PATIENT SAFETY

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Events That Inspired Change: The Importance of Sharing What Happened to Stop It From Happening Again

LETTER *From the Editor*

Regina Hoffman,
Editor-in-Chief
Patient Safety

This March marks the 21st Patient Safety Awareness Week, first initiated in 2002 by the National Patient Safety Foundation to invite conversations on how to reduce harm and improve care.

In this issue, you will find four articles that originated from the Patient Safety Authority's fall master class in writing. Applicants submitted a description of a recent quality improvement study and those selected participated in a two-part workshop. The facilitators, Johns Hopkins' Olivia Lounsbury and *Patient Safety* editors Caitlyn Allen and Eugene Myers, helped translate tremendous patient care into publishable manuscripts. (Keep an eye out for future workshops!)

The manuscripts include strategies to reduce adverse events from moderate sedation from Julia Bayne et al., a central line–associated bloodstream infection (CLABSI) prevention project from Erin Lightheart et al. that applied a unique spin on virtual rounding, a promising approach to increasing sepsis bundle compliance in the emergency department from Megan Kiser et al., and a look at reducing urine culture contamination by Clare Cowen et al.

The team at MedStar Health Research Institute took a deep dive into two critical, fundamental topics: alarm design and equipment safety.

Rounding out the issue is an interview with Patient Safety Authority board chair, Dr. Nirmal Joshi, who has led the most robust patient safety state agency for almost a year. He shared his thoughts on how to—finally—address the challenges we're all facing but have yet to be able to solve.

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

Stay safe and stay well!

ABOUT *PATIENT SAFETY*

As the journal of the Patient Safety Authority, committed to the vision of "safe healthcare for all patients," *Patient Safety* (ISSN 2689-0143) is fully open access and highlights original research, advanced analytics, and hot topics in healthcare.

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

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

 The current issue is available at patientsafetyj.com.

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

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

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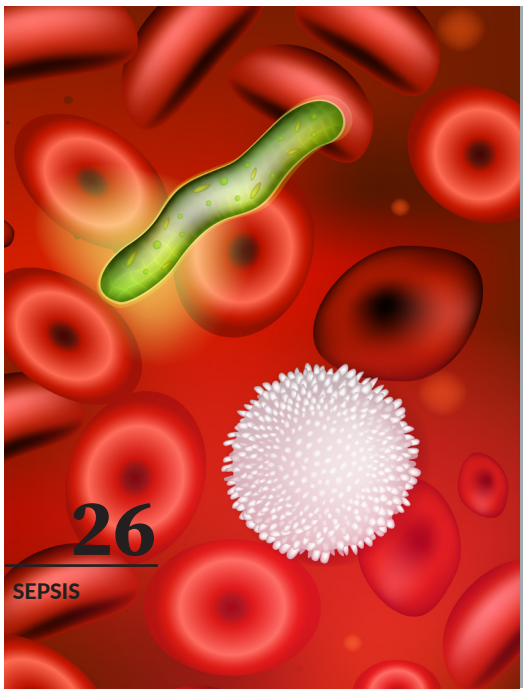

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PATIENT SAFETY INITIATIVE

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

By **Zoe M. Pruitt**, MA[◆], **Lucy S. Bocknek**, MS, OTR/L[◆], **Deanna-Nicole C. Busog**, BS[◆], **Patricia A. Spaar**, MSN, RN[◆], **Arianna P. Milicia**, BS[◆], **Jessica L. Howe**, MA[◆], **Ella S. Franklin**, MSN, RN[◆], **Seth Krevat**, MD[◆†], **Rebecca Jones**, MBA, RN*[‡] & **Raj M. Ratwani**, PhD[◆†]

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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.

Keywords: *auditory alarm, visual alarm, human factors, patient safety*

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.

*Corresponding author
[◆]MedStar Health National Center for Human Factors in Healthcare
[†]Georgetown University School of Medicine
[‡]Patient Safety Authority
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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**.

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.

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.

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.

Design Characteristics		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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.

Specificity		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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		
Highly Relevant Guidelines From Other High-Risk Industries	Considerations for Healthcare	Examples
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.

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 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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About the Authors

Zoe M. Pruitt is a senior human factors specialist at the MedStar Health National Center for Human Factors in Healthcare.

Lucy S. Bocknek is a human factors and safety scientist at the MedStar Health National Center for Human Factors in Healthcare.

Deanna-Nicole C. Busog is a senior research associate at the MedStar Health National Center for Human Factors in Healthcare.

Patricia A. Spaar is a senior clinical safety and research specialist at the MedStar Health National Center for Human Factors in Healthcare.

Arianna P. Milicia is a research associate at the MedStar Health National Center for Human Factors in Healthcare.

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

Ella S. Franklin is the senior director of nursing research and systems safety science at the MedStar Health National Center for Human Factors in Healthcare.

Seth Krevat is the senior medical director at the MedStar Health National Center for Human Factors in Healthcare and an assistant professor at Georgetown University School of Medicine.

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

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

Assessing Equipment, Supplies, and Devices for Patient Safety Issues

By **Raj M. Ratwani**, PhD[◆†], **Katharine T. Adams**, MS[◆], **Tracy C. Kim**, MPS[◆], **Deanna-Nicole C. Busog**, BS[◆], **Jessica L. Howe**, MA[◆], **Rebecca Jones**, MBA, RN[*‡] & **Seth Krevat**, MD[◆†]

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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.

Keywords: *equipment, medical device, human factors, patient safety*

*Corresponding author
◆MedStar Health National Center for Human Factors in Healthcare
†Georgetown University School of Medicine
‡Patient Safety Authority
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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

[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.

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 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.

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.

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 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.

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).

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 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.

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.

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%), 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 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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About the Authors

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

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

Tracy C. Kim is a research and program manager at the MedStar Health National Center for Human Factors in Healthcare.

Deanna-Nicole C. Busog is a senior research associate at the MedStar Health National Center for Human Factors in Healthcare.

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

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

Seth Krevat is the senior medical director at the MedStar Health National Center for Human Factors in Healthcare and an assistant professor at Georgetown University School of Medicine.

Improving Sepsis Compliance With Human Factors Interventions in a Community Hospital Emergency Room

By **Megan Kiser**, RN, MSN◆

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Abstract

Background: Adherence to best practices for sepsis management at a small community hospital was below system, state, and national benchmarks and affected vital indicators, including mortality. This study aimed to improve sepsis best practice compliance by implementing human factors–influenced interventions.

Methods: The Plan-Do-Study-Act quality improvement methodology was used for this project. Baseline metrics included sepsis bundle compliance following CMS (Centers for Medicare & Medicaid Services) core measure standards, hospital mortality, sepsis triage screening, and physician order set use.

Interventions: Several human factors workflows and tools were used to boost early identification with screening opportunities and enhance staff awareness of sepsis indicators.

Results: With the interventions, the hospital's compliance with sepsis best practice treatment improved by a 23 percentage-point increase from baseline. Sepsis triage screening also increased and remained consistent after project interventions.

Conclusions: With the project, using human factors tools enhanced staff engagement and increased sepsis awareness. Engagement increased sepsis identification and screening in a small community hospital setting.

Keywords: *sepsis, human factors, triage, quality improvement*

Introduction

Sepsis is an emergency that significantly increases mortality risks for patients of all ages.[1] Therefore, early identification and treatment are essential in the emergency room setting to prevent further sepsis-related morbidity and mortality.[2]

At Allegheny Health Network (AHN) Grove City Hospital in 2021, adherence to the best practice treatment for sepsis management was low at 44.9% year-to-date compliance. In 2021, the hospital sepsis mortality rate was 7.2%. Overall compliance with the best practice treatment was below national and state benchmarks of 55% for Pennsylvania and 57% nationally.[3] Sepsis was identified as a key driver contributing to the hospital's mortality rate in 2021. In October 2021, a retrospective review of patients diagnosed with sepsis in the emergency room showed that only 42% of patients were screened for sepsis in triage.

Available Knowledge and Rationale

Sepsis results from infection and, if untreated, can lead to organ dysfunction and death. The Centers for Medicare & Medicaid Services (CMS) define interventions to treat sepsis, including early antibiotic administration, fluid resuscitation, and medication to support a patient's blood pressure.[4] However, implementing these lifesaving interventions is contingent on the early detection of sepsis. Early detection significantly influences the likelihood of survival from sepsis, with previous research demonstrating an increase in mortality for every one-hour delay in sepsis recognition and treatment. Early detection can be achieved by recognizing the known sepsis criteria collected through physical patient assessments and lab testing.[4] In addition, nurse-led sepsis screening has aided in early identification to start timely treatment interventions.[5]

◆Allegheny Health Network Grove City

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Though screening tools are known to facilitate the early detection of sepsis, to be helpful, they must be accessible and visible. Previous human factors engineering literature has shown the importance of the designing process that works for frontline users.[6] Additionally, embedding tools such as screening tools into workflows helps minimize human errors and variation between users with varying skill sets. This approach designs a workflow rather than relying on training.[6] Strategies to minimize variation in sepsis screening are of utmost importance. Registered nurses' (RNs) knowledge of sepsis varies based on several factors, including education, work unit, and years of service. Applying a human factors intervention can assist in hardwiring workflows despite any variation of knowledge or care setting, which is particularly imperative in efforts to improve the timely detection of sepsis.

Rationale

Observations and interviews were conducted with frontline employees and management. The frontline observations revealed variations in nurse-led sepsis screening. The observations and interviews also found decreased staff engagement in sepsis tools and processes in the electronic medical record (EMR). In interviews, one root cause identified for decreased engagement was a transition in the hospital to a different EMR system. After transitioning to the new EMR system, the sepsis screening criteria were hidden and calculated with analytics. It was concluded that the change to the new EMR system fragmented sepsis screening criteria and information within the workflow and created a challenge for accurate, reliable screening. We hypothesized that centralizing sepsis screening criteria in one place to ensure congruence with the existing workflow would lead to increased sepsis screening and more timely sepsis detection.

Specific Aims

The project was intended to improve compliance with sepsis best practice treatment and ultimately decrease the overall sepsis mortality rate. The project aimed to increase the sepsis best practice treatment compliance from baseline (44.9% in 2021) to 50% over the next year by implementing human factor interventions. Additional process measures aimed to increase triage screening by 20% and to increase physician treatment order set use by 10% from the baseline in the next calendar year of 2022.

Objectives

The key objective of this project was to be more proactive in identifying and managing potentially septic patients by increasing awareness of sepsis criteria triggers in triage rather than reacting when septic patients begin to deteriorate. In addition, we aimed to apply human factors–based best practices to facilitate sepsis screening and early treatment.

Context

AHN Grove City Hospital is a small community hospital in Grove City, Pennsylvania, with 67 licensed beds and is part of a hospital network consisting of nine hospitals in Pennsylvania and one in New York. AHN acquired Grove City Hospital in December 2020. The electronic medical system changed from The T System to Epic during the transition period in February 2021.

This quality improvement project occurred in the Emergency Department (ED), an eight-bed unit. In 2021, there were 15,363 ED visits. Before the project, there was a vacancy in the quality manager role, and the hospital sepsis workgroup disbanded in May 2021. Therefore, this project began in October 2021 with the acquisition of a quality manager.

Methods

Interventions

Key members in the project's planning included the director of Nursing, the ED nurse manager, the quality manager, and the medical director of the ED. Gaps in the process were identified with the frontline observations and input from the frontline staff and the critical nursing leaders via informal discussions. Based on the data and the feedback gathered, several changes were tested.

The team used the PDSA (Plan-Do-Study-Act) methodology to test potential interventions to make the quickest impact on the hospital's sepsis compliance.[7]

The Reboot of the Multidisciplinary Sepsis Workgroup

The first change was to reinstitute a sepsis work group in November 2021, inviting multidisciplinary hospital members to review sepsis metrics, discuss outliers, and plan improvement activities. We reinstated the workgroup to increase sepsis awareness and ensure a multidisciplinary approach when developing improvement interventions.

Initial attendance of the multidisciplinary workgroup consisted mainly of nurse managers and representatives from senior leadership and ancillary departments, including infection prevention, pre-hospital services, laboratory, and pharmacy. Physician presence in the workgroup started in February 2022. Small changes in the workgroup occurred over time. These changes included increased ancillary department involvement and meeting logistics, such as scheduling for physician availability.

Engagement in the workgroup and attendance were factors that significantly improved the productivity of the workgroup. Completion of action items along with outcome and process measures were monitored for effectiveness by the workgroup. Interventions targeted in the project were increased data transparency, awareness of sepsis triggers in triage, visual cues for sepsis triggers, and visual cues for best practice treatment interventions.

Awareness of Triage Nurse Screening

The quality manager completed an initial gap analysis that consisted of observation of current workflows and interviews with the ED frontline staff, physicians, and the nurse manager. A gap identified in interviews and observations was the need for more data to inform nursing leaders on the utilization of the sepsis triage question in the ED. A manual chart review process was developed to gather data using an existing EMR report to conduct retroactive chart reviews of patients diagnosed with sepsis. Data collected included whether the RN answered the sepsis triage question, the result of the screening, and the reason for the patient coming to the ED. Baseline compliance with the sepsis screening question was shared with the multidisciplinary sepsis work group starting in November 2021 and continued through December 2022. Interventions initially targeted data transparency and staff awareness. Discussions on the data for sepsis screening in triage were held at the workgroup meeting to analyze data and discuss trends. The ED nurse manager used the collected data

to increase awareness by coaching staff on using the RN triage question. Nurse manager coaching of the staff showed an improvement in screening from October 2021 to January 2022.

The work group decided to continue to increase data transparency and staff awareness for the quality manager to provide data to frontline staff directly; a discussion of the importance of sepsis screening and RN screening compliance was included in the weekly staff huddle starting in January 2022. Further development of this intervention resulted from staff input regarding their compliance with screening being lumped together. Due to this, the staff needed help to discern whether they individually were being compliant with the triage screening. From this feedback, triage screening compliance scorecards with individual RN data were developed and shared with staff starting in May 2022. Scorecards were presented to staff monthly at unit staff meetings and sepsis huddles.

Increased awareness and data transparency assisted with improved nurse screening rates. The same concept was used to influence physician process metrics. Physicians were given performance scorecards, including sepsis best practice compliance, outlier reasons, and order set use in April 2022 (Appendix 1). These scorecards were shared with all physicians, the ED medical directors, and the hospital medical director. Increased visibility and leadership support with data support increased order set use.

Visual Cues of Sepsis Criteria

In the past medical record system, all sepsis criteria were visible within the triage screening process. With the new EMR system, the sepsis criteria were not visible, and the staff was asked to screen patients for a possible or known source of infection. At the same time, background analytics was used to determine if the patient met additional sepsis triggers. The fragmentation was hypothesized to contribute to missed RN triage sepsis screenings, as prior to this, the nurses would answer if the patient met any sepsis triggers, which could have led them to start thinking about sepsis.

To address the fragmentation and increase the chance of considering sepsis, visual cues of the critical sepsis criteria were created to provide staff with sepsis information. The hypothesis was that the visual cue would aid as a human factors intervention by decreasing staff reliance on memory and reducing the cognitive burden. The first draft of the visual cue contained criteria and the appropriate sepsis interventions. The ED nursing director reviewed visual cues and gave feedback to condensing the information to only pertinent criteria to increase its visibility (see **Figure 1**). As a result, visual cues were placed at the top of the screen on the clinical computers used by the RNs in March 2022. At the same time, physician-facing visual cues were created to remind them of the elements of the sepsis best practices and critical factors contributing to decreased compliance (such as documentation points). Visual cues of sepsis criteria resulted in improved compliance with the screening question, and retrospective chart reviews showed an increase in accurate sepsis screening after implementing the visual cues.

In addition to attaching the visual cue card to the computer, it was determined that there was an opportunity to provide other references. A reference card attached to an identification badge, known as a "badge buddy," was explored to complement the original visual cue card. The size of the badge buddies allowed the addition of other essential information, including sepsis process reminders (**Figure 2**). Badge buddies were rolled out to the emergency room nurses and physicians in August 2022. The use of badge buddies proved easy to implement, so much so that other departments (e.g., medical-surgical, intensive care unit [ICU]) began to adopt the concept to increase overall awareness of sepsis throughout the hospital. Frontline staff anecdotally felt the resource was valuable and minimized the need for those on the front line to remember all the pertinent information.

