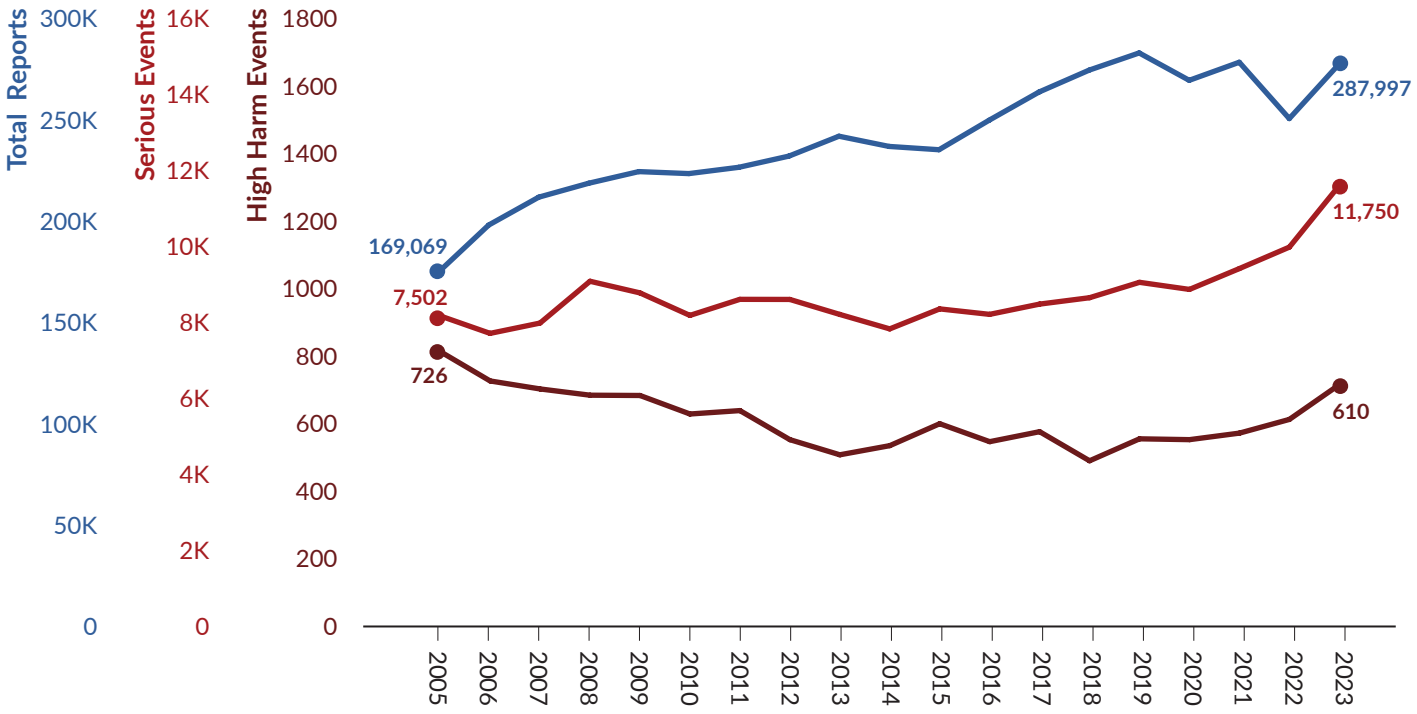
More than half (52.9%; 301 of 569) of the acute care facilities increased their number of report submissions in 2023, with an average increase of 144 reports and median increase of 18 reports. The five facilities with the largest increase in number of reports accounted for 37.0% (11,595 of 31,324) of the total increase in 2023. Nearly two-thirds (64.8%; 7,509 of 11,595) of reports from those five facilities were in the Error Related to Procedure/Treatment/Test (P/T/T) and Medication Error event types.

About half (48.9%; 278 of 569) of the acute care facilities increased their reporting of serious events, with an average increase of 11 reports and median increase of 4 reports. The five facilities with the largest increase in number of serious events collectively submitted 684 more serious event reports in 2023 than in 2022. More than half (56.1%; 384 of 684) of the increase in serious event reports was in the Complication of P/T/T event type, and the majority (53.6%; 206 of 384) of those reports were in the Complication following surgery or invasive procedure event subtype.

Table 2 shows a breakdown of incidents and serious events by facility type from the past three years. From 2022 to 2023, the number of reports submitted by hospitals increased by 30,304 (12.3%), and reports from other acute care facilities (ASFs, birthing centers [BRCs], and abortion facilities [ABFs]) increased by 1,020 (9.7%).

The harm score distributions for reports submitted during years 2021–2023 are shown in **Table 3**. Consistently, the most frequent harm score is C (41.2% of total reports in 2023), and harm score C had the largest growth, increasing by 13,647 reports in 2023. Serious events comprised 4.1% of total reports submitted in 2023, with harm scores E and F being reported most frequently. The largest percentage increase was with harm score G, which increased by 83.0%, going from 53 reports in 2022 to 97 in 2023.

Figure 1. Total Reports, Serious Events, and High Harm Events Submitted to PA-PSRS



Note: High harm events are a subset of serious events, and serious events are a subset of total reports.

Figure 2. Incidents and Serious Events as a Percentage of Total Reports Submitted to PA-PSRS

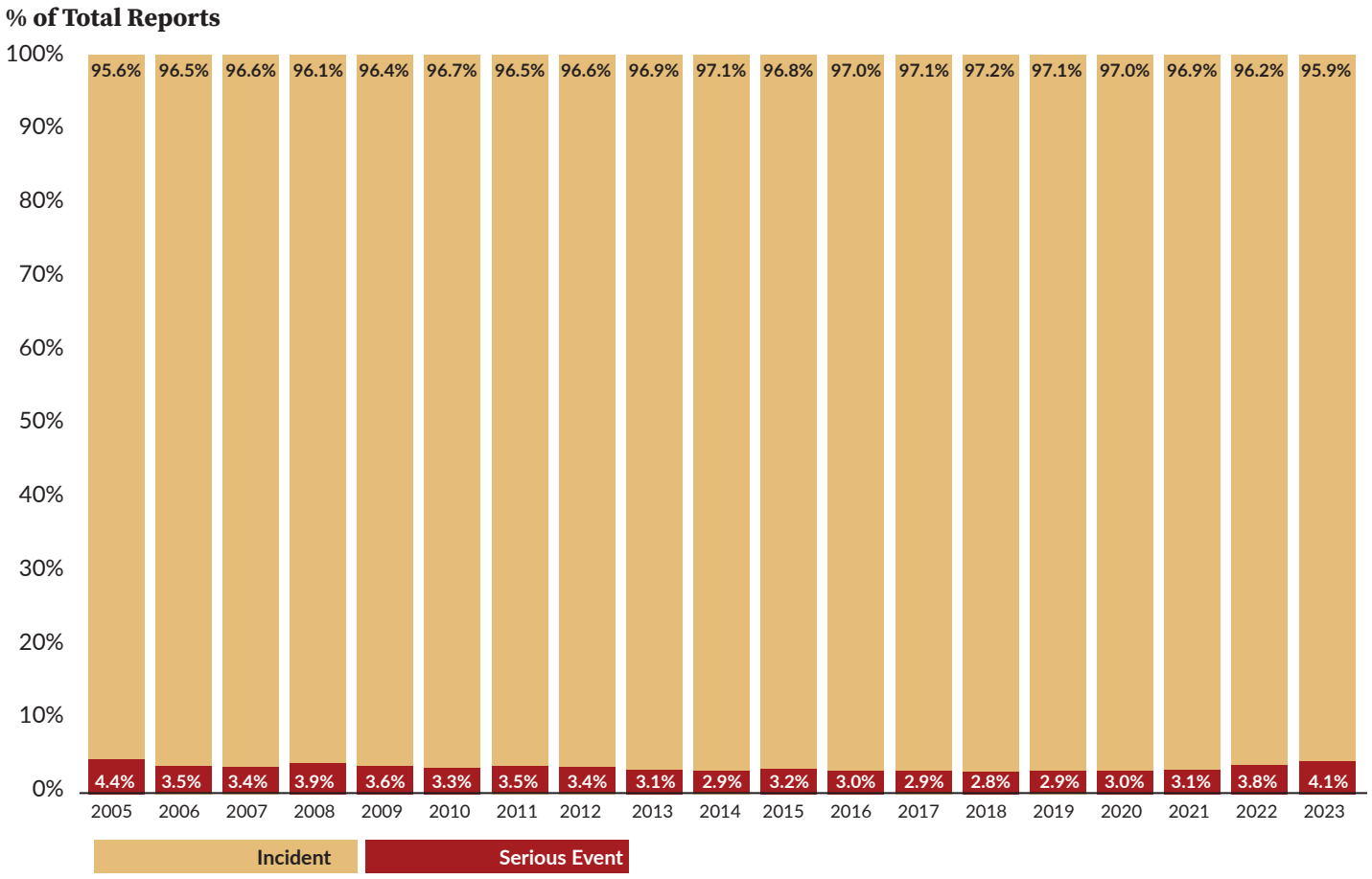


Table 2. Number and Percentage of Reports Submitted to PA-PSRS by Facility Type and Event Classification

Facility Types	Event Classification	Number of Reports 2021	Number of Reports 2022	Number of Reports 2023	% of Total Reports 2021	% of Total Reports 2022	% of Total Reports 2023
Hospitals	Incident	272,445	238,363	266,726	94.3%	92.9%	92.6%
	Serious Event	7,109	7,755	9,696	2.5%	3.0%	3.4%
	Subtotal	**279,554**	**246,118**	**276,422**	**96.8%**	**95.9%**	**96.0%**
Other Acute Care Facilities	Incident	7,370	8,569	9,521	2.6%	3.3%	3.3%
	Serious Event	1,934	1,986	2,054	0.7%	0.8%	0.7%
	Subtotal	**9,304**	**10,555**	**11,575**	**3.2%**	**4.1%**	**4.0%**
Totals	Incident	279,815	246,932	276,247	96.9%	96.2%	95.9%
	Serious Event	9,043	9,741	11,750	3.1%	3.8%	4.1%
	Grand Total	**288,858**	**256,673**	**287,997**	**100.0%**	**100.0%**	**100.0%**

Note: Other Acute Care Facilities include ambulatory surgical facilities, birthing centers, and abortion facilities. Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or classification changes made by reporting facilities.

Table 3. Number and Percentage of Reports Submitted to PA-PSRS by Harm Score With Change in Reports From 2022 to 2023

Harm Score	Number of Reports 2021	Number of Reports 2022	Number of Reports 2023	% of Total Reports 2021	% of Total Reports 2022	% of Total Reports 2023	Change in Reports 2022 to 2023 Number	Change in Reports 2022 to 2023 Percent
A	28,003	29,658	32,725	9.7%	11.6%	11.4%	3,067	10.3%
B1	2,772	2,042	2,617	1.0%	0.8%	0.9%	575	28.2%
B2	35,874	22,236	26,668	12.4%	8.7%	9.3%	4,432	19.9%
C	113,680	105,106	118,753	39.4%	40.9%	41.2%	13,647	13.0%
D	99,486	87,890	95,484	34.4%	34.2%	33.2%	7,594	8.6%
Incidents - Subtotal	**279,815**	**246,932**	**276,247**	**96.9%**	**96.2%**	**95.9%**	**29,315**	**11.9%**
E	6,330	6,811	8,080	2.2%	2.7%	2.8%	1,269	18.6%
F	2273	2442	3060	0.8%	1.0%	1.1%	618	25.3%
G	64	53	97	<0.05%	<0.05%	<0.05%	44	83.0%
H	143	165	211	<0.05%	0.1%	0.1%	46	27.9%
I	233	270	302	0.1%	0.1%	0.1%	32	11.9%
Serious Events - Subtotal	**9,043**	**9,741**	**11,750**	**3.1%**	**3.8%**	**4.1%**	**2,009**	**20.6%**
Total	**288,858**	**256,673**	**287,997**	**100.0%**	**100.0%**	**100.0%**	**31,324**	**12.2%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or harm score changes made by reporting facilities. All percentages that are greater than 0 but would otherwise round to 0.0% are displayed as <0.05%.

Reporting Rates Based on Event Occurrence Date

Reporting rates provide normalized comparisons over time. In this analysis, rates are based on event occurrence dates and calculated per 1,000 patient days for hospitals and per 1,000 surgical encounters for ASFs. **Figure 3** shows that the preliminary rate for hospitals based on data from Q1 to Q2 of 2023 is 2.0 points higher than the 2022 full-year rate. For ASFs, **Figure 4** shows the 2023 preliminary rate is 0.3 points higher than the 2022 full-year rate. Of note, there has been a relatively steady increase in the ASF reporting rate over time.

Event Types

Each PA-PSRS report includes an event type and subtype(s) that are assigned by the reporting facility. The reporting taxonomy for incidents and serious events provides for 10 main event types, with 228 possible combinations of event type and subtype(s).

Table 4 shows the number and percentage of total reports submitted for each main event type over the past five years. For each of the past five years, the most frequently reported event type was Error Related to Procedure/Treatment/Test (P/T/T), with 95,189 reports submitted in 2023 (33.1% of total reports). From a distribution perspective, the greatest increase in percent of total reports in 2023 compared to 2022 occurred with event type Medication Error, which increased by 0.9 percentage points, from 13.2% in 2022 to 14.1% in 2023. The largest decrease occurred with event type Fall, which dropped 1.5 percentage points, from 12.8% in 2022 to 11.3% in 2023. The only raw number decrease in submitted reports was with the Fall event type, going from 32,918 reports in 2022 to 32,606 in 2023.

Table 5 shows the number and percentage of serious events submitted for each event type over the past five years. The most frequently reported serious event type for each of the last five years was Complication of P/T/T, with 6,590 serious event reports submitted in 2023 (56.1% of serious event reports). Complication of P/T/T also showed the greatest increase in terms of distribution of serious event reports, increasing by 2.6 percentage points, from 53.5% of serious events in 2022 to 56.1% in 2023. Similar to our findings for total reports, the largest decrease for serious events was seen with the Fall event type, which dropped 2.4 percentage points in 2023. Fall was also the only event type that had a raw number decrease in serious events in 2023.

Event Subtypes

Each of the 10 main event types has between six and 13 subtypes to further classify the event. The total number of reports and serious events, as well as their associated percentage distributions, are shown in **Table 6**. This is a detailed accounting of reports submitted in 2023 by the first level of subtype for each main event type. The main event types in the left column are listed in descending order by their number of reports (i.e., the same ordering as **Table 4**). Within each main event type, the subtypes are listed in descending order as well.

The subtype with the largest increase in number of reports submitted from 2022 to 2023 was Laboratory test problem, which increased by 4,267 reports. The second highest increase was in the Other (specify) subtype of the Other/Miscellaneous event type, which increased by 3,604 reports. The third largest increase was seen in the Referral/consult problem subtype, which increased by 2,542 reports.

For serious events, the top three increases were all subtypes of the Complication of P/T/T event type. The subtype accounting for almost half (48.2%; 968 of 2,009) of the increase was Complication following surgery or invasive procedure, and 54.6% (529 of 968) of reports in this subtype were due to unplanned returns to the operating room (OR). The second and third largest increases were seen in the Maternal complication and Other (specify) subtypes, which increased by 159 and 121 reports, respectively.

Event Type and Harm Score

Table 7 displays a cross tabulation of submitted reports distributed by harm score for each of the 10 main event types. Colored cells reflect the intersections of event type and harm score that occurred most frequently in 2023, with darker shades representing higher concentrations of reports. For the most frequently reported event type, Error Related to P/T/T, harm score C was reported most frequently; this intersection of event type and harm score was the most common in 2023, with 46,750 reports and representing 16.2% of total reports. The second most common intersection was seen with event type Complication of P/T/T and harm score D, with 22,314 reports and representing 7.7% of total reports.

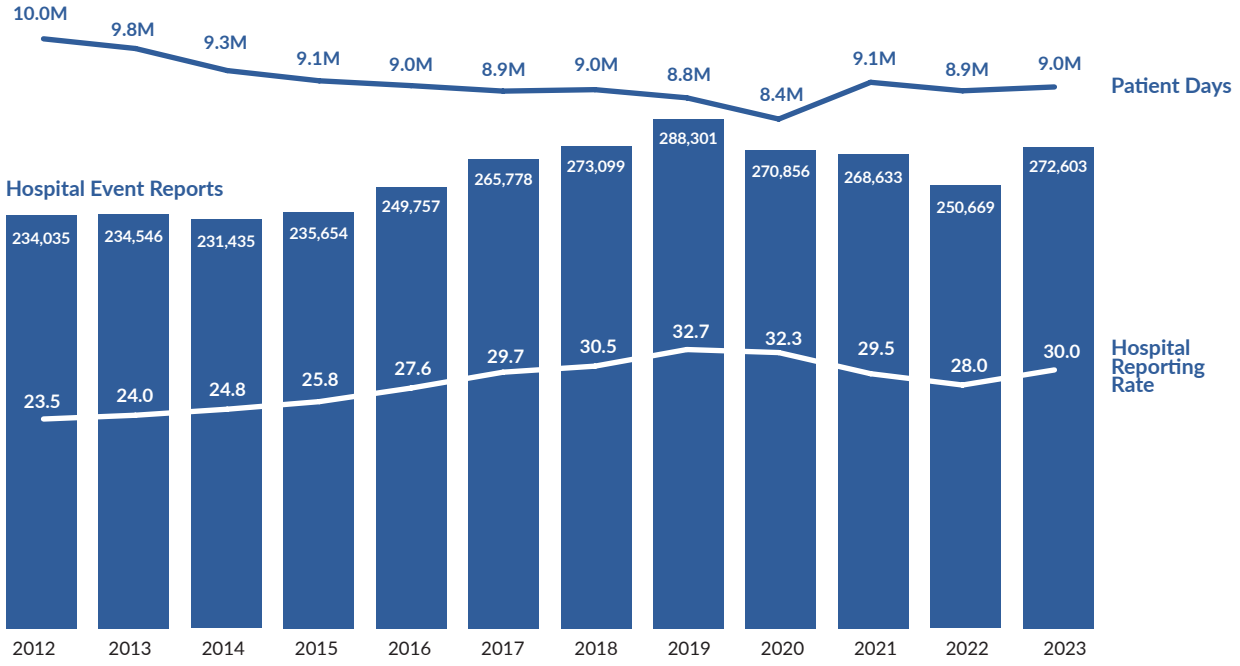
Care Area and Harm Score

The care area can help us identify patterns or trends involving specific patient safety concerns relative to the location where an event occurred. Within the acute care data, there are 168 care area options for facilities to use; we then place these care areas into one of 23 higher-level care area groups. **Table 8** shows a cross tabulation of care area group with harm score. This reflects the same two areas of highest concentration that were seen in the 2022 data, in the cross sections of the Med/Surg care area group and harm scores C and D. Together, these account for 15.3% of total reports submitted in 2023.

Care Area and Event Type

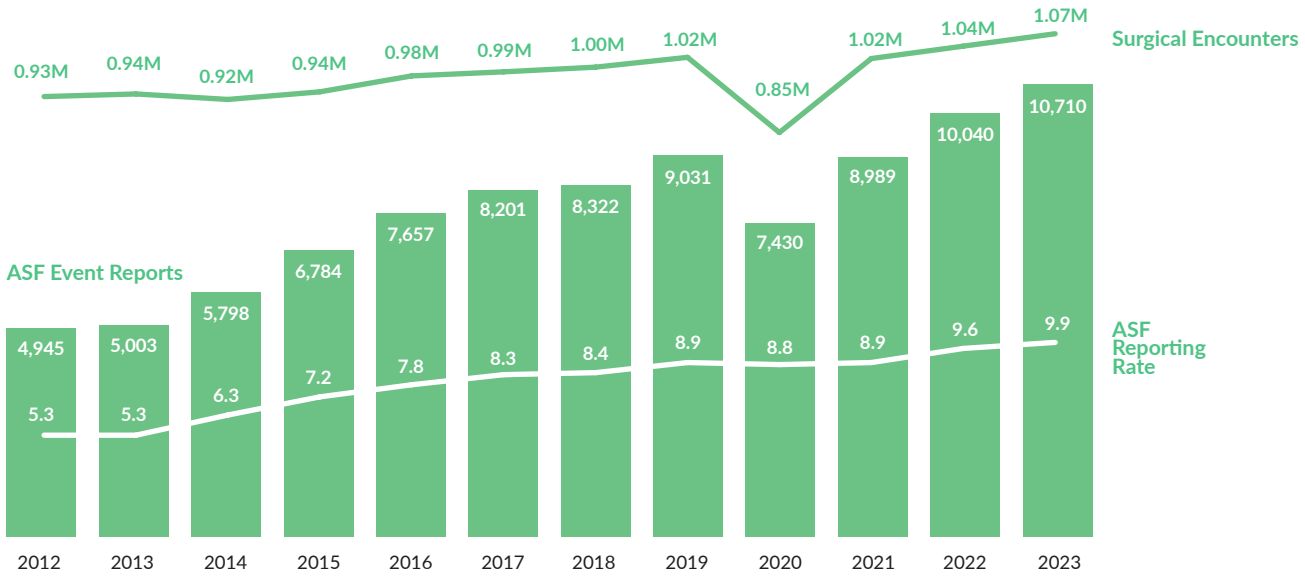
Table 9 shows a cross tabulation of care area group and event type. The three highest concentrations of reports are at the intersections of Error Related to P/T/T with Surgical Services, Emergency, and Laboratory care area groups.

Figure 3. Hospital Event Reports, Patient Days, and Reporting Rates by Year



Note: The number of hospital event reports shown for each year is based on event occurrence date, rather than report submission date, to ensure consistency with the time frame in which the patient days occurred. The 2023 hospital reporting rate is based on event occurrence dates in Q1–Q2 only due to lagged data related to patient days. Rates shown for prior years may differ from previously published rates due to subsequent changes made by reporting facilities.

Figure 4. ASF Event Reports, Surgical Encounters, and Reporting Rates by Year



Note: The number of ASF event reports shown for each year is based on event occurrence date, rather than report submission date, to ensure consistency with the time frame in which the surgical encounters occurred. The 2023 ASF reporting rate is based on event occurrence dates in Q1–Q2 only due to lagged data related to surgical encounters. Rates shown for prior years may differ from previously published rates due to subsequent changes made by reporting facilities.

Table 4. Number and Percentage of Reports Submitted to PA-PSRS by Event Type in Descending Order by 2023 Frequency

	Number of Reports					% of Total Reports				
Event Type	**2019**	**2020**	**2021**	**2022**	**2023**	**2019**	**2020**	**2021**	**2022**	**2023**
Error Related to P/T/T	96,440	89,335	90,452	84,287	**95,189**	32.8%	32.1%	31.3%	32.8%	**33.1%**
Complication of P/T/T	46,691	45,180	44,129	40,144	**45,013**	15.9%	16.2%	15.3%	15.6%	**15.6%**
Medication Error	52,884	46,559	48,714	33,980	**40,680**	18.0%	16.7%	16.9%	13.2%	**14.1%**
Fall	31,978	32,775	35,600	32,918	**32,606**	10.9%	11.8%	12.3%	12.8%	**11.3%**
Other/Miscellaneous	22,761	23,190	27,707	26,652	**31,563**	7.7%	8.3%	9.6%	10.4%	**11.0%**
Skin Integrity	20,546	19,697	20,583	17,146	**17,931**	7.0%	7.1%	7.1%	6.7%	**6.2%**
Equip./Supplies/Devices	8,792	8,062	7,806	7,552	**9,403**	3.0%	2.9%	2.7%	2.9%	**3.3%**
Adverse Drug Reaction	5,700	5,624	5,868	6,527	**7,063**	1.9%	2.0%	2.0%	2.5%	**2.5%**
Transfusion	6,195	5,779	5,648	5,235	**6,033**	2.1%	2.1%	2.0%	2.0%	**2.1%**
Patient Self-Harm	2,188	2,329	2,351	2,232	**2,516**	0.7%	0.8%	0.8%	0.9%	**0.9%**
Total	**294,175**	**278,530**	**288,858**	**256,673**	**287,997**	**100%**	**100%**	**100%**	**100%**	**100%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or event type changes made by reporting facilities.

Table 5. Number and Percentage of Serious Events Submitted to PA-PSRS by Event Type in Descending Order by 2023 Frequency

	Number of Serious Events					% of Total Serious Events				
Event Type	**2019**	**2020**	**2021**	**2022**	**2023**	**2019**	**2020**	**2021**	**2022**	**2023**
Complication of P/T/T	4,529	4,577	4,907	5,216	**6,590**	52.7%	54.7%	54.3%	53.5%	**56.1%**
Fall	932	940	1,046	1,140	**1,098**	10.8%	11.2%	11.6%	11.7%	**9.3%**
Other/Miscellaneous	983	708	849	850	**919**	11.4%	8.5%	9.4%	8.7%	**7.8%**
Error Related to P/T/T	768	753	729	831	**904**	8.9%	9.0%	8.1%	8.5%	**7.7%**
Adverse Drug Reaction	241	344	430	577	**783**	2.8%	4.1%	4.8%	5.9%	**6.7%**
Skin Integrity	654	575	610	633	**765**	7.6%	6.9%	6.7%	6.5%	**6.5%**
Medication Error	182	166	172	227	**294**	2.1%	2.0%	1.9%	2.3%	**2.5%**
Patient Self-Harm	176	166	171	141	**234**	2.0%	2.0%	1.9%	1.4%	**2.0%**
Equip./Supplies/Devices	78	77	96	86	**105**	0.9%	0.9%	1.1%	0.9%	**0.9%**
Transfusion	52	58	33	40	**58**	0.6%	0.7%	0.4%	0.4%	**0.5%**
Total	**8,595**	**8,364**	**9,043**	**9,741**	**11,750**	**100%**	**100%**	**100%**	**100%**	**100%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or event type changes made by reporting facilities.

Table 6. Number and Percentage of Total Reports and Serious Events Submitted to PA-PSRS by Event Type and Subtype in Descending Order by 2023 Frequency

		2022				2023				Change in Reports 2022–2023	
Event Type	Event Subtype	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number	Percent
Error Related to P/T/T	Laboratory test problem	35,767	13.9%	50	0.5%	40,034	13.9%	62	0.5%	4,267	11.9%
	Surgery/invasive procedure problem	19,773	7.7%	592	6.1%	22,118	7.7%	661	5.6%	2,345	11.9%
	Referral/consult problem	7,230	2.8%	16	0.2%	9,772	3.4%	15	0.1%	2,542	35.2%
	Other (specify)	8,124	3.2%	62	0.6%	9,160	3.2%	66	0.6%	1,036	12.8%
	Radiology/imaging test problem	8,318	3.2%	46	0.5%	8,199	2.8%	52	0.4%	-119	-1.4%
	Respiratory care	2,897	1.1%	51	0.5%	3,128	1.1%	40	0.3%	231	8.0%
	Dietary	2,178	0.8%	14	0.1%	2,778	1.0%	8	0.1%	600	27.5%
Complication of P/T/T	IV site complication (phlebitis, bruising, infiltration)	10,756	4.2%	300	3.1%	12,311	4.3%	350	3.0%	1,555	14.5%
	Other (specify)	6,808	2.7%	409	4.2%	7,593	2.6%	530	4.5%	785	11.5%
	Complication following surgery or invasive procedure	5,831	2.3%	2,730	28.0%	6,251	2.2%	3,698	31.5%	420	7.2%
	Maternal complication	2,830	1.1%	352	3.6%	3,414	1.2%	511	4.3%	584	20.6%
	Catheter or tube problem	2,653	1.0%	188	1.9%	3,056	1.1%	221	1.9%	403	15.2%
	Cardiopulmonary arrest outside of ICU setting	2,879	1.1%	84	0.9%	3,025	1.1%	72	0.6%	146	5.1%
	Extravasation of drug or radiologic contrast	2,169	0.8%	65	0.7%	2,662	0.9%	71	0.6%	493	22.7%
	Neonatal complication	2,451	1.0%	149	1.5%	2,461	0.9%	150	1.3%	10	0.4%
	Anesthesia Event	1,116	0.4%	258	2.6%	1,227	0.4%	283	2.4%	111	9.9%
	Healthcare-associated infection	1,149	0.4%	592	6.1%	1,212	0.4%	567	4.8%	63	5.5%
	Onset of hypoglycemia during care	936	0.4%	19	0.2%	1,061	0.4%	34	0.3%	125	13.4%
	Emergency department	562	0.2%	69	0.7%	736	0.3%	102	0.9%	174	31.0%
	Complication following spinal manipulative therapy	4	<0.05%	1	<0.05%	4	<0.05%	1	<0.05%	0	0.0%
Medication Error	Wrong	13,027	5.1%	115	1.2%	15,129	5.3%	128	1.1%	2,102	16.1%
	Other (specify)	8,996	3.5%	25	0.3%	10,935	3.8%	46	0.4%	1,939	21.6%
	Dose omission	4,072	1.6%	26	0.3%	4,755	1.7%	37	0.3%	683	16.8%
	Prescription/refill delayed	2,730	1.1%	2	<0.05%	3,446	1.2%	5	<0.05%	716	26.2%
	Monitoring error (includes contraindicated drugs)	2,147	0.8%	22	0.2%	2,610	0.9%	35	0.3%	463	21.6%
	Extra dose	1,638	0.6%	25	0.3%	2,024	0.7%	27	0.2%	386	23.6%
	Medication list incorrect	666	0.3%	12	0.1%	904	0.3%	15	0.1%	238	35.7%
	Unauthorized drug	643	0.3%	-	-	792	0.3%	1	<0.05%	149	23.2%
	Inadequate pain management	61	<0.05%	-	-	85	<0.05%	-	-	24	39.3%
Fall	Found on floor	8,247	3.2%	399	4.1%	7,687	2.7%	352	3.0%	-560	-6.8%
	Ambulating	5,076	2.0%	263	2.7%	5,319	1.8%	256	2.2%	243	4.8%
	Other/Unknown (specify)	4,239	1.7%	83	0.9%	4,242	1.5%	69	0.6%	3	0.1%
	Toileting	3,228	1.3%	139	1.4%	3,227	1.1%	152	1.3%	-1	0.0%
	Lying in bed	3,056	1.2%	46	0.5%	2,968	1.0%	51	0.4%	-88	-2.9%
	Assisted fall	2,624	1.0%	30	0.3%	2,762	1.0%	18	0.2%	138	5.3%
	Sitting in chair/wheelchair	2,731	1.1%	57	0.6%	2,730	0.9%	60	0.5%	-1	0.0%

Table 6. (continued)

		2022				2023				Change in Reports 2022–2023	
Event Type	Event Subtype	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number	Percent
Fall (cont.)	Sitting at side of bed	1,145	0.4%	26	0.3%	1,140	0.4%	30	0.3%	-5	-0.4%
	Transferring	956	0.4%	34	0.3%	902	0.3%	36	0.3%	-54	-5.6%
	Hallways of facility	590	0.2%	20	0.2%	659	0.2%	26	0.2%	69	11.7%
	From stretcher	368	0.1%	25	0.3%	398	0.1%	28	0.2%	30	8.2%
	Grounds of facility	341	0.1%	8	0.1%	288	0.1%	9	0.1%	-53	-15.5%
	In exam room/from exam table	317	0.1%	10	0.1%	284	0.1%	11	0.1%	-33	-10.4%
Other/ Miscella-neous	Other (specify)	17,325	6.7%	396	4.1%	20,929	7.3%	398	3.4%	3,604	20.8%
	Unanticipated transfer to higher level of care	7,883	3.1%	376	3.9%	8,778	3.0%	449	3.8%	895	11.4%
	Inappropriate discharge	1,327	0.5%	12	0.1%	1,769	0.6%	7	0.1%	442	33.3%
	Other unexpected death	108	<0.05%	57	0.6%	82	<0.05%	60	0.5%	-26	-24.1%
	Death or injury involving restraints	6	<0.05%	6	0.1%	3	<0.05%	3	<0.05%	3	-50.0%
	Death or injury during inpatient elopement	3	<0.05%	3	<0.05%	1	<0.05%	1	<0.05%	-2	-66.7%
	Death or injury involving seclusion	-	-	-	-	1	<0.05%	1	<0.05%	-1	-100.0%
Skin Integrity	Pressure injury	6,510	2.5%	464	4.8%	6,158	2.1%	573	4.9%	-352	-5.4%
	Other (specify)	5,859	2.3%	57	0.6%	6,126	2.1%	51	0.4%	267	4.6%
	Skin tear	2,998	1.2%	40	0.4%	3,527	1.2%	42	0.4%	529	17.6%
	Abrasion	730	0.3%	5	0.1%	904	0.3%	1	<0.05%	174	23.8%
	Blister	470	0.2%	1	<0.05%	481	0.2%	5	<0.05%	11	2.3%
	Laceration	285	0.1%	33	0.3%	317	0.1%	47	0.4%	32	11.2%
	Burn (electrical, chemical, thermal)	176	0.1%	32	0.3%	271	0.1%	41	0.3%	95	54.0%
	Rash/hives	108	<0.05%	1	<0.05%	139	<0.05%	5	<0.05%	31	28.7%
	Venous stasis ulcer	10	<0.05%	-	-	8	<0.05%	-	-	-2	-20.0%
Equipment/ Supplies/ Devices	Equipment malfunction	2,677	1.0%	36	0.4%	3,222	1.1%	41	0.3%	545	20.4%
	Equipment not available	795	0.3%	-	-	1,018	0.4%	3	<0.05%	223	28.1%
	Medical device problem	684	0.3%	17	0.2%	891	0.3%	13	0.1%	207	30.3%
	Broken item(s)	641	0.2%	16	0.2%	841	0.3%	24	0.2%	200	31.2%
	Sterilization problem	763	0.3%	-	-	814	0.3%	5	<0.05%	51	6.7%
	Other (specify)	756	0.3%	8	0.1%	771	0.3%	9	0.1%	15	2.0%
	Equipment misuse	311	0.1%	1	<0.05%	497	0.2%	1	<0.05%	186	59.8%
	Equipment safety situation	202	0.1%	2	<0.05%	334	0.1%	-	-	132	65.3%
	Disconnected	209	0.1%	4	<0.05%	328	0.1%	5	<0.05%	119	56.9%
	Equipment wrong or inadequate	171	0.1%	1	<0.05%	220	0.1%	2	<0.05%	49	28.7%
	Inadequate supplies	151	0.1%	-	-	210	0.1%	1	<0.05%	59	39.1%
	Electrical problem	130	0.1%	-	-	147	0.1%	1	<0.05%	17	13.1%
	Outdated items(s)	62	<0.05%	1	<0.05%	110	<0.05%	-	-	48	77.4%

Table 6. (continued)

		2022				2023				Change in Reports 2022–2023	
Event Type	Event Subtype	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number of Reports	% of Total Reports	Number of Serious Events	% of Total Serious Events	Number	Percent
Adverse Drug Reaction	Other (specify)	4,621	1.8%	319	3.3%	4,976	1.7%	394	3.4%	355	7.7%
	Skin reaction (rash, blistering, itching, hives)	1,251	0.5%	145	1.5%	1,455	0.5%	223	1.9%	204	16.3%
	Mental status change	201	0.1%	50	0.5%	186	0.1%	63	0.5%	-15	-7.5%
	Hypotension	144	0.1%	26	0.3%	166	0.1%	47	0.4%	22	15.3%
	Dizziness	65	<0.05%	2	<0.05%	107	<0.05%	7	0.1%	42	64.6%
	Hematologic problem	117	<0.05%	17	0.2%	100	<0.05%	23	0.2%	-17	-14.5%
	Arrhythmia	29	<0.05%	4	<0.05%	40	<0.05%	17	0.1%	11	37.9%
	Nephrotoxicity	99	<0.05%	14	0.1%	33	<0.05%	9	0.1%	-66	-66.7%
Transfusion	Event related to blood product sample collection	1,533	0.6%	-	-	1,685	0.6%	1	<0.05%	152	9.9%
	Other (specify)	1,510	0.6%	2	<0.05%	1,659	0.6%	3	<0.05%	149	9.9%
	Event related to blood product administration	795	0.3%	7	0.1%	986	0.3%	11	0.1%	191	24.0%
	Apparent transfusion reaction	615	0.2%	31	0.3%	776	0.3%	42	0.4%	161	26.2%
	Event related to blood product dispensing or distribution	425	0.2%	-	-	533	0.2%	-	-	108	25.4%
	Consent missing/inadequate	237	0.1%	-	-	244	0.1%	-	-	7	3.0%
	Wrong patient requested	45	<0.05%	-	-	46	<0.05%	-	-	1	2.2%
	Special product need not issued	21	<0.05%	-	-	26	<0.05%	-	-	5	23.8%
	Special product need not requested	18	<0.05%	-	-	25	<0.05%	-	-	7	38.9%
	Wrong component issued	18	<0.05%	-	-	24	<0.05%	-	-	6	33.3%
	Mismatched unit	11	<0.05%	-	-	19	<0.05%	1	<0.05%	8	72.7%
	Wrong component requested	7	<0.05%	-	-	9	<0.05%	-	-	2	28.6%
	Wrong patient transfused	-	-	-	-	1	<0.05%	-	-	-5	-100.0%
Patient Self-Harm	Other self-harm (specify)	1,351	0.5%	58	0.6%	1,543	0.5%	64	0.5%	192	14.2%
	Self-mutilation	644	0.3%	20	0.2%	615	0.2%	23	0.2%	-29	-4.5%
	Ingestion of foreign object or substance	215	0.1%	50	0.5%	316	0.1%	114	1.0%	101	47.0%
	Suicide attempt - Injury	11	<0.05%	11	0.1%	27	<0.05%	27	0.2%	16	145.5%
	Anorexia/bulemia	9	<0.05%			10	<0.05%	1	<0.05%	1	11.1%
	Suicide - Death	2	<0.05%	2	<0.05%	5	<0.05%	5	<0.05%	3	150.0%
Total		**256,673**	**100%**	**9,741**	**100%**	**287,997**	**100%**	**11,750**	**100%**	**31,324**	**12.2%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or event type changes made by reporting facilities.

