PATIENT SAFETY

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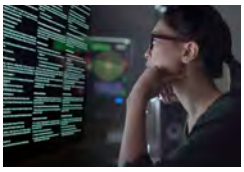
Safety alerts

Equipment-related issues

At-home medication safety



HIGHLIGHTS OF 2023

PA

LETTER *From the Editor*

Regina Hoffman,
Editor-in-Chief
Patient Safety

Welcome to our first highlights issue bringing you the most important information from the Patient Safety Authority (PSA) from 2023. This special edition compiles *Patient Safety* manuscripts, newsletters, interviews, links to resources, and more: the tools you need to keep your patients safe.

To our longtime readers (all 75,000-plus of you across the globe), thank you for your support! Yes, this issue is primarily old favorites, such as the articles on equipment-related problems and optimizing visual display design, but it also features other PSA content about wrong-site surgery, drug-eluting stents, and healthcare disparities that you likely have not seen—but won't want to miss.

If this is your first issue of *Patient Safety*, it's nice to meet you! We launched our journal almost five years ago to fill a void in academic publishing. *Patient Safety* seeks to provide practical, actionable, peer-reviewed information to bedside clinicians and administrators who can most directly impact patient care. This includes quality improvement studies, expert interviews, and original research—much of which is derived from the Pennsylvania Patient Safety Reporting System (PA-PSRS), the largest event reporting database of its kind in the United States. A dedicated team of data and research scientists from the PSA analyzes more than 5 million reports to better understand harm and provide advisement to prevent recurrence.

If you have recently written a manuscript, consider submitting it to *Patient Safety* to get your work published today! *Patient Safety* is listed in several major indexes and provides authors with a quick turnaround to see their name in print. New articles are posted on a rolling basis throughout the year as soon as production is complete, so subscribe to our mailing list for updates and visit patientsafetyj.com often to be among the first to read them.

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.

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

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

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IN OTHER NEWS

PATIENT SAFETY INITIATIVES

PATIENT SAFETY ALERT

Methylprednisolone and Patients With Hypersensitivity to Cow's Milk Components

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Keywords: safety alert, methylprednisolone, patient safety

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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.

About the Authors

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*.

PATIENT SAFETY ALERT

Serious Harm Associated With Failure to Adjust Clozapine Dosing

By **Patient Safety Authority**

We have received Pennsylvania Patient Safety Reporting System (PA-PSRS) reports of serious harm associated with a failure to adjust dosing upon reinitiation of clozapine therapy. Clozapine is an atypical antipsychotic approved for the treatment of treatment-resistant schizophrenia.[1] Despite its clinical effectiveness, it is used as a last-line therapy and has risk evaluation and mitigation strategy (REMS)[a] requirements because it can cause a number of serious and potentially fatal adverse effects such as agranulocytosis.[1,4-6] Additionally, clozapine requires dose adjustments when used concomitantly with several categories of medications, such as CYP inducers and inhibitors, anticholinergic drugs, and drugs that cause QT interval prolongation.[1]

[a]A risk evaluation and mitigation strategy (REMS) is a drug safety program required by the U.S. Food and Drug Administration (FDA) to mitigate a known serious risk of a medication.[2] The goal of the Clozapine REMS Program is to reduce the risk of severe neutropenia associated with the use of clozapine by educating healthcare providers and patients about its risk, ensuring periodic documentation and monitoring of absolute neutrophil count (ANC) levels in patients receiving clozapine, and establishing long-term safety for patients enrolled in the national registry.[3]

Keywords: clozapine, Clozaril, antipsychotic, schizophrenia, medication safety, medication error

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In patients who have discontinued clozapine for two or more days, the manufacturer recommends the therapy be reinitiated at 12.5 milligrams once daily or twice daily to reduce the risk of hypotension, bradycardia, and syncope.[1] Cases of severe cardiovascular effects have been documented in patients whose doses were not titrated appropriately after an interruption in therapy.[7]

Action Items:

- Design and implement effective "hard stops" and alerts in the electronic health record (EHR) to notify any new starts, last date taken, and interruption of therapy for more than two days.
- Document in the EHR any changes that are made to the medication therapy, including the rationale.
- Record the details of medication administration in the medication administration record (MAR) and not solely in the text of the progress notes.
- Ensure medication reconciliation includes date last taken.
- Verify the enrollment of the patient in REMS to avoid a disruption in therapy.
- Educate the multidisciplinary healthcare team on the prescribing and safety information of clozapine, including strategies to detect early signs of adverse effects. Ensure that drug information and institution-specific guidelines, if available, are easily accessible to the healthcare team.
- Ensure periodic review of high-alert medications or medications that require REMS by the pharmacy and therapeutics (P&T) committee. Review should include verification that alerts or hard stops within the EHR function as intended and an analysis of the frequency at which they are triggered.
- Enhance drug-checking software and clinical decision support within the EHR. Review and streamline the process to minimize alert fatigue and continually monitor its effectiveness.

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About the Author

Patient Safety Authority (patientsafety.pa.gov) is an independent state agency that oversees the Pennsylvania Patient Safety Reporting System (PA-PSRS), the largest database of its kind in the United States.

Informing Healthcare Alarm Design and Use: **A Human Factors Cross-Industry Perspective**

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Abstract

Background: Alarms are signals intended to capture and direct human attention to a potential issue that may require monitoring, assessment, or intervention and play a critical safety role in high-risk industries. Healthcare relies heavily on auditory and visual alarms. While there are some guidelines to inform alarm design and use, alarm fatigue and other alarm issues are challenges in the healthcare setting. Automotive, aviation, and nuclear industries have used the science of human factors to develop alarm design and use guidelines. These guidelines may provide important insights for advancing patient safety in healthcare.

Methods: We identified documents containing alarm design and use guidelines from the automotive, aviation, and nuclear industries that have been endorsed by oversight agencies. These guidelines were reviewed by human factors and clinical experts to identify those most relevant to healthcare, qualitatively analyze the relevant guidelines to identify meaningful topics, synthesize the guidelines under each topic to identify key commonalities and differences, and describe how the guidelines might be considered by healthcare stakeholders to improve alarm design and use.

Results: A total of 356 guidelines were extracted from industry documents (2012–present) and 327 (91.9%) were deemed relevant to healthcare. A qualitative analysis of relevant guidelines resulted in nine distinct topics: Alarm Reduction, Appropriateness, Context-Dependence, Design Characteristics, Mental Model, Prioritization, Specificity, Urgency, and User Control. There were several commonalities, as well as some differences, across industry guidelines. The guidelines under each topic were found to inform the auditory or visual modality, or both. Certain guidelines have clear considerations for healthcare stakeholders, especially technology developers and healthcare facilities.

Conclusion: Numerous guidelines from other high-risk industries can inform alarm design and use in healthcare. Healthcare facilities can use the information presented as a framework for working with their technology developers to appropriately design and modify alarming technologies and can evaluate their clinical environments to see how alarming technologies might be improved.

Introduction

The human factors literature defines an alarm as a signal intended to capture and direct human attention to a potential issue that may require monitoring, assessment, or intervention.[1] The Food and Drug Administration (FDA) and other standards organizations distinguish between alarms and alerts for medical devices by stating that alarms should be used when the operator's awareness or response is required for risk control, while alerts provide contextual awareness that is not related to risk control.[2-5] In high-risk industries like healthcare, automotive, aviation, and nuclear, alarms play a central role in identifying system malfunctions, abnormal conditions, and process deviations.[2,6,7] In healthcare, alarms commonly take the form of auditory and/or visual signals embedded in medical devices and play a critical role in overall healthcare system safety and quality of care. When alarms are not designed and implemented optimally, patient harm, clinician burden, and patient frustration can occur.

Many medical devices utilize alarming to convey important information to clinicians, patients, or other users. Medical device alarms are essential to patient care and draw attention to potentially critical changes in patients' physiological states, device malfunctions, or system status. For example, a telemetry monitor alarms staff to a dangerous cardiac arrhythmia and a dialysis machine alarms staff to serious device failures, such as impeded blood flow. While these alarms are helpful in many instances and promote patient safety, poorly designed and implemented alarms can pose patient safety risks by distracting providers from other important information.

From 2005–2010, the FDA's Manufacturer and User Facility Device Experience (MAUDE) database received 566 reports of alarm-related patient deaths.[8] Similarly, from January 2009 to June 2012, The Joint Commission's Sentinel Event Database received 98 reports of alarm-related events, 80 of which resulted in patient deaths.[8] Numerous challenges are associated with alarms that contribute to patient safety risks, including alarms not capturing the user's attention, alarms being detected but not providing the necessary information to address the issue, and frequent inaccurate alarms (e.g., false alarms) leading users to distrust the alarms and discount them over time.[9,10] The need to isolate patients during the COVID-19 pandemic has also presented increased challenges with alarm response, as patient isolation decreases staff's ability to detect alarms.[11]

Alarm fatigue is the widely adopted term that describes healthcare worker desensitization to the numerous alarms in their work environments caused by high exposure to alarms.[10,12] Alarm fatigue contributes to missed, delayed, or inadequate responses to alarms and may put patients at risk for experiencing adverse events.[13-17] One of the many contributing factors to alarm fatigue is the number of alarms in the healthcare environment. A study analyzing physiologic monitor alarms in intensive care units found that 2,558,760 unique alarms occurred over 31 days.[18] Studies have also found that many alarms, 80% to 99% by some estimates, are nonactionable or false alarms, or convey redundant information.[13,16-20] Some studies have attributed the high number of false alarms in healthcare to devices' inappropriate alarm settings and unstandardized alarm sounds.[14,17,20,21]

The science of human factors, which aims to understand human capabilities for the purpose of designing work environments that meet these capabilities and enable optimal human performance, has an extensive body of research to inform alarm design.[22] From a human factors perspective, for an alarm to capture attention and provide appropriate information, the alarm should be detectable (i.e., heard or seen by the user), discriminable (i.e., recognized as separate from noise in the environment), and identifiable (i.e., convey the source or content of the alarm).[23-28]

Numerous studies in the human factors literature have systematically examined alarm features that impact detectability, discriminability, and identifiability from an auditory and visual perception perspective. For example, considering detection, movement in the visual periphery catches attention quickly, so dynamic visual alarms that change (e.g., flashing lights) are easier to detect than static visual alarms.[29-31] Considering discrimination, it is easier to discriminate auditory alarms when they are distinct from the environment, specifically when the alarms are 15 decibels or louder and at a substantially different frequency than environmental noise.[32,33] Considering identification, multiple studies have demonstrated that humans identify red alarms as the most hazardous, followed by orange and yellow.[34-39]

Several high-risk industries have applied the body of human factors knowledge about alarms to develop guidelines that inform safe and effective design and use. These guidelines often provide detailed specifications that should be adhered to in the context of the work performed. Many high-risk industries have federal agencies or other oversight organizations that have reviewed industry-specific and human factors–based guidelines and endorsed these guidelines for use. In healthcare, depending on the type of device, the FDA has some alarm-related guidelines that device manufactures should adhere to. However, some manufacturers may not follow these guidelines; many devices can be customized and configured by healthcare facilities, which may change features of the device alarms that were implemented by the manufacturer; and healthcare facilities often need to manage multiple devices that alarm. As a result, challenges with alarms in healthcare are pervasive and there is an opportunity for cross-industry learning.[40-43]

In this study, we sought to identify alarm design and use guidelines from high-risk industries outside of healthcare to inform healthcare practices. These guidelines may provide insights that can be adopted in healthcare environments to address the numerous alarm issues that impact patient safety. Human factors and clinical experts reviewed guidelines from the automotive, aviation, and nuclear industries to identify those most relevant to healthcare. Based on these guidelines, we provide considerations for alarming in healthcare environments.

Methods

Through an internet search, documents detailing human factors guidelines for alarm design and use endorsed by United States–based oversight agencies (e.g., Federal Aviation Administration for the aviation industry) were identified for the 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 auditory and/or visual alarms; 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 to be used for analysis in this study.[44-46]

A human factors expert extracted the title, date, agency, and specific discrete guidelines from each of the three industry documents that were included in the review and populated a Microsoft Excel spreadsheet. Guidelines were included if they contained information about visual or auditory alarms, regardless of whether they were directly applicable to healthcare, unless the guideline applied to a specific technology that was unique to that industry. For example, a guideline about using visual alarms to convey complex information would be included, but a guideline specifically about lane deviation alarms would not be included since lane deviation is specific to ground transportation. Following extraction, two human factors experts and one clinical expert reviewed each guideline to assess whether it was relevant to either inpatient or outpatient healthcare settings. A guideline was deemed relevant if it could inform the design and use of alarms in healthcare environments, regardless of whether the guideline is already being followed in healthcare. Disagreements between experts were discussed until consensus was reached. Those guidelines that were relevant to healthcare were included in the full analysis.

The healthcare-relevant guidelines were reviewed and grouped into meaningful topics that represented the general focus for informing alarm design and/or use. These topics were identified using a modified reflexive thematic analysis.[47] Two human factors experts familiar with the data independently reviewed a subset of the relevant guidelines and assigned a label to each one to represent the overall theme. Labels were discussed and collated to create an initial set of common themes that applied to the guidelines reviewed from 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 consensus was reached. Topics were reviewed for internal consistency and refined as necessary. The final topics and definitions can be found in **Table 1**.

Table 1. Alarm Guideline Topics and Definitions

Topics	Definitions
Alarm Reduction	Describes strategies for reducing the instances of unnecessary or redundant alarms, particularly what is referred to as false alarms and nuisance alarms.
Appropriateness	Describes general guidelines for when it is most suitable to use auditory alarms, visual alarms, or both.
Context-Dependence	Describes alarm characteristics to consider for better integration of the alarm signal into the environment and workflow of the user and that allow the user to discriminate the alarm from other auditory and visual signals in the environment.
Design Characteristics	Describes specific alarm design qualities and features that adhere to human factors principles.
Mental Model	Describes alarm characteristics that facilitate easy identification and interpretation and are consistent with the users' understanding of how the alarm should be presented.
Prioritization	Describes alarm characteristics that prioritize one alarm over another. These design characteristics pertain to one alarm in comparison with other alarms.
Specificity	Describes alarm characteristics that distinguish one alarm from another.
Urgency	Describes alarm characteristics that convey urgency of the response required by the user. This includes alarm characteristics that are specifically related to conveying time criticality and the level of importance of the alarm.
User Control	Describes aspects of the alarming system that users should and should not control.

After classifying the relevant guidelines by topic, the guidelines were reviewed and segmented by those that applied to the auditory or visual modality, or both. The guidelines were then analyzed to identify important commonalities and differences across industries. From the general set of relevant guidelines under each topic, two clinical experts identified the two to three guidelines that were deemed to be the most highly relevant and applicable to medical devices and should be considered when designing, implementing, and managing alarms.

Results

A total of 356 guidelines were extracted from the industry documents and 327 (91.9%) were deemed relevant to healthcare. By industry, 69 of 94 (73.4%) automotive industry guidelines were relevant, 148 of 152 (97.4%) aviation industry guidelines were relevant, and 110 of 110 (100%) nuclear industry guidelines were relevant. A comprehensive list of all the relevant guidelines can be found in **Online Supplement Appendix A**. In **Online Supplement Appendix B**, we provide a summary of commonalities and differences, organized by topic and segmented by applicability to visual and auditory modalities, auditory only, and visual only. **Table 2** describes the most highly relevant guidelines applicable to medical devices that were identified as potentially having implications for healthcare settings along with considerations for technology developers ("developers") and healthcare facilities ("facilities"), with examples for each.

Discussion

Our analysis of guidelines from the automotive, aviation, and nuclear industries identified numerous guidelines to inform alarm design and use. Unsurprisingly, there were often similarities across the industries, which was expected considering these guidelines were informed by the same body of human factors literature and theories of auditory and visual perception. Given variations in work environments, there were also differences across the industry guidelines, as they need to be relevant to the specific work conditions and tasks for each respective industry. These findings provide insights that may be relevant to healthcare and can inform alarm design and use for multiple stakeholders, including medical device manufacturers, healthcare facilities, and healthcare oversight organizations.

Industry Differences and Using Other Industry Guidelines to Inform Healthcare Setting Practices

While many of the guidelines reviewed from other high-risk industries have implications for healthcare and we have described how healthcare stakeholders might consider applying these guidelines (**Table 2**), there are significant differences between healthcare and other high-risk industries that should be noted. Most high-risk industries have greater control over the specific technologies that are used in their industry as compared to healthcare, which makes it easier to standardize alarm features. Further, having greater control over technologies enables alarm management systems, which are software tools that can support coordination and prioritization of alarms. The FDA provides some guidance on alarm management principles and regulatory requirements, and standards exist; however, software systems that manage alarms are not as prevalent as in other industries. A critical next step for healthcare is to implement alarm management software systems that can coordinate alarms across medical devices, as well as other technologies. Other high-risk industries typically have a limited number of human users in the control room or operating area of the work environment, which enables greater customization to the needs of those users. Another difference is that in healthcare the condition of the patient can be highly variable, whereas in other high-risk industries like aviation and automotive, the condition of the airplane or vehicle is more constant. The variability of patient condition adds tremendous complexity to alarm design and use.

In the absence of tighter controls and higher levels of standardization in healthcare, it will be difficult to apply all the guidelines and principles outlined in this report. However, these high-risk industry guidelines can serve as a framework for discussions with medical device manufacturers to optimize safe and usable alarm parameters, evaluate new products being considered for procurement, and to evaluate and optimize the alarms in the current work environment. These guidelines can also provide a basis for developing internal policies and standards surrounding alarm parameters within a hospital or healthcare system. In essence, these guidelines provide a different lens on the alarm challenges that plague healthcare and may inspire new ideas for effective alarm design and use in the future.

One significant difference between healthcare and the other high-risk industries we analyzed is the level of autonomy at each healthcare facility compared to the work environments in other industries. In aviation, the cockpits across airplanes that are the same model are generally standardized regardless of what airline company is operating the airplane. In the nuclear industry, the control rooms are generally standardized, and the technology being implemented is tightly controlled. In the automotive industry, the in-vehicle technologies are also tightly controlled and there is standardization across the same models of vehicles. While there is a high degree of standardization and regulation, these high-risk industries also have a higher degree of control over the design of their in-house alarm systems. In healthcare, the care environments are often not standardized and several different technologies from different manufacturers or developers may be implemented, customized, and configured at a facility level. Consequently, if general guidelines are followed by a manufacturer or developer, when this technology is used in the actual care environment, it may be used with other technologies that were not considered by the manufacturer or developer. Further, the technology may be customized or configured by a healthcare facility, resulting in deviations from the guidelines.

Policies and Guideline Adoption

The automotive, aviation, and nuclear industries each have at least one federal agency that is, at a minimum, endorsing guidelines to inform the design and use of alarms. These guidelines provide important knowledge to promote greater safety in these high-risk industries. In healthcare, there are few guidelines endorsed by federal agencies to promote safety in a similar fashion to other high-risk industries. The FDA provides some guidelines for medical device manufacturers, as do certain standards organizations, and certain devices require usability testing; however, this is not true for all devices.[2-5] Further, manufacturers are not required to test the device in the context of other devices that also alarm. Organizations such as the Agency for Health Research and Quality, The Joint Commission, and the Association for the Advancement of Medical Instrumentation offer guidelines that address issues of alarm fatigue and summarize best practices surrounding alarm management and risk reduction.[43,48,49] However, these guidelines may not be easily accessible and widely used by frontline decision-makers and

Table 2. Summary of the Guidelines Highly Relevant and Applicable to Medical Device Design From Other High-Risk Industries, Considerations for Healthcare, and Examples per Alarm Guideline Topic

Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
Alarm Reduction		
Alarms should be filtered, suppressed, or the alarm sensitivity reduced in the context of multiple alarms.	For single devices with multiple channels, there is often appropriate filtration, suppression, deactivation, or alarm sensitivity reduction. Facilities should consider situations in which multiple devices are in use for a single patient and how filtration, suppression, deactivation, or sensitivity reduction for each device is handled. There may be an opportunity to adjust these features to improve detection of the most critical alarm.	A low oxygen saturation alarm should be suppressed when a lethal rhythm alarm is simultaneously firing from a bedside physiologic monitor.
Alarm system inputs should be validated to ensure sensors are not faulty and to avoid triggering false alarms.	In most circumstances facilities appropriately validate inputs to avoid triggering false alarms. Facilities should consider extending this practice to all frequently used alarming technologies and developing a systematic process to ensure that devices can be efficiently tracked down to support timely and appropriate usability and maintenance checks.	Periodic usability checks should be implemented to evaluate and maintain proper sensitivity of all frequently used alarming technologies, such as telemetry monitors and bed alarms. There may already be a precedent for this practice (e.g., daily ventilator testing).
Appropriateness		
Bimodal alarms should be used in environments with high ambient illumination, when auditory signals are nonverbal, and as needed to attract attention to visual alarms.	In many environments (e.g., intensive care units and emergency departments) alarm volume can be adjusted. However, it is sometimes difficult to adjust the contrast and/or brightness of a visual alarm. Developers and facilities should consider making these adjustments available on all relevant technologies.	Bimodal alarms should be implemented in high-light conditions such as sunny patient rooms and low-light conditions such as at night.
Speech alarms are appropriate when a tonal alarm may be forgotten, when the ambient environment may mask a tonal alarm, or when presenting continuous information.	Generally, in healthcare environments tonal alarms are common and speech-based alarms may be underutilized. Developers and facilities should consider using speech-based alarms in environments where sound is likely to be masked.	Environments that have numerous tone-based alarms, such as critical care units and emergency departments, should consider the utilization of speech alarms.
An auditory reminder tone should be used to attract attention to unacknowledged alarms.	Developers and facilities should consider using auditory alarms with certain technologies that rely primarily on visual alarms when high-priority visual alarms are not acted upon after a certain time duration.	If a wound vacuum battery is nearly depleted and visual alarms are unacknowledged, auditory alarms should be used to capture the staff's attention before the device runs out of power.
Context-Dependence		
Any speech alarms should be distinct from other recorded speech in the environment.	Facilities should consider evaluating speech-based alarms to ensure that these alarms are distinct from one another and from other stimuli and that the alarms can be understood by the intended user population.	Speech alarms, such as those used in bed exit alarms, should be distinct from speech alarms emitted from other technologies, such as overhead pages.
Auditory alarms should be audible and duplicated at any relevant workstation.	In some environments (e.g., patient rooms), an auditory alarm is emitted from technology in a certain location; however, the intended audience for the alarm is not in the same location and therefore may not hear the alarm. Facilities should consider methods for making the auditory alarm audible to intended users that may be located far away from the emitting technology.	Individual bedside monitor alarms should be replicated in the clinical workstation and relayed to the intended user through a mobile communication device where possible.
Visual alarms should be physically located within the users' workflow and line of sight, especially critical alarms.	In some contexts, important visual alarms may be presented to the user at an inopportune moment, resulting in disruptions to workflow or increased workload. Facilities should place visual alarms at the appropriate time in the users' workflow.	Infusion pumps present visual and auditory alarms at the bedside that should be replicated in the clinical workstation and relayed to the intended user through a mobile communication device where possible.

Table 2. (continued)

Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
Design Characteristics		
Technologies should maintain an alarm log with time stamps to support situational awareness and increased context for the user.	While many technologies create an alarm log, these logs may not be easily accessible by frontline clinicians. Developers and facilities should consider providing additional automated and easily accessible alarm logs to support clinicians.	Some continuous positive airway pressure (CPAP) units emit an auditory alarm and internally record a time stamp when the user has a period of ineffective breathing. This internal file must be accessed using proprietary software. Having easy, point-of-care access to the alarm log could support clinical decision-making, such as modifying treatments or medications.
Technologies should recommend specific frequencies and volume for auditory alarms in general, in comparison to ambient noise, at specific distances, and in the presence of obstacles.	Developers and facilities should consider the range of potential distances between the alarming technology and the intended receiver of the alarm. Alarm volumes may need to be adjusted when the intended receiver is far away from the emitting technology.	Technologies in patient rooms located at the far end of nursing unit hallways may need to have a louder alarm than technologies in patient rooms closer to the clinical station. In addition, obstacles or barriers that may deflect an auditory alarm should be taken into consideration.
Visual alarms should maximize detectability by ensuring flashrates are comprehensible, avoiding bouncing or zooming in on visual alarms, limiting the number of colors, and using simple fonts and icons as well as minimal text.	Facilities should consider standardizing bedside monitors that have color coding and flash alarms enabled. Color codes should be uniform across environments and devices.	In many settings (e.g., telemetry-monitored patient rooms), bedside monitor interfaces are configured to color code various vital signs and incorporate flashing to indicate critical readings.
Mental Model		
Alarms should be consistently formatted on all displays, including word order (e.g., title, value, severity), alarm arrangement (e.g., pressure placed above temperature), and alarm control arrangement (e.g., reset placed below acknowledge); also, consistent terminology, symbols, and standards across alarm displays and procedure manuals should be used.	Across devices that may be used simultaneously (e.g., telemetry monitors and defibrillators) there is often variability in word order, alarm arrangement, terminology, and symbols across alarms. Facilities should consider utilizing technology with similar alarm design standards whenever possible.	A lethal rhythm notification on medical devices throughout the facility should be placed directly above the electrocardiogram waveform.
Auditory alarms should be kept consistent across the system, using standard accents from the user's country, utilizing existing associations for auditory alarms, and avoiding sounds with old associations to represent new concepts.	Developers and facilities should consider providing the option to change the language used for speech-based alarms.	Bed exit alarm technologies often use a speech alarm to capture the patient's attention and deliver a safety reminder. Having the capability to select a speech alarm aligned with the patient's spoken language, dialect, and/or accent may increase the effectiveness of these alarms.
Visual alarms should use symbols and icons, as well as colors, that utilize existing associations (e.g., octagon shape for a stop sign).	On some medical devices (e.g., glucose monitors and wound vacuums), symbols, icons, and colors that have existing associations are used. However, they do not always use well-recognized symbols, icons, and colors.	If a glucose monitor displays a symbol with the test result, it should fit within the users' existing knowledge of symbols and icons, such as an up arrow for high and a down arrow for low.
Prioritization		
An alarm management system should be designed such that it prioritizes urgent and important alarms, and when two alarms appear simultaneously, the higher priority alarm is presented and the lower priority alarm is suppressed.	Some devices have appropriate alarm prioritization within a single technology (e.g., bedside physiologic monitor). However, in the context of multiple technologies emitting alarms for the same patient, prioritization across alarming technologies can be a challenge. Developers and facilities should consider establishing processes to support clinician response for the most commonly occurring scenarios of multiple technologies emitting alarms for the same patient.	If a critical bedside monitor alarm is firing, it may need to compete with a routine infusion pump alarm signaling the infusion is complete. Interoperability between these two technologies should be implemented to increase detectability of the critical monitor alarm by silencing the routine infusion pump alarm until the critical alarm has been addressed.
Visual alarm information should be displayed according to how one reads, with the most important information displayed on the top left of the screen and the least important on the lower right.	While some technologies present the most important alarm information on the top left of the screen, other technologies do not follow this convention. Developers and facilities should consider following this guideline.	Critical alarms on a ventilator should be displayed on the top left of the screen in keeping with industry recommendations.

