PATIENT SAFETY

June 2023 | Vol. 5, No. 2

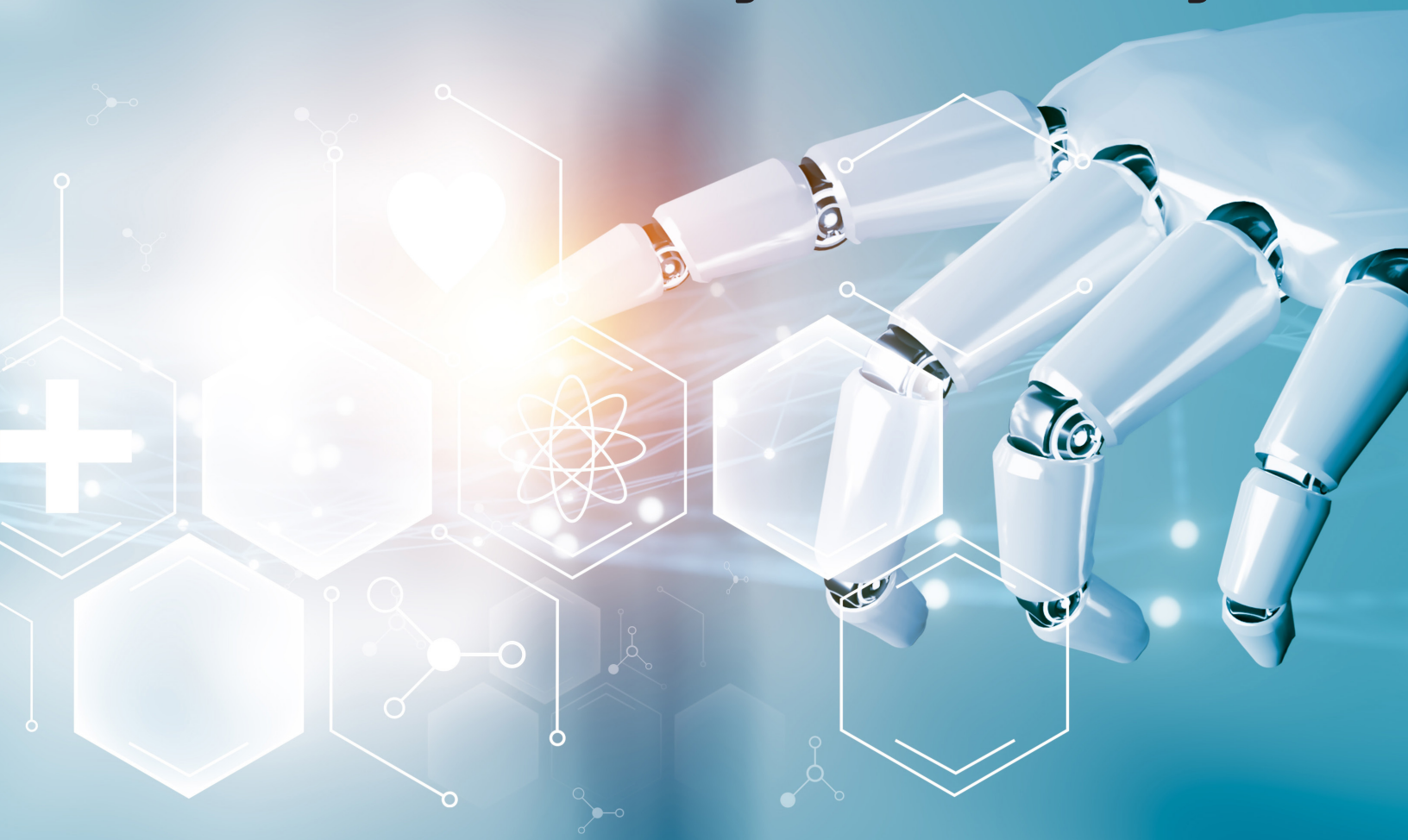
Annual data analyses

Continuous monitoring after discharge

Safety alert: Methylprednisolone

ARTIFICIAL INTELLIGENCE

How "intelligent" is it really?



LETTER *From the Editor*

Regina Hoffman,
Editor-in-Chief
Patient Safety

It's officially summer! The warmer months can bring picnics, barbecues, and fireworks—along with an uptick in related injuries. So, please stay safe to stay away from the emergency room!

Speaking of summer, one of the current "hot" topics is artificial intelligence (AI). What exactly is it? What can it do? Is AI always better than a human? AI researcher Dr. Avishek Choudhury answers these questions and more.

Also in this issue are our annual data analyses for acute care facilities and nursing homes. Don't miss the latest trends in patient safety events throughout Pennsylvania. "Error related to a procedure, treatment, or test" was the most reported category last year. How does that compare to your facility?

Ever log into your electronic health record and feel nostalgic for paper charts because the interface was so hard to read? Zoe M. Pruitt et al. examine characteristics of a poorly designed visual display and provide considerations for how to improve your own system.

Zane Wolf presents an evidence-based teaching approach to raising awareness of the effects of patient harm on caregivers.

A team of researchers from Denmark assessed the feasibility of continuous vital sign monitoring at home to alleviate the shortage of inpatient beds.

Rounding out this issue are a recent safety alert related to methylprednisolone and cow's milk components, and the winners in this year's I AM Patient Safety annual achievement awards.

This journal was designed for our authors to freely share the important work they do to improve patient safety, and for our readers to freely receive the information, strategies, and lessons learned to make the care they provide and receive safer. Thank you to our authors, reviewers, staff, editorial board, and readers for your continued contributions.

Be safe and be well!

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.

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PATIENT SAFETY INITIATIVE

Patient Safety Trends in 2022:

An Analysis of 256,679 Serious Events and Incidents From the Nation's Largest Event Reporting Database

By **Shawn Kepner**, MS*◆ & **Rebecca Jones**, MBA, RN◆

DOI: 10.33940/001c.74752

Abstract

Background: Pennsylvania is the only state that requires acute care facilities to report all events of harm or potential for harm. 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 4.5 million acute care event reports dating back to 2004. Herein, we examine patient safety event reports submitted to the PA-PSRS acute care database in 2022 and compare them to prior years.

Methods: We extracted data from PA-PSRS and obtained data from the Pennsylvania Health Care Cost Containment Council (PHC4). Counts of reports were calculated based on report submission date, and rates were calculated 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: A total of 256,679 reports were submitted to PA-PSRS in 2022, representing an 11.1% decrease from 2021. Three facilities collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease. Reports of serious and high harm events increased by 7.7% and 11.1%, respectively. Of the 256,679 reports submitted, 95.9% were from hospitals, 3.9% were from ambulatory surgical facilities, and 0.2% were from birthing centers and abortion facilities. The vast majority of the 2022 reports were incidents (96.2%) as opposed to serious events (3.8%). For each of the past five years, the most frequently reported event type was Error Related to Procedure/Treatment/Test, accounting for 32.8% of all submitted acute care event reports in 2022. The second, third, and fourth most frequently reported event types in 2022 were Complication of Procedure/Treatment/Test, Medication Error, and Fall, accounting for 15.6%, 13.2%, and 12.8% of submitted reports, respectively. The reported event rate based on occurrence date for hospitals in the first half of 2022 was 27.5 reports per 1,000 patient days. For ASFs, the reported event rate for the first half of 2022 was 9.4 reports per 1,000 surgical encounters.

Conclusions: There was a decrease in the number of incident reports submitted to PA-PSRS in 2022 and an increase in serious and high harm event reports. PSA will continue to work with facilities, monitor reporting, and take further action as needed.

Keywords: *acute care, patient safety, event reports, annual report, incidents, serious events, reported event rate*

*Corresponding author
◆Patient Safety Authority

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

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)[1], which is the largest repository of patient safety data in the United States and one of the largest in the world, with over 4.5 million acute care records.

This article provides details from the PA-PSRS acute care reports submitted in 2022, along with data and insights that can be used to focus improvements in patient safety.

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, 2023, and data from the Pennsylvania Health Care Cost Containment Council (PHC4)[2]. Counts of reports are based on report submission date; 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

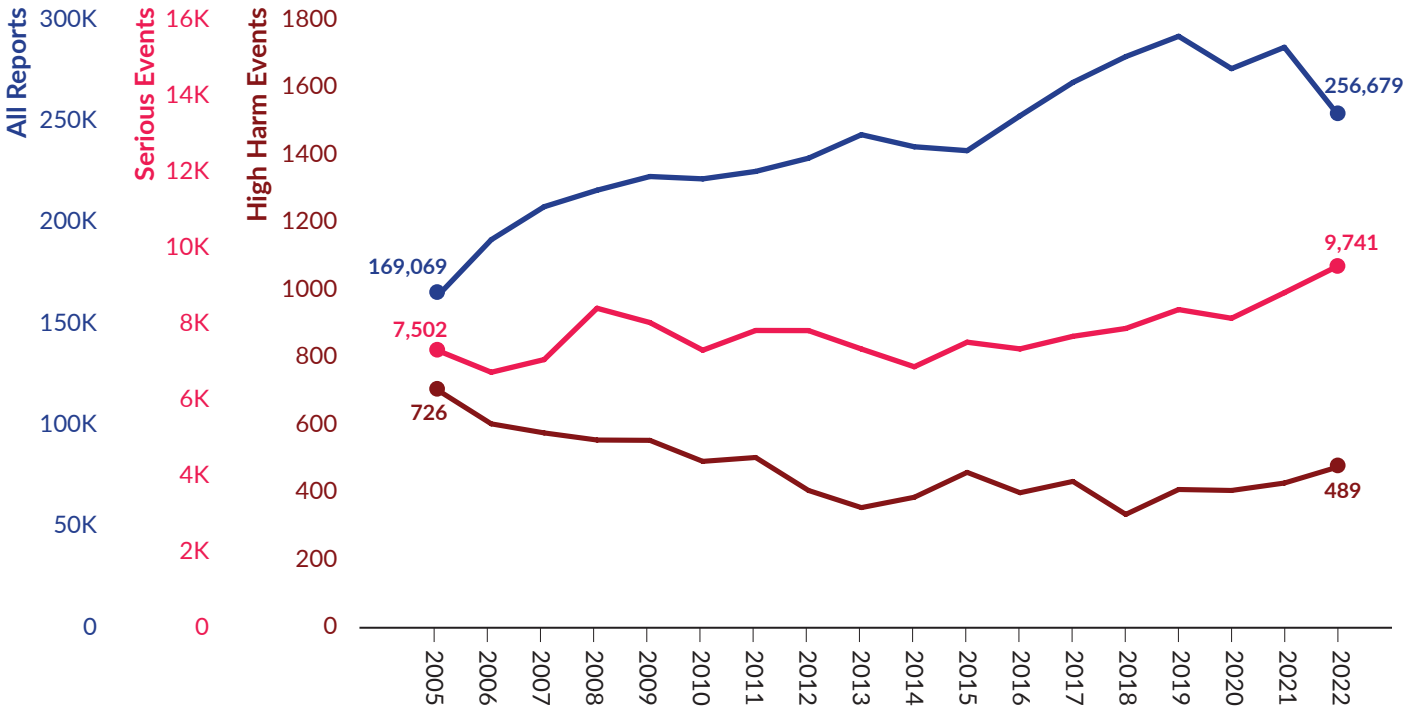
Table 1. PA-PSRS Harm Scores

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

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

[2]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. Total Reports, Serious Events, and High Harm Events Submitted to PA-PSRS



Note: The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.

used for rate calculations to be in line with the same timeframe in which the patient days or surgical encounters occurred. The most current data from PHC4 was for Q2 2022, which allowed us to calculate 2022 rates using the first two quarters of data.

Results

A total of 256,679 reports were submitted by Pennsylvania acute care facilities in 2022, of which 9,741 were serious events. Of those serious events, 489 were classified as high harm (see **Figure 1**). Serious and high harm events increased by 7.7% and 11.1%, respectively, between 2021 and 2022.

The total number of reports decreased 11.1% in 2022 compared to 2021, which represents the largest year-over-year decrease since the inception of PA-PSRS. Further analysis reflects that three facilities collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.

Incidents and serious events expressed as a percent of reports are shown in **Figure 2**. The percentage of reports that were serious events in 2022 represents the largest year-over-year increase, going from 3.1% in 2021 to 3.8% in 2022. While there was an increase in the number of serious event reports submitted in 2022, the increase in percentage of serious events was due, in part, to a significant decrease in the number of incidents submitted.

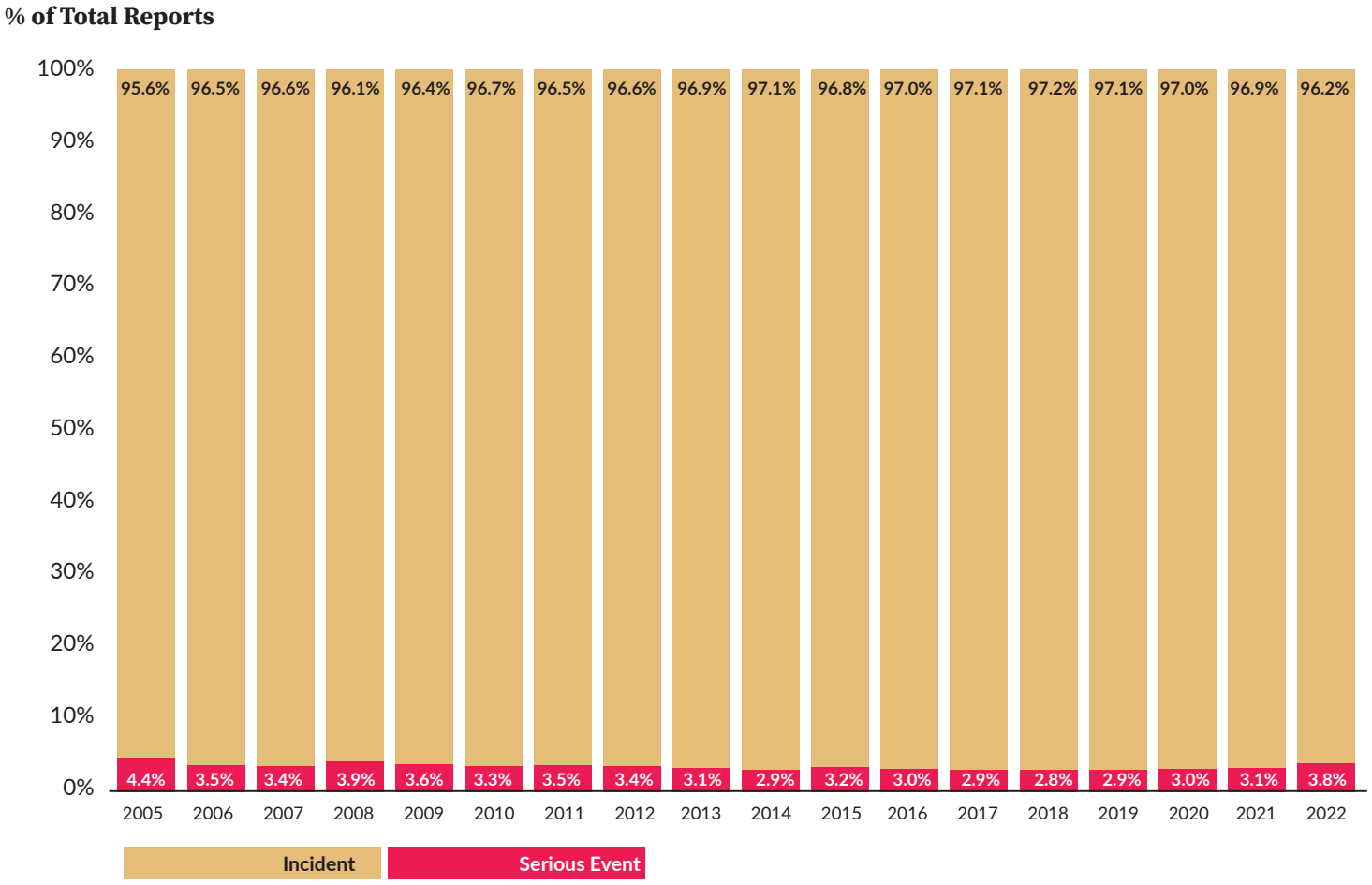
Table 2 shows a breakdown of incidents and serious events by facility type from the past three years. From 2021 to 2022, the number of hospital reports decreased by 33,432 (12.0%), whereas reports from other acute care facilities (ASFs, birthing centers [BRCs], and abortion facilities [ABFs]) increased by 1,253 (13.5%). The percentage of reports submitted by acute care facilities other than hospitals increased for the second straight year, going from 2.8% in 2020 to 3.2% in 2021 and to 4.1% in 2022. The 4.1% in 2022 was comprised of 3.9% from ASFs and 0.2% from BRCs and ABFs. The increase in 2022 is a result of the increase in reports submitted by other acute care facilities and the decrease in reports submitted by hospitals.

The harm score distribution for reports submitted during years 2020–2022 is shown in **Table 3**. Consistently, the most frequent harm score is C (40.9% in 2022), followed by harm scores D, A, and B2. Harm scores B2, C, and D showed the largest decreases in number of reports submitted. Serious events comprised 3.8% of all reports in 2022, with harm scores E and F being reported most frequently.

Reported Event Rates Based on Occurrence Date

Rates are standardized statistics used for direct, per-unit comparisons over time. In this analysis, 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. **Figure 3** shows that

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



Note: While there was an increase in the number of serious event reports submitted in 2022, the increase in proportion of serious events to incidents was due, in part, to a significant decrease in the number of incidents submitted.

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

Facility Types	Event Classification	Number of Reports			% of Total Reports		
		2020	2021	2022	2020	2021	2022
Hospitals	Incident	263,997	272,445	238,367	94.8%	94.3%	92.9%
	Serious Event	6,726	7,109	7,755	2.4%	2.5%	3.0%
	Subtotal	**270,723**	**279,554**	**246,122**	**97.2%**	**96.8%**	**95.9%**
Other Acute Care Facilities	Incident	6,169	7,370	8,571	2.2%	2.6%	3.3%
	Serious Event	1,638	1,934	1,986	0.6%	0.7%	0.8%
	Subtotal	**7,807**	**9,304**	**10,557**	**2.8%**	**3.2%**	**4.1%**
Totals	Incident	270,166	279,815	246,938	97.0%	96.9%	96.2%
	Serious Event	8,364	9,043	9,741	3.0%	3.1%	3.8%
	Grand Total	**278,530**	**288,858**	**256,679**	**100.0%**	**100.0%**	**100.0%**

Note: Other Acute Care Facilities include ambulatory surgical facilities, birthing centers, and abortion facilities.

The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.

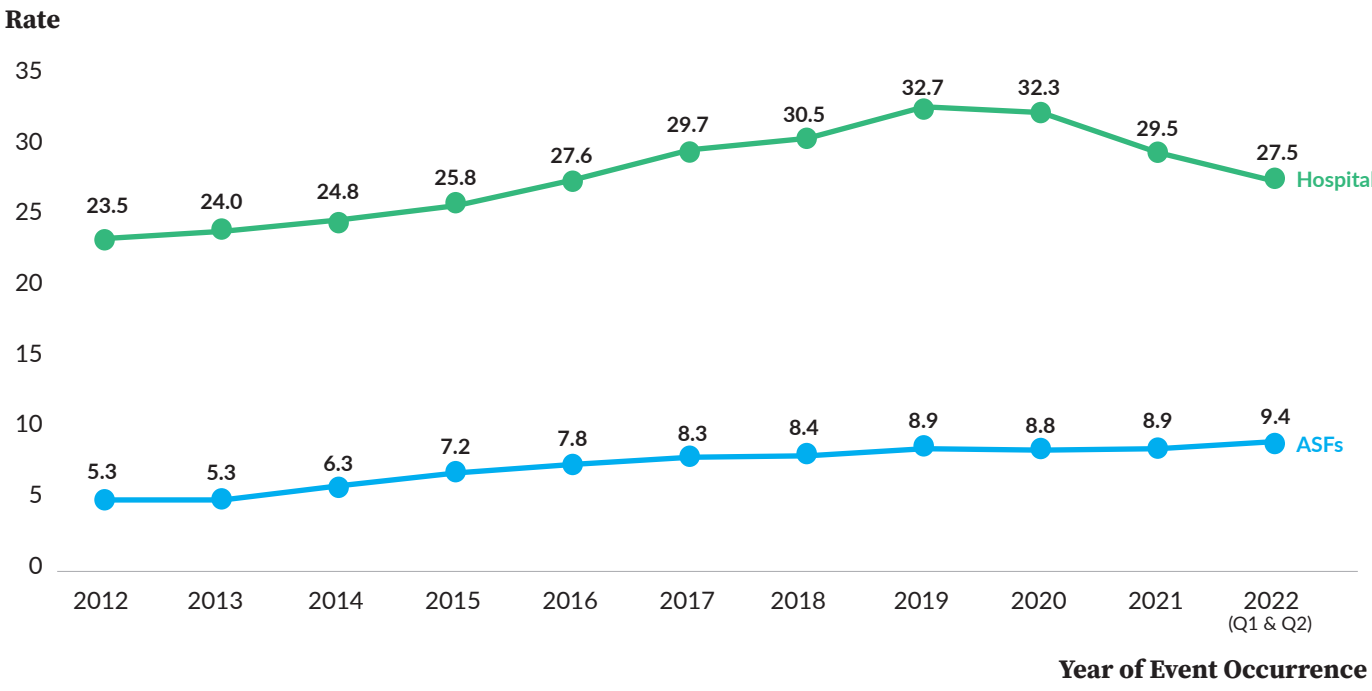
Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or classification changes made by reporting facilities.

Table 3. Number and Percentage of Reports Submitted to PA-PSRS by Harm Score With Change in Reports From 2021 to 2022

	Number of Reports			% of Total Reports			Change in Reports 2021 to 2022	
Harm Score	2020	2021	2022	2020	2021	2022	Number	Percent
A	27,563	28,003	29,658	9.9%	9.7%	11.6%	1,655	5.9%
B1	2,803	2,772	2,043	1.0%	1.0%	0.8%	-729	-26.3%
B2	34,100	35,874	22,236	12.2%	12.4%	8.7%	-13,638	-38.0%
C	112,976	113,680	105,106	40.6%	39.4%	40.9%	-8,574	-7.5%
D	92,724	99,486	87,895	33.3%	34.4%	34.2%	-11,591	-11.7%
Incidents - Subtotal	270,166	279,815	246,938	97.0%	96.9%	96.2%	-32,877	-11.7%
E	5,863	6,330	6,811	2.1%	2.2%	2.7%	481	7.6%
F	2,084	2,273	2,441	0.7%	0.8%	1.0%	168	7.4%
G	56	64	53	0.0%	0.0%	0.0%	-11	-17.2%
H	115	143	165	0.0%	0.0%	0.1%	22	15.4%
I	246	233	271	0.1%	0.1%	0.1%	38	16.3%
Serious Events - Subtotal	8,364	9,043	9,741	3.0%	3.1%	3.8%	698	7.7%
Total	**278,530**	**288,858**	**256,679**	**100.0%**	**100.0%**	**100.0%**	**-32,179**	**-11.1%**

Note: The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.
Numbers shown for prior years may differ from previously published numbers due to subsequent report deletions or harm score changes made by reporting facilities.

Figure 3. PA-PSRS Reported Event Rates Based on Event Occurrence Date for Hospitals (Reports per 1,000 Patient Days) and ASFs (Reports per 1,000 Surgical Encounters)



Note: The 2022 reported event rate is based on event occurrence dates in Q1–Q2 only, due to lagged data related to patient days and surgical encounters.
The decrease in reported event rate in Q1–Q2 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021.
Rates shown for prior years may differ from previously published rates due to subsequent changes made by reporting facilities.

the 2022 reported event rate for hospitals for reports with event occurrence dates through Q2 2022 decreased by 2.0 percentage points from 2021, bringing the reported event rate for the first half of calendar year 2022 to 27.5, the lowest level it has been since 2016 when it was 27.6; for ASFs, the 2022 reported event rate through Q2 2022 is higher than the rate in 2021 (9.4 and 8.9, respectively).

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 of reports for each main event type over the past five years. For each of the past five years, the most frequently reported event type is Error Related to Procedure/Treatment/Test (P/T/T) with 84,287 in 2022 (32.8% of reports).

From a distribution perspective, the greatest increase in percent of reports in 2022 compared to 2021 occurred with event type Error Related to P/T/T, which increased by 1.5 percentage points, from 31.3% of reports in 2021 to 32.8% in 2022. The largest decrease occurred with event type Medication Error, which dropped 3.7 percentage points, from 16.9% in 2021 to 13.2% in 2022. This change can primarily be attributed to one facility that reported a much lower number of medication error incident reports in 2022 compared to 2021, accounting for 84% of the overall decrease in this event type.

The number and percentage of serious events submitted for each event type for the past five years are shown in **Table 5**. In 2022, Complication of P/T/T represented 15.6% of total reports and accounted for the majority (53.5%) of serious event reports. In terms of distribution, Adverse Drug Reactions showed the largest increase among serious event reports, increasing by 1.1 percentage points. The largest decrease was with Complication of P/T/T, which dropped 0.8 percentage points in 2022.

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 2022 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.

While the total number of reports decreased by 32,179 from 2021 to 2022, a large percentage of the decrease (43.2% or 13,912 reports) was due to decreases in three event subtypes, each of which had a single facility comprising at least 75% of the decrease. These three subtypes are Medication Error–Wrong, Medication Error–Other (specify), and Adverse Drug Reaction–Nephrotoxicity.

There were another eight event subtypes for which two to five facilities collectively comprised at least 75% of the decrease. These eight subtypes, which accounted for 27.1% (8,761 reports) of the overall decrease in reports, were as follows: Equipment/Supplies/Devices–Inadequate supplies, Patient Self-Harm–Self-mutilation, Complication of P/T/T–Cardiopulmonary arrest outside of ICU setting, Complication of P/T/T–Emergency Department, Skin Integrity–Other (specify), Skin Integrity–Rash/hives, Equipment/Supplies/Devices–Electrical problem, and Error Related to P/T/T–Laboratory test problem.

If the decreases of 13,912 and 8,761 referenced above are combined, we have a total decrease in reports of 22,673, accounting for 70.5% of the overall decrease of 32,179.

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 2022, 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 2022, with a total of 41,154 reports and representing 16.0% of all reports, increasing from 15.2% of all reports in 2021.

The next most common intersection was with event type Complication of P/T/T and harm score D, with a total of 20,975 reports and representing 8.2% of all reports (the same percentage as 2021).

Care Area and Harm Score

The care area (i.e., location where the event occurred) can help us determine whether there are patterns or trends in reports of specific patient safety concerns related to the location where care is delivered. Within the acute care data, there are 168 care areas for facilities to identify where events occur. We then place these care areas into one of 23 care area groups to produce a cross tabulation with harm score. In **Table 8** we show a cross tabulation of care area group with harm score. This reflects the same two areas of highest concentration as seen in the 2021 data, in the cross sections of the Med/Surg care area group and harm scores C and D. Together these two cells in the cross tabulation account for 16.0% of all reports in 2022.

Care Area and Event Type

Table 9 shows a cross tabulation of care area group and event type. The two highest concentrations of reports are at the intersections of Error Related to P/T/T with Surgical Services (n=18,684) and Emergency (n=13,280) care area groups. The third highest concentration is seen at the intersection of Fall and Med/Surg (n=12,351). These are the same three areas of highest concentration that were seen in the 2021 data.