Table 7. Number of Reports Submitted to PA-PSRS in 2023 by Event Type and Harm Score in Descending Order by Event Type Frequency

Event Type	A	B1	B2	C	D	E	F	G	H	I	Total
Error Related to P/T/T	16,735	985	11,854	46,750	17,961	674	177	23	13	17	**95,189**
Complication of P/T/T	1,903	90	1,307	12,809	22,314	4,056	2,177	49	137	171	**45,013**
Medication Error	3,890	622	8,263	18,792	8,819	218	58	4	6	8	**40,680**
Fall	198	60	307	16,506	14,437	813	262	4	6	13	**32,606**
Other/Miscellaneous	6,237	599	2,690	10,745	10,373	577	240	7	23	72	**31,563**
Skin Integrity	457	1	49	4,485	12,174	738	22	5	-	-	**17,931**
Equip./Supplies/ Devices	2,110	152	1,582	4,005	1,449	93	8	1	3	-	**9,403**
Adverse Drug Reaction	107	-	11	1,290	4,872	663	89	4	16	11	**7,063**
Transfusion	1,053	98	560	2,605	1,659	50	6	-	-	2	**6,033**
Patient Self-Harm	35	10	45	766	1,426	198	21	-	7	8	**2,516**
Total	**32,725**	**2,617**	**26,668**	**118,753**	**95,484**	**8,080**	**3,060**	**97**	**211**	**302**	**287,997**

Table 8. Number of Reports Submitted to PA-PSRS in 2023 by Care Area Group and Harm Score in Descending Order by Care Area Group Frequency

Care Area Group	A	B1	B2	C	D	E	F	G	H	I	Total
Med/Surg	5,089	325	3,130	22,731	21,383	1,295	279	8	28	47	**54,315**
Surgical Services	6,494	602	5,656	14,303	9,534	3,048	1,836	38	83	102	**41,696**
Emergency	6,115	208	2,258	13,991	7,433	391	107	8	13	23	**30,547**
ICU	2,077	134	1,364	8,247	9,372	615	89	9	19	42	**21,968**
Specialty Unit	1,791	135	1,273	6,578	6,961	341	81	7	7	20	**17,194**
Imaging/Diagnostic	1,061	148	1,241	7,025	6,218	358	144	7	17	9	**16,228**
Other	1,641	164	1,596	5,016	4,426	283	148	3	12	12	**13,301**
Laboratory	742	160	1,451	8,240	2,243	38	12	2	-	-	**12,888**
Psychiatric Unit	750	131	448	4,409	4,636	430	63	1	3	16	**10,887**
Clinic/Outpatient Office	725	94	1,728	4,079	3,886	209	66	1	4	7	**10,799**
Pediatric	1,285	107	1,133	4,576	1,957	70	11	1	-	-	**9,140**
Rehab Unit	307	74	576	3,565	3,865	130	43	-	-	10	**8,570**
Intermediate Unit	759	66	787	3,214	3,419	150	27	-	5	6	**8,433**
Labor and Delivery	229	21	211	1,749	4,017	333	67	8	8	4	**6,647**
PICU	1,171	37	1,153	3,108	804	23	4	1	1	2	**6,304**
NICU	952	91	575	2,987	1,407	46	4	-	1	1	**6,064**
OB/GYN Unit	410	29	356	1,838	1,971	264	58	3	10	1	**4,940**
Pharmacy	389	71	1,100	1,203	404	8	3	-	-	-	**3,178**
Rehab Services	95	8	88	1,190	777	23	9	-	-	-	**2,190**
Administration	469	7	446	181	59	5	1	-	-	-	**1,168**
Nursery	64	4	67	311	618	19	7	-	-	-	**1,090**
Respiratory	110	1	31	212	94	1	1	-	-	-	**450**
Total	**32,725**	**2,617**	**26,668**	**118,753**	**95,484**	**8,080**	**3,060**	**97**	**211**	**302**	**287,997**

Table 9. Number of Reports Submitted to PA-PSRS in 2023 by Care Area Group and Event Type in Descending Order by Care Area Group Frequency

Care Area Group	Error Related to P/T/T	Complication of P/T/T	Medication Error	Fall	Other/ Miscellaneous	Skin Integrity	Equipment/ Supplies/ Devices	Adverse Drug Reaction	Transfusion	Patient Self-Harm	Total
Med/Surg	10,074	6,805	10,194	11,634	7,373	5,330	888	790	1,081	146	**54,315**
Surgical Services	20,313	8,440	1,782	598	4,196	1,751	3,597	378	629	12	**41,696**
Emergency	14,430	2,531	3,883	3,182	3,883	280	501	480	1,199	178	**30,547**
ICU	5,904	3,379	4,354	1,084	1,572	3,849	774	220	810	22	**21,968**
Specialty Unit	3,217	2,229	3,585	3,224	2,179	1,511	246	420	532	51	**17,194**
Imaging/Diagnostic	6,996	5,311	234	746	839	488	574	1,005	30	5	**16,228**
Other	4,580	1,590	2,219	1,174	1,818	531	525	583	253	28	**13,301**
Laboratory	11,967	117	38	92	193	10	64	2	405	-	**12,888**
Psychiatric Unit	676	241	836	4,316	2,327	382	49	56	2	2,002	**10,887**
Clinic/Outpatient	3,335	904	1,499	709	819	206	310	2,717	273	27	**10,799**
Pediatric	2,313	2,108	2,163	527	1,251	229	343	35	151	20	**9,140**
Rehab Unit	811	582	1,204	2,747	1,272	1,747	105	71	28	3	**8,570**
Intermediate Unit	1,791	1,216	1,536	1,273	1,219	815	187	150	227	19	**8,433**
Labor and Delivery	1,334	4,224	325	87	334	36	168	32	107	-	**6,647**
PICU	2,069	1,259	1,658	51	474	250	448	5	89	1	**6,304**
NICU	2,683	1,071	921	3	760	150	398	2	76	-	**6,064**
OB/GYN Unit	1,291	2,172	555	147	497	65	91	24	98	-	**4,940**
Pharmacy	68	6	2,983	2	22	-	17	80	-	-	**3,178**
Rehab Services	229	246	46	962	377	283	38	3	4	2	**2,190**
Administration	470	25	542	24	49	3	20	5	30	-	**1,168**
Nursery	391	541	55	6	56	5	25	2	9	-	**1,090**
Respiratory	247	16	68	18	53	10	35	3	-	-	**450**
Total	**95,189**	**45,013**	**40,680**	**32,606**	**31,563**	**17,931**	**9,403**	**7,063**	**6,033**	**2,516**	**287,997**

Other Acute Care Facilities

Since the acute care data predominately reflects reports from hospitals, it is important to separately analyze data from the other acute care facilities (comprised mostly of ASFs, along with BRCs and ABFs) to identify reported patient safety issues from those settings. **Table 10** shows the distribution of reports submitted by these other acute care facilities across the 10 main event types over the past five years. These facilities show a different distribution compared to the overall data in **Table 4**. In comparing the percentage of total reports submitted by all facilities to those submitted by other acute facilities in 2023, the largest difference is seen with the Other/Miscellaneous event type, which made up 24.8% of total reports from other acute care facilities but only 11.0% of reports from all acute care facilities. The second largest difference is with the Medication Error event type, which made up only 1.3% of reports submitted by other acute care facilities but 14.1% of reports from all acute care facilities. The third largest difference is seen with the Fall event type, accounting for only 2.0% of reports from other acute care facilities, but 11.3% of reports from all acute care facilities.

Table 11 shows the distribution of serious events reported by other acute care facilities over the past five years. In 2023, the combination of two event types, Complication of P/T/T and Other/ Miscellaneous, accounted for more than 90% of serious event reports submitted by other acute care facilities.

Table 10. Number and Percentage of **Reports** Submitted to PA-PSRS by Other Acute Care Facilities (ASF, BRC, ABF) by Event Type in Descending Order by 2023 Frequency

	Number of Reports					% of Total Reports				
Event Type	**2019**	**2020**	**2021**	**2022**	**2023**	**2019**	**2020**	**2021**	**2022**	**2023**
Error Related to P/T/T	3,538	3,048	3,333	4,126	**4,850**	38.2%	39.0%	35.8%	39.1%	**41.9%**
Other/Miscellaneous	2,417	1,766	2,283	2,843	**2,868**	26.1%	22.6%	24.5%	26.9%	**24.8%**
Complication of P/T/T	2,478	2,265	2,816	2,659	**2,822**	26.7%	29.0%	30.3%	25.2%	**24.4%**
Skin Integrity	246	206	245	272	**296**	2.7%	2.6%	2.6%	2.6%	**2.6%**
Equip./Supplies/Devices	180	145	160	213	**285**	1.9%	1.9%	1.7%	2.0%	**2.5%**
Fall	150	161	222	225	**228**	1.6%	2.1%	2.4%	2.1%	**2.0%**
Medication Error	173	129	137	130	**149**	1.9%	1.7%	1.5%	1.2%	**1.3%**
Adverse Drug Reaction	79	77	100	79	**71**	0.9%	1.0%	1.1%	0.7%	**0.6%**
Patient Self-Harm	2	10	5	6	**6**	0.0%	0.1%	0.1%	0.1%	**0.1%**
Transfusion	1	-	3	2	**-**	0.0%	-	0.0%	0.0%	**-**
Total	9,264	7,807	9,304	10,555	**11,575**	100%	100%	100%	100%	**100%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or event type changes made by reporting facilities.

Table 11. Number and Percentage of **Serious Events** Submitted to PA-PSRS by Other Acute Care Facilities (ASF, BRC, ABF) by Event Type in Descending Order by 2023 Frequency

	Number of Serious Events					% of Total Serious Events				
Event Type	**2019**	**2020**	**2021**	**2022**	**2023**	**2019**	**2020**	**2021**	**2022**	**2023**
Complication of P/T/T	1,272	1,179	1,372	1,343	**1,447**	67.1%	72.0%	70.9%	67.6%	**70.4%**
Other/Miscellaneous	478	300	417	473	**428**	25.2%	18.3%	21.6%	23.8%	**20.8%**
Error Related to P/T/T	57	74	55	74	**83**	3.0%	4.5%	2.8%	3.7%	**4.0%**
Skin Integrity	30	23	21	36	**30**	1.6%	1.4%	1.1%	1.8%	**1.5%**
Fall	17	18	29	23	**26**	0.9%	1.1%	1.5%	1.2%	**1.3%**
Adverse Drug Reaction	17	24	17	23	**21**	0.9%	1.5%	0.9%	1.2%	**1.0%**
Equip./Supplies/Devices	10	10	13	11	**15**	0.5%	0.6%	0.7%	0.6%	**0.7%**
Medication Error	14	5	8	2	**3**	0.7%	0.3%	0.4%	0.1%	**0.1%**
Patient Self-Harm	1	5	1	1	**1**	0.1%	0.3%	0.1%	0.1%	**0.0%**
Transfusion	1	-	1	-	**-**	0.1%	-	0.1%	-	**-**
Total	1,897	1,638	1,934	1,986	**2,054**	100%	100%	100%	100%	**100%**

Note: Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or event type changes made by reporting facilities.

Discussion

The number of reports submitted to PA-PSRS has fluctuated over the last five years. Nearly 288,000 reports were received in 2023, which is a considerable increase from 2022 but very close to the 2021 total. While report counts provide some useful information, the reporting rate offers a more normalized comparison year over year. Preliminary reporting rates for 2023 show the highest rate for hospitals since 2020 and the highest rate for ASFs based on available data since 2012. The increase in number and proportion of serious events in 2023 may be attributable to the Patient Safety Authority's (PSA) ongoing efforts to improve the accuracy of event classification (i.e., ensuring that events meeting the definition of a serious event are reported as such). For instance, PSA previously focused on accurate classification of unplanned returns to the OR, and this subset of reports accounted for the largest increase in serious events in 2023.

Conclusion

The number of total reports, serious events, and high harm events, as well as preliminary reporting rates for hospitals and ASFs, all increased in 2023. The total number of reports submitted in 2023 is similar to 2021, although reporting rates for both hospitals and ASFs have increased since that time. PSA will continue working with Pennsylvania healthcare facilities to support high-quality reporting and patient safety practices.

Note

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

References

1. Pennsylvania Department of Health. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002). DOH website. https://www.health.pa.gov/topics/Documents/Laws%20and%20Regulations/Act%20 13%20of%202002.pdf. Published 2002. Accessed April 13, 2024.

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2023 Pennsylvania Patient Safety Reporting: Updated Rates for Acute Care Event Reports

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Keywords: acute care, patient safety, reporting rates, hospitals, ambulatory surgical facilities

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Abstract

In the article published on April 22, 2024, on patient safety trends in 2023,[1] reporting rates for 2023 were calculated based on Q1 and Q2 only, as denominator data for Q3 and Q4 were not yet available. This brief update provides the final rates for 2023 using all quarters of data, contrasting them with rates based on Q1 and Q2 only.

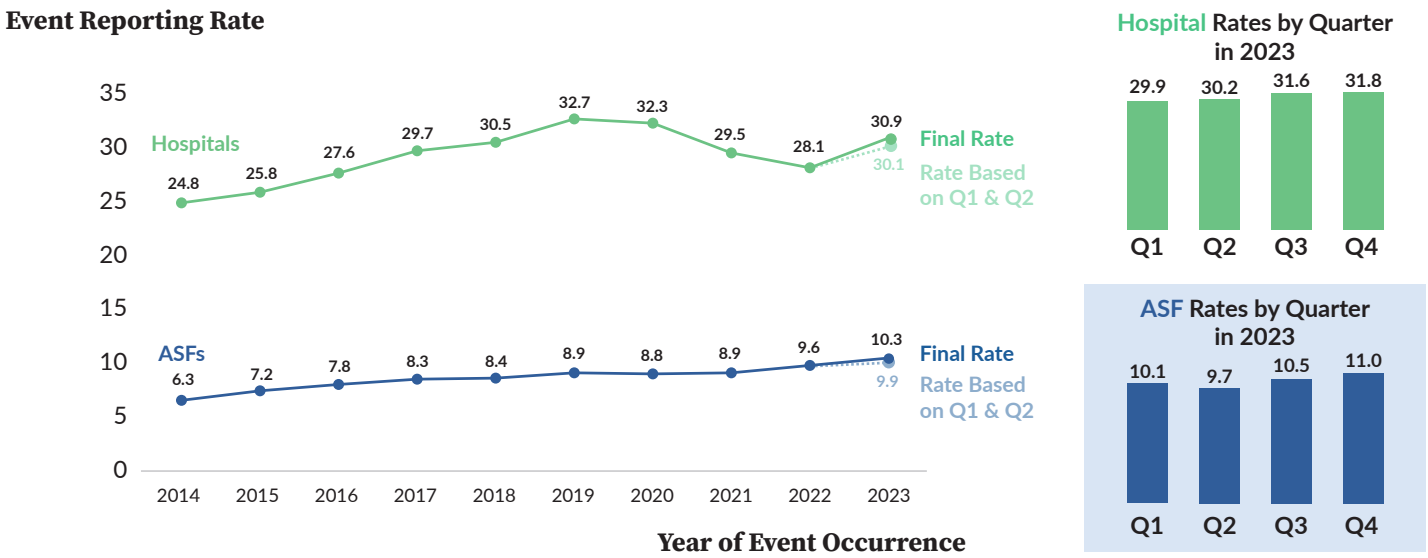
Methods

This analysis was performed using data extracted from the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] on July 16, 2024, and data obtained from the Pennsylvania Health Care Cost Containment Council (PHC4)[b] on July 1, 2024. Rates are calculated as the number of reports of events occurring in a given time frame per 1,000 patient days for hospitals and per 1,000 surgical encounters for ambulatory surgical facilities (ASFs). Since rates are based on the event occurrence date, and

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

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

Figure 1. PA-PSRS Event Report Rates for Hospitals and ASFs From 2014 Through 2023



Note: Since rates are based on the event occurrence date, and not submission date, some rates may be slightly different than previously published. This is due to reports for events that occurred in prior periods being submitted after prior published results.

not submission date, some rates in this brief update are slightly different than previously published rates. This is due to reports for events that occurred in prior periods being submitted after the original data extraction dates.

Results

Figure 1 shows rates by year from 2014 through 2023. With the addition of Q3 and Q4 data, the final hospital rate for 2023 increased by 0.8 points from the rate using only Q1 and Q2. The 2023 hospital rate of 30.9 represents the first increase since 2019. For ASFs, the final rate for 2023 increased by 0.4 points from the rate using only Q1 and Q2. The 2023 ASF rate continued its consistent climb to 10.3. The bar charts in **Figure 1** show rates for each of the four quarters of 2023 for hospitals and ASFs.

Note

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

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2. Medical Care Availability and Reduction of Error (MCARE) Act, Pub. L. No. 154 Stat. 13 (2002). Pennsylvania Department of Health website. https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/laws-and-regulations/Act%2013%20of%202002.pdf. Published 2002. Accessed July 18, 2024.

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Alteplase- and Tenecteplase-Related Errors and Risk Mitigation Strategies in the Treatment of Acute Ischemic Stroke: **A Study of Event Reports From 52 Hospitals**

By **Myungsun Ro**, PharmD, MS[*1], **Matthew A. Taylor**, PhD[1] & **Rebecca Jones**, MBA, RN[1]

Keywords: medication safety, medication error, patient safety, thrombolytics, fibrinolytics, stroke, acute ischemic stroke, TPA, TNK, high-alert medication

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Abstract

Background: Alteplase and tenecteplase are thrombolytic agents used to treat patients with acute ischemic stroke (AIS). Despite the convenient bolus dosing of tenecteplase, its off-label use for AIS creates new patient safety challenges that are understudied.

Methods: The study was conducted in two parts. In Part I, we queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for event reports involving alteplase and tenecteplase that were submitted between 2017 and 2022. Based on results from Part I, in Part II we narrowed the query to reports submitted in 2021–2022 and applied inclusion criteria to identify reports that described a medication error involving the use of alteplase or tenecteplase to treat AIS. In Part II, all reports were reviewed and coded for stages of the medication-use process, associated factors, and event type.

Results: Part I results (N=858) showed a decrease in reports of alteplase events and an increase in reports of tenecteplase events. In Part II (N=92), 52% of reports involved alteplase and 48% involved tenecteplase. *Wrong dose* was the most frequently coded event type for both medications at a combined 48%. Several tenecteplase-related events were attributed to unfamiliarity with the medication, confusion between indications, and incorrect use of the electronic health record (EHR) or failure to use the EHR, whereas many errors unique to alteplase occurred during the multistep calculation, preparation, and administration processes.

Conclusions: Safety events involving alteplase and tenecteplase in the treatment of AIS are diverse. We present a list of potential strategies to prevent and mitigate errors involving these high-alert medications and encourage providers to adopt those that are meaningful to their workflow and practice setting.

Introduction

Thrombolytics (i.e., fibrinolytics) are a class of medications that dissolve blood clots and maintain vascular patency.[1,2] Alteplase and tenecteplase are agents in this class that are currently available for the lifesaving treatment of serious conditions such as acute ischemic stroke (AIS), acute myocardial infarction (AMI), and pulmonary embolism (PE).[3,4]

Alteplase (Activase) is the first recombinant human tissue plasminogen activator approved by the U.S. Food and Drug Administration (FDA) and has been the drug of choice for intravenous thrombolysis since it appeared on the market in 1996.[5,6] It is the only agent within the class that is FDA-approved for AIS, AMI, and PE.[3] For the treatment of AIS, alteplase requires a weight-based dosing with a bolus administration followed by an infusion over one hour.[3]

Tenecteplase (TNKase) is a genetically engineered tissue plasminogen activator that has a faster onset of action, longer half-life, and greater specificity to fibrin than alteplase.[5-8] It has the additional advantages of a single bolus administration and a lower cost compared to alteplase.[9-11] Although currently FDA-approved to treat AMI only, tenecteplase also has been shown to be safe and effective in its off-label use to treat AIS.[12-17] Currently, the guidelines for early management of AIS by the American Heart Association and the American Stroke Association suggest tenecteplase as a reasonable alternative to alteplase, with a Class IIb level of recommendation.[18]

As a class, thrombolytics are considered high-alert medications, meaning that they could cause serious harm to a patient if used in error.[19] Alteplase and tenecteplase have been associated with several types of medication errors due to both medications having multidosing regimens, being commonly referred to by abbreviations, and being dispensed from the same care area to treat similar patient populations.[20-29] Between October 2000 and June 2014, the FDA received 21 reports of wrong-drug errors associated with tenecteplase.[6,30] In 2015, it issued an FDA Advise-ERR to warn against the confusion between alteplase and tenecteplase,[28] including the problems caused by using the abbreviation "TPA," which stands for "tissue plasminogen activator."[20-24,28,31] Despite the aforementioned risks and concerns, we are unaware of any studies that have explored and compared the full range of medication errors occurring with alteplase and tenecteplase during treatment of AIS. (One prior study explored only dosing errors[32] and another study explored only wrong-drug errors.[29])

The purpose of this two-part study is to measure the frequency of event reports in which either alteplase or tenecteplase was the medication prescribed, regardless of indication, and to further analyze medication errors that involved the treatment of AIS. Based on findings related to the stages of the medication-use process, associated factors, and event types, we aim to identify similarities and differences in the patient safety risks associated with these medications when used to treat AIS. We anticipate that the findings of this study will help staff across multiple disciplines identify gaps in their safety practices and develop strategies to mitigate risks associated with the use of alteplase and tenecteplase to treat AIS.

Part I

Methods I

This study used the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a], which is one of the largest patient safety databases in the world and contains more than 5 million event reports submitted by healthcare facilities across the state of Pennsylvania.[33,34] Each PA-PSRS report includes several structured fields (e.g., event date, patient age, patient gender, care area, facility type) as well as free-text narrative fields that the reporter can use to describe the safety event. Due to the unstructured nature of the free-text narrative fields, the quantity and quality of details may vary from one report to another.

For Methods I, we performed a query of the PA-PSRS database "Medication Error" category for reports submitted between January 1, 2017, and December 31, 2022, that used the keywords "alteplase," "tenecteplase," and spelling variations of their generic and brand names in the "Medication Prescribed" field. The objective of Methods I was to explore the extent of reported events involving the two medications, regardless of indication, and guide the design of the inclusion criteria for Methods II of the study.

Results I

Methods I generated a total of 858 reports, of which 92% (791 of 858) involved alteplase and 8% (67 of 858) involved tenecteplase (**Figure 1**). Tenecteplase-related reports had a frequency near zero from 2017 to 2020 and increased in 2021 and 2022, while the number of alteplase-related reports increased in 2018 and 2019 and decreased each year thereafter. As a result of these changes in frequency of reports, we targeted the 2021–2022 time period for further analysis in Methods II.

Part II

Methods II

Based on the findings from Results I, we chose to narrow the scope of Methods II to further examine the nature of events involving alteplase and tenecteplase in the treatment of AIS. As shown in **Figure 2**, we started with 301 reports from Methods I submitted to PA-PSRS in 2021–2022 and then applied the following inclusion criteria:

- The report described a medication error, which we defined as "any preventable behavior or condition directly involving alteplase or tenecteplase that created a potential for harm or caused harm to a patient" (adapted from the National Coordinating Council for Medication Error Reporting and Prevention definition[35])[b].
- Alteplase or tenecteplase was intended for the intravenous treatment of AIS[b].

Variables Coded

Each report that met inclusion criteria was coded with two sets of variables. The first set was coded by the reporter at the time of submission to PA-PSRS and included variables such as the event date, care area[c], facility type, and patient demographic information. The second set of variables consisted of the intended thrombolytic

[a]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).[34] All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

[b]This criterion was verified through manual review of the event narrative in the report.

[c]Within the PA-PSRS acute care database, there are 168 care areas for facilities to use to identify where events occur. Each of these care areas is then placed into one of 23 higher level care area groups.

Figure 1. Results of Methods I Showing the Frequency of Event Reports Involving Alteplase and Tenecteplase Submitted Between 2017 and 2022 (N=858)

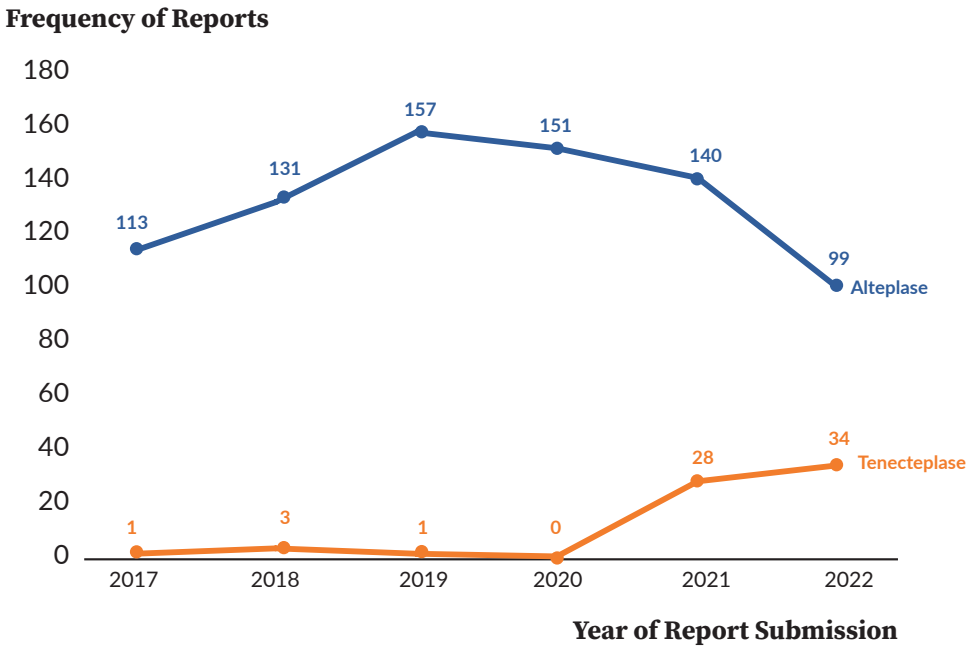
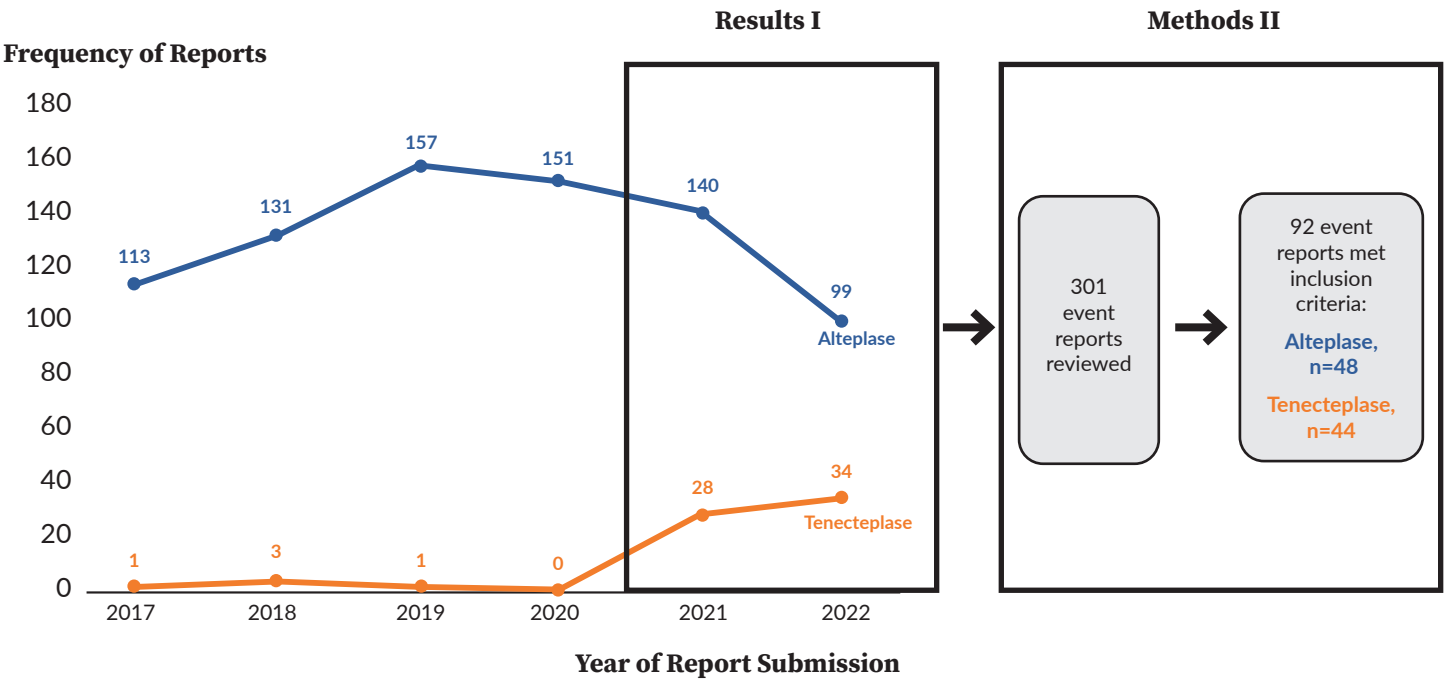


Figure 2. Identification of Relevant Event Reports for Inclusion in Part II of Study



Note: Results I had a total of 301 event reports that were submitted during 2021–2022. In Methods II, the 301 event reports were manually reviewed, and we found that 92 (alteplase n=48; tenecteplase n=44) met the inclusion criteria for analysis in Part II of the study.

medication, near miss, clinical indication, stage of the medication-use process, associated factor, and event type. Each report was reviewed and manually coded by two researchers, and any discrepancies were discussed with a third researcher until consensus was reached. Our coding taxonomies for stage of the medication-use process, associated factor, and event type were developed using a deductive approach by adapting the PA-PSRS taxonomy and prior literature,[27,36,37] combined with an inductive approach to create additional codes where necessary.

Near Miss. The event was considered a near miss if it did not reach the patient (i.e., did not impact or interrupt patient care) due to chance or active intervention.

Clinical Indication. A clinical indication was defined as a medical condition or reason to prescribe the thrombolytic agent. Although all the prescribed thrombolytics included in the study were intended for AIS, we also coded clinical indications for which the medications were incorrectly ordered or dispensed. When not explicitly mentioned in the event details, the clinical indications for which the medication was intended, ordered, and dispensed were identified by examining the dose, consult type, methods used to prepare or administer the medication, and other contextual information provided in the report details.

Stage of the Medication-Use Process. See **Table 1** for definitions of the four stages of the medication-use process that characterize the chronological order of events and behaviors that typically occur in the acute care setting. We coded event reports according to the following four stages of the medication-use process: *Admission and screening, Prescribing and ordering, Verification and dispensing*, and *Administration*. We defined the stage as the point in the medication-use process at which a preventable behavior or condition likely contributed to the safety event (i.e., associated factor; see **Table 2**).

Associated Factor. An associated factor was defined as the preventable behavior or condition that likely contributed to the safety event. Based on the complexity of the safety event and details provided by the reporter, multiple associated factors may have been coded for a single report. When two or more reports shared the same associated factor, a standalone category of associated factor was formed. We identified 24 associated factors occurring across the four stages of the medication-use process. The associated factor *Other* contained reports that did not fit into a more specific category of associated factor for that stage. See **Table 2** for definitions of the 24 associated factors.

Event Type. An event type was defined as the actual or likely result of the associated factor. One event type was coded for each report. If the report lacked sufficient details or the event was a near miss and had the potential for multiple event types, the event was categorized as *Unable to determine*. See **Table 3** for definitions of the nine event types.

Data Analysis

We performed a descriptive analysis to explore the data and identify any phenomena or patterns that may not have been described in previous literature.[38] The analysis was conducted using tables and graphs to triangulate the relation among various combinations of variables. The goal with this type of analysis is to summarize data, describe patterns, and point toward possible causal mechanisms in a meaningful display that is helpful to the reader. The conclusions drawn from our analysis are not intended to establish causal relationships but rather to examine important dynamics between the coded variables, understand gaps in practice, and promote safe use of alteplase and tenecteplase to treat AIS.

Results II

Based on Methods II, we identified 92 event reports (alteplase n=48; tenecteplase n=44) that met inclusion criteria for Part II of our study. These 92 reports are a subset of the sample from Part I of the study.

Demographics

A total of 52 Pennsylvania hospitals submitted at least one report describing an event that was included in our study. Of these, 31 hospitals submitted one report (60%, 31 of 52), 10 hospitals submitted two reports (19%; 10 of 52), and 11 hospitals submitted three or more reports (21%; 11 of 52). More than half of the reports (57%, 52 of 92) were submitted by facilities with more than 300 beds. The "Emergency Department" care area group was identified as the location in majority of reports (71%, 65 of 92). Based on the 92 reports, patient age was an average of 67 years and a median of 68 years (range: 14 to 98 years, 25th percentile: 55 years, 75th percentile: 81 years).

Table 1. Definitions of Stages of the Medication-Use Process

Stage of the Medication-Use Process	Definition
Admission and screening	Patient is examined and assessed for indication of therapy with an IV thrombolytic. Patient information is collected to determine eligibility for treatment and documented in the EHR.
Prescribing and ordering	The prescriber uses clinical decision-making skills to select the appropriate medication and treatment regimen. The medication order, which can be verbal or electronic, is transcribed and entered into the EHR.
Verification and dispensing	The medication order is reviewed independently by a second provider for completeness, accuracy, and appropriateness. Following verification, the medication is prepared and dispensed from the pharmacy or the ADC.
Administration	The medication, which has been prepared to its ready-to-administer form, is given to the patient. Details of the administration are documented in the MAR.

Note: Stages of the medication-use process characterize the chronological order of events and behaviors that typically occur in the acute care setting.
ADC: Automated dispensing cabinet. EHR: Electronic health record. IV: Intravenous. MAR: Medication administration record.