Network Change to Triage Question

In response to the increasing sepsis efforts, AHN changed the EMR to ensure the use of the RN triage question related to sepsis. When the triage question was not answered, it turned red to indicate the need for sepsis screening. Before this change, no indicator would alert a nurse that the sepsis triage question was unanswered. The sepsis screening question was in a line of other frequently used screening tools for triage and was found to be skipped past often. The hypothesis was that the visual cue would aid as a human factors intervention by decreasing staff reliance on memory of completing the triage question regarding whether a patient had a known or possible source of infection. After this change in August 2022, there was a significant improvement in RN triage screening compliance sustained in subsequent months.

RN Sepsis Escape Room

Though triage sepsis screening was increasing, there was significant variation in recognizing sepsis from nurse to nurse, likely because the experience of the frontline nurses in the ED ranged from new graduates to seasoned nurses. As a result, we identified an opportunity to support staff with critical concepts related to sepsis identification and treatment best practices,

Figure 1. Visual Cue of the Critical Sepsis Criteria

Think Sepsis (2 SIRS criteria + suspected infection) ***Document fluids given by EMS***

SIRS Criteria	Possible Signs of Sepsis
Temp >101 F	Altered mental status
Temp < 96.8 F	SBP < 90; MAP < 70
HR > 90	Shivering/very cold
RR > 20	Clammy/sweaty
WBC > 12,000	Short of breath
WBC < 4,000	

Key:
SIRS: Systemic Inflammatory Response Syndrome
EMS: Emergency Medical Services
SBP: Systolic Blood Pressure
MAP: Mean Arterial Pressure
HR: Heart Rate
RR: Respiratory Rate
WBC: White Blood Count

Figure 2. Sepsis Badge Buddies

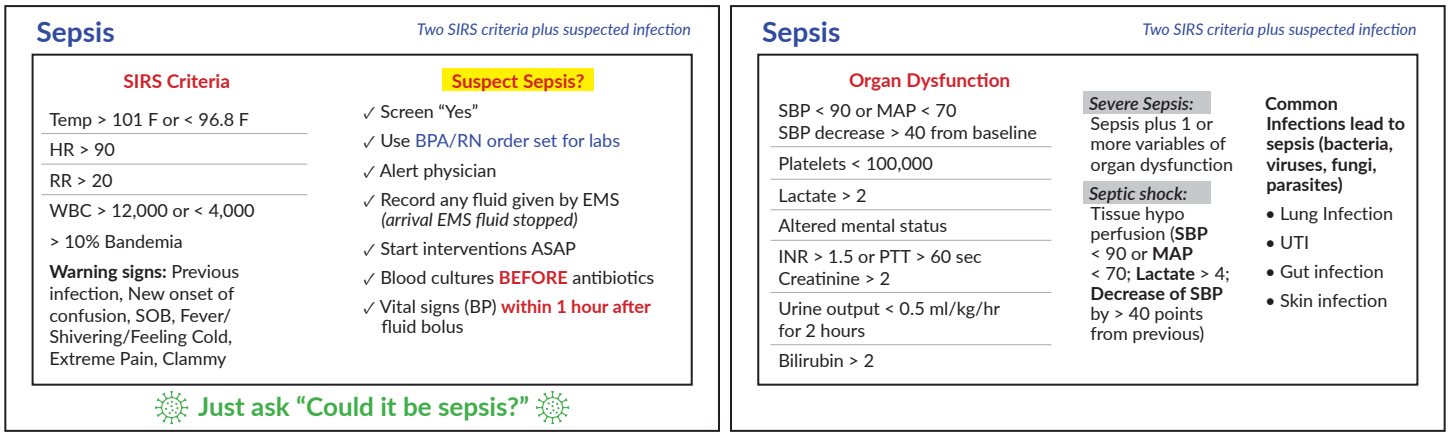


Figure 3. Sepsis Best Practice Treatment Compliance

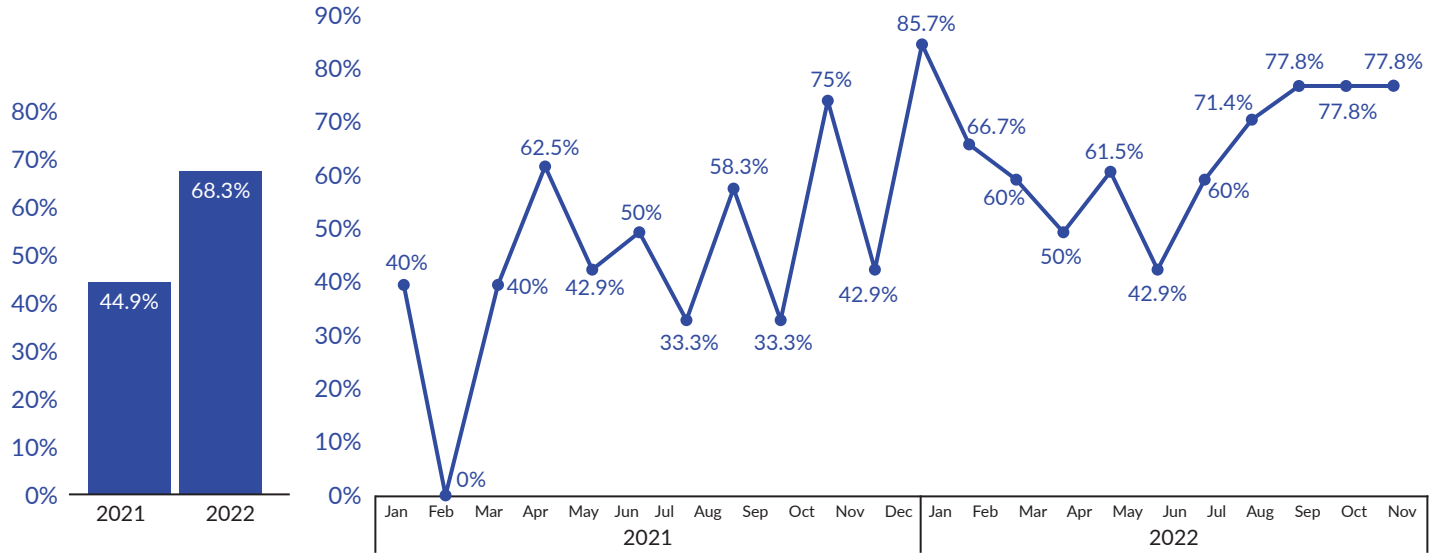


Figure 4. Sepsis Mortality

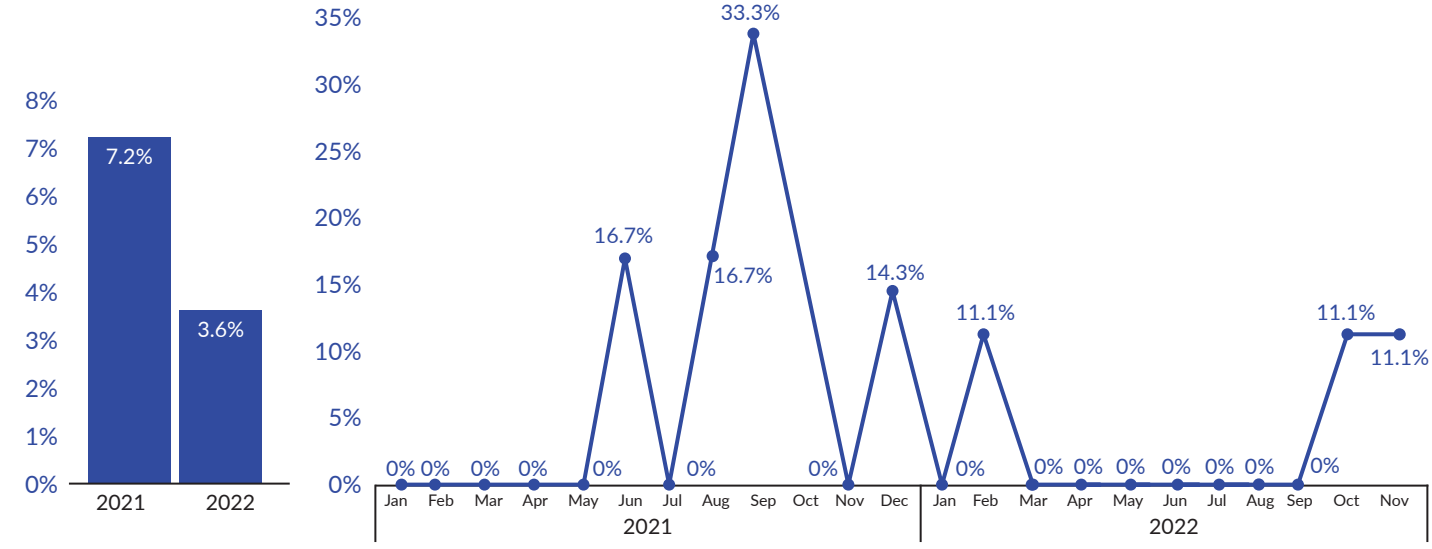


Figure 5. ED RN Triage Screening Compliance

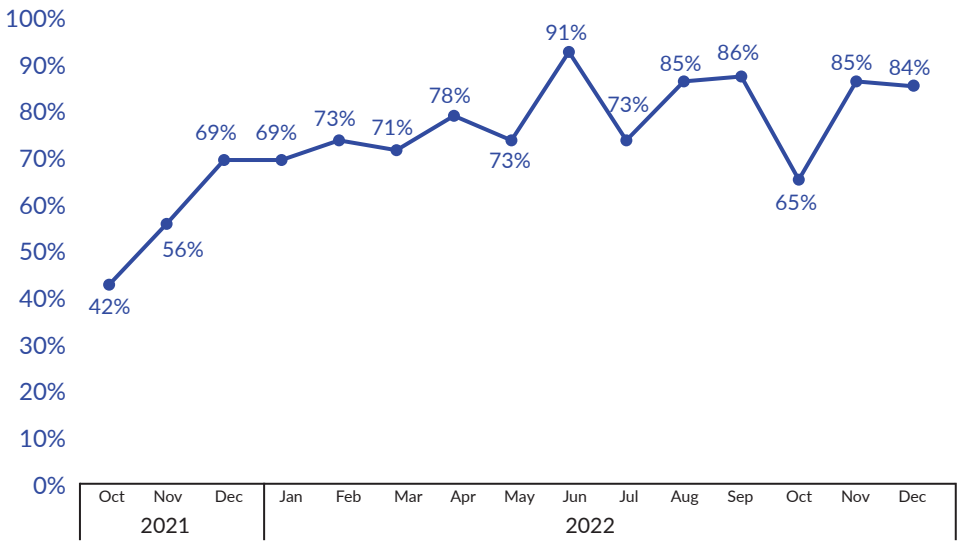
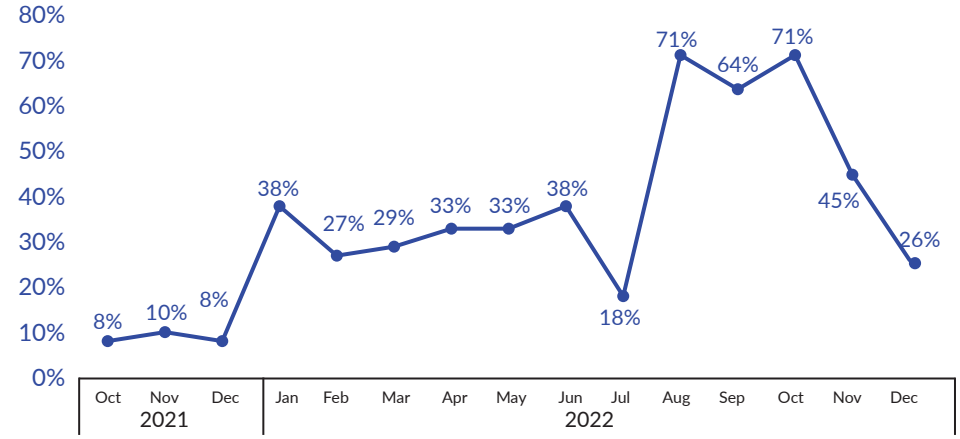


Figure 6. ED Sepsis Compliance and Physician Order Set Use



which we decided to address by designing sepsis escape rooms.

Escape rooms are an activity that can facilitate learning and engagement by using clues and puzzles to enhance staff retention of critical concepts.[8] The concept for the sepsis escape room was created with the Simulation, Teaching, and Academic Research (STAR) Center at AHN. The escape room was conducted during ED RN education days. ED nurses were scheduled to run through the escape room, starting with a scenario and unlocking a set of six toolboxes, answering questions related to sepsis criteria and the treatment best practices. During the education days, 14 ED nurses attended the activity. Though feedback was collected anecdotally from attendees, formalizing pre- and post-tests were identified as a potential future improvement to evaluate the overall effectiveness of the escape room. The RN Sepsis Escape Room was completed in August 2022.

To expand sepsis knowledge and with positive ED feedback, the sepsis escape room was modified for other nursing units in the hospital, including the medical-surgical unit and ICU. It was implemented in those units in October 2022. Nine ED nurses missed the initial escape room education and were required to attend the October 2022 sessions.

Measures

Patients who met CMS sepsis core measure criteria were abstracted by abstractors within AHN after hospital discharge. The abstractors provided measures in a monthly graphical format in Tableau, a data visualization software. Outcome measures for the project included compliance with sepsis treatment best practices and sepsis mortality for the hospital based on the CMS sepsis core measure.

Process measures used through the project included the completion rate of the triage nurse screening question and the physician order set use for sepsis. For this data, the EMR system generated a monthly report of patients who were given a clinical impression of sepsis after an emergency room visit by the ED physician. From the list, the quality manager completed retrospective chart reviews to identify whether the triage sepsis question was used or whether the physician used an order set.

Analysis

The effectiveness of each intervention was measured with process and outcome metrics. All metrics were displayed on run charts. In addition, sepsis treatment best practice compliance and mortality were tracked through the CMS sepsis core measure abstraction and shown in Tableau. Data was updated as abstraction progressed. Run charts were also used to display process measures and were updated monthly by the quality manager after completing chart reviews.

Results

In 2021, the hospital's compliance with the sepsis best practice treatment was 44.9% (n=69). As of November 2022, the hospital compliance with sepsis best practice treatment was 68.3% (n=82). (See **Figure 3.**) In 2021, mortality was 7.2% (n=5), while as of November 2022, mortality was 3.6% (n=3). (See **Figure 4.**)

At the start of the project, there was 42% compliance with RN sepsis triage screening. The screening fluctuated during the project (56%–91%) but achieved a mean of 78.5% from February 2022 through December 2022. (See **Figure 5.**)

Physician use of the order set started at 8% at the beginning of the project. In January 2022, compliance increased from 8% in

December 2021 to 38%; however, variation was noted throughout 2022 (18%-71%). (See **Figure 6.**)

Discussion

Summary

Implementing the interventions resulted in improvement toward the initial aim of 50% for sepsis best practice treatment compliance by increasing by 23 percentage points from the previous year. Sepsis compliance at the hospital as of November 2022 was above the national and state average at 68.3%. In addition, all process and outcome measures showed improvement for the current year.

Interpretation

It was noted that there were marked improvements from the prior year with some variability and opportunity for sustaining improvements in the project period. We discovered that reducing the cognitive burden of remembering all sepsis criteria and treatment allowed frontline staff to focus on utilizing screening and treatment tools to increase sepsis best practice compliance.

Lessons learned included guiding interventions from observations and direct feedback from frontline staff. Using data was imperative to show the need to make process changes to the frontline staff.

Challenges throughout the project included a surge of the coronavirus, which occupied the frontline staff in direct patient care and screening for signs and symptoms to apply isolation precautions properly.

Limitations

The project interventions were conducted in one community hospital, which may have limited the population. Another limitation of the project was the short length of time monitored. Reports were generated from the Epic EMR system; other systems may not have similar functionality. Limitations were also noted with the EMR as reports were not provided in real-time to identify patients who met sepsis criteria.

Conclusion

Technology advancements and healthcare changes are inevitable, especially in community hospitals. Observations of processes intending to drive meaningful improvement can identify key opportunities to implement human factors interventions which have been shown to assist frontline staff in decreasing the reliance on memory and increasing the quality of care. Staff engagement can be improved with data transparency and awareness, and help lead to the development of crucial resources for the identification and treatment of sepsis patients.

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About the Author

Megan Kiser (Megan.Kiser@AHN.ORG) is the manager of Quality Services at Allegheny Health Network (AHN) Grove City since October 2021 and leads the hospital's Sepsis Workgroup. Prior to this role, she held positions within Quality and Patient Safety at University of Pittsburgh Medical Center (UPMC) Horizon/Jameson, Sharon Regional Medical Center, and the Primary Health Network. She received her Master of Science in nursing administration degree from Waynesburg University in 2013 and her Bachelor of Science in nursing degree from Gannon University in 2005. Prior to working in the quality and patient safety field, she worked as a registered nurse in telemetry at UPMC Passavant and obstetrics at UPMC Northwest. Kiser is an avid equestrian and in her free time she rides and competes with her Appaloosa horses.