Other Acute Care Facilities

Given that the acute care data predominately reflects reports from hospitals, it is important to separately analyze data from the other acute care facilities that report to PA-PSRS (comprised mostly of ASFs, along with BRCs and ABFs). **Table 10** shows the distribution of all reports submitted by these other acute care facilities across the 10 main event types in 2022. These facilities show a different distribution compared to the overall data in **Table 4**. In 2022, they reported medication error and fall events less frequently than other event types when compared

Table 4. Number and Percentage of **Reports** Submitted to PA-PSRS by Event Type in Descending Order by 2022 Frequency

	Number of Reports					% of Total Reports				
Event Type	**2018**	**2019**	**2020**	**2021**	**2022**	**2018**	**2019**	**2020**	**2021**	**2022**
Error Related to P/T/T	89,154	96,440	89,335	90,452	**84,287**	31.4%	32.8%	32.1%	31.3%	**32.8%**
Complication of P/T/T	43,202	46,691	45,180	44,129	**40,145**	15.2%	15.9%	16.2%	15.3%	**15.6%**
Medication Error	51,979	52,884	46,559	48,714	**33,982**	18.3%	18.0%	16.7%	16.9%	**13.2%**
Fall	33,657	31,978	32,775	35,600	**32,919**	11.8%	10.9%	11.8%	12.3%	**12.8%**
Other/Miscellaneous	23,139	22,761	23,190	27,707	**26,654**	8.1%	7.7%	8.3%	9.6%	**10.4%**
Skin Integrity	21,752	20,546	19,697	20,583	**17,146**	7.6%	7.0%	7.1%	7.1%	**6.7%**
Equip./Supplies/Devices	7,805	8,792	8,062	7,806	**7,552**	2.7%	3.0%	2.9%	2.7%	**2.9%**
Adverse Drug Reaction	5,958	5,700	5,624	5,868	**6,527**	2.1%	1.9%	2.0%	2.0%	**2.5%**
Transfusion	5,264	6,195	5,779	5,648	**5,235**	1.9%	2.1%	2.1%	2.0%	**2.0%**
Patient Self-Harm	2,439	2,188	2,329	2,351	**2,232**	0.9%	0.7%	0.8%	0.8%	**0.9%**
Total	**284,349**	**294,175**	**278,530**	**288,858**	**256,679**	**100%**	**100%**	**100%**	**100%**	**100%**

Note: The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.
The decrease in number of medication error reports can primarily be attributed to one facility that accounted for 84% of the overall decrease in this event type.
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 2022 Frequency

	Number of Serious Events					% of Total Serious Events				
Event Type	**2018**	**2019**	**2020**	**2021**	**2022**	**2018**	**2019**	**2020**	**2021**	**2022**
Complication of P/T/T	4,183	4,529	4,577	4,907	**5,216**	51.7%	52.7%	54.7%	54.3%	**53.5%**
Fall	961	932	940	1,046	**1,140**	11.9%	10.8%	11.2%	11.6%	**11.7%**
Error Related to P/T/T	799	983	708	849	**850**	9.9%	11.4%	8.5%	9.4%	**8.7%**
Other/Miscellaneous	705	768	753	729	**831**	8.7%	8.9%	9.0%	8.1%	**8.5%**
Skin Integrity	779	654	575	610	**632**	9.6%	7.6%	6.9%	6.7%	**6.5%**
Adverse Drug Reaction	217	241	344	430	**577**	2.7%	2.8%	4.1%	4.8%	**5.9%**
Medication Error	188	182	166	172	**228**	2.3%	2.1%	2.0%	1.9%	**2.3%**
Patient Self-Harm	189	176	166	171	**141**	2.3%	2.0%	2.0%	1.9%	**1.4%**
Equip./Supplies/Devices	56	78	77	96	**86**	0.7%	0.9%	0.9%	1.1%	**0.9%**
Transfusion	17	52	58	33	**40**	0.2%	0.6%	0.7%	0.4%	**0.4%**
Total	**8,094**	**8,595**	**8,364**	**9,043**	**9,741**	**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 2022 Frequency

		2021				2022				Change in Reports 2021–2022	
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	41,948	14.5%	28	0.3%	35,767	13.9%	50	0.5%	-6,181	-14.7%
	Surgery/invasive procedure problem	19,087	6.6%	515	5.7%	19,773	7.7%	592	6.1%	686	3.6%
	Radiology/imaging test problem	8,158	2.8%	37	0.4%	8,318	3.2%	46	0.5%	160	2.0%
	Other (specify)	7,826	2.7%	57	0.6%	8,124	3.2%	62	0.6%	298	3.8%
	Referral/consult problem	7,838	2.7%	17	0.2%	7,230	2.8%	16	0.2%	-608	-7.8%
	Respiratory care	3,419	1.2%	66	0.7%	2,897	1.1%	51	0.5%	-522	-15.3%
	Dietary	2,176	0.8%	9	0.1%	2,178	0.8%	14	0.1%	2	0.1%
Complication of P/T/T	IV site complication (phlebitis, bruising, infiltration)	11,896	4.1%	295	3.3%	10,756	4.2%	300	3.1%	-1,140	-9.6%
	Other (specify)	7,312	2.5%	368	4.1%	6,809	2.7%	410	4.2%	-503	-6.9%
	Complication following surgery or invasive procedure	6,414	2.2%	2,656	29.4%	5,831	2.3%	2,730	28.0%	-583	-9.1%
	Cardiopulmonary arrest outside of ICU setting	3,630	1.3%	84	0.9%	2,879	1.1%	84	0.9%	-751	-20.7%
	Maternal complication	2,527	0.9%	272	3.0%	2,830	1.1%	351	3.6%	303	12.0%
	Catheter or tube problem	3,206	1.1%	208	2.3%	2,653	1.0%	188	1.9%	-553	-17.2%
	Neonatal complication	2,591	0.9%	142	1.6%	2,451	1.0%	149	1.5%	-140	-5.4%
	Extravasation of drug or radiologic contrast	2,323	0.8%	27	0.3%	2,169	0.8%	65	0.7%	-154	-6.6%
	Healthcare-associated infection	1,184	0.4%	557	6.2%	1,149	0.4%	592	6.1%	-35	-3.0%
	Anesthesia event	1,142	0.4%	210	2.3%	1,116	0.4%	258	2.6%	-26	-2.3%
	Onset of hypoglycemia during care	918	0.3%	8	0.1%	936	0.4%	19	0.2%	18	2.0%
	Emergency department	983	0.3%	80	0.9%	562	0.2%	69	0.7%	-421	-42.8%
	Complication following spinal manipulative therapy	3	0.0%	-	-	4	0.0%	1	0.0%	1	33.3%
Medication Error	Wrong	23,666	8.2%	71	0.8%	13,027	5.1%	115	1.2%	-10,639	-45.0%
	Other (specify)	12,244	4.2%	33	0.4%	8,997	3.5%	26	0.3%	-3,247	-26.5%
	Dose omission	4,394	1.5%	20	0.2%	4,072	1.6%	26	0.3%	-322	-7.3%
	Prescription/refill delayed	2,951	1.0%	3	0.0%	2,730	1.1%	2	0.0%	-221	-7.5%
	Monitoring error (includes contraindicated drugs)	2,108	0.7%	15	0.2%	2,148	0.8%	22	0.2%	40	1.9%
	Extra dose	1,804	0.6%	21	0.2%	1,638	0.6%	25	0.3%	-166	-9.2%
	Medication list incorrect	743	0.3%	9	0.1%	666	0.3%	12	0.1%	-77	-10.4%
	Unauthorized drug	737	0.3%	-	-	643	0.3%	-	-	-94	-12.8%
	Inadequate pain management	67	0.0%	-	-	61	0.0%	-	-	-6	-9.0%
Fall	Found on floor	8,729	3.0%	329	3.6%	8,248	3.2%	399	4.1%	-481	-5.5%
	Ambulating	5,097	1.8%	229	2.5%	5,076	2.0%	263	2.7%	-21	-0.4%
	Other/unknown (specify)	5,000	1.7%	92	1.0%	4,239	1.7%	83	0.9%	-761	-15.2%
	Toileting	3,573	1.2%	149	1.6%	3,228	1.3%	139	1.4%	-345	-9.7%
	Lying in bed	3,258	1.1%	41	0.5%	3,056	1.2%	46	0.5%	-202	-6.2%
	Sitting in chair/wheelchair	3,101	1.1%	72	0.8%	2,731	1.1%	57	0.6%	-370	-11.9%
	Assisted fall	2,923	1.0%	21	0.2%	2,624	1.0%	30	0.3%	-299	-10.2%

Event Type	Event Subtype	2021 Number of Reports	2021 % of Total Reports	2021 Number of Serious Events	2021 % of Total Serious Events	2022 Number of Reports	2022 % of Total Reports	2022 Number of Serious Events	2022 % of Total Serious Events	Change in Reports 2021–2022 Number	Change in Reports 2021–2022 Percent
Fall (cont.)	Sitting at side of bed	1,230	0.4%	24	0.3%	1,145	0.4%	26	0.3%	-85	-6.9%
	Transferring	1,038	0.4%	33	0.4%	956	0.4%	34	0.3%	-82	-7.9%
	Hallways of facility	584	0.2%	11	0.1%	590	0.2%	20	0.2%	6	1.0%
	From stretcher	378	0.1%	22	0.2%	368	0.1%	25	0.3%	-10	-2.6%
	Grounds of facility	333	0.1%	12	0.1%	341	0.1%	8	0.1%	8	2.4%
	In exam room/from exam table	356	0.1%	11	0.1%	317	0.1%	10	0.1%	-39	-11.0%
Other/ Miscella-neous	Other (specify)	18,231	6.3%	381	4.2%	17,327	6.8%	396	4.1%	-904	-5.0%
	Unanticipated transfer to higher level of care	8,205	2.8%	401	4.4%	7,883	3.1%	376	3.9%	-322	-3.9%
	Inappropriate discharge	1,140	0.4%	11	0.1%	1,327	0.5%	12	0.1%	187	16.4%
	Other unexpected death	125	0.0%	51	0.6%	108	0.0%	57	0.6%	-17	-13.6%
	Death or injury involving restraints	3	0.0%	3	0.0%	6	0.0%	6	0.1%	3	100%
	Death or injury during inpatient elopement	2	0.0%	2	0.0%	3	0.0%	3	0.0%	1	50.0%
	Electric shock to patient	1	0.0%	-	-	-	-	-	-	-1	-100.0%
Skin Integrity	Pressure injury	8,068	2.8%	483	5.3%	6,510	2.5%	464	0	-1,558	-19.3%
	Other (specify)	6,974	2.4%	40	0.4%	5,859	2.3%	56	0	-1,115	-16.0%
	Skin tear	3,507	1.2%	15	0.2%	2,998	1.2%	40	0	-509	-14.5%
	Abrasion	851	0.3%	3	0.0%	730	0.3%	5	0	-121	-14.2%
	Blister	532	0.2%	5	0.1%	470	0.2%	1	0	-62	-11.7%
	Laceration	292	0.1%	33	0.4%	285	0.1%	33	0	-7	-2.4%
	Burn (electrical, chemical, thermal)	203	0.1%	27	0.3%	176	0.1%	32	0	-27	-13.3%
	Rash/hives	145	0.1%	4	0.0%	108	0.0%	1	0	-37	-25.5%
	Venous stasis ulcer	11	0.0%	-	-	10	0.0%	-	-	-1	-9.1%
Equipment/ Supplies/ Devices	Equipment malfunction	2,519	0.9%	29	0.3%	2,677	1.0%	36	0.4%	158	6.3%
	Equipment not available	952	0.3%	4	0.0%	795	0.3%	-	-	-157	-16.5%
	Sterilization problem	696	0.2%	4	0.0%	763	0.3%	-	-	67	9.6%
	Other (specify)	942	0.3%	12	0.1%	756	0.3%	8	0.1%	-186	-19.7%
	Medical device problem	724	0.3%	24	0.3%	684	0.3%	17	0.2%	-40	-5.5%
	Broken item(s)	627	0.2%	14	0.2%	641	0.2%	16	0.2%	14	2.2%
	Equipment misuse	281	0.1%	2	0.0%	311	0.1%	1	0.0%	30	10.7%
	Disconnected	190	0.1%	4	0.0%	209	0.1%	4	0.0%	19	10.0%
	Equipment safety situation	230	0.1%	1	0.0%	202	0.1%	2	0.0%	-28	-12.2%
	Equipment wrong or inadequate	196	0.1%	-	-	171	0.1%	1	0.0%	-25	-12.8%
	Inadequate supplies	189	0.1%	2	0.0%	151	0.1%	-	-	-38	-20.1%
	Electrical problem	165	0.1%	-	-	130	0.1%	-	-	-35	-21.2%
	Outdated items(s)	95	0.0%	-	-	62	0.0%	1	0.0%	-33	-34.7%

		2021				2022				Change in Reports 2021–2022	
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)	3,939	1.4%	216	2.4%	4,621	1.8%	319	3.3%	682	17.3%
	Skin reaction (rash, blistering, itching, hives)	1,289	0.4%	121	1.3%	1,251	0.5%	145	1.5%	-38	-2.9%
	Mental status change	160	0.1%	34	0.4%	201	0.1%	50	0.5%	41	25.6%
	Hypotension	127	0.0%	30	0.3%	144	0.1%	26	0.3%	17	13.4%
	Hematologic problem	130	0.0%	12	0.1%	117	0.0%	17	0.2%	-13	-10.0%
	Nephrotoxicity	125	0.0%	12	0.1%	99	0.0%	14	0.1%	-26	-20.8%
	Dizziness	67	0.0%	3	0.0%	65	0.0%	2	0.0%	-2	-3.0%
	Arrhythmia	31	0.0%	2	0.0%	29	0.0%	4	0.0%	-2	-6.5%
Transfusion	Event related to blood product sample collection	1,470	0.5%	-	-	1,533	0.6%	-	-	63	4.3%
	Other (specify)	1,674	0.6%	3	0.0%	1,510	0.6%	2	0.0%	-164	-9.8%
	Event related to blood product administration	912	0.3%	5	0.1%	795	0.3%	7	0.1%	-117	-12.8%
	Apparent transfusion reaction	783	0.3%	24	0.3%	615	0.2%	31	0.3%	-168	-21.5%
	Event related to blood product dispensing or distribution	428	0.1%	-	-	425	0.2%	-	-	-3	-0.7%
	Consent missing/inadequate	259	0.1%	-	-	237	0.1%	-	-	-22	-8.5%
	Wrong patient requested	48	0.0%	-	-	45	0.0%	-	-	-3	-6.3%
	Special product need not issued	16	0.0%	-	-	21	0.0%	-	-	5	31.3%
	Special product need not requested	17	0.0%	1	0.0%	18	0.0%	-	-	1	5.9%
	Wrong component issued	17	0.0%	-	-	18	0.0%	-	-	1	5.9%
	Mismatched unit	11	0.0%	-	-	11	0.0%	-	-	0	0.0%
	Wrong component requested	8	0.0%	-	-	7	0.0%	-	-	-1	-12.5%
	Wrong patient transfused	5	0.0%	-	-	-	-	-	-	-5	-100.0%
Patient Self-Harm	Other self-harm (specify)	1,271	0.4%	61	0.7%	1,351	0.5%	58	0.6%	80	6.3%
	Self-mutilation	827	0.3%	19	0.2%	644	0.3%	20	0.2%	-183	-22.1%
	Ingestion of foreign object or substance	229	0.1%	70	0.8%	215	0.1%	50	0.5%	-14	-6.1%
	Suicide attempt - Injury	17	0.0%	17	0.2%	11	0.0%	11	0.1%	-6	-35.3%
	Anorexia/bulemia	3	0.0%	-	-	9	0.0%	-	-	6	200.0%
	Suicide - Death	4	0.0%	4	0.0%	2	0.0%	2	0.0%	-2	-50.0%
Total		**288,858**	**100%**	**9,043**	**100%**	**256,679**	**100%**	**9,741**	**100%**	**-32,179**	**-11.1%**

Note: The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted for 57.8% of the overall decrease.

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 2022 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	15,187	795	10,310	41,154	16,010	600	167	15	24	25	**84,287**
Complication of P/T/T	2,067	110	784	10,993	20,975	3,315	1,626	29	98	148	**40,145**
Medication Error	3,443	465	6,766	15,865	7,215	174	41	0	4	9	**33,982**
Fall	128	45	214	16,929	14,463	872	243	2	14	9	**32,919**
Other/Miscellaneous	5,364	426	2,186	8,489	9,339	521	240	4	14	71	**26,654**
Skin Integrity	521	5	47	4,253	11,688	607	24	1	0	0	**17,146**
Equip./Supplies/Devices	1,650	130	1,333	3,200	1,153	72	12	0	0	2	**7,552**
Adverse Drug Reaction	69	3	16	1,294	4,568	493	71	1	8	4	**6,527**
Transfusion	1,193	56	536	2,048	1,362	29	9	0	1	1	**5,235**
Patient Self-Harm	36	8	44	881	1,122	128	8	1	2	2	**2,232**
Total	**29,658**	**2,043**	**22,236**	**105,106**	**87,895**	**6,811**	**2,441**	**53**	**165**	**271**	**256,679**

Table 8. Number of Reports Submitted to PA-PSRS in 2022 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	4,800	268	2,702	20,318	20,720	1,218	219	5	30	48	**50,328**
Surgical Services	6,241	567	5,290	12,637	9,081	2,483	1,533	22	62	75	**37,991**
Emergency	5,443	188	2,002	13,338	6,521	336	87	6	12	31	**27,964**
ICU	2,098	78	1,099	7,230	8,947	544	46	1	14	32	**20,089**
Specialty Unit	1,479	73	950	5,782	6,645	283	47	3	9	14	**15,285**
Imaging/Diagnostic	1,036	101	1,241	6,057	6,434	284	94	4	11	14	**15,276**
Other	1,480	149	1,341	4,089	3,316	259	133	2	8	12	**10,789**
Laboratory	784	122	1,038	6,803	1,799	33	7	2	0	0	**10,588**
Psychiatric Unit	526	60	273	4,139	4,073	318	39	0	3	8	**9,439**
Clinic/Outpatient Office	543	73	1,405	3,578	3,177	192	58	0	3	3	**9,032**
Rehab Unit	211	63	267	3,687	3,240	119	42	0	0	8	**7,637**
Pediatric	994	68	978	3,631	1,758	45	10	0	0	2	**7,486**
Intermediate Unit	811	38	470	2,732	3,019	111	17	1	6	6	**7,211**
Labor and Delivery	252	21	196	1,512	3,711	247	39	3	5	3	**5,989**
PICU	1,259	45	608	2,581	684	30	2	0	1	1	**5,211**
NICU	517	17	404	2,880	1,307	43	6	1	0	6	**5,181**
OB/GYN Unit	461	34	313	1,393	1,792	218	47	3	1	4	**4,266**
Pharmacy	361	53	1,122	1,095	458	4	1	0	0	0	**3,094**
Rehab Services	81	9	66	966	498	26	7	0	0	1	**1,654**
Nursery	72	3	61	291	596	13	2	0	0	3	**1,041**
Administration	98	6	380	137	46	3	2	0	0	0	**672**
Respiratory	111	7	30	230	73	2	3	0	0	0	**456**
Total	**29,658**	**2,043**	**22,236**	**105,106**	**87,895**	**6,811**	**2,441**	**53**	**165**	**271**	**256,679**

Table 9. Number of Reports Submitted to PA-PSRS in 2022 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	8,571	6,659	8,612	12,351	6,182	5,263	642	993	958	97	**50,328**
Surgical Services	18,684	7,789	1,506	615	3,903	1,564	3,141	299	480	10	**37,991**
Emergency	13,280	2,250	3,615	3,226	3,222	255	367	468	1,099	182	**27,964**
ICU	5,846	2,692	3,510	1,131	1,151	4,054	657	282	748	18	**20,089**
Specialty Unit	2,710	1,884	2,795	3,312	2,017	1,561	171	391	424	20	**15,285**
Imaging/Diagnostic	6,931	4,816	188	739	735	496	390	949	31	1	**15,276**
Other	3,721	1,277	1,462	1,199	1,608	481	275	544	204	18	**10,789**
Laboratory	9,708	107	41	72	210	27	33	3	387	0	**10,588**
Psychiatric Unit	427	204	791	3,868	1,959	297	26	48	3	1,816	**9,439**
Clinic/Outpatient	2,976	853	1,171	687	621	162	248	2,107	194	13	**9,032**
Rehab Unit	602	473	1,119	2,892	1,012	1,376	75	60	21	7	**7,637**
Pediatric	1,824	1,733	1,704	540	968	206	337	33	115	26	**7,486**
Intermediate Unit	1,569	980	1,160	1,154	1,092	768	143	132	195	18	**7,211**
Labor and Delivery	1,149	3,793	324	88	331	30	120	38	116	0	**5,989**
PICU	2,020	1,028	1,155	37	296	202	373	8	91	1	**5,211**
NICU	2,334	916	822	6	489	141	387	2	84	0	**5,181**
OB/GYN Unit	1,074	1,983	486	140	383	31	72	22	73	2	**4,266**
Pharmacy	64	8	2,848	1	23	0	9	141	0	0	**3,094**
Rehab Services	148	116	49	827	279	204	25	2	1	3	**1,654**
Nursery	361	525	58	5	59	8	22	1	2	0	**1,041**
Administration	69	32	481	15	53	5	7	1	9	0	**672**
Respiratory	219	27	85	14	61	15	32	3	0	0	**456**
Total	**84,287**	**40,145**	**33,982**	**32,919**	**26,654**	**17,146**	**7,552**	**6,527**	**5,235**	**2,232**	**256,679**

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 2022 Frequency

	Number of Reports					% of Total Reports				
Event Type	**2018**	**2019**	**2020**	**2021**	**2022**	**2018**	**2019**	**2020**	**2021**	**2022**
Error Related to P/T/T	3,092	3,538	3,048	3,333	**4,126**	35.5%	38.2%	39.0%	35.8%	**39.1%**
Other/Miscellaneous	2,504	2,417	1,766	2,283	**2,845**	28.8%	26.1%	22.6%	24.5%	**26.9%**
Complication of P/T/T	2,426	2,478	2,265	2,816	**2,659**	27.9%	26.7%	29.0%	30.3%	**25.2%**
Skin Integrity	209	246	206	245	**272**	2.4%	2.7%	2.6%	2.6%	**2.6%**
Fall	141	150	161	222	**225**	1.6%	1.6%	2.1%	2.4%	**2.1%**
Equip./Supplies/Devices	133	180	145	160	**213**	1.5%	1.9%	1.9%	1.7%	**2.0%**
Medication Error	104	173	129	137	**130**	1.2%	1.9%	1.7%	1.5%	**1.2%**
Adverse Drug Reaction	84	79	77	100	**79**	1.0%	0.9%	1.0%	1.1%	**0.7%**
Patient Self-Harm	6	2	10	5	**6**	0.1%	0.0%	0.1%	0.1%	**0.1%**
Transfusion	3	1	0	3	**2**	0.0%	0.0%	0.0%	0.0%	**0.0%**
Total	8,702	9,264	7,807	9,304	**10,557**	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 2022 Frequency

	Number of Serious Events					% of Total Serious Events				
Event Type	**2018**	**2019**	**2020**	**2021**	**2022**	**2018**	**2019**	**2020**	**2021**	**2022**
Complication of P/T/T	1,198	1,272	1,179	1,372	**1,343**	68.2%	67.1%	72.0%	70.9%	**67.6%**
Other/Miscellaneous	434	478	300	417	**473**	24.7%	25.2%	18.3%	21.6%	**23.8%**
Error Related to P/T/T	54	57	74	55	**74**	3.1%	3.0%	4.5%	2.8%	**3.7%**
Skin Integrity	23	30	23	21	**36**	1.3%	1.6%	1.4%	1.1%	**1.8%**
Adverse Drug Reaction	17	17	24	17	**23**	1.0%	0.9%	1.5%	0.9%	**1.2%**
Fall	18	17	18	29	**23**	1.0%	0.9%	1.1%	1.5%	**1.2%**
Equip./Supplies/Devices	5	10	10	13	**11**	0.3%	0.5%	0.6%	0.7%	**0.6%**
Medication Error	5	14	5	8	**2**	0.3%	0.7%	0.3%	0.4%	**0.1%**
Patient Self-Harm	1	1	5	1	**1**	0.1%	0.1%	0.3%	0.1%	**0.1%**
Transfusion	1	1	0	1	**0**	0.1%	0.1%	0.0%	0.1%	**0.0%**
Total	1,756	1,897	1,638	1,934	**1,986**	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.

to the overall data (see **Tables 4** and **10**). The three event types reported most frequently were Error Related to P/T/T, Other/Miscellaneous, and Complication of P/T/T, which together account for 91.2% of all reports submitted by these facilities in 2022. **Table 11** shows the distribution of serious events reported by other acute care facilities in 2022; the Complication of P/T/T event type accounted for over two-thirds of these reports.

Discussion

While we are unable to reach a firm conclusion as to the primary reason for the decrease in reports of incidents and increase in reports of serious events to PA-PSRS in 2022, many factors are likely involved. Based on an analysis of the PA-PSRS data alone, more than half of the overall decrease can be attributed to a few facilities that submitted a much lower number of incidents in 2022 compared to 2021. PSA has been working with facilities to identify and correct issues and will continue to monitor their reporting and take further action as needed. Throughout the year, PSA provided ongoing support and education for facilities regarding the accurate reporting of events and contacted patient safety officers in many facilities regarding reports classified as incidents that appeared to describe serious events or nonreportable situations.

Conclusion

There was a decrease in the number of incidents submitted to PA-PSRS in 2022, an increase in serious and high harm event reports, and shifts in the number and distribution of reports for certain event types and subtypes. There was a notable change in reporting activity by three facilities, which had a considerable impact on the number, rate, and types of events reported in 2022. PSA will continue to monitor reporting and take further action as needed.

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%2013%20of%202002.pdf. Published 2002. Accessed April 13, 2023.

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Long-Term Care Healthcare-Associated Infections in 2022:

An Analysis of 20,216 Reports

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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 4.5 million acute care reports, the PA-PSRS database contains more than 396,000 long-term care (LTC) healthcare-associated infection (HAI) reports.

Methods: LTC HAI data from PA-PSRS were extracted on March 1, 2023. 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 20,216 infections were reported in 2022, representing a 12.5% increase from 2021. Overall, the reporting rate from LTC facilities increased from 0.77 in 2021 to 0.87 in 2022. Over half (56%) of the increase in overall rate is due to an increase in the respiratory tract infection rate, with another 27% due to an increase in the gastrointestinal infection rate. All six regions of the state had an increase in overall infection rate from 2021 to 2022. The North Central region of the state had the highest overall rate, as well as the largest increase in rate, with 1.14 reports per 1,000 resident days in 2022, which is an increase of 21.3% over the 2021 rate of 0.94. The Southeast region had the lowest overall rate, at 0.67, which is an 8.1% increase from 2021. The number of reports increased for all five infection types from 2021 to 2022, with gastrointestinal infections increasing the most percentagewise, by 67.7%. Of the 14 infection subtypes, 11 had an increase in number of reports from 2021 to 2022, with influenza showing the largest increase of 857 reports. Norovirus had a larger percentage increase of 942.9%, going from 70 reported infections in 2021 to 730 in 2022. The three subtypes that decreased in number had relatively smaller changes than the increases, with the largest of the decreases occurring with *C. diff*, which dropped by 29 reports from 2021 to 2022.

Conclusions: There was an increase in the total number and rate of infections reported to PA-PSRS in 2022. Patient Safety Authority infection preventionists continue to note operational challenges in LTC facilities and are providing ongoing education and guidance to enhance infection prevention and surveillance strategies and improve reporting of HAIs.

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

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

Introduction

The Pennsylvania Patient Safety Reporting System (PA-PSRS)[1] is the largest repository of patient safety data in the United States. In addition to over 4.5 million acute care records, PA-PSRS has collected more than 396,000 long-term care (LTC) healthcare-associated infection (HAI) reports since 2009. In 2022, 20,216 HAIs were reported by 636 of Pennsylvania's LTC facilities.

Methods

The LTC data from PA-PSRS were extracted on March 1, 2023, to allow additional time for rate calculations based on resident and device utilization days. 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.

Infection counts reflect the year when infection reports were submitted in PA-PSRS. Overall rates are based on infection confirmation dates and resident days. Specific infection rates related to urinary catheters and central lines are based on urinary catheter and central line days, respectively. In addition, rates are expressed as infections per 1,000 resident, catheter, or central line days. Infection rates from prior years may differ from information in previous publications, as facilities may have since submitted or made changes to reports and/or entered utilization data in PA-PSRS.

Results

The number of reports increased by 12.5% from 2021, with 20,216 reported infections in 2022 (see **Figure 1**). This is the first annual increase in reports since the 1.9% increase in 2018. The number of resident days increased by 1.7% from 2021, with 23.4 million resident days reported in 2022 (see **Figure 1**). This is the first annual increase in resident days since the 1.5% increase in 2019. Even with this increase in resident days from 2021 to 2022, the number of resident days was 3.8 million below the number in 2019, the year prior to the COVID-19 pandemic.

In 2022, the overall infection rate was 0.87 infections per 1,000 resident days, which is a 13.0% increase from the 2021 rate of 0.77. Over half (56%) of the increase in the overall rate is due to an increase in the respiratory tract infection rate, with another 27% due to an increase in the gastrointestinal infection rate. As shown in **Figure 2**, the North Central region had the highest rate of reported infections in 2022, with 1.14 reports per 1,000 resident days. The Southeast region had the lowest rate, at 0.67. The distribution of LTC infection reports submitted in 2022 by region is shown in **Table 1**.

Figure 1. LTC Infection Reports Submitted to PA-PSRS by Year With Resident Days and Overall Infection Rates (per 1,000 Resident Days)

Note: 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.

[1]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 Rates per 1,000 Resident Days by Region—2021 Versus 2022

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

Region	2021 Infection Reports	2021 Rate per 1,000 Resident Days	2022 Infection Reports	2022 Rate per 1,000 Resident Days
North Central	1,289	0.94	1,561	1.14
Northeast	2,689	0.91	3,260	1.08
Northwest	1,722	0.84	1,948	0.94
South Central	2,841	0.90	3,079	1.01
Southeast	5,643	0.62	6,158	0.67
Southwest	3,787	0.83	4,210	0.94
Total	**17,971**	**0.77**	**20,216**	**0.87**

Note: 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.

LTC Healthcare-Associated Infections

Reports submitted by LTC facilities to PA-PSRS are classified into five main infection types (see **Figure 3**). In 2019 and 2020, respiratory tract infections were the most frequently reported infection type. In 2021 and 2022, respiratory tract infections were the third most frequently reported, behind skin and soft tissue and urinary tract infections. The number of reports for all infection types increased from 2021 to 2022, with the largest percentage increases occurring with gastrointestinal infection (+67.7%) and device-related bloodstream infection (+48.1%).