Table 2. (continued)

Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
Specificity		
Auditory alarm coding should distinguish signals based on the necessary response.	While many technologies do have distinct auditory signals based on the necessary response, not all embrace this guideline. Developers and facilities should consider reviewing technologies to determine whether the auditory alarm coding can appropriately indicate the necessary response.	A medication infusion pump should emit a different auditory alarm for different conditions. For example, the alarm for a low battery condition should be distinguishable from the alarm for an air-in-line alarm condition to help the user appropriately prioritize their response.
Urgency		
Alarms should indicate the magnitude of the problem they are highlighting.	Technologies such as monitoring devices utilize alarms that appropriately indicate the urgency of the problem. This is not universal. Developers and facilities should identify frequently used devices in which the magnitude of the problem is not aligned with alarm urgency and make appropriate adjustments. They should also look more holistically at the entire care environment to ensure alarm and urgency alignment across technologies.	On some telemetry monitors, a critical low or high heart rate is displayed with black font in a flashing red box. Indications of magnitude such as this one should be standardized.
Alarming systems should use warning signals to indicate conditions requiring immediate action, while caution signals should be used to bring awareness to certain unsafe conditions that do not present immediate danger.	Developers and facilities should consider distinguishing between immediate danger and unsafe conditions, and having alarms appropriately indicate the condition.	A low battery may present an unsafe condition. The alarm indicating this issue should be distinct from an alarm signaling immediate danger, such as the presence of a lethal cardiac rhythm.
Speech-based alarms should use a female voice and specific word rate to convey urgency.	When speech-based alarms are used, they are often presented using a male voice. It is unclear whether word rate is appropriately aligned to alarm urgency. Developers and facilities should explore whether female voice and/or specific word rates might serve to better convey alarm urgency.	Certain defibrillator devices utilize a male voice during operation. The use of a female voice and appropriate word rate should be considered.
User Control		
Users should not be allowed to set alarm parameters when one user might affect the settings of a second user or when parameters are determined by functional, procedural, or legal requirements.	In some settings (e.g., emergency departments), users may adjust the parameters of an alarm and this setting persists for a new user without the new user being aware of the adjustment. Developers and facilities should consider ways to make it clear to users what adjustments are active to prevent certain types of errors that may result if the user is unaware.	Bedside physiologic monitors may not revert to default settings when transitioning between patients. It may be necessary to discharge a patient from the monitor before the settings revert. This process of discharging and reverting to default settings should be automated.
When an alarm's automatic parameters change because of a system decision (or other reason), the user should be notified, and the user should acknowledge the change.	There are times when default alarm parameters are changed. These changes may be driven by a committee decision, a software upgrade from the developer, or for other reasons. When these changes are made the user should be notified of the change in parameters.	If a device software upgrade (e.g., an update to the default dosing parameters of an infusion pump) results in certain alarm parameters being modified, the staff should be notified in case they are relying on the alarm within the previous parameters.
The system should tell users if there is a loss of redundancy in the alarm system, and the technology should continuously display the lack of redundancy until the system is operable.	In some settings (e.g., behavioral health units and telemetry units), remote processes are used to augment in situ monitoring of patient status to provide a redundant alarm system. In these situations, developers and facilities should consider presenting a visual notification when there is a loss of expected redundancy so that the local clinician can adjust the frequency of their monitoring until the redundant system is reestablished.	In cases of remote monitoring (by camera) of patients on a behavioral health unit, if the remote monitoring screen goes down, the nurses on the unit should receive a visual notification that the remote monitor is no longer operational and that they must rely on in situ monitoring only.

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

biomedical engineers in the healthcare facilities adopting alarming medical devices. There is an opportunity for federal and state agencies overseeing healthcare safety to provide more specific guidelines for medical device manufacturers and to identify ways to promote guideline adoption by the healthcare facilities using these devices.

To address this issue, organizations like The Joint Commission or the Centers for Medicare and Medicaid Services could provide basic guidelines for healthcare facilities to adhere to around alarming. This would address the issue of differences between healthcare facilities and the customization and configuration of alarms. These organizations could establish basic safety guidelines to influence the number of alarming devices and characteristics of the alarms.

Limitations and Future Work

There are limitations to our study. The alarm guidelines were based on an internet search, and we sought to retrieve the latest version of the guidelines that were publicly available. However, other guideline documents may exist or more recent versions of the guidelines we reviewed may exist in a private domain. The determination of relevance of the guidelines to healthcare is based on a qualitative assessment and some guidelines deemed to be relevant may not be relevant in a particular context. Similarly, guidelines that were deemed to be irrelevant may be relevant in certain contexts.

There are important opportunities to expand this work. First, these guidelines that have been sourced from other high-risk industries should be compared with guidelines, standards, and regulations from the FDA and other healthcare stakeholders to identify which cross-industry guidelines are unique. Second, the guidelines should be evaluated to determine their effectiveness at addressing alarm safety issues in healthcare.

Conclusion

Effective alarm design and use in healthcare is imperative for patient safety. Human factors–informed alarm guidelines from other high-risk industries provide insights for safe alarm use in healthcare. A review of alarm guidelines from the automotive, aviation, and nuclear industries identified key topics and specific guidelines that should be considered by healthcare stakeholders to improve alarm use in healthcare. These guidelines can serve as a framework for medical device manufacturers and healthcare facilities to evaluate current alarm design and use. In addition, there are opportunities for improved policies from oversight agencies to address alarm safety.

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Assessing Equipment, Supplies, and Devices for Patient Safety Issues

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Abstract

Background: Medical equipment, supplies, and devices (ESD) serve a critical function in healthcare delivery and how they function can have patient safety consequences. ESD-related safety issues include malfunctions, physically missing ESDs, sterilization, and usability. Describing ESD-related safety issues from a human factors perspective that focuses on user interactions with ESDs can provide additional insights to address these issues.

Methods: We manually reviewed ESD patient safety event reports submitted to the Pennsylvania Patient Safety Reporting System to identify ESD-related safety issues using a taxonomy that was informed by the Food and Drug Administration Manufacturer and User Facility Device Experience taxonomy. This taxonomy consisted of the following high-level categories: malfunctions, physically missing, sterilization, and usability. The type of ESD and associated components or ESD subtypes, event classification, and care area group were noted for each report.

Results: Of the 450 reports reviewed, the most frequent ESD-related safety issue coded was malfunction (n=365 of 450, 81.1%) followed by sterilization (n=40 of 450, 8.9%), usability (n=36 of 450, 8.0%), and physically missing (n=9 of 450, 2.0%). Among the coded malfunctions, software/output problem (n=122 of 365, 33.4%) was the most frequent, followed by general malfunction (n=103 of 365, 28.2%); material integrity (n=72 of 365, 19.7%); and activation, positioning, or separation (n=68 of 365, 18.6%). The most frequent ESDs noted were infusion pump, instrument set, and intravenous, and the most frequent components/subtypes noted were alarm/alert, tubing, and tray.

Conclusion: ESD-related patient safety issues, especially malfunctions, impact patient care despite current policies and practices to address these issues. Healthcare facilities may be able to address some ESD-related patient safety issues during procurement through use of the accompanying procurement assessment tool.

Introduction

Medical equipment, supplies, and devices (ESD) are used in nearly all healthcare environments to diagnose and treat patients and are instrumental to the care process. More than 2 million different kinds of medical devices are available worldwide.[1] Depending on the type of ESD, there may be different standards and/or requirements for effectiveness, reliability, and safety.[2-4] There are also federal oversight organizations, such as the Food and Drug Administration (FDA), that provide regulatory frameworks and may require reporting of ESD issues that impact patient safety.[5] Despite these requirements and oversight, ESD-associated safety issues occur and can result in patient harm.[6-9]

Quantifying the frequency of ESD-related safety issues across healthcare settings has been difficult.[10,11] However, numerous studies have shown the impact of ESD issues on patient safety in specific contexts.[6-9,12,13] For example, a systematic review of surgical technology found that failure of equipment and technology account for a median of 23.5% of all errors, with a median of 0.9 equipment errors per surgery.[12] A United Kingdom–based study analyzing patient safety incidents from intensive care units found that nearly 8.5% of those reports were associated with equipment-related issues.[6] One study sought to estimate medical device–associated events from emergency department visits and suggests that regulatory surveillance systems grossly underestimate the number of actual events by as much as four times.[13]

Several recommendations have been proposed to address ESD-related safety issues. There have been requests for oversight agencies to improve their policies and regulations by leveraging advancements in regulatory science.[11,14] There have also been calls for healthcare facilities to improve surveillance of medical device–related issues.[11,15] Some medical specialties have suggested that use of and improvements to registries to track ESD use would support better identification of safety issues.[10,16] These recommendations may all have an impact on improving ESD safety; however, they are difficult for a single healthcare facility to implement on its own.

In this study, we analyzed a subset of ESD-related patient safety event reports to identify the type of safety issue described and the specific ESDs and components or ESD subtypes associated with the safety issue. There are numerous taxonomies to describe safety issues associated with ESDs. Some taxonomies focus on distinguishing between user errors, defined as instances in which the user incorrectly interacts with the ESD, and malfunctions, defined as instances in which the ESD does not function as intended by the manufacturer.[6-8,17,18] To better understand the nature of ESD-related safety issues, our analysis utilizes a human factors approach that focuses on how a user interacts with ESDs to complete their work tasks. With this approach, ESD-related safety issues can be characterized as malfunctions, which are ESD failures that may prevent the user from using the ESD; ESDs with missing parts; ESDs not being sterile, and design-related issues that impact how the user interacts with the ESD (i.e., usability issues). These four categories leverage aspects of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database taxonomy.[19] Based on this analysis, we developed a patient safety procurement assessment tool to guide healthcare facilities in their selection process. Healthcare facilities may be able to improve their procurement processes to make certain ESD-related safety issues less prevalent and mitigate the risks associated with these issues.

Methods

Data Source

We analyzed patient safety event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] between January 1, 2019, and December 31, 2021. All nonfederal, acute care facilities in Pennsylvania are required to report patient safety events through the PA-PSRS system. Each report contains a single event type category and free-text description of the safety issue, along with responses to many additional structured and unstructured questions. Our analysis focused on the Equipment, Supplies, and Devices event type category, as assigned by the reporter, which consisted of 24,660 reports from 334 facilities.

Topic Modeling Sampling Strategy

To understand the breadth of ESD-related safety issues, and the specific ESDs and components or ESD subtypes involved, we used a topic modeling approach to identify reports for manual review. This approach enables rapid identification of reports that have similar information, such as similar types of ESDs, from a large database of reports. We then manually reviewed a selection of reports from each topic (described below). This approach enables a broader understanding of safety issues impacting a variety of ESDs compared to a random sampling of reports, which would be skewed toward ESDs that are reported more often. To identify these topics, we applied a technique called latent Dirichlet allocation (LDA) modeling, commonly called topic modeling, to the event description of each ESD report.[20,21] This technique uses statistical probabilities to create sets of words that are more likely to represent a topic or group and provides the probability of each free-text report being associated with each topic group given the words in the report. Topic modeling requires some preprocessing of event description text as well as model development iterations to identify the ideal number of groups of related ESDs. This topic modeling approach led to 10 groups of related ESDs. Upon clinical review, it was determined that one topic group was not relevant to the scope of this work, and thus, nine groups were included in the analysis.

Coding Process and Analysis Methods

To understand the types of safety issues and other characteristics associated with reports under each topic of related ESDs, we reviewed the 50 most relevant reports per topic based on the highest coherence scores. Each report was manually coded by a human factors expert and a physician with safety expertise to identify the ESD-related safety issue (e.g., malfunction, usability); the ESD(s) associated with the report (e.g., intravenous [IV], ventilator, patient bed); and the associated component(s) (e.g., battery, tubing, screen, button) or ESD subtype(s) (e.g., X-ray, CT). A component was defined as a specific part of an ESD; for example, a wheel lock is a component of a bed. An ESD subtype was defined as a specific ESD that is part of a broader class of ESDs; for example, an X-ray is a subtype of imaging ESDs. The ESD-related safety issues, definitions, and examples are shown in **Table 1** and are based on the FDA's MAUDE taxonomy. One ESD-related safety issue was coded for each report; when multiple safety issues were described, only the initiating event was coded. If a report did not describe an ESD-related safety issue or had insufficient information to determine whether it was ESD-related, the report was excluded from our analysis and replaced with the report with the next highest coherence score

[a] PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety–related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002).[19] All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public. The manuscript has been modified to remove any identifiable information.

from that topic. For each report, the ESD type and component or ESD subtype were noted if they were explicitly mentioned in the event description, with multiple ESDs and components or subtypes coded if referenced in the report.

After the coding was complete, a descriptive analysis was performed to identify patterns in the coded data. The reports comprising these patterns were reviewed by the two subject matter experts to identify clinically meaningful insights. These insights are described in the results following the descriptive analyses.

In addition to coding of the free-text description of each report, one structured category was analyzed: Care Area Group, which indicates the broader care area group associated with the reported patient safety event based on the care area type assigned by the reporting facility.

Results

ESD-Related Safety Issues Identified in Reports

Across all ESD reports reviewed, malfunction was the most frequent ESD-related safety issue coded (n=365 of 450, 81.1%). Among the coded malfunctions, software/output problem (n=122 of 365, 33.4%) and general malfunction (n=103 of 365, 28.2%) were most frequent. The prevalence of software/output problems speaks to the increasingly large role technology plays in the delivery of healthcare and the large number of general malfunctions is indicative of the lack of information found in the free text of patient safety event reports. Other malfunctions included material integrity (n=72 of 365, 19.7%) and activation, positioning, or separation (n=68 of 365, 18.6%). A common theme in the activation, positioning, or separation malfunction category was failed insertion and removal of surgical

Table 1. ESD-Related Safety Issue Codes, Definitions, and Examples

ESD-Related Safety Issue	Definition	Example*
Malfunction - *Activation, Positioning, or Separation*	Malfunction issue associated with any deviations from the documented specifications of the ESD that relate to the sequence of events for activation, positioning, or separation of ESD.	Nurse was attempting to spike a new bag of IV fluids when the spike broke off the tubing after inserting it halfway. Bag of IV fluid and tubing were discarded, and new bag of IV fluids and tubing obtained and spiked without difficulty.
Malfunction - *Software/ Output*	Malfunction issue associated with written programs, codes, and/or software systems that affect ESD performance or communication with another ESD, or a malfunction issue associated with any deviation from the documented specifications of the ESD that relate to the end result, data, or test results provided by the ESD.	Unable to see patient's rhythm on cardiac monitor screen. Called and informed monitor tech. Monitor tech will call with any changes in patient's rhythm. Reported to supervisor who instructed to call Biomed. BioMed representative came and fixed monitor screen.
Malfunction - *Material Integrity*	Malfunction issue associated with any deviations from the documented specifications of the ESD that relate to the limited durability of all material used to construct the ESD.	While the surgeon was using the device, the pad fell off of the device and dropped inside the liver. The surgeon noticed the incident and removed the teflon pad with a forcep and informed me that the device was broken.
Malfunction- *General*	Malfunction issue is cited but there is insufficient information to identify a specific malfunction category.	The nurse assessed IV drips and tubing, prior to going to change IV drip syringes, and noticed fluid dripping out of the infusor bag. Upon tracing the line, the spike (that enters the bottom of the IV bag) had punctured a tiny hole, which had been leaking the IV fluid.
Physically Missing	Part of an ESD is not available when needed for a medical procedure or is noted to be missing at the end of a medical procedure and cannot be located.	After checking with sterile support, the two sets of blades could not be located for start of case. We were informed after the start of the case that the blades had been sent to a wrong location and would be back today.
Sterilization	Issue associated with the presence of any unexpected foreign substance found in an ESD requiring sterilization, on its surface, or in the package materials, which may affect performance or intended use of the ESD, or a problem that compromises effective decontamination of the ESD.	Upon opening instruments for the total knee case, it was discovered that the surgeon's special instrument tray came up from the Sterile Processing Department with no filter in the tray. Instruments were taken out and had to be flash sterilized for the case.
Usability	Issue associated with an act or omission that has a different result than that intended by the manufacturer or expected by the operator; associated with ESD markings or labeling, instructions for use, training and maintenance documentation, or guidelines; or associated with failure to process, service, or operate the ESD according to the manufacturer's recommendations or recognized best practices.	Staff pressed button to put bed in CPR position instead of putting bed rail down, causing patient to lay back quickly, jarring his neck, head, and back. No injuries noted.

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

instruments by the operator and trigger failures for surgical sealant or closure devices. Sterilization (n=40 of 450, 8.9%), usability (n=36 of 450, 8.0%), and physically missing (n=9 of 450, 2.0%) accounted for the remainder of the coded reports. Many of the sterilization and physically missing reports were related to preoperative logistics involving instrument preparation. A review of the reports associated with sterilization and physically missing issues were both related to types of process errors, with a prevalence of reports indicating issues with material handling and preparation by members of the healthcare team.

ESD, Component/Subtype, and Most Frequent ESD-Component/Subtype Pairings

At least one ESD was identified in each of the 450 reviewed reports, with some reports describing multiple ESDs, resulting in 64 unique ESDs identified and a total of 462 ESDs coded across all reports. To gain an understanding of the most frequently mentioned ESDs, **Table 2** shows those ESDs that appeared 1% or more of the time. In total, these 17 ESDs were coded 386 times, and the five most frequent were infusion pump (n=50 of 462, 10.8%), instrument set (n=49, 10.6%), IV (n=49, 10.6%), imaging equipment (n=45, 9.7%), and ventilator (n=43, 9.3%). Two of the three most frequently reported ESDs, infusion pump and IV, were related to the delivery of medications other than via the enteral route.

At least one component/subtype was identified in 348 (77.3%) of the 450 reports reviewed, with some reports describing multiple components/subtypes, resulting in 97 unique components/subtypes identified and a total of 464 times that a component/subtype was coded across all reports reviewed. To gain an understanding of the most frequently mentioned components/subtypes, **Table 3** shows those that appeared in three or more reports. In total, these 49 components/subtypes were coded 405 times and the most frequent were alarm/alert (n=45 of 464, 9.7%), tubing (n=31, 6.7%), tray (n=28, 6.0%), telemetry-related (n=24, 5.2%), and tip (n=24, 5.2%). It should be noted that alarm/alert, balloon, foley, laser, light cord, needle, scissors, screwdriver, pulse oximeter, table and wire are listed as both ESDs and components/subtypes, as sometimes these were the primary ESD noted in the report narrative and sometimes these were described as a component/subtype of an ESD.

To gain a better understanding of the components/subtypes associated with each ESD we examined ESD-component/subtype pairings. To do this, we looked at the ESDs that were reported 3% or more of the time, which resulted in the eight most frequently reported ESDs. Under each ESD we then looked at the components/subtypes with a frequency of 3 or more per ESD and the results are displayed in **Table 4**. The gray-shaded rows show the ESDs coded, and the total number of components/subtypes associated with that specific ESD. For each component/subtype under each ESD, the frequency count and percentage relative to the total number of components/subtypes per ESD are provided (e.g., 22.2% of the total components/subtypes associated with infusion pumps are alarms/alerts). Two components/subtypes (alarm/alert and display) were found to be dominant across multiple ESDs. Alarms/alerts appeared as a top ESD-component/subtype pairing for phones (n=11 of 25, 44.0%), ventilators (n=17 of 52, 32.7%), infusion pumps (n=12 of 54, 22.2%), and patient monitors (n=8 of 51, 15.7%). Displays were also found to be a top ESD-component/subtype pairing across ESDs for ventilators (n=8 of 52, 15.4%) and patient monitors (n=6 of 51, 11.8%). For instrument sets, the components/subtypes identified most frequently were tray (n=28 of 65, 43.1%) and wrapper (n=14 of 65, 21.5%), and all point to these components/subtypes being problematic in the sterilization of equipment and instrument sets.

Table 2. Frequency Counts and Percentages of Most Frequent ESDs

Infusion Pump	50 (10.8%)
Instrument Set	49 (10.6%)
IV	49 (10.6%)
Imaging Equipment	45 (9.7%)
Ventilator	43 (9.3%)
Patient Monitor	38 (8.2%)
Patient Bed	28 (6.1%)
Phone	14 (3.0%)
Sealer	12 (2.6%)
Stapler	10 (2.2%)
Needle	9 (1.9%)
Scope	8 (1.7%)
Clip Appliers	7 (1.5%)
Stretcher	7 (1.5%)
Catheter	6 (1.3%)
Suture	6 (1.3%)
Stent/Balloon Delivery System	5 (1.1%)
Total	**386 (83.5%)**

Percentages are derived from the frequency count divided by the total number of times that an ESD was coded across all reports reviewed (N=462).

ESD-Related Safety Issues by ESD

Table 5 shows the frequency count and percentage of safety issues associated with ESDs that were mentioned 1% or more of the time (17 unique ESDs mentioned 386 times). Software/output malfunctions were dominant with infusion pumps (n=43 of 123, 35.0%), imaging equipment (n=24 of 123, 19.5%), and patient monitors (n=24 of 123, 19.5%). While material integrity malfunctions were the least common malfunction, these were prevalent with IVs (n=17 of 39, 43.6%) and needles (n=9 of 39, 23.1%). Activation, positioning, or separation malfunctions were associated with a variety of ESDs compared to other safety issues. Outside of malfunctions, notable results also included usability issues associated with patient monitors (n=9 of 28, 32.1%), instrument sets (n=7 of 28, 25.0%), and patient beds (n=5 of 28, 17.9%), and sterilization issues associated with instrument sets (n=37 of 38, 97.4%).

Care Area Group by ESD

Table 6 shows the frequency count and percentages of reports for care area group across the 17 most frequently reported ESDs. Surgical services had the largest number of reports across care area groups (n=126 of 386, 32.6%), followed by med/surg (n=49 of 386, 12.7%), intensive care unit (ICU) (n=40 of 386, 10.4%), pediatric intensive care unit (PICU) (n=35 of 386, 9.1%), and neonatal intensive care unit (NICU) (n=31 of 386, 8.0%). The surgical services care area group had the greatest breadth of associated ESDs, with instrument sets (n=49 of 126, 38.9%), imaging equipment (n=14 of 126, 11.1%), and patient beds (n=10 of 126, 7.9%) as the three most prevalent ESDs. Med/surg also had several associated ESDs, with patient monitor (n=17 of 49, 34.7%), phone (n=11 of 49, 22.4%),

Table 3. Frequency Counts and Percentages of Most Frequent Components/Subtypes

Component/Subtype	Frequency Count (%)
Alarm/Alert	45 (9.7%)
Tubing	31 (6.7%)
Tray	28 (6.0%)
Telemetry-Related	24 (5.2%)
Tip	24 (5.2%)
Connector	18 (3.9%)
Display	17 (3.7%)
Filter	17 (3.7%)
Wrapper	14 (3.0%)
CT Scanner	11 (2.4%)
Sensor	9 (1.9%)
Wheel Lock	9 (1.9%)
Wire	7 (1.5%)
Head	7 (1.5%)
Image	7 (1.5%)
Table	6 (1.3%)
Balloon	6 (1.3%)
Cap	6 (1.3%)
Clip	6 (1.3%)
Sterilization Indicator Strip	6 (1.3%)
Pulse Oximeter	5 (1.1%)
Channel	5 (1.1%)
Battery	5 (1.1%)
Button	5 (1.1%)
Blade	5 (1.1%)
Pump Brain	5 (1.1%)
C-Arm	5 (1.1%)
Monitor Box	4 (0.9%)
Valve	4 (0.9%)
Bag	4 (0.9%)
Sheath	4 (0.9%)
Stent	4 (0.9%)
Oxygen Source	4 (0.9%)
Hand Piece	3 (0.6%)
Mammography	3 (0.6%)
X-Ray	3 (0.6%)
Screw	3 (0.6%)
Staple	3 (0.6%)
Fluoro	3 (0.6%)
Controls	3 (0.6%)
Needle	3 (0.6%)
Camera	3 (0.6%)
Spike	3 (0.6%)
Rail	3 (0.6%)
Stand	3 (0.6%)
Cassette	3 (0.6%)
Circuit	3 (0.6%)
Probe	3 (0.6%)
Power Source	3 (0.6%)
Total	**405 (87.3%)**

Percentages are derived from the frequency count divided by the total number of times that a component/subtype was coded across all reports reviewed (N=464).