Adverse Drug Reactions in Moderate Sedation: Process Improvement During a Pandemic

By **Julia Bayne**, DNP, RN*◆, **Amanda Craft**, BSN, RN◆,
Alex Ho, MA, MS◆ & **Jenna Mastromarino Riley**, MSN, RN◆

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Abstract

Background: A gap analysis identified the need for process improvement surrounding the identification and reporting of adverse drug reactions related to moderate sedation. A change to documentation was selected to address this gap. The challenge was disseminating the change in a meaningful way during a time of high census and limited staffing due to the COVID-19 pandemic. Complex adaptive systems theory was used to plan interventions in these conditions.

Methods: Process improvement was organized into Plan-Do-Study-Act cycles guided by the gap analysis, literature, and aims. Quantitative data analysis was conducted using chart audits and a Likert survey.

Interventions: Adoption of end-user-redesigned documentation was completed over time using one-on-one instruction, brief just-in-time education sessions at huddles, and ongoing feedback.

Results: The survey results demonstrated a significant increase in adverse event knowledge ($p=<0.01$) and documentation confidence following just-in-time training ($p<.01$). Chart audits revealed an increase in identification of adverse events ($p=0.03$).

Conclusions: Using a theory-based approach to implement process improvement is a successful way to create change in a challenging environment. Identification of adverse drug reactions related to moderate sedation increased, which is essential for evaluation and safe administration.

Keywords: *moderate sedation, complex adaptive systems, COVID, process improvement*

*Corresponding author
◆Penn State Health St. Joseph Medical Center
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Introduction

At a community hospital in the Northeastern United States, a gap analysis revealed that a process change was needed regarding moderate sedation documentation so that adverse drug reactions (ADRs) were more readily captured. This documentation change would require education for the registered nurses in the departments that perform sedation. The challenge was that a third wave of the COVID-19 pandemic was severely impacting the hospital concurrent to the process improvement project.

Moderate sedation is the practice of methodically reducing patient consciousness to allow a patient to tolerate painful or invasive procedures. Procedural sedation and conscious sedation are equivalent terms to moderate sedation. Moderate sedation carries regulatory reporting requirements and evaluation of any adverse drug reactions.[1]

The COVID-19 pandemic eroded healthcare environments with its impact on census, mortality, and staffing. The length of the pandemic from surges of virus variants stripped away previously used interventions, such as off-unit education for many nurses. The need to keep all available nurses at the bedside dictated that interventions were done in the clinical setting.

Problem Description

Baseline data revealed that ADRs were not consistently identified for evaluation. Moderate sedation audits did not capture any ADRs in a two-year window, which was unlikely and did not match with data from prospective ADR surveillance done via the pharmacy. The Moderate Sedation Committee needed to develop a process to better document when ADRs occurred so that they could be evaluated. This documentation change would create the need for process improvement, and in the challenging climate of the pandemic, the hospital needed a flexible and novel way to implement that process change.

Available Knowledge

Moderate sedation requires prudent administration, management, and monitoring. The moderate sedation program at the hospital is based on guidelines from the American Society of Anesthesiologists (ASA). The guidelines prescribe best practices based on relevant literature and expert consensus. The guidelines include a quality improvement element in which ADRs are evaluated.[2] In order to meet this requirement, accurate data on ADRs are essential.

Regarding education on moderate sedation, Werthman et al. queried hospitals across the country and found that the common practice was annual education combined with advanced cardiovascular life support.[3] This matches the process at the community hospital, where the education is completed online. Because of the nature of the documentation change, updating the annual online education was determined to not be sufficient to ensure meaningful practice change.

Available literature on improving documentation is scant. In one study done specifically on interventions to improve documentation, Moldskred et al. found that effective interventions were to provide educational sessions as well as feedback from ongoing auditing on performance.[4] This concept was used when planning the education intervention in the emergency department (ED). The education sessions started with a case study of a recent patient and audit feedback. In addition, feedback from ongoing audits was shared with registered nurse (RN) documenters across the hospital.

A key element to this process improvement project was the use of theory in building the interventions. Complex adaptive systems, the chosen theory, is part of complexity science and recognizes the importance of the relationships and the interconnectedness of all processes. Healthcare is a dynamic system with many elements and countless interactions. Change is not linear in dynamic systems; therefore, effective change management requires that new processes are able to be embedded into workflows without significant disruption. Complex adaptive systems do not have a single point of control and require distributive decision-making.[5] Applied to this setting and process improvement, the success of new documentation is dependent on the nurses to recognize the importance of accurate documentation and the ability to easily embed it in their workflow. Distributive decision-making occurred when bedside clinicians created the new documentation. Support from leadership includes feedback from ongoing auditing.

Rationale and Aims

This project was designed using complex adaptive systems theory to change moderate sedation practice to reach the goal of identification of ADRs for analysis by the Moderate Sedation Committee. ADR evaluation is part of a robust moderate sedation program. The challenge was that while ADRs were managed appropriately when they occurred, the documentation did not highlight that an ADR occurred, and the audits missed them. Without the ability to consistently identify ADRs, the program could not evaluate performance and safety. A change to the documentation and the audit process were designed to remedy this concern. Complex adaptive systems theory guided the steps of intervention so that the new process would be successful.

The aims of this project were to deploy the new documentation so that ADRs were readily identified for analysis by the Moderate Sedation Committee and to minimize interruption to the clinical environment. The strategy for deployment was education and ongoing auditing with feedback.

Methods

The setting for this process improvement is a 200-plus-bed hospital in Northeastern Pennsylvania, part of a five-location nonprofit health system and academic center. Moderate sedation is performed in select areas only: interventional radiology, the ED, the bronchoscopy suite, and (rarely) critical care. Medications used for moderate sedation in the hospital are primarily benzodiazepines and opioids, with the ED also using ketamine, etomidate, and propofol. Each area has their unique characteristics that affect change. Interventional radiology has a small staff of seasoned RNs, as well as the greatest volume of moderate sedation. The ED has a large staff, a mix of new and seasoned nurses, and a low volume of moderate sedation, which means that the RNs do not have the opportunity to become proficient with the documentation. The bronchoscopy team has low volumes and a small staff to train,

and the critical care areas perform moderate sedation so rarely that proficiency with documentation is not a realistic goal. The timeframe for the project began in June 2021, and documentation changes were enacted in February 2022. Data collection ran for eight months after the intervention.

Intervention

The gap analysis at the community hospital revealed that ADRs were not consistently reported with the original documentation process. This spurred the need to change documentation so that ADRs were readily identified. Because of the importance of the project, it was determined that the project needed to proceed and not wait for a calmer time. The challenge was identifying how to create this change in the current environment. Prior educational interventions were performed by holding in-person classes or lunch-and-learn opportunities, neither of which were feasible given the pandemic and the staffing challenges.

To meet the goal of identifying ADRs more readily in the documentation of moderate sedation, the Moderate Sedation Committee performed multiple Plan-Do-Study-Act (PDSA) cycles. The first cycle was the initial interdisciplinary committee reformation. The committee had been on hiatus during the peak of the COVID-19 pandemic and several of the stakeholders had changed positions. The committee was comprised of nursing, providers, quality and safety, pharmacy, and hospital leadership. The committee performed a gap analysis using ASA guidelines to identify needs. The data gathered revealed that only two ADRs were identified since committee reformation, and zero ADRs in the preceding two years, which was an unlikely scenario. The committee decided to update how moderate sedation was documented in order to address this gap.

The process to change the documentation started with soliciting feedback from end users and looking to see what was routinely missed from the documentation. As the documentation was lengthy and duplicative, it was shortened by removing unnecessary information and consolidating several sections. A section specific to ADRs was added to capture any patient reactions. The options included apnea, oversedation, use of reversal agent, significant change in vital signs, vomiting, and a free-text "other" field. The end users validated that the new documentation met their needs and was an improvement over the prior method. The new documentation was then finalized, and plans were made to launch it.

Education was the primary route to launch the new documentation. The education was personalized to each department. The leaders from each area served on the Moderate Sedation Committee and identified the best methods for their areas. For the areas with small staffs, the education was done on a one-to-one basis by the RN educator. These departments have seasoned staff and minimal turnover. In addition, leaders from each area, such as RN educators or expert evaluators, served on the Moderate Sedation Committee and were charged with personalizing education for their department. Education focused on the addition of the ADR documentation and the changes to shorten documentation.

The leaders also evaluated methods of how new and seasoned staff were educated and how competence was measured and maintained at this time. They identified several areas for improving current training methods of new and seasoned staff. One area that was evaluated was the practice of using online training modules. While the online modules adequately provided information regarding the administration of moderate sedation, the group felt that individual observations were needed. Interventional radiology (IR) was able to implement this during this study. In addition to the online learning modules, the educator in IR observed the staff member administering moderate sedation to five patients as part of their requirement for orientation into IR nursing.

The committee recognized that the ED needed a different plan, given that the environment was dramatically different than interventional areas. The one-on-one training that fit the interventional areas was not feasible in the ED. In addition, the staffing mix included seasoned nurses, new graduates, transfers from other departments, and agency nurses, representing a wide skill mix. While planning for the education in the ED, the COVID-19 pandemic's third wave was cresting, fueled by the omicron variant. This impacted the ED with abnormally high volume along with managing staff sickness. The ED nurses could not come off the floor for training sessions because of this volume. Ideally, this education would have included simulation, but that was not realistic given the healthcare climate.

To overcome these challenges, the leadership of the ED partnered with the Performance Improvement Department to create focused, brief trainings able to be delivered during the shift huddles. The education method selected was just-in-time (JIT) training. JIT traditionally is used to train groups of people on a process just before it is performed and has been used previously in the COVID-19 pandemic. A hospital disaster team in Italy used JIT to train 200 staff members on disaster medicine and personal protective equipment in an environment of anxiety and urgency, and found JIT training effective.[6] While the third wave of the pandemic did not rival the challenges faced in Italy during the first wave, JIT training stood out as the reasonable solution for the moderate sedation education. JIT use has been reported in the hospital setting to educate nurses on clinical deterioration.[7] The relevance of this study is that the nurses appreciated education brought to the bedside and the education increased nurse confidence in identifying deterioration.[7] Looking at complex adaptive systems theory, to achieve meaningful change, one must capitalize on relationships, such as the one between the Performance Improvement Department and ED leadership, and create change that is appreciated. Huddle was selected as the location of training to bring the change to the nurses rather than pulling them out of their environment.

Prior to the education, the leadership from the ED provided a warm introduction to the Performance Improvement staff doing the education for the ED staff. The education started with a case study based on a recent ED patient who had an ADR, and then education on adverse reactions and the new documentation was done. Several aspects of the new documentation were highlighted based on chart audits of what was commonly missed being charted prior to the intervention. This education was repeated multiple times over a two-week period to capture the majority of the RN staff.

The RNs were asked to complete a survey before and after the JIT training that measured their confidence in administering moderate sedation, identifying ADRs, and documenting the ADRs. There was an open field for any comments or questions that were

not addressed in the education. These surveys were distributed on paper just prior to the education. Fruit and candy were also provided to the ED staff at all sessions.

Once the education was complete, the new documentation went live. The last PDSA cycle was establishing meaningful audits. New monthly audits were performed with a different format from previous years. The updated audit captured more data about the patient, the providers, the procedure, and the clinical aspects. The audit included any aberrant vital signs in addition to ADRs, and interventions to treat instability. Completeness of documentation was included in the audit based on the gaps found on prior audits. The auditors had the responsibility to provide feedback to the documenting RNs for anything missed. The feedback was informal and nonpunitive, given face-to-face or via email. When charts were found to be complete, those staff were celebrated.

With the data from the audits, the Moderate Sedation Committee was able to collate the information and create reports detailing how moderate sedation was provided at the hospital, including ADRs. This data analysis ensured that the moderate sedation practices were safe and that patients had the expected outcomes from the procedures, which the committee was able to confirm.

In the ED, documentation errors were more persistent. This may be due to the low volume and large staff. Certain elements were routinely missed in the charting. Because the audits identified these gaps, in addition to personal feedback, the elements routinely missed were added to ongoing education in the department.

Study of Intervention

Improvement in documentation of moderate sedation and ADRs was measured in two ways: a confidence survey and chart audits. In the ED, a convenience sample of RNs completed a pre- and post-JIT survey. Chart audits were completed to identify ADRs and completeness of documentation. Documentation was considered complete when it contained complete sets of vital signs at expected intervals, including cardiac, respiratory, and neurologic assessment.

Measures

The pre- and post-survey for RNs included four Likert scale questions about confidence administering moderate sedation as well as recognizing and documenting adverse events and an open field for questions or comments. A chart audit template was created using a spreadsheet which collected clinical information on the procedure, documentation completeness, and any adverse events identified. The pre-intervention chart audits were retrospectively done via randomly selected moderate sedation cases for the interventional areas. Because the ED had a lower volume of moderate sedation cases, all identified moderate sedation was audited. The audits were looking for ADRs and classified ADRs as either identified or latent. A latent ADR is one that was treated at the time but not flagged for evaluation by the Moderate Sedation Committee. An identified ADR is one that was found in the previous audits and was evaluated by the committee. The goal was to improve the documentation to stop latent ADRs and ensure that all ADRs were identified promptly for evaluation.

Analysis

The RN survey data was collected by providing a paper survey to participants with the pre-survey on one side and the post-survey on the other, allowing for matched samples. The chart reviews were done using the electronic medical record and collected in a spreadsheet.

Statistical analysis was performed using statistical software, SAS 9.4. Measures of central tendency were reported as means ± standard deviations (SD) for RN survey 5-point Likert scale questions (1 "Not confident" to 5 "Very confident") and were compared between pre- and post-intervention studies by the Wilcoxon signed-rank test. To avoid the possibility of incorrectly rejecting a true null hypothesis, a critical significant level of 0.01 (two-sided) was used. The chart audits data were categorical (either positive or negative for adverse events or documentation flaws). An element included in this analysis was whether an adverse event was identified or latent. An ADR was considered latent if it was not brought forward as a case to review. Frequency and percent were calculated and the association between intervention and ADR identification and documentation gap were measured using chi-square or Fisher's exact test where appropriate, and a two-sided significant level of ≤ 0.05 was deemed statistically significant.

Ethical Considerations

This process improvement project was approved by the institutional internal review board and did not require informed consent. Ethical consideration was given to the timing and delivery method given the mental and physical demands of the RNs in the current healthcare climate. This consideration helped form the methods used to disseminate the new documentation.

Results

Data collection was done using a nurses' survey and chart reviews. The survey measured nurse knowledge and confidence on adverse events and documentation (**Table 1**). Four questions were answered by the same nurse in pre- and post-survey, using a Likert scale of 1 to 5. A total of 34 nurses completed these four survey questions. In question 1 (Q1: Identify Adverse Reactions), post-survey achieved significantly higher mean score than in the pre-survey (**Table 1**, 4.59 and 4.29 respectively, $p<0.01$). Similar significant higher scores were shown in Q4 ($p<0.01$) and Q5 ($p<0.01$). Although post-survey had a higher score in Q3 than in pre-survey, the difference was not statistically significant ($p=0.13$). In general, the mean scores on the post-survey were higher than the mean scores on the pre-survey.

The chart audit data collected categorical data, the presence of ADRs, whether the ADR was identified or latent, and the completeness of documentation. Chart audits showed that there were seven adverse drug reactions in the 12-month pre-intervention audit period (**Table 2**). Two were identified at the time and five were latent. Following the intervention, five ADRs were identified over eight months, none being latent. The decrease in latent adverse drug reactions was statistically significant ($p=0.03$). Documentation completeness did not significantly improve, though it has increased since the intervention (**Table 3**); specifically, in the ED where the JIT training was done, documentation errors decreased from 71% prevalence to 62% prevalence.