Table 2. Definitions of Associated Factors

Stage	Associated Factor	Definition
Admission and screening	1. Weight incorrect or not collected	Patient's weight was inaccurate or unavailable.
	2. Medication history inaccurate	Patient's historical medication record or medication reconciliation was incorrect.
	3. Vital signs or lab values not assessed	Essential patient information needed for prescribing, administering, and monitoring of medication was unavailable or disregarded by the healthcare provider.
Prescribing and ordering	4. Order not placed in EHR	Medication order was not placed in the EHR in a timely manner.
	5. Order unclear or ambiguous	Components of the medication order were conflicting or confusing to the receiving healthcare provider.
	6. Order placed under wrong encounter or record in EHR	Medication order was entered under a previous encounter or in the wrong patient's record within the EHR.
	7. Order set available in EHR but not used	Prescriber failed to use the designated order set to place the medication order.
	8. Order misheard or misinterpreted	A verbal order was not heard or not interpreted as intended.
	9. Absence of warning or alert in EHR	Warning or alert did not display at the time of provider's computerized order entry.
	10. Knowledge and/or experience deficit	The event reporter attributed the event to the healthcare provider's lack of knowledge and/or experience.
	11. Order for incorrect indication	Medication order was placed for a wrong indication.
	12. Other	The report contained enough detail to determine that the *Prescribing and ordering* stage was involved in the safety event but lacked sufficient detail to identify an associated factor, or the identified associated factor did not fit into any of the aforementioned categories.
Verification and dispensing	13. Dosing information unavailable or incorrect	Dosing instructions provided in the medication kit or stroke protocol were not available or incorrect.
	14. Drug label wrong or missing	The drug label and/or its accompanying barcode was wrong or missing.
	15. Knowledge and/or experience deficit	The event reporter attributed the event to the healthcare provider's lack of knowledge and/or experience.
	16. Medication in ADC unstocked, inaccessible, or wrong	Intended medication in the ADC was unavailable, inaccessible, or incorrectly stocked.
	17. Wrong volume dispensed	The medication was prepared with a wrong volume, leading to a wrong dose or concentration of the final product.
	18. Medication delivery issues	The medication was not delivered or was delivered to the wrong location.
	19. Calculation error	The dose of the medication was incorrectly calculated and prepared during the dispensing stage.
	20. Other	The report contained enough detail to determine that the *Verification and dispensing* stage was involved in the safety event but lacked sufficient detail to identify an associated factor, or the identified associated factor did not fit into any of the aforementioned categories.
Administration	21. Medication administration not documented in MAR	Details of the medication administration were not documented in the MAR in a timely manner.
	22. Programming error with infusion pump	A programming error occurred with the infusion pump.
	23. Knowledge and/or experience deficit	The event reporter attributed the event to the healthcare provider's lack of knowledge and/or experience.
	24. Other	The report contained enough detail to determine that the *Administration* stage was involved in the safety event but lacked sufficient detail to identify an associated factor, or the identified associated factor did not fit into any of the aforementioned categories.

Note: Multiple associated factors could be coded for each event report. The associated factors *Calculation error, Knowledge and/or experience deficit*, and *Other* were identified across several stages and were counted individually per stage. ADC: Automated dispensing cabinet. EHR: Electronic health record. IV: Intravenous. MAR: Medication administration record.

Table 3. Definitions of Event Types

Event Type	Definition
Wrong dose	The dose ordered, dispensed, and/or administered differed from the dose originally intended by the prescriber and/or recommended by the published guidelines.
Delay of therapy	The medication was not given to the patient in a timely manner or within a period of time deemed acceptable by the reporting facility.
Patient not eligible	Medication was ordered, dispensed, and/or administered to the patient against known contraindications or lack of indication for therapy.
Wrong drug	The medication ordered, dispensed, and/or administered differed from the medication originally intended by the prescriber.
Wrong rate	The medication rate ordered and/or received by the patient was inconsistent with the rate originally intended by the prescriber and/or recommended by the published guidelines.
Wrong patient	The medication was ordered, dispensed, and/or administered to the wrong patient.
Extra dose	A duplicate dose was ordered, dispensed, and/or administered to the patient.
Omission of therapy	The patient did not receive the intended medication.
Unable to determine	The report lacked sufficient detail to identify an event type, or the event was a near miss and had the potential for multiple event types.

Note: Each of the 92 event reports was coded with one event type.

Medication

As shown in **Figure 3**, 52% of the reports involved alteplase (48 of 92) and 48% involved tenecteplase (44 of 92) as the intended medication for AIS. Of the total reports, near misses accounted for 42% (39 of 92) and occurred with an almost equal distribution between the two medications (alteplase 51%, 20 of 39; tenecteplase 49%, 19 of 39). An event attributed to a wrong indication was described in six reports; in five tenecteplase-related events, the indication was confused for AMI, and in one alteplase-related event, the order was incorrectly placed for PE.

Stage of the Medication-Use Process

Figure 4 and **Figure 5** show the distribution of each stage of the medication-use process involved by intended medication. Alteplase-related events occurred with a more similar frequency across the four stages (range of 12 to 14 reports), while the frequency of tenecteplase-related events was highly variable across the four stages (range of 5 to 26 reports). Across both medications, the *Prescribing and ordering* stage was associated with the highest frequency of total events (40 of 92 reports).

Associated Factor and Stage of the Medication-Use Process

Table 4 shows the frequency of associated factors by stage and intended medication. Associated factors were not mutually exclusive, resulting in a total of 120 associated factors that were coded across 92 reports. Seventy-four percent (68 of 92) of reports had one associated factor, 22% (20 of 92) had two associated factors, and 4% (4 of 92) had three associated factors coded. The associated factors we identified most frequently across all reports were *Weight incorrect or not collected* (13%, 15 of 120) and *Order not placed in EHR* (9%, 11 of 120). *Knowledge and/or experience deficit*, when combined across all stages of the medication-use process, was also coded frequently (10%, 12 of 120).

Admission and Screening

Across all associated factors, 16% (19 of 120) occurred during *Admission and screening*. The associated factor *Weight incorrect or not collected* accounted for 79% (15 of 19) of all associated factors coded for this stage and was identified much more frequently in events involving alteplase (alteplase n=11; tenecteplase n=4).

Prescribing and Ordering

Across all associated factors, 40% (48 of 120) occurred during *Prescribing and ordering*. The two associated factors that were identified most frequently during this stage were *Order not placed in EHR* (23%, 11 of 48), which was seen more frequently with tenecteplase (alteplase n=2; tenecteplase n=9), and *Order unclear or ambiguous* (17%, 8 of 48), which also occurred more frequently with tenecteplase (alteplase n=3; tenecteplase n=5). Overall, two-thirds of all associated factors related to this stage involved tenecteplase (67%, 32 of 48).

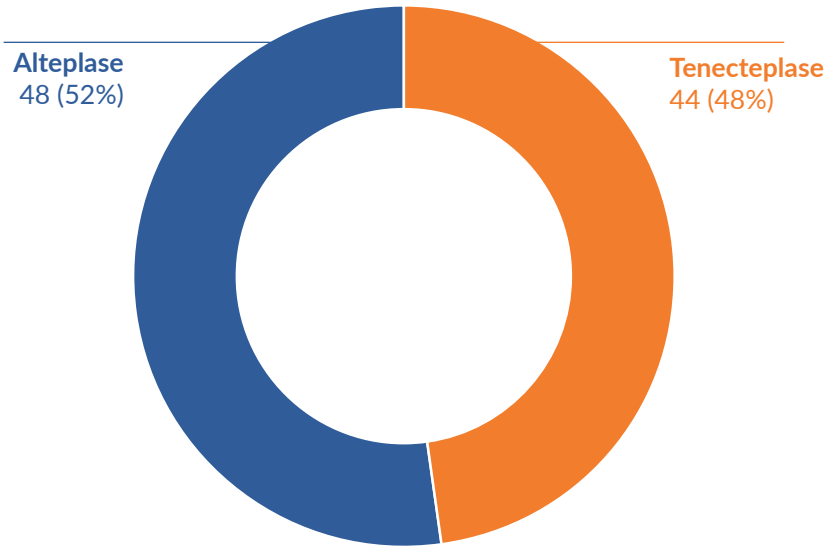
Verification and Dispensing

Across all associated factors, 25% (30 of 120) occurred during *Verification and dispensing*. The associated factor that occurred most frequently during this stage was *Dosing information unavailable or incorrect* (20%; 6 of 30), which was relevant to only tenecteplase (alteplase n=0; tenecteplase n=6). Conversely, associated factors that were unique to only alteplase during this stage were *Drug label wrong or missing* (alteplase n=4; tenecteplase n=0) and *Calculation error* (alteplase n=2; tenecteplase n=0).

Administration

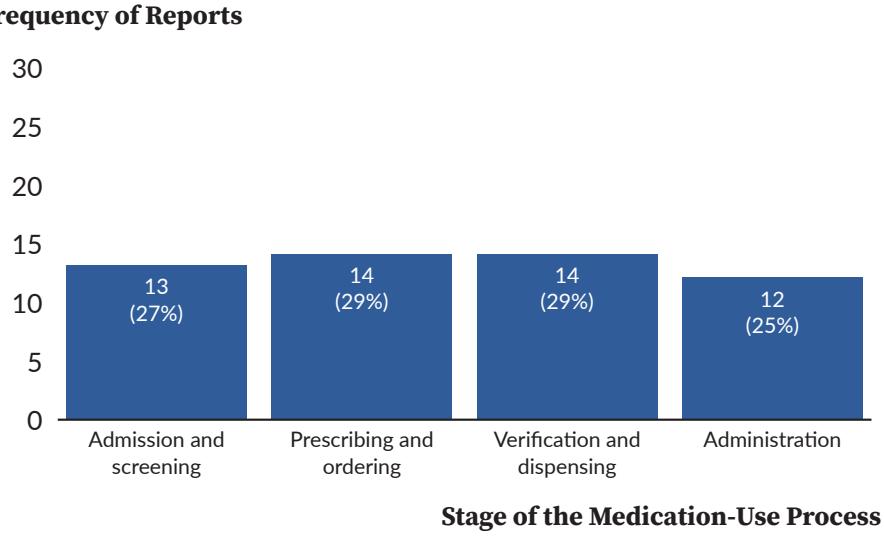
Across all associated factors, 19% (23 of 120) occurred during *Administration*. The most frequent associated factors identified for this stage were *Medication administration not documented in MAR* (26%; 6 of 23), *Programming error with infusion pump* (26%; 6 of 23), and *Other* (26%; 6 of 23). Tenecteplase was more frequently involved with the associated factors *Medication administration not documented in MAR* (alteplase n=1; tenecteplase n=5) and *Knowledge and/or experience deficit* (alteplase n=1; tenecteplase n=4), while

Figure 3. Frequency of Event Reports by Intended Medication (N=92)



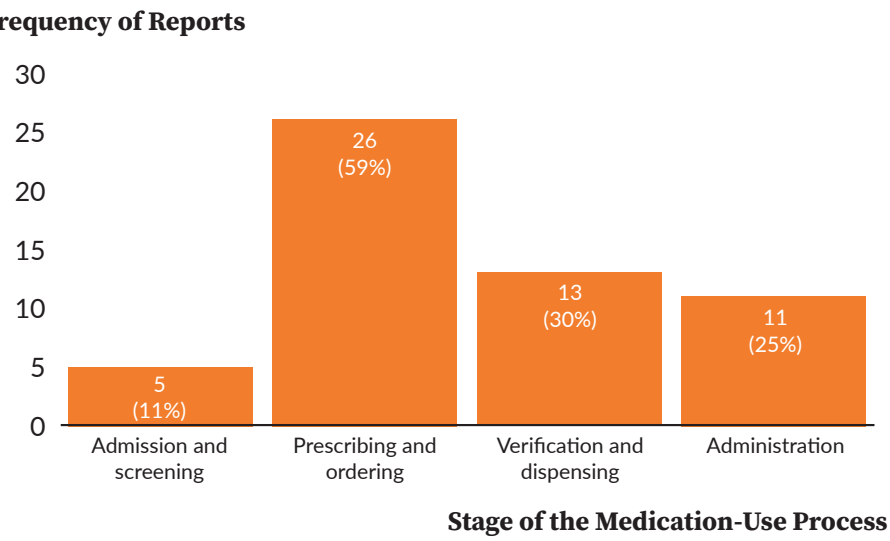
Note: Total number of event reports involving alteplase and tenecteplase included in the study was 48 and 44, respectively. Near misses are included in the total.

Figure 4. Frequency of Events Involving Alteplase by Stage of the Medication-Use Process (N=48 reports)



Note: The figure shows the frequency of events impacted by stage across 48 event reports. Each report may have had more than one stage involved in the event. Percentages shown are based on the denominator of 48.

Figure 5. Frequency of Events Involving Tenecteplase by Stage of the Medication-Use Process (N=44 reports)



Note: The figure shows the frequency of events impacted by stage across 44 event reports. Each report may have had more than one stage involved in the event. Percentages shown are based on the denominator of 44.

Programming errors with infusion pump was relevant to only alteplase (alteplase n=6, tenecteplase n=0). The alteplase-related events coded as *Other, Administration* consisted of the inappropriate administration of infusion prior to bolus, bolus pushed too fast, suboptimal connection of lines preventing drug administration, and wrong manipulation of the infusion bag leading to drug waste.

Event Type

Figure 6 shows the distribution of event types by intended medication. Based on a total of 92 reports, the event types we identified most frequently were *Wrong dose* at 48% (44 of 92) and *Delay of therapy* at 15% (14 of 92). The event type *Wrong rate* was unique to alteplase only (alteplase n=5; tenecteplase n=0), and several event types occurred more frequently for tenecteplase, such as *Wrong drug* (alteplase n=1; tenecteplase n=4).

Figure 7 shows the subcategories of *Wrong dose* for each medication: *Overdose, Underdose,* and *Unable to determine*. Collectively, 75% (33 of 44) of all reports coded as *Wrong dose* resulted in an overdose. Among these, tenecteplase accounted for the majority of events leading to an overdose (alteplase n=13; tenecteplase n=20).

Event Type, Stage, And Associated Factor

Table 5 shows the frequency of stages, associated factors, and event types for each of the intended medications. The distribution of the event type *Wrong dose* and corresponding associated factors by stages are described further in the next section. The event type *Delay of therapy* had the second highest frequency of associated factors (alteplase n=9; tenecteplase n=9), and more than half of these associated factors occurred during the *Verification and dispensing* stage (56%; 10 of 18).

The event type *Wrong drug* was detected more frequently with tenecteplase and could be attributed primarily to the associated factor *Order misheard or misinterpreted* (alteplase n=1; tenecteplase n=3). In fact, all events that had the associated factor *Order misheard or misinterpreted* involved the use of the abbreviation "TPA" and led to the event type *Wrong drug*.

The event type *Wrong rate* was relevant to only alteplase, was mostly impacted by the *Programming error with infusion pump* associated factor (4 of 6), and was related with only two stages of the medication-use process: *Prescribing and ordering* and *Administration*.

The associated factor *Order not placed in EHR* was identified more frequently for tenecteplase (alteplase n=2; tenecteplase n=9) and resulted in the most diverse distribution of event types, which signifies that missing or undocumented orders can lead to many different types of events.

Wrong Dose and Associated Factor

The complete table of associated factors for the event type *Wrong dose*, as detailed by *Overdose, Underdose,* and *Unable to determine*, can be found in **Table 6**. An overdose involving alteplase was most frequently associated with *Weight incorrect or not collected* (n=6), *Wrong volume dispensed* (n=3), and *Calculation error* (n=2). Two of these categories of associated factors, *Wrong volume dispensed* and *Calculation error*, both involved the wrong dose preparation during the *Verification and dispensing* stage as a result of the failure to remove the correct amount of overfill and/or incorrect calculation of bolus and/or infusion doses.

For tenecteplase, overdoses were most frequently related with the associated factors *Knowledge and/or experience deficit* (n=7), *Dosing information unavailable or incorrect* (n=4), and *Order unclear or ambiguous* (n=4). The associated factor *Knowledge and/or experience deficit* spanned across three different stages, *Prescribing and ordering, Verification and dispensing,* and *Administration*, which highlights the prevalence and implication throughout the medication-use process. All four reports coded with the associated factor *Dosing information unavailable or incorrect* involved confusion with the wrong indication for AMI, which led to exceeding the maximum dose of 25 milligrams recommended for the treatment of AIS.

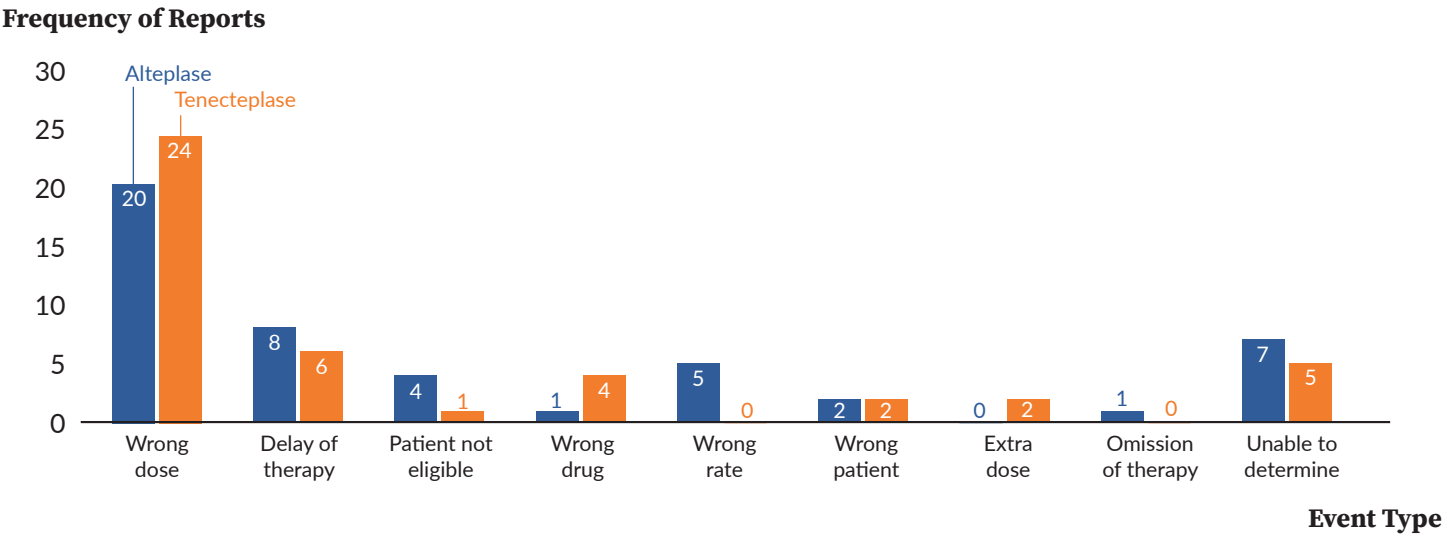
A quarter of all tenecteplase-related overdose events (25%; 5 of 20) involved a wrong indication in which a staff member either chose a wrong order set intended for AMI in the EHR or followed the wrong dosing instructions intended for AMI provided in the medication kit.

Table 4. Frequency of Associated Factor by Stage and Intended Medication (N=120)

Stage	Associated Factor	Alteplase	Tenecteplase	Total
Admission and screening	1. Weight incorrect or not collected	11	4	15
	2. Medication history inaccurate	2	0	2
	3. Vital signs or lab values not assessed	0	2	2
	Subtotal	**13**	**6**	**19**
Prescribing and ordering	4. Order not placed in EHR	2	9	11
	5. Order unclear or ambiguous	3	5	8
	6. Order placed under wrong encounter or record in EHR	3	2	5
	7. Order set available in EHR but not used	1	3	4
	8. Order misheard or misinterpreted	1	3	4
	9. Absence of warning or alert in EHR	1	2	3
	10. Knowledge and/or experience deficit	0	3	3
	11. Order for incorrect indication	1	1	2
	12. Other	4	4	8
	Subtotal	**16**	**32**	**48**
Verification and dispensing	13. Dosing information unavailable or incorrect	0	6	6
	14. Drug label wrong or missing	4	0	4
	15. Knowledge and/or experience deficit	1	3	4
	16. Medication in ADC unstocked, inaccessible, or wrong	2	2	4
	17. Wrong volume dispensed	3	1	4
	18. Medication delivery issues	2	1	3
	19. Calculation error	2	0	2
	20. Other	2	1	3
	Subtotal	**16**	**14**	**30**
Administration	21. Medication administration not documented in MAR	1	5	6
	22. Programming error with infusion pump	6	0	6
	23. Knowledge and/or experience deficit	1	4	5
	24. Other	4	2	6
	Subtotal	**12**	**11**	**23**
	Total	**57**	**63**	**120**

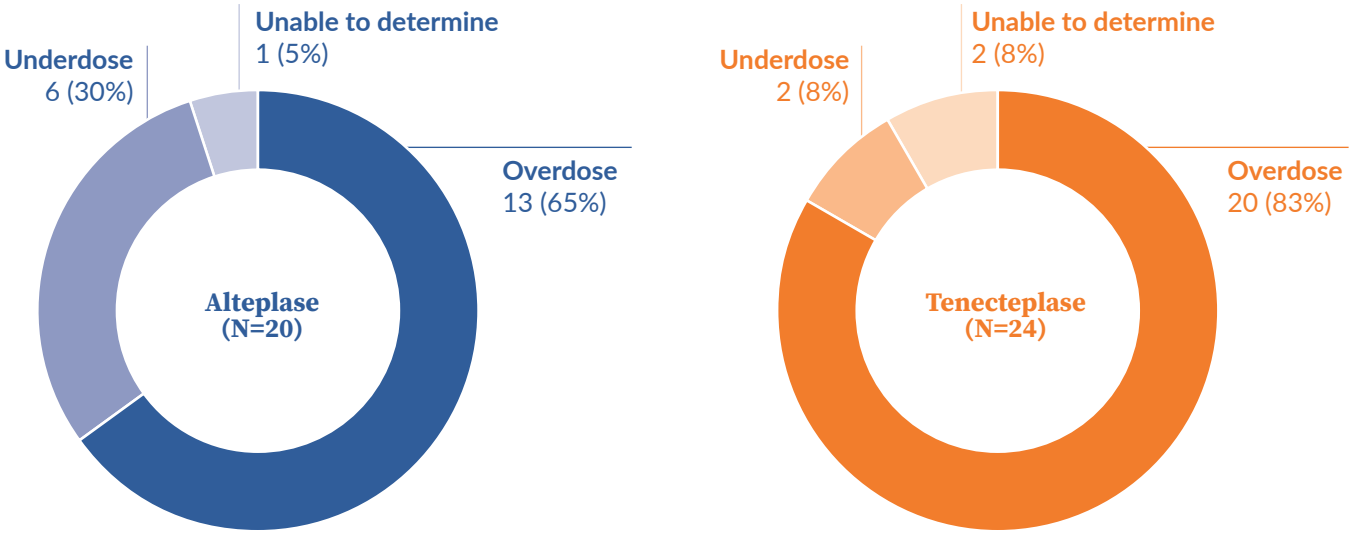
Note: Associated factors were not mutually exclusive; therefore, multiple associated factors could be coded for each report. Across a total of 92 event reports, 120 associated factors belonging to 24 unique categories were coded. ADC: Automated dispensing cabinet. EHR: Electronic health record. IV: Intravenous. MAR: Medication administration record.

Figure 6. Event Type by Intended Medication (N=92 reports)



Note: Each of the 92 event reports was coded with one event type.

Figure 7. Subcategories of Wrong Dose by Intended Medication (N=44 reports)



Note: Each of the 44 reports that were coded as event type *Wrong dose* was further identified as *Overdose*, *Underdose*, or *Unable to determine*.

Table 5. Frequency of Relationships Between Event Types (N=92), Stages, and Associated Factors (N=120)

		Event type																			
		Wrong dose		Delay of therapy		Patient not eligible		Wrong drug		Wrong rate		Wrong patient		Extra dose		Omission of therapy		Unable to determine		Total	
	Total (1 per report)	44 (48%)		14 (15%)		5 (5%)		5 (5%)		5 (5%)		4 (4%)		2 (2%)		1 (1%)		12 (13%)		92 (100%)	
Stage	Associated Factor	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te	AI	Te
Admission and screening	1. Weight incorrect or not collected	11	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	4
	2. Medication history inaccurate	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-
	3. Vital signs or lab values not assessed	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	2
	Subtotal	**11**	**2**	**-**	**3**	**2**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**13**	**6**
Prescribing and ordering	4. Order not placed in EHR	-	4	-	-	-	1	-	-	1	-	-	-	-	1	-	-	1	3	2	9
	5. Order unclear or ambiguous	1	5	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	3	5
	6. Order placed under wrong encounter or record in EHR	-	-	-	-	-	-	-	-	-	-	2	2	-	-	-	-	1	-	3	2
	7. Order set available in EHR but not used	-	3	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	3
	8. Order misheard or misinterpreted	-	-	-	-	-	-	1	3	-	-	-	-	-	-	-	-	-	-	1	3
	9. Absence of warning or alert in EHR	-	1	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-	1	2
	10. Knowledge and/or experience deficit	-	2	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	3
	11. Order for incorrect indication	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1
	12. Other	2	3	-	1	2	-	-	-	-	-	-	-	-	-	-	-	-	-	4	4
	Subtotal	**4**	**19**	**1**	**1**	**4**	**1**	**2**	**3**	**1**	**-**	**2**	**2**	**-**	**3**	**-**	**-**	**2**	**3**	**16**	**32**
Verification and dispensing	13. Dosing information unavailable or incorrect	-	4	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	6
	14. Drug label wrong or missing	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	4	-
	15. Knowledge and/or experience deficit	1	2	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	3
	16. Medication in ADC unstocked, inaccessible, or wrong	-	-	1	1	-	-	-	1	-	-	-	-	-	-	-	-	1	-	2	2
	17. Wrong volume dispensed	3	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	1
	18. Medication delivery issues	-	-	2	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	1
	19. Calculation error	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-
	20. Other	1	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	1
	Subtotal	**7**	**7**	**5**	**5**	**-**	**-**	**-**	**1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**4**	**1**	**16**	**14**
Administration	21. Medication administration not documented in MAR	-	1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	1	3	1	5
	22. Programming error with infusion pump	1	-	1	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	6	-
	23. Knowledge and/or experience deficit	1	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	4
	24. Other	-	2	2	-	-	-	-	-	1	-	-	-	-	-	1	-	-	-	4	2
	Subtotal	**2**	**7**	**3**	**-**	**-**	**-**	**-**	**-**	**5**	**-**	**-**	**-**	**-**	**-**	**1**	**-**	**1**	**3**	**12**	**11**
	Total	**24**	**35**	**9**	**9**	**6**	**2**	**2**	**4**	**6**	**-**	**2**	**2**	**-**	**4**	**1**	**-**	**7**	**7**	**57**	**63**

Note: Across a total of 92 event reports, 120 associated factors belonging to 24 unique categories were coded. Only one event type was identified in each of the 92 reports; however, based on the context of the individual report, more than one associated factor may have been identified in each report. Multiple associated factors per event type indicate that more than one factor was present and may have influenced the event type as described in the report. The area at the top of the table shaded in green identifies the nine categories of event types and the frequency per type. The **tan** shaded areas to the far left represent the stages of the medication-use process and the **grey** shaded areas to the right of the stages show the associated factors. Twenty-four different associated factors were organized into four stages of the medication-use process, which were then tabulated into columns corresponding with each of the nine event types. The last row in each stage of the medication-use process contains the subtotal of the associated factors identified in that particular stage. The far-right column shows the sum of the associated factors across all 9 categories of event type. Cells with a - represent a zero frequency. AI: Alteplase. Te: Tenecteplase

Table 6. Frequency of Associated Factors (N=59) by Subcategories of *Wrong dose* (N=44) and Intended Medications

		Wrong Dose							
		Overdose		Underdose		Unable to determine		Total	
Stage	Associated Factor	Alteplase	Tenecteplase	Alteplase	Tenecteplase	Alteplase	Tenecteplase	Alteplase	Tenecteplase
Admission and screening	1. Weight incorrect or not collected	6	1	4	1	1	-	11	2
	2. Medication history inaccurate	-	-	-	-	-	-	-	-
	3. Vital signs or lab values not assessed	-	-	-	-	-	-	-	-
	Subtotal	**6**	**1**	**4**	**1**	**1**	**-**	**11**	**2**
Prescribing and ordering	4. Order not placed in EHR	-	3	-	1	-	-	-	4
	5. Order unclear or ambiguous	-	4	1	-	-	1	1	5
	6. Order placed under wrong encounter or record in EHR	-	-	-	-	-	-	-	-
	7. Order set available in EHR but not used	-	3	-	-	-	-	-	3
	8. Order misheard or misinterpreted	-	-	-	-	-	-	-	-
	9. Absence of warning or alert in EHR	-	1	-	-	-	-	-	1
	10. Knowledge and/or experience deficit	-	2	-	-	-	-	-	2
	11. Order for incorrect indication	1	1	-	-	-	-	1	1
	12. Other	2	2	-	-	-	1	2	3
	Subtotal	**3**	**16**	**1**	**1**	**-**	**2**	**4**	**19**
Verification and dispensing	13. Dosing information unavailable or incorrect	-	4	-	-	-	-	-	4
	14. Drug label wrong or missing	-	-	-	-	-	-	-	-
	15. Knowledge and/or experience deficit	1	1	-	-	-	1	1	2
	16. Medication in ADC unstocked, inaccessible, or wrong	-	-	-	-	-	-	-	-
	17. Wrong volume dispensed	3	1	-	-	-	-	3	1
	18. Medication delivery issues	-	-	-	-	-	-	-	-
	19. Calculation error	2	-	-	-	-	-	2	-
	20. Other	-	-	1	-	-	-	1	-
	Subtotal	**6**	**6**	**1**	**-**	**-**	**1**	**7**	**7**
Administration	21. Medication administration not documented in MAR	-	-	-	1	-	-	-	1
	22. Programming error with infusion pump	1	-	-	-	-	-	1	-
	23. Knowledge and/or experience deficit	-	4	1	-	-	-	1	4
	24. Other	-	2	-	-	-	-	-	2
	Subtotal	**1**	**6**	**1**	**1**	**-**	**-**	**2**	**7**
	Total	**16**	**29**	**7**	**3**	**1**	**3**	**24**	**35**

Note: Across a total of 44 event reports that were identified with the event type *Wrong dose*, 59 associated factors belonging to 24 total possible unique categories were coded. Multiple associated factors could be coded for each report, while only one event type was coded per report. The area at the top of the table shaded in green identifies the subcategories of *Wrong dose: Overdose*, *Underdose*, and *Unable to determine*. The **tan** shaded areas to the far left represent the stages of the medication-use process and the **grey** shaded areas to the right of the stages show the associated factors. The 24 associated factors were organized into four stages of the medication-use process which are represented in tan. The last row in each stage of the medication-use process contains the subtotal of the associated factors identified in that particular stage. The far-right column shows the sum of the associated factors across all subcategories of *Wrong dose* event type. Cells with a - represent a zero frequency.

Discussion

In Part I of our study, we measured the frequency of reports submitted to PA-PSRS in which either alteplase or tenecteplase was the medication prescribed, regardless of indication, and this revealed a notable increase in reported events involving tenecteplase. In Part II of our study, we analyzed numerous variables to better understand the nature of medication errors involving the use of either alteplase or tenecteplase to treat AIS. To our knowledge, this is the first study of medication events involving alteplase and tenecteplase to treat AIS that delineated event types and associated factors with the stage of the medication-use process.

For both medications, we found *Wrong dose* to be the event type with the highest frequency, which was identified in almost half of all reports included in the study. For alteplase, *Weight incorrect or not collected* was the factor most frequently associated with *Wrong dose*. When an inaccurate weight is used to calculate the dose, the patient could receive a dose that is considerably different from what is appropriate, safe, and effective.[39] For example, two separate studies of reports found that 44% and 42% of all wrong weight events led to an overdose.[39,40] In our study, the associated factor *Weight incorrect or not collected* was identified in 55% of all events that were coded overdoses with alteplase.

Additionally, we found that the *Verification and dispensing* stage and *Administration* stage of the medication-use process were associated with several safety gaps unique to alteplase. Our findings revealed safety challenges associated with the multistep preparation of the bolus and infusion doses of alteplase, use of the infusion pump, and different rates of administration for bolus and infusion. For example, we identified the associated factor *Programming error with infusion pump* and the event type *Wrong rate* only in reports involving alteplase.

Unlike alteplase, the bolus administration of tenecteplase eliminates problems associated with use of an infusion pump, such as setup issues, air in tubing, and staff required during interfacility patient transfers.[10,11] It has also been shown to be associated with a shorter door-to-needle time.[8,32]

Despite these advantages, our study showed that tenecteplase has several distinct safety gaps. Many were related to the use of a medication kit and confusion with a wrong indication (AMI) leading to an overdose. Because tenecteplase is currently approved for the treatment of AMI only, the medication is supplied from the manufacturer inside a kit that contains dosing, preparation, and administration instructions intended for AMI, not AIS.[4,41] The maximum recommended dose of tenecteplase for treatment of AMI as provided in the kit is 50 mg, which is double the maximum recommended dose of tenecteplase for the off-label treatment of AIS. [4,18,41] Accordingly, in our study, all tenecteplase-related events coded as *Dosing information unavailable or incorrect* led to the event type *Wrong dose* and were in fact, overdoses.

Furthermore, more than half of the reports involving tenecteplase involved the *Prescribing and ordering* stage of the medication-use process. In particular, several associated factors involving the use of the EHR were identified more frequently with tenecteplase than with alteplase, such as *Order not placed in EHR, Order set available in EHR but not used,* and *Absence of warning or alert in EHR*. During the *Administration* stage, the associated factor *Medication administration not documented in MAR* was also identified more frequently with tenecteplase. These findings suggest that providers are not using the EHR to place or document an order, orders are placed without using the correct order set, and the EHR is not optimized to detect and mitigate errant orders.

Lastly, the associated factor *Knowledge and/or experience deficit* was identified across multiple stages, occurring throughout *Prescribing and ordering*, *Verification and dispensing*, and *Administration* stages. When combined altogether across the stages, it represented the second most frequently coded associated factor in the study, and 83% of these were observed with tenecteplase. This indicates that the lack of knowledge and/or experience with tenecteplase was a factor in many events.

Potential Strategies

Table 7 shows a list of potential strategies that can be adopted at the provider and system levels. Because every facility has its own unique workflow, processes, and resources, it is important to identify those that are both applicable and meaningful to each facility. The potential strategies should be reviewed with the interdisciplinary members of the stroke team and the relevant hospital committees, as well as the patient safety officer and the medication safety officer of the institution, with the overall goal of assessing current practices and continuously monitoring for improvement.

Limitations

One limitation of our study is the inherent nature of event reporting; a report does not necessarily represent the results of a thorough investigation and therefore may not provide insight into root causes. We do not recommend using our results for benchmarking or direct comparison because differences in culture, patient populations, resources, and error detection methods and systems may exist across facilities.[57] In addition, the definitions used in our study may differ from definitions used in other studies. For example, one study involving alteplase defined "delay" as a contributing factor,[37] while our study described it as an event type. Other studies may also categorize the medication-use process into stages different from those in our study.[60] Readers are encouraged to carefully compare results from other similar studies and refer to Methods II for definitions used in our study.

Given that this study presents aggregate data, facilities may gain important insight from performing site-specific investigations, such as a root cause analysis to retrospectively examine an event, a medication-use evaluation (MUE)[58,59] to answer a particular safety question, or a failure mode and effects analysis (FMEA)[49,50] to prospectively identify and mitigate high risk processes.