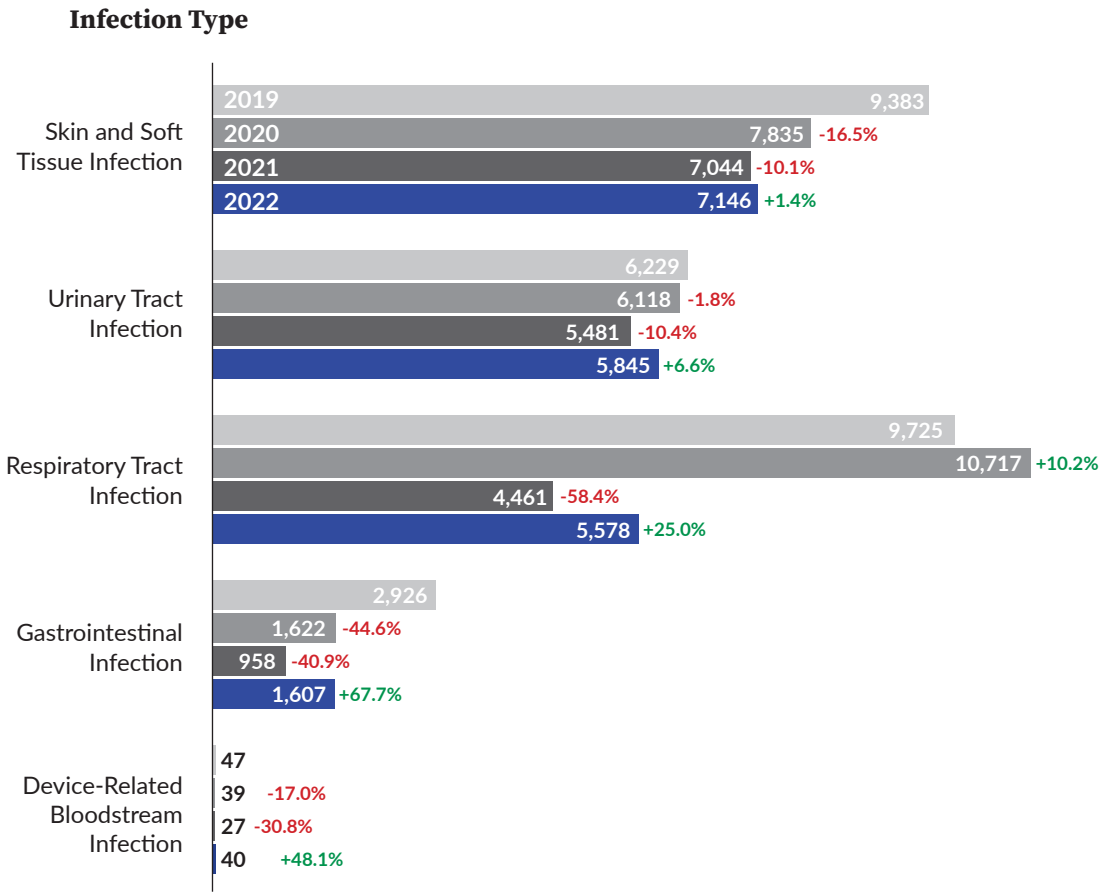
LTC Healthcare-Associated Infection Subtypes

Table 2 shows the number of reports for all infection subtypes. The most frequently reported subtype in 2022 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 year. Of the 14 infection subtypes, 11 had an increase in number of reports from 2021 to 2022, with influenza showing the largest increase of 857 reports. Norovirus had the largest percentage increase of 942.9%, going from 70 reported infections in 2021 to 730 in 2022. The three subtypes that decreased in number had relatively smaller changes than the increases, with the largest of the decreases occurring with *C. diff*, which dropped by 29 reports from 2021 to 2022.

Care Area

Table 3 shows the distribution of 2022 reports by infection type and care area. Skilled nursing/short-term rehabilitation units accounted for the largest proportion of infections (7,178 of 20,216; 35.5%). In 2022, skin and soft tissue infections were reported more than any other infection type in all care areas except ventilator-dependent units, in which respiratory tract infections were most frequently reported. **Table 4** shows the 2022 distribution of infection reports by infection subtype and care area. The largest concentration of reports in 2022 is found with SUTI in skilled nursing/short-term rehabilitation units.

Figure 3. 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.

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 2021 to 2022	
		2019	2020	2021	2022	2019	2020	2021	2022	Number	Percent
Skin and Soft Tissue Infection	Cellulitis/Soft Tissue/ Wound Infection	6,039	5,180	**4,951**	5,081	21.3%	19.7%	**27.5%**	25.1%	130	2.6%
	Conjunctivitis	3,157	2,528	**1,957**	1,937	11.2%	9.6%	**10.9%**	9.6%	-20	-1.0%
	Scabies	187	127	**136**	128	0.7%	0.5%	**0.8%**	0.6%	-8	-5.9%
Urinary Tract Infection	SUTI	4,939	4,715	**4,288**	4,589	17.4%	17.9%	**23.9%**	22.7%	301	7.0%
	CAUTI	1,136	1,251	**1,052**	1,087	4.0%	4.8%	**5.9%**	5.4%	35	3.3%
	ABUTI	154	152	**141**	169	0.5%	0.6%	**0.8%**	0.8%	28	19.9%
Respiratory Tract Infection	Pneumonia	5,282	4,862	**3,004**	3,005	18.7%	18.5%	**16.7%**	14.9%	1	0.0%
	LRTI	2,874	3,769	**1,216**	1,451	10.2%	14.3%	**6.8%**	7.2%	235	19.3%
	Influenza	1,409	1,432	**201**	1,058	5.0%	5.4%	**1.1%**	5.2%	857	426.4%
	Influenza-Like Illness	160	654	**40**	64	0.6%	2.5%	**0.2%**	0.3%	24	60.0%
Gastro-intestinal Infection	*C. diff*	1,358	961	**883**	854	4.8%	3.6%	**4.9%**	4.2%	-29	-3.3%
	Norovirus	1,550	647	**70**	730	5.5%	2.5%	**0.4%**	3.6%	660	942.9%
	Bacteriologic Gastroenteritis	18	14	**5**	23	0.1%	0.1%	**0.0%**	0.1%	18	360.0%
Device-Related Bloodstream Infection	CLABSI	47	39	**27**	40	0.2%	0.1%	**0.2%**	0.2%	13	48.1%
Totals		**28,310**	**26,331**	**17,971**	**20,216**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**2,245**	**12.5%**

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.

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

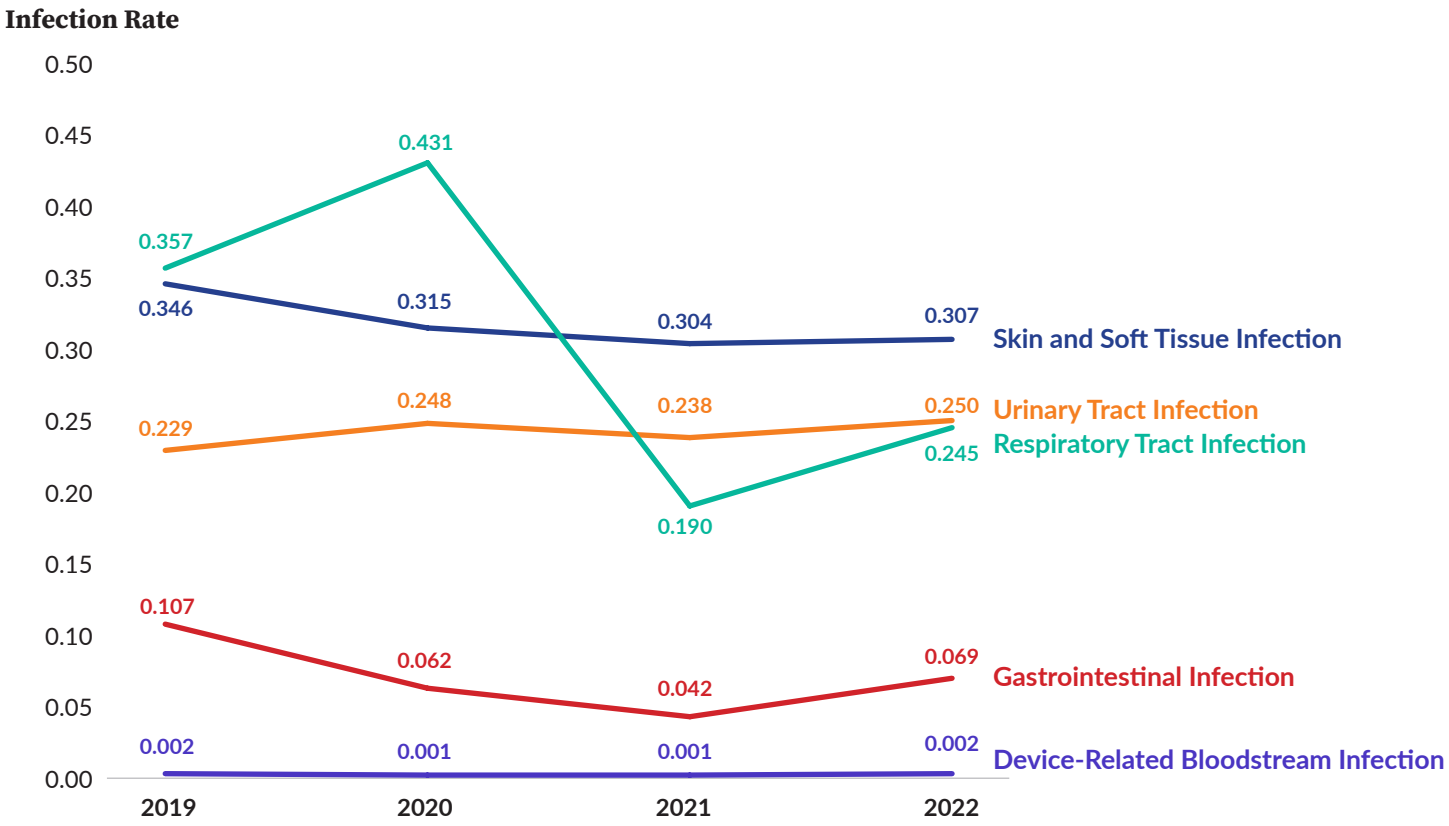
Table 3. LTC Infection Reports Submitted to PA-PSRS in 2022 by Infection Type and Care Area

Infection Type	Skilled Nursing/ Short-Term Rehab. Unit	Nursing Unit	Mixed Unit	Dementia Unit	Ventilator-Dependent Unit	Total
Skin and Soft Tissue Infection	2,373	2,125	2,068	460	120	**7,146**
Urinary Tract Infection	2,154	1,664	1,693	285	49	**5,845**
Respiratory Tract Infection	2,019	1,511	1,503	308	237	**5,578**
Gastrointestinal Infection	610	454	375	146	22	**1,607**
Device-Related Bloodstream Infection	22	7	10	0	1	**40**
Total	**7,178**	**5,761**	**5,649**	**1,199**	**429**	**20,216**

Table 4. LTC Infection Reports Submitted to PA-PSRS in 2022 by Infection Subtype and Care Area

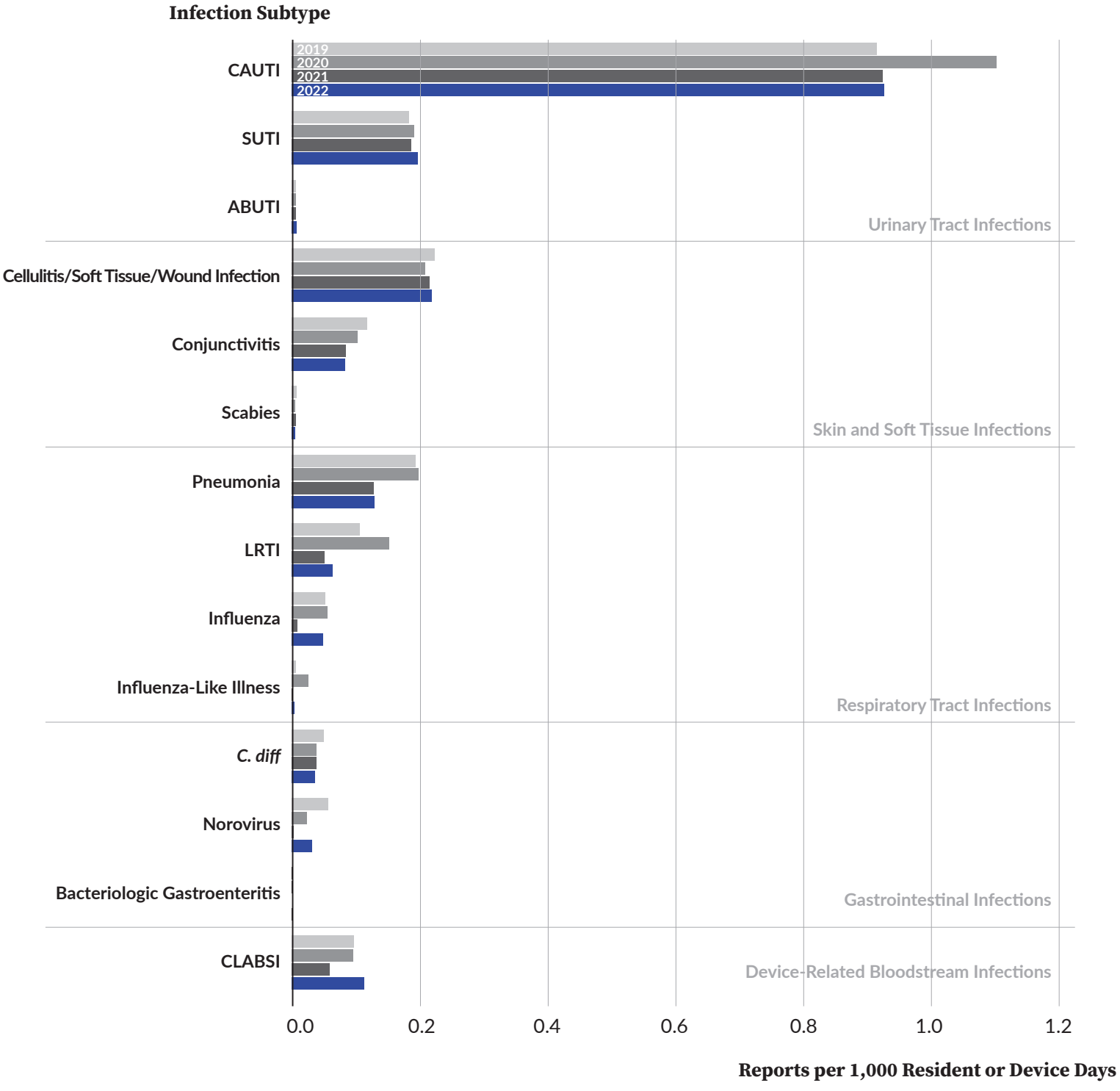
Infection Subtype	Skilled Nursing/ Short-Term Rehab. Unit	Nursing Unit	Mixed Unit	Dementia Unit	Ventilator-Dependent Unit	Total
Cellulitis/Soft Tissue/Wound Infection	1,679	1,566	1,488	293	55	**5,081**
SUTI	1,698	1,295	1,330	243	23	**4,589**
Pneumonia	1,083	742	857	164	159	**3,005**
Conjunctivitis	619	532	563	158	65	**1,937**
LRTI	560	388	318	108	77	**1,451**
CAUTI	393	315	314	39	26	**1,087**
Influenza	340	365	318	34	1	**1,058**
C. diff	347	183	280	22	22	**854**
Norovirus	252	266	88	124	0	**730**
ABUTI	63	54	49	3	0	**169**
Scabies	75	27	17	9	0	**128**
Influenza-Like Illness	36	16	10	2	0	**64**
CLABSI	22	7	10	0	1	**40**
Bacteriologic Gastroenteritis	11	5	7	0	0	**23**
Total	**7,178**	**5,761**	**5,649**	**1,199**	**429**	**20,216**

Figure 4. 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 5. 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.

LTC Healthcare-Associated Infection Rates

Figure 4 shows infection rates per 1,000 resident days for the five infection types for 2019 through 2022. All rates decreased from 2020 to 2021 and increased from 2021 to 2022.

In **Figure 5** and **Table 5**, rates are shown for each infection subtype for 2019 through 2022. Similar to percentage increases in the number of reports, the subtypes with the largest percentage increases in rate from 2021 to 2022 are norovirus (+873.6%) and influenza (+423.8%).

In **Table 6**, the infection rates are displayed by year based on care area and infection subtype. The largest percentage increases in rate from 2021 to 2022 occurred with norovirus in skilled nursing/short-term rehabilitation units (+1,683.2%), influenza in dementia units (+993.1%), influenza in nursing units (+824.6%), and influenza-like illness in mixed units (+778.6%).

Figure 6 and **Table 7** display infection rates for influenza, influenza-like illness, pneumonia, lower respiratory tract infection (LRTI), and norovirus by quarter for 2019 through 2022. These rates are calculated as the number of infections, using the infection confirmation date, by quarter, per 1,000 resident days. As seen in **Figure 6**, over the past four years, norovirus infections hit a peak rate in Q1 2019 with 0.164 infections per 1,000 resident days. Rates for all four respiratory tract infection subtypes increased from Q3 2022 to Q4 2022: influenza (+1,355.6%), influenza-like illness (+700.0%), LRTI (+42.3%), and pneumonia (+30.7%).

Table 5. LTC Infection Rates per 1,000 Resident or Device Days by Infection Subtype and Year in Descending Order by 2022 Rates

	Rates			
Infection Subtype	**2019**	**2020**	**2021**	**2022**
CAUTI	0.911	1.098	0.920	**0.923**
Cellulitis/Soft Tissue/Wound Infection	0.222	0.208	0.215	**0.218**
SUTI	0.182	0.191	0.186	**0.196**
Pneumonia	0.193	0.197	0.128	**0.129**
CLABSI	0.097	0.095	0.059	**0.113**
Conjunctivitis	0.117	0.102	0.084	**0.083**
LRTI	0.106	0.152	0.051	**0.064**
Influenza	0.052	0.055	0.009	**0.049**
C. diff	0.050	0.038	0.038	**0.036**
Norovirus	0.057	0.023	0.003	**0.031**
ABUTI	0.006	0.006	0.006	**0.007**
Scabies	0.007	0.005	0.006	**0.005**
Influenza-Like Illness	0.006	0.026	0.002	**0.004**
Bacteriologic Gastroenteritis	0.001	0.001	0.000	**0.001**

Note: Rates shown as 0.000 are not zero; they are less than 0.001 when rounding. 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 6. LTC Infection Rates per 1,000 Resident or Device Days by Care Area, Infection Subtype, and Year in Descending Order by Percentage Increase From 2021 to 2022 Within Each Care Area

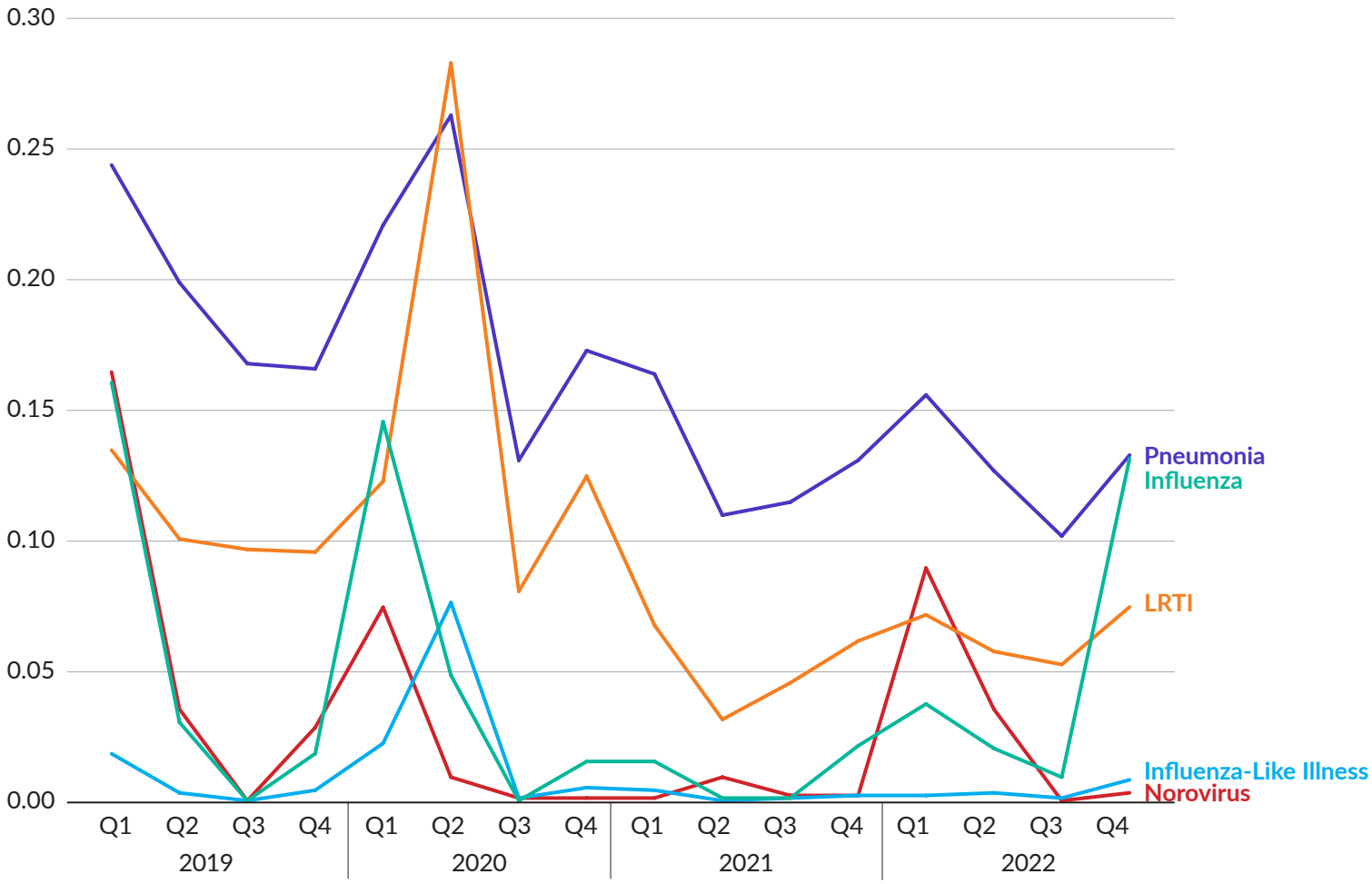
Care Area	Infection Type	2019	2020	2021	2022	2019 to 2020	2020 to 2021	2021 to 2022
Dementia Unit	Influenza	0.040	0.044	0.002	0.023	12.1%	-95.2%	993.1%
	LRTI	0.102	0.136	0.027	0.061	33.9%	-80.0%	124.1%
	CAUTI	1.133	1.105	0.451	0.980	-2.4%	-59.2%	117.1%
	Influenza-Like Illness	0.006	0.032	0.001	0.002	441.8%	-96.7%	98.7%
	SUTI	0.127	0.122	0.107	0.131	-4.5%	-11.7%	21.6%
	Pneumonia	0.146	0.147	0.085	0.088	0.5%	-42.3%	3.7%
	Cellulitis/Soft Tissue/Wound Infection	0.165	0.149	0.151	0.156	-9.5%	1.4%	3.2%
	C. diff	0.016	0.015	0.012	0.012	-1.2%	-20.5%	-0.6%
	Conjunctivitis	0.127	0.107	0.090	0.085	-15.6%	-15.8%	-5.9%
	ABUTI	0.004	0.005	0.004	0.002	20.4%	-14.3%	-50.3%
	Scabies	0.012	0.005	0.014	0.005	-54.2%	153.2%	-65.6%
	Bacteriologic Gastroenteritis	-	<0.001	-	-	-	-100.0%	-
	CLABSI	-	-	-	-	-	-	-
	Norovirus	0.098	0.045	-	0.066	-53.5%	-100.0%	-
Mixed Unit	Influenza-Like Illness	0.007	0.022	<0.001	0.003	217.4%	-98.6%	778.6%
	Bacteriologic Gastroenteritis	<0.001	<0.001	<0.001	0.001	-12.0%	-73.0%	583.3%
	Norovirus	0.065	0.016	0.003	0.014	-76.0%	-82.8%	405.3%
	Influenza	0.055	0.041	0.011	0.053	-24.8%	-73.3%	376.9%
	CLABSI	0.039	0.062	0.051	0.100	60.2%	-17.4%	93.6%
	ABUTI	0.006	0.007	0.006	0.008	7.6%	-13.6%	35.6%
	LRTI	0.110	0.143	0.040	0.052	30.8%	-72.2%	31.3%
	Pneumonia	0.201	0.200	0.123	0.133	-0.7%	-38.4%	8.4%
	C. diff	0.042	0.043	0.040	0.042	3.0%	-8.8%	7.4%
	Cellulitis/Soft Tissue/Wound Infection	0.226	0.215	0.228	0.232	-5.2%	6.0%	2.0%
	CAUTI	0.841	1.256	0.954	0.948	49.3%	-24.0%	-0.6%
	Conjunctivitis	0.126	0.108	0.088	0.087	-14.0%	-18.7%	-1.3%
	SUTI	0.183	0.204	0.209	0.203	11.2%	2.5%	-2.8%
	Scabies	0.006	0.002	0.006	0.003	-70.0%	259.8%	-58.5%
Nursing Unit	Influenza	0.047	0.057	0.005	0.050	19.7%	-90.4%	824.6%
	Norovirus	0.049	0.033	0.006	0.036	-33.5%	-82.1%	508.9%
	CLABSI	0.130	0.151	0.014	0.083	16.3%	-90.9%	506.3%
	Influenza-Like Illness	0.005	0.023	0.002	0.004	398.2%	-89.5%	46.0%
	LRTI	0.098	0.139	0.042	0.055	42.1%	-70.0%	32.2%
	SUTI	0.150	0.164	0.162	0.179	9.2%	-1.5%	10.9%
	Cellulitis/Soft Tissue/Wound Infection	0.200	0.183	0.198	0.213	-8.5%	8.2%	7.6%
	CAUTI	0.751	0.943	0.852	0.914	25.5%	-9.7%	7.3%
	Conjunctivitis	0.103	0.093	0.071	0.072	-9.7%	-22.9%	0.3%
	ABUTI	0.005	0.005	0.007	0.007	1.0%	43.6%	-0.8%
	Pneumonia	0.157	0.164	0.109	0.102	4.6%	-33.8%	-5.7%
	C. diff	0.042	0.025	0.028	0.024	-39.2%	9.6%	-12.6%
	Scabies	0.006	0.005	0.005	0.004	-6.4%	-13.2%	-24.9%
	Bacteriologic Gastroenteritis	<0.001	<0.001	-	<0.001	-22.0%	-100.0%	-

Table 6 (continued).

Care Area	Infection Type	2019	2020	2021	2022	2019 to 2020	2020 to 2021	2021 to 2022
Skilled Nursing/ Short-Term Rehabilitation Unit	Norovirus	0.047	0.014	0.002	0.034	-69.9%	-86.5%	1683.2%
	Influenza	0.056	0.070	0.014	0.052	25.6%	-80.0%	274.5%
	Bacteriologic Gastroenteritis	<0.001	<0.001	<0.001	0.001	-25.5%	9.8%	173.5%
	Scabies	0.007	0.008	0.005	0.010	6.6%	-40.8%	119.4%
	Influenza-Like Illness	0.007	0.030	0.002	0.005	345.0%	-92.3%	104.8%
	CLABSI	0.101	0.095	0.091	0.137	-5.8%	-4.2%	50.8%
	ABUTI	0.007	0.007	0.006	0.008	4.1%	-16.2%	44.5%
	LRTI	0.109	0.169	0.060	0.074	56.1%	-64.3%	22.1%
	SUTI	0.225	0.225	0.214	0.224	0.2%	-5.3%	5.1%
	Conjunctivitis	0.119	0.100	0.083	0.084	-16.5%	-16.3%	0.4%
	Pneumonia	0.223	0.226	0.145	0.143	1.6%	-36.0%	-1.3%
	Cellulitis/Soft Tissue/Wound Infection	0.252	0.239	0.233	0.224	-5.0%	-2.5%	-3.9%
	CAUTI	1.009	1.054	0.950	0.912	4.4%	-9.9%	-3.9%
	C. diff	0.071	0.050	0.052	0.047	-29.3%	3.0%	-8.9%
Ventilator-Dependent Unit	SUTI	0.043	0.109	0.105	0.166	152.3%	-3.7%	57.6%
	Conjunctivitis	0.231	0.289	0.407	0.455	25.2%	40.9%	11.9%
	Pneumonia	0.720	0.892	1.037	1.069	23.8%	16.3%	3.1%
	Cellulitis/Soft Tissue/Wound Infection	0.259	0.340	0.361	0.366	31.1%	6.2%	1.3%
	C. diff	0.122	0.141	0.190	0.152	15.2%	34.8%	-20.3%
	LRTI	0.339	0.449	0.774	0.510	32.6%	72.4%	-34.1%
	CAUTI	1.730	1.785	1.440	0.833	3.2%	-19.3%	-42.2%
	ABUTI	0.007	0.006	0.026	-	-11.0%	309.2%	-100.0%
	Bacteriologic Gastroenteritis	-	-	-	-	-	-	-
	CLABSI	0.724	-	-	0.167	-100.0%	-	-
	Influenza	0.058	0.019	-	0.007	-66.6%	-100.0%	-
	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 exactly zero. If "< 0.001" appears in a cell, it means that the rate is greater than zero but less than 0.001 when rounding. 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. LTC Infection Rates per 1,000 Resident Days Trending for Seasonal Infection Subtypes by Infection Confirmation 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.