Table 4. Most Frequent ESD-Component/Subtype Pairings

ESD-Component/Subtype	Frequency Count of Components/ Subtypes Per ESD (%)
Infusion Pump (n=54 components/subtypes)	
Alarm/Alert	12 (22.2%)
Brain	5 (9.3%)
Channel	5 (9.3%)
Instrument Set (n=65 components/subtypes)	
Tray	28 (43.1%)
Wrapper	14 (21.5%)
Sterilization Indicator Strip	6 (9.2%)
Filter	4 (6.2%)
IV (n=77 components/subtypes)	
Tubing	30 (39.0%)
Connector	18 (23.4%)
Filter	13 (16.9%)
Cap	6 (7.8%)
Bag	3 (3.9%)
Spike	3 (3.9%)
Imaging Equipment (n=62 components/subtypes)	
CT Scanner	11 (17.7%)
Image	7 (11.3%)
C-Arm	5 (8.1%)
Table	5 (8.1%)
Stand	3 (4.8%)
Mammography	3 (4.8%)
X-Ray	3 (4.8%)
Fluoro	3 (4.8%)
Ventilator (n=52 components/subtypes)	
Alarm/Alert	17 (32.7%)
Display	8 (15.4%)
Sensor	5 (9.6%)
Battery	4 (7.7%)
Power Source	3 (5.8%)
Patient Monitor (n=51 components/subtypes)	
Telemetry-Related	21 (41.2%)
Alarm/Alert	8 (15.7%)
Display	6 (11.8%)
Monitor Box	4 (7.8%)
Pulse Oximeter	3 (5.9%)
Patient Bed (n=30 components/subtypes)	
Head	6 (20.0%)
Wheel Lock	5 (16.7%)
Rail	3 (10.0%)
Phone (n=25 components/subtypes)	
Alarm/Alert	11 (44.0%)
Telemetry-Related	7 (28.0%)

Percentages are derived from the frequency count divided by the total number of components/subtypes coded under an ESD.

and infusion pump (n=6, 12.2%) as the three most prevalent ESDs. Another notable finding includes the concentration of reports in the PICU, NICU, and pediatric care area groups, totaling 23.6% (n=91 of 386) for care area groups associated with pediatric populations. The PICU, NICU, and pediatric care area groups were primarily related to IVs (n=37 of 91, 40.7%), infusion pumps (n=28 of 91, 30.8%), and ventilators (n=16 of 91, 17.6%).

Discussion

The results highlight pervasive contributions of ESD malfunctions to patient safety risks. Software/output problems were found to be the dominant malfunction, primarily associated with infusion pumps, patient monitors, and imaging. General malfunctions were the second highest malfunction, followed by material integrity and activation, positioning, or separation. Sterilization comprised nearly 10% of the ESD-related safety issues. Looking at the component/subtypes associated with the ESD reports, alarm/alert was the most frequent and was often identified with infusion pumps, ventilators, patient monitors, and phones. Further research is needed to identify how alarm/alert issues may be contributing to ESD patient safety risks. Usability was the second least frequently coded ESD-related safety issue across all reports. These descriptive analyses and qualitative insights can inform ESD patient safety practices.

Addressing Malfunctions

The prevalence of software/output malfunctions suggests a need to better understand how healthcare providers are interacting with different ESDs and components/subtypes to ensure safe use. There are opportunities to address software/output issues and mitigate safety hazards before they result in patient harm. First, these ESDs should be rigorously assessed during procurement to identify potential issues before purchase. This will prevent ESDs that may pose safety challenges from being introduced in the care environment. A patient safety procurement assessment tool, described later in the discussion, can support healthcare facilities in this process. Second, healthcare facilities should monitor ESDs for malfunctions with biomedical engineers and the ESD manufacturers to understand the context in which these malfunctions are occurring and determine how to best address these safety issues.

Some of the ESD malfunctions were coded as general malfunctions in part because not enough information was provided to identify a more specific code. Healthcare facilities should ensure detailed information is being collected and reported so that the malfunctions can be better understood. For example, certain reports were associated with broken objects during surgery or procedures, specifically needles, wire, balloons, and catheters. Of these broken components/subtypes, some were intentionally retained in the patient due to a high risk of removal and others were unable to be found. As broken components can lead to safety risks or patient harm, manufacturers could explore needle, wire, balloon, and catheter design and reliability to identify possible sources of defects and material strength issues. In addition, when objects break, these safety issues should be investigated to determine what instruments were used to grasp and present them to the surgeon along with the user's understanding of how to use these tools.

A review of reports coded in the activation, positioning, or separation malfunction category revealed that a common theme was failed insertion and removal of surgical instruments by the operator. Further investigation is needed to determine if insertion and removal processes can be improved through more user-centered design modifications or training enhancements. In addition, trigger failures for surgical sealant or closure devices were a dominant theme. This trigger failure theme suggests that the frequency and comprehensiveness of preventive maintenance audits associated with the relevant ESDs (e.g., stapler, sealer) should be reviewed to determine if adjustments are needed for manually activated tools. Optimizing preventive maintenance is critical as a risk mitigation measure but must be balanced against site resources and frequency of safety event occurrence for the specific ESD.[22]

Sterilization and Physically Missing Issues: Process Management

While reports coded as physically missing were not necessarily indicating safety issues related to ESDs themselves, but the processes around handling them, it was a relevant finding worth noting. Specifically, the review showed dominant themes related to preoperative logistics involving instrument preparation (nonsterile instruments found or instruments missing in trays). This information highlights the need for process improvement initiatives to understand the potential causes of these events. Surgical equipment checklists with explicit reference to equipment availability and sterility have been recommended in these contexts to provide an additional preventive mechanism.[23]

Prominence of Usability Issues

Although usability was not a prominent patient safety issue in the patient safety event reports we reviewed, usability issues have been shown to be directly associated with patient harm in research focused on medical devices.[24,25] One reason for this may be the difficulty for reporters to identify and describe usability-related issues. There is a need for a better way to capture usability- and safety-related issues with medical devices.

The most commonly coded ESDs among usability-related safety issues were patient monitor, instrument set, and patient bed. Of clinical significance, a review of patient bed reports often described bed position controls. Bed issues were also prominent among the malfunction categories (general; material integrity; activation, positioning, or separation), due to issues with position changes of the bed and patient transfer into the bed. Even though bed malfunctions were largely associated with manual handling and human-system interaction, due to sparse narrative detail, it was unclear if usability issues influenced the outcome.

Care Area Group Safety Issues

A concentration of reports in PICU, NICU, and pediatric care areas was found for IVs and infusion pumps. This research highlights the need to further explore why pediatric and neonatal care areas are experiencing a large percentage of safety issues related to the tools associated with the infusion of medications. ESD-related safety issues associated with patient monitors and phones were found to be prominent within the med/surg care area group in comparison to the ICU, PICU, and NICU. These results may be indicative of the increased staffing in intensive care units likely leading to fewer monitoring misses and easier communication, with more reliance on monitoring software and technology for communication occurring in med/surg care areas.

Policy Implications

Our results have policy implications for federal organizations like the FDA, as well as for state-level agencies and other stakeholders. For high-risk ESDs that have clear patient safety consequences, guidelines for design and standards for malfunction rates may be warranted. There may be an opportunity to improve manufacturer communication to healthcare facility customers about known malfunctions, and guidance for remediation should be provided in a timely fashion. In addition, healthcare facilities may need certain standards in place to rigorously test ESDs for malfunctions to prevent

Table 5. Frequency Counts and Percentages of ESD-Related Safety Issues per Most Frequent ESD

	Infusion Pump	Instrument Set	IV	Imaging Equipment	Ventilator	Patient Monitor	Patient Bed	Phone	Sealer	Stapler	Needle	Scope	Stretcher	Clip Appliers	Catheter	Suture	Stent/Balloon Delivery System	Total
Malfunctions	50 (16.0%)	-	48 (15.4%)	45 (14.4%)	41 (13.1%)	29 (9.3%)	22 (7.1%)	13 (4.2%)	11 (3.5%)	10 (3.2%)	9 (2.9%)	6 (1.9%)	5 (1.6%)	7 (2.2%)	6 (1.9%)	5 (1.6%)	5 (1.6%)	**312 (100.0%)**
Software/ Output Problem	43 (35.0%)	-	-	24 (19.5%)	19 (15.4%)	24 (19.5%)	-	13 (10.6%)	-	-	-	-	-	-	-	-	-	**123 (100.0%)**
General	5 (5.6%)	-	13 (14.6%)	17 (19.1%)	19 (21.3%)	3 (3.4%)	15 (16.9%)	-	6 (6.7%)	1 (1.1%)	-	2 (2.2%)	5 (5.6%)	1 (1.1%)	2 (2.2%)	-	-	**89 (100.0%)**
Activation, Positioning, or Separation	2 (3.3%)	-	18 (29.5%)	1 (1.6%)	2 (3.3%)	2 (3.3%)	5 (8.2%	-	5 (8.2%)	9 (14.8%)	-	2 (3.3%)	-	6 (9.8%)	4 (6.6%)	-	5 (8.2%)	**61 (100.0%)**
Material Integrity	-	-	17 (43.6%)	3 (7.7%)	1 (2.6%)	-	2 (5.1%)	-	-	-	9 (23.1%)	2 (5.1%)	-	-	-	5 (12.8%)	-	**39 (100.0%)**
Sterilization	-	37 (97.4%)	-	-	-	-	-	-	-	-	-	1 (2.6%)	-	-	-	-	-	**38 (100.0%)**
Usability	-	7 (25.0%)	-	-	2 (7.1%)	9 (32.1%)	5 (17.9%)	1 (3.6%)	1 (3.6%)	-	-	1 (3.6%)	2 (7.1%)	-	-	-	-	**28 (100.0%)**
Physically Missing	-	5 (62.5%)	1 (12.5%)	-	-	-	1 (12.5%)	-	-	-	-	-	-	-	-	1 (12.5%)	-	**8 (100.0%)**
Total	**50 (13.0%)**	**49 (12.7%)**	**49 (12.7%)**	**45 (11.7%)**	**43 (11.1%)**	**38 (9.8%)**	**28 (7.3%)**	**14 (3.6%)**	**12 (3.1%)**	**10 (2.6%)**	**9 (2.3%)**	**8 (2.1%)**	**7 (1.8%)**	**7 (1.8%)**	**6 (1.6%)**	**6 (1.6%)**	**5 (1.3%)**	**386 (100.0%)**

Percentages are derived from row total.

Table 6. Frequency Counts and Percentages of Care Area Group per Most Frequent ESD

	Infusion Pump	Instrument Set	IV	Imaging Equipment	Ventilator	Patient Monitor	Patient Bed	Phone	Sealer	Stapler	Needle	Scope	Stretcher	Clip Appliers	Catheter	Suture	Stent/Balloon Delivery System	Total
Surgical Services	1 (0.8%)	49 (38.9%)	1 (0.8%)	14 (11.1%)	-	-	10 (7.90%)	-	7 (5.6%)	9 (7.1%)	8 (6.3%)	8 (6.3%)	5 (4.0%)	4 (3.2%)	2 (1.6%)	6 (4.8%)	2 (1.6%)	**126 (32.6%)**
Med/Surg*	6 (12.2%)	-	3 (6.1%)	-	1 (2.0%)	17 (34.7%)	1 (2.0%)	11 (22.4%)	3 (6.1%)	1 (10.0%)	1 (2.0%)	-	-	3 (6.1%)	-	-	2 (4.1%)	**49 (12.7%)**
ICU	7 (17.5%)	-	3 (7.5%)	-	18 (45.0%)	6 (15.0%)	4 (10.0%)	2 (5.0%)	-	-	-	-	-	-	-	-	-	**40 (10.4%)**
PICU	10 (28.6%)	-	11 (31.4%)	1 (2.9%)	9 (25.7%)	2 (5.7%)	1 (2.9%)	1 (2.9%)	-	-	-	-	-	-	-	-	-	**35 (9.1%)**
NICU	11 (35.5%)	-	12 (38.7%)	-	7 (22.6%)	1 (3.2%)	-	-	-	-	-	-	-	-	-	-	-	**31 (8.0%)**
Imaging/ Diagnostic	-	-	-	20 (71.4%)	-	1 (3.6%)	2 (7.1%)	-	-	-	-	-	-	-	4 (14.3%)	-	1 (3.6%)	**28 (7.3%)**
Pediatric	7 (28.0%)	-	14 (56.0%)	-	-	2 (8.0%)	2 (8.0%)	-	-	-	-	-	-	-	-	-	-	**25 (6.5%)**
Other	3 (23.1%)	-	1 (7.7%)	4 (30.8%)	2 (15.4%)	-	-	-	2 (15.4%)	-	-	-	1 (7.7%)	-	-	-	-	**13 (3.4%)**
Clinic/Outpatient Office	3 (27.3%)	-	2 (18.2%)	6 (54.5%)	-	-	-	-	-	-	-	-	-	-	-	-	-	**11 (2.8%)**
Emergency Department	-	-	-	-	1 (14.3%)	4 (57.1%)	1 (14.3%)	-	-	-	-	-	1 (14.3%)	-	-	-	-	**7 (1.8%)**
Specialty Unit	1 (14.3%)	-	1 (14.3%)	-	2 (28.6%)	1 (14.3%)	2 (28.6%)	-	-	-	-	-	-	-	-	-	-	**7 (1.8%)**
Intermediate Unit	-	-	1 (25.0%)	-	1 (25.0%)	1 (25.0%)	1 (25.0%)	-	-	-	-	-	-	-	-	-	-	**4 (1.0%)**
Rehabilitation Unit	-	-	-	-	-	1 (25.0%)	3 (75.0%)	-	-	-	-	-	-	-	-	-	-	**4 (1.0%)**
Respiratory	-	-	-	-	2 (66.7%)	1 (33.3%)	-	-	-	-	-	-	-	-	-	-	-	**3 (0.8%)**
Labor and Delivery	1 (50.0%)	-	-	-	-	-	1 (50.0%)	-	-	-	-	-	-	-	-	-	-	**2 (0.5%)**
Nursery	-	-	-	-	-	1 (100.0%)	-	-	-	-	-	-	-	-	-	-	-	**1 (0.3%)**
Total	**50**	**49**	**49**	**45**	**43**	**38**	**28**	**14**	**12**	**10**	**9**	**8**	**7**	**7**	**6**	**6**	**5**	**386**

Percentages are derived from row total.
*The med/surg care area group includes telemetry care areas.

malfunctions during critical patient care activities. Policies internal to healthcare facilities may need to include reliability audits for ESD preventive maintenance and enhanced training and procedural supports for high-risk processes involving ESDs. Further, in addition to the usability testing performed by many manufacturers, healthcare facilities should also perform internal testing for their specific user groups, as procedural needs may vary among users at different sites.

Patient Safety Procurement Assessment Tool

Improved ESD safety assessment during procurement could improve the likelihood of purchasing ESDs that are well designed with low malfunction rates. Preventing poor quality ESDs from being adopted by healthcare facilities is the most proactive patient safety approach a healthcare facility can take. **Online Supplement Appendix A** contains a patient safety procurement assessment tool that healthcare facilities can use to guide their vetting and selection of ESDs. While many healthcare facilities may already be using similar tools and may already follow the recommendations provided below, not all healthcare facilities have adopted these practices.

To address ESD usability issues, healthcare facilities can do the following during procurement:

- Assess the usability and safety of ESDs. Recognizing healthcare facilities have limited resources to conduct assessments, facilities should focus on ESDs that are used frequently and may pose the greatest risk of harm. There are several methods that can be used to do this. Formal usability testing can be conducted, which involves identifying the typical user group of the ESD and having those users complete typical tasks while measuring time to complete the task, error rates, and satisfaction. This process can be expensive and requires usability knowledge to effectively create scenarios and measure efficiency, effectiveness, and satisfaction. Another approach is to complete a rapid heuristic evaluation. **Online Supplement Appendix A** contains a tool to provide knowledge and guidance on how to conduct a heuristic evaluation. This tool can be used to assess the usability of any ESD and does not require usability domain knowledge. Healthcare facilities can also ask ESD manufacturers for information on how the ESD was usability tested and ask for measures of usability. Some manufacturers may provide this information.
- Learn from other organizations. Other healthcare facilities that are already using the ESD could be contacted to inquire about usability and safety issues.

To address malfunctions, healthcare facilities can do the following during procurement:

- Search publicly available databases that contain reports about patient safety issues associated with ESDs. For example, the FDA's MAUDE database contains reports on safety issues associated with medical devices.[19] These databases can provide insights on the types of malfunctions, or other issues, that have been reported about the ESD under consideration.
- Ask the ESD manufacturer for malfunction rates and whether any issues have been reported by users. For new equipment with no history of use, ask the manufacturer about internal testing results related to malfunctions and usability. Compare malfunction information across products under consideration to determine which ESDs would be best suited for your facility.
- Consider contacting other facilities that have already adopted the ESD being considered and ask the facility about malfunctions and other issues they may have experienced.

Limitations

This study is limited to the reports submitted to PA-PSRS over two years so the results may not be generalizable or inclusive of all ESD issues. Despite mandatory reporting laws in Pennsylvania, events are self-reported and may not represent all ESD-related events from the reporting healthcare facilities. Additionally, the search strategy was limited to the ESD event type, and ESD-related safety issues may be present in reports submitted under different event types. Furthermore, our analysis was limited to the information provided in the patient safety event reports and we were not able to follow up with reporters, healthcare facilities, or manufacturers for additional information about ESDs. COVID-19 may have impacted the number and types of ESD issues reported. In addition, if certain ESDs were recalled or highlighted to have certain malfunctions, this information may prompt healthcare workers to report on these issues more frequently. The topic modeling technique required preprocessing of ESD event description text, which included the removal of high-frequency and low-frequency words. This may have resulted in some relevant ESD information being removed from reports and not being included in the topic modeling results.

Conclusion

The continued occurrence of ESD-related safety issues, especially malfunctions, highlights the need for healthcare stakeholders to create more proactive and coordinated risk mitigation efforts. Oversight agencies can provide more optimal guidelines and standards to inform manufacturer design and development and can identify better ways to encourage use of these guidelines and standards. Manufacturers can better identify, measure, and share malfunction types and rates. Healthcare facilities can improve patient safety assessments during the procurement process.

Note

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

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Patient Safety Trends in 2022: An Analysis of 256,679 Serious Events and Incidents From the Nation's Largest Event Reporting Database

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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.

Introduction

Pennsylvania is the only state that requires healthcare facilities to report all events that cause harm or have the potential to cause harm to a patient. These patient safety events are reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a], which is the largest repository of patient safety data in the United States and one of the largest in the world, with over 4.5 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)[b]. 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 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.

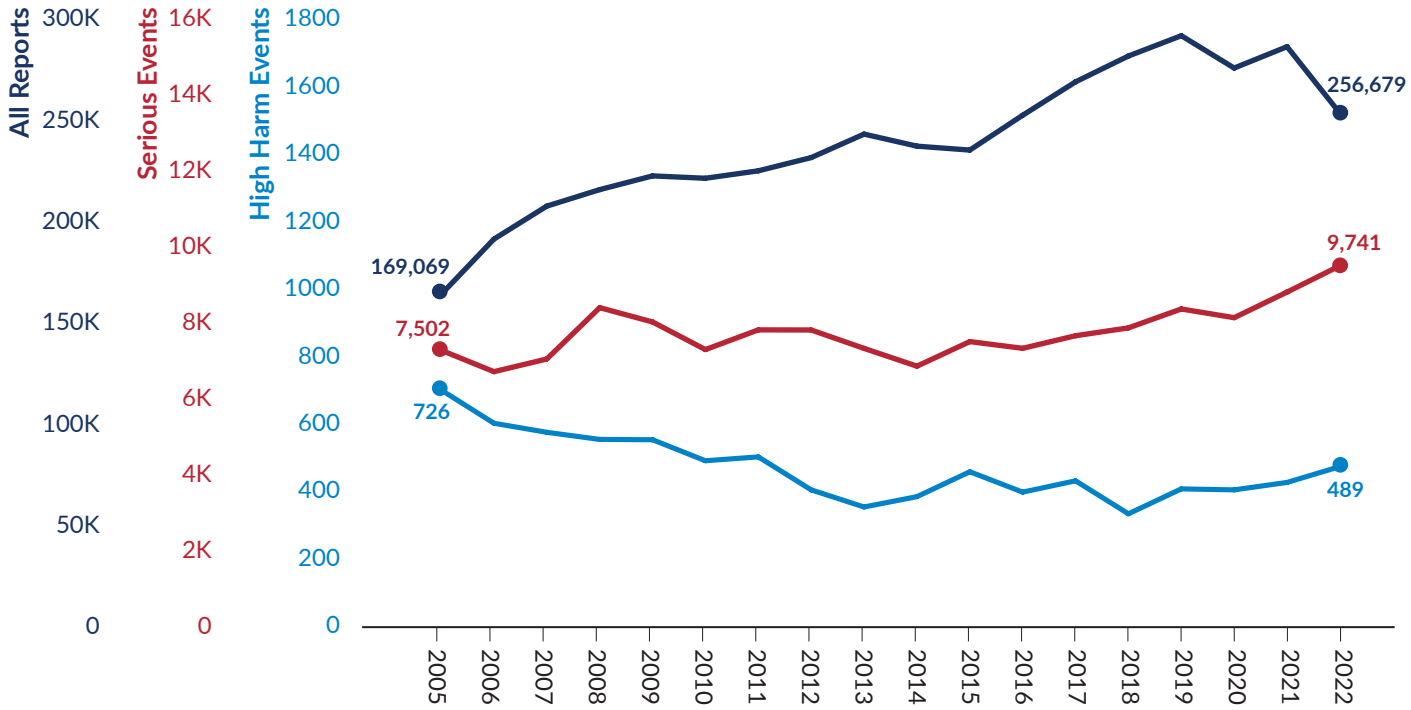
Table 1. PA-PSRS Harm Scores

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

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

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

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.

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.

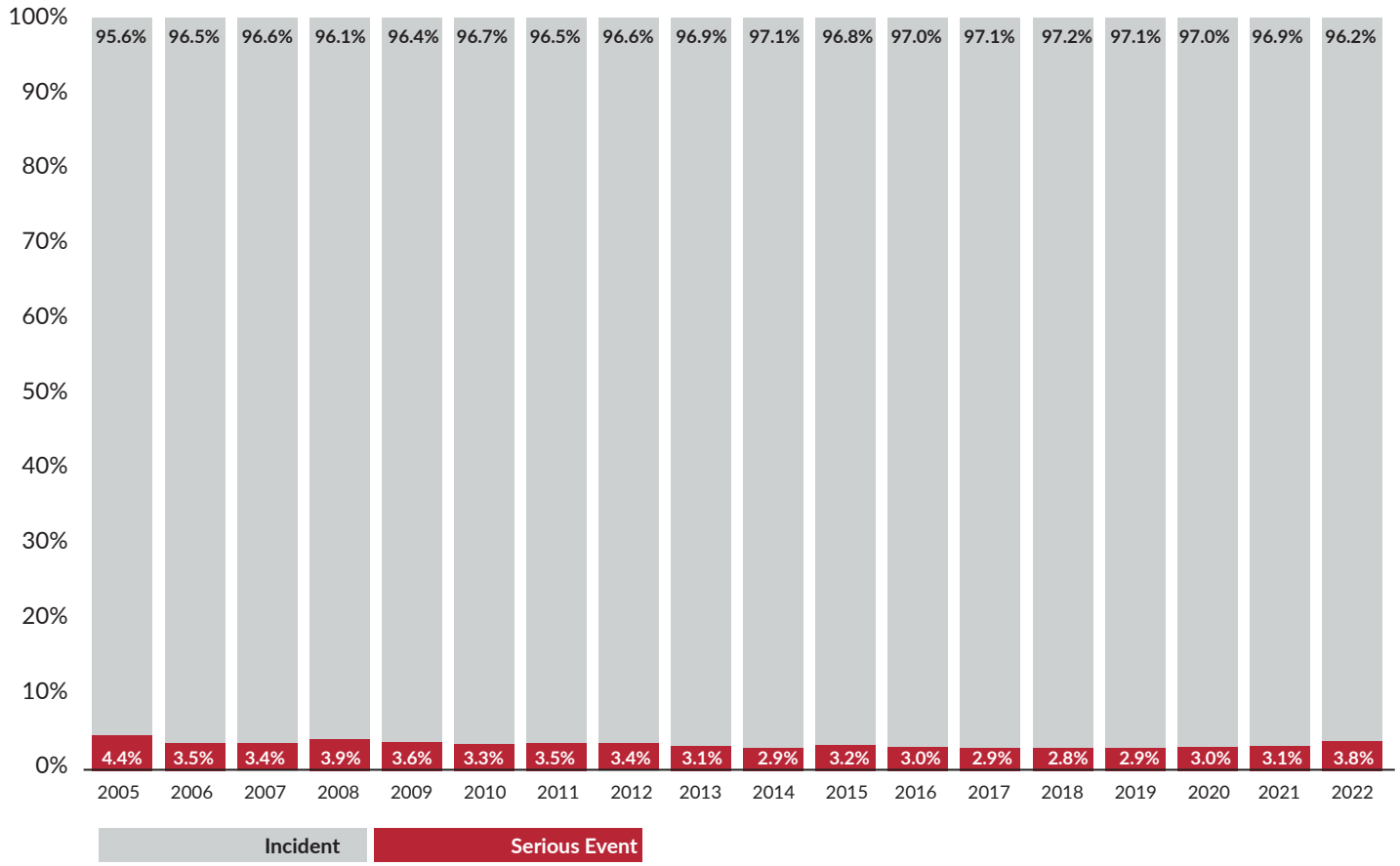
Table 2 shows a breakdown of incidents and serious events by facility type from the past three years. From 2021 to 2022, the number of hospital reports decreased by 33,432 (12.0%), whereas reports from other acute care facilities (ASFs, birthing centers [BRCs], and abortion facilities [ABFs]) increased 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 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).