Table 1. Results of Pre- and Post-Intervention Survey

	Pre-Intervention	Post-Intervention	(Post- to Pre-Intervention)	p-value[b]
Q1: Identify Adverse Reactions	4.29 ± 0.87[a]	4.59 ± 0.61	0.29	<0.01
Q3: Reverse Adverse Reactions	4.41 ± 0.66	4.56 ± 0.56	0.15	0.13
Q4: Document Sedation	4.06 ± 1.10	4.50 ± 0.75	0.44	<0.01
Q5: Document Adverse Reaction	4.00 ± 1.04	4.50 ± 0.75	0.50	<0.01

[a] Mean ± standard deviation
[b] Wilcoxon-signed rank test

Table 2. Adverse Drug Reaction Identification

ADR Identification	Pre-Intervention n (%)	Post-Intervention n (%)
ADR Identified	2 (28.6%)	5 (100.0%)
Latent ADR	5 (71.4%)	0 (0.0%)

p=0.03 (Fisher's exact test)

Table 3. Documentation Gaps

Documentation Gaps	Pre-Intervention n (%)	Post-Intervention n (%)
Emergency Department	15 (71.4%)	8 (61.5%)
Other Departments	6 (28.6%)	5 (38.5%)
All Departments	21 (100.0%)	13 (100.0%)

p=0.71 (Fisher's exact test)

Summary

Updating the moderate sedation documentation during a pandemic required the team leading the change to thoughtfully match the dissemination interventions to the environment. The new documentation was disseminated in the ED starting with a brief education session delivered at routine huddles. This was a successful intervention, as the survey results demonstrated the RNs increased confidence in the documentation and the documentation itself was more complete. Rollout to other areas using a one-on-one method was also successful regarding ADR capture based on chart audits. After rollout, more cases of adverse events were identified than with the old documentation, which allows for a stronger review of moderate sedation practices. The audits ensured that any adverse events were identified and were used to evaluate the completeness of the record. The documentation of sedation improved significantly because of the feedback.

Discussion

This project ensured that the new documentation for moderate sedation was effectively enculturated into workflows. The new documentation was designed with members of the clinical staff, increasing the likelihood of success. The method to disseminate the change was created based on the literature and an assessment of the ability of RNs to learn in a chaotic environment brought by a pandemic and its impact on census and staffing. In the ED, particularly impacted by the pandemic as well as low volume of procedures compared with a large staff, the results of the survey demonstrated that the education method was successful. The RNs felt more confident that they were able to identify and document ADRs. The chart audits demonstrate that the changed documentation forms and the focus on adverse events increased proper identification. This is crucial because adverse drug reactions must be analyzed on several levels, including by the Moderate Sedation Committee.

Interpretation

The timeline was longer than a usual documentation change. The audit/feedback cycle was key for staff improving on documentation. Moving forward, the audits can identify process issues and problems found can spur the next round of education. The process of making this documentation change required a change in focus from creating education and expecting adherence to working more closely with the RNs. The key difference was that the process was designed to meet the nurses where they were. It has changed the approach of how new changes are rolled out in the hospital.

Limitations

The limitation of performing a process improvement cycle in this method is that it requires flexibility and ongoing efforts. Unlike a class or online training that is completed and done, this approach needs more time from the leadership. To mitigate this, the work is divided among departments with support from Performance Improvement. The ongoing time to work on moderate sedation is a proactive patient safety measure that is valued in the organization.

Conclusion

This process improvement was designed for the specific environment at the time of intervention, with high census and tight staffing. Molding a set of interventions to the environment instead of performing process improvement tasks without consideration of other pressures was the key design element. This is generalizable to all process improvements with a scope far beyond moderate sedation. Process improvement in challenging conditions is possible. For success, the process improvement must be of high value, the interventions must fit with the current environment, and the leaders must be willing to change perspective on implementation. Using this method, the hospital was able to evaluate the moderate sedation program and ensure optimal patient safety.

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About the Authors

Julia Bayne (jbayne@pennstatehealth.psu.edu) is a clinical nurse specialist and serves as patient safety manager and peer review coordinator at Penn State Health St. Joseph Medical Center. Her area of interest is sustainable and meaningful healthcare evolution.

Amanda Craft has been a nurse in interventional radiology (IR) for 14 years. In addition to her work with the IR team, she is also the educator for the Radiology Department at Penn State Health St. Joseph Medical Center. Craft has been committed to the safety of patients undergoing moderate sedation procedures and has assisted in the implementation of several policies and practice changes over the years.

Alex Ho is a statistical analyst in the Department of Performance Improvement at Penn State Health St. Joseph. His research interests are biostatistical analysis and epidemiology.

Jenna Mastromarino Riley is the emergency services nurse manager at Penn State Health St. Joseph in Reading, Pennsylvania. She earned her master's degree from DeSales University as an adult-gerontology clinical nurse specialist. She has a passion for patient-centered care and quality improvement.

Reduction of Patient Harm Through Decreasing Urine Culture Contamination in an Emergency Department Using Multiple Process Improvement Interventions

By **Clare Cowen**, MPH*◆, **Shelley Frinsco**, BSN, RN†, **Rebecca Nosal**, PA-C‡ & **Faith Colen**, MSN, RN†

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Abstract

Background: From August 2018 to January 2019, the baseline urine sample contamination rate at an acute care hospital emergency department (ED) was 51%. Urine culture contamination is associated with unnecessary antibiotic use, repeat culture costs, and unnecessary inpatient admissions. These outcomes can lead to additional cost to the patient and healthcare system while leading to additional poor outcomes.

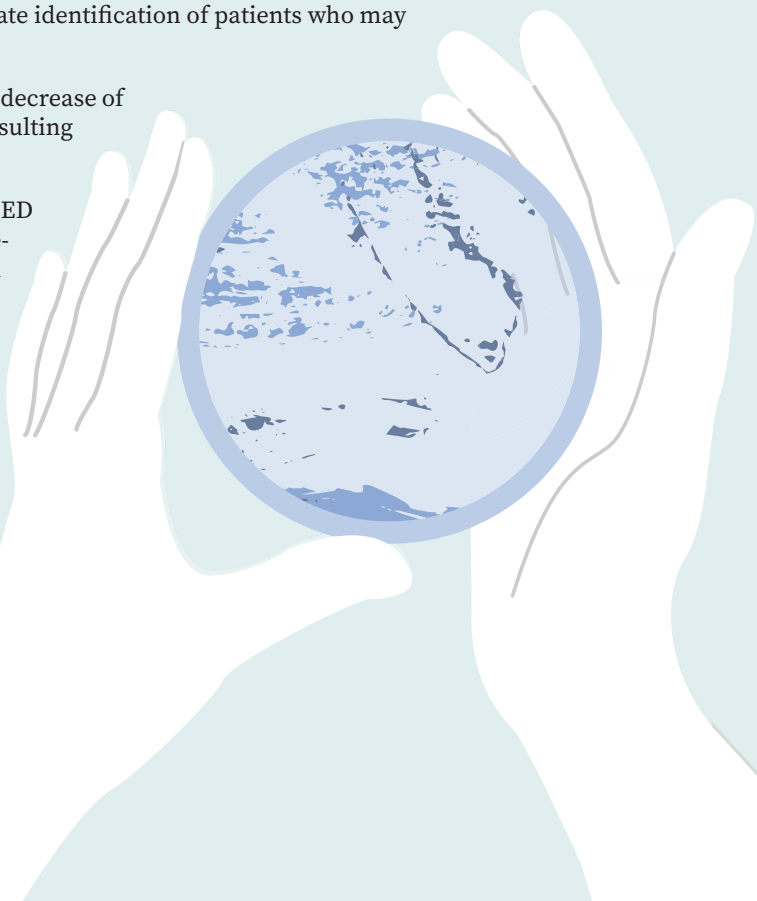
Methods: Culture results were reviewed and the project definition of contamination was applied. Contaminated cultures were reviewed further via manual electronic health record review of ED notes to determine documentation of collection source, education prior to clean catch collection, the cognitive and physical documented descriptions of the patient, and the name of the staff member who collected the sample.

Intervention: Staff were educated on appropriate midstream and straight catheter collection techniques, verbal along with visual education for patients, and appropriate identification of patients who may benefit from straight catheterization instead of clean catch.

Results: The combined interventions resulted in a six-month decrease of contaminated urine samples from the initial 51% to <10%, resulting in an 80% decrease.

Conclusion: Urine culture contamination in an acute care ED was sustainably decreased through multiple process improvement interventions. Secondary outcomes included reduction in unnecessary antibiotic use and unnecessary admissions.

Keywords: *contamination, urine culture, antimicrobial stewardship, unnecessary admissions, straight catheter, patient education, infection prevention*



*Corresponding author
◆University of Pittsburgh Medical Center (UPMC) McKeesport
†UPMC St. Margaret
‡TeamHealth
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Introduction

Problem Description

Physicians raised a concern to the Quality Department about patients who were diagnosed in the emergency department (ED) with a urinary tract infection (UTI) but who later were clinically reviewed and found to be without disease. These patients were often admitted and treated with potentially unnecessary antibiotics.

Available Knowledge

Urine cultures are intended to accurately identify if someone has enough bacteria in their urine to suggest they have a UTI and to identify the type of bacteria in the urine for appropriate antimicrobial therapy needed. Urine culture contamination prevents this purpose from being fulfilled by compromising the sample and affecting the culture growth and interpretation. The definition of a contaminated urine sample is any urine culture with mixed growth. Factors contributing to contamination include specimen handling, storage, and compromised collection techniques.

Delayed transfer from specimen collection cup to tubing with boric acid (known to slow organism growth), delayed transport of specimen to laboratory, and improper specimen storage all contribute to organism growth outside of the urinary tract, which can lead to misinterpretation of test results.

Midstream clean catch specimens are recommended to identify what organism is growing in the urinary tract. The first urine voided washes microorganisms and cellular debris out of the urethra. Bedpans and urinals should not be used for culture purposes as the vessels themselves are not sterile, it eliminates the midstream catch, and urine is often not collected directly after void.

Urine collection from a single catheter when there is high risk of contamination due to operator error is optimal[1] compared to clean catch. Two-person urinary catheter insertion is recommended for both indwelling urinary catheter placement and straight catheter urine collection purposes.[2] Both procedures are meant to be as sterile as possible to prevent transfer of organisms to the urinary tract while inserting the device.

Verbal patient education has been shown to be effective in reducing contamination[3] and visual education has also been shown to separately reduce contamination.[4]

Previous literature has shown that urine culture contamination is directly related to adverse outcomes, including unnecessary antibiotic use,[5] repeat culture costs,[6] and unnecessary inpatient admissions.[7] These outcomes can lead to additional cost to the patient and healthcare system while leading to additional poor outcomes.

Rationale

The Infection Prevention Department performed a current state assessment of 877 patients with contaminated urine cultures between August 2018 and January 2019. Of these patients, 79% were >65 years of age and 86% were female. The current state assessment showed that the average baseline urine culture contamination was 51% of all emergency department (ED) urine cultures. Urine culture contamination and resulting patient harm were investigated.

Specific Aims

Literature reviews show patient and staff education of a clean catch urine culture collection technique alone is not always effective at consistently reducing urine culture contamination.[8,9,10] The intervention team hypothesized that an effective multifactorial method to reduce urine culture contamination would be a combination of staff education on appropriate midstream and straight catheter collection techniques, verbal and visual education for patients, and staff and physician identification of patients who would provide more accurate urine cultures via straight catheterization than clean catch.

The goal of this process improvement was to reduce unintended patient consequences of unnecessary admissions, unnecessary antibiotic treatment, and repeat urine cultures through reducing contaminated ED urine samples to ≤10% monthly contamination.

Key Project Terms and Definitions

- Contaminated urine culture: any urine culture with mixed growth of more than two species of organisms identified.
    - The presence of *Candida* and common skin organisms were excluded from the contaminated culture definition, as their presence is deemed acceptable per the Centers for Disease Control and Prevention.
    - Urine collection sources of nephrostomy, urostomy, suprapubic catheter, and indwelling urinary catheters are known to be contaminated sources but were included in the contaminated culture count regardless.
- Antibiotic recommended for UTI: >100,000 colonies of at least one identified bacteria genus in culture. For retrospective data analysis purposes only, symptoms were not considered.
    - If the urine culture had contamination but also >100,000 colonies per millileter (col/mL) predominate bacteria, antibiotic treatment was considered appropriate.
    - In these instances, antibiograms could generally be performed.
- Unnecessary antibiotics: Patient prescribed antibiotics for a urine culture finalized with mixed growth of unknown genus and <100,000 colonies of bacteria, regardless of a main genus identified.
    - Antibiotics may have been given and appropriate for another reason. A repeat noncontaminated culture may have been performed which indicated appropriate antibiotics, but only the initial contaminated result was considered. Clinically, it may have been appropriate to treat the patient, especially if symptoms of infection were present.

Methodology

Context

The 250-bed teaching hospital specializing in geriatric and orthopedic acute care is part of a multihospital health system. The average ED patient visits are approximately 2,500 per month.

Interventions

1. Building the Team:

The team of stakeholders started as two ED nurses, one infection preventionist (IP), one Quality nurse, and the Quality manager. The team was supported by the ED unit director and clinicians. As time passed, the stakeholders adjusted to one ED nurse, one ED physician's assistant (PA), one IP, the Quality manager, and the Quality director. The aim was to get all team members together at least once per month.

An IP pulled monthly ED reports of urine cultures through a TheraDoc application. They reviewed the culture results and applied the project definition of contamination. They then reviewed contaminated cultures further via manual electronic health record review of ED notes to determine collection source documented; whether education was documented prior to clean catch collection; the cognitive, physical, and mobility documented descriptions of the patient; and the name of the staff member who collected the sample. Data analysis through chart review of patients with contaminated urine cultures suggested a multifactor cause for contaminated cultures. In February 2019, interventions began.

2. ED Staff Urinal and Bedpan Education:

The baseline data was limited due to low staff documentation; however, it suggested that staff were using bedpans and urinals to collect urine culture samples. Both straight catheter and clean catch cultures were contaminated. Less than half of the patients providing clean catch samples had chart documentation indicating that staff provided education on technique prior to the sample. The first initiative was to reduce the collection of urine for culture through bedpans or urinals. Two ED nurse stakeholders provided peer-to-peer education as to why bedpans and urinals are not acceptable for culture collection.

The ED nurses created a presentation for the ED staff that consisted of

1. What's currently happening
2. What not to do
3. Why you should not collect from bedpans, urinals, etc.
4. What to do: clean catch or straight catheter, and document

Discussions regarding teach-back patient education and quick transfer between collection cup and tubing with boric acid were determined not to be the primary focus at this time.

ED staff education began at the end of March 2019. Signs were hung in the ED supply room next to the bedpan and urinals that reiterated not to use these items for urine culture collection.

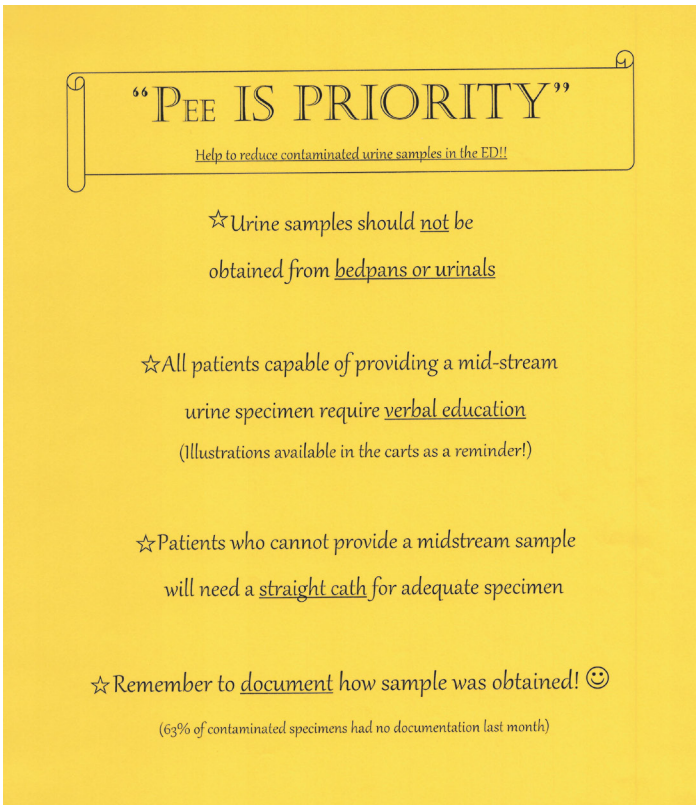
In August 2019, documentation of bedpan and urinal usage was slowing; however, stakeholders were still observing this process during rounds. In October 2019, staff flyers were made (**Figure 1**) and printed on bright yellow paper with the headline "Pee IS PRIORITY." The first bullet point education was another reminder to not use bedpans or urinals for urine culture collection. The flyer used minimal wording and underlined key words. Two other initiatives and a reminder to document in the electronic health record how samples were obtained were on the flyer. These were placed around the ED halls, in the break room, and in staff bathrooms.