Discussion

Pennsylvania's LTC facilities reported 20,216 infections and 23.4 million resident days in PA-PSRS in 2022, resulting in a rate of 0.87 infections per 1,000 resident days. This represents a 12.5% increase in the total number of infection reports and a 13.0% increase in the rate of reported infections when compared to 2021. Over half of the increase in overall rate is due to an increase in the rate of reported respiratory tract infections, with another quarter due to an increase in the rate of reported gastrointestinal infections. The number of reports for all five main infection types also increased from 2021 to 2022. The infection subtype with the greatest increase in number of reports in 2022 was influenza, which is consistent with the high prevalence of influenza across the United States during the fourth quarter of 2022.[2] In terms of percentage, the largest increase was seen with norovirus. The increases noted with influenza and norovirus may be related to changes in state guidance[3] and less-restrictive requirements for personal protective equipment to prevent transmission of COVID-19 in LTC facilities.

The years since COVID-19 have been especially hard on LTC facilities as emergency priority changes and staffing issues have impacted operations. Through outreach activities, the Patient Safety Authority's (PSA) infection preventionists (IPs) continue to note high turnover and the assignment of additional responsibilities to LTC IPs, which has likely impacted reporting. For example, some LTC IPs have erroneously presumed that reports of COVID-19 suspected or confirmed infections reported to the Centers for Medicare & Medicaid Services (CMS) through the National Healthcare Safety Network (NHSN) fully met all reporting requirements for these events. As a result, it is likely that some influenza-like illnesses and LRTIs have gone unreported to PA-PSRS. PSA IPs continue to work with LTC facilities to provide guidance and education, including purposeful outreach to LTC facilities that have reported a low volume of infections or incomplete information in PA-PSRS, formal and informal education, access to toolkits and surveillance materials, one-on-one training, and collaborative activities with facility administrative teams.

Table 7. Overall LTC Seasonal Infection Rates per 1,000 Resident Days by Quarter

	Influenza	Influenza-Like Illness	LRTI	Norovirus	Pneumonia
2019 Q1	0.160	0.018	0.134	0.164	0.243
Q2	0.030	0.003	0.100	0.035	0.198
Q3	0.000	0.000	0.096	0.000	0.167
Q4	0.018	0.004	0.095	0.028	0.165
2020 Q1	0.145	0.022	0.122	0.074	0.220
Q2	0.048	0.076	0.282	0.009	0.262
Q3	0.000	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	0.000	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**	**0.071**	**0.089**	**0.155**
Q2	**0.020**	**0.003**	**0.057**	**0.035**	**0.126**
Q3	**0.009**	**0.001**	**0.052**	**0.000**	**0.101**
Q4	**0.131**	**0.008**	**0.074**	**0.003**	**0.132**

Note: Rates shown as 0.000 are not zero; they are less than 0.001 when rounding. 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.

Conclusion

In 2022, there was an increase in the total number and rate of infections reported to PA-PSRS by Pennsylvania's LTC facilities. There were also increases in the number of reports submitted for all five main infection types. Reports of respiratory tract infections and gastrointestinal infections accounted for more than three-quarters of the rate increase, with influenza and norovirus infection subtypes showing the most significant increases in number and percentage of reports between 2021 and 2022. PSA IPs continue to note operational challenges in LTC facilities and are providing ongoing education and guidance to enhance infection prevention and surveillance strategies and improve reporting of HAIs.

Note

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

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Informing Visual Display Design of Electronic Health Records: A Human Factors Cross-Industry Perspective

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Background: Despite their prevalence, poorly designed electronic health records (EHRs) are common, and research shows poor design consequences include clinician burnout, diagnostic error, and even patient harm. One of the major difficulties of EHR design is the visual display of information, which aims to present information in an easily digestible form for the user. High-risk industries like aviation, automotive, and nuclear have guidelines for visual displays based on human factors principles for optimized design.

Purpose: In this study, we reviewed the visual display guidelines from three high-risk industries—automotive, aviation, nuclear—for their applicability to EHR design and safety.

Methods: Human factors experts extracted guidelines related to visual displays from automotive, aviation, and nuclear human factors guideline documents. Human factors experts and a clinical expert excluded guidelines irrelevant to EHR. Human factors experts used a modified reflexive thematic analysis to group guidelines into meaningful topics. Disagreements were discussed until a consensus was reached.

Results: A total of 449 guidelines were extracted from the industry documents, and 283 (63.0%) were deemed relevant to EHRs. By industry, 12 of 44 (27.3%) automotive industry guidelines were relevant, 43 of 115 (37.4%) aviation industry guidelines were relevant, and 228 of 290 (78.6%) nuclear industry guidelines were relevant. Guidelines were grouped into six categories: alphanumeric; color, brightness, contrast, and luminance; comprehension; design characteristics; symbols, pictograms, and icons; and tables, figures, charts, and lists.

Conclusion: Our analysis identified visual display guidelines organized around six topics from the automotive, aviation, and nuclear industries to inform EHR design. Multiple stakeholders, including EHR vendors, healthcare facilities, and policymakers, can apply these guidelines to design new EHRs and optimize EHRs already in use.

Keywords: *visual display, health IT, electronic health record, human factors, patient safety*

Introduction

Visual displays present information to users in various forms, including text, numbers, graphs, maps, diagrams, and pictures.[1] Effectively designed visual displays allow users to extract important information and view and understand patterns in data to accomplish a specific goal. Visual displays are not always safety-critical, but in high-risk industries like healthcare, automotive, aviation, and nuclear, visual displays play a central role in data comprehension, reasoning, communication, and decision-making.[2,3]

Health information technologies (health IT), specifically electronic health records (EHRs), are used by most healthcare facilities in the United States and this technology relies on visual displays to communicate information to users. Health IT visual displays convey information such as patient identifiers, patient history, lab and imaging results, provider notes, medication information, and ancillary content like site policies and drug interaction data.[4,5]

An effective visual display helps providers accurately interpret patients' health data, an essential aspect of providing quality care. Unfortunately, EHR visual displays have been suboptimal partially because of the amount, complexity, and diversity of information that needs to be represented.[6] Studies have shown that the visibility of data, defined as where information is located and how it is presented, is a common problem in electronic medication administration records (eMARs) and computerized provider order entry

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(CPOE) systems.[7–11] The consequences of poor visual display are profound. When visual displays are ineffectively designed, they can lead to clinician burnout,[12–15] diagnostic error,[5,16,17] and even patient harm.[7,11,18]

Human factors is a scientific discipline that aims to understand human capabilities to design work environments that meet these capabilities and enable optimal human performance.[1] From a human factors perspective, designing an effective visual display requires considering the purpose of the visual display and the information that needs to be conveyed through the display, as well as the strengths and limitations of human perception. For example, we can perceive a limited portion of the light spectrum (i.e., 380 to 700 nanometers) and cannot see information in the visual display if it is below human detectability levels. Nevertheless, our perception allows us to find patterns and identify meaning in the abstract (e.g., we connect red with the meaning "stop" and "emergency").[19] These features of human perception, both the ways it hinders and helps us interpret the world, can be understood and leveraged to make effective visual displays.

Many high-risk industries other than healthcare have historically incorporated human factors into their visual display designs by developing guidelines for optimal use. However, there are no required human factors guidelines or standards for the design of EHR visual displays. Consequently, EHR vendors and healthcare facilities may create and use design principles that may not adhere to human factors principles. There are EHR design recommendations from different agencies, including the National Institute of Standards and Technology (NIST). However, these are not required and often not adhered to.[20]

In this study, we sought to identify visual display guidelines used in the automotive, aviation, and nuclear industries to inform healthcare practices. If adopted in healthcare, these guidelines may address the plethora of visual display issues in EHR design and safety. Human factors and clinical experts reviewed the automotive, aviation, and nuclear industry guidelines to identify those most relevant to EHRs. Based on these guidelines, we provide considerations for visual display design in the EHR.

Methods

Previously described in Pruitt et al.,[21] human factors guidelines documents endorsed by United States–based oversight agencies (e.g., Federal Aviation Administration) were identified for automotive, aviation, and nuclear industries. Two human factors experts evaluated the documents for inclusion based on the following four criteria: the publication must be endorsed by a federal government agency or be recognized by a federal government agency as applying to the industry for which the agency has oversight; be related to the automotive, aviation, or nuclear industry; contain principles, guidelines, and/or standards related to visual displays; and have been published after January 2012. Each reviewer independently evaluated each document to assess whether the document met inclusion criteria, and then each document was jointly discussed to ensure agreement. Through this process, we identified one comprehensive document from each industry for analysis in this study.[22–24]

A human factors expert extracted the title, date, agency, and specific discrete guidelines from each of the three industry documents included in the review and populated a Microsoft Excel spreadsheet. Guidelines were included if they contained information about the visual display, regardless of whether they were directly applicable to healthcare. Following extraction, two human factors experts and one clinical expert reviewed the guidelines to assess whether they were relevant to either inpatient or outpatient EHR design, including eMAR and CPOE, for frontline staff. Quality metrics in the EHR, such as sepsis rates for leadership or administration and demographics information, were not considered when determining relevance. Disagreements between experts were discussed until a consensus was reached. The guidelines that were relevant to healthcare were included in the full analysis.

The EHR-relevant guidelines were reviewed and grouped into meaningful topics. These topics were identified using a modified reflexive thematic analysis.[25,26] Two human factors experts familiar with the data independently reviewed a subset of the relevant guidelines and assigned a label to each to represent the overall topic. Labels were discussed and collated to create an initial set of common topics that applied to the guidelines reviewed by all three industries. Using these inductively generated topics, the human factors experts independently classified the remaining guidelines, modifying topics as necessary and discussing discrepancies until a consensus was reached. Topics were reviewed for internal consistency and refined as necessary. The final topics and definitions can be found in **Table 1**.

From the relevant guidelines under each topic, a clinical expert identified three guidelines per topic that were deemed to be the most relevant to the visual display of EHR design, considerations for healthcare, and examples.

Table 1. Visual Display Guideline Topics and Definitions

Topics	Definitions
Alphanumeric	Guidelines that describe how to visually display alpha (i.e., letters) and numeric (i.e., numbers) values
Color, Brightness, Contrast, and Luminance	Guidelines that describe how to visually display color, brightness, contrast, and luminance
Comprehension	Guidelines that describe how to visually display information to aid readability, legibility, and understanding of the information presented
Design Characteristics	Guidelines that describe visual display design qualities and features that adhere to human factors principles (e.g., proximity, similarity, organization)
Symbols, Pictograms, and Icons	Guidelines that describe how to visually display symbols, pictograms, and icons
Tables, Figures, Charts, and Lists	Guidelines that describe how to visually display tables, figures, charts, and lists

Results

A total of 449 guidelines were extracted from the industry documents and 283 (63.0%) were deemed relevant to EHRs. By industry, 12 of 44 (27.3%) automotive industry guidelines were relevant, 43 of 115 (37.4%) aviation industry guidelines were relevant, and 228 of 290 (78.6%) nuclear industry guidelines were relevant. A comprehensive list of all the relevant guidelines can be found in **Online Supplement Appendix A**. **Table 2** describes guidelines highly relevant and applicable to EHR design from other high-risk industries, considerations for EHRs, and examples per visual display guideline topic.

Discussion

Our analysis identified visual display guidelines, organized around six different topics, from the automotive, aviation, and nuclear industries to inform EHR design. Of note, there were far more EHR-applicable guidelines from the nuclear industry than from the aviation and automotive industries. The quantity of EHR-relevant nuclear guidelines may be due to similarities in the purpose of information displays in nuclear and healthcare compared to aviation and automotive. In both the nuclear and healthcare industries, displays may be used by several users with different roles and responsibilities (e.g., engineers and control room operators in nuclear and physicians and nurses in healthcare), while in the aviation and automotive industries, the visual displays are typically designed for a single user profile (e.g., a pilot or a driver).

Many cross-industry guidelines address EHR usability and safety issues experienced by frontline clinicians and described in the literature.[7–9,11,27] The final guidelines provide insights that may inform EHR design and optimization to improve patient safety. The guidelines apply to multiple stakeholders, including EHR vendors, healthcare facilities, and policymakers.

Implications for EHR Vendors and Healthcare Facilities

There are several opportunities for EHR vendors and healthcare facilities to leverage these visual display guidelines to improve the usability and safety of EHRs. EHR vendors can use these guidelines to inform their design and development process. Specifically, EHR vendors can update current design standards or create new design standards that adhere to these guidelines. Updated designs would improve the EHR visual displays provided to customers since their product designers would use design standards informed by human factors principles. In addition, EHR vendors can develop test case scenarios based on these guidelines to evaluate EHR visual displays during their usability testing. Test case–based usability testing would help identify possible usability and safety issues before the EHR is used in the clinical environment.

Table 2. Summary of the Guidelines Highly Relevant and Applicable to EHR Design From Other High-Risk Industries, Considerations for EHRs, and Examples per Visual Display Guideline Topic

Alphanumeric		
Highly Relevant Guidelines From Other High-Risk Industries	**Considerations for EHRs**	**Examples**
For a given font, it should be possible to clearly distinguish between the following characters: X and K, T and Y, I and L, I and 1, O and Q, O and 0, S and 5, and U and V.	It is important that clinicians can easily distinguish between different characters in the EHR to avoid misinterpreting displayed information (e.g., patient names, medication names). Consequently, EHR information should be easily distinguishable.	The EHR font should make it easier to distinguish between similar patient identifiers, such as Aubrey and Audrey, Kay and Kat, Garrik and Garrix.
Leading zeros in numeric entries for whole numbers should be suppressed. For example, 28 should be displayed rather than 0028. A leading zero should be provided if the number is a decimal with no preceding integer (e.g., 0.43 rather than .43).	If clinicians incorrectly read numbers in the EHR, they may make incorrect or unsafe decisions. Leading zeros for decimals, and decimals only, can help clinicians distinguish between whole numbers and decimal values.	EHRs should use leading zeros for decimals and not whole numbers. This will help clinicians read the information in the EHR and successfully order and administer medications, especially medications that can be given as decimals or whole numbers (e.g., 0.5 mg of morphine versus 5 mg of morphine).
Numeric displays should accommodate the parameter's full range. The full range of the parameter includes highest and lowest values that the parameter is expected to take on, under any conditions (normal or emergency operations) for the tasks the display is designed to support.	Clinicians work with multitudes of data types, from vitals to labs, with different range parameters. It is unreasonable for clinicians to remember the range parameters for each condition. Consequently, displays must provide appropriate contextual information, such as the parameter's full range.	Pediatric medication dosing typically relies on the patient's weight in relation to dosing ranges (e.g., give X dose if the patient is between Y and Z kg). It is important that the EHR clearly displays dosing ranges for a clinician's entire patient demographic.

Table 2. (continued)

Highly Relevant Guidelines From Other High-Risk Industries	Considerations for EHRs	Examples
Color, Brightness, Contrast, and Luminance		
The color is associated with the level of warning: red is normally associated with danger or critical situations, yellow is normally associated with caution, and green is normally associated with normal operation; however, other considerations about warning conspicuity may necessitate using a different color.	Within hospitals and the EHR, colors are used to convey information. Sometimes the same color is used to indicate multiple, disparate types of information (e.g., green can represent normal lab values; pro re nata [PRN] medications; facility evacuations; or a specific healthcare team member, like medical assistants). Colors like red and green that have existing meanings outside of healthcare should be used in line with these existing meanings whenever possible.	EHRs should exclusively use the color red for critical patient information, such as critical lab values or vitals. Red should not be used for any non-patient-related information (e.g., inability to sign an order, system error, or incorrect data entry).
Color coding should be redundant with some other display feature. Pertinent information should be available from some other cue in addition to color. Displayed data should provide necessary information even when viewed on a monochromatic display terminal or hardcopy printout, or when viewed by a user with color vision impairment.	Color coding can be a helpful signal when designing an interface. However, users' success at using the tool should not be predicated on their knowledge of the EHR's color coding strategies or their biological ability to see color (i.e., color blindness). Thus, color codes should have redundant information, such as labels, to help users interpret the EHR's visual display.	In the CPOE, clinicians sometimes need to fill out additional fields before signing a medication order. Some EHRs highlight the required fields that must be filled in before signing to indicate that users need to input data. To ensure users understand that the EHR requires a field to be filled, a system should add a redundant signal, such as the word "REQUIRED," to the field.
The quantity of colors used to code information is minimized; do not exceed four color codes.	One major issue with EHR visual displays is the quantity of information the systems contain. Colors can help users sort through information by helping focus attention on the most meaningful data (e.g., critical values, late medications, new orders). Users will struggle to prioritize information if there are too many colors in the display. Thus, it is helpful to use a few colors and only when they are necessary.	EHRs should use fewer color codes. These color codes should emphasize important and/or timely information. For example, red should be used to indicate critical values. Green should indicate noncritical task completion (e.g., completed lab in a normal range).
Comprehension		
A display should include a reference index when the user must compare displayed information with some critical value.	Clinicians work with multitudes of different data types, from vitals to labs. These data types have different critical values, and the same data type can even have different critical values between patients with different characteristics. It is unreasonable for clinicians to remember critical ranges for all the metrics they must understand; consequently, displays must provide appropriate contextual information, such as the data types of critical values.	EHRs should display a lab value's normal range in proximity to a patient's lab value for easy reference and comparison.
Information should be displayed to users in directly usable form consistent with the task requirements. Users should not have to convert displayed data into another form to make it useful to the ongoing task. A user should not have to transpose, compute, interpolate, or translate displayed data into other units or refer to documentation to determine the meaning of displayed data.	EHRs often ask clinicians to transform information outside of the EHR's interface. These transformations introduce the possibility for error and should be minimized as often as possible. For example, nurses may be asked to provide a dose smaller than existing pills, requiring the pill to be cut into a smaller portion. Or clinicians may need to calculate titratable medications manually.	Whenever possible, EHRs should provide actionable information to users that does not require extra actions or calculations. For example, if a patient is scheduled to receive a titratable medication like insulin, the EHR should display the exact dose based on documented blood glucose.
If users must evaluate the difference between two sets of data, the difference should be presented on the display. If it is important for the user to be aware of a discrepancy between two sets of data, the difference should be highlighted on the display.	Patient data is stored in many ways, and clinicians may need to cross-check the information in the EHR with another medical device for accuracy. When information needs to be compared, from two different modalities or across time, the EHR should help users identify differences. Most EHRs do not help clinicians accomplish these functions, which can lead to errors if differences are missed.	Medication reconciliation is the process of ensuring a patient's medication list is up to date. EHRs should aid users in comparing medication lists by highlighting key differences for the clinician to review, investigate, and address.

Table 2. (continued)

Highly Relevant Guidelines From Other High-Risk Industries	Considerations for EHRs	Examples
Design Characteristics		
It is important to distinguish between blanks (i.e., no value) and a value of zero. Some special symbol might be adopted to denote null entry.	Because the components (e.g., hemoglobin, white blood cells, and platelets for a complete blood count [CBC]) of a blood test (the CBC) may take different times to process, the results may be uploaded to the EHR at different times. Some EHRs do not indicate when a lab test or individual components of that test are in process. This makes it difficult for clinicians to distinguish between pending (not visible in the EHR) and completed lab values.	When labs are in process and do not have a value displayed, the EHR should indicate the lab's in-progress status. For example, the EHR could report the lab's status as "pending."
Information that must be compared or mentally integrated should be presented in close spatial proximity. If possible, the information items should be contained on the same display page and grouped together. Spatial proximity may also be achieved by presenting the display pages in adjacent display windows or on adjacent display devices that can be viewed together.	Patient health data is typically grouped by topic in the EHR (e.g., labs, medications, vitals), but clinical decision-making relies on taking multiple aspects of patient health data into account. Consequently, clinicians must search for and remember information from multiple EHR pages, which can lead to errors. EHRs should consider users' clinical decisions and put relevant information on the same page.	When administering medications dependent on lab results (e.g., potassium chloride, vancomycin, insulin), the patient's relevant lab results should be displayed proximal to the administration screen.
Information should be organized in some recognizable, logical order to facilitate scanning and assimilation. If the data in the rows have order, the order should be increasing from left to right. If the data in the columns have order, the order should be increasing from top to bottom of the display. Items in lists should be arranged in a recognizable order, such as chronological, alphabetical, sequential, functional, or importance. Where no other principle applies, lists should be ordered alphabetically. It is the user's logic that should prevail rather than the designer's logic, where those are different.	EHRs contain many lists that users must scan (e.g., search results, problem lists, medications). These lists can be long, contain irrelevant information, and be organized in an illogical manner (e.g., American Standard Code for Information Interchange [ASCII] ordering). EHRs should make it easier for users to find information in lists by providing consistent, easy-to-understand, and expected manners of organization.	Search results should be presented logically when ordering medications, such as alphabetical, dictionary order.
Symbols, Pictograms, and Icons		
Icons should be designed to look like the objects, processes, or operations they represent, by use of literal, functional, or operational representations. Some pictorial symbols have conventional meanings within a user population, which must be followed to ensure their correct interpretation. The following are examples of representations: literal, a figure of a pump; functional, a figure of a file cabinet; and operational, a hand on a switch.	EHRs should have intuitive icons that rely on existing iconography or common symbols. Some icon-heavy EHRs use vague icons, such an abstract shapes and single letters, to communicate information. Vague icons can make learning to use software difficult and can lead users to perform actions incorrectly or inefficiently.	EHRs should use ubiquitous symbols in software design (e.g., a house for "home," a gear for "settings," a magnifying glass for "search"). Unique symbols such as a mortar and pestle should be as literal as possible to indicate pharmacy. Clear language should be used if a ubiquitous or representational symbol cannot be identified.
Special symbols should be used exclusively to signal critical conditions.	EHRs convey both critical and noncritical information. It is important that critical information, especially time-critical information, be easy for users to identify visually. However, some EHRs use exclamation points to indicate critical information like out-of-range lab values and indicate forms with missing information. To maintain clinicians' alertness to critical values, the strategies used to indicate critical values should not be used outside of critical contexts.	EHRs should choose a symbol for critical values (e.g., red exclamation point) and only use that value to convey the most critical health information. Other symbols should be used to indicate system errors and noncritical information.
Icons should be accompanied by a text label. To the extent that it does not clutter or cause distortion of the icon, the label should be incorporated into the icon itself. When icons are designed such that the label is inside the icon, the number of perceptual objects is reduced, resulting in enhanced processing of the label and the icon. The text label may be omitted for icons having unambiguous meanings to users.	Icon-heavy EHRs often use vague icons, such as abstract shapes and single letters, to communicate information. Vague icons can make learning to use software difficult and can lead users to perform actions incorrectly or inefficiently. One way to disambiguate icons, even common or representational icons, is to provide redundancy and text label the icons with the intended goal.	EHRs can and should use icons for commonly used tasks, but the icons should have labels adjacent to, inside, or upon hover to aid understanding (e.g., phone signal strength icon to represent taper medications that say "taper medication" when the cursor hovers over the icon).

Table 2. (continued)

Tables, Figures, Charts, and Lists		
Highly Relevant Guidelines From Other High-Risk Industries	**Considerations for EHRs**	**Examples**
Labels should include the unit of measure for the data in the table; when cells have the same measurements, the units of measurement should be part of row or column labels.	Medicine uses a multitude of different units of measure. Some of these units of measure can be easily confused or have significant consequences on how patients are treated. It is important that the EHR accurately labels data with appropriate units whenever data is entered or displayed.	While pounds are the most common weight measure for the United States populace, kilograms are often used in healthcare settings. It is important that the EHR requests and reports weights with the accurate unit of measurement attached for clarification.
Old data points should be removed after some fixed period of time. Ideally, as one new point is plotted, the oldest point should be removed, thereby maintaining a constant number of displayed points.	EHRs are repositories for patient data that can help clinicians understand their patient's health over time. However, historical data can be used incorrectly (e.g., insulin dose based on an old glucose value, treatment plan based on an old X-ray). It is important that EHRs accurately label old data points to dissuade incorrect use of the data during decision-making.	eMARs should visually indicate which medications are active and which medications are discontinued. For example, active medications could be listed at the top with a blue background and discontinued medications could be listed at the bottom with a grey background.
Graphs should convey enough information to allow the user to interpret the data without referring to additional sources.	Visualizations help clinicians make sense of data to understand and treat patients. Information in the EHR is typically grouped by topic (e.g., labs, medications, imaging), and clinicians must find, remember, and synthesize the data. However, to make graphs and other visualizations effective, they should contain the data types that a clinician needs to make a decision.	Prothrombin time (PT)/international normalized ratios (INRs) are used to determine heparin dose adjustments. EHRs should display PT/INRs on the same graph to help clinicians make clinical decisions about heparin dosing.

Note: Some of the practices identified in these examples may already be in place in some EHRs.

Healthcare facilities can use these guidelines to evaluate the usability and safety of EHR visual displays when considering a new EHR product. The guidelines can also be applied to optimize currently used EHRs. Many EHRs are configured and customized by healthcare facilities, and these processes give rise to the visual display that frontline clinicians use. Previous research has shown tremendous variation in the same EHR vendor product across different healthcare facilities because of configuration and customization decisions, and these variations are associated with different task completion times and error rates.[8,9] The guidelines can be used by healthcare facility EHR experts to inform their customization and configuration decisions. Further, high-risk functions in the EHR can be evaluated by examining the visual display elements when using those functions to ensure the display adheres to the guidelines presented here. When specific functions and/or features not aligned with the cross-industry human factors guidelines are identified, facilities can work with their EHR experts to determine whether they can customize or configure their EHR to meet the guidelines. If they cannot make the appropriate changes, healthcare facilities can work with their EHR vendor to make improvements.

In addition to using these guidelines, there are several other resources for healthcare facilities to assess and improve the safety of their EHR. These resources include several self-assessment tools[28–32] and test cases for EHR usability evaluation.[33,34]

Implications for Policymakers

Identifying cross-industry guidelines relevant to EHR visual displays also has policy implications. Currently, the Office of the National Coordinator for Health Information Technology (ONC), the federal agency that oversees EHRs, does require that EHR vendors follow specific design standards. The ONC requires EHR vendors to perform usability testing for certain EHR functions. There is an opportunity for the ONC to develop required usability test cases that embed these guidelines in the test cases. Test case development would promote EHR vendor adoption of these safety-critical human factors principles. The ONC could also include these guidelines as part of their real-world testing requirements focused on assessing EHR vendor products in actual clinical environments. Finally, the ONC could work with NIST to develop EHR-specific design guidelines or standards to inform EHR vendor practices.

Limitations

Aviation, automotive, and nuclear industry guidelines were identified through an internet search. We may have missed alternate industry guidelines or more recent versions in a private domain. We used qualitative assessment to identify which guidelines are relevant to EHR visual displays. Therefore, some guidelines marked as relevant may be irrelevant, and conversely, some guidelines marked as irrelevant may be relevant.

Future Research

Future research should consider the applicability of these guidelines to other healthcare software, such as patient portals. Despite being essential to effective patient care, many non-EHR software are neglected in human factors research. Additionally, future research should investigate how guidelines in other industries compare to the guidelines currently outlined in healthcare.

Conclusion

Poor EHR usability has consequences for patient safety and clinician burnout. Relevant visual display design guidelines from other high-risk industries—aviation, automotive, and nuclear—were identified to inform safe and efficient EHR design. These guidelines can be used by EHR vendors, healthcare facilities, and policymakers to improve the usability and safety of EHR visual displays.

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Evidence-Based Teaching Plan, Test, and Evaluation on Caring for Healthcare Provider Second Victims

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Abstract

Background. Healthcare providers as second victims witness significant patient or employee crises. Their intense emotional responses have been recognized by healthcare institutions.

Purpose. The study developed a literature- and expert-validated, evidence-based teaching plan and matching multiple-choice test for nursing staff and professional development educators. The teaching plan can structure educational sessions that disseminate content on second victim experiences.

Methods. The study used a mixed-method design to build an evidence-based teaching plan and multiple-choice test, and qualitative analysis of second victim literature to generate teaching plan components. Quantitative analysis was used to evaluate experts' ranks on the teaching plan and pretest drafts.

Results. The mean pretest score was low, possibly showing that doctoral students may lack knowledge of the second victim phenomenon. Test statistics indicate the need for item revision.

Conclusion. Teaching sessions based on the revised teaching plan and test might raise awareness of aspects of the second victim experience and program among nursing staff and multidisciplinary team members.