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%**

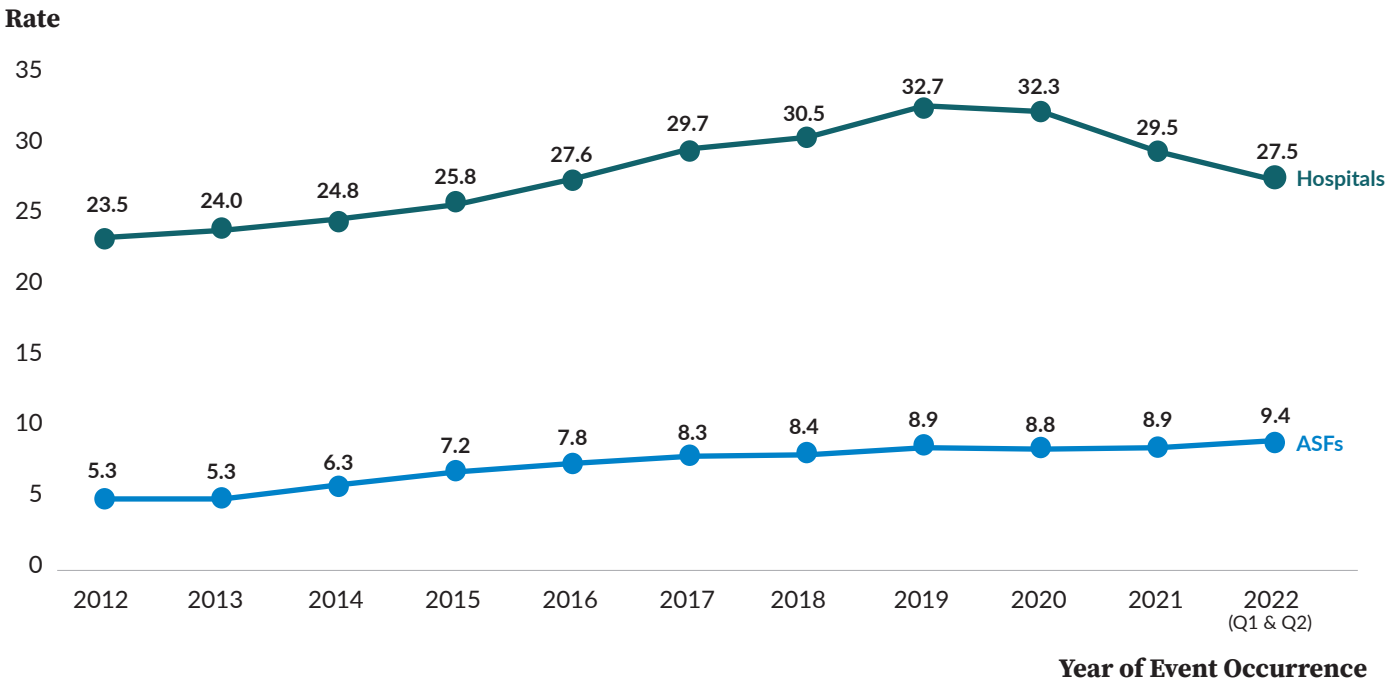
Note: Other Acute Care Facilities include ambulatory surgical facilities, birthing centers, and abortion facilities.
The decrease in total number of reports in 2022 can primarily be attributed to three facilities that collectively submitted 18,601 fewer reports in 2022 compared to 2021, which accounted 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.

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 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.

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%

Table 6. (continued)

		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
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	100.0%
	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%

Table 6. (continued)

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
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.

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.

Introduction

The Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] is the largest repository of patient safety data in the United States. In addition to over 4.5 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.

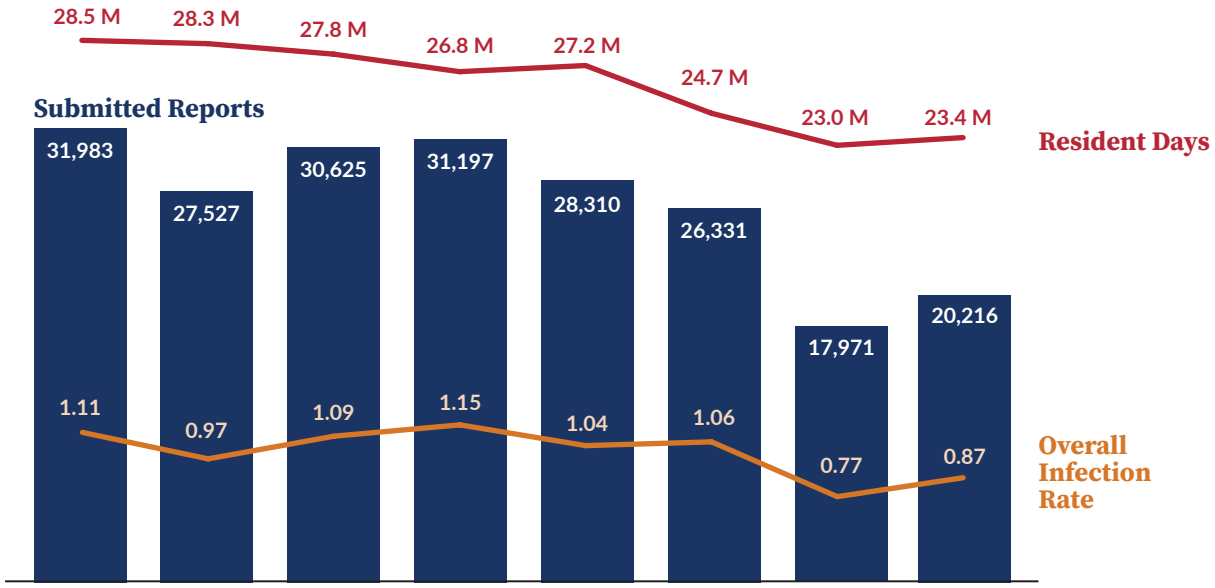
Infection counts reflect the year when infection reports were submitted in PA-PSRS. Overall rates are based on infection confirmation dates and resident days. Specific infection rates related to urinary catheters and central lines are based on urinary catheter and central line days, respectively. In 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.

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

Figure 2. PA-PSRS LTC Infection Rates per 1,000 Resident Days by Region—2021 Versus 2022

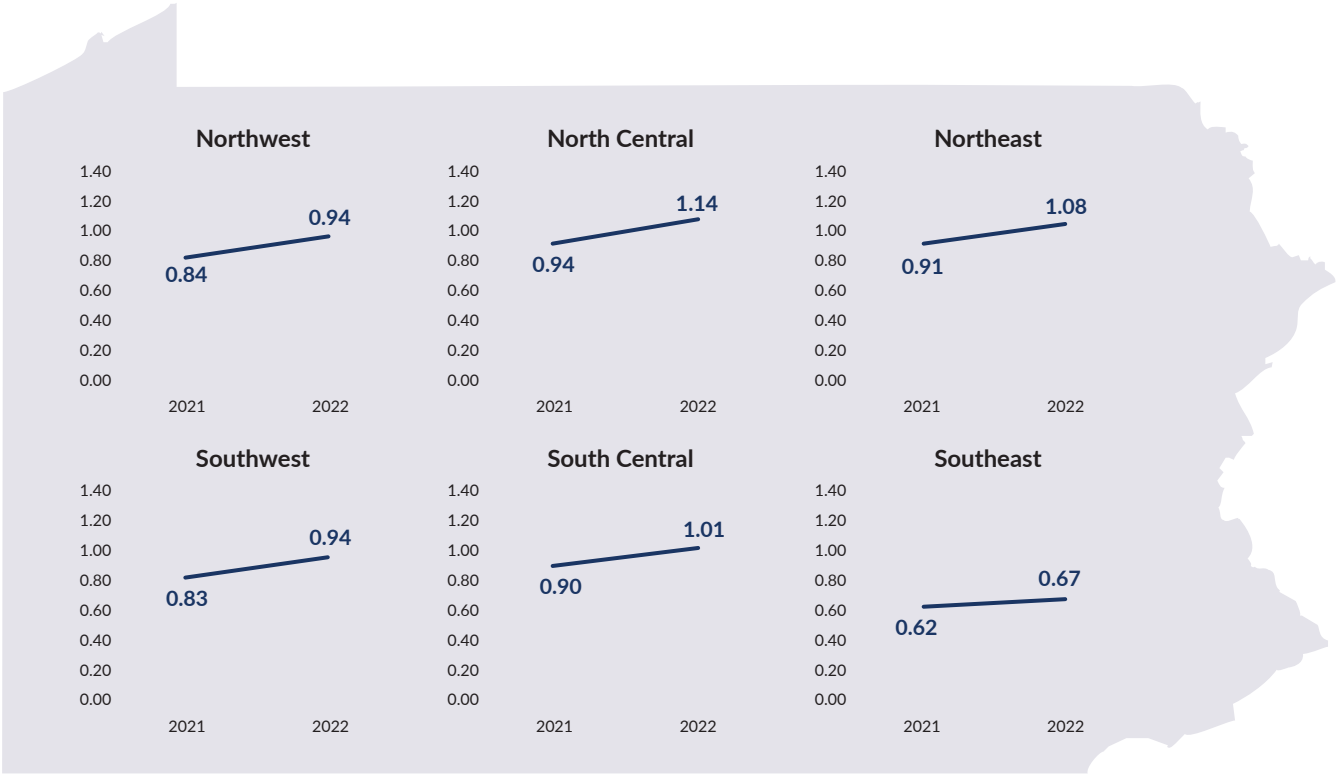


Table 1. LTC Infection Reports Submitted to PA-PSRS and Infection Rates per 1,000 Resident Days by Region

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%).

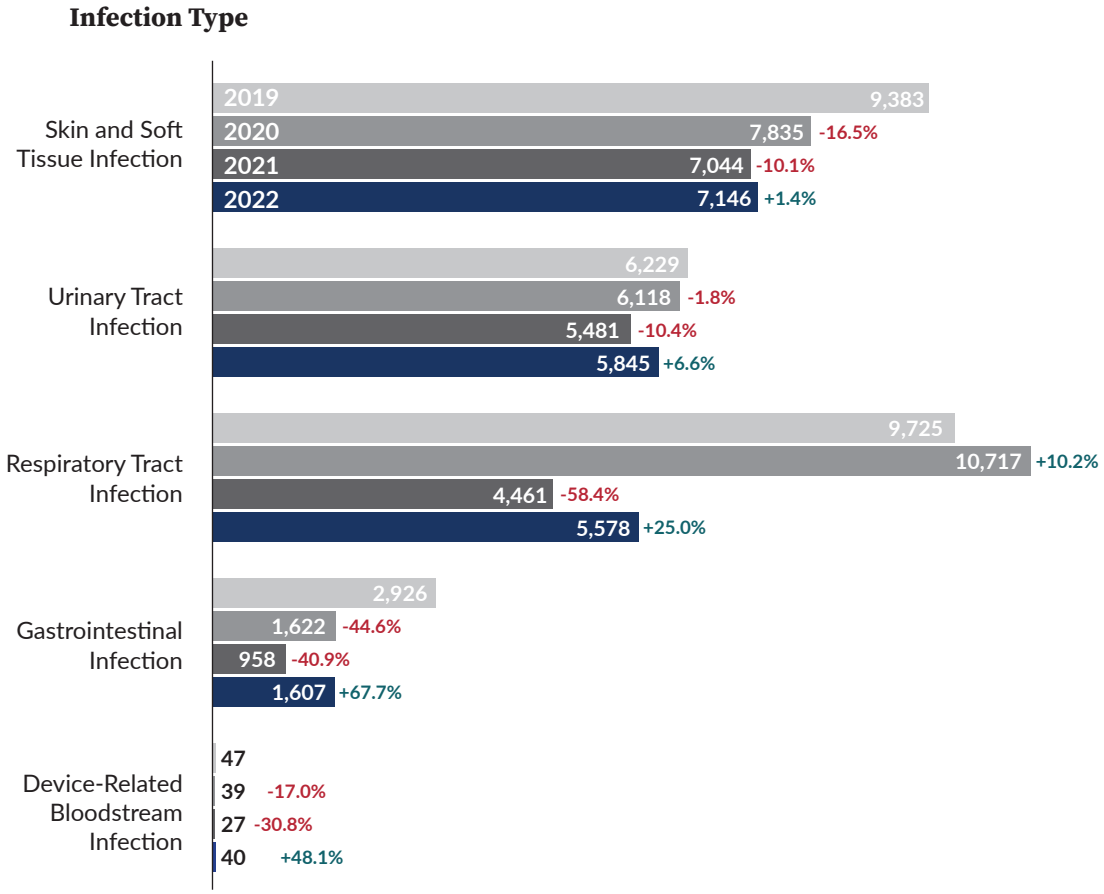
LTC Healthcare-Associated Infection Subtypes

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

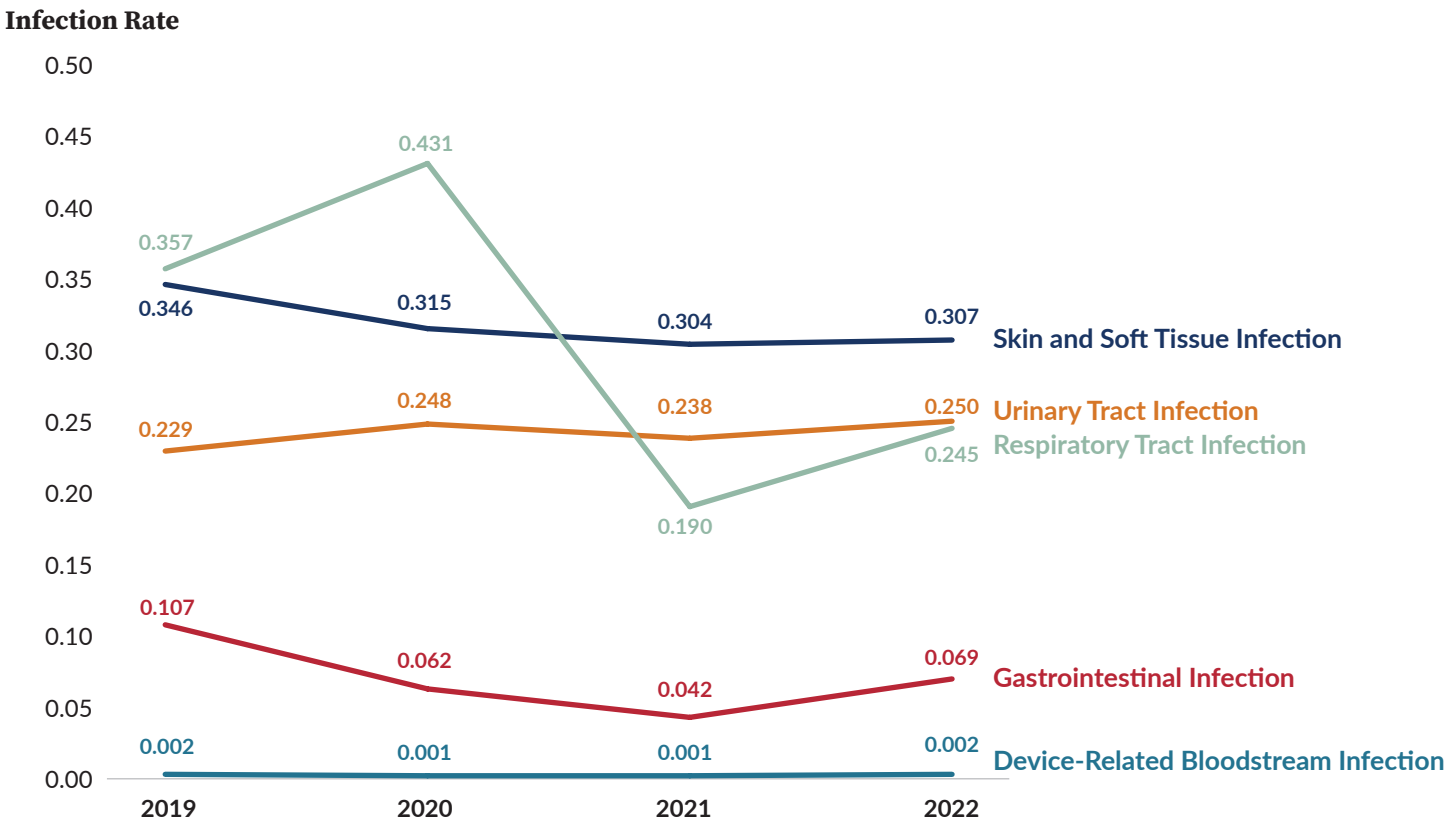
Table 3. LTC Infection Reports Submitted to PA-PSRS in 2022 by Infection Type and Care Area

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

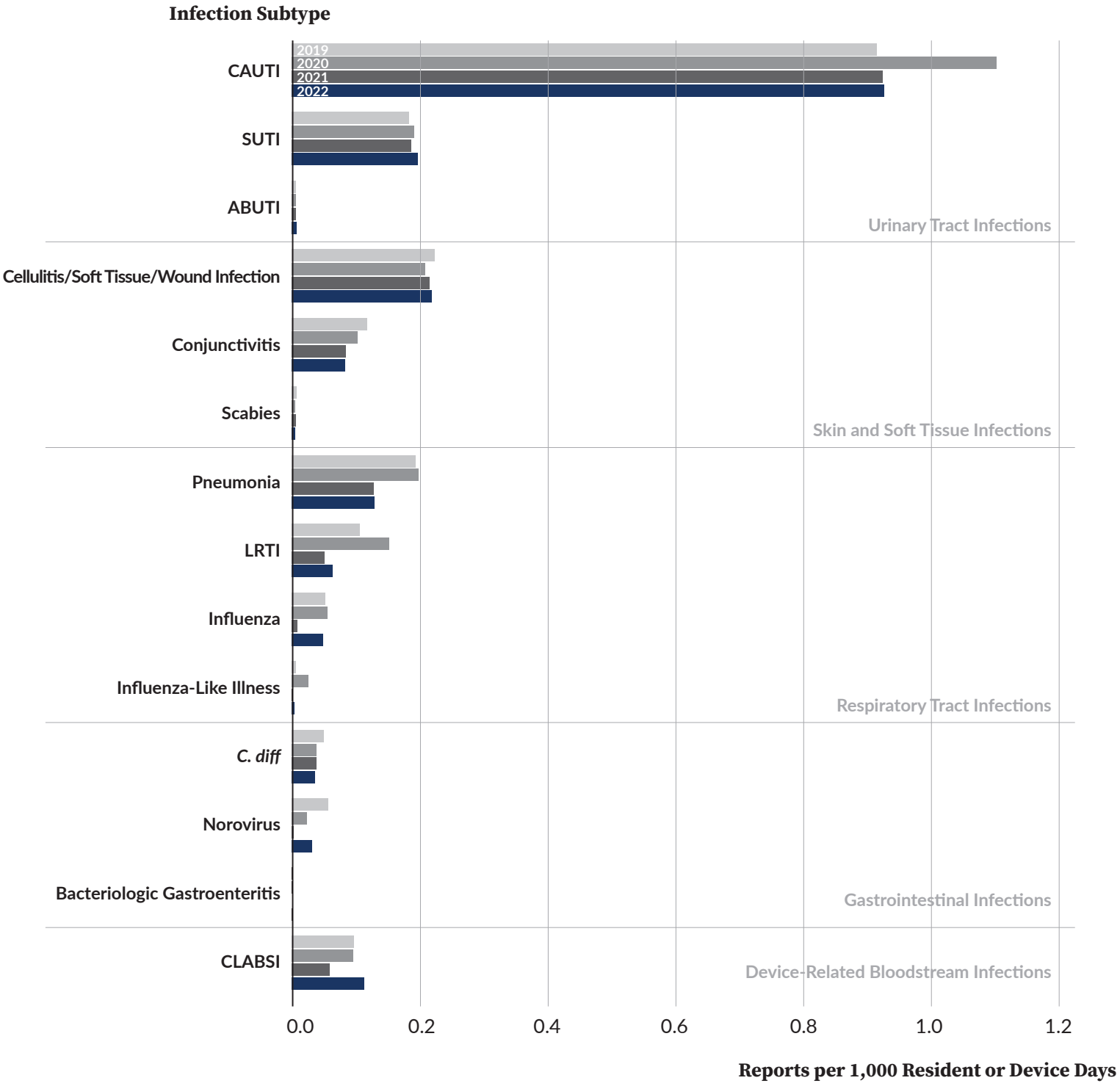
Infection Subtype	Skilled Nursing/ Short-Term Rehab. Unit	Nursing Unit	Mixed Unit	Dementia Unit	Ventilator-Dependent Unit	Total
Cellulitis/Soft Tissue/Wound Infection	1,679	1,566	1,488	293	55	**5,081**
SUTI	1,698	1,295	1,330	243	23	**4,589**
Pneumonia	1,083	742	857	164	159	**3,005**
Conjunctivitis	619	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

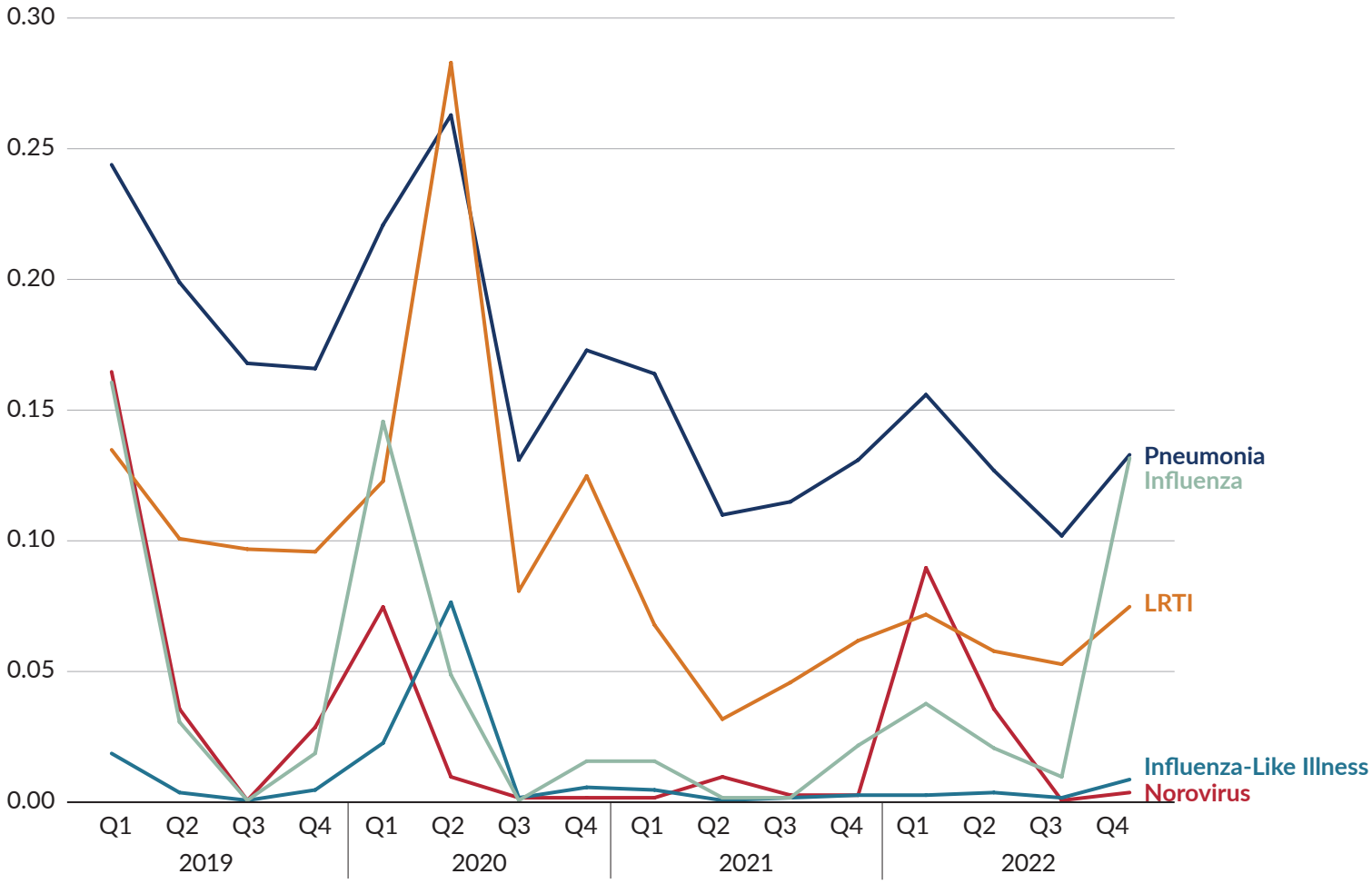
Care Area	Infection Type	2019	2020	2021	2022	2019 to 2020	2020 to 2021	2021 to 2022
Dementia Unit	Influenza	0.040	0.044	0.002	0.023	12.1%	-95.2%	993.1%
	LRTI	0.102	0.136	0.027	0.061	33.9%	-80.0%	124.1%
	CAUTI	1.133	1.105	0.451	0.980	-2.4%	-59.2%	117.1%
	Influenza-Like Illness	0.006	0.032	0.001	0.002	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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Abstract

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.

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 (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

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

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.

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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2022 Pennsylvania Patient Safety Reporting: **Updated Rates for Acute Care Event Reports**

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

[1]Patient Safety Authority

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Introduction

In the article published on April 28, 2023, on patient safety trends in 2022,[1] reporting rates for 2022 were calculated based on Q1 and Q2 only, as denominator data for Q3 and Q4 were not yet available. This brief update provides the final rates for 2022 using all quarters of data, contrasting them with preliminary rates based on Q1 and Q2 only.

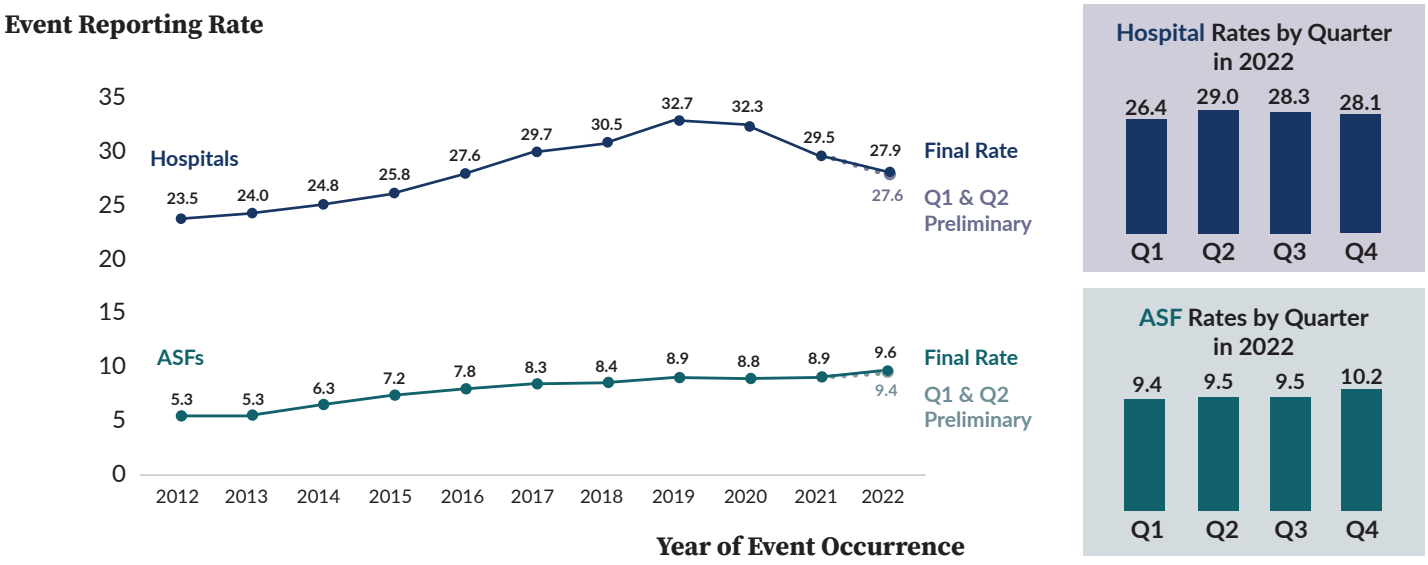
Methods

This analysis was performed using data extracted from the Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] on August 4, 2023, and data obtained from the Pennsylvania Health Care Cost Containment Council (PHC4)[b] on July 20, 2023. Rates are calculated as the number of reports of events occurring in a given timeframe per 1,000 patient days for hospitals and per 1,000 surgical encounters for ambulatory surgical facilities (ASFs). Since rates are based on the event occurrence date, and not submission date, some rates in this brief update are slightly different than previously published rates. This is due to reports for events that occurred in prior periods being submitted after the original data extraction dates.