Between the end of November and early December 2019, the ED nurse stakeholder began providing face-to-face small huddles or individual feedback for staff who had ≥3 contaminated urine cultures the prior month. Feedback included documented details associated with the contamination, including bedpan or urinal usage, whether patient education was documented prior to clean catch samples, and any commendations for appropriate procedure documented. Personal conversations were supplemented with continued "Pee IS PRIORITY" flyers, weekly update emails to staff, and a section on urine culture contamination in the monthly ED newsletter. Discussions with staff during rounding suggested that email was not their preferred method of contact.

High census in winter 2019–2020 and the COVID-19 surge starting in March 2020 delayed further initiatives in this project. In July 2020, a "staff myths" survey was sent to the ED based on myths that were discovered during peer-to-peer rounding discussions. Questions included:

1. Do you use two staff members to assist with inserting a urinary catheter/straight catheter?
2. What are some barriers to using two staff members?
3. Do sterile straight catheter procedures cause UTIs?
4. Would visuals help to educate patients when there are language/learning barriers?
5. Select reasons why patients would not require education:
    a. History of UTIs
    b. History of pregnancy
    c. Adult female
    d. Patient frequently seen in ED
    e. Patient states they have given urine samples before
    f. None of the above
6. Do you change urinary catheter tubing before or after urine culture sample collection?
7. Do you obtain urine samples with a bedpan or urinal?
8. Do you have any concerns or questions regarding urine collection?

Figure 1. Pee IS PRIORITY Flyer



Of the 18 staff members who completed the survey, two stated that they still use bedpans or urinals. Staff education needed to be an ongoing initiative throughout the entire project.

3. Patient Education Initiative:

One initiative consistently mentioned at each stakeholder meeting was patient education prior to obtaining clean catch samples; the education needed to include the cleaning of the peri area and mid-stream collection process. Feedback from ED staff indicated that patients may have verbalized that they understood the process but were still producing contaminated cultures. There was concern regarding language barriers. The intervention team decided that visual education for patients may be the best alternative.

A picture of the female clean catch urine collection process was reproduced from "Illustrations Reduce Contamination of Midstream Urine Samples in the Emergency Department"[4] with arrows added to indicate the process flow (**Figure 2**). The pictures were printed on 4-by-5 paper to maintain patient privacy and were initially distributed in August 2019. There was an immediate decline in urine culture contamination starting in September 2019.

Although there was a decline in contamination, the number of handouts used was not documented and it was noted that stock did not need to be replenished. Post-intervention rounding and feedback from ED staff over the next few months suggested there was minimal staff buy-in with the visual education largely due to the cartoon depiction that staff did not find appropriate. As a result, **Figure 2** visual education was pulled from the ED in November 2019 to better understand if other initiatives were the source of the contamination reduction.

Verbal patient education and advocating for patient teach-back continued to be requested from the ED staff. In November 2019, the ED staff nurse and ED PA on the intervention team discovered that patients who presented to registration triage in the ED were often given a urine specimen cup while in the waiting area to provide a sample, but were not given education on the collection process. This was immediately rectified and urine specimen cups were no longer distributed until education could be provided.

The "Pee IS PRIORITY" flyers and individual staff education with specific details for each staff member to improve continued. The staff myths survey results showed that 100% of the 18 staff members who completed the survey believed that visuals would help to educate patients where there are language/learning barriers, while 3 staff members believed there were reasons why you would not need to educate a patient on clean catch procedures again, including the patient stating they had given a urine sample before. This data was used to reinforce that education should be provided to every patient for every sample because there is no guarantee that they were educated appropriately in the past or that they remembered all required steps for clean catch.

One last visual education effort was made in May 2021 to provide drawings that were more accepted by staff. The simple drawings for both male and female clean catch available in both English and Spanish in **Online Supplent Appendix A**[11] were used. The education was made available to the entire health system print shop in 4-by-6 handouts, full-page handouts, and 11-by-17 posters. Next planned steps were to order posters and place them in ED patient restrooms.

4. Advocating for Straight Catheter Collection:

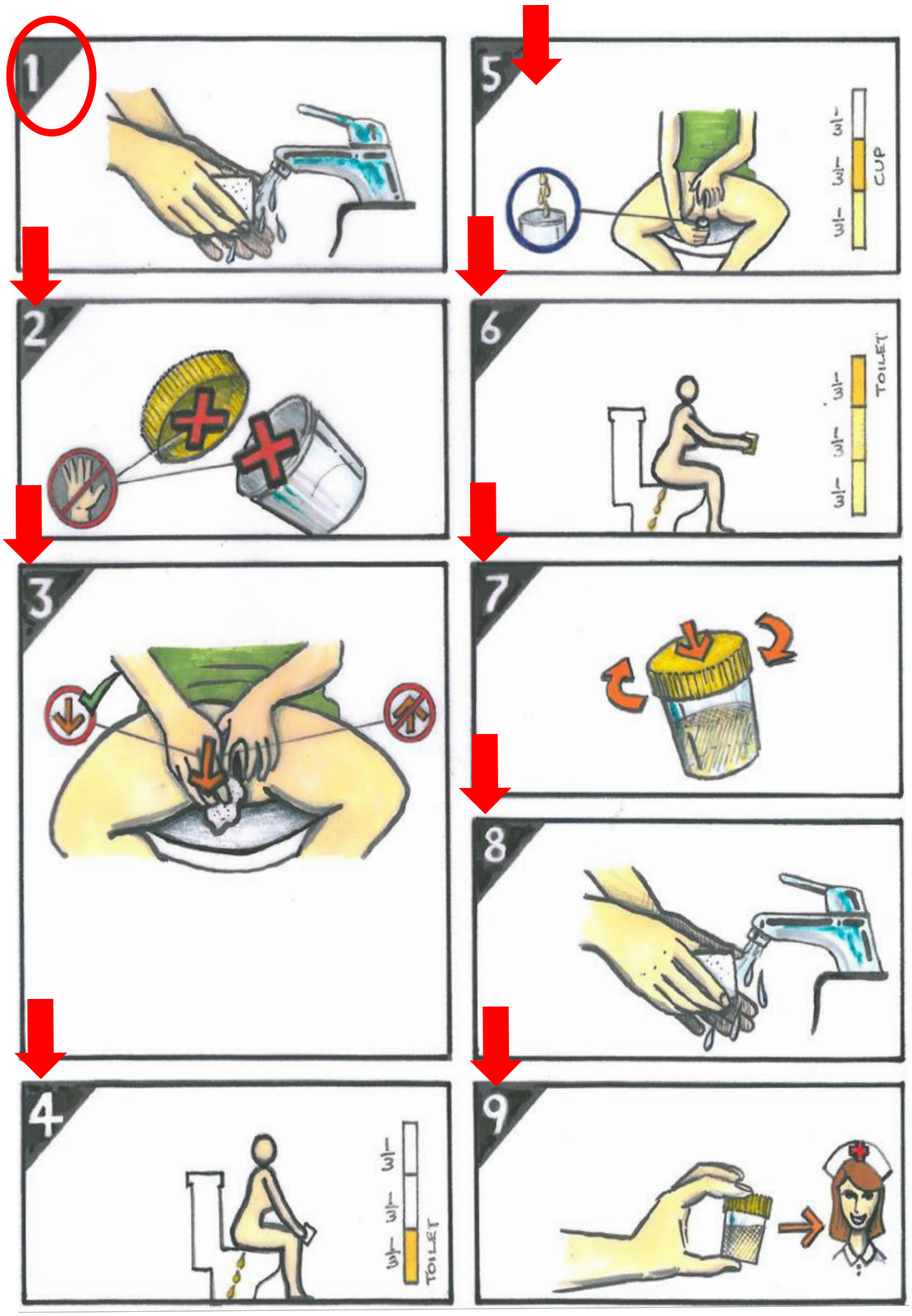
It was discussed during the team meeting in August 2019 that a small amount of bedpan and urinal collection was still occurring, straight catheter urine collection remained low, and documented clean catch samples were mostly older females needing assistance to ambulate. Straight catheterization was deemed more appropriate than clean catch procedure to produce an accurate urine culture when patients required mobility assistance, had physical barriers to follow each clean catch step, or had an altered mental status. The ED PA stakeholder was helpful in advocating for increased straight catheter orders by providers. She attended and presented at ED provider meetings from September through October 2019 and as needed.

The "Pee IS PRIORITY" flyers and the peer-to-peer staff education helped to advocate for straight catheter usage and dispel any myths. The staff myths survey resulted in the following:

- 16 of the 18 ED staff members who completed the survey stated that they did use two employees to insert a urinary catheter or straight catheter.
- 16 staff members gave reasons as to the barriers preventing the use of two employees for insertion: staff availability, department census, the belief that this would increase the risk of compromising the sterile field, and patient embarrassment.
- ED staff, including nursing leadership, had mentioned several times during rounding that they were concerned an increase in straight catheterizations would cause UTIs. The myth survey only showed that 1 out of 18 ED staff still believed a sterile straight catheter procedure would cause a UTI.

Figure 2. Original Female Clean Catch Urine Visual Patient Handout

Adapted from "Illustrations Reduce Contamination of Midstream Urine Samples in the Emergency Department" by Robert Eley, Chantelle Judge, Lisette Knight, Goce Dimeski, and Michael Sinnott, with permission from BMJ Publishing Group Ltd.[4]



Patients who were straight catheterized were resulting with contaminated urine cultures. ED competencies in October 2022 included completing online simulation training and hands-on sterile insertion technique with mannequins to improve straight catheter sterile technique. All newly hired ED staff received this same education. Although the team advocated for two-person urinary catheter insertion and straight catheter technique, this was not performed on a routine basis.

5. Additional Efforts:

Throughout the project, the team mentioned to staff the need to handle and store the urine samples in such a way to prevent further contamination. If there appeared to be a delay in documentation between urine collection and being sent to the lab, this was also included in one-on-one education to ensure use of boric acid collection technique and to encourage timely delivery of culture to lab. This was mentioned, but was not a priority initiative.

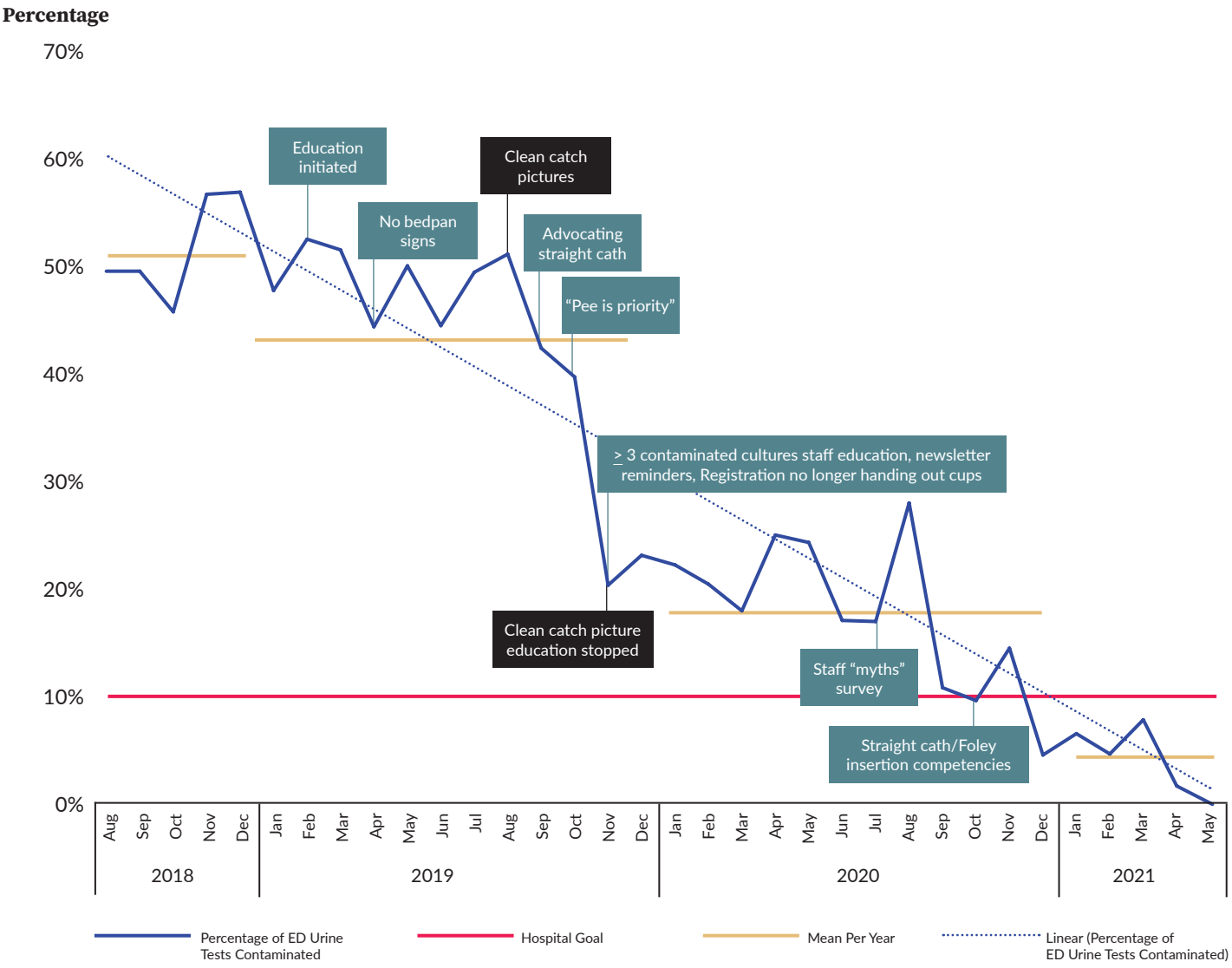
In October 2020, a cake with a graph of contamination progress printed on the top was used to celebrate one year of decreased urine culture contamination rates. The purpose was to commend the staff on their work so far and maintain motivation to meet the goal of <10% sustained contamination.

Measures

Data measured included contamination percentage of all total urine cultures performed in the ED per month. Details of the contaminated cultures included collection source documentation, patient education prior to clean catch collection documentation, straight catheterization candidate factors, and the name of the staff member who collected the sample.

Straight catheterization, repeat urine cultures, antibiotics prescribed, and primary diagnosis of UTI with contaminated culture constituting as an unnecessary admission were also measured through patient coding.

Figure 3. Percentage of ED Urine Tests Contaminated From August 2018 to May 2021



Analysis

Quantitative data for contamination rate was calculated.

Supplemental data of documented urine source, staff member who obtained sample, documented patient education prior to clean catch, and staff survey results were all used as qualitative data to summarize the types of issues causing contamination.

Results

Stata 17 was used to perform statistical analyses at a 95% confidence interval. Urine contamination rates decreased from baseline average of 51% to six months of <10%, resulting in an 80% decrease (P<.001, CI 18.4-34). The highest contamination rate prior to interventions was 57.1% in December 2018 and decreased to the lowest contamination rate of 0.0% in May 2021 (**Figure 3**).

Due to the inability to manually pull data from all patient charts, a comparison of data was compiled between January 2019 within the baseline, January 2020, and January 2021 for approximate annual improvements (**Figure 4**). Overall urine culture contamination decreased each year. Documentation of urine source for collection increased each year. Bedpan or urinal documentation of use was only documented in January 2019. Zero documentation of bedpan or urinal use in 2020 or 2021 is not conclusive that usage of these items was eliminated, only that this procedure was not documented as performed. Straight catheter and documentation of urine source from high-risk contamination sources, such as nephrostomy, urostomy, suprapubic catheter, and indwelling urinary catheter, did increase from baseline to post-intervention. Patients with contaminated urine cultures in January 2019, before the interventions, required repeat urine culture within seven days of contaminated culture. This was not needed for patients in January 2020 and 2021. Patient education documentation did increase from baseline to post-intervention months.