Keywords: *second victim, teaching plan, test*

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Introduction

Healthcare providers involved in serious clinical errors; who have witnessed significant patient or employee trauma; or who have experienced critical incidents, such as the intense COVID-19 pandemic,[1] are second victims, wounded healers,[2] or walking wounded.[3] The term "second victim" has been adopted across healthcare settings.[4] Second victims are healthcare providers involved in unanticipated adverse patient events, medical errors, and patient-related injuries, and traumatized by these events. They feel responsible for unexpected patient outcomes, think they have failed their patients, and second-guess their clinical skills and knowledge base.[3]

Examples of situations or incidents that result in the second victim experience include sudden death or deterioration of patients;[5] assaultive, violent patients or family members;[5,6] complications of treatments;[3] traumatic injuries of patients;[7] multicausality disaster or terrorism events;[7] unexpected pediatric deaths;[5] and medication errors. Healthcare providers involved in extraordinary situations bear the wounds of patients, family members, and healthcare team members.[8] They live with many consequences of traumatic experiences and may not be able to address or resolve the personal or professional effects of them.

Healthcare providers as second victims witness significant patient or employee crises. Their intense emotional responses have been recognized by healthcare institutions.

The personal, substantial effects of provider involvement in traumatic situations for second victims are numerous and disrupt many relationships, such as with patients.[9] Emotional responses consist of anxiety, shock, panic, inability to perform direct patient care, post-traumatic stress syndrome, self-blaming, worry, vulnerability, fear of punishment, moral distress, insomnia, helplessness, sadness, grief, depression, shame, intrusive reflections, flashbacks, emotional outbursts, suicidal thoughts, social isolation, denial of an incident, doubt of clinical knowledge and skills, and threatened professional identity. Physical reactions are fatigue, rapid heart rate, increased blood pressure and respirations, and muscle tension. Professional concerns for second victims consist of a potentially career-ending outcome, such as damage to reputation; being blamed, singled out, or exposed in a public tragedy; lost confidentiality; inability to escape the trajectory of events; stigmatization; documentation in the employee record; licensing board disciplinary action; litigation stress; criminal charges; imprisonment; and termination from position.[5,8,10-17]

Family members and fellow employees often provide informal support to second victims; however, after recognizing the threats linked to outcomes for healthcare providers and other staff resulting from traumatic situations, leaders have initiated strategies and programs to support and retain wounded personnel and have addressed the implications of publicized errors and other traumatic events. Concern about all victims, patients and family members, employees, and healthcare institutions have impelled healthcare administrators to manage risk, provide peer support services, refer to employee assistance programs and psychological counseling, and create and implement evidence-based second victim programs. Expert recommendations have guided programmatic plans consisting of compassionate and understanding responses to traumatic situations, supportive care, respect for victims, treatment recommendations, and transparency.[16] Programs have incorporated principles of Critical Incident Stress Management programs,[7,18] Scott Three-Tiered Interventional Model of Support,[3,19] Medically Induced Trauma Support Services (MITSS),[20] and the Resilience in Stressful Events Program (RISE).[21] The support provided to second victims can advantage healthcare institutions and match the fourth Quadruple Aim by fostering the well-being of healthcare providers through safe and healthy workplaces.[22]

Content on the impact of traumatic, critical incidents for providers and on the characteristics of effective programs supporting them needs to be disseminated. Knowledge of the experiences of second victims and targeted programs could assist healthcare leaders in providing interventions that prevent outcomes such as second victims' sustained suffering, absenteeism, and leaving their professions. Therefore, the purpose of this educational initiative was to create an evidence-based teaching plan and matching test of knowledge concentrating on traumatized healthcare employees' experiences and second victim support programs. The evidence-based teaching plan and multiple-choice test were framed by related literature; the project's future aim was to disseminate the plan and the multiple-choice test to the global community, including university faculty, professional development educators, and leaders of healthcare institutions who might use the plan as a basis for teaching sessions. The project's questions were: What were the literature- and expert-validated components of a teaching plan and pretest on second victim experiences and support programs? What were the results of a pretest, matching the contents of the evidence-based teaching plan, on volunteers' knowledge of second victim experiences and support programs?

The following conceptual definitions were used. Critical incidents are complex, varied, and multicausal adverse and traumatic events occurring in the delivery of healthcare experienced by patients, family members, hospital employees, and leaders that witness and participate in these situations.[12,23] Second victims are healthcare professionals traumatized by critical incidents in healthcare environments, which suffer secondary traumatic stress when caring for traumatized patients,[23] resulting in personal and professional repercussions[3,25] and needing immediate and sustained support.

The teaching plan on the second victim experience and support programs is an evidence-based blueprint and four-column structure. The logical pattern of the teaching plan is aimed at enhancing healthcare provider knowledge.[26] The entire plan or its parts can be used to orient an educational intervention for healthcare students and employees. The cognitive domain content column is framed by evidence-based research and peer-reviewed articles addressing facts, principles, and theories on second victims' experiences and targeted support programs. The multiple-choice test is an evidence-based exam on knowledge of second victim experiences and support programs. The test items match the content and objectives of the teaching plan. The time allotted to different sections of the plan during teaching sessions is deferred to clinical educators. The evaluation methods are the multiple-choice test questions.

This study is framed by the theory of nurses' psychological trauma.[27] The theory examines traumatic situations that result in physical and emotional stress reactions for nurses when providing routine nursing care. Foli categorized psychological traumas as avoidable and unavoidable. The theorist described seven nurse-specific and nurse-patient-specific, acute or chronic, psychological traumas experienced during the act of caring. Although the theorist described one of the seven traumas, second victim trauma, the other six could cause nurses' psychological injuries. Foli also noted the secondary traumatic stress responses associated with the nurse-patient relationship when nurses review their experiences. The author acknowledged positive (resilience, post-traumatic growth, compassion toward others) and negative (depression, anxiety, overinvolvement, substance use, compassion fatigue) outcomes of psychological trauma.[27]

Foli[27] focused nurses' psychological trauma theory on concern for nurses' well-being. Foli charged organizational leaders to create an environment in which trauma-informed care supports nurses. As leaders resolve organizational problems, nurse-specific traumas might decrease nurse-specific trauma. Educational sessions based on a teaching plan could also reduce nurse trauma. Foli urged nurse leaders to provide critical support, since nurses are recipients of care and providers of care. Programs such as the Scott Three-Tiered Interventional Model of Support[3,19] might reduce the effect of critical, traumatic incidents and experiences on nurses. Knowledge of second victim experiences might stimulate healthcare institutions to launch support programs.

Methods

Design

The project used a mixed-method design to develop a teaching plan as a basis for an educational intervention.[28] Qualitative analysis of literature generated content areas of the teaching plan. Quantitative analysis evaluated the ranks reported by experts on the teaching plan and pretest drafts, and on results of the piloted pretest.

Face and Expert Validity Processes for the Teaching Plan

The project used content analysis methods to derive content areas of the teaching plan from printed versions of empirical and peer-reviewed literature. The citations, obtained through database search strategies (i.e., Summon, CINAHL, Cochrane Library, HaPI, and PubMed), used these search terms: "second victim," "wounded healer," "critical incident," "program," "employee support," and "support programs." The literature spanned several decades of published material on second victim or wounded healer experiences and support programs. Literature was analyzed using Hsieh and Shannon's[29] content analysis approach; the matrix is available on request. The draft teaching plan was grounded in peer-reviewed literature.

The nine sections of the draft and final teaching plan on second victim experiences and support programs include purpose, statement of overall goal, objectives, content outline, methods of teaching, and resources.[26] Time allotted and methods of evaluation were not included because clinical educators may allocate preferred times to the teaching plan and the evaluation methods were the test items. The teaching plan (**Table 1**) was revised based on expert review.

Multiple-Choice Pretest

The multiple-choice test matched the teaching plan. After revisions based on experts' judgments, the test was piloted as a pretest with volunteer doctoral students (*N*=18 out of 28) before they examined content in a course module on healthy work environments including strategies, civility, and second victim experiences. The pretest was developed as an initial exam that could be adopted and modified by professional development educators.

Ethical Considerations

Institutional review board review approval was obtained under expedited review (IRB: 23-02-009). Data analyzed on the literature were textual. No names of content experts were identified. The test grade was not part of volunteer students' course assignments. Eighteen students participated.

Instrumentation

Content Areas of the Teaching Plan: Analysis of Literature and Test Blueprint

The content areas of the teaching plan's outline were generated through inductive, conventional content analysis of pertinent empirical and peer-reviewed literature on second victim experiences and support programs.[29] The column headings of the coding matrix were major themes, minor themes, indicators from literature, and citations. Themes and indicators were selected to build the content outline statements for those components of the teaching plan.[26] Face validity was established because the content areas of the teaching plan originated in second victim literature.[28] Test items matched the teaching plan objectives and the content outline. Items were organized using a content specification matrix for subcomponents of the content outline and knowledge/comprehension, analysis, and application objectives.[30]

Experts' Judgments on Content Areas of the Teaching Plan and Multiple-Choice Pretest

Seven experts were invited via email to judge the content areas of the draft teaching plan and test items using an expert validity form. The five anonymous, traditional, and experiential experts that participated were doctoral-prepared safety content and test construction experts.

Table 1. Healthcare Second Victim Experiences and Support Programs

Purpose: The aim of the teaching plan is to provide an evidence-based content outline and matching test on the second victim experience and second victim support programs so that staff nurses and other healthcare providers deepen their awareness of the threats of critical incidents and opportunities for healing.
Goal: To educate students and employees of the healthcare professions about the second victim experience and corresponding support programs.

Objectives At the end of the teaching session, participants will be able to:	**Content Outline**	**Methods of Instruction***
Component 1: Second Victim Definition and Examples of Critical Incident Categories		
1. Discuss definitions of second victim (SV) concept and examples of critical incident categories.	*Definition* • Healthcare providers involved in a patient adverse event or medical error, and as a result, experience emotional and sometimes physical distress • A healthcare provider involved in an unanticipated adverse patient event, medical error and/or a patient-related injury who becomes victimized in the sense that the provider is traumatized by the event. Frequently second victims feel personally responsible for the unexpected patient outcomes and feel as though they have failed their patient, second-guessing their clinical skills and knowledge. • Potentially tragic implications for patients, family members, healthcare providers, healthcare institutions *Examples of Critical Incident Categories* • Care-associated (e.g., pressure injuries, falls), device malfunction, provider error, systems problems, medication, preventable harm to patient, surgery or other procedures, diagnosis, infections, acute patient deterioration, accidents, injury to provider, storms, terrorism, hostage situation in healthcare facility, active shooter in community	Lecture/ Discussion MP4 PowerPoint slides
Component 2: Individual Effects of Second Victim Experiences		
2. Describe personal and public effects of being an SV.	*Emotional, Psychological, and Public Effects of Second Victim Experience* • Multifaceted responses to personal, vulnerable, experience • Stress response: anxiety, worry, emotional upset, shock, horror, emotional trauma, emotional outbursts, burnout, panic, suicidal • Depression: sadness, grief, despondency, helplessness • Post-traumatic stress • Feeling stigmatized, blamed, shamed, singled out, exposed • Self-blame • Personal failure: doubt clinical skills and knowledge, feel inadequate, threat to identity, intention to leave position • Persistent recollections: relive event; intrusive reflections, flashbacks, haunted for rest of life, attempt to bury critical incident • Spiritual and moral distress • Disruption of daily activities • Fear of punishment and termination from position • Public tragedy: altered interpersonal relationships, social isolation, blamed for incident	Lecture/ Discussion MP4 PowerPoint slides
3. Describe common physical signs and symptoms linked to the SV experience.	*Physical Signs and Symptoms* • Physiological: increased heart rate, blood pressure, respiratory rate, muscle tension • Symptoms: headache, stomach pain, insomnia, fatigue • Unexpected health events	
4. Compare types of professional distress connected to the SV experience.	*Professional Distress: Institutional and Legal* • Institutional: career-ending situation, fear of retaliation, damage to reputation, loss of job, recorded in permanent employee record, threats, reprimands, lack of confidentiality, gossip • Unit: avoid obtaining information about patient's condition, avoid discussions of critical incidents with colleagues and supervisors • Legal: dereliction of duty charge, fear of licensing board disciplinary action, lawsuits (litigation stress), criminal charges, imprisonment, inability to escape trajectory of events, acquittal	

Table 1. (continued)

Component 3: Second Victims' Strategies to Mitigate Effect of Critical Incidents		
5. Identify professional, beneficial strategies initiated by SVs to reduce the negative effects of vulnerability after critical healthcare incidents.	*Professional, Ethically Based Strategies* • Report critical incident on discovery • Acknowledge personal responsibility for incident • Discuss safety threat with patient and family members • Apologize to patient and family members • Implement lessons learned in own clinical practices • Demonstrate performance improvement activities • Practice institutional patient safety initiatives • Participate in safety conferences • Make amends by sharing experience as lessons learned with healthcare providers • Provide teaching sessions and speeches	Lecture/ Discussion MP4 PowerPoint slides
6. Evaluate self-care, healing strategies to decrease the distress of the SV experience.	*Healing-Promoting Interventions* • Obtaining psychological counseling • Ongoing commitment to learning from incident and making constructive change • Engaging in spiritual or religious practices • Seeking supportive people with whom to share critical incident • Practicing expressive writing • Returning to work after receiving support	
Component 4: Professional and Unprofessional Responses to Second Victim Experiences		
7. Compare unprofessional to professional, kindness-oriented responses of healthcare providers to SVs involved in critical incidents.	*Unprofessional Responses* • Isolate provider involved in error, neglect colleagues' need for help, make light of colleagues' responsibility for error, humiliate provider, condemn provider, punish provider, supervisor denouncement that provider that made error not allowed to give medications, transfer of involved provider to another clinical activity, assumption that second victims can manage situation themselves *Professional Responses* • Peer supporters: immediate support, share error stories, reassure SV of competency, establish trusting relationship, ask about emotional impact of incident and coping, avoid condemnation, practice attentive listening • Peer support: evaluate if peer supporters have secondary traumatic stress, burnout. Measured by Professional Quality of Life: Compassion Satisfaction and Fatigue, Version 5 (ProQOL 5)	Lecture/ Discussion MP4 PowerPoint slides
Component 5: Second Victim Needs and Recovery Stages		
8. Describe needs of SVs and stages of the SV recovery process.	*Second Victim Needs* • Sustained nonpunitive institutional culture • Robust incident reporting system and response process • Access to supportive colleagues, especially in early stages to provide immediate, targeted support • Systematic availability and support by easily accessible, multidisciplinary healthcare professionals in institution • Acceptance by colleagues and supervisors that emotions and reactions change over time, including socially undesirable feelings • Continue supervisory relationship for new and seasoned clinicians • Local unit and system improvements in response to critical incidents • Supportive and constructive unit climate • Institutional programs to develop diverse coping skills • Yearly presentations on responses to tragic event programs implemented by institution *Six Recovery Stages of Hall & Scott* • Stage 1: Chaos and accident response (turmoil and need for support, self-recrimination) • Stage 2: Intrusive reflections (haunted reenactments of situation, "what if?) • Stage 3: Restoring personal integrity (seek support from trusted colleague, friend, or family, stabilize patient) • Stage 4: Enduring the inquisition (concern about institutional repercussions, job security, licensure, litigation stress) • Stage 5: Obtaining emotional first aid (seek emotional support from family, colleagues at work) • Stage 6: Moving on, dropping out, surviving, or thriving (difficult to put event behind and move on)	Lecture/ Discussion MP4 PowerPoint slides

Table 1. (continued)

Component 6: Peer Support Relationships Framed by Nursing As Caring Theory Concepts		
9. Describe strategies framed by caring theory to provide structure for colleagues supporting SVs in relationship.	*Team Members Involved in Critical Incidents Need Support to Navigate Experience* • Second victims: need kindness, reassurance, concern, understanding, counselling, time to reflect and learn • Employees and interprofessional healthcare team need support and time to reflect and learn *Caring Actions Based on Nursing As Caring Theory Concepts and Scott & Hall Recovery Stages* **Phase 1:** • Peers offer immediate support, or emotional first aid, to second victims engaged in caring nursing situation with them • Peer supporters recognize that they and second victims are caring persons • Peers and supervisors start to interact with second victims, are intent on and commit to learning about their experiences with critical incidents • Peers commit to support and nurture second victims during their relationship as effects of incidents evolve • Peers and second victims develop short-term, intermediate-term, and long-term relationships; supervisors may also support second victims at this time • Peers value vulnerability of second victims and respect different expressions connected to incidents, such as hope, fear, grief, stress, self-blame, courage, humility • Peers are attentive and listen to second victims • After assessing safety of situation, peers escort second victims to another location if possible **Phase 2:** • Peers and supervisors continue to support and relate to second victims as they feel their personal integrity restored • Second victims' experiences are affirmed as peers and supervisors share their personal responses to critical incidents and effects on institution • Peers and supervisors reflect on conversations with second victims **Phase 3:** • Second victims may continue to suffer from critical incidents, calling for peers and supervisors to continue to be available and supportive, and to listen to their experiences • Peers and supervisors care for second victims and note their surviving, thriving, moving on, or dropping out	Lecture/ Discussion MP4 PowerPoint slides
Component 7: Effect of Critical Incidents on Healthcare Organizations		
10. Evaluate the institutional effects of critical incidents on reputation of healthcare organizations.	*Corporate Effects of Critical Healthcare Incidents* • Organization as third victim • Goal: to foster a culture in which all employees were resilient and mutually supportive before, during, and after stressful events • Second victim phenomenon as serious consequence for institution, public tragedy and influence on reputation, incident as corporate emergency, risk to reputation, product risks such as medication shortages • Culture change of norms to safety culture, personnel knowledge of investigational process after events, need to understand long-term support may be needed, negative to positive attitude change, eliminate stigma, available psychological support through mental health services	Lecture/ Discussion MP4 PowerPoint slides
Component 8: Organizational Process Improvement Strategies		
11. Describe organizational process improvement strategies in support of SVs.	*Post-Critical Incident Strategies* • Open, nonpunitive approach • Vigilant about patient safety • Report but do not overreport constructive changes • Support from unit managers, peers, supervisor, physicians, etc. • Share "blame and shame" stories to teach staff about prevention of like incidents • Share details of event with patients using informal and formal support, safety officer responsibility • Debrief when emotional intensity subsides after critical incident • Establish venue for discussing emotions after critical incidents • Offer training and retraining sessions on civility, incident disclosure, and mentor and peer support • Conduct root cause analysis in response to incidents • Structure availability of supportive employees: risk managers, chaplains, social workers, mental health clinicians, child life therapists, palliative care practitioners	Lecture/ Discussion MP4 PowerPoint slides
12. Share examples of types of safety strategies implemented by healthcare institutions to increase patient and provider safety.	*Examples of Technological Strategies* • Electronic adverse event reporting system, barcode technology, electronic health record, infusion pumps, error-reduction simulations, medication dispensing systems, intranet safety reporting systems, etc. *Examples of Safety Strategies Promoting Safety* • Develop and periodically assess culture of safety • Emphasize systems' roles in critical incidents • Avoid blaming personnel for safety threats and critical incidents • Maintain anonymous reporting system on intranet • Manage root cause analysis processes • Report safety risks and critical incidents to quality improvement, mortality and morbidity, and safety committees • Apologize to patients and family members: patient safety officer or another administrator • Facilitate smooth return of involved SVs to patient care	

Table 1. (continued)

Component 9: Program Creation and Implementation		
13. Describe institutional principles and goals that orient SV programs.	*Program Goals and Principles in Support of Second Victims* • **Goal Examples** 1. To provide awareness of supportive strategies available to prevent clinicians and other healthcare employees from extreme stress after critical incidents. 2. To identify the contributions of ongoing process improvement activities that periodically evaluate and modify programs targeted at supporting second victims. • **Foundational Principles in Second Victim Program Development** ○ Program creation and implementation by committed, core interprofessional team ○ Development of policies and procedures ○ Proactive, consistent, timely support strategies ○ Immediate post-event first aid for involved employees ○ Identification of professional referrals for psychological and other types of support services ○ Systematic approach to education sessions, onboarding, evaluating, and maintaining program ○ Periodic evaluation of program performance ○ Periodic staff training • **Team Engagement and Commitment** ○ Establish core multidisciplinary committee: clinicians, quality improvement, hospital leaders, safety experts, risk management ○ Focus on Quadruple Aim: workforce well-being and safety	Lecture/ Discussion MP4 PowerPoint slides
14. Compare types of programs implemented by healthcare organizations in support of SVs .	*Program Types and Organizational Strategies to Implement Programs* *Critical Incident Stress Management (CISM)* Multicomponent crisis intervention system: small and large scale applications • **P**rovision of psychological support in field • **I**mmediate, rapid support • **E**xpectancy: viewing extreme stress reaction as normal and not pathological reactions • *Best* practices: early intervention, complete care, complete care, peer support, specialized training • Core competencies: assessment and triage, crisis intervention with individuals, small-group and large-ground crisis intervention, strategic planning • Critical Incident Stress Debriefings (CISD): Crisis debriefing, emergency responder involvement **Scott Three-Tiered Interventional Model: Framework of Caring–**Support for Second Victims • Tier 1: "Local" (Unit/Department) Support: all employees trained to know how to identify a second victim and how to provide initial support to a second victim. • Tier 2: Trained Peer Supporters, Patient Safety & Risk Management Resources: Trained peer supporters, individuals who have been educated on conducting one-on-one and group debriefings, give further assistance to a second victim by asking appropriate questions and providing a listening ear. • Tier 3: Expedited Referral Network: Trained professionals outside of the pharmacy department (e.g., pastoral care, employee assistance program, social work, and behavioral health staff) are contacted when care needs to be escalated and professional support is required. ***Essentials:*** • Team training of "clinician lifeguards" • Administrative framework • Monitoring rapid response system interventions **Toolkit for Hospitals on Second Victims–**Institutionwide support program for clinicians • Modular: Multiple actions that could occur concurrently, best practices, evidence-based; Modules: internal culture of safety, organizational awareness, multidisciplinary advisory committee; leadership buy-in; risk management considerations; policies, procedures, and practice; operational staff training communication plan; learning and communication opportunities • Personnel: Identify core steering team; identify executive sponsor; develop unit-based teams; develop team branding/marketing; educate and train peer supporters; track data to insure effectiveness teams; funding initiatives; design of support system important for impact • Implementation: **Tool Kit for Healthcare Organization** on Clinician Support Toolkit Plans for Program Implementation **RISE Resilience in Stressful Events (Johns Hopkins Hospital)–**Peer support program: Provide resources to reduce harm to self or others; confidential • Initial peer support and active listening throughout; debriefing as learning opportunity • Recruit and train peer supporters; apply to peer program; train peers; RAPID (Reflective listening, Assessment, Prioritization, Intervention, Disposition) psychological first aid; ongoing training; 2-tiered call system (2 peers, 1 as backup); % budget allocation for program director. • Three-Tiered approach rapid response; 1 = rapid responders, peers; 2 = 24 x 7 rapid response from institutional experts; 3 = availability of professional support and counseling	Lecture/ Discussion MP4 PowerPoint slides

Note: Time in minutes is allocated to connect is specified by educator
*Citations included in References section of paper.

The draft teaching plan consisted of nine content areas. Relevance of the content areas was elicited on a two-point scale for the content areas or components (0=*vital part missing*, 1=*vital part present*) and through comments. The teaching plan's item content validity indexes (I-CVIs) and survey content validity average (S-CVI/Ave) were 1.0 for all components of the plan. Overall, experts' comments were positive on the details of the plan. The indexes and comments supported content relevance.

The five experts critiqued the relevance of 22 test items. Test item relevance was elicited on a four-point scale (1=*not relevant*, 2=*somewhat relevant*, 3=*quite relevant*, 4=*highly relevant*) and through comments.[27] The I-CVIs ranged from .83 to 1.0. The S-CVI/Ave for test items was 0.97. Changes were made to test items based on comments, such as grammar, modification of distractors, multiple-multiple items revised to multiple-choice format, and inclusive language use. The pretest of the multiple-choice exam was administered online via a learning management systems-formatted test during a course. Total scores were obtained.

Data Analysis

The four-column coding matrix (major themes, minor themes, indicators from literature, and citations) structured data analysis of literature that generated components of the teaching plan on the second victim experience and support programs. Inductive, conventional content analysis[29] structured the analysis as the literature was read; themes were named and recorded in matrix columns and aligned with references. Minor themes were grouped into major themes. Quantitative data on experts' judgments of the teaching plan's content outline and test items were analyzed using Excel. Pretest item statistics and Cronbach's alpha coefficient were analyzed using Canvas statistical operations (San Francisco, CA); recommendations vary on sample size for alpha coefficients.[31] Descriptive statistics on the total score for the pretest were analyzed with IBM SPSS Statistics 28.

The credibility of the teaching plan and pretest was established by the expert content validity process completed on the content outline and test items. A seasoned qualitative researcher followed the audit trail of the content analysis, reviewed the revised teaching plan and test items, and approved the quality of methods and results.

Results

The content column of the plan was based on related literature, as supported by the coding matrix. Expert review supported the integrity of the nine components of the plan. The revised teaching plan is found in **Table 1**. It can provide structure for educators as they instruct healthcare providers on the knowledge of the second victim experience and available support options. The plan can offer guidance to educators and foster the standardization of teaching sessions in clinical settings.[26] They most likely will conduct group sessions so that costs are contained. The teaching plan might be judged as internally consistent in that objectives match the other parts of each component.

The pilot test results were based on a Canvas-formatted exam administered to volunteer doctoral students (N=18, response rate=64.3%). Descriptive statistical findings on the summed, correct items showed the following: M=8.09. MD=7.00, SD = 4.75. The mean on test-takers' knowledge was very low, suggesting a need for educational sessions on the content. The Cronbach's alpha coefficient was .441.

The findings on pretest items are included in **Table 2**. The multiple-choice test item format was preferred to other formats because of rapidity of administration. Additionally, item test statistics assist in evaluating first-time administered tests, such as this example. Descriptive statistics on items (frequency/percentage of correct items, proportion correct indexes, or difficulty and discrimination indexes) can call attention to the need to consider revision. However, they do not confirm whether an item is good or bad.[30] Negative and low discriminability values suggested the need to evaluate items for item revision. One item had extremely low discriminability because all test-takers answered the question correctly. Other items' discriminability scores were also low. Students may not have known some details about the second victim experience. See **Table 2** for more details on items needing revision. Correct items are bolded.

Discussion

Crisis situations are occurrences in acute care hospitals and other clinical settings because of the nature of nurses' caring work for patients and families. Therefore, second victims witness and participate in experiences that may be catastrophic. Those involved in serious incidents could benefit from initial and continued support after involvement in traumatic experiences in healthcare institutions, such as gun violence situations, partner violence, and child abuse. The emotional and professional effects of these events persist as an aftermath.[13]

The results of the pretest, although in initial development, suggest that knowledge about the second victim experience may not be well known or disseminated. The relevance of an evidence-based teaching plan and a test on the second victim phenomenon is that they can serve as resources for professional development educators when offering teaching sessions in healthcare institutions. The structure and details of the teaching plan can be easily modified by educators. The content of the teaching plan could also be included in a series of sessions.

Perceived institutional support for second victims has been described as contributing to the safety culture and decreased emotional exhaustion of clinicians.[32] Organizations might retain skilled healthcare providers when emotional first aid is given and if resources continue to be available. Education of healthcare employees about the trauma of second victims might encourage healthcare professionals to develop peer support skills and offer them to colleagues.[33]

The teaching plan's content areas need to be reviewed; the content analysis of the literature was conducted by one researcher. The plan and the test items, although supported overall by experts' judgments of their relevance, call for future revision. The teaching plan should be modified periodically based on current literature. The test items need to be revised based on the item statistics and suggestions seen in **Table 2**.

Future research is needed on the effect on implementing educational sessions framed by the teaching plan on nursing staff's knowledge of the second victim experience and support programs. The intervention is the teaching session and the outcome measure is the scores of the revised test. Researchers could conduct a pretest/post-test, quasi-experimental study comparing knowledge of the second victim experience. One group could be instructed using the teaching plan-based session and the comparison group would not receive the instruction.