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

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

Figure 1. PA-PSRS Event Report Rates for Hospitals and ASFs From 2012 Through 2022



Note: The dotted sections of the line chart lead to the partial 2022 rates based on Q1 and Q2, and the solid sections of the lines lead to the final 2022 rates based on all four quarters.

Results

Figure 1 shows rates by year from 2012 through 2022. With the addition of Q3 and Q4 data, the final hospital rate for 2022 increased by 0.3 points from the rate using only Q1 and Q2. The 2022 hospital rate of 27.9 represents the third annual decrease and is a 5.4% reduction from the 2021 rate. For ASFs, the final ASF rate for 2022 increased by 0.2 points from the rate using only Q1 and Q2. The 2022 ASF rate of 9.6 is the highest rate since 2012, and it is the first time it has been above 9. The bar charts in **Figure 1** show rates for each of the four quarters of 2022 for hospitals and ASFs.

Note

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

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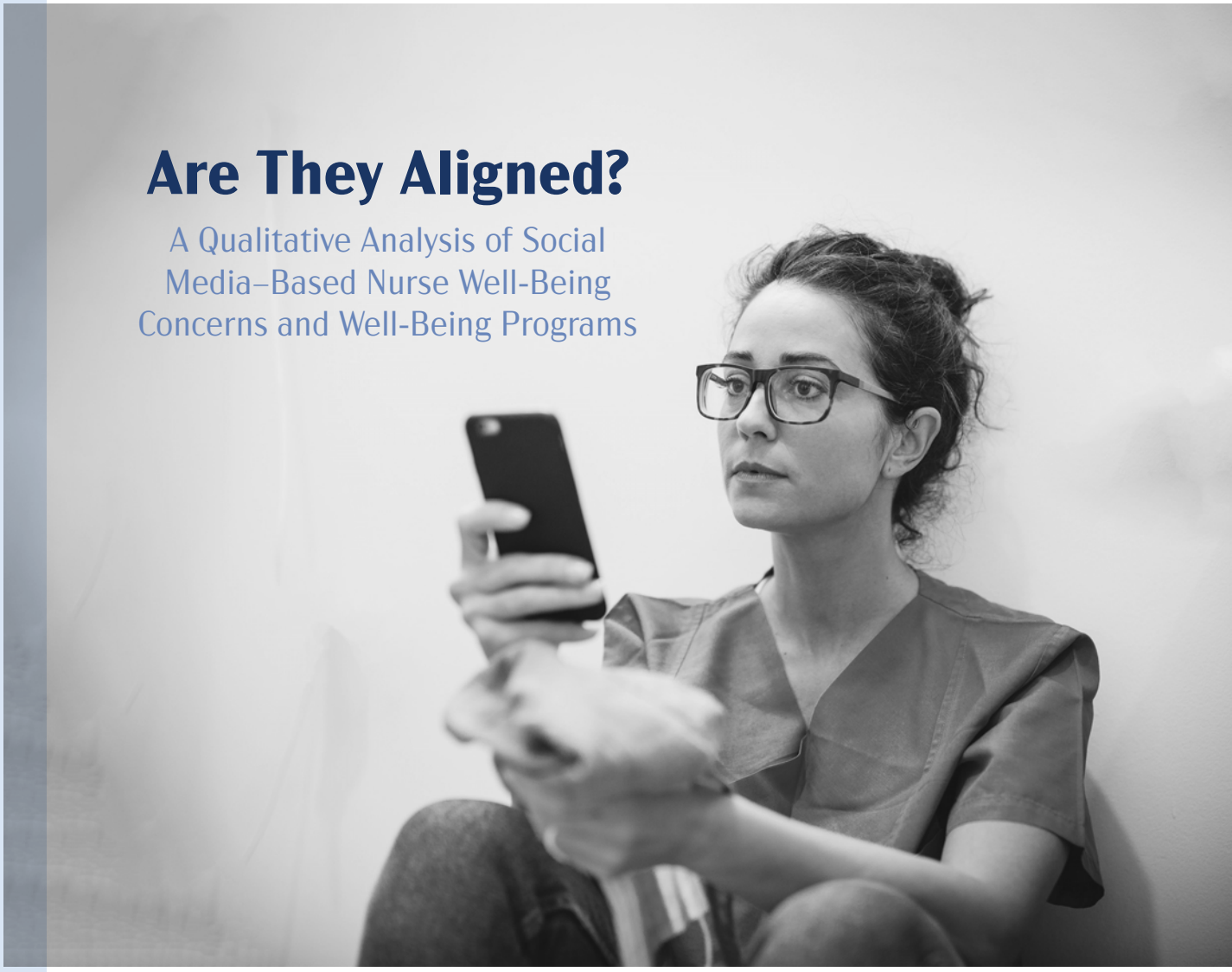
Are They Aligned?

A Qualitative Analysis of Social Media–Based Nurse Well-Being Concerns and Well-Being Programs



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Abstract

Background: Nurse burnout and distress pose patient safety risks due to impaired nurse attention, increased likelihood of medical error, and increased nurse turnover leading to a reduction in the number of nurses available to deliver care. Some healthcare facilities have launched well-being programs in response to increasing rates of burnout. Many of these programs are based on survey data which may be incomplete, resulting in programs that are not as comprehensive as they should be. We sought to identify nurse concerns related to burnout and well-being through analysis of social media data. We aligned these concerns with well-being program leader perceptions of factors contributing to burnout and well-being program initiatives.

Methods: We conducted a qualitative study composed of two parts: social media analysis and semistructured interviews with well-being leaders. The social media analysis focused on 120 nurse comments on Reddit that were retrieved based on a keyword search using the terms "burnout," "stress," and "wellbeing." The interviews were conducted with nine well-being leaders from seven different healthcare systems. Well-being program leaders were asked about factors contributing to burnout and lack of well-being, initiatives to address these factors, and metrics used to evaluate their programs. The social media comments and interview data were reviewed by two experts to identify topics, themes, and subthemes grounded in wellness models.

Results: Of the 120 social media comments analyzed, the most frequent topic was *Lack of Meaningful Recognition, Compensation, and Influence* (n=46 of 120, 38.3%), followed by *Work Environment* (n=43, 35.8%) and *Uninformed or Misinformed Public* (n=31, 25.8%). Several themes emerged and the most prevalent was Constrained Professional Agency with the most prevalent subtheme of health system or macrosystem policies or regulations that limit nurses' ability to respond effectively to patient care needs. Of the seven healthcare systems interviewed, the most common topics that emerged from asking about the factors contributing to the lack of nurse well-being were the *Work Environment* (n=6 of 7, 85.7%), followed by *Lack of Meaningful Recognition, Compensation, and Influence* (n=4, 57.1%), and *Inadequate or Inaccessible Well-Being Resources* (n=3, 42.9%). Several novel initiatives were identified, and most healthcare systems relied on surveys as their key metric.

Conclusion: The social media analysis revealed nurse concerns that may not be identified as factors contributing to lack of well-being by well-being program leaders. There is an opportunity to optimize our understanding of nurse concerns around well-being through social media, and an opportunity to better align nurse concerns with the focus of well-being programs.

Keywords: nursing, well-being, burnout, patient safety

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Introduction

Nurse burnout and poor well-being have direct implications for patient safety. First, burnout in nurses often manifests as impaired attention, which has been demonstrated to increase the likelihood of being involved in medical errors.[1-4] For example, Melnyk and colleagues demonstrated a 26% to 71% higher likelihood of medical errors by healthcare providers reporting lower levels of physical and mental well-being.[5] Second, burnout and poor well-being contribute to nurses leaving the workforce, which, in turn, reduces the number of nurses available to care for patients, reduces ongoing patient monitoring, and contributes to the loss of nursing expertise.[4,6,7] Addressing the challenge of burnout and nurse well-being is a national priority.[8,9]

Burnout refers to the emotional depletion and loss of motivation from prolonged exposure to chronic emotional and interpersonal stressors on the job.[10] Burnout has been described as high levels of emotional exhaustion and low sense of accomplishment and motivation within the workplace.[11,12] Nurse burnout rose during the COVID-19 pandemic, with one study finding that over half of the nurses surveyed experienced burnout.[13] While the recent data on nurse burnout and well-being are staggering, these issues have affected nurses for decades.[14] Stress and burnout have been widely studied and identified as occupational hazards and key factors influencing nursing quality of life, quality of care, and patient outcomes.[14-17] Studies conducted between 2003 and 2021 identified workload demands, work environment, and reduced resources as contributors to stress, impaired physical and mental well-being, and burnout among nurses.[11,16-27]

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With the COVID-19 pandemic bringing greater attention to nurse burnout, there has been an increased effort to understand prevalence and key contributing factors to burnout. Several surveys have been conducted to determine the impact of the pandemic on nurses' well-being and to identify specific stressors associated with intent to leave.[28-33] In the second year of an annual COVID-19 survey conducted by the American Nurses Foundation in 2022, over 12,000 nurses were surveyed to gain additional insight on the effect of the pandemic on nurses, staffing, and intent to leave the profession. Findings included a statistically significant relationship between age and emotional health of nurses; an increase in the percentage of nurses intending to leave their position; and increases in staff shortages, incivility, and bullying.[29]

In response to the high levels of nurse burnout and well-being challenges, some healthcare facilities have launched programs focused on improving nurse well-being. Compared to well-being initiatives focused on physicians, especially trainees, nurse well-being programs are quite new and little research has been done to evaluate whether these programs are addressing nurses' concerns.[34-39] Having effective well-being programs in place to support nurses is critical for nurse safety, retention, and patient safety.

In this qualitative study we sought to identify whether nurses' concerns about burnout and well-being are aligned with the focus of healthcare system well-being programs intended for nurses. We focused on sourcing nurse concerns from social media posts. Social media often provides an anonymous platform for expressing concerns, which may potentially result in more open and honest sharing compared to organizational surveys and interviews that can be perceived as not being anonymous.[40,41] Identifying misalignments between nurse well-being concerns and the focus of current well-being programs offers the opportunity to optimize these programs to provide better support to the nurse workforce. Based on our analysis, we provide recommendations for improving methods for sourcing information on nurse concerns and for improving current well-being programs.

Methods

Social Media Analysis

We analyzed social media content from a nurse-specific Reddit forum. Reddit forums are structured with an initial post, which is a user leaving a comment/question, and then subsequent comments/questions are presented in response to the initial post. Together, the post and resulting comments/questions make up a thread.

We first retrieved all publicly available did not contain language relevant to any of the eight domains and were removed from analysis, resulting in 27 threads included for analysis. From these 27 threads, the five highest-rated, first-level comments from self-reported registered nurses were extracted from each post, yielding 135 comments for review. These comments were also reviewed for relevance based on the Swarbrick model. Fifteen comments did not contain language relevant to any of the eight domains and were removed, resulting in 120 comments for qualitative analysis. **Figure 1** summarizes the data selection process.

Using the topics and themes in **Table 1**, as well as subthemes (shown in **Table 2**) the 120 social media comments were then manually reviewed and dually coded by a nurse and human factors expert, with discrepancies reconciled through group discussion. Each comment was coded into a single primary topic, theme, and subtheme to best reflect the nature of the comment. The topics, themes, and subthemes were based primarily on Swarbrick's wellness model, as well as healthy work environments (HWEs), and the National Academies of Sciences, Engineering, and Medicine's (NASEM) systems model of burnout and well-being.[42-44] **Table 1** shows the complete list of topics and themes used to code the social media and interview data, with details of the interview method presented below. Note: Some topics, themes, and subthemes were only relevant to the social media analysis, while others were only relevant to the interviews.

Semistructured Interviews

Semistructured interviews were conducted with nine leaders of nurse well-being programs from seven healthcare systems with varying geographic locations. The goal was to understand their perception of the factors contributing to poor nurse well-being, of initiatives to address these contributing factors, and of metrics used to evaluate their own well-being initiatives. A convenience sample of healthcare leaders involved in nurse well-being initiatives was recruited. Interviews were led by clinical and human factors experts and conducted over two months, with each interview lasting approximately 30 minutes. All participants provided verbal consent before starting the interview. Interviews were conducted via video teleconference using a moderator guide. After consent from participants, interviews were recorded and electronically transcribed. Participants were compensated with a $25 Amazon gift card. This study was approved by MedStar Health Research Institute Institutional Review Board.

Participants' responses were segmented into discrete statements. A grounded theory approach was used to analyze interview data.[45] The same codes iteratively developed for the social media data were also applied to the interview data. Participants' responses were mapped to the topics and themes by one researcher, and independently confirmed by a second researcher. Discrepancies were resolved through group discussion. Descriptions, examples, and representative quotes were used to provide insight and support for identified topics and themes.

Results

Social Media Results

Of the 120 comments analyzed, the most frequent topic was *Lack of Meaningful Recognition, Compensation, and Influence* (n=46 of 120, 38.3%), followed by *Work Environment* (n=43, 35.8%) and *Uninformed or Misinformed Public* (n=31, 25.8%). There were no comments related to the topic of *Inadequate or Inaccessible Well-Being Resources*. Frequency counts and percentages of the topics, themes, and subthemes are displayed in **Table 2**, below.

The comments related to *Lack of Meaningful Recognition, Compensation, and Influence* included the themes of Constrained Professional Agency and Compensation. There were no comments related to the theme of Lack of Opportunity to Influence Organizational Decisions. Constrained Professional Agency accounted for 32 comments (of 46, 69.6%) (the most frequent theme across all topics and themes), and the most frequent subtheme was health system or macrosystem (i.e., federal, state, or funders) policies or regulations that limit nurses' ability to respond effectively to patient care needs (n=22 of 32, 68.8%). Compensation accounted for 14 comments (of 46, 30.4%)

Figure 1. Data Selection of Nurse Well-Being Social Media Comments for Qualitative Review

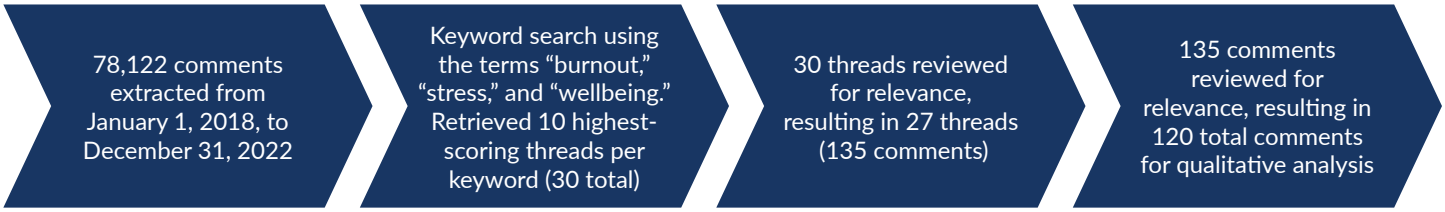

Table 1. Topics, Themes, Definitions, and Examples of Factors Contributing to Lack of Nurse Well-Being

Topic or Theme	Definition	Example
Work Environment	Includes the physical environment that enables nurses to function fully within their abilities to provide quality care to patients. Includes the day-to-day job demands that impact nurse well-being.	"We have an almost 900-pound patient right now. We don't have enough staff to be able to turn him (it takes MULTIPLE people) so SECURITY has been helping us … It is so unsafe to take that many people off a floor where patients need close monitoring AND taking away security for actual emergencies."
Inadequate Nurse Staffing	Relates to staffing that is needed for patient care, the unstable workforce, nurse retention (or lack thereof), and the skill gap between experienced nurses and new-to-practice nurses.	"A nearby hospital had a patient die in their emergency department waiting room last week [due to] staffing issues as they had lost a significant number of their emergency nurses recently."
Violence Against Nursing	Relates to any act or threat of physical violence, threatening behavior, or verbal abuse that occurs in the work setting.	"We shouldn't be worried about being attacked at work. There is already enough on our plates right now."
Emotional Burden of Nursing	Relates to the psychological fatigue associated with effective interpersonal engagement with patients and families to identify necessary interventions to reduce pain, anxiety, and suffering; to facilitate the patient's return to health when possible; and to serve as the patient's advocate.[4]	"It's a hopeless feeling watching them struggle to breathe, alone in the room, after they have shared their fears with you."
Unusable or Burdensome Technology	Relates to healthcare technology and medical devices that inhibit effective and efficient work.	"…gets in the way of the job that they're supposed to do, when technology entered, the art of nursing left."
Lack of Meaningful Recognition, Compensation, and Influence	Systemic, organizational, and cultural components impacting nurse well-being, including lack of meaningful recognition, financial compensation, or influence in decisions affecting nursing care delivery.	"Ancillary staff was cut and all of it, right down to transport, became the extra responsibility of nursing. That is what got us here. And if you think about it, the only reason hospitals are even able to keep afloat with this model is because at the end of every semester there is a brand-new batch of new grad RNs to replace the ones that walked (or jumped). No other industry could have sustained under these terms for this long."
Constrained Professional Agency	Relates to the hindrance of one's ability to implement the best evidence-based nursing intervention for patients or families due to poor policies or inadequate resources in the workplace. May include organizational and situational mandates to modify standards of care and to limit flexibility or autonomy from a systemic level. These actions may affect personal identity, career, and practices.[4]	"We're all just numbers to them but the machine absolutely depends on us to work. The engine is the most important part of the car."
Compensation	Relates to monetary benefits, including inequitable compensation between healthcare executives and floor nurses, and/or traveling nurses and floor nurses, and insensitive communications around compensation.	"And to pay their staff close to nothing compared to what their [executives are] making is a slap in the face."
Lack of Opportunity to Influence Organizational Decisions	Relates to the nursing voice not considered in daily decisions and in leadership and organizational decisions.	"There is a lack of professional voice given to nurses."

Table 1. (continued)

Uninformed or Misinformed Public	The public's lack of knowledge regarding the role of nurses in healthcare and the risk of severe illness and hospitalization during the COVID-19 pandemic.	"It won't matter to them until they need some medical treatment that is either significantly delayed or just straight up unavailable."
Uninformed Knowledge of Healthcare Operations/ Personnel	Relates to the public's lack of knowledge regarding healthcare operations and personnel and their impact on healthcare.	"I've seen this concept for years while trying to explain the concept of "no rooms available" to bed holds in the ER [emergency room]… Oh, well in that case let me just wave my magic wand and poof one out of thin air."
COVID-19 Misinformation	Relates to the public's belief in incorrect information regarding the COVID-19 pandemic and subsequent actions based on that.	"People are getting hurt because a huge portion of our country isn't taking this seriously. This spike is worse than it was all of last year and people don't even believe it."
Inadequate or Inaccessible Well-Being Resources	The lack of access to well-being resources; training and education; and inadequate scope of well-being resources, such as employee assistance programs, that do not support the needs of nursing.	"Feeling like they're not able to access support resources or things that could kind of sustain and maintain their well-being."
Lack of Access to Resources to Maintain/Promote Well-Being	Relates to inadequate access to resources that maintain or promote well-being and includes not having the time, financial means, or availability to obtain the materials or attend activities.	"I started printing things, posting on their units or in their offices, and made it so they can take it with them and use it when they have time. I wanted everything to be accessible and easy."
Inadequate Employee Assistance Program and Benefits	Relates to employee assistance programs and other benefits not fully supporting the needs of nurses and not recognizing life outside of healthcare impacts work, such as needing day care and tutoring services for their children.	"We did change this [Employee Assistance Program] during pandemic as the program wasn't performing the way it needed to and the structure was replaced."
Lack of Well-Being Training and Education	Relates to the lack of well-being training and education provided to nurses in school or on the job.	"We have failed miserably at teaching nurses what it looks like to take care of themselves and things to be on the lookout for."

Note: Topic rows are highlighted, followed by their related themes.

and comments were almost evenly distributed between the three subthemes of disparity between staff nurses and travel nurses, disparity between salaries of nurses and health system executives, and insensitive/disrespectful organizational communications regarding healthcare worker compensation (n=5 of 14, 35.7%; n=5, 35.7%, and n=4, 28.6%, respectively).

The comments related to *Work Environment* included themes of Inadequate Nurse Staffing, Violence Against Nursing, and the Emotional Burden of Nursing, with the two most prominent being Inadequate Nurse Staffing and Violence Against Nursing (both accounting for 16 of 43 *Work Environment* comments, 37.2%). There were no comments related to the theme of Unusable or Burdensome Technology. Within the theme of Inadequate Nurse Staffing, most comments were related to ineffective organizational strategies to retain (original staff/pre-pandemic staff) nurses (n=9 of 16, 56.3%). Subthemes related to Violence Against Nursing were roughly evenly split between physical violence (n=6 of 16, 37.5%), nurse-to-nurse/ nurse-to-student incivility (n=5, 31.3%), and culturally motivated violence (n=5, 31.3%). Nearly three quarters of the comments related to Emotional Burden of Nursing included the subtheme of emotional toll of being with patients as they die—often the nurse was the only one with the patient, as the family may not have been permitted to be physically present (n=8 of 11, 72.7%).

The comments related to *Uninformed or Misinformed Public* were coded as the third most frequent topic, accounting for roughly a quarter of all comments (31 of 120, 25.8%), and included themes of Uninformed Knowledge of Healthcare Operations/Personnel (n=17 of 31, 54.8%) and COVID-19 Misinformation (n=14, 45.2%). All subthemes related to both themes were roughly evenly distributed.

Semistructured Interview Results

The interviews of the nine nurse well-being leaders from seven healthcare systems revealed information about the factors contributing to the lack of well-being, the current well-being initiatives that have been put in place to address these contributing factors, and metrics for measuring improvements in well-being. Results of the interview data are discussed at the organizational level with a sample size of seven.

Factors Contributing to the Lack of Nurse Well-Being

Of the seven healthcare systems interviewed, the most common topics that emerged from asking about the factors contributing to the lack of nurse well-being were the *Work Environment* (n=6 of 7, 85.7%), followed by *Lack of Meaningful Recognition, Compensation, and Influence* (n=4, 57.1%), and *Inadequate or Inaccessible Well-Being Resources* (n=3, 42.9%). There were no comments related to the topic of *Uninformed or Misinformed Public*. **Table 3** summarizes these results.

Table 2. Frequency Counts and Percentages of Social Media Analysis of Factors Contributing to Lack of Nurse Well-Being By Topic, Theme, and Subtheme

Topic	Theme	Subtheme	Frequency Count (%)
Lack of Meaningful Recognition, Compensation, and Influence (46 of 120 total comments, 38.3%)	Constrained Professional Agency (32 of 46, 69.6%)	Health system or macrosystem policies or regulations that limit nurses' ability to respond effectively to patient care needs	22 (of 32, 68.8%)
		Lack of influence to change conditions	5 (15.6%)
		Calling for collective action	5 (15.6%)
	Compensation (14, 30.4%)	Disparity between staff nurses and travel nurses	5 (of 14, 35.7%)
		Disparity between salaries of nurses and health system executives	5 (35.7%)
		Insensitive/disrespectful organizational communications regarding healthcare worker compensation	4 (28.6%)
Work Environment (43, 35.8%)	Inadequate Nurse Staffing (16 of 43, 37.2%)	Ineffective organizational strategies to retain (original staff/pre-pandemic) nurses	9 (of 16, 56.3%)
		Inadequate staff for patient care or regulatory tasks that require more than one nurse	4 (25.0%)
		Associated with preventable patient safety events and near miss events	2 (12.5%)
		Implicit or explicit threats from leadership regarding leaving/travel contracts	1 (6.3%)
	Violence Against Nursing (16, 37.2%)	Physical violence	6 (of 16, 37.5%)
		Nurse-to-nurse/nurse-to-student incivility	5 (31.3%)
		Culturally motivated violence	5 (31.3%)
	Emotional Burden of Nursing (11, 25.6%)	Emotional toll of being with patients as they die—often the nurse was the only one with the patient, as the family may not have been permitted to be physically present	8 (of 11, 72.7%)
		Moral distress associated with insufficient resources to provide high-quality nursing care and deciding what care will be left undone	3 (27.3%)
Uninformed or Misinformed Public (31, 25.8%)	Uninformed Knowledge of Healthcare Operations/ Personnel (17 of 31, 54.8%)	Public doesn't appreciate/understand the role of nurse	9 (of 17, 52.9%)
		Emergency department/hospital is unable to fill its mission of responding to emergencies and trauma due to public flooding hospitals with minor symptoms	8 (47.1%)
	COVID-19 Misinformation (14, 45.2%)	Increased burden on health system and nurses due to societal anti-vaccination beliefs/misinformation	8 (of 14, 57.1%)
		Frustration with the public's failure to acknowledge the risk of severe illness, hospitalization, or death associated with COVID-19 infection	6 (42.9%)
TOTAL			**120 (100.0%)**

Table 3. Frequency Counts and Percentages of Interview Results of Factors Contributing to Lack of Nurse Well-Being By Topic and Theme

Topic	Theme	Frequency Count (%)
Work Environment (6 of 7 healthcare systems, 85.7%)	Inadequate Nurse Staffing	6 (of 6, 100.0%)
	Emotional Burden of Nursing	4 (66.7%)
	Unusable or Burdensome Technology	2 (33.3%)
	Violence Against Nursing	1 (16.7%)
Lack of Meaningful Recognition, Compensation, and Influence (4, 57.1%)	Lack of Opportunity to Influence Organizational Decisions	4 (of 4, 100.0%)
	Compensation	3 (75.0%)
	Constrained Professional Agency	2 (50.0%)
Inadequate or Inaccessible Well-Being Resources (3, 42.9%)	Lack of Access to Resources to Maintain/Promote Well-Being	2 (of 3, 66.7%)
	Inadequate EAP and Benefits	1 (33.3%)
	Lack of Well-Being Training and Education	1 (33.3%)

Table 4. Frequency Counts and Percentages of Interview Results of Current Well-Being Initiative By Topic

Current Well-Being Initiatives	Frequency Count (%) N=7
Work Environment	
Created a physical space for relaxation before, during, or after shifts	2 (28.6%)
Changing policy	2 (28.6%)
Changing work processes	1 (14.3%)
Optimizing technology	1 (14.3%)
Lack of Meaningful Recognition, Compensation, and Influence	
Financially incentivized participation in well-being programs	4 (57.1%)
Created gratitude programs	2 (28.6%)
Inadequate or Inaccessible Well-Being Resources	
Implemented peer support and mentoring programs	4 (57.1%)
Held well-being events	4 (57.1%)
Shared well-being resources	3 (42.9%)
Improved EAP and benefits	3 (42.9%)
Created and shared well-being content during new employee orientation	3 (42.9%)
Hired well-being leaders to help with well-being initiatives	3 (42.9%)

Note: Topic rows are highlighted, followed by their related initiatives.