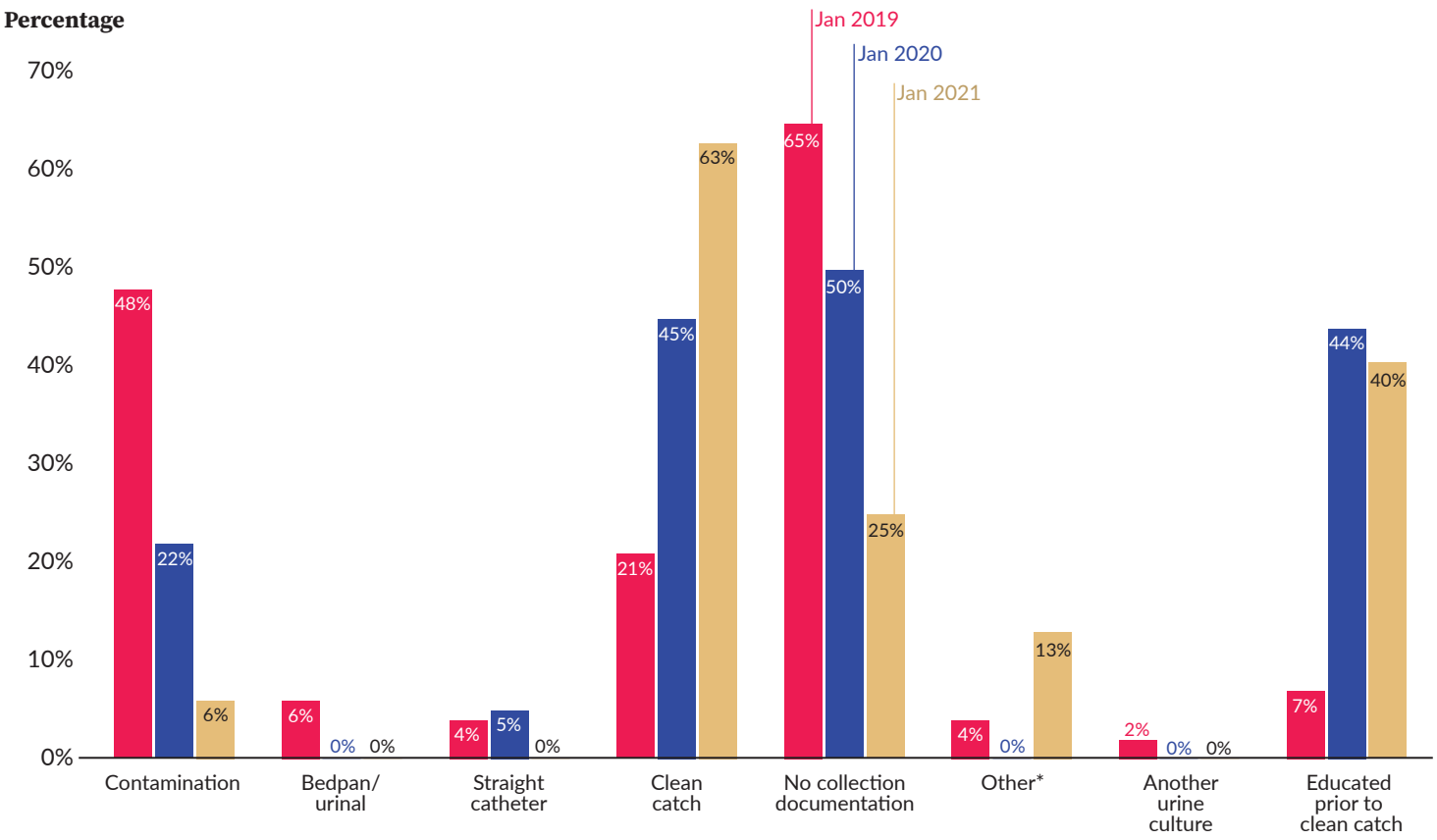
Straight catheterization codes for all ED patients within the project timeframe of August 2018–May 2021 were reviewed and did show a trending increase (P=.003).

Secondary outcomes

Unnecessary Antibiotic Reduction

The admission codes of patients in the study were used to identify patients with contaminated urine cultures who were prescribed common antibiotics for patients with UTIs. Urine cultures were then reviewed to determine if the antibiotic was required or if the antibiotics were unnecessary. **Figure 6** shows the decrease in unnecessary antibiotics for UTIs over time (P=.02).

Figure 4. Comparison of Baseline January 2019 Data to Annual Post-Intervention Results



*Urine collection source of nephrostomy, urostomy, suprapubic catheter, or urinary catheter

Figure 5. Overall Total Straight Catheters Performed in the ED

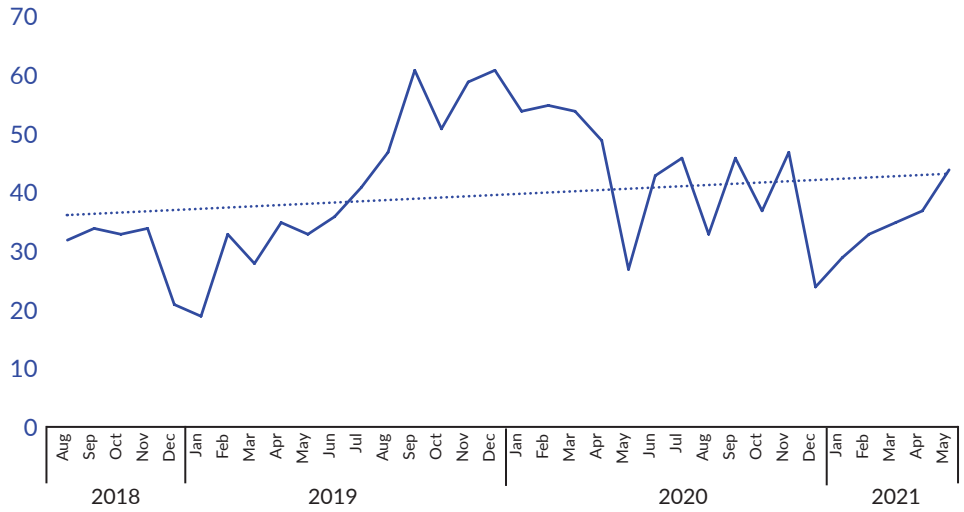


Figure 6. Percentage of ED Patients With Contaminated Urine Cultures Compared to Percentages of Patients With Contaminated Urine Receiving Unnecessary Antibiotics and Repeated Urine Cultures

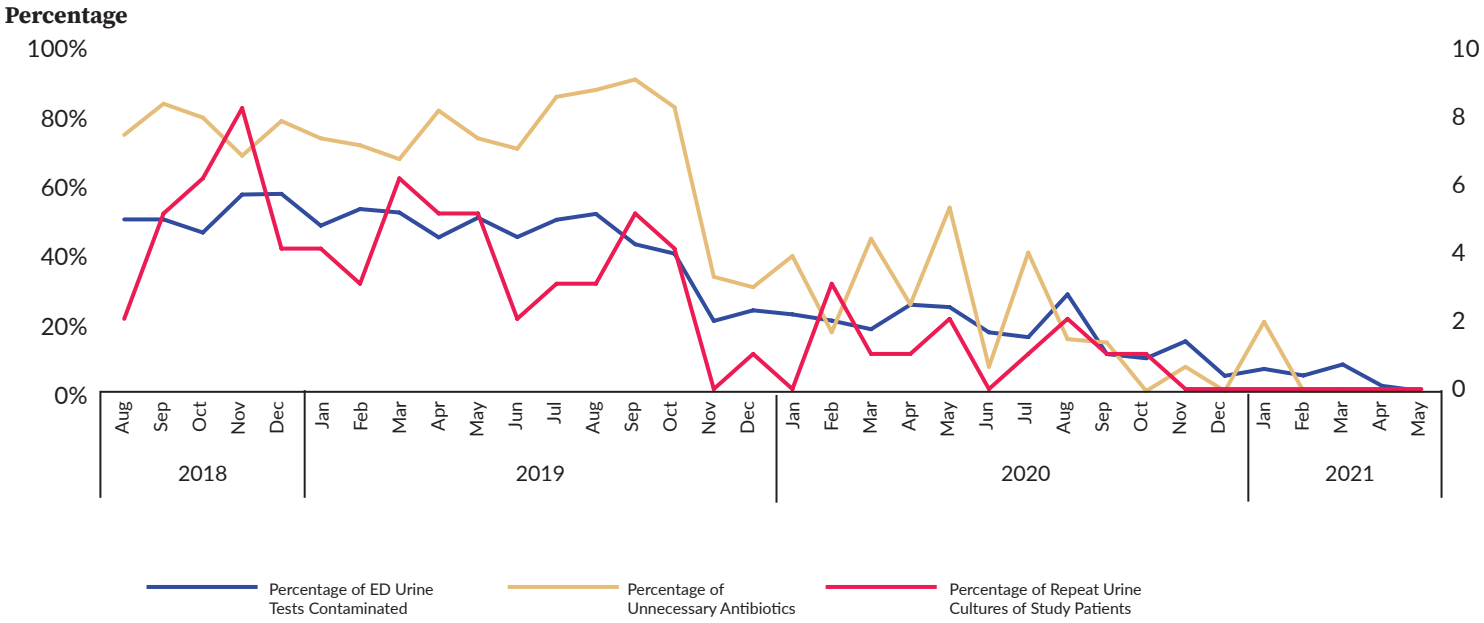
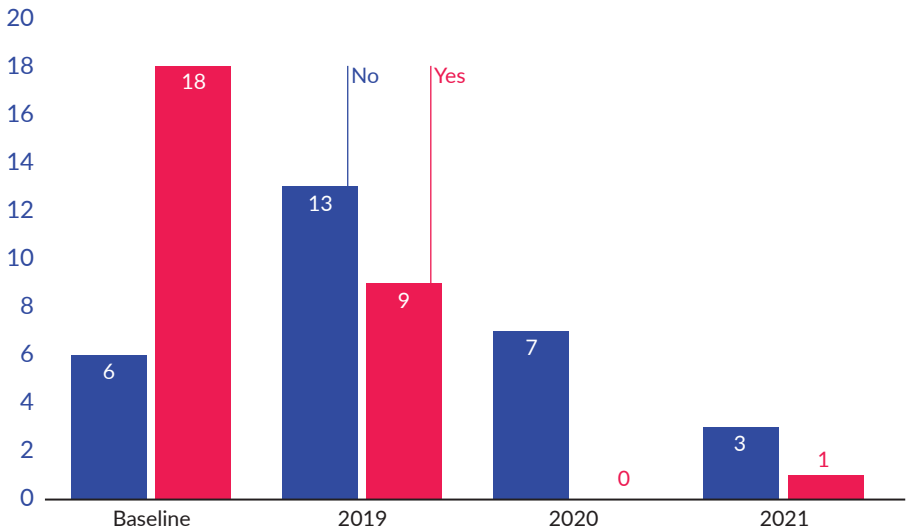


Figure 7. ED Patients With Contaminated Urine Cultures Admitted With Primary Diagnosis of Urinary Tract Infection



Repeat Urine Culture Reduction

The admission codes of patients in the study were also compared with urine culture charge codes to identify patients who had a contaminated urine culture collected in the ED during the timeline and who had a repeat urine culture performed within seven days. **Figure 6** shows the decrease in repeat urine culture ordering after contamination. This decrease is not statistically significant (*P*=.054).

Unnecessary Patient Admissions Reduction

There were 57 patients with contaminated urine cultures that were admitted or in observation and had a primary admit diagnosis of UTI. Out of those 57, 28 did not have a urine culture result indicating antibiotics were needed, meaning they were likely unnecessarily admitted. If the urine culture grew >100,000 bacteria or was not the reason for admission, any unnecessary admission was not attributed to the contaminated urine culture. Unnecessary admissions indicated by the orange columns in **Figure 7** did show a declining trend between baseline and post-intervention patients (*P*=.001).

Discussion

The steep decline in culture contamination starting in September 2019 is correlated with repetitive messaging not to use bedpans or urinals for collection, signage in the supply room, patient visual education handouts, and the increase in physicians ordering straight catheter collection (*P*<.001). The final strides to attaining consistent levels of contamination <10% was a combined effort to continually educate staff on proper collection techniques, increased provider orders for straight catheterization, and improved verbal education techniques prior to patient clean catch. Frequent rounding, in-person discussions, and hands-on education are what drove the staff education.

The snapshot comparison between January 2019, 2020, and 2021 indicates possible secondary outcomes associated with urine contamination reduction. Documentation of urine source collection provided evidence that clean catch cultures were the main culprit for contamination. Although documentation of bedpan/urinal use decreased, rounding observations and answers to the staff myths survey indicated that this practice was not eliminated. Although documentation of straight catheter as the source of urine collection in January 2021 was zero, this was post-competency education and indicates that straight catheter source was decreasing in contamination. This snapshot comparison is the only quantitative data reflecting whether patient clean catch education increased throughout the project. The data reflects that documentation of patient education did increase following the intervention, but there is no evidence to validate that patient education increased from baseline and that documentation was the missing baseline factor.

The matching trending decline between urine culture contamination, unnecessary antibiotic prescriptions, and unnecessary admissions of primary UTI diagnosis shows the correlation between contaminated urine cultures and two outcomes that could cause patient harm. Further analysis is needed to assess the correlation between urine culture contamination and repeat urine cultures within seven days.

Limitations

The knowledge that staff documentation was being audited did not appear to confound the results even though documentation of bedpan and urinal collection usage decreased, as did the contamination rate—showing that practice was changing, not just documentation. Frequent changes in ED staffing were a limitation to the stakeholder education abilities. Some staff working in the ED during the pandemic in 2020 were team members from other health system facilities that may not have been educated on proper urine collection techniques.

Readmission was a key focus for hospitals and that may have contributed to the success.

Laboratory urine culture reporting changes were made in October 2019 to report approximate col/ml of bacterial isolates for predominate pathogens. This change would not affect the project definition of contamination but could have contributed to more appropriately identifying patients requiring antibiotics for UTI. This may have skewed the results to appear that the project efforts decreased inappropriate antibiotic use more than the correlation should have reflected.

The Pharmacy Department initiated a quality improvement project in December 2019 comparing empiric antibiotic accuracy rates for UTIs based on resulted ED urine cultures and local antibiograms. This is not believed to have affected urine culture contamination but may have been a contributing factor to appropriate antibiotic improvement for UTIs.

Conclusion

Since adequate staff support of visual patient education was lacking until the end of the last month of the study, future investigations at other facilities would be intriguing to see if urine culture contamination would decrease faster with visual education that staff approved, combined with straight catheter competencies, increased straight catheter ordering, and elimination of bedpan and urinal collection all implemented together from the beginning. This project supports available literature that patient education on clean catch technique alone is not effective in decreasing urine contamination rates. Urine contamination decreased with a combination of staff education, patient education prior to clean catch, near elimination of bedpan or urinal collection, improvement in sterile straight catheter technique, and increased straight catheter ordering.

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About the Authors

Clare Cowen, the Infection Prevention Program manager at the University of Pittsburgh Medical Center (UPMC) McKeesport, has a public health background with a specific interest in infectious diseases and microbiology. She has worked as an infection preventionist at UPMC since 2015 and currently leads the Infection Prevention Program at UPMC McKeesport. Cowen was instrumental in overseeing the safety of all staff, visitors, patients, and community members during the COVID-19 pandemic. She is part of the hospital Quality team and believes everyone deserves high quality care.

Shelley Frinsco, a senior professional staff nurse at UPMC St. Margaret has been a nurse for 14 years, the last seven of which have been to provide care in the emergency department. Since working on this project, Frinsco has found a new passion in quality improvement and advocates for incorporating safety processes in regular nursing routines.

Rebecca Nosal is a certified physician assistant who graduated from Duquesne University in 2012. She has worked clinically in emergency medicine both in Pittsburgh, Pennsylvania, and now in Charleston, South Carolina. She is passionate about patient safety.

Faith Colen, the director of Quality and Patient Safety at UPMC St. Margaret, has direct oversight of patient safety, quality, infection prevention, regulatory, privacy, compliance, risk management, clinical care coordination, and discharge planning, and the orthopedic and stroke programs at UPMC St. Margaret. Colen has a background in oncology, nursing education, emergency nursing, and quality improvement. Colen has published and presented internationally and nationally on topics of emergency nursing quality improvement, and patient advocacy.

Preventing Central Line Bloodstream Infections: An Interdisciplinary Virtual Model for Central Line Rounding and Consultation

By **Erin Lightheart**, MBA*◆, **Mary E. Guyton**, RN, MEd◆, **Cheryl Gilmar**, MS, MT (ASCP)◆, **Jillian Tuzio**, MSN, RN◆, **Matthew Ziegler**, MD† & **Colleen Kucharczuk**, DNP, CRNP◆

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Abstract

Background: Central line–associated bloodstream infections (CLABSI) account for many harms suffered in healthcare and are associated with increased costs and disease burden. Central line rounds, like medical rounds, are a multidisciplinary bedside assessment strategy for all active central lines on a unit. In-person line rounds in this 144-bed oncology acute care setting are challenging due to a variety of unchangeable factors. The aim was to develop a process for addressing concerning central lines in this context.