Table 7. Potential Strategies for Prevention of Medication Errors Involving Alteplase and Tenecteplase Throughout the Medication-Use Process

Stage of the Medication-Use Process	Potential Strategies
Admission and screening	Obtain an accurate weight of the patient
	• Establish a routine procedure for weighing patients upon admission and routinely reweighing patients in anticipation of fluctuating weight.[39,40,42,43] • Obtain weight in metric units, e.g., kilograms. [39,40,42,43] • Standardize weight measurement in metric units on medication orders, medical records, guidelines, protocols, infusion pumps, and other medication devices.[39,40,42,43] • Require the entry of weight prior to processing orders.[39,40,43] • Avoid the use of an estimated, stated, or historical weight.[39,40,42,43] • Document the date of the weight measurement.[39,40] • Build a "hard stop" or automated clinical decision support into computerized provider order entry (CPOE) systems to ensure the documentation of the most recent weight.[39,40]
	Screen for indication and patient eligibility for treatment
	• Obtain the best possible medication history (BPMH) using multiple sources such as patient interview, medical records, pharmacy records, and interview with a family member or caregiver.[44] • Assess for any contraindications by obtaining and reviewing:[45] ◦ Medication history ◦ Laboratory results ◦ Past medical history ◦ Allergies and associated reactions
Prescribing and ordering	Ensure the correct indication of the order
	• Require the placement of an order using the appropriate order set. • Establish a separate order set for each indication.[20,21,24,31] • Confirm the accuracy of the medication order by reviewing:[45] ◦ Medication administration record (MAR) ◦ Current medical condition ◦ Past medical history
	Minimize the risk of confusion between alteplase and tenecteplase
	• Do not use the abbreviation "TPA" to refer to the entire class of tissue plasminogen activators.[20,21,24,25,28,46] Do not use "TPA" to refer to alteplase or "TNK" for tenecteplase[6,20,21,24-26,28,30,47] • Remove the abbreviation "TPA" or "TNK" from standardized order sets, CPOE screens, and treatment protocols.[6,28,30,31,46] • Use the full generic names of the medications in verbal orders, order sets, and treatment protocols.[6,20,21,24-26,28,30,46] • Repeat back the verbal orders to ensure that they are heard correctly.[48] • Limit fibrinolytic agents on the hospital formulary.[20,21,25] If not possible, consider limiting one fibrinolytic to an indication. • When discussing the addition of a thrombolytic to the formulary, include a section on safety assessment and recommendations after reviewing the literature[49] and/or the results of a failure mode and effects analysis (FMEA).[50]
	Establish clinical decision support within the EHR
	• Create a hard stop for: ◦ A dose exceeding 25 mg for the treatment of AIS. **(Tenecteplase only)** ◦ Absent documentation of the most recent weight.[39,40] ◦ Duplicate therapy. ◦ Any present or past use of anticoagulants when thrombolytics are ordered. ◦ Absolute contraindications per the manufacturer, such as active internal bleeding and severe uncontrolled hypertension.[4] ◦ Relative contraindications per institutional guidelines, such as low platelet levels. • Automate the stat status with the thrombolytics order to expedite its preparation and delivery during the stroke alert. • Continuously monitor for effectiveness of the alerts and combat alert fatigue (e.g., compare the number of times an alert has triggered against the number of times a change has been made based on the alert).
	Other recommendations to optimize the use of the EHR
	• Review the "hold" functionality within the EHR and implement strategies as necessary, such as implementing pharmacist reverification upon release of held orders, evaluating parameters for orders on hold, and ensuring continuity of therapy when orders are held during transfer.[51]
	Provide education and competency training for staff
	• Establish protocols and guidelines for stroke alert and/or the use of thrombolytics. The document should be available and easily accessible to all members of the healthcare team. Include instructions pertaining to the use of thrombolytics throughout all stages of the medication-use process. • Provide competency assessment at orientation and prior to any changes to the stroke protocol. • Provide routine education to providers regarding updates to the formulary.[24,25] • Identify the personnel who are trained and qualified to routinely handle the fibrinolytic agents.[20,21]

Verification and dispensing	Confirm the accuracy of the medication
	• Do not prepare or dispense the medication until the order has been placed and, as much as possible, verified independently by a second healthcare provider such as a pharmacist. If the independent double check is not possible due to the emergent nature of the situation, confirm the details of the order verbally out loud for the members of the healthcare team to verify.[20,21,24,45] • Do not autoverify thrombolytics, given that they are considered high-alert, require weight-based dosing, interact with other medications, and require multistep dose calculation and preparation.[52] • Include a pharmacist in the interdisciplinary team who can ensure correct eligibility, dosing, and admixture administration of the fibrinolytics.[37]
	Minimize compounding errors
	• Prepare the medication using the IV workflow management system, if available. • Dedicate specialized personnel to prepare the medication,[20,21] especially during dose calculation and preparation of alteplase. • Adhere to best practices such as avoiding the syringe pull-back method.[49] Whenever possible, have the pharmacist prepare and/or physically inspect the final product with the accompanying supplies.
	Minimize errors involving the ADC
	• Dedicate a separate medication kit for individual medication based on indication.[20,21] Ensure that the kit contains supplies and dosing instructions appropriate for the indication. • Affix dosing and warning stickers on medication kits to identify the indication and medication name. • Require a medication order before the medication can be dispensed from the ADC.[53] • Provide profiled ADCs by directing providers to patient-specific medications that have been reviewed and verified by pharmacy.[53] • Establish a protocol if overrides are allowed at the institution.[49,53] Require the provider to indicate the rationale for override, and assess the frequency and reason for overrides to continuously monitor and create strategies for improvement. • Display medication names using full generic names.[54] See above category "Minimize the risk of confusion between alteplase and tenecteplase" for additional recommendations. • Require scanning of the individual medication prior to stocking the ADC.[20,21,53] • Establish a clean, quiet, distraction-free work environment for preparing and dispensing the medication[45,48,53]
Administration	Minimize programming errors involving the infusion pump **(Alteplase only)**
	• Do not assume units when programming parameters into the infusion pump. Confirm that all units are correct (e.g., min vs hr, mg vs mL) • Perform and document an independent double check of high-alert medications to verify:[20,55] ◦ Patient ◦ Patient weight ◦ Drug name ◦ Drug concentration ◦ Rate of infusion ◦ Channel selection ◦ Line attachment
	Build an optimal drug library and build support for the infusion pumps **(Alteplase only)**
	• Include the indication in the drug library.[20,21] • Remove the abbreviation "TPA" from the drug library and infusion pumps.[31,46] See above category "Minimize the risk of confusion between alteplase and tenecteplase" for additional recommendations. • Implement dose error-reduction systems (DERS) such as hard stops on maximum dose and infusion rate.[55,56] • Build a clinical advisory into the infusion pump to require a second nurse to independently verify and document the correct programming of the pump.[55] • Monitor error frequencies and use data (i.e., compliance rate with DERS) on infusion pumps.[42,48,55]
	Document medication administration correctly in EHR
	• Use barcoded medication administration (BCMA).[49] • Require a dual sign-off on the MAR at medication administration. • Avoid backcharting the order or administration in the EHR. Document the placement of the order or the administration of the medication in a timely manner. • Avoid documenting the administration solely into the patient's progress notes of the EHR. The medication administration should be scanned into the patient's MAR.

Note: ADC: Automated dispensing cabinet. BCMA: Barcoded medication administration. BPMH: Best possible medication history. CPOE: Computerized provider order entry. DERS: Dose error-reduction systems. EHR: Electronic health record. FMEA: Failure mode and effects analysis. IV: Intravenous. MAR: Medication administration record.

Conclusions

Both alteplase and tenecteplase have been used in clinical practice for decades; however, the increasing off-label use of tenecteplase for the treatment of AIS[5,7,8,11,61,62] created new safety challenges. By analyzing the stages of the medication-use process, associated factors, and event types, we identified aspects to medication safety that occurred with both alteplase and tenecteplase, as well as those that were unique to each individual medication. The event type *Wrong dose* was the most prevalent event type for both medications; however, the related stages and associated factors for the individual medication were variable. Our study underscores the need for increased awareness surrounding these medication errors and the provision of necessary support and training for providers. We encourage readers to review the potential strategies that fit the needs of their institutions and to supplement the analyses of their own institution-specific data and investigations with our findings to improve safety of patients receiving thrombolytics for treatment of AIS.

Note

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

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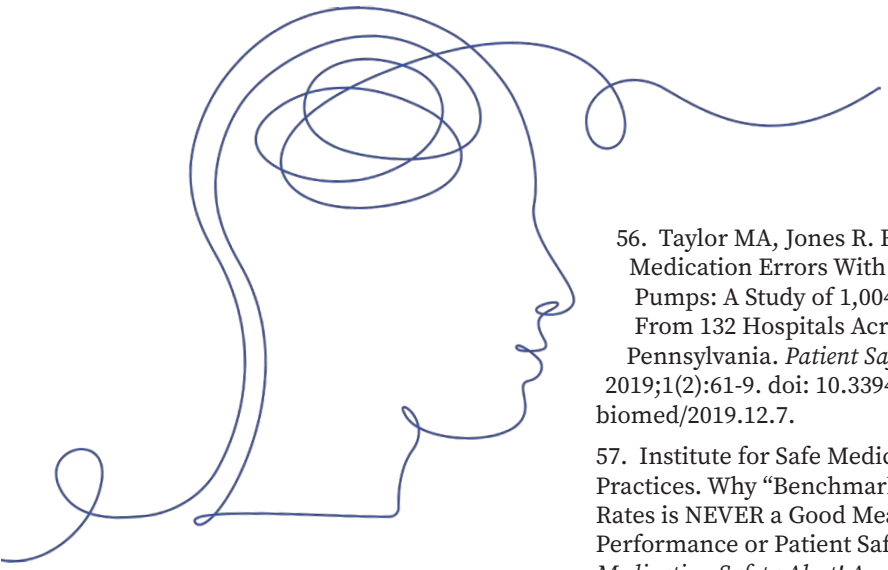

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Free Text as Part of Electronic Health Record Orders: **Context or Concern?**

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Abstract

Background: When placing orders into the electronic health record (EHR), prescribers often use free-text information to complement the order. However, the use of these free-text fields can result in patient safety issues. The objective of our study was to develop a deeper understanding of the conditions under which free-text information, or special instructions, are used in the EHR and the patient safety issues associated with their use, through an analysis of patient safety event (PSE) reports.

Methods: We identified 847 PSE reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) between January 1, 2021, and December 31, 2022; this dataset was reduced to 677 after controlling for oversampling from particular facilities. After limiting to reports that mentioned the terms "special instructions," "order instructions," "order comments," or "special comments," we analyzed a total of 329 reports. A physician and human factors expert independently reviewed the reports and assigned each a code from the following categories: general care process, medication class, information expressed in the special instruction, special instruction issue, department or staff for which special instruction was intended, and whether the error reached the patient.

Results: Almost three quarters of the special instruction reports were related to Medication (n=233 of 329, 70.8%), followed by Laboratory/Blood Bank (n=54, 16.4%), and Radiology (n=23, 7.0%). Medication classes most frequently associated with special instructions included infectious disease medications (n=51 of 230, 22.2%), antithrombotic/antithrombotic reversal agents (n=32, 13.9%), and nutritional/electrolytes/intravenous fluids (n=32, 13.9%). Nearly one quarter each of medication-related special instructions were about timing (n=58 of 233, 24.9%) and dosing (n=54, 23.2%); most about laboratory/blood bank were related to the site of the blood draw (n=33 of 54, 61.1%), and many involving radiology were related to radiology/echocardiography instructions (n=16 of 23, 69.6%).

The most frequent issues associated with special instructions were containing information contradictory to the order or other information (n=62 of 329, 18.8%); being confusing, incorrect, or used incorrectly (n=58, 17.6%); and not seen (n=25, 7.6%), not viewable (n=11, 3.3%), or instructions absent (n=11, 3.3%). In more than half of the reports, special instructions were intended for nursing staff (n=184 of 329, 55.9%), followed by pharmacy (n=49, 14.9%), radiology (n=21, 6.4%), and laboratory/blood bank (n=20, 6.1%). The error reached the patient in roughly three quarters (n=243 of 329, 73.9%) of the reports reviewed.

Conclusion: Special instructions are frequently used to provide additional context about medication orders and laboratory and radiology procedures and are often intended for nurses and pharmacists. However, these instructions can result in errors and may cause patient harm. Based on our analysis, we provide EHR design strategies and policies and protocols to address patient safety issues associated with free text to enable safer and more resilient care delivery.

Introduction

Electronic health records (EHRs) are central to care delivery, with nearly every healthcare facility in the United States using this technology.[1] EHRs are powerful tools that have digitized medicine and, in many circumstances, have provided a structured format for communicating critical information between different healthcare team members. For example, computerized provider order entry (CPOE) enables prescribers to place medication, laboratory, and radiology orders that can be electronically transmitted to other members of the healthcare team in a consistently structured format which may help reduce variability that can cause patient safety issues.[2,3] CPOE typically contains structured fields in which medication-specific information (e.g., dose, frequency, route) can be entered. Aside from CPOE, there is other EHR functionality that enables structured documentation of allergies, height, and weight. This information then serves to guide a host of services from dietary to medication dosing.

While structured fields bring standardization and consistency to how information is collected, documented, and communicated, they may be insufficient at providing the full context of what is needed for safe and effective care delivery. For example, when placing a medication order, a prescriber may wish to add information to complement the structured order, such as instructing the nurse to give a medication only if a certain condition has been met (e.g., the patient has completed hemodialysis, one hour before a procedure/test is to begin).[4] It is difficult to design EHR interfaces that provide structured fields and information categories for all the different types of information a provider may wish to communicate. For this reason, many EHR functions contain a field that enables free text so providers can communicate additional contextual information. This free-text information is known by various names in clinical practice and the research literature, including special instructions, special comments, order comments, or order instructions.

Patient safety issues have been associated with the use of free text—especially in CPOE systems—due to information that is inconsistent or contradictory with other structured parts of a CPOE order.[5-8] One study showed that 13.5% of all prescriptions with special instructions included discrepancies that could lead to adverse drug events, including underdosing, incorrect route, or ignoring dose escalation or tapering.[9] Special instructions through free-text fields may never be received if different healthcare team member roles have different levels of access to such fields, or if they are not plainly visible in the order.[10,11] Discrepancies between free-text instructions and the order they are associated with could potentially be intercepted by pharmacists at the dispensing stage when pharmacists receive the free-text information. One study found 34.3% of information about how to fill a prescription that was intended for pharmacists could have resulted in patient harm if it were missed by the pharmacist.[12] Another consequence of using free-text to complement orders is when incomplete or unclear instructions about medication usage are given to pharmacy personnel, they may make inaccurate assumptions and delete directions or rewrite them inaccurately without checking back in with the prescriber.[11] However, clarifying the order with the prescriber can cause workflow inefficiencies and delay medication delivery to the patient.[9]

One study looking at medication-related patient safety event (PSE) reports showed that an electronic medication administration display that was confusing, cluttered, or inaccurate resulted in missed special instructions (e.g., note entered by ordering provider for medication to be administered only after dialysis, but special instructions not seen by administering team), which may also contribute to errors when receiving the free-text information.[13] Issues may also arise when special instructions about laboratory orders are entered into a free-text field in the EHR order form but that information does not get transferred to the laboratory information systems interface. This issue can result in delays if laboratory offices have to call the clinician's offices for clarification, missed laboratory orders, tests performed on the wrong date, and a disruption of laboratory workflows.[14]

Developing a deeper understanding of the conditions under which free text is used to complement orders in the EHR may provide an opportunity to optimize EHR interfaces and healthcare facility processes and procedures. For example, the frequent use of free-text comments in prescriptions may suggest a lack of suitable structured functions within the EHR.[5] In this study, we seek to develop a deeper understanding of when free text is used in EHR orders through the analysis of PSE reports. Based on our analysis, we provide EHR design strategies and policies and protocols to address patient safety issues associated with free text to enable safer and more resilient care delivery.

Methods

Data Source and Selection

We analyzed PSE reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] between January 1, 2021, and December 31, 2022. All nonfederal, acute care facilities in Pennsylvania are required to report PSEs through PA-PSRS. To identify PSE reports that likely referred to safety issues connected to free-text entries and EHR ordering, we searched the free-text event details of the PSE and its other relevant free-text and structured fields with the following keywords: "special instruction(s)," "order instruction(s)," "order comment(s)," and "special

[a]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.

comment(s).” Additionally, we expanded the search to allow for up to five words between the first and second words of each (i.e., between “special” or “order” and “instruction[s]” or “comment[s]”) to capture a wider array of relevant phrasing. This search resulted in 847 reports; however, 182 (21.5%) reports were submitted by one facility.

To prevent oversampling from one facility, we randomly selected a maximum of 42 reports (5% of total reports retrieved) from each facility. Based on this sampling strategy, a total of 677 reports from 129 facilities were reviewed. Of the 677 reports reviewed, 329 (48.6%) reports were included in our analysis. Reports were included if special instructions, order instructions, order comments, or special comments were mentioned in the PSE report and the special instructions, order instructions, order comments, or special comments contributed to the safety issue. In some cases, it was not entirely clear whether the use of a term such as “special instructions” in the PSE report (e.g., “staff unaware of special instructions for transport”) referred to a free-text comment in the EHR or a more general guideline regarding the need for special handling/treatment; in these situations, we used best judgment to determine whether reports met inclusion criteria.

Coding Taxonomy and Analysis Methods

The PSE fields of “event description” and “event recommendation” were qualitatively analyzed using a grounded theory approach and additional structured report categories were analyzed for further context. Examples of structured report categories included Event Type, Event Subtype, Care Area Type, and Patient Status. Our coding taxonomies were iteratively developed.

Reports that met the inclusion criteria were further reviewed. Each report was assigned a single code for each of the criterion described below:

- General care process: Describes the care process associated with the safety issue (see **Table 1** for definitions of general care processes).
    - Medication class: If the report was categorized into the Medication category, the specific medication that was involved in the special instruction issue was identified either in the free-text description or the required PA-PSRS “medication prescribed” name field. If multiple medications were noted within one report, a primary medication was identified. A clinical expert then classified medications into a medication class (see **Table 2** for medication classes).
- Information expressed in the special instructions: Details about what the ordering provider was attempting to communicate within each general care process category (see **Table 3** for categories of information expressed under general care processes).
- Special instructions issue: Specific type of difficulty in accessing, understanding, or interpreting the special instruction (see **Table 4** for definitions of types of issues).
- Department or staff that received or was supposed to act on the special instruction: The specific healthcare staff (e.g., nurse, pharmacy) or department (e.g., laboratory/blood bank, radiology) for which special instructions were intended (see **Table 5**).
- Reached the patient: The error related to use or absence of required special instructions impacted the patient’s care.

Coding Process

A physician and human factors subject matter expert independently reviewed and coded all reports, resulting in each report being dually coded. Discrepancies were discussed until consensus was reached.

Table 1. Frequency Counts, Percentages, Definitions, and Examples of General Care Process (N=329)

Category	Frequency Count (%)	Definition	Example PSE
Medication	233 (70.8%)	Special instructions were related to medication ordering, pharmacy verification, administration, monitoring, or reconciliation.	Isosorbide mononitrate ER was ordered for oral route. Pill was crushed and given via NG tube despite order instructions stating “DO NOT CRUSH OR CHEW.”
Laboratory/ Blood Bank	54 (16.4%)	Special instructions were related to laboratory or blood bank ordering or collecting samples.	COVID swab not being ordered as rapid; however, comments being placed to have test “run as rapid,” which creates admission bed assignment delays.
Radiology	23 (7.0%)	Special instructions were related to radiology ordering or conducting of radiological exams.	Reviewed study before performing. Did not note order comments to include additional images. Patient called to return for further imaging.
Other	19 (5.8%)	Special instructions were related to other healthcare processes, such as dietary, infection precaution, and speech language pathology.	Staff member reports that he found an order discrepancy while reviewing infant feeding orders. Part of the order asked for breast milk to be fortified to 24 calories under the “additive” section but had 22 calories written in the “formula concentration with additives” and “special instructions” section. Provider notified and order was corrected to 22 calories.

Note: Details of the PA-PSRS event narratives described in the Example PSE column have been modified for readability and to preserve confidentiality.

Results

Below we describe results for the following categories of the 329 reports included in our analysis: general care process, medication class, information expressed in the special instructions, special instructions issue, who or what department received/was supposed to see or act upon the special instructions, and whether the error reached the patient.

General Care Process

About three-quarters of the special instruction reports were related to Medication (n=233 of 329, 70.8%) followed by Laboratory/Blood Bank (n=54, 16.4%), Radiology (n=23, 7.0%), and Other (n=19, 5.8%) (**Table 1**).

Medication Class

All special instruction reports in the Medication general care process explicitly stated the medication involved except three reports (N=230), and these medications were categorized into their respective medication classes. The three most frequent medication classes accounting for more than 10% of reports included infectious disease medications (n=51 of 230, 22.2%), antithrombotic/antithrombotic reversal agents (n=32, 13.9%), and nutritional/electrolytes/intravenous (IV) fluids (n=32, 13.9%). A comprehensive table of all medication classes is displayed in **Table 2** below.

Information Expressed in the Special Instructions

We analyzed information expressed in the special instructions by the general care process. In the general care process of Medication, roughly a quarter of reports reviewed were related to timing (n=58 of 233, 24.9%) and nearly another quarter were related to dosing (n=54, 23.2%). Most of Laboratory/Blood Bank special instructions information was related to confusion caused by special instructions about the catheter or location on the patient's body from which the blood was drawn (site of blood draw, n=33 of 54, 61.1%). Many Radiology issues were related to radiology/echocardiography instructions (n=16 of 23, 69.6%). About half of the Other special instructions information was related to a special diet, feeding, or NPO (i.e., nothing by mouth) status (n=9 of 19, 47.4%). A comprehensive table of special instruction information expressed by the general care process is displayed in **Table 3** below.

Special Instructions Issue

In approximately one-fifth of reports reviewed (n=62 of 329, 18.8%), the special instructions contradicted other information in the order. The second most frequent issue was special instructions being confusing, incorrect, or used incorrectly (n=58, 17.6%), followed by not seen (n=25, 7.6%), not viewable (n=11, 3.3%), and instructions absent (n=11, 3.3%). There was insufficient information to determine the specific special instructions issue in roughly half of the reports reviewed (n=162, 49.2%) (**Table 4**).

Who or What Department Received/Was Supposed to See or Act Upon the Special Instructions

Nursing (n=184 of 329, 55.9%) was the role that most frequently received or was supposed to see or act upon the special instructions, followed by pharmacy (n=49, 14.9%), radiology (n=21, 6.4%), laboratory/blood bank (n=20, 6.1%), and other hospital staff (n=12, 3.6%). There was insufficient information in 43 reports (13.1%) to determine who or what department received or was supposed to see or act upon the special instructions (**Table 5**).

Error Reached the Patient

The error reached the patient in roughly two-thirds (n=243 of 329, 73.9%) of the reports reviewed.

Table 2. Frequency Counts and Percentages of Medication Classes Related to Issues With Special Instructions (N=230)

Category	Frequency Count (%)
Infectious Disease Medications	51 (22.2%)
Antithrombotic/Antithrombotic Reversal Agents	32 (13.9%)
Nutritional/Electrolytes/IV Fluids	32 (13.9%)
Cardiovascular Agents	20 (8.7%)
Antidiabetic Agents	13 (5.7%)
Opioids	12 (5.2%)
Other	11 (4.8%)
Gastrointestinal Medications	10 (4.3%)
Behavioral Health Medications	10 (4.3%)
Systemic Corticosteroids	8 (3.5%)
Hematology/Oncology Medications	7 (3.0%)
Antiseizure Medications	5 (2.2%)
Nonopioid Analgesics	5 (2.2%)
Immunosuppressants	4 (1.7%)
Endocrine Medications	3 (1.3%)
Urology Medications	3 (1.3%)
Neurology Medications	2 (0.9%)
Vaccines	2 (0.9%)

Table 3. Frequency Counts and Percentages of Information Expressed by General Care Process

	Frequency Count (%)
Medication (n=233)	
Timing	58 (of 233, 24.9%)
Dosing	54 (23.2%)
Hold or Administration Parameters	32 (13.7%)
Monitoring Requirements	19 (8.2%)
Misc. Medication Instructions	19 (8.2%)
Do or Do Not Crush or Chew	11 (4.7%)
Rate	9 (3.9%)
Route	9 (3.9%)
Stop Date or Time	8 (3.4%)
Medication Protocol	7 (3.0%)
Discontinue	4 (1.7%)
Medication Compatibility	2 (0.9%)
Do Not Substitute	1 (0.4%)
Laboratory/Blood Bank (n=54)	
Site of Blood Draw	33 (of 54, 61.1%)
Laboratory Instructions	8 (14.8%)
Type of Lab Test	7 (13.0%)
Timing	4 (7.4%)
Number of Units of Blood	2 (3.7%)
Radiology (n=23)	
Radiology/Echocardiography Instructions	16 (of 23, 69.6%)
Timing	4 (17.4%)
Contrast Instructions	3 (13.0%)
Other (n=19)	
Special Diet/Feeding/NPO Status	9 (of 19, 47.4%)
Device Care	2 (10.5%)
Activity Orders	1 (5.3%)
Consult Request	1 (5.3%)
Equipment Detail	1 (5.3%)
Home Health Instructions	1 (5.3%)
Isolation Precautions	1 (5.3%)
Monitoring Requirements	1 (5.3%)
Patient Education	1 (5.3%)
Respiratory Care	1 (5.3%)

Note: Sum of percentages may not equal 100 due to rounding.

Table 4. Frequency Counts, Percentages, Definitions, and Examples of Special Instructions Issues (N=329)

Category	Frequency Count (%)	Definition	Example PSE
Contradictory Information	62 (18.8%)	Special instructions were entered but contradicted the order or other information.	During verification, pharmacist noted that provider ordered hydralazine 10 mg P [orally] BID [twice a day] but noted in special comments section to administer 10 mg once a day on Tuesday, Thursday, Saturday, and Sunday. Pharmacist noted that in the EHR this information would not populate correctly and the order would still populate as BID, causing a medication error. Pharmacist modified the order prior to medication administration.
Confusing, Incorrect, or Incorrect Use	58 (17.6%)	Special instructions were entered but were confusing, incorrect, or used incorrectly, or special instructions were entered and should not have been used.	Doctor entered an order for azithromycin 600 mg x 1 dose for a 3-year-old, 13 kg patient. In order comments, stated "Please give 150 mg PO now, then bottle to go, then take 75 mg PO daily for four additional days." Pharmacists were confused if this meant 600 mg total dose (six additional days of azithromycin after first dose) or standard 5-day dose. Pharmacist called to confirm, and modified order to accurately reflect dose.
Not Seen	25 (7.6%)	Special instructions were entered but were not seen, potentially because of user interface issues.	X-ray of the right knee was ordered. Technician did not notice in the ordering comments that the provider wanted a Rosenberg and patella view of the patient's knee. The patient was notified of need to return to have X-rays repeated. Patient returned two days later to have missing views completed. No harm to patient.
Not Viewable	11 (3.3%)	Special instructions were entered but were not viewable to other staff.	Patient was held overnight to have repeat CTA done at 0200 to rule out PE, but the scan was not completed. Radiology tech explained that entering a time to do an exam does not cross-over to the radiology request. Special instructions must be entered under the comments section for Radiology staff to be aware of the request.
Instructions Absent	11 (3.3%)	Special instructions should have been used but were not entered.	Patient presented to the outpatient radiology location with orders for several X-ray exams, but no specifications as to which views the provider wanted. The technologist called the ordering provider to get the necessary details, that should have been listed in the order comments. The correct exams were completed with no harm to the patient.
Insufficient Information	162 (49.2%)	The report describes general information related to special instruction issues.	Vancomycin trough level ordered as a stat timed for 9/15 at 1400 with special instructions to draw prior to 1500 vancomycin dose. Trough level was drawn at 0921, leading to an inaccurate result and the need to reorder a trough level.

Note: Details of the PA-PSRS event narratives described in the Example PSE column have been modified for readability and to preserve confidentiality. Sum of percentages may not equal 100 due to rounding.

Table 5. Frequency Counts, Percentages, Definitions, and Examples of Who or What Department Received or Was Supposed to See or Act Upon the Special Instructions (N=329)

Category	Frequency Count (%)	Definition	Example PSE
Nursing	184 (55.9%)	Special instructions were supposed to be received, seen, and/or acted upon by nursing.	Patient was ordered Suprep prior to colonoscopy. Doctor had specific orders under special instructions which read "Please give suprep as soon as possible on arrival to the floor. Give 2nd dose 6–8 hours later. Ignore Pharmacy Directions." Nursing followed Pharmacy directions and second bowel prep was not started until morning, which caused a delay in care for the patient.
Pharmacy	49 (14.9%)	Special instructions were supposed to be received, seen, and/or acted upon by pharmacy, including pharmacists, pharmacy technicians, and other pharmacy staff.	Admitting provider ordered Tapazole 10 mg frequency as "daily" with admin instructions of "Takes M,W,F." After calling outpatient pharmacy to confirm dose, verifying pharmacist changed frequency to "User specific - Mon, Wed, Fri." Adding in order comments MWF is not appropriate, as the order would have been verified as daily for nursing to administer.
Radiology	21 (6.4%)	Special instructions were supposed to be received, seen, and/or acted upon by radiology, including radiologists, radiology technicians, and other radiology staff.	AP C-spine view performed but was not requested. Technologist did not see comments under "reason for exam" and under "order comments." Also, "Ordering Comments" area on patient details area of technologist worklist was empty; therefore, no note populated in order comment column on technologist worklist.
Laboratory/ Blood Bank	20 (6.1%)	Special instructions were supposed to be received, seen, and/or acted upon by laboratory/blood bank, including pathologists, laboratory technicians, and other laboratory staff.	A wound culture swab was submitted on an outpatient with the source as "nose." No additional information was provided in the order comments. When the specimen was received into Microbiology, it was canceled as an inappropriate source per protocol but was not investigated prior to canceling.
Other Hospital Staff	12 (3.6%)	Special instructions were supposed to be received, seen, and/or acted upon by other hospital staff, including roles such as dieticians and speech language pathologists.	The patient was ordered a renal pureed diet per speech therapy's recommendations for patient to consume pureed foods. Patient had been receiving regular consistency foods even though "pureed" was included in the diet order. Staff member reviewed the chart again and noticed that the error was within the chart interface to the kitchen. The "puree" indication in the diet order was typed in the free-text special instructions box, which does not interface to the kitchen and therefore was missed. Speech and the resident were notified.
Insufficient Information	43 (13.1%)	The special instructions report does not specify what role or department was supposed to receive, see, and/or act upon the instructions.	Following treatment, Occupational Therapy noted order for splint and sling at all times. This order was entered in the comment section of the device care order instead of the special instructions and so did not flow to the precaution.

Note: Details of the PA-PSRS event narratives described in the Example PSE column have been modified for readability and to preserve confidentiality.

Discussion

Special instructions are frequently used to add context about orders in the EHR but can be associated with patient safety precursor and harm events. We analyzed PSE reports related to special instructions to investigate the types and frequency of medical care processes associated with special instructions, and to understand how their use contributes to patient safety issues. Our analyses provide important insights to guide the use of special instructions and potential redesign of EHR functionality.

Special instructions were most frequently associated with medication orders (specifically dose and timing of the medications) and laboratory orders (specifying the site of blood draws). A recent systematic review found that 9% of pooled patient incidence records about medication errors were associated with harm.[16] Fifty-eight percent of these medication errors occurred at the stage of medication prescribing. Although CPOE can help in reducing some types of medication errors, such errors remain prevalent despite the adoption of electronic prescribing, dispensing, and administration.[17] Further, many studies on medication errors typically analyze the information in structured fields such as dose, time, and route, and potentially do not count the contribution of confusion about information contained in free-text fields such as special instructions to the overall medication error rate. In fact, special instructions are often used as a workaround to give medication directions that are not present in current structured fields on the CPOE.[18-20] This workaround suggests an opportunity to reevaluate the current design of medication and laboratory orders to add fields to specify the context provided by special instructions.

It was noteworthy that the special instructions in almost a fifth of the reports we reviewed contradicted the information contained in other places in the order. This contradiction has also been found in previous literature, contributing to confusion in interpreting special instructions.[21] In addition, special instructions were also associated with other problems, including containing incorrect information and not being viewable or visible, which also supports previous literature about usability challenges of special instructions.[22] Nurses were the intended recipients of over half of the special instructions, followed by pharmacists. Previous research already indicates the importance of physician-nurse communication on timely and accurate administration of the care plan, as well as challenges in using special instructions to communicate many aspects of medications and the care plan.[20,23]

Taken together, these findings suggest that most special instructions may be written by prescribers to alter or supplement the available medication order fields in CPOE and to try to alert nurses and pharmacists to medication administration and dispensing that is different from usual practice. The ubiquitous use of special instructions as a workaround is an indication of a system failure related to communication. Special instructions may also reflect poor usability of CPOE to match clinical workflows, specifically limited capabilities of CPOE to adjust to dynamic changes in the patient's status or medication availability that may ultimately influence medication administration, or challenges that healthcare teams face in communicating with each other about the patient's medications and care plan.[22]

Strategies to Address Special Instruction Patient Safety Issues

There are several strategies that follow from our analysis of PSE reports. These strategies can broadly be described as EHR-based strategies and policy/protocol-based strategies.

EHR-Based Strategies

Assess whether free text could be transitioned into creation of new structured fields: Facilities should routinely investigate the information content of special instructions (e.g., medications, labs, blood tests), and consider adding new structured options to the EHR to integrate this information into the ordering workflow and/or clearly describing standard organizational processes for handling situations in which structured fields do not support ordering.

Determine whether free text should be used if an alternate structured field already exists: The design of EHRs may make it difficult for physicians to find structured fields they intend to use to input specific types of information. Facilities should review the label of existing structured fields to ensure they are easy to understand and find so that structured fields are used as designed.

Simplify ordering interfaces: Some EHRs contain two or more free-text entry fields and the purpose of these fields may be unclear to the ordering provider. Facilities should consider removing unnecessary fields and clearly explaining the purpose of different types of free-text entry fields so providers know which fields to use for what purpose.

Evaluate the entire ordering process: There were several special instruction issues associated with the nurse or pharmacist not seeing the special instructions or the information not being available in their view of the EHR. Facilities should conduct end-to-end usability testing which entails analyzing the workflow of ordering from the point of order entry by the clinician to execution of the order. Each EHR interface involved in this process across all stakeholders should be analyzed to determine whether critical ordering, dispensing, and administration information is appropriately available.

The following principles should be used to guide this type of testing:

- Providers should be able to see which team members will be able to see the special instructions.
- When special instructions are used, there should be an indicator that they are associated with an order.
- Special instructions should be easily accessible and viewable (e.g., on the main screen or within a click).
- The information referenced by the special instructions should be presented concurrently with the special instructions on the screen to avoid memory burden of remembering the details from the instructions.

Policy/Protocol-Based Strategies

Develop shared awareness and expectations for when special instructions should not be used: Facilities should develop protocols regarding conditions for which special instructions should not be used.

One example is clinical nuances that require back-and-forth communication between different members of the healthcare team (e.g., deciding when medications should be administered relative to time of hemodialysis). These protocols should be shared with all members of the care team, especially physicians, nurses, and pharmacists, to ensure shared awareness.

Establish synchronous or near-synchronous communication pathways integrated into the EHR: Facilities should institute protocols to guide communication about when electronic, asynchronous communication should be converted into real-time synchronous or near-synchronous communication. For example, there should be pathways in the EHR to quickly obtain feedback or clarification about unclear special instructions for time-sensitive or high-risk orders.

Establish protocols about details included in distinct free-text fields: There may be instances in which multiple free-text fields are necessary for each order. In cases where the use of multiple free-text fields is warranted, facilities should establish clear protocols about what types of information should be included in each field and ensure that data are distinct from each other. In addition, facilities should also establish protocols about which members of the healthcare team can see which types of special instructions.

Limitations

We examined PSE reports which represent a single data source from one state (Pennsylvania), so results may not be generalizable across other data types or states. In addition, because of the limited descriptive information in the PSE reports, we were unable to understand the larger context of the error reported. In some cases, the special instruction may refer to a certain laboratory or blood bank specimen that needed special treatment (e.g., during transport); however, our analysis did not exclude these cases. Finally, we did not follow up with facilities to gather additional information about each specific report.

Conclusion

Special instructions are often intended for nurses and pharmacists, and are frequently used to provide additional context to guide medication administration and dispensing, as well as laboratory and radiology procedures. However, these instructions can lead to errors because they can be contradictory to the medication order, confusing or incorrect, or not be viewable, and may result in patient harm. Human factors principles can be used to design EHR-based strategies and protocols to improve the safety of special instructions.

Notes

This study was approved by the MedStar Health Research Institute institutional review board.