Of the six healthcare systems that noted the *Work Environment* topic as a contributing factor to the lack of nurse well-being, Inadequate Nurse Staffing (n=6 of 6, 100%) was noted by all systems. Other *Work Environment* themes that impacted lack of nurse well-being included the Emotional Burden of Nursing (n=4, 66.7%), Unusable or Burdensome Technology (n=2, 33.3%), and Violence Against Nursing (n=1, 16.7%).

Of the four healthcare systems that noted *Lack of Meaningful Recognition, Compensation, and Influence*, all systems noted the Lack of Opportunity to Influence Organizational Decisions (n=4 of 4, 100%). Compensation was mentioned by three quarters of the well-being leaders interviewed (n=3 of 4, 75%) and Constrained Professional Agency was noted by two healthcare systems (n=2, 50%).

Of the three healthcare systems that noted *Inadequate or Inaccessible Well-Being Resources*, two of the systems stated that nurses felt like they did not have Access to Resources to Maintain/Promote Well-Being (n=2 of 3, 66.7%). Inadequate Employee Assistance Program (EAP) and Benefits and Lack of Well-Being Training and Education were both noted by a single healthcare system (n=1 of 3, 33.3%).

Current Well-Being Initiatives

To address the *Work Environment* as a topic contributing to the lack of nurse well-being, healthcare systems have implemented several well-being initiatives, including creating a physical space for relaxation before, during, or after shifts (n=2 of 7, 28.6%); changing policy (n=2, 28.6%); changing working processes (n=1, 14.3%); and optimizing technology (n=1, 14.3%). **Table 4** shows a summary of current nurse well-being initiatives offered by the healthcare systems interviewed. One policy change example is a healthcare system updated their policy so that staff could safely take a power nap during their 30-minute unpaid lunch break. Previously, nurses would be terminated if they slept anytime during their shift. Another healthcare system described a pilot program in their emergency department where they changed a work process allowing nurses to request a 5-to-10-minute well-being break on a communication application on their phone during their shift. Finally, one healthcare system is making improvements to "minimize nursing documents and function so they have time for clinical thinking" (optimizing technology).

> "Nurse burnout and lack of well-being not only impact nurses, but also have serious patient safety consequences and are associated with increased likelihood of medical error and reductions in workforce which result in fewer nurses available to deliver care.

Table 5. Comparison of Social Media Analysis Results and Well-Being Leader Interviews

Topic or Theme	Social Media Analysis of Staff Nurses	Well-Being Leader Interviews
Lack of Meaningful Recognition, Compensation, and Influence	✓	✓
Constrained Professional Agency	✓	✓
Compensation	✓	✓
Lack of Opportunity to Influence Organizational Decisions	×	✓
Work Environment	✓	✓
Inadequate Nurse Staffing	✓	✓
Violence Against Nursing	✓	✓
Emotional Burden of Nursing	✓	✓
Unusable or Burdensome Technology	×	✓
Uninformed or Misinformed Public	✓	×
Uninformed Knowledge of Healthcare Operations/Personnel	✓	×
COVID-19 Misinformation	✓	×
Inadequate or Inaccessible Resources	×	✓
Lack of Access to Resources to Maintain/Promote Well-Being	×	✓
Inadequate EAP and Benefits	×	✓
Lack of Well-Being Training and Education	×	✓

Note: Topic rows are highlighted, followed by their related themes.

To address the *Lack of Meaningful Recognition, Compensation, and Influence* as a topic contributing to the lack of nurse well-being, healthcare systems interviewed described two programs. Some healthcare systems (n=4 of 7, 57.1%) described financially incentivizing well-being, including paying cash rewards (up to $1,000 per year) for utilizing a well-being application that tracks movement (specifically steps taken) and other healthy habits, and paying employees to take educational programs that promote well-being. Another example of a healthcare facility financially incentivizing well-being includes linking participation in well-being activities to medical insurance premiums. One participant noted, "Connection with the medical premiums and seeing how much money that you can save has been kind of a no-brainer for all of us that are on the medical insurance." Two healthcare systems (28.6%) described gratitude programs. An example of a gratitude program is the "Thank You Project," an opportunity for someone who's received care at the hospital to recognize anyone who was part of their patient experience.

To address *Inadequate or Inaccessible Well-Being Resources*, healthcare systems have completed a variety of things. Over half of the healthcare systems interviewed (n=4 of 7, 57.1%) have implemented peer support and mentoring programs, including initiatives such as Stress First Aid and Care for the Caregiver. Many healthcare systems (n=4, 57.1%) have held well-being events, such as yoga classes or pet therapy, and provided education, such as healing touch classes. Healthcare systems have started to share more well-being resources and made them more accessible (n=3, 42.9%), improved their EAP and benefits (n=3, 42.9%), and created and shared well-being content during new employee orientation (n=3, 42.9%). Healthcare systems have also hired well-being leaders to help with well-being initiatives (n=3, 42.9%).

Metrics of Well-Being Initiatives

Metrics used to measure nurse well-being at healthcare systems varied. Surveys were the most common method to measure nurse well-being (n=4 of 7, 57.1%), followed by utilization rates of programs (n=3, 42.9%), anecdotes (n=3, 42.9%), and retention rates (n=2, 28.6%). Interestingly, one healthcare system (14.3%) was utilizing medical claims as a metric of nurse well-being.

Discussion

Nurse burnout and lack of well-being not only impact nurses, but also have serious patient safety consequences and are associated with increased likelihood of medical error and reductions in workforce which result in fewer nurses available to deliver care.[1-3,6,7,46] Ensuring that appropriate well-being programs are in place to support nurses is critical to patient safety.[47,48] Our unique analysis focused on analyzing social media data related to burnout and well-being to identify nurse concerns and interviewing well-being leaders to understand the factors contributing to lack of well-being, current well-being initiatives, and metrics associated with their programs.

Comparing the social media–based concerns to the topics that emerged from interviews focused on factors contributing to the lack of well-being and current initiatives provides one perspective on whether the well-being programs are meeting the needs of nurses. **Table 5** shows a direct comparison of the topics and themes identified from the social media analysis and interviews. Identifying misalignments between the social media analysis and well-being leader interviews may present opportunities to improve well-being programs.

> "Fundamental to addressing nurse burnout and well-being is understanding the factors that are driving these issues. While many facilities conduct surveys to understand factors contributing to burnout and lack of well-being, surveys alone may not capture all the key concerns.

Based on the social media analysis, the most prominent topic was *Lack of Meaningful Recognition, Compensation, and Influence* followed by *Work Environment*, and finally *Uninformed or Misinformed Public*. From the interviews, at the topic level the most prominent was *Work Environment*, followed by *Lack of Meaningful Recognition, Compensation, and Influence*, and then *Inadequate or Inaccessible Well-Being Resources*. Interestingly, the topic of *Uninformed or Misinformed Public* which surfaced from the social media analysis was not mentioned by any of the well-being leaders. On the contrary, the topic of *Inadequate or Inaccessible Resources* was a contributing factor topic for well-being leaders but was not mentioned in the social media analysis.

While the topics of *Lack of Meaningful Recognition, Compensation, and Influence* and *Work Environment* were identified through social media analysis and interviews, there were some differences in the specific themes. The social media analysis did not reveal any explicit comments related to the theme of Lack of Opportunity to Influence Organizational Decisions under the topic *Lack of Meaningful Recognition, Compensation, and Influence*. In addition, the social media analysis did not reveal any comments related to Unusable or Burdensome Technology under the theme of *Work Environment*. This is surprising given both themes have been discussed extensively in the literature and other forums.[49-52]

In the social media analysis, there is not a substantial difference in frequency of comments related to the topics of *Lack of Meaningful Recognition, Compensation, and Influence* and the topic of *Work Environment*; however, many comments fell under the subtheme of health system or macrosystem policies or regulations that limit nurses' ability to respond effectively to patient care needs. This suggests that addressing this subtheme will be important for addressing overall nurse burnout and lack of well-being. This subtheme will be challenging to address at a health system or national level given the diversity of stakeholders and the complexity of the issues impacting these policies and recommendations.

The interview data revealed some interesting well-being initiatives addressing some concerns expressed in the social media analysis. There is an opportunity to further study the impact of these initiatives and to share the most effective initiatives nationally. The biggest gap noted in the well-being initiatives described is addressing the topic of *Uninformed or Misinformed Public*.

The interview data surrounding metrics of well-being initiatives highlight the opportunity to improve our measurement of these initiatives. Survey-based instruments were the most common and

while survey data are important, additional methods are needed to better quantify the potential impact of well-being programs. This is a key area for future research and development.

Recommendations for Healthcare Facilities

Fully addressing nurse burnout and well-being will require federal, state, and institutional changes to certain policies, compensation models, and numerous other factors. In addition to those efforts, our social media analysis and interviews lay the foundation for several recommendations healthcare facilities should consider in their immediate efforts to address nurse burnout and well-being. These recommendations include:

Use a multipronged approach to understand nurse concerns: Fundamental to addressing nurse burnout and well-being is understanding the factors that are driving these issues. While many facilities conduct surveys to understand factors contributing to burnout and lack of well-being, surveys alone may not capture all the key concerns. Further, there can be tremendous variation in the factors that contribute to burnout from facility to facility and even department to department. These factors are difficult to capture by surveys alone. In addition to surveys, healthcare facilities should interview nurses; use different polling platforms, including social media; and conduct observations to identify what tasks and interactions may be contributing to burnout.

Embrace positive deviance: Positive deviance is focused on identifying groups or individuals with better outcomes than their peers, studying their behaviors, and then using this knowledge to inform the practices of others.[53] Many healthcare facilities focus on those individuals with high levels of burnout. While this is important, there can also be lessons learned from understanding what factors contribute to low levels of burnout. Observing, interviewing, and surveying those with low levels of burnout may surface key insights that can be brought to those with high levels of burnout.

Develop ways to address nurse concerns around constrained professional agency: The social media analysis revealed that Constrained Professional Agency was one of the most frequently discussed issues. Constrained professional agency is the hindrance of one's ability to influence and make choices in a way that affects their personal identity, career, and practices, including lack of flexibility or autonomy from a systemic level.[54] Facilities should focus on addressing these issues at a local level. One approach is to conduct focus groups with nurses to learn how they might be better supported on this issue.

Develop strategies to discuss issues around uninformed or misinformed public with nurses: This issue surfaced in the social media analysis and was not described by any of the well-being leaders, suggesting there may be a significant gap. Facilities should develop strategies for discussing this issue with their nurses, acknowledging that this is a known issue and developing interventions to relieve the stress associated with this problem.

Improve well-being program measurement efforts: To develop a successful well-being program, frequent measurement of program goals is important. Facilities should develop data points aimed at measuring burnout, well-being, and the impact of programs. These can be operational metrics (for example, number of surveys completed) though we recommend that at a minimum they include some outcome metrics, such as any improvement in well-being and whether implemented programs are having an impact. Measurements taken at regular intervals with the least amount of burden on staff are important. Consistency in measurement is also important for benchmarking and understanding well-being in context—aligning measurement efforts with existing standards will speed implementation and allow for effective comparisons within and across organizations.

Engage other well-being leaders to share what is and isn't working: The interviews we conducted served to identify several different well-being initiatives. There is an opportunity to increase knowledge sharing across organizations and given the common ground of wanting to improve nurse well-being and patient safety, there should be little hesitation to sharing what works. Current collaborative efforts to share in both well-being measurement and knowledge sharing around programs and solutions include the Healthcare Professional Well-being Academic Consortium, which has recently expanded its nurse well-being survey content to develop national benchmarks for nurse well-being.[55]

Limitations

There are several limitations to our study. Our social media analysis was based on data from a Reddit forum focused on nurse-related topics. However, we cannot verify the identity of social media posters to determine if they are, in fact, nurses that are engaging in this social media platform. We also have no way to verify the accuracy of the questions/comments that were analyzed. We sampled a small segment of the social media content, and the coding of this content may not accurately reflect the entire dataset. As with all interviews, we captured the experiences of those individuals interviewed; however, we were not able to verify the accuracy of these experiences. Additionally, we utilized a convenience sample of nurse leaders from a small subset of healthcare facilities in the United States and the results may not be generalizable to all healthcare facilities.

Conclusion

Nurse burnout and lack of well-being have clear implications for patient safety, and addressing the factors contributing to burnout is a national priority. Nurse concerns about burnout and well-being may not be fully addressed by current well-being programs. There is an opportunity to optimize current well-being programs by ensuring alignment between nurse concerns and well-being program initiatives and by improving measurement of the effectiveness of well-being programs.

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View From the Top: An Interview With Patient Safety Authority Chair, Dr. Nirmal Joshi

By **Nirmal Joshi,** MD[1] & **Caitlyn Allen**, MPH*[2]

In 2002, a dedicated group from Pennsylvania passed the Medical Care Availability and Reduction of Error (MCARE) Act, the most robust state-level legislation of its kind. Its legacy remains 21 years later. Patient Safety Authority chair, Dr. Nirmal Joshi, sat down with Patient Safety *managing editor, Caitlyn Allen, to discuss ways care has improved, what challenges persist, and how to achieve the unachievable—true culture change.*

Keywords: patient safety, interview, Pennsylvania, culture

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Photo Credit: Joe Hermitt (PennLive)

Caitlyn Allen: Dr. Joshi, you've been chair of the Patient Safety Authority board since last summer. What were your expectations coming into the role and how did they compare to your experience?

Nirmal Joshi: I had dealt with the Patient Safety Authority from the healthcare management side: running hospitals, running health systems as the chief medical officer. So, I knew Pennsylvania is unique with its large database of patient safety information that is ripe for analysis, for review, for publishing, and—most importantly—for feedback back to the stakeholders to make appropriate changes to improve care.

But until you step on the other side, within the Authority itself, you don't quite grasp the detail. How does the data look on the other end? The analyses? And so on. Most people aren't privy to that piece. I wanted to understand that in my new role, because the single most important thing is safety. You want to make sure patients get quality care when they and their families are their most vulnerable. So, when I was invited to participate as the board chair, I very willingly said yes.

Back to your question around my expectations: At a high level, there were no real surprises. I knew PA-PSRS [Pennsylvania Patient Safety Reporting System] was a large database. I knew it analyzed events from across the commonwealth.

However, the breadth and the depth of what actually happens within the Authority was a surprise—in a good way. Meaning the extent of the research, the extent of data analysis, and the extent of education that uses that analysis and gives that data back to the stakeholders. There is a lot more that happens than I realized when I was not part of it.

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When you need people to change or you want systems to improve, you can't depend solely on legislation or being overly firm and prescriptive. That's not how human nature works.

It's always better when it's a good surprise. You mentioned how unique Pennsylvania is, and even though it's been 20 years since we passed the MCARE [Medical Care Availability and Reduction of Error] Act, we still have the most robust reporting laws. We also have the largest event reporting database in the country. Do you think that those two things have to go hand in hand, or are there ways to encourage event reporting without the legislation to back it?

I've always believed accountability is the key for anything. Legislation is one way to ensure that accountability and is an important way to accomplish it. However, there is a delicate balance. When you need people to change or you want systems to improve, you can't depend solely on legislation or being overly firm and prescriptive. That's not how human nature works. If you want to have sustained improvements and improve care, you need to have a critical mass of people who are willing to change and willing to lead the way. You can't do that by the stick, you really can't. It's the difference between "transactional" leadership and "transformational" leadership.

As leaders, we all know that if something needs to be done quickly, you have to say, "Hey, so-and-so, do this now." Take codes for example: Someone suddenly collapses, everyone jumps into action and there are black-and-white orders like the military, and you get it done. That's what I call transactional. It must be that way at that time.

However, for most things, you must be transformational if you want things to improve over extended lengths of time. The Authority does this so well now: Look at the data, analyze the data, and then go back to stakeholders, educate them about what the data means, and in plain English what are some take-home things that they can do.

Back to your question, having the backing of good legislation is crucial. But if we are to make meaningful change, we have to effectively appeal to both people's heads with data and their hearts by asking, "What happens to my loved one when they're in the hospital?" That kind of messaging allows for truly transformative work in patient safety. Many people think you can just tell people what to do and they'll somehow comply. Well, that's not really how human behavior works.

You mentioned the military, which is an industry to which healthcare is often likened. Another is aviation. Do you think there are components of these other industries that we should borrow or is healthcare just its own quirky beast?

That's a great question, particularly the comparison to the aviation industry, which has been discussed so often that if you begin raising that in healthcare forums, it's almost irritating.

There are significant components that we should not only borrow but literally replicate from other industries like aviation. One example is processes that need to be followed down to the T. I'm sure you've read the book called *The Checklist Manifesto* by Atul Gawande. The author, who is a well-accomplished surgeon, talks about the importance of discrete checklists. Was X done or was it not done?

And that's where we should strive to mimic the aviation industry: more and more checklists, making as many things dummy-proof, because to err is human, right? We refer to it over and over again, but it's probably the single most important realization that we, as human beings, are inherently prone to making mistakes. So, we'd be better the more we recognize fallibility with checklists and so on. That's the piece that we need to plagiarize from the airline industry.

Where things differ, however, is that we are not dealing with a machine, but we're dealing with the human body. Something immensely humbling for anyone in medicine is that sometimes the human body just decides to respond the way it feels like responding. You get a person who's 80 years old with multiple medical diseases, who is fine. On the other hand, you can get a 50-year-old, where they have almost no other diseases, and for whatever reason that we don't understand, they can have an adverse outcome.

The point being that regarding the human body, two plus two does not always make four. And that's where I think we need to set community expectations in a way that says, "We believe strongly in accountability when it comes to actions that we perform at the bedside. However, despite best efforts from the entire team, things can go sour," which is very different than the airline industry. If you did everything perfectly other than things like weather, you should have a fairly predictable outcome, while in healthcare, that doesn't always happen.

I read an article in *AORN* [Association of periOperative Registered Nurses] *Journal* that cautioned against comparing healthcare to aviation. In healthcare, it's humans working alongside other humans on other humans, and there are too many variables for a direct comparison, which aligns with what you're saying. Speaking of *To Err Is Human*, the landmark report put patient safety on the map in 2000. In many ways, healthcare is infinitely safer than it was 25 years ago, yet incidents of harm continue. Do you think that we'll ever achieve a level of zero patient harm?

We should always strive to accomplish zero patient harm. I don't think any healthcare worker would deny that. I think we go into the field with an inherent intent to help people. And when things don't work out as we hope, we are not only saddened, but we go back and look carefully, "What is something we might have done differently?"

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So, yes, we should strive for perfection. However, given A) what I just said earlier is that we're dealing with the human body and B) to your earlier point, we are also dealing with human beings caring for human beings. Those two elements make it hard to accomplish zero patient harm entirely.

So, the question is, "How can we minimize that to the point that we can comfortably say, 'We did the very best we could.'" Having a system in place that we follow 100% of the time is accountability. If there is a checklist prior to surgery, if there is time-out and we look at 20 things, did people follow each one 100% of the time? That's accountability. Then, if there is an adverse outcome, it likely only resulted from things beyond our control.

Your background is in infectious disease. How much did that prepare you to handle the pandemic? How much on-the-job training did you have to do?

I started at Mount Nittany in 2016, and right around late 2019 just before COVID hit, I started my foundation and was going to go part time. That's when my CEO requested me to stay on more, because I was the chief medical officer of the health system, and I was also trained in infectious diseases, so it made no sense for me to step back.

Handling the pandemic was one of the most rewarding times that I've had in healthcare, because it was an opportunity to do something with the expertise in infectious diseases that I had not been really using. Being in management, I had not done frontline clinical care for a while. And this gave me the opportunity to jump back into it.

When you're thrown in the front lines of managing this whole process, it's a tremendous opportunity to be able to serve and do something with your expertise.

Communicating well is one of the biggest challenges in any industry, let alone healthcare. I know improving doctor-patient communication is an interest of yours.

It's important in healthcare that we communicate well, we understand both sides, we understand the patient and their family's point of view. One reason, among many, is that our diagnostic process starts with information. If we don't get a complete enough picture during the patient interview, one's diagnosis can only be as good or bad as the information received. And often, if we are unable to do that well, everything that follows is potentially flawed and can lead to mistakes, poor clinical quality, and so on.

The second of a zillion reasons why doctor-patient communication is so critical is that in the context of disease, we are dealing with real human beings. We're dealing with emotions. We are dealing with people who care about each other— family member expectations. And if we are unable to communicate to them in a compassionate, empathetic way, then something is missing. Our discipline is so unique compared to any other. We deal with people when they are in many ways down-and-out, in many instances when they are so vulnerable that they have no control in their lives because of a stroke of destiny or whatever else.

Some of the most rewarding times in my life have been when I've been able to stand by patients and their families with compassion, with care. And that's something that not only do I strongly believe in, but also I strongly believe in being able to teach the importance of those moments. You can impact people's lives. And those moments never go away.

It's one thing just to believe that, but you walk the walk. And one of the ways you've done that was by founding the Joshi Health Foundation.

That's something that is very near and dear to my heart. We always want to do the best we can, but sometimes we find ourselves in a situation where we think, "Could we have helped more people?"

And then, you ask yourself, "Would there be a time when my livelihood doesn't depend only on being reimbursed for patient care?" I had hoped that I could become reasonably financially independent to do for others without asking for anything in return—those who may be most vulnerable, who have no way of paying for healthcare.

I read a book called *The Second Mountain* by David Brooks, a *New York Times* reporter that analogizes our lives as mountains: The first mountain is when we are trying to make a living. We're trying to get dinner on the table. We are trying to do everything for ourselves and our families.

And there comes a point after you've done that he refers to as the second mountain, which is when the true joy begins. When, if you can, you give to others, to your community, to other people

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We should always strive to accomplish zero patient harm. I don't think any healthcare worker would den that. I think we go into the field with an inherent intent to help people. And when things don't work out as we hope, we are not only saddened, but we go back and look carefully, "What is something we might have done differently?"

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And if we are unable to communicate to them in a compassionate, empathetic way, then something is missing.

who are in need. And the joy that you get out of that is unmatched compared to the first mountain, which is more transactional. The second mountain is much more fulfilling, rewarding, and gives inner peace and inner pleasure.

Thankfully, the time came about two or three years ago when I planned to go part time and step down as the chief medical officer to start the Joshi Health Foundation. As they say, charity begins at home. I felt I should do this right where I live, because this is the community that has helped me, my children, my family over the last 35 years. So, I started the Foundation that offers care to individuals, primarily those who have no insurance or means to pay.

I provide clinical consultation and tests, such as, bloodwork, X-rays, and so on, by way of partnerships from local health systems that I have developed over time. I pay the subsidized amount, so the patient does not have to pay anything. So, we can care for those who may be the most vulnerable in our society. It's been a joy and a privilege and a blessing.

Another one of your passions that you mentioned earlier is training the future generation of leaders. What does that look like? And what do you think the challenges are going to be facing future physicians, maybe a decade from now, that you didn't necessarily face during that stage of your career?

For most of my life I have had the good fortune of being intimately connected to education, whether it be graduate medical education or teaching medical students. When I was at Penn State in Hershey, I was strongly involved with training students. And then, when I was with Pinnacle, now UPMC [University of Pittsburgh Medical Center] Pinnacle, I actively participated in the resident training program. In fact, I was the program director for Medicine for a period as well.

When I became CMO and then subsequently at Mount Nittany, there was no direct opportunity to instruct residents and students, so I have been actively involved with the Pennsylvania Medical Society in training upcoming physician leaders. I've done that for the last eight years or so, where we have very structured courses for physicians who either self-identify themselves as being leaders

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When, if you can, you give to others, to your community, to other people who are in need. And the joy that you get out of that is unmatched.

or who are referred from their institutions for leadership training. We have structured courses throughout the Pennsylvania Medical Society for which I serve as either a leader or as a faculty member.

As I said, I have been blessed that I have both things in my life: the ability to see people who are vulnerable and to educate a new cohort of physician leaders. There were practically no such courses back when I was stepping into these roles. You just showed up, and you learned on the job. Even today, I would venture to say about 80% of the time, physicians walk into a leadership role, big or small, with no formal management training. We've attempted to create processes that train physicians in formal systems of management, whether it be things like finance or communication that look much more like an MBA-type course rather than a traditional medical one.