Table 2. Test Item Statistics on 22-Item Draft Second Victim Multiple-Choice Test (N=18)

Item With Distractor	N Items Correct (%) Difficulty or Proportion Correct Index	Discrimination Index	Revision Needed
1. What types of critical incidents result in healthcare provider trauma? • Physical assaults on healthcare staff • Unexpected patient deaths • Deaths of children • **All of the above**	18 (100)	-0	Multiple-choice item with the new recommended distractor. Extremely poor discriminability. Further revision may be needed.
2. Which best describes a personal and professional consequence of the second victim experience? • **Threatened professional identity** • Periodic emotional outbursts • Frequent intrusive thoughts • Self-blaming episodes	6 (33.3)	0.30	
3. Which behavior further victimizes healthcare providers involved in very traumatic events? • **Gossiping about guilt of involved staff** • Avoiding discussions about the critical situations • Making light of the incident during meetings • Describing the situation in personnel records	5 (27.8)	0.36	
4. Which result of a critical incident is a legal consequence linked to the second victim experience? • Fear of State Board disciplinary action • Inability to escape the situation • **Dereliction of duty charge** • Damage to professional reputation	4 (22.2)	0.54	
5. What is a personal strategy used by second victims to alleviate the effects of their involvement in traumatic incidents? • Discuss certain causes of the incident with many colleagues • **Implement practice changes based on lessons they learned** • Return to work as soon as possible on their assigned unit • Query colleagues about their patient's present-day status	7 (38.9)	0.08	Punctuation revised. Low discriminability; further revision may be needed.
6. What is a personally motivated intervention of second victims to promote healing? • Attending professional patient safety conferences • Performing process improvement activities • Discussing critical incidents with division leaders • **Participating in spiritual practices**	18 (100)	-0	Easiest item; based on knowledge; extremely poor discriminability. Revision needed.
7. What is the most important activity by peer supporters for second victims following critical incidents? • Acceptance of report • Targeted interventions • **Immediate support** • Facilitated coping	10 (55.6)	-0.13	Poor discriminability; revision may be needed.
8. Which institutional characteristic frames second victim programs? • **Nonpunitive institutional culture** • Analysis of incident causes • Correction of negative emotions • Reduced access to supervisors	14 (77.8)	0.29	
9. Which phrase best describes the intense experience of trained peer supporters of second victims? • Long-term commitment • **Secondary traumatic stress** • Provider emotional first aid • Skilled in emotion-focused coping	5 (27.8)	-0.02	Poor discriminability; revision may be needed.
10. What is an example of type of long-term support needed by second victims? • Safety nets for seasoned clinical peers • Supervisory monitoring of unit-based practices • **Accessible multidisciplinary professionals** • Transfer to another clinical division	12 (66.7)	0.11	

Table 2. (continued)

Item With Distractor	N Items Correct (%) Difficulty or Proportion Correct Index	Discrimination Index	Revision Needed
11. When second victims endure the post-incident "inquisition," they predict that the institution's leaders will conduct which of the following actions? • Counseling by direct report supervisor • Contributing to a failure modes and effects analysis • **Being fired from their position** • Receiving alternate unit assignments	7 (38.9)	0.21	
12. A critical care nurse made a serious medication error. They attributed the error to medication packaging, nurse staffing, and a dilution miscalculation. The charge nurse immediately reassured them, shared stories of personal errors, and managed patient care. Which of the following describes the charge nurse's response? • Kindness • Support • Professionalism • **All of the above**	14 (77.8)	0.55	Revised gender language based on expert comment; revised to multiple-choice item.
13. A critical care nurse criticized their patient care as not being aggressive enough in treating a patient's deterioration. After the patient died, they described very deep, very disturbing regret to the nurse manager; the manager listened carefully to the story about the experience. Which is the best caring intention demonstrated by the nurse manager? • **Committed to understanding their regret about their patient care** • Provided an opportunity for the nurse to reflect on the patient's situation • Critiqued the nurse's missed opportunities to advocate for the patient • Decided against reassigning the nurse to a different critical care unit	2 (11.1)	-0.22	Grammar correction: plural; revised gender in distractor. Negative items have poor discriminability; further revision may be needed.
14. The goal of the hospital was to foster a culture in which all employees were mutually supported throughout the long-time pathway of critical, stressful events. Which of the following descriptions fits this goal? • **Leaders implemented plans to assure availability of mental health clinicians for second victims of traumatic events** • Division directors planned education for professional staff on how to actively participate in the root cause analysis process • Safety officer discussed the incident which involved nursing staff before describing the fatal diagnostic error with the patient and family • Supervisors continued to evaluate critical incidents by looking for provider-caused behaviors leading to future healthcare errors	12 (66.7)	0.66	Most discriminating item.
15. Which of the following strategies implemented by healthcare leaders shows their continued support for employees following traumatic critical incidents? • Support failure modes and effects analysis on preventing future, similar incidents • **Participate in an incident debriefing meeting with clinicians when emotions decrease** • Share details of the incident with clinicians in informal support networks • Publicize the results of safety culture efforts periodically on institutional intranet	11 (61.1)	0.45	
16. What is a strategic activity by clinical unit and divisional leaders that shows sensitivity and concern for second victims? • Detect failure modes in high frequency error categories to target prevention strategies • Report increased safety risks and statistics to employees through quarterly intranet messages • Identify results of outcomes assessment on supportive programs provided for second victims • **Facilitate the return of clinicians involved in traumatic incidents to patient care positions**	2 (11.1)	0.37	

Table 2. (continued)

Item With Distractor	N Items Correct (%) Difficulty or Proportion Correct Index	Discrimination Index	Revision Needed
17. Which program served as a foundation for many second victim programs? • **Critical Incident Stress Management (CISM)** • Scott's Three-Tiered Interventional Model of Support[23] • Johns Hopkins Resilience in Stressful Events (RISE) • Mitigating Impact in Second Victims (MISE)	4 (22.2)	-0.02	Negative items have poor discriminability; revision may be needed.
18. What is a potential effect of publicized patient tragedies on involved healthcare organizations? • Normative revision • Challenge to mission • Knowledge of community response • **Stigmatization in the community**	13 (72.2)	0.35	
19. In addition to guiding second victim programs in healthcare organizations, which of the following activities do core steering committee members perform to secure second victim programs? • Report safety risks to quality improvement and other safety-oriented committees • Ensure the anonymity of reporters to the institution's intranet safety reporting system • Notify new staff about components and members of an institution's second victim program • **Advise leaders of healthcare agencies of the need for second victim policies and procedures**	4 (22.2)	0	Revision needed due to no discriminability value.
20. What is a clinician's response to a serious patient-care error when employed in a healthcare institution with a nonpunitive culture? • Freed from negative consequences of adverse events • **Reduced anxiety when reporting safety threats** • Increased security about preventing negative outcomes • Limited accountability for personal recklessness	12 (66.7)	0.36	
21. During a committee meeting, the chairperson of the second victim steering committee encouraged discussion on a highly publicized "shame and blame" story about a serious medication error of a registered nurse that resulted in a patient's death. Which of the following shows the chairperson's intent? • Encourage reporting • Avoid litigation • **Learn from error** • Prevent guilt	10 (55.6)	0.2	Revised stem for flow.
22. The healthcare system's second victim program was disrupted during the COVID-19 pandemic; multiple stressors affected frontline staff. Which of the following strategies is the best action of the second victim core steering committee? • Set baseline data using four months of data for year two of the pandemic • **Brainstormed to identify actions that might revitalize the three-tiered program** • Invited hospital leaders to sponsor an entire reboot of the second victim program • Planned several programs that encouraged workplace engagement in changes	6 (33.3)	0.31	

Conclusion

Some healthcare agencies have adopted and sustained support programs for second victims that continued throughout the COVID-19 pandemic. However, the need to recognize the pandemic's effect on clinicians and organizations is a concern, as noted by Hall.[34] Education and research on the effects of the COVID-19 pandemic are needed as clinicians reemerge from the pandemic and encounter future traumatic events.

Continuing education on the second victim experience is needed. The teaching plan should be updated periodically using evidence-based literature and test items need to be revised to fit changes. Although peer support may be preferred to other resources offered in second victim programs, the needs of affected staff need to be understood by nurses and their team members.[1] The trauma felt by second victims can require professional counseling[21] and long-term support services; peers that support them are not immune to the trauma. Educational sessions can increase awareness of support available;[35] periodic education grounded in an evidence-based teaching plan could also enhance awareness so that when crises occur, clinicians might access institutional resources.

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Continuous Monitoring of Vital Signs After Hospital Discharge: A Feasibility Study

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Abstract

Introduction

Increasing demand for inpatient beds limits capacity and poses a challenge to the healthcare system. Early discharge may be one solution to solve this problem, and continuous vital sign monitoring at home could safely facilitate this goal. We aimed to document feasibility of continuous home monitoring in patients after hospital discharge.

Methods

Patients were eligible for inclusion if they were admitted with acute medical disease and scheduled for discharge. They wore three wireless vital sign sensors for four days at home: a chest patch measuring heart rate and respiratory rate, a pulse oximeter, and a blood pressure (BP) monitor. Patients with ≥6 hours monitoring time after discharge were included in the analysis. Primary outcome was percentage of maximum monitoring time of heart rate and respiratory rate.

Results

Monitoring was initiated in 80 patients, and 69 patients (86%) had ≥6 hours monitoring time after discharge. The chest patch, pulse oximeter, and BP monitor collected data for 88%, 60%, and 32% of the monitored time, respectively. Oxygen desaturation <88% was observed in 92% of the patients and lasted for 6.3% (interquartile range [IQR] 0.9%–22.0%) of total monitoring time. Desaturation below 85% was observed in 83% of the patients and lasted 4.2% (IQR 0.4%–9.4%) of total monitoring time. 61% had tachypnea (>24/minute); tachycardia (>130/minute) lasting ≥30 minutes was observed in 28% of the patients.

Conclusions

Continuous monitoring of vital signs was feasible at home with a high degree of valid monitoring time. Oxygen desaturation was commonly observed.

Keywords: *continuous monitoring of vital sign, home monitoring, acute medical disease, feasibility.*

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Introduction

The world's population has grown in number and age over time. It is estimated that the world's population will grow by another 0.5 billion persons within the next seven to eight years, and over the next 25 years average life expectancy will increase by 4.5 years.[1] An aging population with more chronic diseases poses a challenge to the healthcare system, as these patients are expected to be admitted more often and for a longer duration. Consequently, the number of admitted patients may exceed the limited number of available hospital beds. Therefore, it is necessary to reconsider where else patients can be observed within the healthcare system. Alternatives such as preventing admission, admission at home, or earlier discharge should be considered. If acute admissions are to be avoided, a need exists for identification of patients at high risk of getting admitted and readmitted.

It is well described that patients with chronic diseases have a considerably higher risk of admission and readmission, e.g., patients with chronic obstructive pulmonary disease (COPD) have a 30-days readmission rate of 20%.[2–4] However, predicting early deterioration is challenging. Previous studies have found that spot measurement of vital signs at home was insufficient for predicting acute exacerbation of COPD (AECOPD)[5–7] but prediction improves by adding daily self-assessment and measurement of C-reactive protein.[6] Another alternative is to admit patients in their own homes.

Patients admitted in their own homes report greater satisfaction[8,9] and are more physically active, and mortality may be lower,[10] but concerns have been raised regarding home admission and safety. In recent years "telemedicine" has been a priority of politicians due to its potential to relieve healthcare professionals, identify deterioration early, and initiate treatments before illness necessitates admission.[11] Continuous monitoring by wearable vital sign sensors is one aspect of telemedicine. The sensors exist and have been validated in-hospital; however, researchers must now determine feasibility for out-of-hospital use.

The aim of this study was to document feasibility of continuous home monitoring, described as duration of valid data collection, and to examine frequency and duration of deviating vital signs during the first days after hospital discharge.

Methods

Participants

Patients were eligible if they were 18 years or older, were admitted with an acute medical disease based on the International Classification of Diseases, Tenth Revision (ICD-10) classification and noted in the patient's record, and had a discharge disposition to home. The patients were recruited at Bispebjerg Hospital, Copenhagen, Denmark, in the period August 2021 to May 2022. Patients were excluded if they were allergic to plaster, plastic, or silicone; had an implanted pacemaker or implantable cardioverter-defibrillator (ICD) device; or if they were not able to open the front door for investigator visits. Demographic data and 30-days follow-up were collected from the electronic patient records. The study was approved by the Committees on Health Research Ethics in the Capital Region of Denmark (H-20009132) and registered at ClinicalTrials.gov (NCT05223504). All participants provided written informed consent prior to inclusion.

No formal power calculation was performed, as this was a pragmatic feasibility study intended to provide basis for further studies.

Monitoring

The following wireless monitoring sensors were used to record vital signs continuously:

1. A single lead electrocardiogram (ECG) patch (Isansys Lifecare, Oxfordshire, UK) placed on the chest. The chest patch measured heart rate (HR) and respiratory rate (RR).

2. Nonin WristOx 3150 (Nonin Medical inc., Minnesota, USA), a bracelet connected to a finger pulse oximeter measuring peripheral oxygen saturation (SpO2).

3. A&D ambulatory blood pressure (BP) sensor (A&D Medical, California, USA), a compact, non-invasive, oscillometric upper arm BP sensor.

BP was automatically measured every 30 minutes during daytime (7 a.m.–9:59 p.m.) and every 60 minutes at nighttime (10 p.m.–6:59 a.m.). Measurements were sent via Bluetooth to a gateway placed in the patient's home, from where data were downloaded on a dedicated secure server. If patients were out of Bluetooth range, data were stored on the sensors and transferred when within range, except for the BP sensor that required Bluetooth connection to collect data. Data was processed on the server, where an algorithm removed noise and artifacts, e.g., changes in SpO2 >4% per second and nonphysiological R-peak intervals from the ECG signal were considered artifacts.

Patients were able to see the vital sign measurements during monitoring, but the investigator could only view the measurements once data had been downloaded from the gateway after the end of each patient's monitoring period. Patients were not required to wear all sensors, but wearing the chest patch was mandatory. Monitoring was initiated prior to discharge and continued at home. Four patients started monitoring after discharge in their own homes; monitoring was initiated between four and 48 hours after discharge. Investigators encouraged patients to wear sensors for at least four days until a maximum of eight days.

Patients were contacted daily by phone to check if sensors were still working and to remind them of battery change. In case of questions, patients were able to contact a hotline. In case of monitoring for more than four days, an additional visit was set up to change the chest patch due to battery durability. An investigator visited the patient on the final monitoring day to end the session, talk about experiences of home monitoring, and collect sensors.

Outcomes

The primary outcome was percentage of maximum monitoring time of HR and RR data collected from the chest patch after artifact removal (valid collected data).

Secondary outcomes were:

- Duration of valid SpO2 and BP monitoring as a percentage of maximum monitoring time
- Cumulated duration of desaturation as a percentage of maximum monitoring time for the following SpO2 levels: SpO2<88%, SpO2<85%, and SpO2<80%
- Number of sustained desaturations with SpO2<88% in ≥10 consecutive minutes, and SpO2<85% in ≥5 consecutive minutes
- Number of sustained deviating vital signs in accordance with predefined thresholds

As an explorative outcome, patients' experiences and feedback on monitoring at home were examined.

Data analysis

Patients were included in the analysis of patient experiences if sensors were mounted and monitoring of vital signs were initiated. To be included in the analysis of vital signs monitoring, patients needed to be monitored for ≥6 hours after discharge within the first 24 hours. Time of discharge was defined as the time of last early warning score measurement or at the beginning of monitoring just prior to the patient leaving the hospital. Results are reported according to the day of discharge, with day 0 defined as the day of discharge and day 1 being the first full day (24 hours) at home from midnight to midnight, etc.

Duration of monitoring was the total maximum monitoring time per day (1,440 minutes for days where patients were monitored 24 hours). Duration of valid monitoring time was defined as the number of minutes where data was collected after artifact removal and periods in which patients were not wearing the sensors. Duration of valid monitoring time was given as a percentage between valid monitoring time and duration of maximum monitoring. Valid monitoring time was calculated both for patients who were intended to wear the sensors and those who actually were monitored by the sensors on the particular day (having valid collected data). Values are presented with median and IQR. IBM SPSS statistics 25.0 was used to perform the analysis.

Results

Participants

406 patients were screened for inclusion and 80 patients gave consent to participate. Main reasons for exclusion were declined consent (n=175), lack of investigator or sensors (n=57), or because the patient was deemed unable to cooperate (n=45) (**Figure 1**). When comparing patients who declined to participate with those who participated, the proportion of females was 62% vs. 50%; and median age was 70 years (IQR 46–78) vs. 59.5 years (IQR 36–76).

Among included patients, 29 patients (36%) were considered healthy without chronic medical diseases prior to hospital admission. Clinical Frailty Scale (CFS)[12,13] indicated that most patients managed well. Respiratory disease was the primary reason for acute admission in 56% of included patients (**Table 1**).

A total of 69 patients were monitored for ≥6 hours after discharge and included in the analysis of monitoring data. These patients did not differ from those who were not included in the analysis of monitoring data.

Monitoring

For each day, the number of patients who wore the sensors is illustrated in **Figure 2**. For the chest patch and SpO2 sensor, >70% of the patients continued to wear the sensors for the full monitoring period. Adherence to wear the BP sensor was 96% on the day of discharge and 50% on day 2.

For the full monitoring period, the median percentage of valid monitoring time for patients expected to wear the sensor was 88% (IQR 57%–96%) for the chest patch, 60% (IQR 24%–84%) for the SpO2 sensor, and 32% (IQR 11%–63%) for the BP sensor (**Figure 2A**).

When considering only patients who actually wore the sensors, the median duration of valid monitoring time was 92% (IQR 79%–99%), 67% (IQR 41%–87%), and 52% (38%–82%) for the chest patch, SpO2 sensor, and BP sensor, respectively (**Figure 2B**).

Vital signs

The SpO2 sensor was worn by 63 patients. Fifty-eight patients (92%) had at least one episode with SpO2<88%, for a median cumulative duration of 6.3% (IQR 0.9%–22.0%) of the total monitoring time, corresponding to 91 minutes per day. Oxygen desaturation<85% was observed in 52 patients (83%), with a median duration of 4.2% (IQR 0.4%–9.4%] of the monitoring time (34 minutes per day). Thirty-nine patients (62%) had desaturation<80%, with a median cumulative duration of 0.3% (IQR 0%–1.7%) of the monitoring period (four minutes per day).

Sustained deviating vital signs

Occurrence of sustained deviating vital signs are shown in **Table 2**. Tachypnea with RR>24/min for ≥5 minutes was observed in 42 patients (61%). Bradypnea with RR<5/min and HR>10/min for ≥1 minute was observed in 20 patients (29%), and tachycardia with HR>130/min for ≥30 minutes was observed in 19 patients (28%).

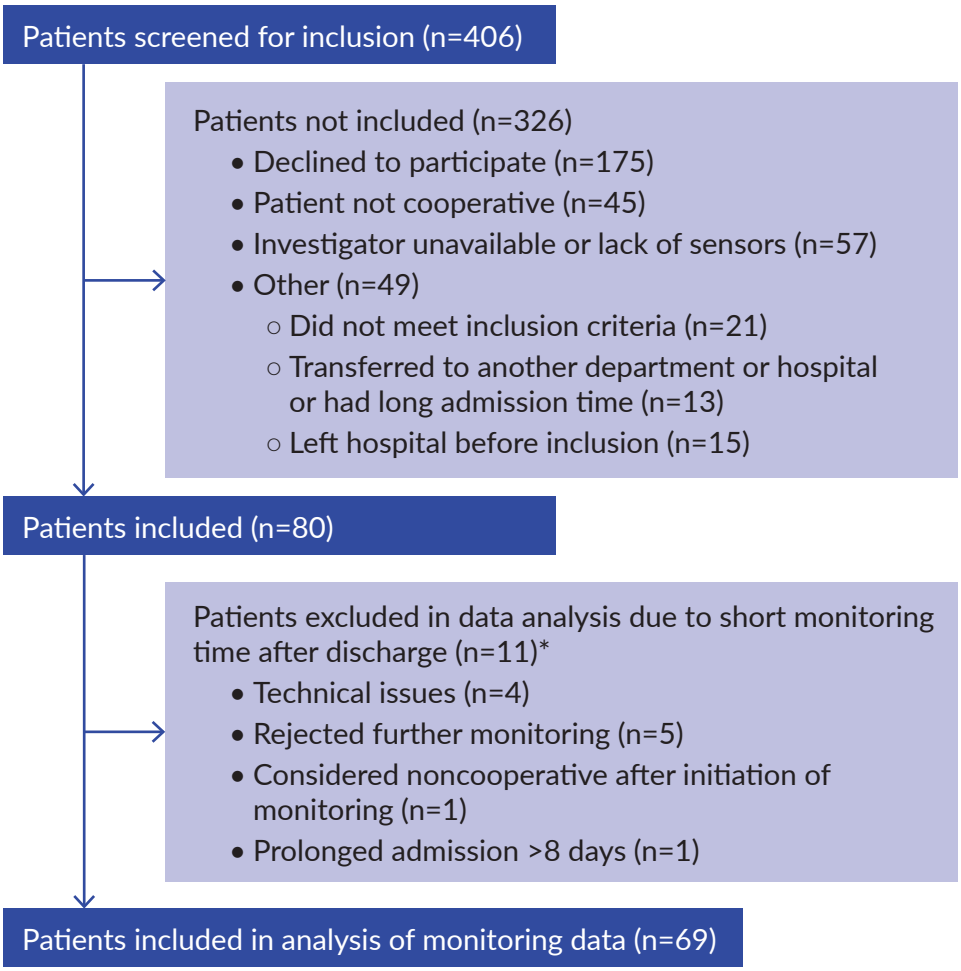
30-days follow-up

Within 30 days of discharge, 20 (25%) patients were readmitted, and none died. Nine (45%) patients had a previous medical history with asthma or COPD, and six (30%) had diabetes mellitus. Six (30%) patients did not have any previous medical history besides the acute reason for admission. Respiratory reasons (AECOPD, pneumonia, or asthma exacerbation) accounted for half of the readmissions (n=11, 55%), and all these patients were also primarily admitted with a respiratory diagnosis. Patients who were readmitted had a median age of 66.5 years (IQR 49–77) compared to 57 years (IQR 35–76) for the patients who were not readmitted. CFS of 5 was observed in 20% of the patients who were readmitted, but only in 5% of the patients who were not.

Feedback from patients

Fifty percent had no complaints regarding wearing the chest patch (**Table 3**). Forty-two percent had no complaints about the SpO2 sensor, and 19% reported that the SpO2 sensor hindered daily activity, e.g., work or cooking. The BP sensor received the most complaints, and the main complaint was discomfort (48%), with pain associated with inflation of the cuff. Thirty-three percent of patients discontinued BP monitoring on day 1, 50% on day 2, and 54% on day 3 (**Figure 2**).

Figure 1. Study Flowchart



* To be included in the analysis of vital sign monitoring data, patients needed to be monitored for ≥6 hours after discharge within the first 24 hours.

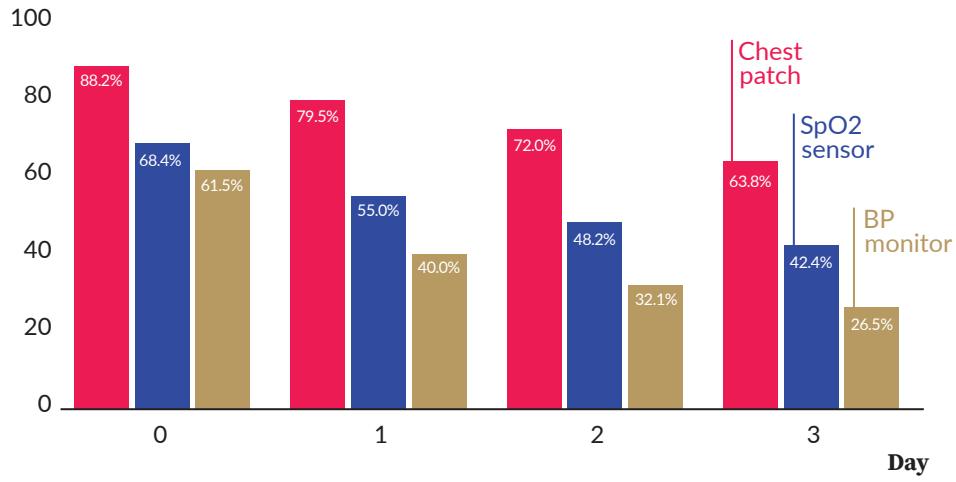
Table 1. Characteristics of Patients

	Total (n=80)	Patients included in monitoring data analysis (n=69)
Age	59.5 [IQR 36–76]	60 [IQR 42–76]
Sex: male	40 (50.0%)	37 (53.6%)
BMI	24.7 [IQR 22.1–28.5]	24.6 [IQR 22.1–28.5]
Smoking (never/previous/current)	31 (38.8%)/34 (42.5%)/15 (18.8%)	27 (39.1%)/28 (40.6%)/14 (20.3%)
Alcohol (below recommendations/ above recommendations)	74 (92.5%)/6 (7.5%)	63 (91.3%)/6 (8.7%)
Clinical Frailty Scale		
1 – Very fit	7 (8.8%)	4 (5.8%)
2 – Well	16 (20.0%)	14 (20.3%)
3 – Managing well	39 (48.8%)	35 (50.7%)
4 – Vulnerable	11 (13.8%)	10 (14.5%)
5 – Mildly frail	7 (8.8%)	6 (8.7%)
Previous medical history		
No previous medical disease	29 (36.3%)	24 (34.8%)
Previous myocardial infarction	3 (3.8%)	3 (4.3%)
Heart failure	2 (2.5%)	2 (2.9%)
Atrial fibrillation	11 (13.7%)	10 (14.5%)
Cerebrovascular disease	7 (9%)	6 (8.7%)
Asthma	16 (20.0%)	15 (21.7%)
COPD	17 (21.3%)	17 (24.6%)
Renal failure	6 (7.5%)	4 (5.8%)
Diabetes	13 (16.3%)	12 (17.4%)
Insulin-dependent diabetes	5 (6.3%)	5 (7.2%)
Non-insulin-dependent diabetes	8 (10.0%)	7 (10.1%)
Cancer diagnosis	14 (17.5%)	12 (17.4%)
Primary cause of hospital admission		
Respiratory (asthma, AECOPD, pneumonia, COVID-19, dyspnea)	45 (56.3%)	41 (59.4%)
Infectious (urinary tract infection, soft tissue infection, infection of unknown origin)	19 (23.8%)	15 (21.7%)
Anemia	5 (6.3%)	4 (5.8%)
Other (dysregulated diabetes, gastroenteritis, acute kidney insufficiency, electrolyte derangement)	11 (13.8%)	9 (13.0%)

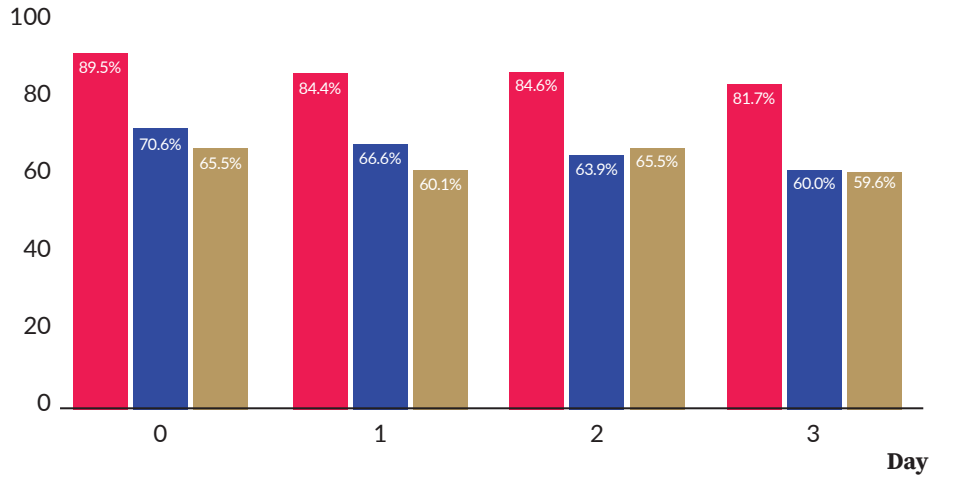
BMI = body mass index, COPD = Chronic obstructive pulmonary disease, AECOPD = Acute exacerbation of COPD

Figure 2. Duration of Data Collection After Discharge Per Day

A. Patients intended to be monitored



B. Patients actually monitored



C. Monitored/intended to be monitored

	Day 0	Day 1	Day 2	Day 3
Chest patch	68/69 (99)	65/69 (94)	57/67 (85)	50/63 (79)
SpO2 sensor	61/63 (97)	52/63 (83)	46/61 (75)	41/57 (72)
BP monitor	46/48 (96)	32/48 (67)	23/46 (50)	20/44 (45)

Bars are mean percentage of valid monitoring time for (A) all patients intended to be monitored and (B) for patients who actually wore the sensors. In (C) a ratio is given as number of patients actually monitored vs. number of patients intended to be monitored if they were monitored for all four days.

Table 2. Sustained Deviating Vital Signs at Home

	Patients with sustained deviating vital sign	Number of sustained deviating vital signs
Respiratory events		
Desaturation: SpO2<92% for ≥60 min	46 (73.0%)	3 [1–7]
Desaturation: SpO2<88% for ≥10 min	47 (74.6%)	4 [2–8]
Desaturation: SpO2<85% for ≥5 min	47 (74.6%)	4 [1–8]
Bradypnea: RR≤5/min + HR>10/min for ≥1 min	20 (29.0%)	1 [1–3]
Tachypnea: RR>24/min for ≥5 min	42 (60.9%)	4 [2–11]
Hypoventilation: RR>11/min + SpO2<88% for ≥5 min	4 (6.3%)	2 [1–3]
Circulatory events		
Tachycardia: HR>130/min for ≥30 min	19 (27.5%)	1 [1–3]
Tachycardia: HR>111/min for ≥60 min	23 (33.3%)	2 [1–3]
Bradycardia: HR<30/min for ≥1 min	13 (18.8%)	2 [1–5]
Bradycardia: HR 30–40/min for ≥5min	13 (18.8%)	1 [1–2]
Hypotension: SBP<90 mmHg at least 2 measurements	9 (18.8%)	1 [1–3]
Hypotension: SBP<70 mmHg at least 1 measurement	6 (12.5%)	1 [1–1]
Hypertension: SBP≥180 mmHg at least 2 measurements	8 (16.7%)	1 [1–1]
Hypertension: SBP>220 mmHg at least 1 measurement	8 (16.7%)	1 [1–1]

Values are number of patients or median number of sustained deviating vital signs for patients with at least one event [IQR]. Number of patients who initiated monitoring with the sensors: Chest patch n=69, SpO2 sensor n=63, and BP sensor n=48. SBP = Systolic blood pressure

Table 3. Patient Feedback From Wearing Home Sensors

	Chest patch (n=80)	SpO2 sensors (n=72)	BP sensor (n=54)
No reported discomfort	40 (50.0%)	30 (41.7%)	7 (13.0%)
Stressfull to wear or hindering daily activity	10 (12.5%)	14 (19.4%)	8 (14.9%)
Discomfort	13 (16.3%)	16 (22.2%)	26 (48.1%)
Skin reaction	4 (5.0%)	0	1 (1.9%)
Technical problems	9 (11.3%)	9 (12.5%)	10 (18.5%)
Other	4 (5.0%)	3 (4.2%)	2 (3.7%)

Values are number of patients or median number of sustained deviating vital signs for patients with at least one event [IQR]. Number of patients who initiated monitoring with the sensors: Chest patch n=69, SpO2 sensor n=63, and BP sensor n=48.