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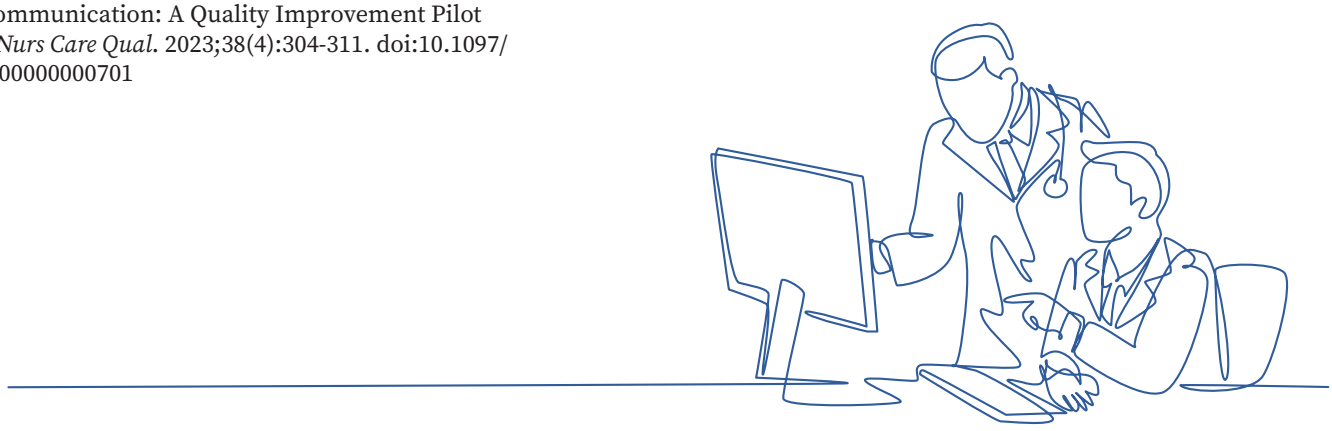

Unmasking the Contributing Factors to **Oxygen Disruption Events** in the Inpatient Environment and Emergency Department

Keywords: oxygen therapy, human factors, patient safety

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Abstract

Background: Medical oxygen is frequently used in healthcare settings. Challenges with oxygen disruption, such as oxygen tanks running out due to communication issues between staff or tanks not being set up properly, have been noted in the limited existing literature. Challenges and patient safety issues associated with oxygen disruption persist. Utilizing a human factors approach, our study aims to understand the contributing factors and context of oxygen disruption–related patient safety event reports in the inpatient setting and provide person-based and system-based solutions.

Methods: Through keyword matching, we identified and then qualitatively analyzed 298 patient safety event reports to understand the factors contributing to oxygen disruption, patient location when the oxygen disruptions occurred, hand-off breakdowns by healthcare team member role, and whether high supplemental oxygen was being administered.

Results: The most frequent contributing factor to oxygen disruption was the patient not being transferred to another source of oxygen (n=135 of 298, 45.3%), followed by tank found empty (n=107, 35.9%), patient connected to a functioning oxygen source, no oxygen flowing (n=25, 8.4%), oxygen delivery device malfunction (n=22, 7.4%), and no oxygen available (n=9, 3.0%). Over one-third of all oxygen disruption events occurred on the unit where the patient was admitted (n=109 of 298, 36.6%). Roughly 40% of reports involved a hand-off breakdown (n=123 of 298, 41.3%) and the most frequent breakdowns occurred between a nurse and a patient transporter (n=47 of 123, 38.2%). Almost one quarter of reports involved a patient with high supplemental oxygen requirements (n=74 of 298, 24.8%).

Conclusion: Oxygen disruption events can have serious patient safety implications. Many of the oxygen disruption events we reviewed occurred due to lack of situational awareness and hand-off breakdowns. Combining person-based solutions, such as paper-based tools and checklists, with system-based solutions involving central monitoring and supervisory systems may help reduce the risk of oxygen disruption events.

Introduction

Medical oxygen has been identified by the World Health Organization as an essential medicine used in the treatment of patients across the entire spectrum of healthcare.[1] Its administration as a medical intervention has become one of the most frequently employed treatments for patients experiencing acute health challenges. Given the vital role of oxygen therapy in patient care, oxygen use in hospital settings has been the subject of healthcare literature for several decades. Key focus areas within the hospital setting include oxygen use in acute care and other inpatient care areas, oxygen therapy guidance, and delivery systems and routes of administration.[2-4]

Literature concerning patient safety has focused on oxygen prescribing practices and evolving challenges within oxygen therapy and resultant harm, as well as the enhancement of oxygen administration practices and oxygen delivery systems.[3,5-14] Within the literature identifying issues associated with oxygen therapy, issues related to inappropriate administration of oxygen, improper dosing leading to hypoxia and hyperoxia, and oxygen therapy interruptions have been described.[3,5,8,13,15,16]

Disruption in oxygen therapy is mentioned in the existing literature surrounding intrahospital patient transport events. The literature describes challenges with oxygen therapy interruptions, patient oxygen desaturation due to communication issues between staff, oxygen tank depletion, tanks not being turned on, and oxygen flow set below patient needs.[15-18] While oxygen tank depletion is identified as a concern, this safety risk is the subject of very little literature. In a *Pennsylvania Patient Safety Advisory* article from the Patient Safety Authority (PSA) on supplemental oxygen for intrahospital transport, the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] was queried for events from a 10-year period from January 2005 through December 2014. Analysts identified 393 oxygen tank–related events, 360 of which were associated with unintended interruptions in the administration or management of oxygen. Among events involving interruption, 303 events were associated with depleted oxygen tanks.[16] In a PSA safety column discussing the standardization of tasks involving supplemental oxygen to prevent therapy disruptions during transport, PA-PSRS events were presented indicating oxygen disruptions due to tanks emptying, along with oxygen sources not being turned on and disconnected oxygen tubing.[15]

The majority of proposed solutions are primarily tailored towards mitigating intrahospital transport events overall, providing some guidance to address the occurrence of oxygen-related events involving interruption and tank depletion. Specifically, proposed solutions have included standardizing hand-off communication and procedures, education of transport personnel, and use of transport checklists.[15-17,19-21] Solutions specific to the maintenance of oxygen during transport include training transport personnel in oxygen use, conducting checks of oxygen tank levels prior to transport, performing calculations using calculator apps, formulas or lookup tables, and use of a transport form providing details on the available minutes within a portable oxygen cylinder.[15,16,19-21]

As limited literature focuses on oxygen disruption and oxygen tank depletion issues, in this study we sought to identify factors contributing to disruption of supplemental oxygen in inpatient settings. Further, we build upon previously proposed solutions, which tend to be person-based, and propose human factors–based system solutions that may be more durable.

Methods

We analyzed patient safety event (PSE) reports submitted to PA-PSRS between January 1, 2022, and July 31, 2023[a]. All nonfederal, acute care facilities in Pennsylvania are required to report patient safety events through PA-PSRS. We identified potentially relevant reports by searching the free-text fields of each report for at least one of the following keywords or keyword stems: "oxy tank," "oxy canister," "O2 tank," and "O2 canister." A total of 528 reports were identified for initial manual review. The reports retrieved from keyword matching were further constrained. Reports were included in the analysis if they met all of the following criteria:

- The event occurred in the inpatient environment or the emergency department (ED)
    - The PA-PSRS field Care Area Type and the context of the report were utilized to determine where events occurred. There were 28 reports that occurred in the ED that were assigned the PA-PSRS Patient Status of Unknown (n=11 of 28) or Outpatient (n=17 of 28). They were reassigned as Inpatient for the purpose of analysis.
- There were an additional 17 reports of events that occurred in care areas other than the ED that were assigned the PA-PSRS Patient Status of Unknown (n=14 of 17) or Outpatient (n=3 of 17). From the context of the report, it was clear that these events had occurred in the inpatient environment. They were reassigned the Patient Status of Inpatient and included for analysis.
- The report involved the use of supplemental oxygen provided by the healthcare facility via tank or wall
- The patient used a nasal cannula, high flow nasal cannula, non-rebreather mask, continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), ventilator, or extracorporeal membrane oxygenation (ECMO) to receive supplemental oxygen
- The patient's flow of supplemental oxygen was disrupted (i.e., oxygen temporarily ceased to flow to the patient)

Reports were excluded from the analysis if:

- The report described an issue with supplemental oxygen equipment other than disrupted airflow (e.g., an oxygen tank fell on a patient's foot)
- The patient was using oxygen from home

[a]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).[29] All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

- The patient was in respiratory distress not due to disrupted airflow from supplemental oxygen
- The report described oxygen tank delivery or education at discharge
- The report described an oxygen tank that ran low but was caught before airflow was disrupted

For the reports that met the inclusion criteria, the structured fields of Event Classification (incident[b] or serious event[c]), and Care Area Group were analyzed. Care Area Group indicates the broader care area group associated with the reported PSE based on the Care Area Type assigned by the reporting facility. The event description free-text field was qualitatively analyzed using a grounded theory approach. Using this approach, researchers analyze existing data to form theories and hypotheses. Grounded theory is an inductive approach to research as opposed to a deductive approach, which formulates a hypothesis and then analyzes data to prove or disprove it.[23]

The coding taxonomy was iteratively developed by two human factors subject matter experts and a clinician. The taxonomy definitions and examples are described in **Tables 1–4**. For purposes of coding, we defined wall oxygen as the patient receiving oxygen via tubing or device connected to a source built into the wall. Oxygen tank refers to the patient receiving oxygen via tubing or device connected to a portable pressurized oxygen tank. Reports were independently reviewed and coded by two researchers. In instances where the coders did not agree, the report was reviewed jointly by the coders and discussed to arrive at a final consensus.

We first categorized each report into one of five general contributing factors to the oxygen disruption (**Table 1**). While there may be more than one factor contributing to an oxygen disruption, a single contributing factor was assigned to each report based on what the coders interpreted as the primary reason why the patient was temporarily deprived of supplemental oxygen.

Each report was also categorized into one of five patient locations on or off unit to better understand the context for when and where

Table 1. Frequency Counts, Percentages, Definitions, and Examples of Primary Contributing Factors to Oxygen Disruption, N=298

Primary Contributing Factors	Frequency Count (%)	Definition	Example
Patient not transferred to another source of oxygen	135 (45.3%)	The report described a patient who should have been transferred to wall or tank oxygen but was not.	A nurse went to a patient's room after they returned from an off-unit procedure. Per protocol, patients should be transferred to wall oxygen when they are returned to their room. The nurse found the patient was still hooked up to an oxygen tank instead of being transferred back to the wall oxygen. Due to the length of time the patient was connected to the tank, the tank was empty when the nurse discovered the patient.
Tank found empty	107 (35.9%)	The report described a patient who was connected to an oxygen tank that was discovered to have run out of oxygen.	A patient was transported to an off-unit procedure. Upon arrival the technician discovered that the patient's oxygen tank was empty.
Patient connected to functioning oxygen source, no oxygen flowing	25 (8.4%)	The report described a patient who was connected to wall or tank oxygen, but oxygen was not flowing for a reason other than a device malfunction (e.g., the wall flow meter was not turned on).	A patient arrived to an off-unit procedure connected to an oxygen tank. The technician discovered that the tank dial was set to 0 liters/minute.
Oxygen delivery device malfunction	22 (7.4%)	The report described a break or malfunction involving a device or part of a device that delivers supplemental oxygen (e.g., wall oxygen connector, oxygen tank, connective tubing, or ventilator).	A patient required an oxygen tank to be transported to an off-unit procedure. The tank liter flow did not show up on the digital display. A new tank had to be found.
No oxygen available	9 (3.0%)	The report described a patient who required an oxygen tank or a connection to wall oxygen but there was none available.	A patient required an oxygen tank to be transported to a new unit. There were no oxygen tanks available in the medical supply closet and the nurse had to leave the patient without oxygen to find one.

Note: Details of the PA-PSRS event narratives described in the Example column have been modified for readability and to preserve confidentiality.

[b]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 health care services to the patient."[22]

[c]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 unanticipated injury requiring the delivery of additional health care services to the patient."[22]

oxygen disruptions occurred (**Table 2**). If sufficient information was provided in the report, reports were then categorized into one of six hand-off breakdowns by healthcare team member roles (**Table 3**). Finally, for each report it was noted if the patient had high supplemental oxygen needs (**Table 4**).

Results

Of the 528 reports reviewed, a total of 298 (56.4%) reports met the inclusion criteria. These 298 reports served as the basis for all further analyses. Of the 298 reports, nearly all were incidents (n=296 of 298, 99.3%) and there were two serious events (0.7%). The three care area groups where oxygen disruption events occurred most frequently were the Emergency Department (n=86 of 298, 28.9%), Imaging/Diagnostic (n=51, 17.1%), and Medical/Surgical (n=37, 12.4%).

The most frequent contributing factor to oxygen disruption was the patient not being transferred to another source of oxygen when they should have been (n=135 of 298, 45.3%). The second most frequent contributing factor to oxygen disruption was tank found empty (n=107, 35.9%) followed by patient connected to functioning oxygen source, no oxygen flowing (n=25, 8.4%), oxygen delivery device malfunction (n=22, 7.4%), and no oxygen available (n=9, 3.0%). Frequency counts and percentages for primary contributing factors are shown in **Table 1**.

Over one-third of all reports occurred on the unit where the patient was admitted (n=109 of 298, 36.6%). Approximately one quarter of reports occurred upon the patient's return from off-unit care (n=66, 22.1%), and one-fifth of reports occurred upon the patient's arrival to off-unit care (n=53, 17.8%). Admission to a new unit and during off-unit care were the least frequently occurring patient locations to be impacted by oxygen disruption (n=38, 12.8% and n=32, 10.7%, respectively). Definitions and examples of patient location where the oxygen disruption occurred are shown in **Table 2**.

Because the patient not being transferred to another source of oxygen and the tank being found empty were the most frequent contributing factors to oxygen disruptions, these reports were further analyzed to understand them within the context of the location where the disruption occurred. Of the reports that involved a patient not being transferred to another source of oxygen when they should have been, over one-third of these

Table 2. Frequency Counts, Percentages, Definitions, and Examples of Patient Location Where the Oxygen Disruption Occurred, N=298

Patient Location	Frequency Count (%)	Definition	Example
On unit	109 (36.6%)	The report described an issue with oxygen disruption on the patient's unit where they were admitted (including the ED).	A respiratory therapist conducted a spot check of a patient's oxygen while the patient sat in their wheelchair in their room. The respiratory therapist found the wall flow meter was turned off and no oxygen was flowing.
Return from off-unit care	66 (22.1%)	The report described an issue with oxygen disruption upon the patient's return to the unit where they were admitted after completing a procedure, treatment, or test.	A patient was returned from radiology but the nurse was unaware that the patient had come back. The patient was not transferred back to wall oxygen and the nurse found that their oxygen tank had run out.
Arrival to off-unit care	53 (17.8%)	The report described an issue with oxygen disruption upon the patient's arrival to a procedure, treatment, or test taking place off the unit where they were admitted.	A patient arrived to radiology and as they were about to be taken to X-ray the technician discovered that their oxygen tank was empty.
Admission to new unit	38 (12.8%)	The report described an issue with oxygen disruption during the patient's transfer from one unit to another (e.g., the patient was transferred from the ED to the medical/surgical unit).	A patient was brought to the intensive care unit (ICU) from the ED without a respiratory therapist escort. When the patient arrived on the unit it was found that their oxygen tank was empty.
During off-unit care	32 (10.7%)	The report described an issue with oxygen disruption during a procedure, treatment, or test that the patient was receiving off the unit where they were admitted, or mid-transfer if it was not specified where the patient was being transferred to.	A patient required a high level of supplemental oxygen. There was no wall oxygen available while they were in X-ray and their oxygen tank ran out.

Note: Details of the PA-PSRS event narratives described in the Example column have been modified for readability and to preserve confidentiality.

Table 3. Frequency Counts, Percentages, Definitions, and Examples of Hand-Off Breakdowns by Healthcare Team Member Roles, N=123

Healthcare Team Member Roles	Frequency Count (%)	Definition	Example
Nurse/Patient Transporter	47 (38.2%)	The report involved a breakdown in communication or hand-off protocol between a nurse and a patient transporter.	A patient was returned to their room after a computed tomography (CT) scan by patient transport. The nurse was not aware and the transporter did not hook the patient up to wall oxygen.
Unknown Roles	32 (26.0%)	The report involved a breakdown in communication or hand-off protocol but there was insufficient information to determine the roles of the team members involved.	A patient arrived to a new unit with a nasal cannula in their nose but was not connected to the oxygen tank that was with them.
Nurse/ Technician	20 (16.3%)	The report involved a breakdown in communication or hand-off protocol between a nurse and the technician responsible for the patient's care during an off-unit procedure, treatment, or test. If the report described a patient undergoing an off-unit procedure, it was inferred that the person responsible for the patient was a technician unless explicitly stated otherwise.	A patient was transported back to their room after a CT by the CT technician. The technician did not connect the patient to wall oxygen and their oxygen tank ran out.
Nurse/Nurse	11 (8.9%)	The report involved a breakdown in communication or hand-off protocol between a nurse and another nurse that assumed responsibility for their care. This could be as a result of the patient's transfer to another unit or because the patient's primary nurse was unavailable.	A patient was transported to a new unit. The receiving nurse was given a report that the patient was supposed to be on oxygen but the patient arrived without any supplementary oxygen equipment.
Nurse/Therapists	11 (8.9%)	The report involved a breakdown in communication or hand-off protocol between a nurse and a physical, occupational, speech, or respiratory therapist.	A patient was transported to the ICU by a nurse without an RT escort to manage their BiPAP. The RT checked the patient and saw that the patient's oxygen tank was empty.
Patient Transporter/ Technician	2 (1.6%)	The report involved a breakdown in communication or hand-off protocol between a patient transporter and the technician responsible for the patient's care during an off-unit procedure, treatment, or test.	Patient transport brought the patient to CT. The technician was unaware of the patient's arrival and the patient's oxygen tank ran out.

Note: Details of the PA-PSRS event narratives described in the Example column have been modified for readability and to preserve confidentiality.
Sum of percentages may not equal 100 due to rounding.

Table 4. Frequency Counts, Percentages, Definitions, and Examples of High Supplemental Oxygen Requirements, N=298

High Supplemental Oxygen Requirements	Frequency Count (%)	Definition	Example
Yes	74 (24.8%)	The report described a patient who was on more than 6 liters of oxygen via nasal cannula or that the patient was utilizing a device indicative of their need for high levels of supplemental oxygen, including high flow nasal cannula, non-rebreather mask, CPAP, BiPAP, or ventilator.	A patient was transported to an off unit procedure on 10 liters of oxygen. When the patient arrived at the procedure it was discovered that the patient's tank had run out.
No/Unknown	224 (75.2%)	The report described a patient who was on 6 liters or less of oxygen via nasal cannula or the oxygen requirement was not noted.	The patient arrived to physical therapy in the gym and the oxygen tank was empty. Pulse oxygen was 88% on room air. Patient was placed on 4 liters and recovered to 94% within 30 seconds.

Note: Details of the PA-PSRS event narratives described in the Example column have been modified for readability and to preserve confidentiality.

occurred upon the patient's return from off-unit care (n=52 of 135, 38.5%). Of the reports that involved the patient's oxygen tank being found empty, over one-third of these occurred while the patient was on their unit (n=42 of 107, 39.3%).

Over one-third of all reports reviewed involved a hand-off breakdown (n=123 of 298, 41.3%). Frequency counts and percentages of hand-off breakdowns by healthcare team member role are shown in **Table 3**.

Because the patient not being transferred to another source of oxygen and the tank being found empty were the most frequent contributing factors to oxygen disruptions, these reports were further analyzed to understand them within the context of hand-off breakdowns. The majority of the reports that involved a patient not being transferred to another source of oxygen involved a hand-off breakdown (n=87 of 135, 64.4%). Of the reports that involved the patient's oxygen tank being found empty, over one-fifth of these reports involved a hand-off breakdown (n=24 of 107, 22.4%).

One quarter of reports reviewed involved a patient with high supplemental oxygen requirements (n=74 of 298, 24.8%). Frequency counts and percentages of high supplemental oxygen requirements are shown in **Table 4**.

Discussion

Supplemental oxygen is a life-saving medication, yet limited literature exists studying the nature of oxygen disruptions in the inpatient environment. The literature that does exist has identified oxygen tanks running empty and patients being transferred within the hospital as major factors contributing to safety events. Our findings support the literature on this topic and further identify that patients not being transferred to another source of oxygen when they should be is the most frequent contributing factor to oxygen disruptions, followed by tanks being found empty.

When thinking about how to solve the safety issues identified related to oxygen disruptions and developing interventions, there are at least two important human factors concepts for consideration. The first is the concept of situational awareness, which is one's ability to perceive, understand, and respond to the changing environment.[24] Shared situational awareness is a team's ability to have the same understanding of the environment. If a patient is picked up by a transporter and dropped off with a radiology technician, there is ambiguity of when the patient stops being the responsibility of the transporter and starts being the responsibility of the radiology technician. Therefore, there is also ambiguity of who is responsible for connecting and disconnecting the patient from their oxygen source. To mitigate this risk requires a high level of individual and shared situational awareness.

The second concept is that humans have limited cognitive resources and these resources are stretched when complex and simultaneous tasks, such as knowing the oxygen level in the tank, monitoring the patient, and performing other job duties, come into play. The design of most oxygen tanks, the processes needed for healthcare workers to manage them, and the patient's oxygen flow require a high level of cognitive resources. Calculating the amount of oxygen in the tank even without all the other interruptions and simultaneous tasks would be difficult and requires extensive working memory load. Reducing the cognitive burden is critical to addressing the underlying patient safety issues. These concepts are important to consider when designing any kind of intervention to address oxygen disruption issues.

Addressing these oxygen-related patient safety issues, with an emphasis on situational awareness and cognitive burden, will require both person-based and system-based solutions. Person-based solutions typically focus on individual training and behavior change, while system-based solutions focus on improvements to the overall work system.[25] Person-based solutions tend be less expensive to implement but are less durable, while system-based solutions tend to be more expensive and more durable.[26]

Person-Based Solutions: Enhancing Oxygen Delivery Protocols

The existing literature recommends interventions that are more person-based and focused on improving hand-off communication.[16,1,20,21] Additional person-based interventions include:

- *Clarify the responsibilities of the entire care team during hand-offs (e.g., nurses, transporters, procedure technicians, and therapists):* Hand-off breakdowns occurred in 41.3% of reports reviewed. Facilities should review their protocols associated with hand-offs. The protocol should include the specific tasks expected of each role in relation to preparing the patient to be transported off the unit and when the patient is returned to the unit (e.g., the nurse must complete necessary paperwork, check patient's oxygen tank, and have face-to-face communication with the transporter, while the transporter must fetch the patient's oxygen tank, have face-to-face communication with the nurse, and reconnect the patient to the wall when returning the patient to their room). Ensure that any protocol includes whether the staff member is expected to connect or disconnect the patient from their oxygen source (e.g., is the transporter expected to connect the patient to wall oxygen after returning the patient to their room?). If no protocol exists, consider involving frontline staff to clearly define roles in collaboration with each other.
- *Conduct oxygen rounds in the ED and imaging:* Oxygen disruption events occurred most frequently in the Emergency Department (n=86 of 298, 28.9%) and Imaging/Diagnostic (n=51, 17.1%). In both locations, patients may be expected to wait for long periods of time before receiving individualized attention. Wait times may be unpredictable and wall oxygen may not always be available, which puts patients on oxygen tanks at increased risk of the tank running out. Conducting rounds to specifically check oxygen tank levels while patients are awaiting care would increase staff's situational awareness and may catch patients whose tanks are close to emptying before their flow of oxygen is disrupted or who have not been transferred to another source of oxygen when they should be.
- *Evaluate the design of oxygen delivery devices for usability when procuring new products:* A small number of reports (n=25 of 298, 8.4%) involved an oxygen disruption in which the patient was connected to working supplemental oxygen, but the oxygen did not flow. For example, a patient was connected to a working oxygen tank, but the dial was not turned and therefore oxygen did not flow. While there was insufficient information in the reports to determine to what extent the

usability of the supplemental oxygen devices impacted these events, it is possible that design-related issues may be misattributed to user error and not accurately reported. It is worth considering the usability of supplemental oxygen products before implementation. For example, when considering the procurement of new oxygen tanks, the legibility of the gauge, the volume of the alarm, and the intuitiveness of the markings on the dial should be evaluated.

A System-Based Solution: Supervisory Control for Oxygen Tank Monitoring

One potential system-based solution is to develop a supervisory control structure to address oxygen tank depletion. Supervisory control is a process used to monitor different components that may be distributed across a larger work system.[27] The standard process of a supervisory system begins with the communication process, with field devices sending their data to the central software core responsible for distributing and managing data flow to various modules until it is presented to the system operator in the desired format. This format allows the operator to monitor the status and progress of the devices.[28] A concrete example of a supervisory control structure in healthcare is centralized telemetry monitoring for patients who are at risk for cardiac arrythmias. Centralized telemetry has been found to reduce the risk of alarm fatigue for the on-site care team while maintaining a safe level of detection of cardiac rhythm changes.[29] While centralized monitoring presents its own challenges with visual fatigue and attentiveness, the benefit of a centralized team that is charged with supervising is that it can be highly specialized and focused specifically on the task of monitoring.

Currently, supervisory systems are sometimes used to monitor oxygen tank supply and location, but there is limited technology developed to monitor oxygen tank levels. The technology that is available to monitor oxygen tank levels appears to be designed for single tanks and is typically for home use. A more robust solution for the future state of oxygen safety in the inpatient environment is to design a supervisory system that monitors individual tank oxygen levels (e.g., pounds per square inch, rate of oxygen flow, and likely time until empty) and tank location, and sends a message to a centralized display that is actively monitored. When an individual tank is near emptying, a message would be generated indicating the tank's specific location and how much time is left before the tank runs out. The patient's care team member could be notified if an issue is detected. It may also be beneficial to provide notifications to the patients themselves so that those who are able can advocate for their own care and practice the skills they may need to monitor personal use of oxygen at home.

Limitations

We examined PSE reports which represent a single data source from one state (Pennsylvania), so results may not be generalizable across other data types or states. Also, despite mandatory reporting laws in Pennsylvania, reported events may not represent all events that occurred. In addition, due to limited descriptive information in some PSE reports, we were unable to understand the larger context of the error reported, and we did not follow up with facilities to gather additional information about each report. Finally, our keyword search may have limited the number of reports that fit our inclusion criteria.

Conclusion

Oxygen disruptions frequently occur due to lack of situational awareness and hand-off breakdowns. Existing solutions include improving hand-off communications and providing paper-based tools and checklists. Drawing on the concept of central monitoring in healthcare and supervisory systems in human factors may provide more durable, technology-based solutions to prevent oxygen disruptions and reduce harm to patients. As a next step, clinical, patient safety, and information systems leadership should be engaged to assess what existing technology can be leveraged, what new technology must be acquired or developed, and whether to design a central monitoring workflow. Additionally, patient safety and supply chain professionals should consider working with oxygen tank vendors and policy leaders to develop standards for an optimal oxygen tank design.

Note: This study was approved by the MedStar Health Research Institute institutional review board.

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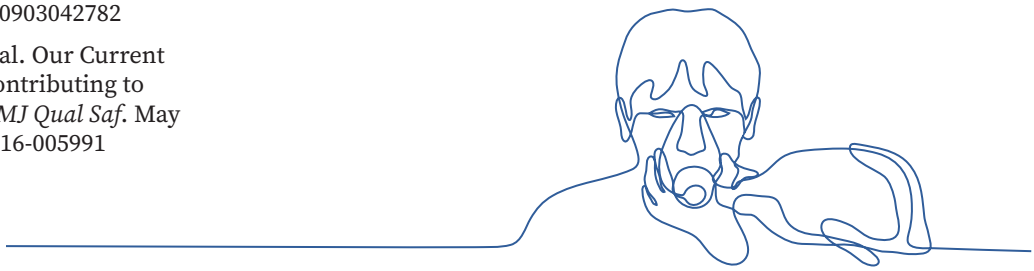

Risk Factors for Wrong-Site Surgery: A Study of 1,166 Reports of Informed Consent and Schedule Errors

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Abstract

Background: The accuracy of informed consent and procedural schedule are important components in a process for preventing wrong-site surgery.

Methods: In our study of a four-year period, we used the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to explore the occurrence of consent and/or schedule errors at all licensed hospitals and ambulatory surgical facilities (ASFs) in Pennsylvania. We also evaluated the reports for consent and schedule error subtypes: side, procedure, site, and patient.

Results: Over a four-year period, 1,166 event reports described a consent and/or schedule error, and 86% of the reports were from hospitals and 14% were from ASFs. Among the 1,166 reports, 56% described a schedule error, 34% had a consent error, and 10% involved both error types. In the sample of reports, the frequency of error subtypes were ranked in the following sequence: side (69%), procedure (24%), site (4%), and patient (3%). The analysis also revealed similarities and differences in the distribution of error types and subtypes across hospitals and ASFs.

Conclusions: Based on the results, it is evident that consent and schedule errors are issues across many healthcare facilities. The findings by error subtype (side, procedure, site, patient) show some similarity in distribution with previous studies of wrong-site surgery events. We recommend that readers review **Table 4** and **Table 5** for a brief literature review of risk factors for consent and schedule errors and strategies for preventing and detecting the occurrence of those errors, respectively.

Introduction

Informed consent documents and procedural schedules, in combination with other sources of information, are commonly used by surgical teams to plan for and verify the accuracy of the planned procedure.[1-4] Numerous studies and investigations have shown that the accuracy of a consent document and the procedural schedule are critical components to preventing a wrong-site surgery.[1,5-10]

Previous studies explored the frequency and/or rates of consent or schedule errors,[1,2,5-7,11,13,21-23] but we were unable to identify any that measured the occurrence of both consent and schedule errors, error subtypes (e.g., side, procedure, site, and patient), and across a large sample of healthcare facilities. Based on communication with surgical services staff at hospitals and ambulatory surgical facilities (ASFs) in Pennsylvania, consent and schedule errors are a common and ongoing issue.

The purpose of this study was to use the Pennsylvania Patient Safety Reporting System (PA-PSRS) database[a], which receives event reports from all licensed hospitals and ASFs in Pennsylvania, to explore the occurrence of consent and schedule errors over a four-year period. We also evaluated error subtypes (side, procedure, site, and patient) and error occurrence by facility type (hospital or ASF). Finally, we provide a brief literature review of risk factors and strategies to mitigate risk of consent and schedule errors.

Methods

Data Source and Sample

We used data from reports of patient safety events that were submitted by hospitals and ASFs to the PA-PSRS acute care database, which is affiliated with the mandatory event reporting laws in Pennsylvania. The event reports include structured fields (e.g., event date, patient age, care area) and unstructured fields (i.e., free text), which are used by the reporter to describe the event and actions taken. The reports are often concise and do not include medical records.

The query and review of events for inclusion in the present study consisted of a two-phase process. In the first phase, we queried the PA-PSRS database for events that occurred within a four-year period (1/1/2019 to 12/31/2022) and met one or more of the following inclusion criteria:

- Event was classified within the PA-PSRS taxonomy as an *Error Related to Procedure/Treatment/Test - Surgery/Invasive Procedure Problem* and one of the following response options was selected: *wrong site*, *wrong side (L vs R)*, *wrong procedure*, *wrong patient*, or *preparation inadequate/wrong*.
- Event was classified within the PA-PSRS taxonomy as *Error Related to Procedure/Treatment/Test - Surgery/Invasive Procedure Problem* and at least one of the unstructured fields contained the words "left" and "right" or "incis" and "excis"[b].

[a]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.

[b]The purpose of these criteria was to identify reports that described a wrong-side or wrong-procedure error. Event reports that describe a wrong-side error typically state both left and right sides. Additionally, when event reports describe a wrong procedure error involving incision or excision, they typically state both procedures.

Informed Consent

What?

It involves a formal document and communication between a medical professional and patient/representative about the risks and benefits of planned procedure, description of the planned procedure, and alternative treatments.[1,4,9,11-15] The consent document also identifies the patient, planned procedure, side, and site.[4,14,16,17] The attending provider should obtain informed consent.[6,12,14] Consent is obtained from the patient/representative through a signature or other form of affirmation.[11,13]

When and Where?

It takes place during a clinical consult at a doctor's office, clinic, or at the facility where the procedure is performed.[11,12] When possible, consent should occur well in advance of the procedure, not the day of the procedure while the patient is in the preoperative area.[1,12]

Why?

The consent process is designed to ensure that the patient/representative understands key elements of the procedure, has an opportunity to ask questions, and makes an informed decision about whether or not to proceed with the procedure.[4,9,13,14]

Procedural Schedule

What?

It is a document and/or electronic communication used by medical staff that conveys the date, time, provider, procedure, patient, side, site, and any other pertinent information.[16-18] The schedule is based on a consultation from the provider and typically involves information from and communication among multidisciplinary team members across various departments, including the provider's office staff.[4,19]

When and Where?

Typically, the procedure is scheduled by communication between provider's office staff and staff at the procedural facility via phone, fax, email, or an electronic portal.[20,21]

Why?

It supports clinical preparation for an efficient and safely performed procedure.[2,4,18]

- Event was classified under the Surgical Services care area group[c] and at least one of the unstructured fields contained any of the following phrases: "wrong site," "wrong side," "wrong level," "wrong procedure," "wrong patient," "time out," "incorrect side," "incorrect site," "incorrect procedure," "incorrect patient," "block," or "mark."
- Event was classified under the Surgical Services care area group and at least one of the unstructured fields contained any of the following combinations of phrases: "consent" or "schedul" and "wrong," "incorrect," or "error."

In the second phase, one researcher reviewed each report to identify those that met the inclusion criteria by describing a consent and/or schedule error, an error subtype, and that the error corresponded with an invasive operative procedure. We defined an invasive operative procedure as "…skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice."[16,24] We further defined the invasive operative procedure as beginning "regardless of setting, at the point of surgical incision; tissue puncture; or the insertion of an instrument into tissues, cavities, or organs" and ending "after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting."[16,24] Based on the query criteria and review of event reports, a total of 1,166 reports were included in the study.

Design, Analysis, and Variables Coded

We used a retrospective mixed-methods design with an exploratory sequential approach,[25] where we began with a focus on the qualitative data and then quantified those data for further analysis. The qualitative data from PA-PSRS event reports were processed through a content analysis[26-29] using a framework method[25,30,31] with categories of variables that were developed deductively based on our prior study.[3] The variables were measured by frequency and assessed using a descriptive analysis. Descriptive analysis is a quantitative method where phenomena are explored and patterns are identified with the purpose of better understanding and explaining the phenomena occurrence.[3,32] This is often achieved through visual presentation of the data that shows multiple combinations of variables and allows for a triangulation of insights.

The patient gender, patient age, event date, and facility type (hospital or ASF) were identified in structured fields of the reports. Through review of the unstructured fields, a researcher identified the error type (consent, schedule, or consent & schedule, which are mutually exclusive categories) and error subtype (side, procedure, site, or patient, which are mutually exclusive categories), which are both defined in **Table 1**.

Table 1. Definitions and Examples of Error Types and Subtypes

Error Types	Definition	De-Identified Examples From PA-PSRS
Consent	The consent form contained incorrect information related to the subtype (procedure, side, site or patient's name/ identifier).	Patient having right craniotomy for tumor removal and consent written for left side. Surgeon notified and consent fixed prior to surgery.
Schedule	The procedural schedule contained incorrect information related to the subtype.	Case scheduled incorrectly as right knee arthroscopy. Patient arrived and registration confirmed the procedure to be performed. Patient said it was left knee arthroscopy.
Consent & Schedule	Both the consent form and the procedural schedule contained incorrect information related to the subtype.	Patient's paperwork was sent from surgeon's office. The scheduling sheet and consent stated the procedure was to be on the right hand; the correct procedure was on the left hand.
Error Subtypes	**Definition**	**De-Identified Examples From PA-PSRS**
Side	The procedure was listed to be performed on the wrong side, right versus left.	Patient stated she was having a right hip replacement. The operating room schedule incorrectly stated left side.
Procedure	The wrong procedure was listed.	Online operating room consent stated procedure was for a hysterectomy. Patient to have a hysteroscopy, not hysterectomy.
Site	The wrong site was listed.	Patient is here for left knee arthroplasty and the surgeon consented the patient for left hip. Both patient and surgeon signed.
Patient	The wrong patient name and/or identifier was listed.	Nurse contacted ordering neurologist to request that she speak to concerned patient at bedside to help her understand exactly why this procedure (lumbar puncture) was necessary. This is when the ordering neurologist acknowledged that the orders were entered for the incorrect patient.