More personally, I also always try to learn from a mistake or something that didn't go well and try to use that as a teaching moment.

Pennsylvania is a peculiar place, with two big urban centers and a lot of rural area in between. How do you balance preparing the next generation of physicians and similarly, looking at patient safety on a broad scale where there are these two very diverse environments?

That's an interesting question. I've been in a few health systems now, and each can be quite different in its culture, location, patient expectations, physician expectations, etc.

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More personally, I also always try to learn from a mistake or something that didn't go well and try to use that as a teaching moment.

When it comes to patient safety, and maybe other elements of medicine as well, the basic tenets are the same regardless of where you are. For example, in the operating room, which has been likened to the aviation industry most often, the expectations are the same: strive to minimize patient harm. Follow the checklists and the other standardized processes. Some things are black-and-white and should be followed in the same way regardless of your location.

On the other hand, culturally, how people respond, the methods for educating people, the way to get there, change from place to place. There are places where a slightly more transactional tilt tends to help, while there are other places that wouldn't respond well to that approach. So, the methods can vary, but you have to understand people, and people's expectations are amazingly different from one place to another.

But when it comes to the basic principles of patient safety, the outcomes can be somewhat beyond our control at the end, but compliance in doing things the way they're supposed to be done, that is well accepted by the best available evidence, ought to be something that we hold everyone to the same standard of accountability; whether it's the Eastern part of the commonwealth or the Western part of the commonwealth, rural, urban, semiurban, expectations ought to be similar.

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Healthcare, we’re dealing with human beings, like we said to begin with, where unfortunately there are no 100% answers or no 100% solutions.

A universal challenge affecting patient safety is staffing shortages. This is occurring on multiple levels: not enough instructors to teach enough students to fill enough spots, and then there are limited residencies available, even if we had more students. How might we be able to address these challenges?

It depends. Consider scope: There are rigid guidelines for what someone can do. For example, can a medical assistant give shots? With staffing shortages, it’s sometimes great to have the creativity to say, “OK. If X can’t do it, can Y be trained to do the same thing?” But sometimes regulation gets in the way. “No. If this person can’t do it, they can’t do it.” It’s inflexible. That’s not criticism. Rules exist for a reason but can stifle creative solutions to some of these systemic challenges.

On the other hand, where more regulation and help from the federal government can be very helpful is when there is an absolute shortage. You’ve tried all this creative stuff, and there is still a shortage. Individual hospitals work on razor-thin margins these days and simply cannot afford to be able to pay people to the point of going bankrupt. And there have been systems within Pennsylvania and elsewhere that have gone bankrupt. So that’s where the federal government can treat healthcare differently from other industries and incentivize healthcare workers apart from the institution itself.

That may encourage people to consider healthcare careers, which can be very demanding. Not just physicians, but for everyone. The shifts, the night work, and what sometimes feels a thankless job can be challenging. So, on one end is maybe more help from the federal government, on the other hand, is maybe getting out of the way a little bit. The trick is to find that right balance.

It seems like a theme throughout this conversation has been finding the right balance. Healthcare seems to be best when it exists in lots of shades of gray and not in absolutes.

I think that is so true. Healthcare, we’re dealing with human beings, like we said to begin with, where unfortunately there are no 100% answers or no 100% solutions.

About the Authors

Nirmal Joshi is an experienced physician executive and internal medicine physician, with an extensive background in clinical quality and patient safety. *Becker’s Hospital Review* recognized Dr. Joshi as one of their “100 Hospital and System CMOs to Know” in 2016. He currently serves as chief medical officer for Population Health at Mount Nittany Health system in State College, Pennsylvania, and as president of the Joshi Health Foundation in Mechanicsburg, Pennsylvania—a nonprofit charitable organization that he founded two years ago with the intent of providing free care to those unable to afford care.

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ARTIFICIALLY INTELLIGENT?

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

By **Avishek Choudhury**, PhD[1] & **Caitlyn Allen**, MPH[*2]

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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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.

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.

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> 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.
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> 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.

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.

> 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.

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.

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.

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.

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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.

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.

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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.

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.

> "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.

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.

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About the Authors

Dr. Avishek Choudhury, an assistant professor at West Virginia University, is renowned for his contributions to the field of systems engineering. He focuses his research on the intersections of patient safety, artificial intelligence (AI), cognitive human factors, neuroergonomics, and clinical decision-making. He is a pioneer of efforts to incorporate the principles of human factors and systems thinking to seamlessly integrate AI into clinical workflows. His research delves into the complex world beyond mere algorithmic performance, striving to humanize technology to enhance usability and drive adoption. Dr. Choudhury also collaborates with international nonprofits to achieve the global Sustainable Development Goals; his work targets public health issues and digital divide concerns, particularly in low-income countries, leveraging the transformative power of human factors science and AI.

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No Time To Lose

Meet the Physician Predicting the Healthcare of Tomorrow

By **Eyal Zimlichman**, MD, MSc[1] & **Caitlyn Allen**, MPH[*2]

Introducing Dr. Eyal Zimlichman, chief transformation officer at Sheba Medical Center. His job is to predict the future of healthcare—then figure out how to make it reality.

Keywords: innovation, transformation, medicine, artificial intelligence, patient safety

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Caitlyn Allen: What does your role as the chief transformation and innovation officer entail?

Dr. Eyal Zimlichman: We try to predict what healthcare will look like five to 10 to 20 years out and how we can innovate to get there by solving many of our major crises that healthcare has: the challenges and gaps. One of them being quality and patient safety. I have a saying that "innovation is the fun part," because you get to deal with interesting people and cool toys. But transformation is the difficult, even the painful part, which actually deals with change—changing how we do things, changing the culture, which as we know in healthcare is always the major challenge.

Handling innovation and transformation allows me to design solutions but then implement them on a large scale and not just settle for the innovation itself. My origins are quality and patient safety, which is what I've been doing most of my career as a doctor.

I'm an internal medicine physician by training and have done quality and patient safety in Boston, working at Partners HealthCare (what is now Mass General Brigham) and here at Sheba, and then was the chief medical officer at Sheba.

I view quality, patient safety, and innovation as being on the same continuum where we're always trying to improve what we're doing. Never being satisfied with what we have, but rather always looking out for ways to do better. Innovation is about thinking differently on how to engage with those problems.

You mentioned that one of your roles is predicting where healthcare will be in the near future. What do you see?

It's a long answer, but one major change we're seeing is transitioning from hospital care to home-based care, where many patients who would have been admitted are now being treated at home, which involves digital health transformation and virtual care.

Number two is a much bigger emphasis on prediction and prevention. Again, using digital health tools like artificial intelligence [AI] and precision medicine to understand the individual patient better and to predict what's going to happen: for example, complications developing or response to therapy, whether it's for cancer patients or other types of illnesses. Moving towards prediction and prevention rather than treating illness.

> I view quality, patient safety, and innovation as being on the same continuum where we're always trying to improve what we're doing.

Another change is moving from just focusing on healthcare, which is treating the sick, to looking at a much broader scope, the "social determinants of health." We have to look at patient education and patients' capacity to be more active in their care.

All are a major shift from the more traditional, paternal system that tells patients what to do, towards a system with patients at the center. We're equipping them with the right knowledge and right tools to take an active role in care. There are others, but these are the major changes that will impact everything we're doing in healthcare. Of course, the first to see the benefits will be the patients themselves.

How might we navigate the transition to home-based care?

We need to identify how we can improve care. We're not just moving from hospital to home so patients stay in their environment, which of course makes sense, but also because we think we can provide better care. We think outcomes can be better at home, which can seem counterintuitive.

The key would be to reach better results at lower cost while having patients move from the traditional hospital environment, well-equipped to treat sick patients, to the home environment, not so much equipped to treat sick patients.

This will be the main challenge. Digital health solutions, innovation, and transformation will allow us to make that leap. There are technologies today that allow us to monitor patients at home, to be able to figure out whether a patient is in the right environment, because if his condition is deteriorating, maybe we do need to move him back to the hospital.

We have technology today that allows doctors, nurses, and other health professionals to treat patients from afar without the need to physically be at the home, because that's not a sustainable model. We will not be able to drive nurses and doctors to every patient's home to the extent that we're used to having them be at the bedside in the hospital, because that just won't work from a financial perspective.

Plus, we have a well-known crisis in workforce shortages, and most doctors and nurses aren't willing to spend time driving around the city, visiting multiple patient homes a day. So, how do we solve this issue by using technology again to allow clinicians to provide care to patients at home virtually? I think these will be the main challenges we see that will allow us to improve outcomes for patients treated at home while reducing cost and turn this to a viable model.

You mentioned the social determinants of health, which are routinely a challenge in healthcare. How would you recommend hospitals start to look at them and what solutions could they implement to try and address them?

We need to realize that it's up to us as healthcare systems to solve these problems. We cannot say, "Well, this is beyond the scope of what we do," because we are more and more accountable for those patients. Payment models are changing. We're seeing it with value-based healthcare. We're seeing this with accountable care organizations.

In that regard, we will be held fully accountable and paid in a way to motivate us to keep patients as healthy as possible. We will understand that it is within our scope and within our capabilities to impact what patients eat, for example, or what kind of education they're receiving or transportation if they need to get somewhere.

All of those, which traditionally were outside our scope, are becoming central in the modern healthcare system and what healthcare systems will have to do over the next couple of years.

Well, especially if we do move to a home-based model. Arguably things like diet will affect you more in your home than if you're staying in the hospital for a week.

Absolutely. Consider dietary restrictions. It's cheaper for us as healthcare systems to buy the right food for our patients, rather than to treat those patients later if they develop a disease, which will obviously become much, much more expensive for us.

We need to look long-range financially and understand that we're investing now in saving costs later for those many patients. Sometimes for chronic disease patients, this can be very quickly gained. For example, patients with congestive heart failure who eat a high salt diet will more often require hospitalization because of episodic deterioration.

If we can make sure they eat what they need to eat, we can prevent those hospitalizations. Then it even makes sense financially, and of course it makes sense from a patient's perspective and from what healthcare is trying to achieve.

How would you grade innovations in patient safety compared to other areas of medicine?

Patient safety is the number one area where we need innovation. One thing that we've seen, and repeatedly over the last few years, is that we're making very little progress in preventing harm for patients, especially in the hospital.

Earlier this year, David Bates and his team at Harvard[1] showed that there's been little change from the initial numbers we measured back in 1991 in the Harvard Medical Practice study—almost 30 years where there's been very little progress.

So, we're frustrated with how much has been done and how much money has been invested in patient safety. Governments have put forward programs to try and tackle this and provide incentives. There's a large industry that has developed and so on, and still, we've made very little progress. We have to start thinking differently.

If we continue to just go back to the old paradigms of quality and patient safety, we will just have the same outcomes that we've seen over the last 30 to 40 years. We must start thinking differently. Technology, specifically digital health, will have to play a growing role.

For example, a major known problem in patient safety is adverse drug events and medication errors. We've been trying to tackle this for years using solutions such as decision support systems on CPOE, computerized physician order entries, which have caused a huge amount of desensitization and alert fatigue among staff who ignore those alerts as they pop on the screen because they're used to the false alerts.

> We're not just moving from hospital to home so patients stay in their environment, which of course makes sense, but also because we think we can provide better care. We think outcomes can be better at home, which can seem counterintuitive.

As we advance with artificial intelligence, we will be able to create alerts that are much more accurate with minimal alert fatigue. This happened at Sheba Medical Center when we introduced an AI solution on top of the traditional decision support system. Staff said they are paying much more attention to the alerts coming from the AI system versus the alerts coming from the rule-based approach that has been used around the world for the last couple of years. Innovation; digital health; and, in this example, artificial intelligence can enhance these types of systems.

Another example is being able to read CT scans within milliseconds, because that's how quick the AI works. Say a patient who has come in with a stroke, maybe cerebral hemorrhage, might be delayed in diagnosis for another 30 to 60 minutes, because it's a busy ED [emergency department], and by the time the radiologist gets to read the scan, those 60 minutes might have passed and could be critical to really impact the outcomes on these patients. We know diagnosis of stroke very early on is critical so that we can initiate therapy as fast as possible and prevent any long-term effects and disabilities.

Within milliseconds, the AI can read the CT, identify the hemorrhage in the brain, and alert the doctors very early on about a possible hemorrhage in the brain so the doctor can log into the CT, acknowledge that there is a hemorrhage, and initiate the protocols to treat those patients. By that, we have shown that we have been able to reduce mortality considerably, reduce long-term disability on those patients, and reduce cost because of improved efficiency in the emergency department setting.

AI is undoubtedly a game changer and the future of healthcare. However, there is a presumption that AI always outperforms humans. Have you found that to be the case?

We look at AI as augmenting doctors, not replacing them. AI can alert doctors to something that may have taken us longer to get to. Not because we're better or worse than the AI, but it's a fact. We're unable to read a large number of CT scans the same way that the AI would.

In this regard, it can prioritize which CT scans I should read first. If I'm a radiologist in the ED, just that is enough. And maybe the AI made a mistake such as wrongly diagnosing the CT. But if the accuracy is high enough, we will be able to see clinicians enjoying this augmentation and improving our outcomes.

The same would be, for example, finding the right medication for cancer patients. AI is better at looking at very large-scale data sets coming from our patients and suggesting how we should start treating this specific patient based on his genetic material, CT scans, pathology, and laboratory information. The AI could suggest a first therapy, rather than trial and error like we often do today, and potentially improve our ability to hit it right on the first time.

If we can hit it more accurately on the first try, we could save a lot of money and, of course, more importantly, improve the outcomes and improve the quality of life for those patients.

What are some things that you could implement that may not cost as much money as a new AI system?

First, AIs are not costly. They are a data algorithm. You need an electronic medical record, which is quite common today. And implementing an algorithm is much cheaper than buying a surgical robot or another MRI scanner. AI can also improve decision-making in rural hospitals that may lack the right manpower that you would see in the major cities. An AI algorithm that can be implemented easily everywhere will improve health equity. Unlike many other technological solutions that are typically costly, AI can extend care remotely and create a huge amount of value for patients.

For example, small rural hospitals may not have a doctor in their emergency room or ICU [intensive care unit] during the night. However, tele-ICU allows one centrally located doctor to take care of 10 ICUs in 10 rural areas.

> AIs are not costly. They are a data algorithm. And implementing an algorithm is much cheaper than buying a surgical robot or another MRI scanner.

Of course, that has economies of scale, and it's more financially sustainable than having a doctor in each of those sites 24/7. That's the advantage of digital health rather than say a robot, to improve patient outcomes and reduce cost.

That makes a lot of sense and underscores that implementing AI does not need to be costly.

We're seeing very high uptake of these solutions. For example, that AI I mentioned that reads the CT scans in the emergency department is a company called Aidoc that came out of Sheba after a successful pilot here in 2018. In a short time, it's already deployed in more than 1,200 hospitals around the world. I think about 800 in the United States.

The AI allows us to deploy those solutions quickly and for a fairly minimal investment, yet with a huge impact on patient outcomes. This is one way digital health promises to transform patient safety and improve quality over the next decade.

Tell me more about the pilot with the CT scans. Was there any resistance, and if so, how did you overcome it?

When we started this, 2016, 2017, AI was still not well accepted, and there was a lot of initial resistance. Implementation takes a lot, and sometimes a great technology can fail during execution because you haven't really thought it through.

The workflow needs to be seamless for the clinicians and does not impose on them. We stated originally, "The only role of this AI is to prioritize for the radiologist what to read first, because something might be time sensitive."

We got the usual response from some radiologists who said, "So what? You think this would replace me and I'll be out of a job?" Which we hear a lot when we talk about AI, and not just in healthcare. But when we say, "No, this is just setting priorities for you to read," it takes away much of the tension, and opens up clinicians to work with this new technology.

After they started using it and confirmed it could diagnose dangerous complications early (not just, by the way, bleed in the brain, but also pulmonary emboli and hemorrhage in the abdomen and other critical diagnoses), we heard from radiologists who said, "This was great. I'm becoming a fan of this technology, and I'm going to use this for the rest of my career."

We've heard more and more clinicians refer to it as a great complement to their skillsets rather than competition. So how do you bring this to the clinicians? How do you package it? How do you intuitively incorporate it into the workflows in a nonthreatening way to clinicians that actually reduces their workloads? These elements are critical to success.

Beyond the CT scans, you're changing culture—the white whale in healthcare.

Culture change is a daily topic when we deal with transformation. And as somebody who came from the origin of quality and patient safety, we know how important culture change is. We measure culture of patient safety using surveys in every hospital in the U.S., and we always try to improve it.

Culture change is a daily topic when we deal with transformation.

How can we create the right environment for this to happen? How can we drive the changes? Because healthcare, as you know, is not a very dynamic industry, and we have to change some of the ways that we've been handling things to drive meaningful and substantial improvements.

What's been my guiding light through culture change wherever I worked was to start with champions. We always need to find the right champions in any environment and create the evidence locally. It's not enough to base your arguments on evidence created in some other hospitals, many times in another country, maybe on another continent, and then say, "Well, there's evidence that it works."

But rather test it in your own environment using your clinical champions. And clinical champions always exist. Create the evidence on the production floor of your specific location and scale up once you have a local proof of concept. That's a huge motivator to push these changes forward locally at your environment.

You would recommend starting smaller and more focused and then try and scale up like a single unit, single hospital, as opposed to trying to implement a broad change across the whole facility.

Exactly, and work with your local clinicians to always be dynamic. That's part of why you're starting small, because you want to learn. And again, not everything that has worked in another institution will work in yours. Learn what needs to change for your environment, work with the clinicians and provide them the confidence to change what is needed.

If it were just the world according to you, what is one thing we should do to improve patient safety?

We need to more actively create evidence from technological solutions in the U.S. and most developed countries. Again, when I say technology, it doesn't need to be very costly.

And even in developing countries, we're seeing digital health play a major role, because it's affordable. Not just artificial intelligence: telemedicine and augmented reality [AR] and virtual reality to improve our ability to treat patients.

There are many avenues that we still need to tap into more seriously to drive solutions. Take augmented reality: We have augmented reality glasses for surgeons that enable us to be much more accurate, because we're able to navigate much better to reduce the length of time for surgery.

For example, we have seen the length of the procedure for implants specifically for spinal pacemakers reduced by 50% from about an hour and a half to 45 minutes just by using AR. But not just the length of this procedure being cut in half, but also the number of complications was lower, because we were able to implant the specific pacemaker at the right location without cutting in the wrong location and creating more blood loss or other complications of surgery.

This is something we're going to see much more of. Apple recently came out with their augmented reality glasses. They're still expensive, but 10 years from now, every surgeon is going to use augmented reality glasses to be much more accurate, reduce complications, and reduce the time of surgery.

This will be transformational to surgery at large. So taking all of this in together, digital health offers us the possibilities to drive quality and patient safety forward in a very sustainable and cost-sensitive fashion. This is what's going to create most of the transformation in the next decade.

That's astounding. What do the glasses allow you to perceive that you wouldn't otherwise be able to?

Because we've already done an MRI on this patient, we know exactly where there's a tumor we need to cut out, or if there's a specific location to implant the pacemaker, or whatever the procedure is. When we're just looking at the patient with our bare eyes, we don't have all this knowledge we've gained from the scans.

At best, we have the scan on a wall on an LCD we can look at, but then we need to go back to the patient and try to orient to where exactly we need to make the cuts. But if I have my augmented reality glasses on, and they are being fed the MRI, then I will see overlaid on my patient the exact tumor or the exact location or when I need to make my cut or implant my pacemaker. With that, it makes surgery much easier, much simpler. It doesn't take as long and can reduce complications.

It sounds like science fiction, but it's already happening and there's a growing literature to show the benefits. But again, as you're asking me what needs to be done over the next few years, it's creating more evidence for the use of these types of technology and the benefits they can produce.

That's incredible. It's like *Star Trek*–level medicine.

Exactly. It sounds like science fiction, but it's already happening and there's a growing literature to show the benefits. But again, as you're asking me what needs to be done over the next few years, it's creating more evidence for the use of these types of technology and the benefits they can produce. The costs will go down considerably over the next few years and will become something that every hospital and clinic will be using five to 10 years from now.

We need to shift our way of thinking because traditionally, as somebody who's lived my life professionally in the world of patient safety, it's always about trying to do better next time.

If a nurse or doctor makes a mistake, we apologize and try better next time and hope it will be the last time. But we need to move away from trying better to a place where technology will enable us to really have zero errors being performed. Only technology will allow us to do this, because otherwise we're all humans.

The Institute of Medicine report that came out in 1999 was called *To Err is Human*, so maybe this is where we need to start thinking differently and have technology able to compensate for our failings as human beings.

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A Knife Is Not a Pill Cutter

(And Other Home Medication Safety Tips)

By **Kathleen E. Walsh**, MD, MSc[1], **Michelle Bell**, BSN, RN[2] & **Caitlyn Allen**, MPH*[2]

Children are more than twice as likely as adults to experience a medication error at home. Dr. Kathleen Walsh, pediatrician at Boston Children's Hospital, discusses why that is the case and tips to keep kids (and anyone) safe.

Michelle Bell: Home medication management has not been a common research focus. What drew you to this topic?

Dr. Kathleen Walsh: That's a great question. First, well one of the things is that I'm a primary care physician, so that's where I see patients. Second, I'm a parent, so home is where I give my family medications. One of my first research projects was a four site study that looked at outpatient medication safety in children and adults with cancer. We found that the rates of medication errors in the home were quite high in children. In fact, the rate of errors overall in children was more than double that of adults with cancer: about 20% in children and 7% in adults, and it was entirely due to increased error rates in children at home. The rate of errors in children receiving chemotherapy infusion in the clinic was actually similar to adults.

There are two possible reasons for that: One is when pediatricians work with parents around medication use, we recognize that it can be challenging to get kids to take meds, especially kids with cancer. I think it's a little easier to discuss that in pediatrics with parents so it's more likely to be recorded in the chart. In addition, pediatric medication use is pretty complicated and error prone. So, it is more likely that they would have errors at home. Honestly, when I read the charts, I was struck by how incredibly hard this must be. They take 10 to 20 medications a day, they take multiple pills. It's extremely complicated.

MB: We know how complicated the medication process is within facilities, where we have so much more control of the system. In the study,[1] the research nurses used a four-pronged approach to

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find errors. Was any one of those more effective than another at identifying errors?

KW: The interesting conclusion from that study was that the rates of errors were extremely high, much higher than we had anticipated. Errors are ubiquitous with home medication use. And unfortunately, different methods discovered different errors. To find all the different types of errors, you need to use each method: observation, medication review, chart review, and parent interviews—the most effective being the chart review. It's the easiest thing to do, but you miss important things if you're only doing chart review. Some of the more serious errors were identified through parent interview and in-home medication review. For example, one family had moved and had a different concentration of oral chemotherapy at home than what the clinic chart had. So, they were giving a different dose than what the clinic thought they were giving. We were able to find that in the home because we looked at the bottle.

MB: Did any of the study results surprise you?

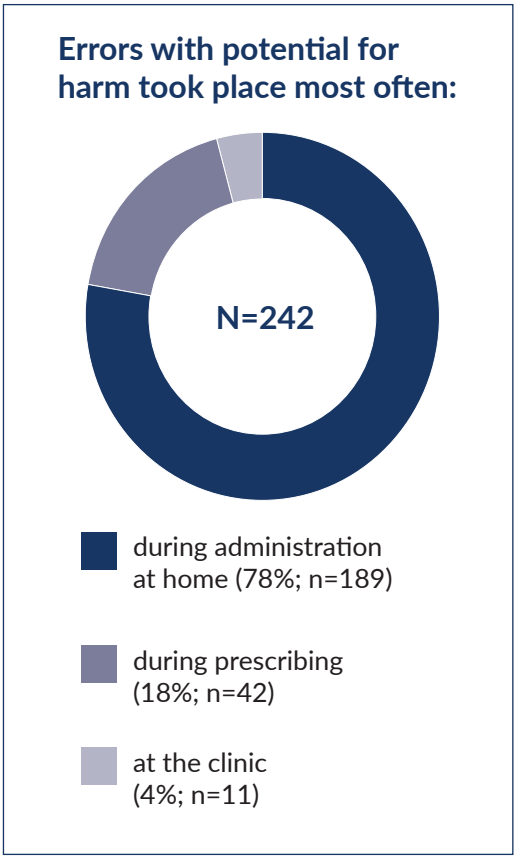
KW: Probably the most surprising thing in this study was how long errors in the home can last. In the hospital, most errors are intercepted before they reach the patient. In the home, if errors get to the point of administration, there's no one to catch it. As a result, errors in the home went on for a long time.

MB: That's consistent with what we see in acute care literature as well.

KW: Except the errors in the home may last for months, which differs from hospital care because more errors in hospitalized patients are intercepted before reaching the patient.

MB: You used the NCC MERP [National Coordinating Council for Medication Error Reporting and Prevention] harm scores to assess the actual outcome, along with severity scores for the potential worst outcome. Why did you choose to look at the possibility in addition to the actual outcome? And how do you differentiate between "significant," "serious," "life-threatening," and "fatal?"

KW: Those terms [e.g., significant] were developed in the 1990s and are commonly used in safety research. "Significant" is generally any pain or a medically important change in your labs. For example, constipation, headache, an increase in your INR [international normalized ratio, which measures how long it takes for blood to clot] might be considered significant. "Serious" usually refers to more commonly known things like a pressure injury, a CLABSI [central line–associated blood stream infection], a serious medication error. We decided for this study, for example, that chemotherapy missed doses or underdoses are serious.



Because children with leukemia need 90% 6-MP [6-mercaptopurine, an oral drug used to treat cancer] adherence, or they end up being at a significantly higher risk for relapse.

"Life-threatening" is very uncommon. For example, a hypoglycemic seizure in a child with diabetes would be considered life-threatening. Those decisions are made by two physicians independently, and we do assess inter-rater reliability for those. The NCC MERP worked pretty well.

MB: There were a lot of variations noted in the safety practices and cultures of facilities, and that's something that we see as well when interacting with facilities—the difference culture makes. Did this influence the types of errors? I noticed site 1 reported more errors than sites 2 and 3 in the study. Was that due to culture or better identification?