Discussion

Continuous monitoring of vital signs at home was feasible. The number of patients who completed the four days monitoring period was high for the chest patch and the SpO2 sensor, but BP monitoring was only achieved in approximately half of the patients. When patients wore the sensors, percentage of time with valid monitoring, after artifact removal, was high (59%–89%). Occurrence of sustained deviating vital signs was high, particularly occurrence of deviating respiratory vital signs.

Monitoring of vital signs

The chest patch was the sensor which most patients wore throughout the monitoring period and collected the most valid monitoring time. Adherence to wearing the SpO2 and BP sensors was poorer, and percentage of valid monitoring time was lower. Duration of valid monitoring time, based on all patients intended to wear the sensors, was comparable to our experiences from in-hospital monitoring.[14–17] This was surprising, as patients were free to move around and do everyday activities. An advantage of admission at home and early discharge is that patients can be more physically active;[18] however, increased activity causes more noise to the signal, and it is described that activity disturbs accuracy of continuous monitoring.[19] In a study by Buekers et al., 20 patients wore an SpO2 sensor like the one we used and an activity sensor. They found that up to a third of the collected SpO2 data was considered invalid due to motion artifacts.[20] In our study we did not detect that high amount of data loss; however, we have not measured activity, and therefore we cannot rule out whether our patients were less active compared to the study by Buekers et al.

Vital signs

Most patients had periods with sustained deviating vital signs. Particularly, respiratory vital signs deviated often. Almost all patients had periods with oxygen desaturation. Deviating vital signs were expected, as we observed patients during the transition period from acute admission to the first days after discharge. In three previous studies on admitted patients, detection of deviating vital signs was far more frequent when using continuous monitoring compared to spot measurements: In postoperative patients, desaturation<85% was observed in 88% of patients by continuous monitoring compared to only 4% of the patients when using spot measurements.[14] In another study, oxygen desaturation <90% was observed four times more frequently by continuous monitoring compared to spot measurements.[21] When looking at patients admitted due to AECOPD, desaturation below 80% was observed in 63% of the patients by continuous monitoring, but none of the patients had a comparable low SpO2 registered by spot measurements.[15] A part of this discrepancy may be explained by periods without observations, but it has also been shown that manually recorded SpO2 measurements on average have 6.5% higher values than undisturbed continuous monitoring measurements.[22]

A third of the patients in our study population had no previous medical disease, and even though more than half of the patients were admitted due to a respiratory cause, we were surprised to observe the high occurrence of desaturation and tachypnea. The rate of sustained deviating vital signs was comparable to a previous study from our group based on continuous in-hospital monitoring of patients admitted with AECOPD.[15]

Bradypnea was observed more frequently (29%) than expected. In the literature, prevalence of sleep apnea in the population is 2%–25%;[23] the high prevalence of bradypnea episodes and oxygen desaturations may reflect undiagnosed sleep apnea episodes, as we also monitored patients during the night. With this high rate of deviating vital signs, we must ask whether we can trust in our measurements. A previous validation study has shown that our sensors measure HR and SpO2 accurately, whereas measurement of RR had wider limits of agreement (-6 to 7.5/min) than clinically accepted (±3/min).[24] We cannot rule out that this imprecision for RR detection may interfere with our results; however, it cannot explain the high occurrence of sustained oxygen desaturation episodes.

Our thresholds for sustained deviating vital signs were based on assumptions made for in-hospital patients, and these thresholds may not be appropriate to transfer to an out-of-hospital setting. Moreover, tachypnea and periods of oxygen desaturation could be signs of ongoing respiratory infection and activity. Further study is needed to clarify an acceptable range of vital signs in patients and healthy subjects who are monitored continuously in a home setting.

30-days follow-up

Continuous monitoring of post-discharge patients may enable early discharge and shorter hospital stays, but deterioration of the primary cause of admission may be undetected. Twenty patients (25%) were readmitted within 30 days after discharge, which is in concordance with previous published data.[2–4,25] The most common reason for readmission was respiratory, which could be explained by a worsening of the primary cause of admission. Due to the study design, we were not able to determine whether an intervention during the observation period could have avoided the readmission, but we can infer that a deterioration of vital signs could have been detected earlier and readmission could have been avoided.

Feedback from patients

Adherence to wearing sensors decreased over days and the drop-out rate was most evident for the SpO2 and BP sensors. Despite that half of the patients expressed discomfort after wearing the chest patch, adherence to continued monitoring was high; this was not the case for the BP sensor, where the drop-out rate was >50% on day 3 and most of the patients criticized the BP sensor. We have not found any studies describing compliance in the continuous wearing of a BP sensor or

SpO2 sensor, but Downey et al. have previously evaluated a sensor similar to the chest patch during hospitalization, and their experiences were that 82% of the patients found the patch comfortable; however, they had a low response rate (42%) and a drop-out rate of 24%.[26] This may indicate an overestimation of positive feedback. Another factor may be that patients in our study wore more sensors and that they were monitored in their own homes, thus increasing the patients' awareness of the sensors.

Two complaints were dominating: sensors were stressful to wear and were associated with discomfort. With these complaints it is difficult to call the technology "wear-and-forget."

Strengths and limitations

A strength of our study is that we explored feasibility of continuous monitoring in a home setting in 80 newly discharged patients with an acute medical condition. More than 70% of the patients continued wearing the chest patch and SpO2 sensor for the whole monitoring period, and valid monitoring time was high, which indicated that patients were motivated for wearing the sensors and that the sensors could detect and collect data in a home setting where patients were able to move around.

Our study also comes with limitations. Because only few exclusion criteria were set, the population was very heterogenous. We observed that the study population was younger than those who declined to participate, and it is possible that included patients were more positive about new technology. A selection bias could have been introduced, as the patients were enrolled from the acute medical ward and had short admission time, but 30 days readmission rate was comparable to previously reported readmission rates among medical patients,[25] and we consider the population to represent a group of patients who might have a great benefit of home monitoring.

Another limitation was the fact that live transmission of data was not possible. This may affect motivation to continue monitoring, as we were not able to detect if there were any technological problems and we were not able to give patients feedback on their measurements during daily contact. Lack of feedback has been shown to decrease trust of health technology among patients.[27] Implementation of live transmission is planned for future studies and is an important step when planning to introduce the technology in a home setting, because a major challenge may be connectivity issues and how we manage to handle alerts from patients monitored in their own homes.[11]

Conclusion

Monitoring of continuous vital signs was feasible at home with a 59%–89% of valid monitoring time. Adherence to wearing sensors reduced over days, especially for the SpO2 and BP sensors, which could be attributed to discomfort. The lack of live transmission in this study could also affect patients' motivation. In the transition period after discharge, sustained deviating vital signs were commonly detected, also in patients without chronic medical diseases. Continuous monitoring of vital signs has the potential to improve patient safety by providing crucial information about early deterioration and triggering an intervention; however, defining acceptable vital sign ranges for continuous monitoring at home still needs to be elucidated.

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Author Contributions

NS: Conceptualization, Methodology, Formal Analysis, Investigation, Writing – Original Draft. **TS:** Conceptualization, Methodology, Investigation, Writing – Original Draft. **MSVJ:** Conceptualization, Methodology, Investigation, Writing – Review & Editing. **ME:** Conceptualization, Methodology, Writing – Review & Editing. **HBDS:** Conceptualization, Software, Resources, Writing – Review & Editing. **EKA:** Conceptualization, Methodology, Resources, Writing – Original Draft, Project Administration. **CSM:** Conceptualization, Methodology, Resources, Writing – Original Draft, Project Administration. **VRE:** Conceptualization, Methodology, Formal Analysis, Investigation, Writing – Original draft, Project Administration.

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I AM PATIENT SAFETY 2023 ANNUAL ACHIEVEMENT AWARDS

By **Eugene Myers**◆

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Since the Patient Safety Authority introduced the I AM Patient Safety awards in 2013, this annual contest has celebrated hundreds of teams and individuals for their advancements, outcomes, and commitment to patient safety. The awards are judged by a cross-section of national and regional healthcare executives; patient safety advocates; and government, university, and patient representatives. These judges evaluated nominations from healthcare facilities throughout Pennsylvania and nationwide for innovation, impact, sustainability, and scalability. In addition to the honorees in 10 juried categories, PSA Executive Director Regina Hoffman, MBA, RN, selected a Choice Award winner for special recognition.

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

Executive Director's Choice Award

Jesse Hixson, MSN, RN, Administrator

Allegheny Health Network Monroeville Ambulatory Surgery Center

In May, a patient was in the facility to have a procedure. When Jesse Hixson, the nursing leader, was made aware that this patient had been seen in a hospital for suicidal ideations, he took the patient to a quiet consult room to discuss that they were not going to have the procedure due to the hospital visit and medications that were given. The patient threatened him and the staff. Uncertain whether the patient had a weapon, Jesse de-escalated the situation and distracted the patient so they could alert other staff to call for help. He was barricaded in the room with the patient for almost 30 minutes to ensure that staff and visitors were safe behind the locked doors, until police arrived and apprehended the patient for transport to the hospital. Through this difficult and dangerous incident, Jesse remained clearheaded and proactive, going above and beyond to keep the patient, staff, and visitors safe. As a result, security systems were improved and on-site security has been provided.

Executive Director's Choice award winner, Jesse Hixson, from Allegheny Health Network Monroeville Ambulatory Surgery Center

Sepsis

Jaber Monla-Hassan, MD, Olivia Johnson, PharmD, Christopher Anderson, PharmD, and Kim Mikula, MSN, RN

Einstein Medical Center Montgomery

Over several years, the Adult Intensive Care team worked on ensuring compliance with the three-hour and six-hour sepsis bundles. Despite ongoing education, optimization of a prescriber order set, and great compliance with various components, documentation of focused exams continued to be a problem.

The team posed a question of whether a smart notification could be built to fire when the sepsis order set was being signed in the electronic medical record. They worked with the technology department to implement such an alert; when fired, this notification not only reminds the provider but also opens the specific field for documentation. When the alert went live, providers were provided with education that explained the components of the three- and six-hour bundle, the order set's design to help capture each element, and the importance of utilizing the order set when sepsis is identified.

Compliance with this element has improved from 66.7% in February 2022 to 100% throughout the first and second quarter of fiscal year 2023.

Sepsis award winners, Dr. Jaber Monla-Hassan, Olivia Johnson, Christopher Anderson, and Kim Mikula, from Einstein Medical Center Montgomery

Ambulatory Surgical Facility

Mary Houton, Susan Walker, and the Ambulatory Surgical Center and Infection Prevention Registered Nurses

Penn Medicine Pennsylvania Hospital

The nursing staff at the Ambulatory Surgical Center and Infection Prevention (IP) teamed up to create a competency-based education collaboration. The team designed an infection prevention training program for healthcare personnel with measurable competencies for the observable knowledge, skills, and behaviors that one possesses to perform job responsibilities correctly and skillfully. To ensure that this education and training was translated effectively to practice, the team performed audits and encouraged feedback from staff. The goal of the education was to promote adherence with standards of care and help sustain effective practices.

Competency-based training is one of the key components to consider when designing an infection prevention training program for healthcare personnel and must be designed to meet the needs of a diverse group of learners. Key stakeholders included in the process were nurses, anesthesia, surgeons, surgical technicians, and surgical care associates. The observations included five areas of focus: surgical scrub technique, maintaining a sterile field, point-of-use instrument cleaning, traffic patterns in the operating room (OR), and room cleaning between cases. The observers assessed each component as either compliant or noncompliant. Benefits of this intervention include fostering a culture of safety, compliance, and interdisciplinary collaboration.

Number of observations per quarter:

- Goal of 10 observations per OR location per quarter
- Each observation includes the five areas of focus
- Each area of focus contains five components that observers will assess as either compliant or noncompliant; clinical staff will have input to ensure observations are meaningful to practice
- Areas of focus were chosen based on current competencies/policies and opportunities identified across the health system

Qualtrics audit form potential benefits:

- Building relationships between OR clinical staff and IP department
- Maintaining compliance and creating a culture of safety
- Excellent opportunity for clinical nurses interested in quality improvement projects or looking to advance on clinical ladder
- Successful standard process implementation can be translated to other areas of practice, such as the procedural areas (Interventional Radiology, Gamma Knife/Spine Center, Cardiology Services)

Ambulatory Surgical Facility award winners, Susan Walker and Mary Houton (top), and the Ambulatory Surgical Center and Infection Prevention registered nurses (bottom), from Penn Medicine Pennsylvania Hospital

Results:

- Observation period July 12, 2022, to August 2, 2022
- 117 observations made in each area of focus:
  - Surgical scrub (35)
  - Maintaining the sterile field (21)
  - Point-of-use instrument cleaning (23)
  - Traffic patterns in OR (15)
  - Room cleaning between cases (23)
- Service lines observed: Ortho, ENT, Neuro, Breast, Colorectal Surgery, General Surgery, OB/GYN, Interventional Pulmonology, Vascular, Plastics, Urology, Ophthalmology

Long–Term Care Facility

Donelle Grove, RN, Infection Preventionist

South Mountain Restoration Center

Donelle Grove, RN, had worked at South Mountain Restoration Center as a floor nurse for many years, always interested in caring for her residents and learning new and better ways to do things. On January 1, 2022, she took over as the facility's infection control preventionist and jumped into the role with both feet. She took the Advisory Committee on Immunization Practices (ACIP) training and passed on her first attempt. She used her class work to review and update several of the facility's policies related to infection control, contributing to its increase to a five-star rating. Shortly after she came on board, she helped the facility navigate through an outbreak of COVID-19, during which only six residents became acutely ill—all on the same unit of 33 residents.

Long–Term Care Facility award winner, Donelle Grove, from South Mountain Restoration Center

Grove took over coordinating COVID vaccine booster clinics, with 96% of residents having their primary series, 90% of residents having at least one booster, and 76% being considered completely up-to-date. She managed a recent flu vaccination clinic with more than 97% of residents accepting the flu vaccine and 98% of employees having received the vaccine or actively declined it. She has actively reviewed the vaccination status of all residents for pneumococcal, shingles, and hepatitis.

She has coordinated the sterilization of reusable equipment used by facility physicians and in the podiatry and dental clinics, and overseen the quality checks of sterilization equipment. She has provided training to staff on the use of personal protective equipment (PPE), glucometers, and maintenance and cleaning of the equipment.

Grove was instrumental in understanding the new Enhanced Barrier Precautions and assisted in developing the necessary policies and procedures. She upgraded the management of PPE supplies on the units for efficiency and accountability to allow the implementation of the Enhanced Barrier Precautions and efficient deployment when the need arises for acute infections.

In short, she has had a major impact for the better on the facility's ability to maintain patient safety and an environment free of infectious disease.

Transparency and Safety in Healthcare

Behavioral Health 6 Spruce Shared Governance

Penn Medicine Pennsylvania Hospital

Transparency and Safety in Healthcare award winner, Behavioral Health 6 Spruce Shared Governance, from Penn Medicine Pennsylvania Hospital

Upon arrival to an inpatient unit, there are times when the disorganized behavioral health patient is extremely ill and cannot answer questions surrounding naming the people that they would like to get information about them. Sometimes there are many people that care about the patient, family members or peers, who may call multiple times a day for information on how the patient is doing. The Behavioral Health Shared Governance team saw an opportunity to collaborate on creating a process that would enhance communication while also keeping patients safe. The result was the creation of a patient/family satisfaction form.

They asked both the patient and their family questions about the most important information that would help them feel good about the care being received and what times would work to make sure that they got this information. The team decided that there should be some type of identifier: the patient giving consent and the names of two people they were OK with having information; in addition, the two support people would have an identifier to use when calling.

Once the patient can communicate and understand what was being asked, the unit clerk asks them to name two support people that they consented to getting information about their care. The patient is then told the last four digits of their medical record number (MRN) to provide to these support people, which is the identifier used when the support person calls the unit. Once the support people have been identified, the patient signs the form, the last four numbers of the MRN are placed at the top, and the names of the support people are written in. This stays in a binder at the unit clerk's desk so that everyone knows who has permission to receive information.

Once a relationship with the patient and their support people is created, a registered nurse will speak to the support people about good times in the morning and afternoon to call the unit for information. These times are set up so that information can be shared with the least number of interruptions from external stimuli, such as medication administration, treatment team, and hand-off. Since implementing this process, staff have reported less-distressed calls from support people around their loved one's care and that there is more confidence in knowing who the patient wants to receive information about them. The transparency around vulnerability and safety by the team surrounding safe, quality care is what made this project come to fruition.

Improving Diagnosis

Jung Yun, MD, Ryan Lee, MD, Peter Wang, MD, Meera Kasireddy, Terence Matalon, MD (Radiology Department), and Kevin Lo, MD (Internal Medicine Department)

Einstein Healthcare Network, Part of Jefferson Health

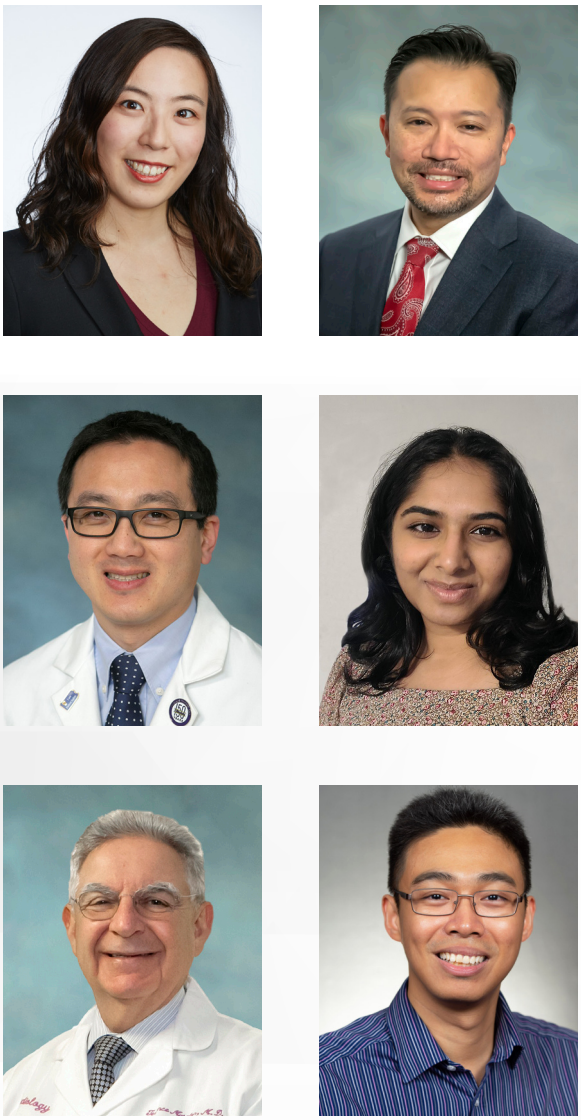
The Network serves an underserved population in which access to healthcare, including imaging, can be challenging. Traditionally, follow-up recommendations for imaging studies by radiologists were primarily initiated by the provider who ordered the original study. This team sought to improve compliance rates of these radiologist-recommended follow-up studies by also including the patient in the administration of their own healthcare.

In collaboration with a start-up software company, they helped develop and implement a natural language processing (NLP) algorithm and tracking-and-reminder system that identifies patients requiring follow-up imaging based on radiology reports, organizes follow-up recommendations by due date, and reminds patients of due or overdue recommendations via text messaging.

Patients were randomly assigned into control and intervention groups prospectively. Patients were deemed compliant with recommendations if exams were ordered, scheduled, or completed within a period spanning 30 days before and 60 days after the specified due date (the compliance range suggested by the American College of Radiology). The control group received no reminders during the study period. The intervention group received a reminder three weeks after the initial exam and up to three additional reminders after the due date (one reminder every two weeks). The compliance rate, or the percentage of compliant follow-up recommendations as defined above, was calculated for both groups.

The team analyzed a total of 268 outpatient radiology reports during the study period. The control group had a total of 179 recommendations and 54 noncompliant follow-up exams, for a 70% compliance rate. The intervention group had a total of 89 recommendations and 12 noncompliant follow-up exams, for an 87% compliance rate. This represents a 24% improvement (p=0.003) in compliance of recommended follow-up studies utilizing the automated software system of notifying patients compared to the baseline.

With this new workflow, the team demonstrated that implementation of an automated system that includes recommendation cataloging via NLP, follow-up compliance tracking, and patient reminder messaging can significantly improve rates of imaging follow-up and ultimately improve patient care and outcomes. As a result of this project, they have fully implemented this workflow to include all patients in the Network.



Improving Diagnosis award winners, Dr. Jung Yun, Dr. Kevin Lo, Dr. Peter Wang, Meera Kasireddy, Dr. Terence Matalon, and Dr. Ryan Lee, from Einstein Healthcare Network, part of Jefferson Health

Safety Story

Suzanne Swift, 4 South, and Nancy Patterson, Professional Development/Med-Surg

St. Christopher's Hospital for Children

Safety Story award winners, Suzanne Swift and Nancy Patterson, from St. Christopher's Hospital for Children

Pediatric patients admitted with a new diagnosis of diabetes receive education to learn to safely care for their disease at home, which includes adding the number of units of insulin to prepare the proper dose. One patient and his mother could not grasp the concept of adding the appropriate numbers and often miscalculated the insulin dose. As an incorrect insulin dose could be fatal, there was great concern for this child's return home, and a potential plan was made for medical foster care.

Nurses Suzanne Swift and Nancy Patterson knew there had to be a way to help this family stay together. They developed a simple addition sheet that formats the numbers to add the insulin dosages for blood sugar and amount of carbohydrates. The sheet includes a visual line for each dose followed by a plus sign, and finally the line at the bottom to indicate how much insulin the child should receive. They worked with the hospital's special education teacher, Colleen Cerebe, to focus school sessions on this newly created insulin dose calculation sheet.

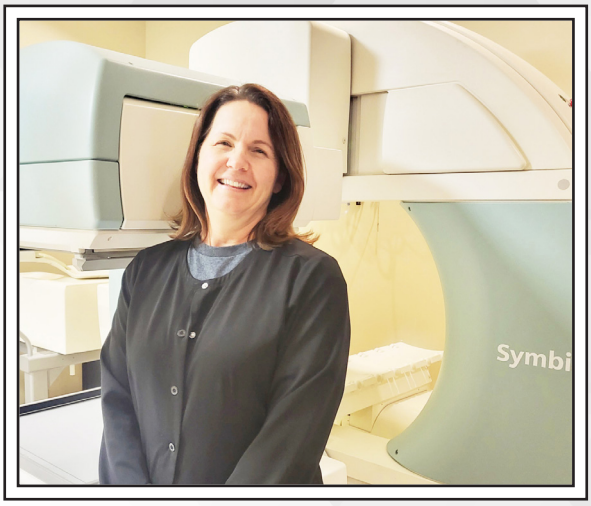
The sheet worked! For this patient and mom, it presented the information in a clearer and more concise manner, combining verbal and visual cues to make the dose calculation process safer. Although a seemingly simple concept, this newly created sheet was designed to help families with health illiteracy have a better understanding of their child's treatment plan. The insulin dose calculation sheet has been used for many patients since this one and has made a huge difference for some families—enabling them to be go home with a confident understanding of how to care for their child's diabetes.

Nationwide Warriors

Cyndi Brinkley

Riverside Walter Reed Hospital
Gloucester, Virginia

When the health system transitioned to a positive pressure, needleless intravenous site connector, Cyndi Brinkley raised a concern about its design posing a high risk of spilling nuclear medicine when the syringe is removed. Such spills can result in unnecessary exposure and temporary shutdown of the room, delaying patient testing and care. The product representative confirmed this was expected and a change in technique may not avoid the risk. Supply chain leadership supported the safety concern and sent a neutral valve to be used with the at-risk nuclear med patients across the health system, until further evaluation can be conducted.



Nationwide Warriors award winner, Cyndi Brinkley, from Riverside Walter Reed Hospital

Individual Impact

Jenny Rex, MSN, RN, Nursing Professional Development Specialist, Pediatric Intermediate and Intensive Care Units, and Adrian Zurca, MD, MEd, Staff Physician, Pediatric Intensive Care Unit

Penn State Health Milton S. Hershey Medical Center

During routine rounds, a graduate nurse approached Jenny Rex and asked how staff would perform cardiopulmonary resuscitation (CPR) on a complex patient with severe spinal hyperextension. Given the shape of the patient's spine, traditional CPR would not be possible. Rex immediately set to work exploring the literature and collaborating with the Simulation Center and Dr. Adrian Zurca to develop a plan to ensure the safety of this patient. They worked with the fabrication shop teams to design and create a custom backboard that would allow clinical staff to safely and effectively perform CPR for this patient.

Using X-rays and dimensions of the patient's spinal curvature as a guide, the team created a 7 by 50 cm board with chamfered edges to prevent abrasion to both the users and the patient, with a hole at the top of the board for ease of handling. Once the board was created, they tested the methods of providing compressions with it in various forms. The team piloted various techniques while measuring effectiveness with an electronic CPR analyzer.

Once the most effective approach was identified, Rex developed a comprehensive training program to ensure all clinical staff who cared for this patient were proficient in the techniques needed to use the board effectively. The height of the bed needed to be adjusted to allow for the appropriate 90-degree angle and lateral approach to compressions, counterbalance was needed to prevent movement of the board during use, and staff needed to take a wide stance to ensure the necessary force was applied. Rex provided hands-on training to all nurse, respiratory therapy, and physician staff who could potentially be involved in a resuscitation event.

Weeks after development and training were complete, the patient required transfer to another facility for short-term specialized treatment. Rex contacted the clinical team at the receiving facility and provided virtual training on the use of the custom board. During the course of the patient's treatment, there was a resuscitation event that required the use of the custom board and innovative CPR techniques. The clinical teams were able to quickly and effectively implement the methods they were taught by Rex, and the patient experienced a positive outcome.

Rex's willingness to go above and beyond, think innovatively, collaborate with clinical and nonclinical teams, and keep the patient at the center of all she does ultimately saved this patient's life. Additionally, because of this work, there is now a blueprint for all patients with severe spinal hyperextension to be provided safe and effective CPR when needed.

Individual Impact award winners, Jenny Rex and Dr. Adrian Zurca, from Penn State Health Milton S. Hershey Medical Center

Physician Offices

Quality Department

OSS Health

With many surgeries being outpatient or inpatients being discharged within a few days after surgery, hospitals and ambulatory surgery centers can have a hard time identifying postop complications. A process was created between a hospital and the clinic where patients were seen for their postop visits for infection control surveillance, to identify postop infections. An opportunity to identify other postop complications or events was identified and merged with the surgical surveillance process. In this program, for three months postop surgeons' staff ask every surgical patient a series of questions to identify postop complications. When the patient is roomed for the postop visit, the clinical staff ask patients about:

- Urgent care, emergency room, or hospital visits since their surgery
- Bleeding or blood clot issues
- Medication reactions
- Infection or wound healing issues or concerns
- Swallowing issues

This information is reviewed by the surgeon who may need to provide treatment or interventions and is used for surveillance.

Patient Safety staff from the hospital where the surgery was performed review the information and if a patient answered yes, a more thorough chart review is done to determine if there was a postop complication. The data is reported to the Patient Safety Committee and/or the Infection Control Committee, as well as being available to the Surgical Department monthly, and is used to identify trends with infections, wound healing, postop deep vein thrombosis (DVT) and other issues. The hospital has both an operating room—where patients are admitted to the hospital, placed in extended recovery, or are discharged from the post-anesthesia care unit (PACU)—and an Ambulatory Surgery Center. The same process is used for both.

Physician Offices award winner, the Quality Department, from OSS Health

In the first 10 months of 2022, patients were asked the questions 16,715 times. For every surgical patient, on average they were asked the questions 3.35 times. One in every 26 postop patients responded with a yes to one or more of the questions. One in every 160 patients who were asked the questions had a postop complication or issue that was reported to the appropriate committees and departments for follow-up. One in every 522 patients who answered the questions was found to have a serious event.