Note: Details of the PA-PSRS event narratives have been modified for readability and to preserve confidentiality.

[c]Within PA-PSRS, the event reporter chooses among 168 care areas to indicate the location where an event occurred. In order to simplify our analysis, we sorted each of the care areas into higher-level care area groups.

Results

Patient Age, Patient Gender, and Facility Type

Among the 1,166 event reports, 81% (950 of 1,166) identified the patient gender; 49% (462 of 950) were male and 51% (488 of 950) were female. Patient age had a mean of 55 years and a median of 61 years (minimum of <1 year, 25th percentile of 45 years, 75th percentile of 71 years, and a maximum of 99 years)[d]. The 1,166 event reports were submitted by 104 hospitals and 56 ASFs.

Error Type and Subtype

See **Figure 1** and **Figure 2** for graphs that show the distribution of consent and/or schedule errors. The consent or schedule errors were identified as occurring alone in 90% (1,052 of 1,166) of the reports and concurrently in 10% (114 of 1,166) of the reports. Across a four-year period, 66% (772 of 1,166) of the event reports included a schedule error, either alone (56%, 658 of 1,166) or concurrent with a consent error (10%, 114 of 1,166). The consent errors were reported in 44% of the events (34% alone, 394 of 1,166; 10% concurrent with schedule errors, 114 of 1,166). Across each of the error types (consent and/or schedule), **Figure 2** shows a year-over-year decrease with a similar pattern and proportion.

Table 2 shows that error subtypes ranged in percentage and were ranked in the following order: side (69%, n=808), procedure (24%, n=281), site (4%, n=47), and patient (3%, n=30). This ranking of subtypes is identical within each category of error type: schedule, consent, and consent & schedule. Within each category of error subtype, the relative proportion of consent & schedule errors varied. For example, within the side subtype the schedule errors (n=466) were reported nearly two times more than the consent errors (n=252), but within the site subtype the schedule (n=21) and consent (n=23) errors were nearly equal. Across the categories of error type and subtype, the most frequent combination of errors was a schedule error that identified the wrong side (40%, n=466). In contrast, consent & schedule errors and wrong patient errors were the least frequent combination, which had a zero frequency across the total sample of event reports.

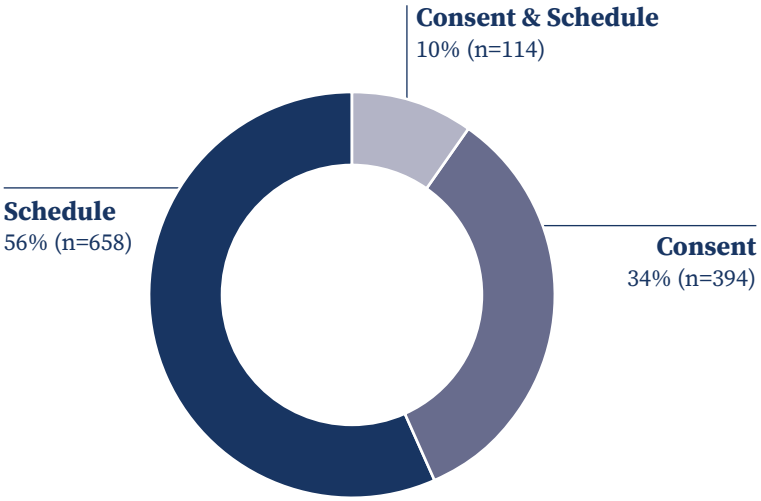
Facility Type by Error Type and Error Subtype

As presented in **Figure 3**, 86% (n=1,003) of events were reported by hospitals and 14% (n=163) by ASFs. Readers should note that our results only represent the distribution of events reported to PA-PSRS and may not represent the true distribution of occurrence across facilities.

Table 3a and **Table 3b** correspond with findings from hospitals and ASFs, respectively, and both show the distribution of error type and error subtype. A close review of **Table 3a** and **Table 3b** reveal a pattern of findings very similar to those shown in **Table 2**, which displays the error type and subtype collapsed across facility type. Despite the similarities in findings between the two facility types, there are a few noteworthy differences in the distributions across **Table 3a** and **Table 3b** that are highlighted below:

- Schedule errors were reported 9 percentage points greater at hospitals (58%, 578 of 1,003) than at ASFs (49%, 80 or 163).
- Side errors were reported 14 percentage points more at hospitals than at ASFs; however, procedure errors were 18 percentage points higher at ASFs (40%, 65 of 163) than at hospitals (22%, 216 of 1,003).
- Among the ASFs, the percentage of reports with a wrong-side schedule error (25%) was very similar to the percentage with a wrong-side consent error (23%). In contrast, at hospitals the wrong-side schedule errors (42%) were reported twice as often as the wrong-side consent errors (21%).
- For hospitals, the percentage of wrong-procedure schedule errors (11%) were comparable to the wrong-procedure consent errors (9%). The ASFs reported nearly twice as many wrong-procedure schedule errors (23%) than wrong-procedure consent errors (13%).
- Hospitals reported patient errors as being a small percentage of the distribution (3%, 30 of 1,003) and ASFs reported 0.

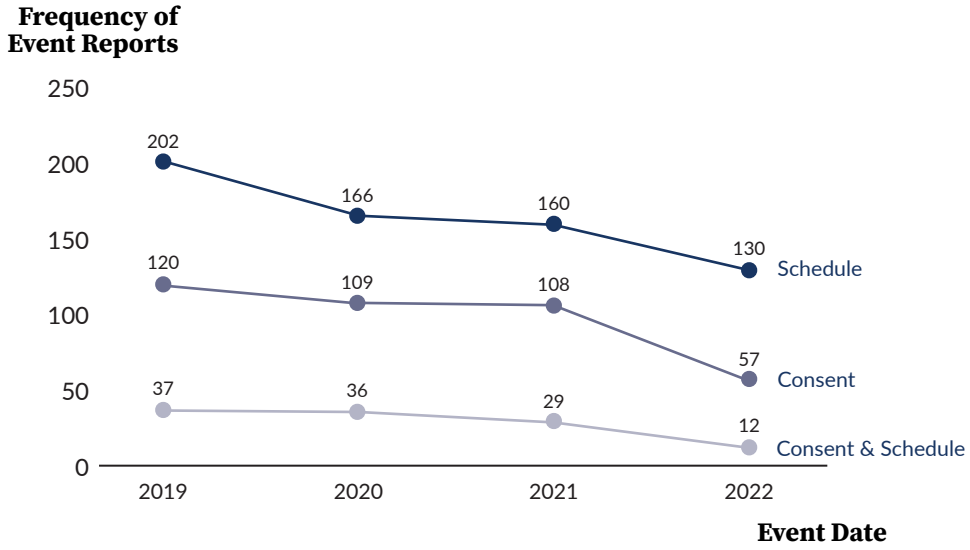
Figure 1. Frequency and Percentage of Error Type Across 2019–2022; N=1,166 PA-PSRS Event Reports



Note: The categories of Error Type and Subtype are mutually exclusive per event report. Consent & Schedule=concurrent occurrence of both consent errors and schedule errors in a single event report.

[d]Patient age was able to be obtained from all but one of the event reports.

Figure 2. Frequency of Error Type by Year; N=1,166 PA-PSRS Event Reports



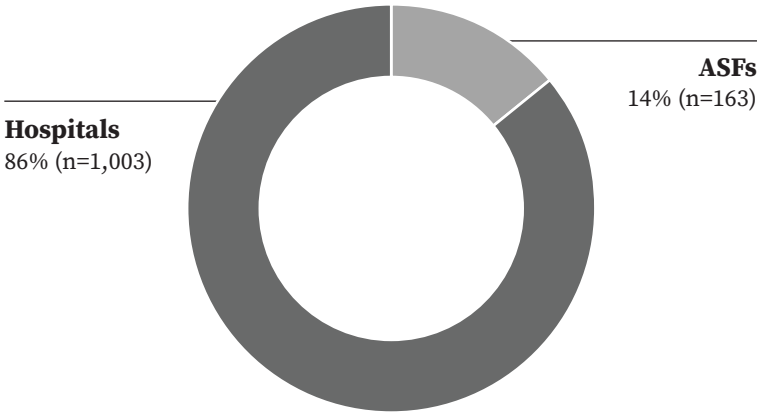
Note: The categories of Error Type and Subtype are mutually exclusive per event report.
Consent & Schedule=concurrent occurrence of both consent errors and schedule errors in a single event report.

Table 2. Percentage and Frequency of Error Type and Subtype Across 2019–2022; N=1,166 PA-PSRS Event Reports

	Error Subtype				
Error Type	**Side**	**Procedure**	**Site**	**Patient**	**Total**
Schedule	40% (466)	13% (151)	2% (21)	2% (20)	**56% (658)**
Consent	22% (252)	9% (109)	2% (23)	1% (10)	**34% (394)**
Consent & Schedule	8% (90)	2% (21)	<1% (3)	-	**10% (114)**
Total	**69% (808)**	**24% (281)**	**4% (47)**	**3% (30)**	**100% (1166)**

Note: The categories of Error Type and Subtype are mutually exclusive per event report. The parenthetical numbers represent the frequency.
Consent & Schedule=concurrent occurrence of both consent errors and schedule errors in a single event report.

Figure 3. Percentage and Frequency of Consent and/or Schedule Errors Across 2019–2022; N=1,166 PA-PSRS Event Reports



Note: The figure only represents the distribution of events reported to PA-PSRS and may not represent the true distribution of occurrence at facilities.

Table 3a. Hospitals Only: Percentage and Frequency of Error Type and Subtype Across 2019–2022; n=1,003 PA-PSRS Event Reports

	Error Subtype				
Error Type	**Side**	**Procedure**	**Site**	**Patient**	**Total**
Schedule	42% (425)	11% (114)	2% (19)	2% (20)	**58% (578)**
Consent	21% (214)	9% (87)	2% (21)	1% (10)	**33% (332)**
Consent & Schedule	8% (76)	1% (15)	<1% (2)	-	**9% (93)**
Total	**71% (715)**	**22% (216)**	**4% (42)**	**3% (30)**	**100% (1,003)**

Table 3b. ASFs Only: Percentage and Frequency of Error Type and Subtype Across 2019–2022; n=163 PA-PSRS Event Reports

	Error Subtype				
Error Type	**Side**	**Procedure**	**Site**	**Patient**	**Total**
Schedule	25% (41)	23% (37)	1% (2)	-	**49% (80)**
Consent	23% (38)	13% (22)	1% (2)	-	**38% (62)**
Consent & Schedule	9% (14)	4% (6)	1% (1)	-	**13% (21)**
Total	**57% (93)**	**40% (65)**	**3% (5)**	**-**	**100% (163)**

Note: The categories of Error Type and Subtype are mutually exclusive per event report. The parenthetical numbers represent the frequency. Consent & Schedule=concurrent occurrence of both consent and schedule errors in a single event report. The tables only represent the distribution of events reported to PA-PSRS and may not represent the true distribution of occurrence at facilities.

Discussion

Consent and schedule errors create inefficiencies[1,2,11,18,33] and additional costs in patient care[2,11,13] and are a risk factor for wrong-site surgery.[1,5-10] Our analysis, which presents findings across all combinations of error type, error subtype, and facility type, allows for a triangulation of variable relations and a more complete understanding of the distribution of consent and schedule errors. We believe that the results can be used by healthcare organizations as a basis for their own investigation into consent and schedule errors.

Our study revealed that schedule errors occurred more frequently than consent errors, which is inconsistent with previous research.[1] Our study expanded upon much of the previous literature by revealing the distribution of error types and subtypes across hospitals and ASFs. The distribution of error subtypes in our study (side, procedure, site, and patient) is similar with the occurrence reported in prior studies.[2,21,22]

When comparing the error subtype distribution between our current study and our previous study on wrong-site surgery,[3] we found similarities with side errors being the most frequent and patient errors as the least frequent; however, the occurrence of procedure errors and site errors was inconsistent across studies. This difference in distribution could be attributed to the lack of specificity in describing the site in the consent document and procedural schedule; therefore, a site error would be less likely to be detected.

Our results also show that there has been a decrease in reporting of consent and schedule errors from 2019 to 2022. It is unclear if this finding reflects a true reduction in errors and/or an underreporting of errors. Readers should note that all consent and schedule errors are mandatory reportable events under MCARE (Act 13 of 2002) within the commonwealth of Pennsylvania. Despite the possibility of underreporting,[6] it remains the responsibility of each healthcare organization to ensure that their processes are adequately designed and staff are making efforts to detect and prevent the errors which create a risk for patient harm.

We recommend that stakeholders view **Table 4** and **Table 5** for a concise literature review of preprocedural factors (prior to patient's arrival at procedural facility) that may increase the possibility of consent and schedule errors, and preprocedural strategies for mitigating the risk of those errors, respectively. The PA-PSRS event reports often lacked detail sufficient to pinpoint the factors that contributed to the event occurrence and/or strategies that the organization chose to mitigate risk; therefore, the content listed in the two tables was largely derived from a literature review of articles that ranged in levels of evidence, including expert opinion.[34] In addition to the items listed in **Table 4** and **Table 5**, we recommend that readers review references 4, 11, 13, 35, and 36 for additional information related to the processes of informed consent and references 2, 4, 19, and 20 for additional information related to procedural schedules.

Table 4. Preprocedural Risk Factors That May Increase the Likelihood That Consent and Schedule Errors Occur and Are Undetected During the Preprocedural Phase

Error Type	Risk Factors
Consent	Patient/representative consents to erroneous information.[6] This could be attributed to challenges with the patient/representative having a low level of health literacy, anxiety, and inattention to the form, and the provider offering insufficient and/or incomprehensible information during the consent process.[1,13,36-39]
	Consent is obtained by a person other than the attending provider.[4,12,14,33,40] This is a concern because the person may not be sufficiently knowledgeable with the planned procedure. Nevertheless, some U.S. states legally permit staff other than the attending physician to obtain informed consent.[41]
	Nonstandardized and/or paper-based forms.[4]
Schedule	Absent, inconsistent, and/or incorrect information on the consent form.[20,42]
	*Scheduler does not confirm the accuracy of primary documents.[20,22,42]
	*Scheduler receives only a verbal order.[20,22,42]
	*Scheduler is not sufficiently knowledgeable with the clinical content.[42]
	*Scheduler is simultaneously booking multiple cases.[42]
	Greater heterogeneity in procedures performed by the provider.[18]
	On scheduling forms, fields that allow for open text and/or are presented in a sequence inconsistent with the flow of topics.[19]
	When using both hardcopy and electronic scheduling forms, there is risk of error when fields do not match.[19]
	Hardcopy scheduling forms that have multiple versions and/or layouts that are inconsistent with other medical records.[19]
**Both Consent and Schedule	Absent, inconsistent, and/or incorrect information in the primary documents (e.g., history, physical, and/or provider's procedural orders).[20]
	Handwriting on primary documents that includes cross-outs and/or illegible content.[1,4,11,20,22,42]
	Use of abbreviations, particularly those that are error-prone and/or unapproved by the procedural facility.[1,4,11,20,22,42]
	Failure of staff at provider's office to reconcile all primary documents that are used to verify accuracy of the planned procedure.[6]
	Tasks that rely on manual verification and vigilance, as opposed to automated cross-checking.[1]
	Breakdown in communication between providers and their office staff, and among procedural facility intra- and interdepartmental staff.[1,42]
	Staff at provider's office are not receptive to inquiries about potential errors.
	Nonstandardized workflow and communication.[40]
	Disconnect between electronic documentation systems.[40,42]

Note: This list is comprised of preprocedural risk factors (prior to patient's arrival at procedural facility) that could contribute to the occurrence of consent and schedule errors and the failure to detect those errors during the preprocedural phase. The risk factors in this list were largely derived from a literature review of articles that ranged in levels of evidence, including expert opinion.[34] *"Scheduler" refers to both the person at the provider's office and the person at the facility where the procedure will be performed. **The risk factors corresponding with the "Both Consent and Schedule" error type could cause, independently or concurrently, consent and schedule errors and prevent detection of those errors.

Table 5. Preprocedural Strategies That May Reduce the Occurrence of Consent and Schedule Errors and Increase the Detection of Those Errors During the Preprocedural Phase

Error Type	Strategies
Consent	Consent is obtained by the attending provider.[6,12.14]
	Train new providers on the process for effectively obtaining informed consent.[13,43]
	Make all records easily accessible to staff while they obtain the patient's consent.[22]
	Active involvement by the patient/representative.[14,44-46] Some have recommended that the patient/representative be required to "sayback" or "readback" the consent to the provider.[6,14]
	Engagement of the patient/representative is particularly important during the consent process when the patient is a child or is nonverbal, comatose, or has an intellectual or developmental disability.[35,44]
	Use layman's terms, in addition to technical terminology, that can be understood by the patient/representative.[4,14,45] This will help the patient/representative detect potential consent errors. The patient is often the most consistent source of accurate information.[6,33]
	Obtain consent prior to the preoperative phase and, ideally, prior to the day of the procedure (e.g., at the provider's office, clinic, inpatient bedside).[12,14] As much as possible, consent should be obtained in a situation that may induce the least stress for the patient/representative.[4]
	Check accuracy of the consent document the same day that scheduling orders are created.[11]
	Create a standardized consent form template and processes.[13,14,43] Consider developing forms where information is added through checkboxes or drop-down menus, as opposed to free response.[4,13]
	Consider utilizing an electronic consent system to manage the documents.[13,43]
	If handwritten consent is accepted by the procedural facility, then it must be legible and without cross-outs.[20]
	Communicate (e.g., email, posters, meeting) with all relevant staff about the occurrence of errors and the potential effect.[11,13] Provide staff with individualized feedback on errors.[11,13]
	Meet with leadership to get buy-in on efforts to increase accuracy of consent forms.[13]
	Involve a quality improvement team or develop a departmental workgroup to target errors, depending on the prevalence of errors and extent of other deficiencies.[13]
	Audit accuracy of consent documents to create a baseline and a benchmark for improvement.[13]
	Train staff who schedule procedures to review primary documents and detect consent errors.[11]
Schedule	Scheduling is performed by a person knowledgeable of the procedure and other relevant clinical content.[44]
	Compare the scheduled procedure with other primary documents to ensure accuracy of the order.[1,46]
	Provider takes responsibility for the accuracy of the scheduled procedure.[8]
	Accept only written orders for a procedure.[1,20,46]
	If verbal orders are accepted, then use a "readback" and "hearback" technique to confirm each order.[42,47]
	When possible, the scheduling process should be standardized across all procedures.[1,46]
	Use computer automation when scheduling the procedure.[48]
	Use a centralized scheduling process.[49]
	Audit accuracy of procedural orders and schedule.[21]
**Both Consent and Schedule	In patient's records, the procedural provider should note in sufficient detail the indication, recommended procedure, site, and side.[6,7,16,17]
	Use only approved abbreviations or do not allow use of abbreviations.[17,20,45,48]
	Use an integrated paperless system with templates for obtaining consent and scheduling procedures.[4] This can streamline the administrative process and help to ensure that documents are accurate and easily accessible.
	Use a review and verification system with independent and redundant steps to help ensure that information is consistent and accurate.[33] This may consist of a simple checklist and/or some type of automated monitoring tool.[1,7,13,21,23] For a template checklist to be used by a provider's office, see the Patient Safety Authority's website.[50] The system should target primary documents, not secondary documents.[33]
	One to two days prior to the procedure, review and reconcile all primary documents: history, physical, provider's procedural orders, consent form, and procedural schedule.[11,20,33,48] Accurate reconciliation is the shared responsibility of the procedural provider and the facility where the procedure will be performed.[16]
	If revisions are made to a primary document, ensure that all relevant perioperative services receive the current documents.[7]
	Create a guidance document on requirements for consent and scheduling forms to be clear and acceptable.[13,21] Distribute the guidance document to providers' offices as a form of education. Train the perioperative staff on best practices, as needed.[13,21] Thereafter, return the unacceptable documents to the office.[20]
	In support of process improvement, develop a culture of open communication between providers' offices and the procedural facility.[51] This may involve 360-degree feedback and active participation among all relevant staff who have a role in creating and processing primary documents.

Note: This list is comprised of preprocedural strategies that were largely derived from a literature review of articles that ranged in levels of evidence, including expert opinion.[34] **The strategies corresponding with the "Both Consent and Schedule" error type could be effective in preventing and detecting both consent and schedule errors, which may occur independently or concurrently.

Limitations

Prior studies[2,11,13,21-23] explored the rates of consent and/or schedule errors; however, we chose not to calculate rates for several reasons. First, a rate would reflect a reporting rate, not an occurrence rate, which could be misunderstood by the reader. Additionally, our definition of an invasive operative procedure[16,24] is broader than the inclusion criteria used by our reference procedural volume database (Pennsylvania Department of Health's annual survey of Health Facilities),[52] which could cause an erroneous estimation of the rate.

Through our previous study,[3] we found that PA-PSRS reports of wrong-site surgery infrequently noted risk factors (i.e., factors that contributed to the occurrence of the event). Therefore, we chose not to explore the relation between consent and schedule errors and wrong-site surgery out of concern that the results would produce a substantial underestimation of the relation between the variables. Finally, we were unable to explore the frequency of consent and schedule errors according to clinician specialty and type of planned procedure due to those variables being infrequently reported in our sample of PA-PSRS reports.

Conclusion

Based on previous research, consent and schedule errors have been shown to create workflow inefficiencies, additional costs, and considerable risk for wrong-site surgery. Our analysis and results expand upon previous studies by showing a triangulation of variables across the occurrence of consent and schedule errors, error subtypes (side, procedure, site, and patient), and facility type. The findings reveal that the errors are an ongoing challenge in Pennsylvania and distribution of error types vary across hospitals and ambulatory surgical facilities. We believe that our data can be used as a basis for staff to investigate the prevalence of errors at their own facilities. We anticipate that provider offices, clinics, and hospitals will find value in **Table 4** and **Table 5**, which provide a brief literature review of risk factors for consent and schedule errors, and strategies for preventing and detecting the occurrence of those errors, respectively. A review of the content in those tables reveals that there are many factors that may contribute to consent and schedule errors and that many of the strategies are interrelated and may require notable resources to implement. Nevertheless, we believe that the efforts and investments required to reduce the occurrence of those errors can both produce net financial benefits and ensure patient safety.

Note

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

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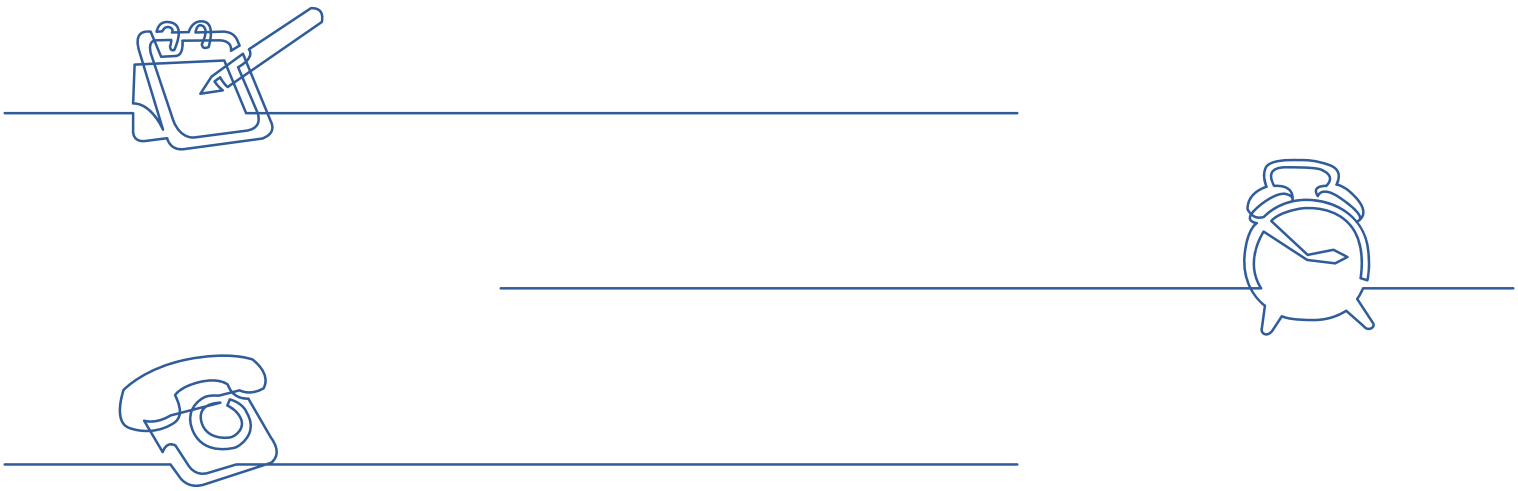

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Broken Drill Bits During Surgical Procedures: A Review of 156 Patient Safety Events

By **Christine E. Sanchez**, MPH[1]

Keywords: orthopedic surgery, drill, drill bit, surgery, patient safety

[1]Patient Safety Authority

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Abstract

Background: Broken surgical drill bits pose a risk to patient safety. A routine review of event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) uncovered an increase in the number of event reports related to broken drill bits, prompting an exploration to better understand patterns of drill bit breakage in Pennsylvania.

Methods: We queried the PA-PSRS database to identify event reports describing a broken drill bit during surgery submitted between January 1, 2021, and December 31, 2023. Event reports were manually coded to identify the procedure, anatomic location of breakage in the patient's body, timing of discovery, and fragment fate.

Results: A total of 156 relevant event reports were identified. The procedure being performed was determined in 64 of 156 event reports. Fracture repair procedures were most commonly reported to encounter a broken drill bit (27 of 64; 42.2%). We were able to determine the anatomic location in the patient's body where the drill bit breakage occurred in 108 of 156 event reports. The most commonly reported anatomic location was the femur (27 of 108; 25.0%). We were able to determine the fate of the broken drill bit in 141 of 156 event reports, and most drill bits were retained in the patient (99 of 141; 70.2%).

Conclusion: This data analysis provides insight into broken drill bits in Pennsylvania facilities. Because drill bits are commonly broken pieces of equipment and the fragments from these broken pieces are frequently retained, it is important to prevent drill bit breakage to improve patient safety. **Table 2** outlines prevention strategies established by equipment manufacturers and previous research. Implementing these strategies can address breakage across multiple procedures and patients.

Introduction

Instruments used in surgical procedures have the potential to break while in use, which can threaten patient safety. The rate of instrument breakage during emergency and elective orthopedic procedures is estimated to be between 0.18% and 0.35%.[1,2] Drill bits are one of the most frequently broken surgical instruments.[3-6] Retained drill bit fragments can threaten patient safety due to the potential for migration.[3,7,8] This is especially dangerous when fragments are retained near the spine,[7] pelvis,[8,9] or close to neurovascular regions.[6] Despite previous research outlining the prevalence of of and risks associated with broken drill bits, much of this research is derived from data from a single health system[1,2,9] or case studies[3,5,7,10] describing a single surgical case.

During a routine review of reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a], we observed an increase in the number of events involving broken and retained drill bits during surgery. This led to an exploration of similar reports to summarize information related to broken surgical drill bits in Pennsylvania facilities. Our analysis will expand upon existing literature by including data from multiple facilities over a three-year period and providing prevention strategies from previous research and equipment manufacturers in a concise presentation.

Methods

Data Query

Data for this study were collected from event reports in the PA-PSRS database. PA-PSRS reports contain responses to structured fields (e.g., event date, patient age), as well as free-text narrative fields that allow reporters to describe event details in their own words. We queried the PA-PSRS acute care database for event reports submitted between January 1, 2021, and December 31, 2023, that contained the word "drill" within 10 characters of either "tip" or "bit" in the free-text fields (event details, event comments, event recommendations, event subtype - other). The query produced a total of 259 event reports that were manually reviewed for inclusion. Event reports met inclusion criteria if they described a drill bit breaking during a surgical procedure.

Variables Coded

We analyzed two sets of variables from the data available in the event reports. The first included patient age and sex, which were entered by the event reporter at the time of submission to PA-PSRS. The second set of variables was manually coded by the researcher and included the following:

- Procedure: Type of surgery that was being performed when the drill bit broke.
- Anatomic Location: Part of the patient's body in which the drill bit broke or where the drill bit fragment was found.
- Timing of Discovery: When the broken drill bit, or drill bit fragment, was found in relation to the procedure.
  - During Procedure: Any time during the procedure before closing (i.e., the time the surgical wound is stitched, stapled, or otherwise adhered as an end to the surgery).
  - Postoperatively: Any time after the closing of the surgical wound.
  - Unknown: The timing of discovery was unable to be determined from the information provided.
- Fragment Fate: The outcome involving the piece(s) of the broken drill bit after the original procedure (i.e., the procedure during which the broken drill bit occurred).

Data Analysis

We performed a descriptive data analysis to identify patient demographics and patterns in drill bit breakage.

Results

Demographics

Manual review of event reports identified a total of 156 relevant event reports from 72 facilities. Across all event reports, 59.6% (93 of 156) involved male patients, and 39.1% (61 of 156) involved female patients. The sex of two patients was not provided. The mean patient age was 52.2 years, ranging from 16 to 90 years. Over half (57.7%; 90 of 156) of the broken drill bit events occurred in patients over 50 years old.

Procedure and Anatomic Location

We were able to identify the type of procedure that resulted in a broken drill bit in 64 of the 156 event reports. **Figure 1** shows the procedures related to a broken drill bit. Most broken drill bits occurred during a fracture repair (42.2%; 27 of 64) or a joint replacement surgery (20.3%; 13 of 64). Details of the fracture repairs and joint replacements are outlined in **Table 1**.

We were able to determine the anatomic location in which the drill bit broke in 108 of the 156 event reports. Broken drill bits most frequently occurred in the femur (25.0%; 27 of 108). **Figure 2** shows the anatomic locations of the broken drill bits.

Timing of Discovery

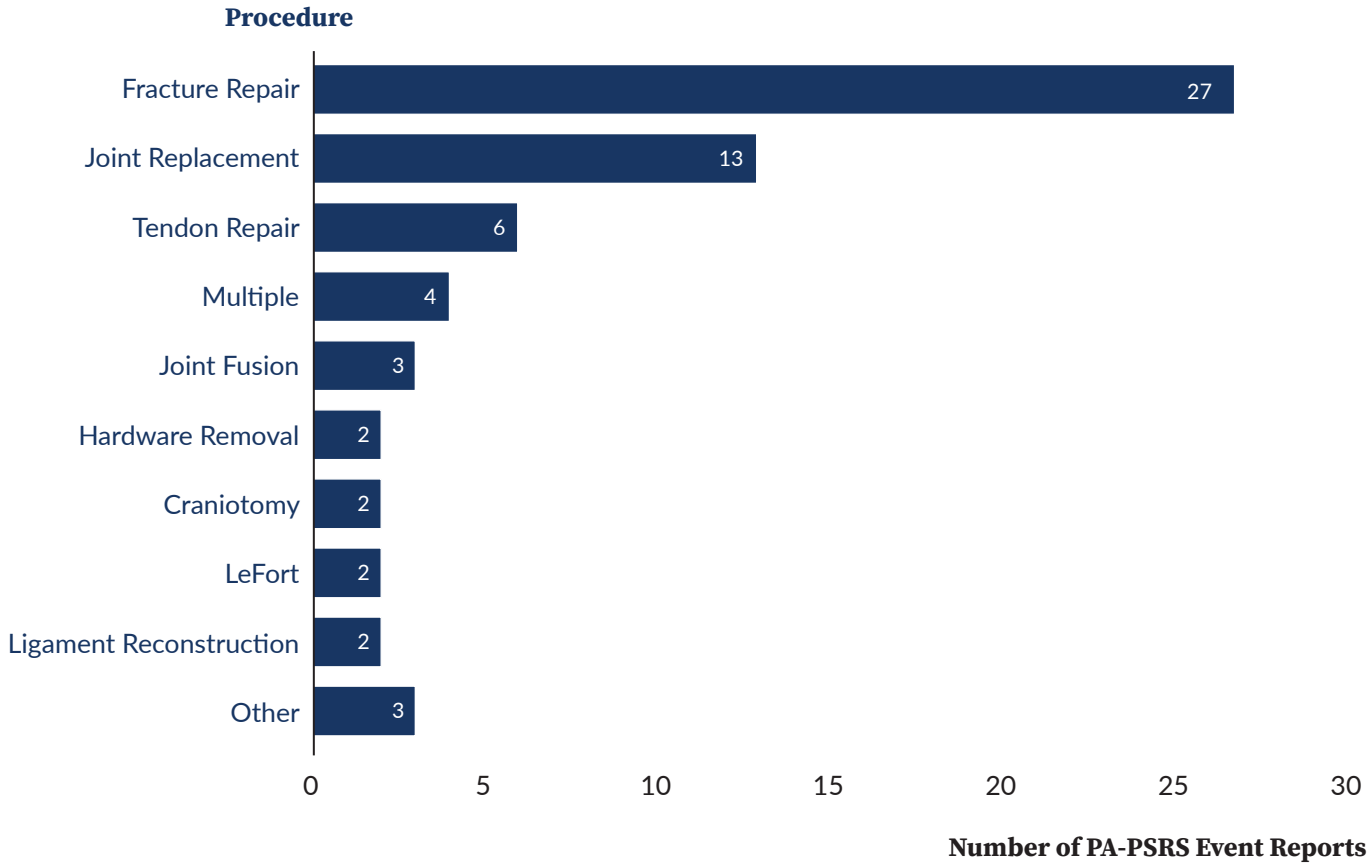
Figure 3 shows the frequency and percentage of the timing of when the broken drill bit was discovered. In 93.6% (146 of 156) of event reports, the broken drill bit was discovered during the procedure. The broken drill bit was discovered postoperatively in 2.6% (4 of 156) of event reports.

Fragment Fate

We were able to determine the fate of the drill bit fragment(s) in 141 of the 156 event reports. The fragments were removed during the original procedure in 29.8% (42 of 141) of event reports. Over two-thirds (70.2%; 99 of 141) of the event reports indicate that the fragments were retained following the original procedure. Of the 99 event reports with a retained fragment, 97 describe no further intervention and two describe fragment removal during a subsequent surgery.