Methods: The project team designed a HIPAA-protected, text-based process for assessing central lines for risk factors contributing to infection. Staff initiated a consultation via a virtual platform with an interdisciplinary team composed of oncology and infectious disease experts. The virtual discussion included recommendations for a line-related plan of care.

Results: The number of consultations averaged about five per month, with 27.4% resulting in the central line being removed, which is believed to have contributed to an overall reduction in infection rates. The CLABSI standardized infection ratio, a risk-adjusted measure which accounts for patient acuity and volumes, improved from 0.85 prior to the intervention (November 2020–October 2021) to 0.57 after the intervention (November 2021–August 2022), a 33% reduction.

Conclusion: A virtual process for central line consultation and interdisciplinary planning was effective and, in this setting, perhaps optimal. This type of process could be applied to nearly any aspect of clinical care where teams are solving problems in an environment with complex geography and relationships.

Keywords: *CLABSI, healthcare-associated infections, central line rounds, virtual rounding, patient safety, interdisciplinary*

*Corresponding author
◆Hospital of the University of Pennsylvania
†University of Pennsylvania
Disclosure: The authors declare that they have no relevant or material financial interests.

Introduction

Central line–associated bloodstream infection (CLABSI) as defined by the Centers for Disease Control and Prevention's National Healthcare Safety Network is a bloodstream infection (BSI) in a patient with a central venous catheter (CVC), without another attributable source of infection, that occurs when the CVC has been in place for more than two calendar days or removed the day before the BSI.[1] In relation to other healthcare-associated infections (HAIs), CLABSIs are associated with an increase in patient morbidity and mortality and a high financial burden, accounting for approximately $46,000 per case.[2]

Cancer patients frequently require CVC for cancer-directed treatment, prolonged courses of intravenous (IV) antibiotics, and parenteral nutrition. The combination of an immunocompromised state and prolonged central venous access places patients at an elevated risk of developing a BSI.[3,4] Development of a CLABSI prolongs hospitalization, causing an excess in resource utilization and treatment cost, and often delaying anticancer treatment, and is associated with a significant increase in mortality in cancer patients.[5]

An evidence-based bundle approach, in which a variety of clinical best practices are combined for insertion and maintenance of CVCs, has been documented in many studies and quality improvement projects.[6-8] Adequate training, education, staffing, and leadership involvement are equally important standards in CLABSI prevention,[9] as is the use of chlorhexidine (CHG) bathing.[10] Removal of a central line when it is no longer clinically necessary is an important aspect of infection prevention. This is a careful consideration with cancer patients, as they receive important therapy through these lines. Additionally, the use of multidisciplinary central line rounds has proven to be instrumental in providing expert feedback to staff and gathering data.[11]

There are currently no reports in the published literature of virtual central line rounds being conducted. However, as care teams have grown and geographic coverage has increased, virtual technology has allowed healthcare professionals to connect when in-person options are not available.[12] This virtual infrastructure has also strengthened as the COVID-19 pandemic ensued. New requirements for physical distancing, personal protective equipment shortages, and overtaxed inpatient medical and educational care prompted an inpatient virtual care model.[13]

Rationale and Current State

At our institution, nurses perform daily assessments and monthly audits of central lines to ensure alignment with a maintenance bundle. The bundle includes several components: assessing the line dressing and IV tubing, ensuring that disinfection caps are appropriately changed and secured, assessing if central line lumens remain patent, and verifying CHG-impregnated dressing was applied and CHG bathing performed. The care team also checks each shift for signs of infection, such as redness, pain, or swelling at the insertion site. Compliance with the bundle components is monitored by nursing leaders and reported on a monthly basis. Care teams have the ability to consult infectious diseases (ID) experts as needed.

In 2019, the medical intensive care unit (MICU) adopted a multidisciplinary model for central line rounding wherein a team rounded weekly to directly assess CVCs. The team included nurses, providers, and infection preventionist (IP) leaders. The term "provider" refers to physicians and advanced practice providers (APP), and APPs include clinicians licensed as advanced practice registered nurses, nurse practitioners, and physician assistants. The result of the MICU line rounds was a substantial decrease in CLABSIs from the previous fiscal year.[11]

Driven by the success of the MICU initiative, we sought to adopt a similar model; however, there were several considerations specific to the oncologic population which informed the approach (**Table 1**).

Specific Aims

1. Design an interdisciplinary process for assessing central lines for risk factors contributing to infection, to counter challenges related to staffing, geography, central line volumes, and the COVID-19 pandemic.

2. Ensure the process allows for development of a plan of care to mitigate infection risk.

3. Reduce the CLABSI standardized infection ratio (SIR) by 10%, from 0.85 (November 2020–October 2021) to 0.77 in the 10 months after the intervention. The SIR is a ratio of observed infections to predicted infections, adjusted for facility and population-level risk factors.

Methods

Context

The intervention took place at a 910-bed tertiary care facility, part of an academic medical center and a six-hospitals-based health system in an urban center. The inpatient hospital oncology service cares for up to 144 patients across four units. The patient population is a mix of hematological and solid tumor malignancies, including bone marrow transplantation and cell-mediated immunotherapies.

Planning, implementation, and ongoing support was done by an existing oncology HAI subcommittee that meets monthly to tackle specific quality improvement efforts that align with hospital and system goals. The subcommittee is supported by an overarching clinical effectiveness team (CET), which steers and supports all aspects of inpatient quality and safety improvement efforts. The subcommittee is composed of ID and oncology physicians, APPs, clinical nurse specialists (CNS), clinical practice leaders (CPL), IPs, and a certified quality improvement advisor, all with a specialty in oncology. This group has existed since 2017, with CLABSI reduction as an ongoing focus.

In response to the barriers to in-person rounding described in the Rationale and Current State section above and with the additional infection prevention measures that interrupted in-person care due to COVID, there was a need to explore ways to support clinical review of central lines virtually. Looking to other areas where technology was leveraged to take the place of in-person clinical care, the group decided to use existing technology, a virtual platform, to fill the gap.

Table 1. Oncologic Population Considerations for Central Line Rounds Approach

Category	Salient Features	Relevance
Patient groups and clinical acuity	· Hematological malignancy 62%–65% · Solid malignancy 35%–38% · Cancer-directed treatment, including active chemotherapy, bone marrow transplant, and cellular immunotherapy	Many of these patients have an elevated risk for CLABSI because of their immunosuppression and cancer-directed therapies[3]
Spatial separation and patient volumes	· 4 units across 3 hospital floors · Oncology census: about 113 per day in 2021 and about 132 per day in 2022	This makes contiguous rounding with a multidisciplinary team difficult
Device utilization	· 66% patients with a central line · About 74 patients with a central line per day in 2021 and 87 per day in 2022	High device utilization makes rounding on all patients challenging
Care team engagement	· Oncology attending physicians change every 1–2 weeks · Medical residents change every 2 weeks	Frequent rotations limit provider engagement
Clinical resources and time	· Substantial time commitment for multidisciplinary staff · Estimated 6–8 hours per week for comprehensive rounds	Not feasible to round on all patients with entire multidisciplinary team
Clinical decision-making	· Individual patient needs and provider preference · Decision to remove a line is nuanced	Care plans are difficult to standardize
COVID-19 considerations	· Personal protective equipment (PPE) shortages · Conservative approach to infection prevention	In-person rounding drastically limited

The choice to leverage existing technology allowed for quicker rollout of the intervention, limited training for staff, and required no purchase of additional technology with potentially lengthy organizational negotiations or approvals for use of a new platform. Additionally, the choice of developing this intervention within an existing platform allowed for smoother and quicker uptake by utilizing a mechanism that is already embedded in the culture of communication among staff.

Intervention

Summary of the intervention

The project team designed a HIPAA-protected, virtual process for assessing central lines for risk factors contributing to infection. Staff initiated a consultation via virtual platform with an interdisciplinary team composed of oncology and ID experts. Line management recommendations were provided.

Throughout the intervention's implementation, the team solicited feedback from users. Feedback was discussed at monthly HAI subcommittee meetings, and changes were incorporated through Plan-Do-Study-Act (PDSA) cycles.

Through a virtual platform, frontline oncology clinicians (nurses, APPs, physicians, IPs) sent a message to a receiving consultant group. This virtual consultation mechanism is called the Central Line Hotline (CL Hotline). The key consultants on the receiving end were members of the oncology HAI subcommittee with expertise in reducing CLABSI, including ID physicians, oncology APP leaders, CNSs, CPLs, and IPs.

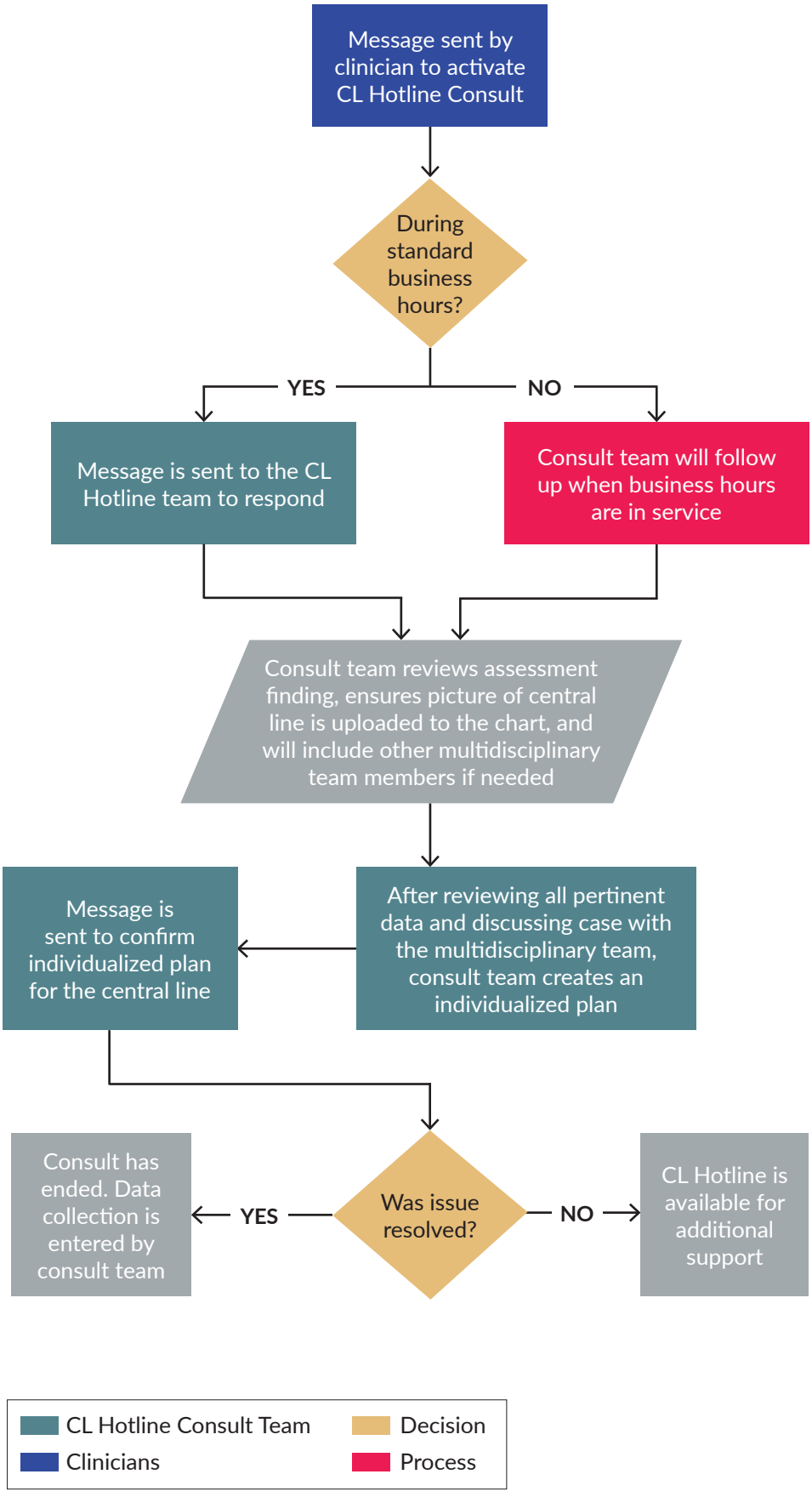
The consultation could be placed by any clinician within inpatient oncology. Reasons why the consultation could be placed included concerning central line assessment findings (e.g., pain or tenderness, induration, significant erythema or concerning discharge); difficulty with central line dressings (e.g., line-site dermatitis, bleeding, adherence); issues with CVC maintenance (e.g., CHG bathing concerns); or clinical concerns for central line infection and consideration of central line removal (e.g., persistent fevers, bacteremia). The consultation message included central line assessment details, indication for the line, and a current photo.

Once the consultation was placed, the CL Hotline team reviewed the assessment findings and pertinent clinical data and discussed next steps directly within the virtual text thread. The receiving consultation group could add to or remove from the text thread any other members of the care team, as needed. The consultation team created an individualized plan of care for the patient's central line. Meaningful aspects of care plans included the utilization of specialty central line dressings or products, administration of antibiotics, and central line removal. If the care team had not been part of the discussion up until this point, they were added to the virtual communication thread, and the plan was communicated to them then. Though members of the care team could arrange to meet at the bedside, this was not required, and all communication could feasibly happen virtually. After recommendations were made, nursing leadership and bedside nurses monitored the central line closely and consulted the CL Hotline again, if needed.

PDSA 0 (Pre-intervention) – Decision to focus on high-risk central lines

Before the CL Hotline's conception, the project team decided to target its efforts on those patients whose central lines were considered at highest risk of developing a CLABSI. This included lines where concerns were identified during routine line care (e.g.,

Figure 1. Detailed Description and Process Map for Central Line Hotline



line-site erythema, dressing concerns, or issues related to CHG adherence). This was driven by the oncology population's particularly high volume of central lines. For several months, IPs, CNSs, and CPLs attempted to reach out to a small group of oncology infection prevention experts via email to discuss these high-risk central lines.

PDSA 1 (Primary intervention) – Decision to develop a virtual consultation process

1a. Choosing a virtual platform

Line evaluation via email proved cumbersome, as it was difficult to ensure the key people were included on each thread, and it was easy for emails to be missed or lost.

Additionally, the COVID-19 pandemic spurred an opportunity to address central lines virtually. A virtual platform was already widely embedded in patient care in the hospital units and easily adaptable for multidisciplinary consultations in the oncology units. Additionally, this texting platform allows for closed-loop communication, in which senders can see when and by whom messages have been read.

1b. Selecting the consultation team

The project team knew the consultation team needed to include representatives from across the inpatient care continuum—nursing leaders with extensive bedside experience and expertise caring for this population, APP leaders currently caring for hematological malignancy patients, ID physicians with specific expertise in oncology, and IPs focused on oncology infection prevention. As these stakeholders were all part of the oncology HAI subcommittee, a well-established and high-functioning team, the project group already knew their commitment to ongoing improvement in this area.

1c. Staff education

Prior to the implementation of the CL Hotline, education was disseminated to nurses, APPs, and physicians. Education included a one-page handout that was disseminated and discussed in various venues, including nursing huddles, staff meetings, and resident didactic sessions.

PDSA 2 – Increasing visibility and APP/resident engagement

One month into the intervention, the team received feedback from users that finding the correct group (the CL Hotline consultation group) was challenging. In response, the team worked with the organization's communication colleagues to ensure the consultation group was viewable in the organization's directory of consult services. The consultation criteria and goal of the initiative are listed within the directory.

The project team also sought to increase resident and APP engagement with the CL Hotline. The challenge here was that residents rotated into the oncology service every two weeks, with a new group of residents each time. So, additional education about the CL Hotline was incorporated into residents' orientation onto the oncology service. Also, the hematological malignancy APP team incorporated regular progress updates in their staff meetings.

It is important to note that, at this time, frontline clinical nurses caring for patients were not directly consulting the CL Hotline. Those nurses were instructed to notify their nursing leaders (CNS, CPL, or nurse manager), who would consult the CL Hotline on their behalf. This decision was made to limit consultations to the CL Hotline because we were concerned that requests would surpass capacity.

PDSA 3 – Clarifying the nature of CL Hotline support

Five months after the initial implementation of the CL Hotline, the team learned of a lack of clarity about the longevity of support conferred by consulting the CL Hotline. Some staff assumed that consulting the CL Hotline meant their patient would be followed long-term by the consultant team, which was not the case. To address this, the team established a scripted response to be used as a reply to the initial consultation, so staff would understand that the consultation was a one-time intervention. Staff were asked to consult the CL Hotline again if new or lasting concerns arose.