KW: It's not clear whether the detection was better at some sites than others or if rates of errors are higher at certain sites. There's been a lot of work on how to maximize detection. I've never done a study without substantial site-to-site variation.

Sometimes the site with the highest rate prescribed the most medications. Once you address that, the rate goes down. In this study, that was not the case. The site with the highest rate also administered the largest number of medications, but when you accounted for the number of medications across

the three sites, their rate was still highest. So, it's hard to know for sure what the issue was. That site also had a lot of people that spoke different languages. But the types of errors were very similar across all the sites. I wish I could tell you. That would be an opportunity for collaboration between the sites to try to identify best practices.

But back to your question, you need to be able to benchmark right? You're talking about a place we would love to get to, where there are measures that can be used by health systems to know the rate of errors for use in quality improvement to reduce it. It's where we need to be in the next five years.

MB: Another challenge is quantifying events that didn't happen. A student once asked me, "How do you get to a denominator? All the events that didn't happen." I told them that's kind of like asking, "How many car accidents did you not get into on your way to school today?" Because the possibilities are so infinite as to where things can go wrong, capturing the potential failure points is almost impossible. How challenging is it to develop interventions in a system where you don't have much control?

KW: We outline some in Table 4, but it doesn't address everything that needs to happen. We developed it based on published research, but the field is evolving. Health system leaders need to recognize that they're not just responsible for harm caused by healthcare within the walls of their hospital, but also that they share some responsibility when harm occurs from a medication prescribed in the hospital and administered at home.

Second, providers need to think about how well their plans can be implemented at home. For example, we visited the home of a teenager who was supposed to take 13 pills per dose, which sounds very difficult. I don't know how the child did that. Sometimes children are prescribed things like 3.75 milliliters of a medication, which we would round. But parents may be uncomfortable just doing that on their own. At home, management of epilepsy, sickle cell, diabetes, and even asthma can be very challenging.

There's a lot that we can do to help create a system that's at least as safe at home as it is in the hospital for caregivers who aren't formally trained. Parents are expected to give at-home medications where the dose on the prescription label is not the same as what they're supposed to administer, which a nurse in the hospital would never do. This is because the dose has changed since it was dispensed. They would just send it back to the pharmacy to have it labeled properly.

Caitlyn Allen: How might the label that the parent sees differ from the one that was prescribed?

KW: There are a lot of medications that we have to titrate, meaning the doses go up and down to find the one that's most effective. We titrate seizure medications, psychiatric medications, chemotherapy, steroids, hydroxyurea that we use for sickle cell. That's just a few. The titration is a long process that parents often do in collaboration with their doctor. Take psych meds, which are common. If there is still medicine left in the bottle, the same bottle at home is often used even after the dose changes, so the label will often reflect the initial dose or some sort of attempt at summarizing how you titrate.

There have been many errors with this because it's too complicated to try to follow the titration in your head. Or someone will follow the bottle label when it's wrong, not follow the bottle label when it's right. For kids with cancer, about 1 out of 10 meds at home has an old label on it and is not the current dose. That may be true for kids on psych meds or epilepsy meds as well. Does that help?

CA: That does. It's really, really interesting.

KW: Yeah, it's a big problem. If that happened in the hospital, no one would ever administer it. We'd just send it back. But it's hard to figure out how to fix that problem. What you try to do is provide the dose on written material, then the family can kind of check it off. But everyone giving the medication in any setting has to have access to that.

CA: How often do pediatric doses change?

KW: Often enough. Back to the psych meds, if your child with autism is on antipsychotic medications, the doses in the beginning may increase. If there are side effects or the child grows, especially with weight-based meds, then the dose changes again. For example, even when we give kids regular Tylenol, the dose changes as they get bigger.

MB: What can facilities do today to prevent at-home medication errors?

KW: There are a few things. We're working on measure development. Having a measure is the first step to quality improvement; health systems need to measure the problem continuously, then they can attempt different interventions to see if it improves. For example, you would look at central line–associated bloodstream infections or adverse drug events in the hospital. You measure them, then look for the reduction as you intervene. If you don't have a measure, you won't know if your interventions work and you won't be able to benchmark performance. So, our top priority is doing a better job measuring outpatient medication errors. Right now, the best way to do that is through incident reporting in the ambulatory setting.

There are a lot of medications that we have to **titrate**, meaning the doses go up and down to find the one that's most effective.

Once we have good measures, we can do a lot to try to intervene. Another thing providers can do is demonstrate how to measure the dose of a liquid medication with the family. Studies show that 100% of parents can accurately measure medications if you give them a syringe with a line on it and demonstrate the dose for them. Little things can help a lot.

The issue is for children on multiple medications, then they go home and have 10 different syringes. They need to attach the syringe to the bottle with a rubber band. That's helpful. So is a written medication administration list. We should encourage using tools at home. We found in our research that among parents who don't use any support tools with medications, 95% have errors. It's less than half of that if they use something, a pill bottle, an alarm system, a calendar. I think the combination of system-level measurement and at-home safety tools are two places to start. Then just more innovation around what works to support families at home.

CA: Most of the time when we talk about medication errors, it's related to the patient. This article discusses harm that can befall the person administrating the meds. Tell me more about that.

KW: This came up in our research for families using chemotherapy at home. You're not supposed to touch oral chemotherapy. Publications from the 1970s showed that nurses managing these drugs developed urinary levels of the chemotherapy they were working with. Although parents are instructed not to touch the chemotherapy, most of them do anyway.

CA: How can parents protect themselves?

KW: They're supposed to wear gloves and use pill cutters. The pill cutters are particularly important. A lot of parents don't use them. They'll break it with their hands. The problem is, if the child is taking a half pill a day and you break it off, it will likely crumble and result in a substantial difference in dose.

CA: Is using a kitchen knife a fair substitute for a pill cutter?

KW: Not really, no. Knives don't work as well. Some pills are small, like an oral birth control pill. You can imagine, if you're trying to cut that with a knife, it will crumble. Then your child gets less medication, and if the pieces are not cleaned up well others at home may be exposed to it. it. Plus, pill cutters are super cheap, or you can get a prescription for them.

We also don't consider how safe or unsafe a medication at home may be in the same way we do in other settings. It's hard to think that I'm giving something unsafe—or potentially harmful—to my child.

CA: Especially because it came from the physician, so therefore it has to be safe.

KW: Exactly, it can be counterintuitive. There are certain medications that are safe for anyone to take and others that are safe for one person and dangerous for another, based on your size, and how long you've been on it or whether you've titrated the dose.

CA: Is there any kind of guidelines for caregiver instructions?

KW: No, there isn't really a standardized way that we talk to families about all medications. In fact, that's one thing that we really need. I was never taught, "These are the things you have to tell a parent to administer a medication." A standard approach would be helpful to give families expectations around the types of information they need to know when they receive a prescription. We're working on standardizing conversations in the outpatient setting, so standardizing conversations around meds would be a really helpful thing to do.

CA: Speaking of improving conversations around meds, one of the more serious errors in the study was about a miscommunication between caregivers. Any suggestions about how to mitigate that?

KW: It's funny you asked about that. We just accidentally overdosed my dog this week because of that problem. Fortunately, she was OK. My husband and I have made that mistake with our kids, I think because we both work. Often, one parent gives the dose, and then goes to work. The other parent doesn't realize the first one gave the morning dose, and then gives it again. Or alternatively, one parent misses the dose, assumes the other one gave it, and the other also skips the dose, so no dose is given. It can be not just parents, but other caregivers as well. These double-dose errors at home are some of the most common errors.

Using a written tool addresses that. You write down a calendar that shows all the doses due while the child is on the medication, and you check it off when it's given. Our problem this week with our dog was that I gave the medication but forgot to check it off on the calendar. So, written and verbal hand-offs help.

A similar error we also frequently saw was that one parent would go to the doctor and not tell the other about a change in dose. Then the other parent would give the old dose. That is particularly dangerous because it can go on for a long time, if the parents don't regularly check in, for example if a parent is away or if they don't live together.

CA: Could a patient portal help with that?

KW: A patient portal wouldn't stop the double dosing with the two parents at home, but it may with the titration problem. My guess is often there's one person who's really in charge. Then they go away and the other is on over the weekend, and that's when the communication failure occurs, or vice versa. Everyone may not have access to the portal as well.

CA: And like you said, the portal is only going to fix some of the problems.

KW: Exactly. I've known of parents of children with diabetes who are separated, who needed a dynamic solution, because diabetes requires regular, frequent checks throughout the day. So, they had an electronic tool that everyone could update in real time, the school nurse and both parents. That was pretty effective.

MB: I'm visualizing an app with an eMAR [electronic medication administration record] built into it.

KW: Yes, exactly. There are apps, but they're not that sophisticated. If you're on a lot of meds, and the doses are changing frequently, or the dose changes on different days of the week, the apps I'm aware of are not that good. Someday soon.

CA: Hopefully. Is there anything else that we didn't cover, that you think would be important for folks to know?

KW: Medication errors in the outpatient setting, including at home, are common and dangerous—particularly for children with chronic conditions like cancer or diabetes, but even asthma or food allergy care can be complex and at times lifesaving. It's important to remember that mistakes can happen and can have important consequences. But we can take basic steps to prevent these errors, such as prescribing doses that can be easily administered, trying to make sure that people know how to use their medications, and reducing the number of medications a child is on. Clinicians also need to recognize that the care we provide in clinic continues at home, and we influence that care. Whereas right now, at best we're envisioning outpatient care as a hand-off rather than as a shared responsibility.

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"CORRECT" CLASSIFICATION AND REPORTING OF A PATIENT SAFETY EVENT

By **Patient Safety Authority**

Keywords: Pennsylvania, incidents, serious events, infrastructure failures, MCARE Act, known complications, high risk, return to surgery, event reporting

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Patient safety in Pennsylvania is largely directed by Pennsylvania's Medical Care Availability and Reduction of Error (MCARE) Act, which requires some healthcare organizations to report incidents, serious events, and infrastructure failures (see MCARE for definitions) into the Pennsylvania Patient Safety Reporting System (PA-PSRS).[1] Many variables, including the complexity of healthcare, impact reporting and create inconsistencies.

This is most evident in facility determination of serious events. Final Guidance[2] developed by key stakeholders provides criteria for serious event classification, with the intent to create consistency in reporting among facilities. The PSA encourages the use of the Final Guidance, as well as the FAQs and Reporting Decision[3] Tree, to help make determinations in reporting.

A recent review of PA-PSRS events related to returns to surgery uncovered opportunities for reinforcement related to two specific guidance principles, known complications and high risk.

The PSA found that many return to surgery events are reported as incidents. If you perform surgical procedures in your area, consider reviewing the Final Guidance, #3 and #4.

1. **Known Complications (FG3)**[a]

   A known complication is not typically considered anticipated by the patient.

   If a patient experiences a "known complication" and/or a situation that is "discussed during consent," the event is likely still reportable as a serious event if no other exclusion criteria apply, such as the patient being a higher-than-normal risk.

2. **High Risk (FG4)**[b]

   If a patient is at "high risk" for a return to surgery, it would be considered anticipated and not reportable as a serious event or incident. There is no need to enter a report into PA-PSRS. Two conditions **must** be met for a patient to meet high-risk criteria.

   a. Disclosure to the patient (of the high probability of complication)

   b. Documentation in the chart/consent (of the high probability of complication)

   Note: This does **NOT** pertain to the "standard" consent discussion or document (see #1 above).

Disclose High Risk	Document High Risk	Event Classification
Y	Y	No Report
N	N	Serious Event
N	Y	Serious Event
Y	N	Serious Event

Most return to surgery events should be reported into PA-PSRS as serious events. Nothing in healthcare is absolute and there are many nuances that make each situation unique which may impact the report classification. Please contact your facility's patient safety liaison for additional support.

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Patient Safety Authority (patientsafety.pa.gov) is an independent state agency that oversees the Pennsylvania Patient Safety Reporting System (PA-PSRS), the largest database of its kind in the United States.

[a]"The disclosure of a potential complication on a patient consent form does not, in itself, constitute anticipation of the complication by the patient."[2]

[b]"Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record."[2]

INCREASE NOTED IN REPORTED WRONG-SITE SURGERY EVENTS FROM INTERVENTIONAL RADIOLOGY

By **Patient Safety Authority**

Keywords: wrong-site surgery, interventional radiology, surgery, medical error, events, wrong site, wrong side, wrong procedure

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Patient Safety Authority. Increase noted in reported Wrong-site surgery events from Interventional Radiology. *Patient Safety*. 2023;5(Highlights of 2023):91634.

Wrong-site surgery (WSS) is a well-known type of medical error that continues to occur in healthcare facilities. Wrong-site surgery involves all surgical procedures performed on the wrong patient, wrong body part, wrong side of the body, or wrong level of a correctly identified anatomic site.[1,2] Wrong-patient surgery may include patients who were never scheduled for a procedure, procedures performed that were not scheduled, and procedures scheduled correctly in which a different one was performed.[2]

The National Quality Forum (NQF) defines surgery as "an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice. Surgery begins, *regardless of setting*, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs."[3]

Research published by the Patient Safety Authority revealed that these events occur on average of 1.42 WSS events per week in Pennsylvania.[4] While it is true that a majority of the WSS events occur in the perioperative areas, a steady number of these events arise outside of the operating theatre in areas such as interventional radiology (IR).

In our December 2020 study published in *Patient Safety*, research found that "The frequency of WSS was consistently greater in the hospital OR (operating room) than IR; nevertheless, IR experienced a range of 6 to 13 WSS events per year, over the 5-year period."[4]

Ongoing research into reported WSS events has revealed an alarming finding. For the period January 1, 2023, through March 31, 2023, there were eight WSS events originating from interventional radiology. These reported WSS events (examples below) included wrong site, wrong side, and wrong procedure cases. The number of IR WSS cases in the first quarter of 2023 was the highest quarterly total since the PSA initiated including procedural WSS events occurring outside of the perioperative setting in 2015.

"A patient goes to interventional radiology (IR) for nephrostomy tube placement. Upon return to the inpatient unit, it is realized that the tube was placed on the wrong side. The patient returns for the correct tube placement the following day."

"… patient with a compression fracture of T-12 vertebra … underwent a kyphoplasty in IR … after reviewing CT results, MD discovered the T-12 fracture remained with kyphoplasty being performed on T-11 …"

In 2008, the Standards of Practice Committee of the Society of Interventional Radiology released the current "Quality Improvement Guidelines for Preventing Wrong Site, Wrong Procedure, and Wrong Person Errors: Application of the Joint Commission 'Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery' to the Practice of Interventional Radiology."[5] These guidelines supplement The Joint Commission Universal Protocol[6] as well as the PSA's Principles for Reliable Performance of Correct-Site Surgery[7] and the PSA/Department of Health Final Recommendations to Ensure Correct Surgical Procedures and Correct Nerve Blocks.[8]

We encourage facilities to review/revise their universal protocol policies and procedures and monitor for compliance to decrease the likelihood of a future WSS event both in the perioperative areas as well as the interventional medicine departments.

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PATIENT SAFETY EVENTS RELATED TO THE PLACEMENT OF DRUG-ELUTING STENTS

By **Patient Safety Authority**

Keywords: drug-eluting stents (DES), coronary artery stents, percutaneous coronary intervention (PCI), device malfunction, patient safety

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Patient Safety Authority. Patient Safety Events Related to the Placement of Drug-Eluting Stents. *Patient Safety*. 2023;5(Highlights of 2023):91635.

Drug-eluting stents (DES) offer patients less invasive options to reopen and maintain blocked coronary arteries. Advances in the design and manufacture of DES have made them smaller, allowing them to be placed in more severely blocked arteries. This also allows more complex patients to undergo less invasive stenting procedures.

A recent review of high harm event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) included a patient safety event involving the failure of a DES during a percutaneous coronary intervention that resulted in a patient's death. In this event, the balloon shaft broke, and the balloon was left in the coronary artery. Attempts to retrieve and remove the balloon failed, and the patient suffered cardiac arrest and passed away.

This event report prompted further investigation into the complications associated with the placement of DES. Balloon tears or ruptures,[1,2] stent separation from the balloon,[3] and guidewire fractures[4] are serious complications that can arise when placing DES and can result in patient harm. We searched PA-PSRS for other similar event reports and found an increase in the number of these types of events from 2021 to 2022. Representatives from the Patient Safety Authority (PSA) also spoke with clinicians familiar with the placement of DES. From these conversations, it was determined that these types of events were likely due to a failure of the device. Furthermore, these events may be underreported in PA-PSRS, as there is some expectation of complications from a clinician's perspective, especially given the complexity of some of the patients who require this type of procedure.

It is important for clinicians to remember that any occurrence that meets the definition of an incident or serious event[5] must be reported to PA-PSRS, including events that are not anticipated by the *patient*. Accurate reporting is crucial for keeping track of any new or upgraded devices and understanding any potential complications to ensure patient safety. When these events are reported to PA-PSRS, the PSA can analyze their impact on patient safety and identify any trends or mitigating factors to improve patient safety. The PSA can then share this information with facilities and practitioners across the state and beyond, ultimately preventing harm by providing awareness and tools to enhance patient safety.

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HOLDING GLP-1 AGONISTS PRIOR TO ELECTIVE PROCEDURES

By **Patient Safety Authority**

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Patient Safety Authority. Patient Safety Events Related to the Placement of Drug-Eluting Stents. *Patient Safety*. 2023;5(Highlights of 2023):91636.

We have been increasingly hearing concerns from healthcare facilities about a class of medications known as glucagon-like peptide-1 receptor (GLP-1) agonists and their impact on patients receiving anesthesia for procedures. GLP-1 agonists and their potential for delayed gastric emptying may be associated with an increased risk of regurgitation and aspiration of gastric contents during general anesthesia and deep sedation.[1] Over the past few months, we have also received event reports in the Pennsylvania Patient Safety Reporting System (PA-PSRS) involving complications resulting from GLP-1 agonists not being discontinued prior to a procedure, including one that resulted in aspiration pneumonitis.

Current GLP-1 Agonist Medications

- Dulaglutide (Trulicity)
- Exenatide (Byetta)
- Exenatide extended-release (Bydureon BCise)
- Liraglutide (Saxenda, Victoza)
- Lixisenatide (Adlyxin)
- Semaglutide (Ozempic, Rybelsus, Wegovy)
- Tirzepatide (Mounjaro)*

*Tirzepatide is a dual GLP-1 and glucose-dependent insulinotropic peptide (GIP) receptor agonist

Agents in this class are approved for treatment of type 2 diabetes and reduction of cardiovascular disease, as well as weight management.[1] As the use of these medications increases, this is an opportunity for facilities to review their preadmission screening and medication reconciliation processes. As some patients may lack awareness about the importance of including GLP-1 medications on their current medication list, facilities should directly ask all patients if they are taking any of these medications. This question should be asked with sensitivity due to the potential of past experience with weight stigma. Please review the American Society of Anesthesiologists (ASA) guidance for patients taking GLP-1 agonists who are having elective procedures.

Action Items:

- Obtain a complete and accurate medication history prior to the procedure.
- Ask specifically if the patient is taking any of the GLP-1 agonist medications.
- Be sure to include the brand name, dose, route, frequency, and indication of each GLP-1 agonist medication, if applicable.
- Consider holding GLP-1 agonists on the day of the procedure or a week prior to the procedure, depending on the dosing schedule of the individual GLP-1 agonists.[1]
- If the GLP-1 medication prescribed for diabetes management is held for longer than the dosing schedule, refer patients to their healthcare team for continued management to prevent the risk of hyperglycemia.[1]
- Monitor the patient on the day of the procedure for presence of any gastrointestinal symptoms (e.g., nausea and vomiting, bloating, abdominal pain) and adherence to holding the GLP-1 agonists as instructed.[1]
- Refer to the guidance from the ASA surrounding the preprocedural instructions for patients taking GLP-1 agonists.

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UNDERSTANDING HEALTHCARE DISPARITIES IN PENNSYLVANIA: **WE NEED YOUR HELP**

By **Patient Safety Authority**

Keywords: Pennsylvania, healthcare disparities, patient demographics, patient safety

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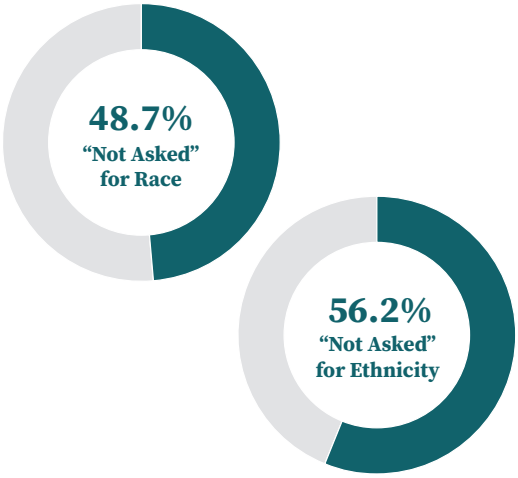
Patient Safety Authority. Understanding Healthcare Disparities in Pennsylvania: We Need Your Help. *Patient Safety*. 2023;5(Highlights of 2023):91637.

Disparities in healthcare pose a significant patient safety threat.[1] In 2021, The Joint Commission issued a Sentinel Event Alert titled "Addressing Health Care Disparities by Improving Quality and Safety".

Because population-specific data can reduce harm and improve patient care, the Patient Safety Authority (PSA) updated the Pennsylvania Patient Safety Reporting System (PA-PSRS) to capture patient demographics, including race, ethnicity, sex assigned at birth, gender identity, sexual orientation, and ZIP code.

During 2022, the first year of data collection, reporters selected "Not Asked" for patient Race in 48.7% of event reports and "Not Asked" for patient Ethnicity in 56.2% of event reports.

"Not Asked" should only be selected if facilities do not have this patient information. Choosing this option as a default affects our ability to accurately track and analyze disparities occurring throughout Pennsylvania, which could further perpetuate healthcare disparities.



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About the Author

Patient Safety Authority (patientsafety.pa.gov) is an independent state agency that oversees the Pennsylvania Patient Safety Reporting System (PA-PSRS), the largest database of its kind in the United States.

I AM PATIENT SAFETY 2023 ANNUAL ACHIEVEMENT AWARDS

Since the Patient Safety Authority (PSA) 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, selected a Choice Award winner for special recognition.

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

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

Physician Offices

Quality Department
OSS Health

Physician Offices award winner, the Quality Department, from 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.

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.

[1]Patient Safety Authority

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

Transparency and Safety in Healthcare

Behavioral Health 6 Spruce Shared Governance

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 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

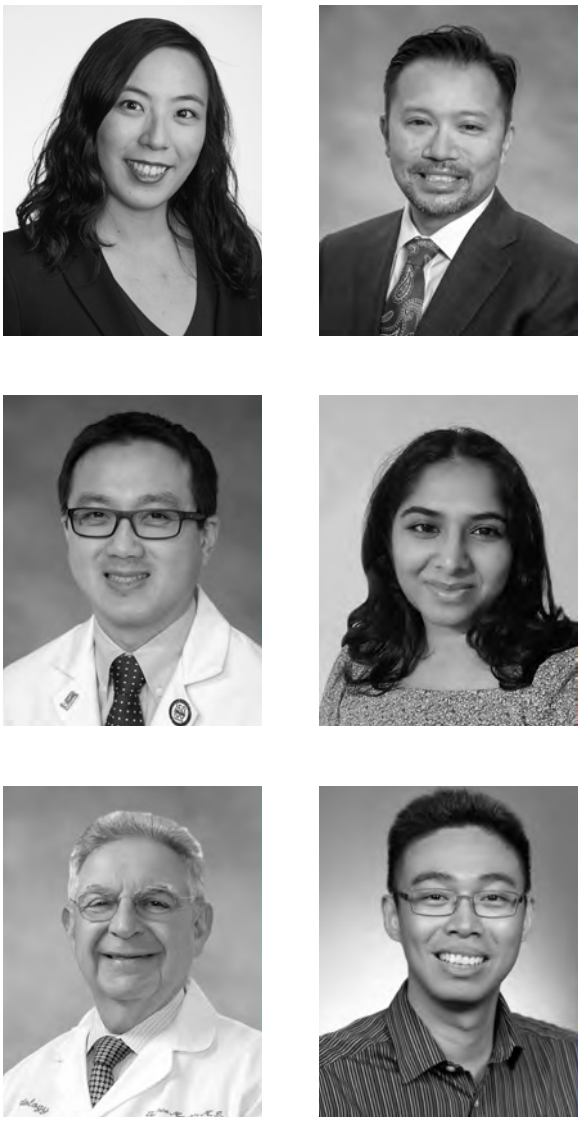
The Network serves an underserved population in which access to healthcare, including imaging, can be challenging. Traditionally, follow-up recommendations for imaging studies by radiologists were primarily initiated by the provider who ordered the original study. This team sought to improve compliance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

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

Donelle Grove 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

Donelle Grove, RN, Infection Preventionist
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.

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

Ambulatory Surgical Facility

Mary Houton, Susan Walker, and the Ambulatory Surgical Center and Infection Prevention Registered Nurses
Penn Medicine Pennsylvania Hospital

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

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)

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

Sepsis

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

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

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 mother, 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.

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

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*

I **AM** PATIENT SAFETY **2023**

Thank you to this year's judges:

Mike Bruno, MD, *Penn State*
Sophie Campbell, MSN, RN, *PADONA/LTCN*
Dan Degnan, PharmD, MS, *Purdue University*
Jackie Ewuoso, MPH, *Betsy Lehman Center*
Diane Frndak, PhD, MBA, *Robert Morris University*
Regina Hoffman, MBA, RN, *Patient Safety Authority*
Dani Jurgill, *Patient representative*
Stephen Lawless, MD, *Nemours Children's Health*
Ariana Longley, MPH, *Patient Safety Movement Foundation*
Dwight McKay, *Patient representative*
Adam Novak, MA, *Michigan Health & Hospital Association*
Amelia Paré, MD, *Paré Plastic Surgery*
Marty Raniowski, MPP, *PAMED*
Veronica Richards, Esq., *Richards & Richards, LLP*
Rob Shipp, PhD, RN, *HAP*
Stanton Smullens, MD, *Retired*
Eric Weitz, Esq., *The Weitz Firm*

About the Author

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

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PA PATIENT SAFETY

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