[a]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).[11] All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Figure 1. Procedures Involving Broken Drill Bits, N=64* PA-PSRS Event Reports



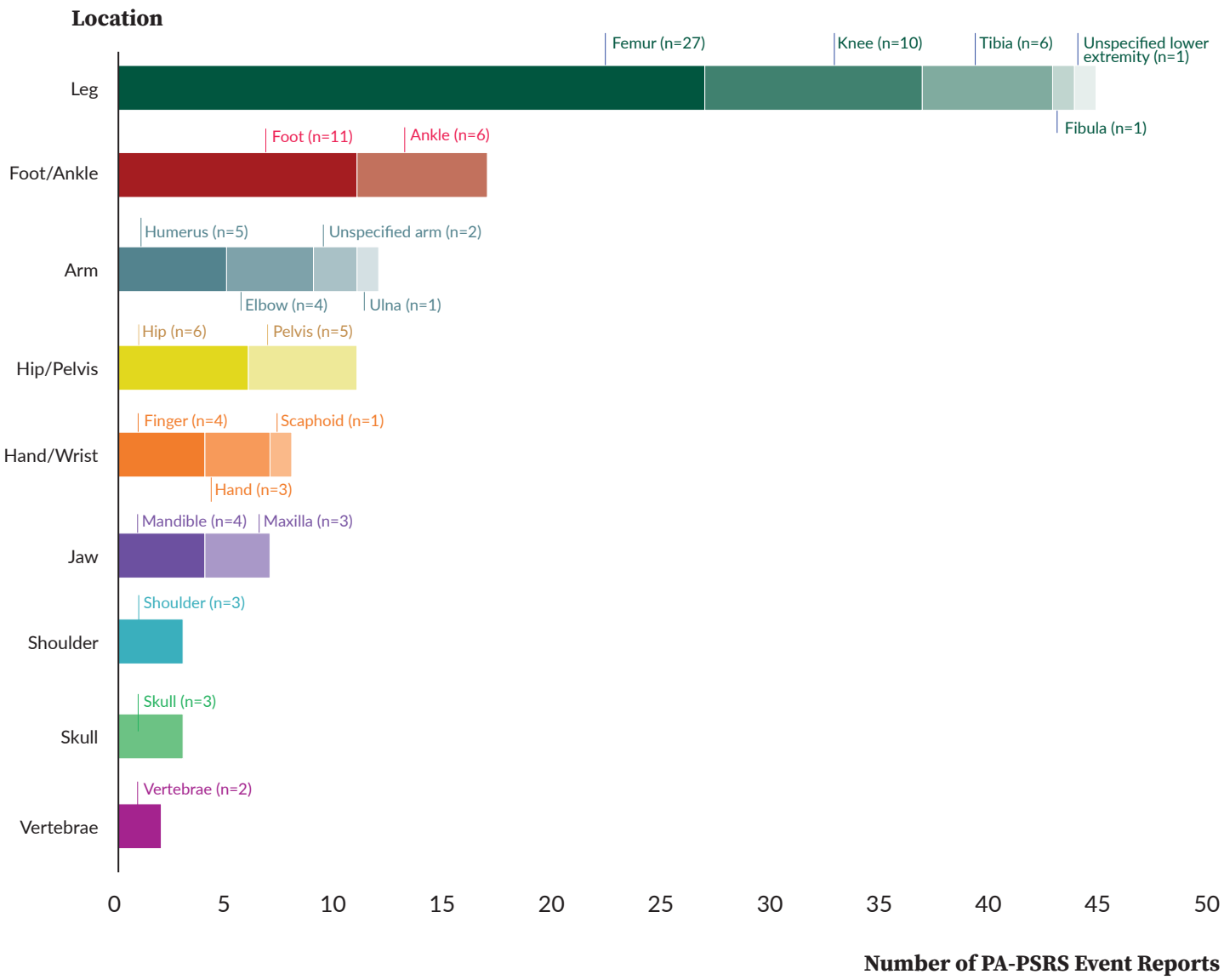
*__Note:__ There were 92 event reports with no procedure specified. Each of the 64 event reports was coded as having only one procedure category.
"Multiple" was coded when the event report described multiple procedures in a localized part of the body (i.e., foot, ankle, hand) and we were not able to determine during which procedure the broken drill bit occurred.
LeFort is a surgery that repositions the upper jaw to correct midface deformities.
"Other" includes excision of heterotopic bone, curettage and cementation with internal fixation, and osteotomy with internal fixation/cementation.

Table 1. Details of Fracture Repair (n=27) and Joint Replacement (n=13) Procedures

Procedure	Procedure Details	Number of PA-PSRS Event Reports
Fracture Repair	Femur	9
	Tibia/Fibula	4
	Hand	3
	Hip	3
	Elbow	2
	Humerus	2
	Mandible	2
	Ankle	1
	Unspecified	1
Joint Replacement	Hip	8
	Shoulder	3
	Knee	2

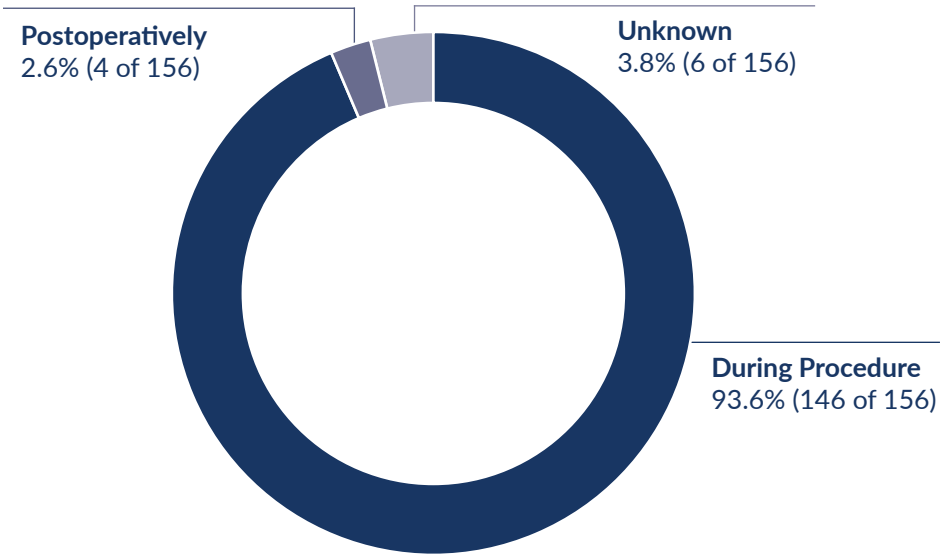
Note: Details in this table relate to the procedure identified in the event report and may not reflect the exact location in the patient's body where the broken drill bit occurred.

Figure 2. Anatomic Location in Which Drill Bit Breakage Occurred, N=108* PA-PSRS Event Reports



***Note:** There were 48 event reports with no location specified. Each of the 108 event reports was coded as having only one location.

Figure 3. Timing of Discovery of Broken Drill Bits, N=156 PA-PSRS Event Reports



Discussion

Our analysis outlines the procedures, locations, discovery information, and fragment fate related to 156 events involving broken drill bits submitted by Pennsylvania facilities over a three-year period. Retained fragments from broken drill bits have the potential to negatively impact patient safety by requiring additional surgeries for removal, increasing exposure to unnecessary radiation from X-rays,[12] and/or raising the risk of complications in the event of fragment migration.[3,7]

Although removing broken drill bit fragments is recommended,[1,10] the risks must be weighed against the benefits. Removal can increase the risk of damage to surrounding areas, which may lead to surgeons deciding to leave the fragment in place.[5,6] While the immediate risks of removal may outweigh the benefits, the risk to patient safety is a concern.[3]

Data from this analysis highlights procedures and anatomic locations that were reported to result in a broken drill bit. Our data shows that broken drill bits occur in both male and female patients and across a range of patient ages. While broken drill bits occurred most frequently during a fracture repair procedure, it is important to consider that fracture repairs are a common surgical procedure.[13] This suggests that the high frequency of broken drill bits during fracture repairs could be due to the volume of fracture repair procedures and not because fracture repairs are at particularly high risk for drill bit breakage.

Our analysis shows that drill bit breakage occurred across a range of procedures and in varied anatomic locations, highlighting the need to understand and implement strategies to prevent drill bit breakage across all procedures. Due to the unknown cause(s) of drill bit breakage in our dataset, we chose to focus on existing literature and clinical knowledge when giving recommendations to prevent drill bit breakage. Previous research[4,6,9,16] and information from medical device manufacturers[17-19] provide strategies for preventing drill bit breakage during use in surgery. These strategies, which can be categorized as surgical technique; sterilization, reprocessing, and storage; and general safety measures, are provided in **Table 2**.

Limitations

The quality of information provided in the free-text fields of PA-PSRS event reports varies, and some reports contain more detailed information than others. Our analysis is limited by the information provided. With many event reports missing information related to the type of procedure and anatomic location, we did not explore relationships between these and other variables, as they may misrepresent true relationships and associations due to the missing data. We were also unable to determine the specific reason(s) for drill bit breakage because most event reports do not contain this type of detail. Furthermore, the exact cause may be unknown to the event reporter. In addition, despite mandatory reporting laws in Pennsylvania, it is possible that the events reported to PA-PSRS may not represent all occurrences of broken drill bits during surgery.

Conclusion

Previous literature[1-6] has identified drill bits as surgical equipment that commonly breaks during use. This information, combined with data from this analysis describing fragments that were retained in high-risk anatomic locations or that required a return to surgery for fragment removal, shows that drill bit breakage can threaten patient safety in Pennsylvania. Implementing strategies to prevent drill bit breakage is key to reducing the potential negative impact on patient safety.

Notes

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

Data used in this study cannot be made public due to their confidential nature, as outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Pennsylvania Act 13 of 2002).

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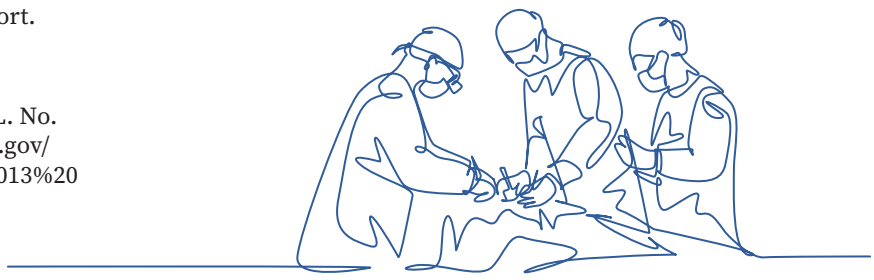

What to Know About Glacial Acetic Acid: **STOP USING IT**

Keywords: glacial acetic acid, acetic acid solution, vinegar, medication safety, medication error, patient safety

[1]Patient Safety Authority

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Ro M. What to Know About Glacial Acetic Acid: Stop Using It. *Patient Safety*. 2024;6(1):116280. doi:10.33940/001c.116280

By **Myungsun Ro,** PharmD, MS[1]

Multiple events involving patient harm from the use of undiluted glacial acetic acid have been reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS). Glacial acetic acid is anhydrous pure acetic acid available in concentrations between 99.5% and 100%.[1-4] Unlike acetic acid solutions which have various medical uses when diluted to different concentrations (e.g., 0.25% for irrigation, 2% for otic use), glacial acetic acid is highly corrosive; has no medical purpose; and has been associated with serious patient harm, such as severe tissue damage and third-degree burns.[1-4] Because glacial acetic acid is not considered to be a drug, it is not regulated by the U.S. Food and Drug Administration (FDA) to have standardized labeling on its containers to prominently display the strength of acetic acid and warnings against medical use.[2,3] Despite our previous publication describing two cases involving unintended applications of glacial acetic acid and several strategies to prevent error,[1] we have recently received PA-PSRS reports of additional patient injuries due to the use of glacial acetic acid. Therefore, we advise facilities to review and implement the Action Items listed below.

Action Items

Completely eliminate the use and storage of glacial acetic acid from the facility.[1-4]

Purchasing and acquisition:

- Purchase commercially available premixed acetic solutions at the lowest concentrations deemed medically effective at the facility.[1-4]
- Assign a specific individual or department to be in charge of purchasing acetic acid solutions for all procedural areas.[3]
- Purchase 4% or 5% acetic acid as vinegar to reduce the potential for confusion with glacial acetic acid.[1-4]
- Obtain premade acetic acid solutions of desired concentrations from a reputable compounding pharmacy to minimize in-house dilutions.[1,2]
- Remove glacial acetic acid from the available purchasing options.[1-3]
- Manually examine any product that does not have a National Drug Code (NDC) or a scannable barcode upon delivery.

Prescribing and ordering:

- Require prescribers to indicate the specific strength of acetic acid and indication for use in the order.[1-3]
- Require orders for acetic acid to be sent to the pharmacy at least one day in advance to allow sufficient time for verification, compounding, and dispensing.[1,2]
- Remove the term "glacial" from all orders for acetic acid solution.[1,2]
- Prescribe and dispense acetic acid on a patient-specific basis rather than making it available as a batch in patient care areas.[2]
- If continuing the use of acetic acid solution from home, perform an accurate medication reconciliation using the patient as a historian.[2]

Dispensing and administration:

- Develop a standard formula for in-house compounding of diluted acetic acid solutions by the pharmacy.[2]
- Implement an independent double check and/or an observation process to ensure the accuracy of the acetic acid dilution before dispensing or administering the product.[1-3]
- Minimize distractions and interruptions in the compounding area.[1]
- Apply a barcoded label on all compounded acetic acid solutions that must be scanned prior to patient administration.

Education and training:

- Educate staff members that undiluted glacial acetic acid has no medical use and should not be confused for diluted acetic acid solutions.[1-3]
- Instruct staff members to not use acetic acid if it smells stronger or different than usual.[1]
- Confirm the availability of up-to-date drug information references containing clinical and compounding information for acetic acid.[1,2]
- Instruct staff to neutralize acetic acid with baking soda should any exposure occur. Stock baking soda in all areas where acetic acid solutions are used.[1,2]

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Transfusion-Associated Circulatory Overload (TACO): **Strategies to Mitigate the Risk of Harm**

Keywords: pulmonary edema, lung injury, TRALI, red blood cells, hemoglobin

[1]Patient Safety Authority

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Taylor MA. Transfusion-Associated Circulatory Overload (TACO): Strategies to Mitigate the Risk of Harm. *Patient Safety*. 2024;6(1):118615. doi:10.33940/001c.118615

By **Matthew A. Taylor**, PhD[1]

What is Transfusion-Associated Circulatory Overload (TACO)? TACO has been defined as "acute or worsening respiratory compromise and/or acute or worsening pulmonary [edema] during or up to 12 hours after transfusion, with additional features including cardiovascular system changes not explained by the patient's underlying medical condition, evidence of fluid overload and a relevant biomarker."[1] Definitions of TACO vary across the literature[1,2] and some of its features may overlap with the definition and presentation of transfusion-related acute lung injury (TRALI).[2,3] Risk factors for and clinical presentation of TACO are reviewed in several resources[1,2,4] and we recommend that clinical staff read references 1, 2, and 4.

Occurrence of TACO and Impact on Patients. The Medicines and Healthcare products Regulatory Agency in the United Kingdom released an April 2024 National Patient Safety Alert informing the healthcare community of an increasing trend of TACO-related deaths and major morbidity.[1] Through an exploration of data in the Pennsylvania Patient Safety Reporting System (PA-PSRS), the Patient Safety Authority (PSA) also found that hundreds of TACO events have been reported across Pennsylvania in recent years, *including reports of serious patient harm and death*. PSA encourages the healthcare community to be aware of risk factors for, clinical presentation of, and strategies to mitigate the risk of TACO.

Strategies to Mitigate the Risk of TACO.[1]

- Use a pretransfusion risk assessment.
- Ensure that only necessary transfusions are performed.
- Use weight-based dosing of red blood cells, particularly for patients with low body weight.
- Consider using a validated red blood cell calculator to estimate the amount of transfusion required to meet the target hemoglobin.
- Transfuse a single unit or the minimum number of units necessary to achieve the hemoglobin target.
- Transfuse at recommended rates, no faster.
- If appropriate, administer a diuretic, oxygen, or other adjunct treatments.
- During and following transfusion, closely monitor the patient's vital signs, and promptly intervene, if necessary.

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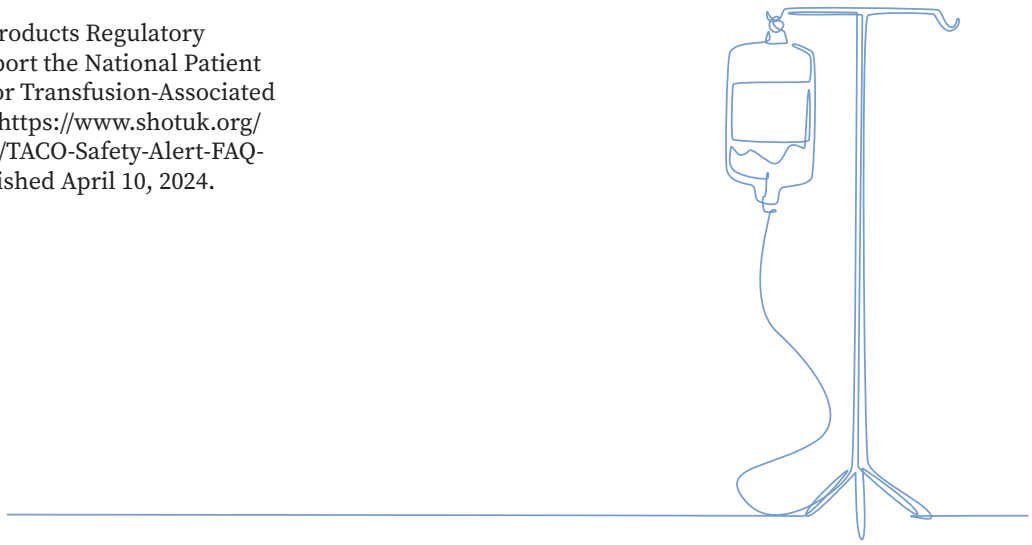

Technology **Failures**

Keywords: technology dependency, technology reliance, unplanned downtime, vial administration

[1]Patient Safety Authority

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Dominick S. Technology Failures. *Patient Safety*. 2024;6(1):120538. doi:10.33940/001c.120538

By **Shirley Dominick**, MSN, RN[1]

Technology in healthcare has expanded substantially over the last two decades. From electronic health records and barcode scanning to intravenous pump integration and best practice alerts, the work of healthcare providers is more automated now than ever before. But does this technology always make patient care safer? What happens when things don't go as planned? The following are examples of reported events that illustrate errors based, at least in part, on the reliance of technology.

A new registered nurse (RN) went to administer insulin but realized that the medication was dispensed in vial form, which they were not familiar with, as their clinical training in nursing school had been limited to administering insulin via patient-specific pens. Consequently, they failed to recognize that they needed to use an insulin syringe instead of a 10 milliliter syringe that was used for many other vial-based medications. They relied on the dispensing instructions from Pharmacy which read "dose 28 units, dispense 1" instead of the medication administration record (MAR) instructions. They then proceeded to scan the medication vial appropriately and entered the correct amount to match the order, assuming that the contents of the vial contained the dose of units. The patient received more than 35 times the intended dose, developed hypoglycemia, and was transferred to the intensive care unit (ICU). The patient recovered and was discharged from the ICU three days later.

In this scenario, the RN was not familiar with the use of an insulin syringe and did not realize that the Pharmacy instructions were different from the MAR. Creating alerts, such as having a picture of the syringe in the MAR to indicate there is something "different" about the administration of this medication, could be an option to prevent the recurrence of a similar event in the future. Adding an alert that notifies the user of a "partial" dose may also help to mitigate risk.

During an unplanned downtime, a patient who was nonverbal and had a documented allergy to strawberries received a meal tray with a fruit salad. The fruit salad contained strawberries and was fed to the patient. The patient developed an anaphylactic response which led to respiratory arrest. They were coded successfully and transferred to the ICU. Upon review of the event, it was determined that Dietary did not have established downtime procedures. Their computer system was linked to the electronic medical record (EMR), and they were unable to account for any allergies. The patient care assistant who was working with the patient was from the float team and was on the floor temporarily to assist as needed. They were asked to feed the patient and were not told about any allergies. The RN assigned to the patient was also acting as the charge nurse and in the middle of implementing the downtime processes for the floor when the patient received their meal tray.

Downtimes, whether planned or unplanned, can cause many challenges for staff. Most staff are unfamiliar with the use of paper charts as they have used EMRs for many years. One strategy which has been shown to be effective is to initiate the facility's command center to help manage overall operations.[1] More frequent drills of downtime procedures can increase staff knowledge and comfort with the process. Consider including all ancillary departments in these drills, such as Environmental Services and Dietary. Debrief staff after all downtimes to provide a just-in-time learning opportunity.

An overreliance on technology can lead to reduction in critical thinking skills when faced with complex or ambiguous situations. Critical tasks, such as medication administration, can become routine, causing the nurse to not consider important aspects of the patient's overall condition or their health record.

It is essential for healthcare workers and healthcare organizations to mitigate errors related to overreliance on technology by recognizing its limitations; actively cultivating critical thinking skills through ongoing education, training, and opportunities for reflection and discussion; identifying how technology can fail and proactively working to mitigate those failures; and practicing downtime procedures frequently.

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Identifying Racial Disparities Based on PA-PSRS Maternal Complication Reports: **Limited Demographic Data Results in Inconclusive Findings**

Keywords: patient safety, maternal complications, demographic data, racial disparity

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Jones R. Identifying Racial Disparities Based on PA-PSRS Maternal Complication Reports: Limited Demographic Data Results in Inconclusive Findings. *Patient Safety*. 2024;6(1)121666. doi:10.33940/001c.121666

By **Rebecca Jones**, MBA, RN[1]

Data from the National Vital Statistics System reflect a maternal mortality rate for non-Hispanic Black or African American mothers that is 2.6 times higher than for non-Hispanic White mothers.[1] Although the definition upon which the maternal mortality statistics are based differs in many ways from the definitions of reportable patient safety events in Pennsylvania, the Patient Safety Authority (PSA) sought to determine whether reports of maternal complications in the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] suggest a similar disparity.

We queried PA-PSRS for reports submitted between 1/1/2023 and 6/7/2024 under the event type/subtype *Complication of Procedure/Treatment/Test – Maternal Complication* ("maternal complications"). We also used the most current year of live birth statistical data available from the Pennsylvania Department of

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

Health (DOH)[3] for comparison[b]. After excluding data with an unknown race from both datasets, we calculated the distribution of live births and maternal complications by race. Compared to the proportion of live births by Black[c] mothers, we found that the distribution of maternal complications was higher than expected for Black/African American mothers across all reports (incidents and serious events) and lower than expected when looking at serious event reports only.

We also calculated rates[d] based on maternal complications per 1,000 live births for Black/African American mothers and White mothers. Across all reports (incidents and serious events), the rate was 1.36 times higher for Black/African American mothers than for White mothers; however, for serious event reports only, the rate was 1.29 times higher for White mothers than for Black/African American mothers.

Although we did not find the level of disparity in maternal complications for Black/African American mothers that might be expected based on maternal mortality statistics, we cannot be fully confident in these results for several reasons. One noteworthy limitation relates to the PA-PSRS reports that were excluded due to an unknown race (i.e., responses of *Not asked or Patient declined to answer*); excluded data accounted for 17.7% of all reports (incidents and serious events) and 10.7% of serious event reports. Many of the excluded reports identified patient ZIP codes in areas with higher proportions of live births by Black mothers; therefore, the distribution and rates for Black/African American mothers may have been higher if race had been specified in those reports.

While we have seen major progress in the reporting of race data to PA-PSRS since 2022, there is still room for improvement. PSA encourages all acute care facilities in Pennsylvania to ensure that accurate and complete demographic data are being captured in your internal event reporting systems and provided in your reports to PA-PSRS. Continued improvements in reporting will lead to higher confidence in our findings.

[b]These data were provided by the Pennsylvania DOH. The DOH specifically disclaims responsibility for any analyses, interpretations, or conclusions. Although the most current year of available live birth data, from 2022, does not align with the time frame of PA-PSRS reports in this analysis, the live birth distribution by race has been relatively consistent over the past five years.

[c]The Pennsylvania DOH lists the race category as *Black*; PA-PSRS lists the race category as *Black/African American*.

[d] Rates were calculated solely for a point of comparison; they do not reflect a true rate of maternal complication events in Pennsylvania.

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Enhancing the Process of Collecting Patient Medical and Surgical History: **Navigating Sensitive Topics and Evolving Practices**

Keywords: patient history, medical history, sensitive medical topics, preadmission testing, preoperative intake assessment

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Sanchez CE, Reynolds CM. Enhancing the Process of Collecting Patient Medical and Surgical History: Navigating Sensitive Topics and Evolving Practices. *Patient Safety*. 2024;6(1):123552. doi:10.33940/001c.123552.

By **Christine E. Sanchez**, MPH*[1] & **Catherine M. Reynolds**, DL, MJ, RN[1]

A complete and accurate patient history is essential for patient safety. Medical and surgical information is typically reported by the patient using a checklist to indicate medical and surgical history and current medications and supplements. This method has been shown to be generally successful in obtaining an accurate history in most healthcare settings.[1,2] However, there are instances when patients may withhold information. Patients may hesitate to disclose information when they fear a procedure may be canceled, when a topic is sensitive,[3-5] or when they don't understand that a particular detail is important to their care.[5] Examples of sensitive topics may include pain management, abortion care, weight loss, gender-affirming care, and medical marijuana use.

Recent event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) included patient safety events that involved patients withholding relevant medical information for fear of a procedure being canceled. Some event reports described patients who underwent a surgical procedure and experienced complications, which necessitated transfer to a higher level of care. After a discussion between the facilities' patient safety officers and Patient Safety Authority advisors, it was discovered that these patients had a

known medical condition but did not disclose this on their medical history form because they were worried that their procedure might be canceled. In these cases, these preexisting conditions would not have necessitated cancellation, but their course of treatment would have been modified to prevent the complication and, in turn, the transfer to a higher level of care. Other event report submissions describe procedure cancellations due to an active infection, which the patient did not initially disclose to avoid the cancellation. Each case involved sensitive topics and procedures, which may have led to patients withholding information.

As medical care, social norms, and laws change, it is important to review the process of collecting medical information to ensure that new medications, treatment modalities, and other factors are considered. Instead of asking patients to indicate pertinent medical and surgical history on a paper or electronic form, it may be helpful to actively discuss patients' history with them. This will allow for both healthcare providers and patients to better understand the risks involved and how changes may be made to their course of treatment. Additionally, the medical history form could be updated to include a statement explaining that the list of conditions being asked about is to ensure patient safety and may not require a procedure to be canceled. Updating the process of obtaining patient medical and surgical history can ensure collection of more accurate and comprehensive information, enhancing patient safety by adapting to healthcare and societal changes.

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Mpox

An Update on the New Public Health Emergency

Keywords: mpox, virus, rash, clade, pustules

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Bingman C, Cutting D. Mpox: An Update on the New Public Health Emergency. *Patient Safety*. 2024;6(1):124257. doi:10.33940/001c.124257

By **Christine Bingman**, DNP, RN[1] & **Denise Cutting**, MSN, MSH, RN*[1]

Mpox, previously known as monkeypox virus, is an infectious disease spread through close contact and respiratory droplets.[1] Exposure to the virus can occur during travel to an area with sustained human-to-human transmission; contact with a confirmed, probable, or suspected case; contact with a dead or live wild animal or exotic pet that is a central African endemic species; or use of a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.).[2] Mpox symptoms typically start within 21 days of exposure with influenza-like symptoms, followed by a vesicular or pustular rash one to four days later. The rash is generally located on the palms of hands, soles of feet, genitalia, and anus.[3]

The disease is drawing more attention in the health community due to the ease of transmission and higher fatality rate as compared to previous years.[2] The World Health Organization has declared mpox a global public health emergency for the second time in two years.[4] The two circulating clades are responsible for confirmed cases identified in 116 countries worldwide, including the United States.[4] As of August 2024, subclade Ib is responsible for the upsurge of severe cases of mpox in several African countries, Europe, and Asia.

Providers are urged to include mpox in their list of differential diagnoses when vesicles or pustules are present with influenza-like illness. Patients should be assessed for contact with others who have a rash and recent travel to areas where mpox cases have been identified.[2]

Infection can be confirmed by various methods, including polymerase chain reaction (PCR) testing, next-generation sequencing (NGS), or mpox culturing from clinical specimens.[5] Consult public health authorities for access to mpox treatment recommendations. Oral treatment with tecovirimat can be considered for patients who meet eligibility criteria.[5]

People can protect themselves by

- Getting vaccinated if appropriate. To determine eligibility and locate vaccines see https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html
- Avoiding close, skin-to-skin contact with people who have a rash that looks like mpox
- Avoiding contact with objects and materials that a person with mpox has used
- Washing hands often[6]

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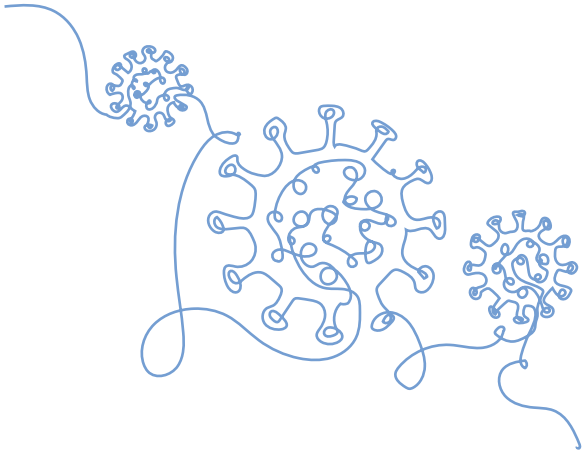

Multidose Nitroglycerin Bottles Associated With **25-Fold Overdose Errors**

Strategies for safe dispensing and administration of nitroglycerin tablets to prevent an unintended overdose

Keywords: medication error, medication safety, overdose error, patient safety, nitroglycerin, Nitrostat

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Ro M. Multidose Nitroglycerin Bottles Associated With 25-Fold Overdose Errors. *Patient Safety*. 2024;6(1):125483. doi:10.33940/001c.125483

By **Myungsun Ro**, PharmD, MS[1]

The Patient Safety Authority has received multiple reports to the Pennsylvania Patient Safety Reporting System (PA-PSRS) describing erroneous dispensing and administration of whole bottle contents (up to 25 tablets) of sublingual nitroglycerin instead of a single tablet. As a result of these events, patients have required resuscitative measures and/or transfer to a higher level of care.

Sublingual nitroglycerin (Nitrostat) is a nitrate vasodilator used to treat episodes of chest pain in patients who have coronary artery disease.[1] The tablets are supplied in small, amber bottles that are tightly capped to keep out light, moisture, and air.[2] The loss of potency from environmental exposure[2] often prevents repackaging of the tablets from a multidose bottle into single doses. Therefore, without single doses prepackaged ahead of time and proper safeguards to warn against the multidose bottle, an overdose of up to 25 times the intended dose can occur.

Following are summaries of some of these events reported to PA-PSRS.

> *Patient was ordered sublingual nitroglycerin for chest discomfort, and one bottle of sublingual nitroglycerin was retrieved from the ADC [automated dispensing cabinet]. The nurse scanned the barcodes on patient's ID band and the medication bottle and administered all tablets in the bottle. A few minutes later, the patient called the nurses' station and reported feeling sick. He was found to be hypotensive and diaphoretic, ultimately requiring resuscitation and transfer for increased monitoring.*
>
> *PRN [i.e., prescribed "as needed"] sublingual nitroglycerin was ordered for a patient experiencing chest pain. After scanning the patient's wristband and the bottle, the nurse administered the full bottle to the patient. The patient vomited and became hypotensive. A rapid response was called, fluids were administered, and the patient was transferred to a higher level of care.*
>
> *Nitroglycerin 0.4 mg sublingual tablet was ordered PRN for chest pain. Patient received nitroglycerin 10 mg (entire 25 bottle dose) at one time. Patient's blood pressure immediately dropped, and patient became lethargic requiring pressors and transfer to ICU [intensive care unit].*

For safe dispensing and administration of sublingual nitroglycerin tablets, please consider the following safety strategies:

- Create an alert in the automated dispensing cabinet (ADC)[3] with instructions to dispense individual tablet(s) from the multidose bottle (e.g., "Warning: this is a multidose bottle. 1 tablet = 0.4 mg").
- Minimize distractions and multitasking during the medication selection and removal process from the ADC.[3] Examine environmental factors such as lighting, noise level, and telephone interruptions.[4]
- Instruct nurses to monitor patients for desired therapeutic effects and potential adverse effects following medication administration,[4] and for the need to administer additional PRN doses.[1]
- Explore various targeted opportunities that fit the needs and workflow of the facility to educate healthcare providers about safe dispensing and administration of sublingual nitroglycerin tablets.

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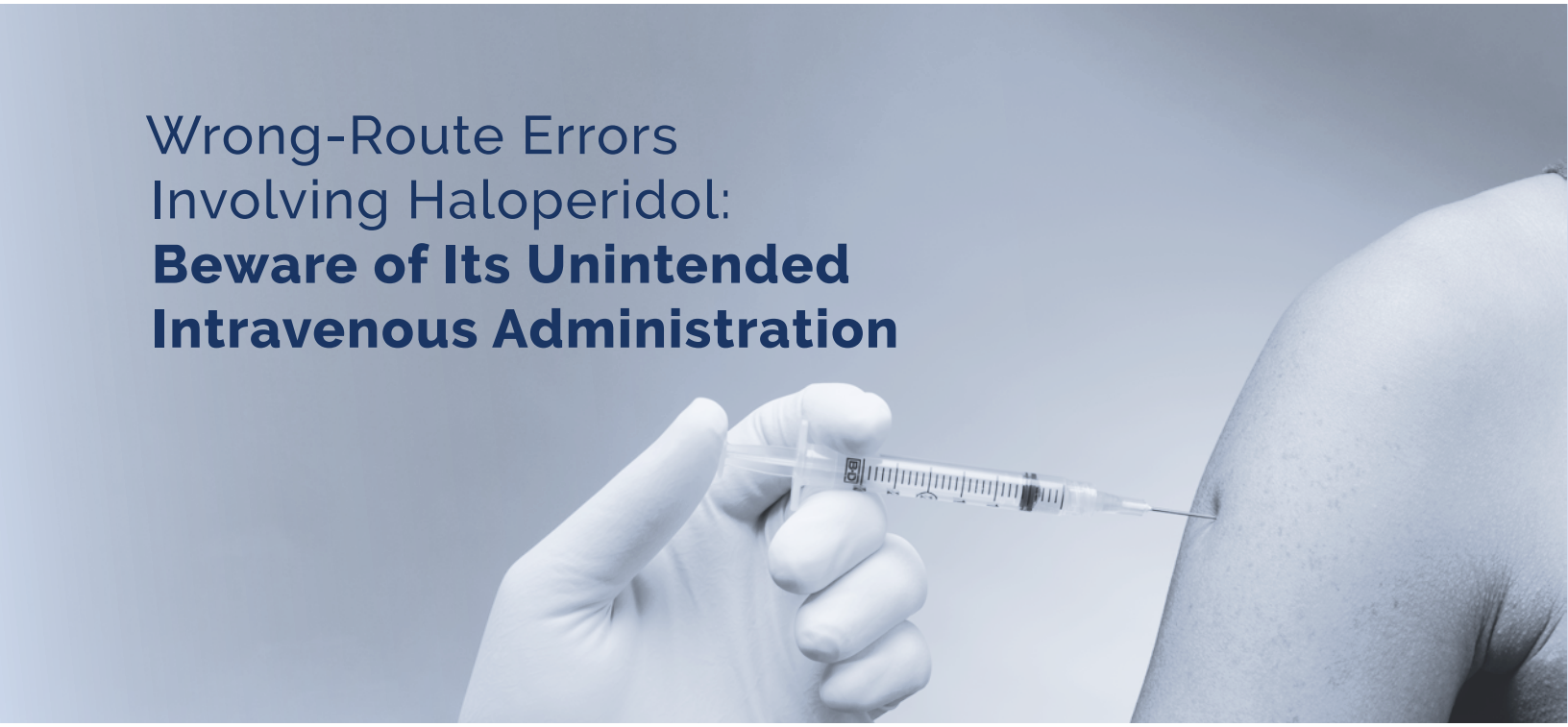
Wrong-Route Errors Involving Haloperidol: **Beware of Its Unintended Intravenous Administration**



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Ro M. Wrong-Route Errors Involving Haloperidol: Beware of Its Unintended Intravenous Administration. *Patient Safety*. 2024;6(1):125740. doi:10.33940/001c.125740

By **Myungsun Ro**, PharmD, MS[1]

Haloperidol is a butyrophenone antipsychotic that is approved for the treatment of schizophrenia.[1] Only the intramuscular route is approved for parenteral use by the U.S. Food and Drug Administration (FDA); however, intravenous (IV) haloperidol lactate has been used over the years for several off-label indications.[2-4] The long-acting depot formulation, haloperidol decanoate, should never be administered intravenously.[5]

The IV administration of haloperidol carries a label warning relating to QTc prolongation and Torsades de Pointes, for which electrocardiogram monitoring is recommended.[1,5] A review of Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] event reports found adverse drug reactions involving IV haloperidol include ventricular tachycardia, apnea requiring intubation, neuroleptic malignant syndrome, and seizure.

[a]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).[6] All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

Over 200 events describing wrong-route errors involving haloperidol have been reported to PA-PSRS. Of these, almost half detail cases in which parenteral haloperidol, which was originally intended for *intramuscular* injection, was administered *intravenously*. Most of these events involve the haloperidol lactate formulation; however, accidental IV administration with the decanoate formulation has also been reported.