Although this process is time intensive, it shows the organization's commitment to patient safety and to identifying issues and improving patient outcomes. What started as a creative idea to capture surgical site infections has blossomed into a unique way to identify postop complications or issues that otherwise probably would have not been identified.

Time–Outs

Sara Frey, PharmD

Lehigh Valley Health Network

An order was placed for compounded sodium chloride 0.22% for enteral use for a 23-day-old infant. Pharmacist Sara Frey, recognizing the gravity of providing hypertonic saline to an infant who does not require it—including major fluid shifts and brain side effects—performed her own time-out after the solution was compounded and scanned appropriately. Upon visual inspection, she realized that the dispense prep computer program had a malfunction which allowed incorrect components to be barcode scanned without an error alert—and the order had been prepared using 23% sodium chloride instead of 0.22% sodium chloride. Had this solution reached the patient it would have barcode scanned for Nursing without error and could have resulted in serious harm to the patient. The dispense prep system was fixed so that this error does not occur again.

Time–Outs award winner, Sara Frey, from Lehigh Valley Health Network

Runners–Up

Sepsis

Jenna Mastromarino Riley, *Penn State Health St. Joseph Medical Center*

Jefferson Health Sepsis Team, *Jefferson Health*

Ambulatory Surgical Facility

Adrienne Bellino-Ailinger, *Einstein Endoscopy Center Blue Bell*

The Direct Access Colonoscopy Team, *Einstein Endoscopy Center Blue Bell*

Long–Term Care Facility

Nicole Ross, Angela Borgo, Susan Bell, Kerri Brooks, Lynn Sauers, Jake Thieret, Douglas Zundel, Rachael Blank, and Lisa Painter and the UPMC Senior Living Multidisciplinary Team, *UPMC Senior Living*

Sugar Creek Station Managers, *Sugar Creek Nursing and Rehabilitation*

Transparency and Safety in Healthcare

Patient Safety Officers, *Allegheny Health Network*

Vicenta Gaspar-Yoo, MD, President; William Bailey, DO, Chief Medical Officer; Milissa Hammers, Chief Nursing Officer; Quality Safety Value Team (Patient Safety Officer, Regulatory Manager, Infection Control Nurse, and Quality Manager), *Allegheny Health Network*

Improving Diagnosis

Kara Mascitti, MD, MSCE, Medical Director, Healthcare Epidemiology and Infection Prevention; Alex Matika, PharmD, Pharmacist, Clinical Specialist; and Lauren Allen, PharmD, Pharmacist, Clinical Specialist, *St. Luke's University Health Network*

Critical Care Unit, *WellSpan Health York*

Safety Story

The Operating Room Department at Forbes Hospital and Sara Angelilli, *Allegheny Health Network*

Beth Lindell, OR Manager, *Allegheny Health Network Saint Vincent Hospital*

Nationwide Warriors

Chrissie Blackburn, *Project Patient Care*

Vidya Saldivar, PharmD, Medication Safety Specialist; Mobolaji Adeola, PharmD, Medication Safety Specialist; and Archana Sadhu, MD, Chair of Diabetes Action Council, *Houston Methodist Hospital, Houston, Texas*

Individual Impact

Kristen Farrell, Oncology Infusion Center, *St. Christopher's Hospital for Children*

Alyssa Tousignant, RN, BSN, *Allegheny Health Network-Allegheny General Hospital*

Physician Offices

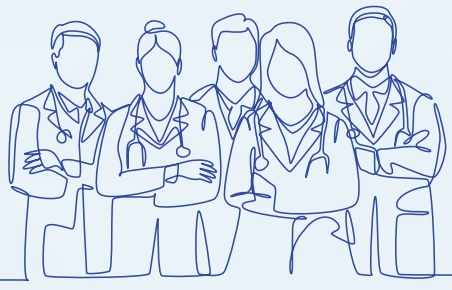
Amy Coppersmith, *WellSpan Health*

Tiffany Irwin, Practice Coordinator, *UPMC Hamot*

Time–Outs

Emily Roth, BSN, RN, Oncology Nursing, *Children's Hospital of Philadelphia*

Samantha Braverman, *Einstein Medical Center Montgomery*



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Patient Safety Alert: Methylprednisolone and Patients With Hypersensitivity to Cow's Milk Components

By **Catherine M. Reynolds**, DL, MJ, RN*◆ & **Myungsun Ro**, PharmD, MS◆

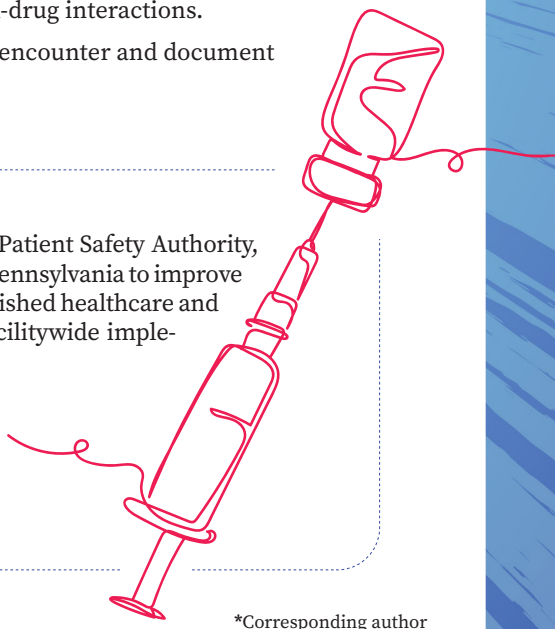
DOI: 10.33940/001c.77633

A patient with a known hypersensitivity to milk experienced an anaphylactic reaction after receiving an intravenous dose of methylprednisolone drawn from 40 mg vials.

Following the event, the facility reviewed the drug package insert, which included a contraindication and warning for patients with known or suspected hypersensitivity to cow's milk or its components.

Solutions

- Check your formulation(s) of methylprednisolone for the presence of lactose monohydrate. Different vial sizes may contain different components.
- Verify that clinical data support systems alert when methylprednisolone containing lactose monohydrate is ordered for a patient with a documented milk allergy.
- Review your internal process for identifying and cross-referencing food-drug interactions.
- Review and update patients' allergies, including food allergies, at every encounter and document the date and type of manifestation as appropriate.



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Catherine M. Reynolds (catreynold@pa.gov) is a patient safety advisor with the Patient Safety Authority, working directly with more than 80 healthcare facilities in the Southeast region of Pennsylvania to improve patient safety through consulting, education, and collaboration. She is an accomplished healthcare and patient safety professional, specializing in the analysis of adverse events and facilitywide implementation of patient safety plans.

Myungsun (Sunny) Ro is a research scientist on the Data Science and Research team at the Patient Safety Authority (PSA). Her responsibilities include analyzing and synthesizing data from various sources to identify opportunities to improve patient safety, as well as writing scientific articles for publication in the PSA's peer-reviewed journal, *Patient Safety*.

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

ARTIFICIALLY INTELLIGENT?

Machine Learning in Healthcare and Why It May Not Be As Advanced As You Think

By **Avishek Choudhury**, PhD◆ & **Caitlyn Allen**, MPH*†

DOI: 10.33940/001c.77632

Machine learning: What exactly is it, and how is it being used in healthcare? Are machines always better than a person? How do we know? Managing editor, Caitlyn Allen, sat down with Dr. Avishek Choudhury, artificial intelligence healthcare researcher, to answer these questions and more.

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

Caitlyn Allen: How do you define artificial intelligence [AI] and what are the different types?

Dr. Avishek Choudhury: AI is any technology mimicking how humans think and process information: any technology that can mine data, understand patterns, and then propose a conclusion based on previous experiences.

Much of your research surrounds AI use in healthcare. Is this a relatively new phenomenon or something that we've been using in healthcare for a while?

While AI's potential in healthcare is impressive, its implementation remains largely in the research stage. Very few practitioners have fully integrated AI into their clinical routines. This limited adoption is driven by several key concerns, including accountability, the risk of over-reliance, and challenges with usability.

Firstly, the question of accountability is paramount. When an AI aids in decision-making, who bears the responsibility for that decision, particularly if the outcome is not favorable? This is an issue that hasn't been thoroughly addressed yet. Secondly, there's the fear of blind trust. While AI has shown promise in data processing and pattern recognition, it's critical to remember that these systems are not infallible. They rely on the quality and accuracy of the data they're given. There's a danger that over-reliance on AI may lead to overlooking its limitations and potential errors. Thirdly, usability is another substantial hurdle. The integration of AI into existing workflows in a manner that is seamless and user-friendly remains a challenge. Moreover, there's a lack of comprehensive research detailing the safe and effective integration of AI into clinical workflows.

When an AI aids in decision-making, who bears the responsibility for that decision, particularly if the outcome is not favorable?

We have seen numerous studies demonstrating the performance of specific algorithms in research settings. Yet, there's a dearth of information on how these tools impact patient outcomes when implemented in the chaos of a real-world clinical environment. The gap between AI's potential and its real-world application in healthcare is substantial. We have yet to address these concerns fully or explore how AI can be safely and effectively used by doctors and nurses—those on the front lines of patient care—in their day-to-day operations.

It's often assumed that a computer will automatically outperform a human, but it sounds like that has not really been tested.

Correct. The perception often associated with AI is that it transcends human capabilities, demonstrating almost miraculous abilities. However, this isn't the entire truth. AI shines in pattern recognition and data processing—areas where the cognitive workloads far exceed what humans can handle. This edge doesn't make AI superior to humans, but simply more efficient in certain tasks, akin to a crane being able to lift heavier weights than humans.

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Where AI truly demonstrates its value is in its ability to enhance human efforts. In healthcare, for instance, AI can be an invaluable tool. Imagine the case of a patient with multiple comorbidities, devoid of insurance, and without familial support. To plan optimal treatment in such cases, the amount of information to process is immense. This is where AI steps in, distilling vast amounts of data and providing healthcare professionals with a more manageable, efficient decision-making process. Of course, when we talk about raw speed and consistency in processing, AI excels. Yet, it's important to understand that AI's performance is tethered to its predefined parameters and quality of data. AI requires explicit directives about intended outcomes in different scenarios.

Now, consider the scenario of a healthcare professional at the end of a grueling 12-hour shift. Under such circumstances, fatigue might cloud their judgment or lead to oversights. AI, on the other hand, doesn't experience fatigue. It remains consistent in its operations and won't overlook critical patient information, such as high blood pressure, due to exhaustion. Therefore, if we were to characterize AI as "better," it would be in this context: AI excels not by superseding humans but by amplifying human capabilities and mitigating human errors, especially in high-pressure environments like healthcare.

What about areas where humans often outperform AI?

Indeed, while AI excels at pattern recognition and data processing, its abilities fundamentally depend on the data it's been trained on. Therefore, in scenarios where there's no preexisting data, humans will often outperform AI. For instance, consider a blood test that reveals a hitherto unknown pattern. AI would be at a loss, unable to classify this pattern without a reference point. For AI to recognize, "This is disease X," it would need a vast amount of data—perhaps thousands of data points—highlighting different scenarios that lead to disease X. Only then can AI learn and identify the associated patterns. Given a new pattern, the AI could potentially relate it to a known pattern, suggesting, "This pattern resembles one seen 20 years ago, and there's a 60% likelihood that it corresponds to disease X." However, should disease X be a novel or rare condition, the AI will be unable to reliably identify it. It can only highlight the presence of a new pattern. The onus then falls on a human clinician to deduce what this novel pattern signifies. This underlines one of the inherent limitations of AI—it can't independently discover or invent, but rather is fundamentally reliant on the data it's been trained on. This is why the human element in healthcare will always be essential, to interpret and investigate when AI encounters the unknown.

What kind of quality control, if any, goes into vetting the data?

It depends on whoever created the AI. A developer can ask the algorithm to weigh sources differently, but it's optional. Some automatically assign higher weights to some data points, but many do not.

Could that cause the algorithms to eventually become biased?

AI algorithms are inherently neutral—they are mathematical constructs devoid of bias. However, if they are trained on biased data, they will reflect and propagate that bias.

For example: An AI system trained on data from Indian patients, many of whom have a diet rich in spicy foods, might develop an association between being Indian and having digestive issues. If the data predominantly showcases such cases, the algorithm may erroneously predict digestive problems even for an Indian patient who doesn't consume spicy food. It's important to clarify that this isn't a bias in the algorithm, but rather a reflection of bias in the data.

Similarly, disparities in healthcare also can influence data and, consequently, AI. In low- and middle-income countries, healthcare access may be limited, and record-keeping may be less digitized, leading to fewer data points for AI to learn from. Furthermore, if there are systemic biases in how different demographic groups are treated, these biases will be reflected in the data, skewing the AI's analyses accordingly.

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And like you said, AI can do well what you tell it to do, but it's still operating within those constraints.

Correct.

You mentioned in a recent study[1] that drug safety is one of the most common areas in patient safety where AI is being used. Why might that be the case?

Absolutely, drug safety is a prime area where AI research is extensively used because it's not only safer but also feasible, given the accessibility and nature of the data involved. AI is adept at identifying potential drug interactions—a critical aspect of patient safety. In a typical clinical scenario, a doctor might be unaware of the full range of medications a patient is taking, or a patient might unintentionally omit certain medications during their consultation. This could potentially lead to harmful drug interactions, such as prescribing drug X that negatively interacts with drug Y.

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The nature of drug interaction data—structured, comprehensive, and readily accessible—makes it particularly amenable to AI study and implementation. This contrasts with other areas of healthcare that may involve unstructured data or require nuanced human interactions, which are more complex for AI to handle.

However, AI has the capability to overcome this human limitation. AI algorithms can be trained on expansive databases that encapsulate a wide range of possible drug interactions. This allows them to predict and alert healthcare professionals about harmful drug combinations, like drugs X and Y. Every time this drug combination is prescribed for a patient, the AI system would generate an alert, allowing the doctor to adjust the prescription accordingly.

Additionally, the nature of drug interaction data—structured, comprehensive, and readily accessible—makes it particularly amenable to AI study and implementation. This contrasts with other areas of healthcare that may involve unstructured data or require nuanced human interactions, which are more complex for AI to handle. Thus, due to the feasible study design, the accessibility of data, and the tangible impact on patient safety, AI has become an integral tool in enhancing drug safety.

In that paper,[1] you also mentioned that an AI-attributable error might lead to mass patient injuries compared to those attributable to a single provider's error. Tell me more about that.

Indeed, the broad impact of AI tools in healthcare can potentially amplify errors in a way that is not seen with individual providers. The critical factor here is the scale at which AI operates and the delay in feedback that might occur.

For example, consider an AI-powered recommendation system used by a doctor. This AI tool, even if highly competent, can become biased if exposed predominantly to a specific patient type over a period. Suppose the AI system is self-learning or adaptive; in such a scenario, it might gradually become more tailored to that patient population. Now, when a different patient type presents, the AI system's recommendation might not be as accurate or appropriate. The doctor, having trusted the AI system over the past months, follows the recommendation and prescribes a particular medication. However, this prescription might not be suitable for the patient, which is not immediately apparent. The impact of the erroneous recommendation may not be detected until the patient has been on the medication for a few weeks. During this lag time, the AI system may have made similar recommendations for other patients. Thus, by the time the initial error is discovered, multiple patients may have received incorrect treatment. This potential for mass patient impact is a unique challenge associated with AI use in healthcare. It highlights the importance of rigorous testing, continuous monitoring, and safeguards to prevent the propagation of errors in AI systems.

Because the AI is the tool that everybody is dipping into. So, if the pool is tainted, it's worse than just a tainted cup of water.

Correct.

What do you think is the next iteration of AI in healthcare?

Looking ahead, I see several exciting possibilities for the next iteration of AI in healthcare, with three areas standing out: digital twins, mental health diagnosis, and analysis of clinical notes.

A digital twin is essentially a real-time, virtual clone of a patient. With the continuous exchange of data between the patient and their digital twin, we can simulate various health scenarios and interventions. For example, if a patient is experiencing certain symptoms, their digital twin can illustrate what's occurring within their body and suggest modifications to optimize health. It allows physicians to see a computerized version of the patient's health status and predict the likely outcomes of different treatment options. For instance, administering medication to the digital twin can simulate the patient's potential reactions, offering valuable insights for treatment planning.

So, if you're experiencing chest pains, your doctor can show you what's causing the pain and what will happen if they give you drug X as a treatment?

Correct. A real-time data transformation. It already exists in manufacturing, but people are working on digital human twins. At the 2023 National Academies workshop on integrated diagnostics, we discussed how AI-based digital twins can help with oncology.

AI also has the potential to revolutionize the field of mental health. By analyzing patterns in speech, language use, facial expressions, and even social media activity, AI could help identify signs of mental health conditions much earlier than currently possible. This could greatly improve the prognosis for many conditions by enabling earlier intervention.

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Next, clinical notes are a treasure trove of valuable patient information, but their unstructured nature makes it difficult for healthcare providers to extract insights manually. AI algorithms, particularly those using natural language processing (NLP), can help analyze these notes, identify relevant information, and present it in a structured format for clinicians. This could significantly enhance patient care by making it easier for providers to access and understand a patient's full medical history.

Taking notes is one of the most time-consuming things any nurse or doctor has to do. There's a huge opportunity that generative AI [e.g., ChatGPT] can allow doctors and nurses to have more patient time versus time spent documenting.

I suspect that will make clinicians ecstatic if they could spend less time on documentation.

Certainly, easing the burden of documentation could be a significant boon for clinicians, allowing them to devote more time to direct patient care. However, transitioning this from an exciting possibility into a practical reality does require careful consideration of numerous factors, including policy and accountability.

These advancements represent just a few ways AI can further improve healthcare. The key will be to ensure these technologies are developed and deployed responsibly, with patient safety, usability, privacy, and equity always in mind.

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The goal should be to build a framework where AI can augment human skills and judgement, improve healthcare outcomes, and do so in a manner that is ethically sound, accountable, and financially sustainable.

In our current healthcare system, if a clinician makes an error, they bear the responsibility and potentially face penalties. This clear line of accountability becomes more complex when AI is involved. If a mistake occurs while using an AI system, should the clinician be held responsible? Or should the blame be attributed to the AI, the developers, or the institutions that implemented it? These are important questions that need answers to promote the safe and effective use of AI in healthcare. Financial considerations also play a crucial role in this. Developing, validating, implementing, and maintaining AI systems in healthcare is an expensive process. Ensuring these systems are reliable, safe, and accountable requires significant investment, which can be a barrier to their widespread adoption.

Addressing these issues will be critical in shaping the future of AI in healthcare. The goal should be to build a framework where AI can augment human skills and judgement, improve healthcare outcomes, and do so in a manner that is ethically sound, accountable, and financially sustainable. But for this to be a real-life thing, there has to be policy and accountability in place, which is not there. If you make a mistake as a person, you get penalized. If you make a mistake while using an AI, regardless of whether it was the AI's fault, you still get penalized. That's a big thing people are not working on because of many factors, mostly money.

As you mentioned, AI in healthcare is currently in its research phase. Maybe as this becomes more of a part of our day-to-day experience, the policies will start to catch up. Tell me about "vertical standards" and how they come into play in patient safety.

Indeed, the current landscape of AI in healthcare lacks concrete benchmarks or vertical standards that define the level of accuracy or performance required for different healthcare settings and tasks. Without these, it's challenging to gauge whether an AI system is "good enough" for use in clinical practice.

For instance, let's consider an AI tool that has a 90% accuracy rate in detecting drug reactions. Is this satisfactory? Should we deploy this tool in a clinical setting? There are no clear answers to these questions currently. The prevalent trend seems to be a competitive race among researchers to incrementally improve accuracy, but without a defined threshold of acceptability, it remains unclear when an AI tool is ready for clinical use. This situation underscores the need for setting vertical standards in healthcare AI. We need guidelines tailored to the specific requirements of different departments and tasks, as the risk and acceptable margin of error may vary significantly. For example, the acceptable error margin for AI systems analyzing clinical notes might be higher than for those diagnosing critical conditions such as pancreatic cancer. Without these standard benchmarks, it's challenging to determine the performance level that an AI system should achieve for a specific task to be considered safe and effective for use. Creating these standards will provide much-needed clarity and confidence in deploying AI tools in healthcare, helping to ensure patient safety and optimal care outcomes.

And it sounds like this goes back to quality control: Is 90% more accurate than how a human would perform?

Correct. And that 90% is tested on the research dataset. Will it perform the same in a clinic in Monongalia County in rural West Virginia? We don't know. It may or it may not.

What about when it comes to scale: using AI on a micro level [e.g., an individual facility] versus on a macro level [e.g., across multiple health systems]?

At the micro level, such as in a single facility or a specific clinical specialty, the use of AI can be highly tailored to the unique needs of that setting. For example, if a clinic primarily serves a particular patient cohort, an AI system could be trained specifically on that population's data. This would allow the AI to become very adept at understanding that population's unique health characteristics and trends, leading to potentially higher accuracy and effectiveness. However, it also means that the AI might not perform as well when faced with patient data outside of its training set.

Conversely, implementing AI on a macro level, such as across multiple health systems, allows for the analysis of much larger and diverse datasets. This broad perspective can reveal patterns and trends that would be impossible to discern at a smaller scale, potentially leading to more generalized insights. However, the diversity and complexity of these large datasets can also introduce challenges. There may be numerous missing or inconsistent data points, and variations in how data is collected and recorded across different systems could lead to discrepancies. Moreover, patient privacy and data security become even more critical issues at this scale.

Overall, whether you use AI at a micro or macro level depends on your specific goals and constraints. The key is to carefully consider the unique advantages and challenges of each approach and choose the one that best fits your needs.

And I would think similarly for larger datasets, that it would be important for the information to be uniform and uniformly collected. If the information from different hospitals looks different, that would create a challenge to analyze it.

Absolutely, uniformity in data collection and documentation is crucial for successful AI analysis, especially on a larger scale. The lack of standardized procedures or documentation formats across different healthcare providers or institutions is indeed a significant challenge in healthcare data analysis.

Let's say we're dealing with a symptom as common as a stomachache. Different doctors may order different diagnostic tests based on their own medical judgement and experiences. This leads to varied datasets even for the same symptoms, creating a challenge for AI systems that need consistent data to function effectively.

If an AI system is trained on a dataset that includes certain diagnostic tests, but is then implemented in a setting where these tests are not typically conducted, this could lead to incomplete data inputs. The AI system may not perform optimally in this new setting due to the missing data.

Therefore, to maximize the effectiveness of AI systems in healthcare, efforts should be made to standardize data collection and documentation practices across different healthcare providers. This would ensure that AI systems are trained and tested on datasets that accurately reflect the diversity and complexity of real-world healthcare scenarios, increasing their robustness and generalizability.

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And when you have those holes across multiple patients in multiple hospitals, that's another way that the data could get biased?

Correct. That's the difference between real-world data versus university-collected data. Datasets collected for research from research institutes are good because everything is there. But in most places, that might not be the case.

Most healthcare data involves protected information. How secure is the information fed into the algorithms?

One of the foundational tenets of data privacy in healthcare is that individual patient data is de-identified before being used for analysis or machine learning. This process ensures that the algorithm, on its own, cannot identify individuals from the data it is analyzing. However, the potential for re-identification, especially with the presence of unique characteristics or outliers, is a complex and sensitive issue.

Consider the example where we have a patient cohort largely composed of South Asians with one exception of an East Asian. If the ethnic background data was used in the model, the lone East Asian patient could potentially be re-identified, especially if the users of the AI system have access to the original data source. In this respect, it's crucial to have robust data privacy policies and technologies in place to protect individuals' health information. This is especially important as we leverage AI and machine learning more in healthcare, where the use of large and diverse datasets is integral. Sometimes, certain personal information may be necessary for tailoring healthcare services to an individual's needs. For instance, knowing whether a patient has insurance could enable an AI system to recommend treatments that the patient can afford. In such cases, patients should be clearly informed about how their data will be used and protected, and their consent should be obtained. This way, we can strike a balance between personalized healthcare delivery and data privacy.

That goes back to the eventual need to reconcile policy. Is there anything else about AI or machine learning that we didn't cover?

Trust, workload, and accountability. Take workload. Developers don't often understand the end user and their digital literacy. When we see a healthcare provider who may be struggling with Epic [electronic health record software] and then, if you add another AI module in that already complex software, it overcomplicates things for that end user. Instead of reducing the workload, it's an extra thing they're doing. You must consider, if there is an AI that works well, how do you integrate it in the clinical workflow? You cannot just disrupt everything that's going on and then say, "Okay. From tomorrow we'll do this." That will not go well. That ties back to trust.

If you're using something that's working well and you are blindly trusting it and then something goes wrong and there's a disaster, you'll stop trusting it. Or you just don't trust AI because of all the myths and hypes, you'll miss that opportunity to use that good technology. So, we need balance and some policy to build around that.

And accountability. If the end user is responsible for everything, why would that person use AI? What's the point? If anything goes wrong, then their license will be at stake. So, why invest and learn a new technology if there is no reward for the end user?

That makes a lot of sense. Well, it sounds like AI is going to continue to play a supporting role in healthcare, at least for a while. Do you think that will always be the case?

The notion of AI replacing human roles in healthcare is a complex and nuanced issue, primarily due to the importance of accountability. Theoretical scenarios where AI could replace a nurse or a doctor hit a wall when we consider liability related to medical errors. In our current understanding, if something goes wrong, we trace it back to the source—which could lead us to the data, the algorithm, the data collecting agency, and the AI developer. These organizations are often large entities, and imposing accountability on them could lead to many complications.

Thus, the reality is that AI in healthcare will likely play a significant supportive role rather than a replacement one. By supplementing human decision-making with AI, we hope to boost efficiency, reduce human errors, and free up valuable time for healthcare professionals. This way, doctors and nurses can focus on more nuanced aspects of patient care or perhaps even devote more time to innovation and discovery.

The key will be to ensure AI tools are reliable, accurate, and accountable, and that they are used in a way that enhances the role of healthcare professionals rather than attempts to replace them. This balanced approach will likely yield the greatest benefits for healthcare providers and patients.

Staffing shortages in healthcare are pervasive, but perhaps AI may be a way to free up clinicians' time and provide a stopgap.

Correct. It can help the doctor integrate all the information and summarize it. It can help the patients to learn about what's going on with their health. It can help us identify a patient who is prone to commit suicide, for example. It's very common in a cancer setting when you deliver a diagnosis, and you see that patient went home and committed suicide. There have been cases like that for pancreatic or liver cancer, which are high-risk and have

higher mortality rates. They often commit or attempt suicide. AI can be used to identify those at-risk patients based on their brain activity or facial expression. It'll never be a replacement, because the patient wants a doctor, and everything is around the patient. If future patients say, "I don't want a doctor," then maybe. It depends on what patients need.

Are there any other less-obvious uses for AI?

Identifying burnout in healthcare workers. That can then reduce human error. Consider nurses working 12 hours who then go home, with a one-hour travel time, then sleep for four hours, wake up, one-hour travel time, back on duty three times or four times a week. AI can identify those nurses or doctors who are prone to human error because they're too tired.

You mean like looking at schedules to identify where there might only be limited time for sleep?

Not just schedules, but actually the people there. If we can link AI to a smartwatch or something like that, you can monitor heart rate, rate of perspiration. There are EEG [electroencephalography] monitors, glasses that analyze pupil dilations and facial expression, and could say, "This person is tired, the brain is not working as well. Maybe he should be given a two-hour break." AI can do that. It's very simple, because everything exists, you just have to adapt and use it.

Do we have existing datasets for this type of thing, or would we need to build them first?

It can be done in parallel because some of the things that identify burnout are known. If heart rate is elevated, then you know that person is anxious. If the EEG signals a certain pattern, you know that brain is not functioning well. AI can be used to detect that. That's it. You don't need to train anything because you're not predicting anything. You're just saying, "The brain activity for this doctor is 10% lower." Then the manager or attending will be able to identify potential healthcare workers who are more prone to commit an error because they're too tired.

That is fascinating. What about near misses? We often learn the most by trying to determine why something did not occur.

AI has significant potential in learning from "near misses" in healthcare. Near misses, or close calls that could have resulted in harm but didn't, are a gold mine of information because they provide insights into areas of vulnerability that otherwise might not be noticeable. However, as you noted, detailed data about these events is often not captured or analyzed.

AI could be particularly useful in this context by tracking and analyzing these near miss events. For instance, it could monitor healthcare workflows and processes, identifying when deviations occur from established protocols. Over time, it could gather a wealth of data about these events, providing insights into why they occur and how they are typically handled. For example, if a physician consistently deviates from a blood transfusion guideline, an AI system could flag this pattern. Further investigation could then reveal whether the deviation was justified (perhaps due to unique patient characteristics not adequately accounted for in the guidelines) or if it was a potential area of concern that needs addressing. This information could be invaluable in informing the refinement of healthcare protocols, improving training programs for healthcare providers, and designing systems that are more resilient to errors. It would also contribute to a culture of continuous learning and improvement in healthcare, where every event, even near misses, is seen as an opportunity to enhance patient safety and care quality.

"AI has significant potential in learning from "near misses" in healthcare. Near misses, or close calls that could have resulted in harm but didn't, are a gold mine of information because they provide insights into areas of vulnerability that otherwise might not be noticeable.

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