To prevent wrong-route errors with haloperidol lactate, we advise that facilities examine and consider implementing the action items below.

- Restrict verbal orders to urgent situations where computerized provider order entry is not possible or practical. Reevaluate and/or create guidelines for the appropriate use of verbal orders, specifying the required information that should be included and recommending safe practices such as the readback method to confirm the order.
- Require pharmacist verification of the order and subsequent profiling of medication in the automated dispensing cabinet (ADC).
- Follow proper protocol in labeling and scanning the medication prior to administration.
- Create an alert in the ADC and/or barcode medication administration to remind the user of the intended route of administration.
- Reduce distractions during dispensing, preparation, and administration of the medication.
- Supervise students and trainees throughout all stages of the medication-use process.

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About the Author

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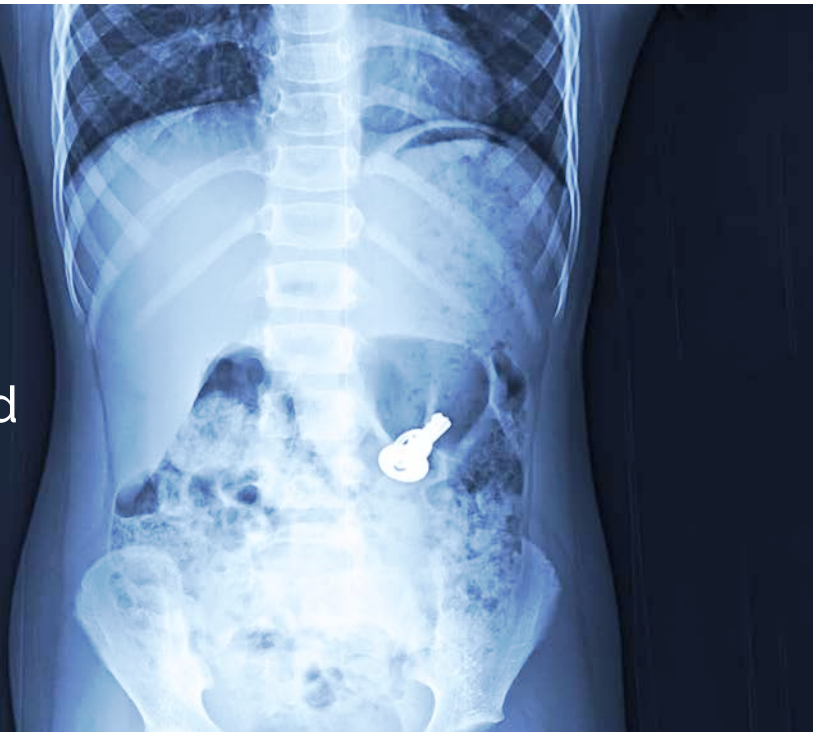
Pica Behavior in Acute Care Hospitals

Strategies for Screening and Mitigating Risk of Harm



Keywords: neurodevelopmental disorders, sickle cell disease, autism, schizophrenia, ingestion, foreign body

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Thomas BR, Taylor MA. Pica Behavior in Acute Care Hospitals: Strategies for Screening and Mitigating Risk of Harm. *Patient Safety*. 2024;6(1):126759. doi:10.33940/001c.126759

By **Benjamin R. Thomas**, PhD*[1,2] and **Matthew A. Taylor**, PhD*[3]

The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received hundreds of event reports describing patients who ingested inedible objects while receiving treatment in acute care hospitals. Some of these event reports specifically reference patients with a diagnosis of pica who experienced serious harm and required surgical intervention.

What Is Pica?

Pica is a dangerous disorder involving the persistent ingestion of nonfood, foreign bodies (e.g., plastic, coins, hair, fibers, feces, garbage, medical equipment).[1] The American Psychiatric Association diagnostic criteria specifies that pica behavior persists over one month and is developmentally inappropriate (i.e., patient is age 2 years or older) and is not part of a culturally/socially accepted practice.[1]

Pica is underdiagnosed and patient risk factors are not well screened or documented in medical settings.[2,3,4,5] Pica behavior most frequently occurs in patients with neurodevelopmental disorders.[2,3] Pica is reported in approximately 14%–28% of patients with autism and/or intellectual disabilities and up to 75% of children with sickle cell disease.[2,3] Additionally, each of the following are independent risk factors for pica behavior: Children younger than 6 years old, persons with increased severity of intellectual disability, persons with severe social and leisure deficits, and/or those who are institutionalized.[2,3,6] Pica is also associated with pregnancy; chronic kidney disease; and psychiatric disorders, such as schizophrenia, trichotillomania (hair pulling), trichophagia (ingesting hair), excoriation (skin-picking), and dermatophagia (chewing, ingesting skin/nails).[1,4]

Impact of In-Hospital Pica Behavior on Patients and Care

We reviewed a sample of PA-PSRS event reports about patients with a diagnosis of pica who ingested inedible objects while in an acute care hospital. Based on the event reports, we found that ingestion of inedible objects occurred across a range of areas within the hospitals (e.g., emergency department, cardiac unit, intensive care unit, medical-surgical, pediatric unit, surgical areas). The reports described the following items being ingested by patients: needles, gloves, batteries, intravenous (IV) catheter and lines, peripherally inserted central catheter (PICC) lines, jejunostomy tube (J-tube), specimen lid, plastic spoon, diaper, gauze, device lead, glass, paper clip, pen/pencil, straw, toothbrush, and pieces from eyeglasses. Following the ingestion, many patients required invasive and exploratory procedures (e.g., endoscopy, colonoscopy, and laparotomy). Based on PA-PSRS reports and/or prior literature,[7,8] pica behavior can lead to disruptions in care and the following health complications: choking, aspiration, pharyngoesophageal ulceration, stricture, gastrointestinal obstruction or perforation, acute weight loss, bezoar formation, parasitic infection, poisoning, or death (e.g., from ingesting a latex glove or sharp-pointed object).

Potential Strategies to Mitigate Risks Associated With Pica Behavior While a Patient Is in Hospital

Screening

- Review patient's medical records for a history of pica and risks of pica behavior: (1) diagnosed pica (*International Classification of Diseases*, Tenth Revision, Clinical Modification [ICD-10-CM] codes F98.3 in children, and F50.89 and/or F50.83 in adults) or undiagnosed pica (i.e., ingestion/swallowing of foreign bodies) and (2) associated diagnoses (e.g., autism, intellectual disabilities, sickle cell disease, schizophrenia, trichotillomania, trichophagia, excoriation, dermatophagia, chronic kidney disease, pregnancy).
- Interview the patient and/or caregiver to screen for risk of pica behavior. Consider asking the following screening questions: (1) In the past six months, did the patient attempt to chew, eat, or drink something that is not food and should not be consumed?; (2) Outside of the hospital, what are the nonfoods that should not be consumed, but the patient attempts to eat, chew, or drink?; and (3) In a hospital environment, what nonfood item(s) do you think are at risk of being chewed, eaten, or drunk?
- Use clinical judgement, based on both record review and interview with screening questions, to guide a decision whether to implement safety strategies.

Safety Strategies

- Assess the area/room during each shift, and then secure and move items of concern.[9,10] Regularly evaluate equipment for damage or missing parts, which may have been caused by the patient.
- If medical equipment at risk of being ingested is unable to be removed from the patient's reach, consider using a caregiver or 1:1 sitter who can sit in close proximity to observe the patient and physically block pica behavior, if necessary. Sitting in close proximity and blocking may not be feasible or effective as a sole strategy, so it should be implemented in conjunction with other strategies.[5]
- Attain a behavior plan from the community provider or previous admission; if necessary, create a more robust plan. A behavior plan is often developed in consultation with a psychiatrist, psychologist, behavior specialist, and/or applied behavior analyst.[5,10]
- Create an enriched environment with pica-safe physical and mental activities to distract the patient from their desire to ingest inedible objects.[5] For younger patients and if available, consider an order for a child life specialist who could help with this strategy. Use alternative sources of oral stimulation dependent on the patient's diagnosis and history, such as snacks or chewy teethers. Staff should seek a consult from an aforementioned specialty or a speech language pathologist or occupational therapist.
- Use of more restrictive interventions (e.g., mechanical restraint) must be aligned with the patient's plan of care, governmental regulations, and hospital policy, and authorized and monitored by the appropriate level of clinical staff.
- Closely monitor patients with risk of pica behavior throughout their time in a hospital for changes in health condition, which may reflect ingestion of inedible objects prior to admission or a covert occurrence *during* admission.[7,8]

Documentation and Care Coordination

- Document patient and/or caregiver responses to the screening questions about previous pica behaviors and nonfood items at highest risk of being chewed, eaten, or drunk.
- Document safety strategies implemented and the corresponding results during each shift and for all areas inhabited by the patient.
- For patients with repeat admissions related to pica behavior, create a referral to mental health providers specializing in pica, challenging behavior, and/or eating disorders.

- To help create clinical staff awareness during future patient visits, the clinical coder should use the ICD-10-CM codes for pica, which are F98.3 in children (24 months and older) and F50.83 in patients 15 years and older (specify "pica").

This list of potential strategies was derived from both the cited literature and the first author's clinical experience. We encourage readers to critically review these potential strategies prior to implementation.

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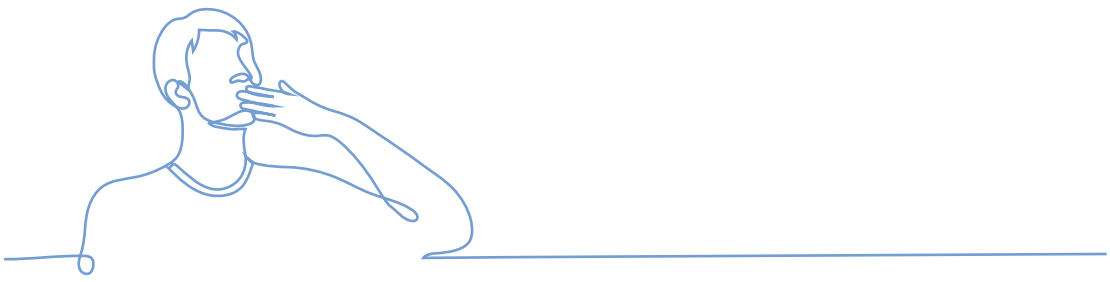
Matthew A. Taylor (MattTaylor@pa.gov) is a research scientist on the Data Science & Research team at the Patient Safety Authority (PSA), where he conducts research, uses data to identify patient safety concerns and trends, and develops solutions to prevent recurrence.



Healthcare can be confusing for patients.

Despite everyone's good intentions, **patients and healthcare providers often have difficulty understanding one another.** So, the Patient Safety Authority, in collaboration with patients and clinicians, created a handbook to improve communication during a healthcare encounter.

The Patient's Companion explains roles in the care team, guides patients in giving an accurate medical history, encourages patients and their loved ones to ask more instructive questions, and provides advice and tips on many other topics.

Read this free handbook in English, Spanish or Simplified Chinese at patientsafety.pa.gov/handbook and share it with your patients and colleagues.

For more information or to request a customizable version, email patientsafety@pa.gov.

PSA PATIENT SAFETY

2024 I AM Patient Safety Annual Achievement Awards

By **Eugene Myers**, BS[1]

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The Patient Safety Authority (PSA) established the annual I AM Patient Safety Achievement Awards[1] to recognize Pennsylvania healthcare staff who have shown an extraordinary commitment to improving the well-being of patients. Even as we strive toward a goal of zero harm, it is also essential to recognize when things go right in hospitals and facilities. The IAPS contest is an opportunity to celebrate and share those stories, that they may inform and inspire others in their work.

Although there can be only one winner in each category, every person or team nominated by their peers and grateful families deserves recognition for their committed efforts, accomplishments, and influence on patient safety. In addition to acknowledging the runners-up for this year's awards, many of the nominees' stories are published on the PSA's Changemakers: Stories That Made a Difference site, which highlights examples of how event reporting can trigger change that improves care within a facility, a health system, or even nationwide.[2]

The 2024 IAPS awards were judged by patient safety advocates; government, university, and patient representatives; and healthcare executives, who carefully evaluated 130 nominations from 74 healthcare facilities for innovation, impact, sustainability, and scalability. In addition to the nine juried awards, PSA Executive Director Regina Hoffman, MBA, RN, selected a Choice Award winner for special recognition.

Executive Director's Choice Award

Nikki Verkleeren and the Pharmacy Team

Forbes Hospital, Allegheny Health Network

Nikki Verkleeren, one of the *Executive Director's Choice* award winners, from Allegheny Health Network Forbes Hospital

When a patient received high amounts of a narcotic due to their patient-controlled analgesia (PCA) pump being reprogrammed for an ordered increase, Nikki Verkleeren, PharmD, and the Pharmacy team at Forbes Hospital became passionate about addressing this safety risk. Their efforts turned into a network-level project with multiple facets that ultimately led to not only a new and improved and standardized PCA order set, but also a standardized drug library, standardized epidural orders, and a networkwide equipment upgrade.

Steps involved in this very lengthy process involved a PCA order set redesign including the following components: review of ISMP recommendations and data analysis, design of orders to limit need for higher concentration/admixed bags to lessen the chance for medication errors, and extensive work with the information technology department to define the build and validate on numerous occasions. In addition, Verkleeren and her team updated and personally built the PCA library, employing double checks by Pharmacy and incorporating recommendations from the epidural library reviews. The extensive work with the library was duplicated for pediatric populations as well.

Education was systemwide, with Verkleeren working with a physician advisory group to ensure provider education was adequate and order set wording was clear from a physician standpoint. She and the team reworked verbiage on high-dose PCAs to ensure the practice was feasible at all hospitals, even if palliative care is not available, and worked with all disciplines on education regarding this important safety measure. Verkleeren coordinated with the vendor and the installation of software and was the point person for the overall network go-live.

The work and leadership required to carry this project through while Verkleeren conducted her normal day-to-day responsibilities was immense, but patients are safer across the entire system for it.

Time–Outs Award

The Department of Surgery

Jefferson Abington Hospital

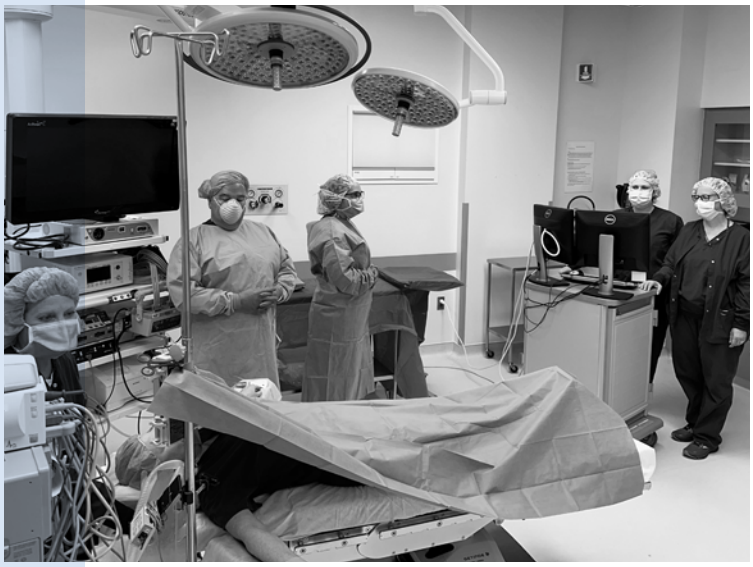
The Department of Surgery at Jefferson Abington Hospital identified an opportunity to revise its time-out policy when there is a change in surgical modality, such as minimally invasive surgery (laparoscopic or robotic) to open surgery. When there is a pivot from one procedure to another, a mandatory second time-out will occur. This is an innovative solution to a low-volume, high-risk situation and puts patient safety first.

Time–Outs award winner, the Department of Surgery, from Jefferson Abington Hospital

Ambulatory Care/Surgery Facility Award

The Staff of the Reading Hospital SurgiCenter at Spring Ridge

Reading Hospital SurgiCenter at Spring Ridge



Ambulatory Care/Surgery Facility award winner, the staff of the Reading Hospital SurgiCenter at Spring Ridge

According to The Joint Commission, wrong-side or -site surgery accounts for about 6% of all sentinel events reported in 2022; however, these statistics do not include near misses. The fast-paced environment of an ambulatory surgery center lends itself to creating opportunity for error. Recognizing this, the staff of the Reading Hospital SurgiCenter at Spring Ridge made it their mission to prevent future wrong-patient, -implant, -side, and -site surgery—and supplied a solution to a potential patient safety threat.

Quarterly audits were conducted on a variety of surgical specialties for staff to identify ways to decrease the chance for wrong-side or -site surgery. Audits include the pre-procedure verification, where the focus is on correctness of the consent and history and physical examination (H&P), in addition to surgical site identification and site marking. The second phase includes the operating room (OR) staff and the time-out (final pre-procedure pause). An average of 45 cases per quarter are observed and reported.

The findings revealed that patient identification, documentation verification, and site marking are completed without incident in preop. Findings from the OR revealed the staff were engaged during the time-out process, meaning all work stops except ventilation, and verbal acknowledgement occurred. The greatest area of concern noted from the audits involved surgeons: The results revealed physician engagement during the time-out process was at 83% (calendar year 2021).

Knowing that there was the potential for a wrong-site surgery, staff ran with ideas on how to improve engagement. Staff were reeducated on the importance of all work stopping and focusing on the time-out. Administration empowered staff to speak up if they noted someone was distracted. Surgeons who did not properly perform the time-out were identified. Our results increased to 86% (CY 22).

Staff next decided to do a deeper dive into the results. Additional questioning of staff found that during the time-out phase, surgeons were verbally acknowledging the specific patient information; the problem was getting the surgeon to stop what they were doing and give their undivided attention to the circulating nurse who was conducting the time-out. To combat this situation, staff decided they would have the surgical technician keep the back table away from the surgical field, thus creating an environment where the surgeon could be more engaged during the time-out process. Our current surgeon engagement rate sits at 92% (CY 23, quarters 1–3).

Throughout the patient encounter from scheduling until surgical start time, staff are responsible and empowered to speak up if they have a concern. Registration staff will seek clarification from the surgeon's office when scheduling the case. Preop staff question the surgeon if the consent varies from the H&P. As an added safeguard, the patient participates in the process. Even when everything goes accordingly with pre-procedure verification and the time-out, mistakes can still occur. Staff stay vigilant in the OR when moving to different phases of the surgery.

This project was staff driven and received full support from administration. Staff are awarded "Good Catches" when finding inconsistencies in the documentation, and their stories are shared with the unit.

Transparency and Safety in Healthcare Award

OB/Newborn Patient Safety and Quality Committee

UPMC Hamot

A young couple came to UPMC Hamot to deliver their first child—what is supposed to be one of the most exciting moments of their lives. The labor was long and complicated, requiring a vacuum delivery due to recurrent significant variable decelerations, but he arrived, and his parents held and snuggled their perfect baby boy. Although he met the criteria for a healthy newborn, several post-delivery medical errors resulted in him going undiagnosed with a subgaleal hemorrhage which led to his death.

Transparency in healthcare is so important to patient safety and yet it is so challenging when things go dreadfully wrong. Despite how daunting the task was, the team had a duty to reflect on their errors, identify process improvement strategies for implementation, and share the story. That has been the guiding principle of their OB/Newborn Patient Safety and Quality committee.

A subgaleal hemorrhage is a rare but potentially lethal event in newborns: a life-threatening emergency caused by bleeding that accumulates between the skull and the scalp. The hemorrhage is typically caused by a rupture of the emissary veins (especially with vacuum-assisted births). It can lead to hypovolemic shock, anemia, coagulopathy, and death. Treatment includes bandage compression, aggressive administration of blood products, and surgery. This team learned from its extensive review of this case that opportunities existed in education, assessment skills, and the need for the development of a tool that would enable the staff to identify potential brain bleeds in these cases more quickly.

For future patient safety in the hospital's most vulnerable population, this committee developed necessary education and a tool that is now mandatory for all staff in the maternity departments. All newborns delivered with an instrumental assist are to have surveillance observations and examination at 1, 2, 3, 4, 6, 8, and 12 hours of age. In addition to baseline newborn observations (activity, color, heart rate, respiratory rate, and temperature), examination of the head includes visual inspection of the scalp and palpating the head to note any ballotable mass or movement of fluid (gravity dependent) in the scalp. Staff also notes the color and head shape, including displacement of the ears or pitting edema, and a head circumference. If there are any changes in the newborn from the immediate baseline, staff is to reach out for a bedside evaluation by the neonatal intensive care unit (NICU) or pediatric provider and a complete blood count is to be ordered.

An open culture of transparency and patient safety allows for greater innovation to occur, as demonstrated by this committee in sharing the unfortunate, but impactful story with other newborn facilities for awareness and education to avoid another newborn tragedy in the future.

Transparency and Safety in Healthcare award winner, the OB/Newborn Patient Safety and Quality Committee from UPMC Hamot

Sepsis Award

Crystal Ratkovsky, CCRN

UPMC Hamot

Sepsis award winner, Crystal Ratkovsky, from UPMC Hamot

Crystal Ratkovsky, CCRN, is a dedicated nurse at UPMC Hamot with over 15 years of experience who has a focused passion around sepsis. She led the initiative to introduce a sepsis alert for patients meeting the criteria of sepsis/systemic inflammatory response syndrome (SIRS) and developed a sepsis screening tool and checklist. Recognizing the need for staff on all units to be well versed on the topic of sepsis, early recognition, and proper and timely treatment, she also developed a sepsis committee to focus on active staff participation in providing sepsis education to clinical and medical staff.

Through this committee, Ratkovsky was able to engage nurses and physicians to commit to being a sepsis coach and champion in any sepsis alert and drive sepsis awareness. She collaborated with other disciplines for their buy-in and engagement around this initiative. She went above and beyond to not only make this team, but also to help them be successful with the implementation of sepsis protocol for the sepsis alert. Following staff feedback on how they will be most responsive to answering to the sepsis conditions, the alert is text paged in addition to being announced on the overhead speaker, and a sepsis checklist bundle enables them to act appropriately and with confidence.

She continues to drive sepsis recognition and staff education by engaging the sepsis committee and unit-based clinicians. She put together an entire sepsis awareness campaign and started an annual sepsis walk. She held a one-hour sepsis lecture in which two sepsis survivors spoke about their experience, underscoring the importance of early recognition and timely sepsis treatment. Ratkovsky monitors all sepsis patients, and outcomes, and sepsis bundle treatment, and provides constructive feedback to staff on any outliers in treatment.

Her sepsis initiatives have had a significant impact on reducing further harm and improving patient care and outcomes, and it is sustainable, reliable, and scalable. The sepsis alert alone has helped staff become more knowledgeable in identifying the signs and symptoms of sepsis, and they have become more confident in collaborating with providers with their assessment. The team of sepsis coaches and champions she developed has educated their peers on sepsis recognition and improved the treatment of sepsis.

Improving Diagnosis award winners, Neophytos Zambas, Jessica Schumann, and Parmjyot Singh
Not pictured: Benjamin Slovis and Jaclyn King, from Jefferson Torresdale Hospital

Improving Diagnosis Award

Jessica Schumann, DO, Parmjyot Singh, DO, Neophytos Zambas, DO, Benjamin Slovis, MD, MA, and Jaclyn King, MS, RT

Jefferson Torresdale Hospital

Emergency department (ED) clinicians routinely use clinical calculators and scores to aid in medical decision-making, and these evidence-based tools are built into Jefferson's electronic health record (EHR). An ED physician, residents, and EHR experts at Jefferson Torresdale Hospital conducted a laborious review of the existent tools and updated clinical scores and assessments. These updates are more user-friendly and help clinicians create patient care plans more quickly and efficiently across 11 Jefferson EDs.

Safety Story Award

The Emeritus Nurse Program

Penn State Health Milton S. Hershey Medical Center

Safety Story award winner, the Emeritus Nurse Program at Penn State Health Milton S. Hershey Medical Center

The Emeritus Nurse Program has arguably prevented harm in hundreds of vulnerable patients. Emeritus nurses (E-RNs) are seasoned and often retired registered nurses who work on a per diem basis, primarily supporting the bedside nursing staff in reviewing and delivering discharge instructions directly to patients. Originally created and launched as an innovative staffing strategy, the E-RNs have emerged as safety champions. They have documented and helped resolve over 215 near miss events related to discharge instruction errors. These great catches are frequently found in conversation with the patient and through investigation into the electronic health record, including home medication reconciliation, inpatient orders, and physician progress notes. Because their time is dedicated to this work, E-RNs have been able to stop and resolve many discharge medication errors related to duplication, omission, and appropriate dosing. Below are several examples of specific patient interactions that highlight their nomination for the Safety Story award.

On the surgical care unit, an E-RN identified that in the written instructions the provider stated the patient would be discharged on Lovenox [an anticoagulant that helps prevent blood clotting] injections. However, when the medication list was reviewed, Lovenox had not been ordered. The E-RN contacted the physician directly to clarify the orders. The provider placed the correct orders and the patient was given correct discharge information with the correct prescriptions. It could have been very dangerous had this been missed, as this postoperative patient was likely at high risk for a pulmonary embolism, stroke, or heart attack.

On the medical oncology unit, an E-RN noted that a patient was ordered sliding scale insulin and nitroglycerin tablets on discharge. The sliding scale did not have clear dosage times, and the nitroglycerin tablets did not clarify when to stop taking the medication and call 911, especially if their chest pain continued. The E-RN contacted the covering physician, who updated the orders, and a new discharge document was printed. Both these medications require this key information to keep patients safe at home. Unknown insulin administration times could lead to hyper- or hypoglycemia [high or low blood sugar, respectively], and not notifying 911 could delay lifesaving care.

Other examples include rectifying double orders of narcotics with differing doses, clarifying orders for medications with conflicting diet instructions, and even hand-delivering discharge instructions to patients in the main lobby after they were forgotten accidentally. Even small corrections to discharge instructions and understanding can prevent future harm, including readmission or death.

While not all 215 examples can be provided, it is clear that E-RNs utilize their nursing experience to reduce harm events by reviewing discharge instructions away from a traditional assignment and independently requesting changes as needed from providers. In a time when technology can be slow, incomplete, complicated, and expensive, E-RNs have been able to intervene as a final safety barrier in the continuum of care. Discharge can be a confusing time for patients and their families, but E-RNs' knowledge and diligence have been a true gift to them and the organization over the last year.

Long–Term Care Facility Award

Patients at Risk Committee Members: Rosie Minniti, Senida Nuhanovic, Angela Wright, Jodie Roese, Suzanne Sawicky, Sarah Leuch, Jillian Wagner, DJ Turner, Brianna Houck, Dina Alexander, and Dawn Snyder

Providence Point, Baptist Senior Family

Long–Term Care Facility award winner, Patients at Risk Committee members, from Providence Point

In October 2022, Baptist Senior Family decided to close its Mt. Lebanon campus, a facility with 125 years of service and a five-star rating, displacing approximately 90 residents and the staff. During the transition, many of its dedicated staff members from all departments transferred to a sister location, Providence Point. Mixing two unique cultures is never an easy task; however, these individuals did so with grace and dignity and came together to provide optimal outcomes to our residents with a focus on use of clinical data.

The Patients at Risk (PAR) meeting was formed as a way for the new interdisciplinary team to engage in meaningful discussions and formalize residents' individual plans of care, considering their emotional, social, and spiritual needs. Healthcare truly takes a team to deliver the best experiences to residents. This often begins before a resident steps foot through the facility's doors. This team, being relatively new to one another and to the facility, strived for the best outcomes for the residents and worked together to identify resident risk and swift intervention to promote positive outcomes.

The team met weekly and proactively identified residents at risk using analytical data derived from clinical software, such as review of residents triggering on the quality measure reports, infections, falls, grievances, weights, therapy concerns, and medical record documentation.

The kick-off meeting was held in June 2023 and the team determined to focus on falls with major injuries, associated in-house acquired infections, and antipsychotic medications.

Reviewing first quarter data, the team

- Conducted training on falls and fall prevention
- Identified residents at risk for falls via assessment and event reports
- Updated care plan with specific, resident-centered interventions in mind
- Implemented telehealth (Third Eye Health) with physician access 24/7, leading to a 92% treat-in-place rate
- Formed a monthly infection control meeting with the interdisciplinary team and medical director
- Provided in-services by the infection preventionist on handwashing and urinary tract infection (UTI) prevention, including Foley catheter care, peri-care, incontinence care, increasing fluid intake, Enhanced Barrier Precautions
- Increased access to eye washing stations in community soiled utility rooms
- Held a monthly Antipsychotic Stewardship Meeting that included the pharmacy consultant, psychiatric nurse practitioner, social service, medical director, and nursing administration, to monitor generic dispersion ratio, behaviors, 14-day stop dates, and to avoid PRN ("as necessary") use

Below is the analytical data and outcomes benchmarked as a result of formation of PAR Meetings beginning first quarter 2023 on the areas of focus:

Quality Measures	Quarter 1	Quarter 2	Quarter 3
Falls with major injury	3.57%	3.3%	0%
UTI	6.9%	5.08%	0%
New antipsychotics (ST)	15.6%	0%	0%

This team's commitment to patient safety and continued dedication to provide the best outcomes for residents, and their ongoing efforts in identifying, planning, educating, and coaching, will continue to have a positive impact on the resident experience.

Physician Offices Award

Dr. Mohamed Shitia, Dr. Kevin Colleran, Dr. Arron Wey, and Dr. Shazad Shaikh

Geisinger Orthopaedics and Sports Medicine Scranton

Physician Offices award winners, Dr. Mohamed Shitia, Dr. Kevin Colleran, and Dr. Arron Wey, from Geisinger Orthopaedics and Sports Medicine Scranton. Not pictured: Dr. Shazad Shaikh

Terri Krevey writes: My daughter has been a patient with this orthopedic group for the past five years. She is a senior this year. She played intermural soccer for two years and travel for 11. During her travel career she played on two teams within her club, in two different age groups. She played ODP [Olympic Development Program] for two years as well as guest played for other teams. Practice was twice a week and two to six games on the weekend. We traveled all over eastern Pennsylvania, New Jersey, and Delaware. Tournaments and league games were all year round. We were deeply invested in soccer.

In her 8th grade year, at a tournament, she went for a block tackle and went down. She had to be carried off the field. We went to urgent care and they recommended orthopedics. She saw an awesome orthopedic physician, Dr. Kevin Colleran. He was comforting and informative. He felt it could be one of two things: a fracture or an ACL [anterior cruciate ligament] tear. We all were scared. After an MRI, our biggest fear was an ACL tear, but to our hope and surprise it was two slight fractures in her growth plate of the femur. Dr. Colleran followed her through the recovery process, and she was back to playing soccer in the fall, both travel and now high school.

On a Saturday in the spring of freshman year, her travel team was in the semifinals for the State Cup Championship. They won. On that same weekend she played for the Level Up team within the club; with two minutes left in the game, she went for a block tackle and went down. Again, carried off the field. Back to the orthopedic office. MRI#2 showed an ACL tear. Because of her age she saw the pediatric orthopod, Dr. Shazad Shaikh. He was so compassionate, caring, and friendly. He explained everything. She missed her entire sophomore year of high school. She was back on the field for her junior year thanks to Dr. Shaikh. It was a long haul, but she was back to playing and they won Conference and District titles that year.

In the winter of our daughter's junior year, in a league game, she rolled her ankle over the ball. MRI#3 and another big injury, tears to the tendon and ligament in the ankle and an issue with the medial talar dome. Dr. Arron Wey steps in after Dr. Shaikh left the area. He was friendly and compassionate. High school track season had started. she made it through half of the season before having to be non-weight bearing for six weeks. Then back to the soccer field she went after not being able to finish the track season.

She still had pain and it was getting worse. A sports medicine specialist then stepped in, Dr. Mohamed Shitia. With a complete and detailed examination, he made several recommendations that helped our daughter through her senior year—conference and district titles for the third straight year. The Scranton orthopedics team members were incredible beyond words. The future is hers to take thanks to this group of physicians.

Individual Impact Award

Dawn Goodwin and Shamaine McGlone

Jefferson Torresdale Hospital

At Jefferson Torresdale Hospital, Dawn Goodwin, patient care technician, and Shamaine McGlone, patient safety associate, worked closely with a patient whose behavior was not initially favorable to receiving safe care in the hospital to being receptive to inpatient care and treatment. They were able to do this by building a good rapport with the patient, and this connection comforted and redirected the patient. Their patience and caring greatly improved the situation for the patient and their colleagues.

Individual Impact award winners, Dawn Goodwin and Shamaine McGlone, from Jefferson Torresdale Hospital

Runners–Up

Sepsis

Sepsis Improvement Team, *Regional Hospital of Scranton, Commonwealth Health*

Emergency Department, *Grove City Hospital*

Ambulatory Care/Surgery Facility

Einstein Endoscopy Center Blue Bell, *Jefferson Health*

Randi Shupp, PA-C, *Lehigh Valley Health Network–Tilghman*

Long–Term Care Facility

Georgina Philbin, RN, *Willow Brooke Court Skilled Care Center at Brittany Pointe Estates*

Juniper Bucks Skilled Nursing Rehab: Theresa Bush, RN, Stephanie Nemeth, RN, Nicole Sokolowska, Emily Kielar, Princy Vaidyan, RN, Heidi Burk, Dr. Neal Mermelstein, *Juniper Village at Bucks County Rehabilitation and Skilled Care*

Transparency and Safety in Healthcare

Magdalena Moyer, *Penn State Health St. Joseph - Cancer Center*

Surgical Services and Executive Leaders, *UPMC West Shore*

Improving Diagnosis

The Center for Diagnostic Leadership Team: Dan Hyman, MD, Kathy Shaw, MD, Eileen Ware, MSN, RN, Meghan Galligan, MD, Cara Jefferies, MSN, RN, Irit Rasooly, MD, Jill Krause, MD, Morgan Congdon, MD, Rich Scarfone, MD, *Children's Hospital of Philadelphia*

Emergency Department, Emergency Department Registration, and Cardiology Department EKG Techs, *Saint Vincent*

Safety Story

Lyndsay Horwedel, BSN, RN, Olivia Johnson, PharmD, Kelly Romano, Carlos Ayala, *Jefferson Einstein Montgomery*

Emergency Response Team, *WVU Medicine–Uniontown Hospital*

Individual Impact

Chelsea Johns, RDN, *Hamilton Health Center*

Ruchi O'Reilly, MSN, RN, *Thomas Jefferson University Hospitals*

Physician Offices

Medical Oncology Department: Jill Ranochak, RN, Maggie Spaeder-Hodges, RN, Danielle Klingerman, RN, and Valerie Dietz, *Jefferson Einstein Montgomery Hospital*

Lindsay Liggett, *WellSpan Franklin ENT*

Time–Outs

Joanne Braswell, Forbes Hospital, *Allegheny Health Network*

Abbe Seidel, RN, *Lehigh Valley Hospital–Cedar Crest*

I **AM** PATIENT SAFETY **2024**

Thank you to this year's judges:

Mike Bruno, MD, *Penn State Milton S. Hershey Med. Center*

Sophie Campbell, MSN, RN, *PADONA/LTCN*

Dan Degnan, PharmD, MS, *Purdue University*

Diane Frndak, PhD, MBA, *Robert Morris University*

Regina Hoffman, MBA, RN, *Patient Safety Authority*

Stephen Lawless, MD, *Nemours Children's Health*

Ariana Longley, MPH, *Patient Safety Movement Foundation*

Dwight McKay, *Patient representative*

Adam Novak, MA, *Michigan Health & Hospital Association*

Marty Raniowski, MPP, *PAMED*

Rob Shipp, PhD, RN, *HAP*

Stanton Smullens, MD, *Retired*

Eric Weitz, Esq., *The Weitz Firm*

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About the Author

Eugene Myers (eugmyers@pa.gov) is the associate editor of Engagement and Publications for the Patient Safety Authority. He previously served as editor-in-chief of Communications, Office of Institutional Advancement, at Thomas Jefferson University and Jefferson Health. He earned his bachelor's degree from Columbia University, is a graduate of the Clarion West Writers Workshop, and is an award-winning author of seven novels for young adult readers.

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