PDSA 4 – Increasing nurse engagement, part 1

Eight months into the CL Hotline intervention, the project team sought to increase utilization by connecting into already existing processes within nursing. The team added a prompt into the device utilization tracking process to ask nursing leadership to consult the CL Hotline for concerning lines. At the same time, the team incorporated formalized education about the CL Hotline into orientation for new oncology nurses.

PDSA 5 – Increasing nurse engagement, part 2

Nine months after the start of the intervention, in further discussions about how to increase utilization, the team revisited the prior decision to have clinical (frontline) nurses reach the CL Hotline indirectly through their nursing leaders. The team agreed that not only could we accommodate more consultations, but also, more importantly, it would be beneficial for those closest to patient care to be able to consult the CL Hotline directly. The team did a new round of education with current clinical nurses about the change and modified oncology nurse orientation to reflect the change as well.

A summary and timeline of the team's interventions and PDSA cycles is in **Table 2**.

Table 2. PDSA Cycles and Interventions

Approximate Timeframe	Prompting Factor(s)	Modifications Made
PDSA 0	High volumes of central lines within the oncology population precluded in-person line rounds	Project team attempted to assess high-risk central lines via email
PDSA 1 (primary intervention) – Nov 2021	Line evaluation via email was cumbersome; COVID-19 pandemic made virtual models more compelling	Began consultation via virtual application, dubbed the Oncology Central Line Hotline
PDSA 2 – Dec 2021	1. Finding the correct group to message was challenging 2. Desire to increase resident and APP engagement with the CL Hotline	1. Made the virtual consultation group viewable in the organization's directory 2a. Incorporated education about the CL Hotline in resident orientation to oncology 2b. Incorporated regular progress updates to the hematological malignancy APP team in staff meetings
PDSA 3 – Apr 2022	Lack of clarity about longevity of support conferred by consulting the CL Hotline	Established a scripted response to be used as a reply to the initial consultation
PDSA 4 – Jul 2022	Desire to increase registered nurse (RN) engagement with and utilization of the CL Hotline	Added a prompt in oncology's device utilization tracking process to ask leadership to consult the CL Hotline for lines of concern; added formal education about the CL Hotline in orientation for new oncology nurses
PDSA 5 – Aug 2022	Desire to increase RN engagement with and utilization of the CL Hotline	Expanded the group within nursing who could consult the CL Hotline from nursing leaders to all bedside RNs

Study of the Intervention

The project team used a Lean Six Sigma approach to assess the impact of the intervention, including the use of quantitative and qualitative data, Pareto charts, and run charts.

To establish whether the observed outcomes were due to the intervention, we plotted the timeline of interventions along the run chart for the primary outcome measure.

Measures and Analysis

The primary outcome measure we chose was the standardized infection ratio (SIR) for CLABSI, which is a risk adjusted measure which accounts for patient acuity and volumes. For process measures we tracked CL Hotline consultation volumes, line removal rates, and consult initiation by discipline and by unit.

We captured each instance of the intervention using an electronic data collection tool, collecting a selection of qualitative and quantitative data elements. We used Pareto charts to visualize the qualitative elements and to guide us toward adjustments in the PDSA cycles. We used run charts to gauge progress in the primary process and outcome measures, and to understand the effects of time as a variable.

The project team met regularly to review the data at a granular level, ensuring that those responsible for collecting the data understood the operational definitions of each data element and were capturing them similarly. To ensure the completeness and accuracy of infection data, we partnered with data experts within the Infection Prevention department. The team reported progress to an oncology-focused HAI subcommittee, who helped develop interventions and identify contextual elements that contributed to successes and failures.

Ethical Considerations

This quality improvement project was granted institutional review board exemption by the Human Research Protections Program, Office of Institutional Review Board within our institution. A HIPAA-compliant system was utilized to protect the privacy of the participants. Identifiable patient information was used for tracking and evaluation with a secure database. No data was collected directly from patients or families.

Participation from the consultative group and staff was voluntary and received no additional reimbursement for participation. Employees were invited to participate in the project voluntarily. Refusal of participation did not result in any punishments from the hospital leadership team.

Results

The CLABSI SIR has improved from 0.85 prior to the intervention (November 2020–October 2021) to 0.57 after the intervention (November 2021–August 2022) (Figure 2).

The number of CL Hotline consultations averaged about 5 per month. We were not able to identify what drove the unusually large number of consultations in March 2022 (**Figure 3**).

Of the 51 central lines cases submitted to the CL Hotline for consultation, 27.4% resulted in the central line being removed, which we

Figure 2. Oncology CLABSI Standardized Infection Ratios Over Time

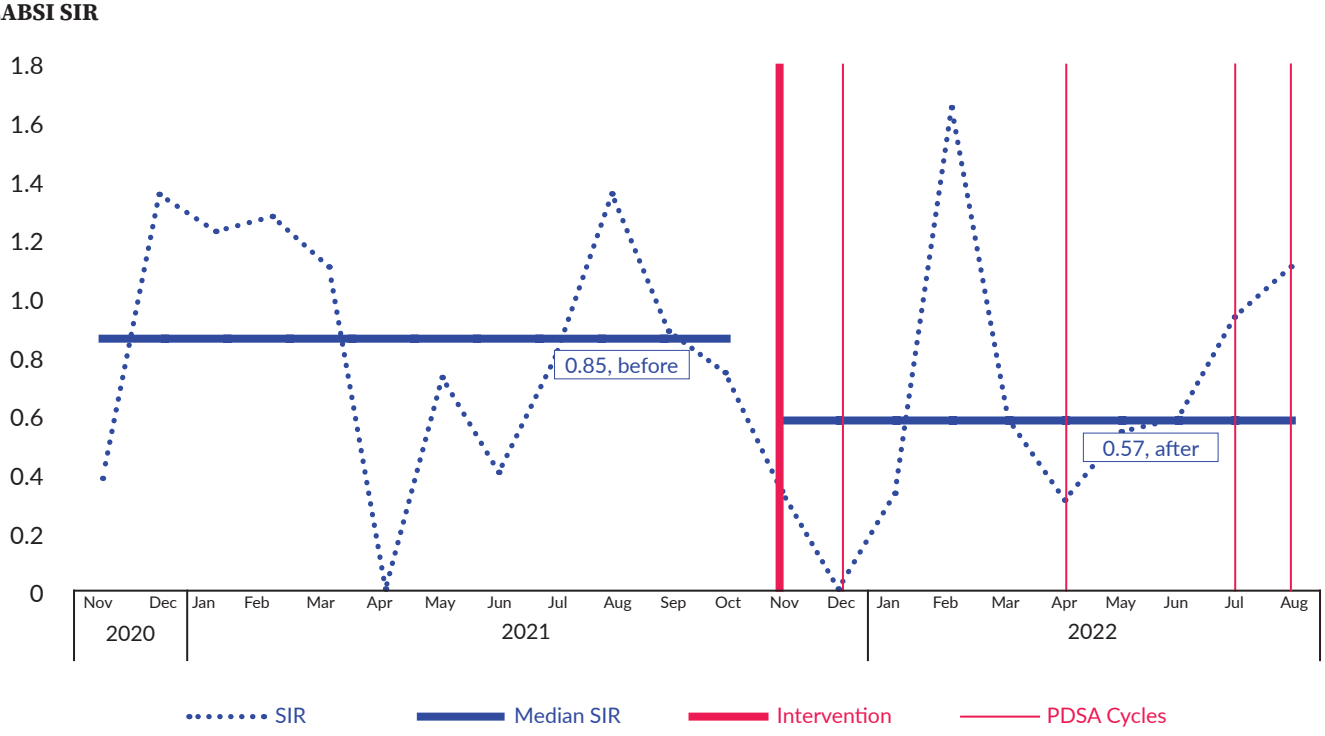


Figure 3. CL Hotline Consultation Volumes Over Time

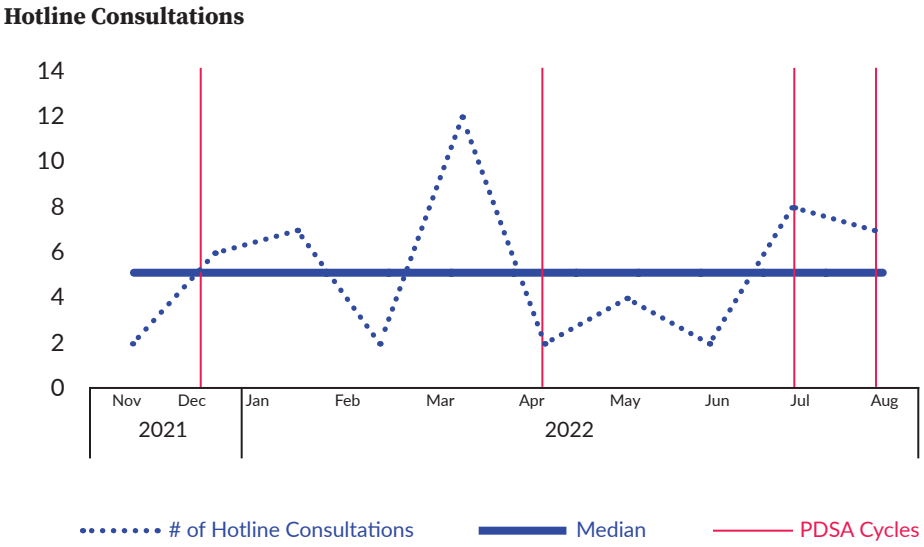


Figure 4. Number of CL Hotline Consultations by Unit

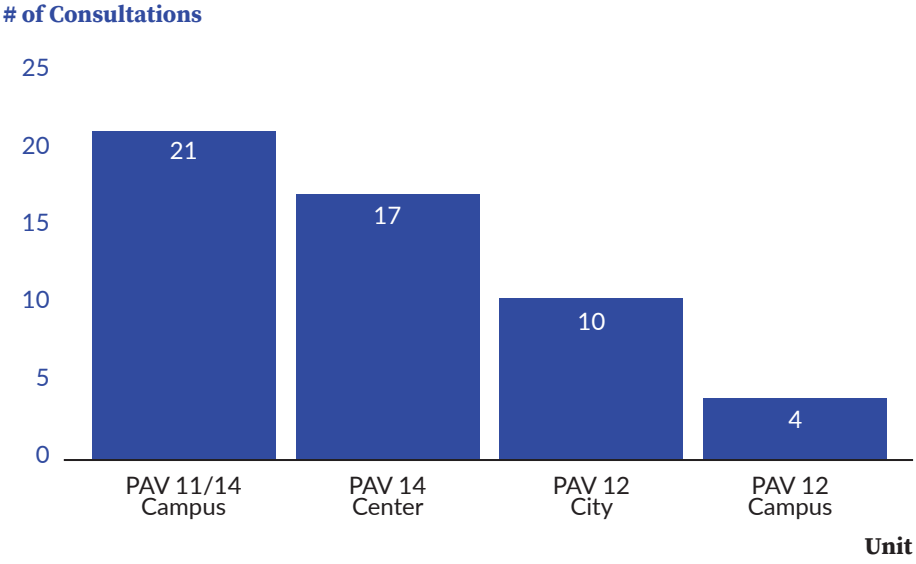
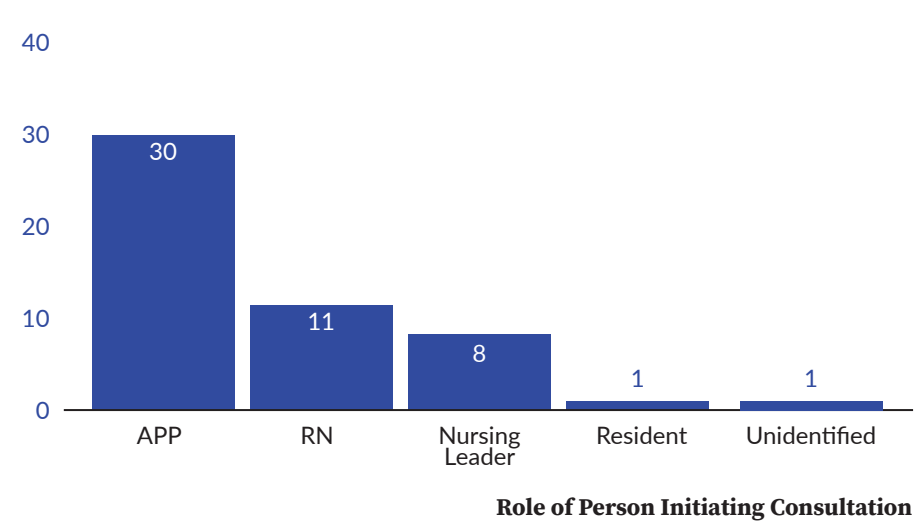


Figure 5. Number of CL Hotline Consultations by Group



believe contributed to the overall reduction seen in infection rates.

One substantive contextual element that may have interacted with the intervention is the opening of a new building within the hospital, which occurred at the same time as the intervention. All oncology units moved from their previous locations into the new building.

Anecdotally, communication and collaboration became more challenging in the new space, due to patient beds being spread out across larger areas and redesigned workspaces that sometimes resulted in providers being more isolated from nurses. The CL Hotline may have served as a tool to help mitigate some of these challenges.

The hospital's oncology units exhibited variation in consultation volumes (**Figure 4**), with the most frequent unit usage being five times that of the least frequent. This could be due to the mix of patients on the unit (fewer central lines), and to variation in how unit leadership emphasized the intervention. These results will guide future PDSA cycles to increase CL Hotline utilization.

Additionally, as an academic medical center, many of the hospital's patients were managed by resident physicians. Because these resident teams rotated onto the oncology service for two two-week periods at a time, it was challenging to establish a standardized process for these groups to consult the CL Hotline. Therefore, the project team focused initially on improving nurse engagement as a strategy, rather than resident engagement. These results guide future efforts to engage residents and other members of the care team (**Figure 5**).

Discussion

Interpretation

We found that after implementing a virtual line assessment tool

1. Staff utilized the CL Hotline and utilization volumes remained relatively consistent
2. Consultation to the CL Hotline facilitated the removal of lines which could potentially contribute to infection
3. The CLABSI SIR rate improved

The CL Hotline allowed the bedside clinicians to have a clear plan in place, individualized for the patient, after each consultation was completed. Advocating for central line removal can be overwhelming for staff members, and staff verbalized that they felt supported by the CL Hotline in this regard. The CL Hotline also expedited the management of site-specific concerns, such as dressing issues, to potentially decrease line-related morbidity.

The ability to share clinical details through photography, perform a virtual assessment, and produce an individualized care plan could be rolled out to other areas of practice. The CL Hotline had an oncology-focused lens, and expanding to a different patient population would require participation from other experts. This could be translated into many other areas where in-person rounding is challenging.

A limitation of the intervention was the hours of operation for the CL Hotline are only Monday through Friday during regular business hours. However, when the CL Hotline was not in operation, the medical team still had access to ID physicians, as normal and if needed. Additionally, our intervention was primarily reactive to issues and concerns brought up by the clinical care team and did not proactively identify issues. However, we believe proactive assessments are adequately addressed through other interventions, specifically central line maintenance bundles and central line audits.

Adapting existing technology had downsides. Using a prebuilt platform, the team was not able to customize features to support the particular intervention. For example, the virtual platform did not connect to our electronic medical record (EMR), preventing seamless linking of clinical information and the ability to automate documentation and follow-up actions. Unless a nurse or provider manually documented in the EMR that the CL Hotline has been engaged, this information was lost. A future goal is to explore options for integration into the EMR that would provide more streamlined communication between the CL Hotline and the patient's care team.

Anecdotally, providers expressed concern that the CL Hotline would only lead to one outcome: the removal of the central line. In order to overcome this barrier, education was disseminated on the outcomes of the CL Hotline, which showed that line removal occurred only after 27.4% of the consults. Additional education was disseminated to discuss the other outcomes of CL Hotline usage, such as the utilization of specialty dressings, administration of IV antibiotics, and increased monitoring of the central line.

As reflected in PDSA cycle 5, changes were made to allow participation from bedside nurses. The team felt strongly about this shift to best address clinical needs and empower the nurses to participate when they identified concerns.

The team focused especially on striking a balance between increasing utilization and access to the service while maintaining capacity for the consult team to answer the volume of consultations. Consult team members participated in the service as an addition to their existing work and arrangements were made for coverage during time off. Since participation was voluntary and unpaid, expanding this service would be a challenge for the implementation team and likely would require participation from additional experts to share the volume of work. Capacity and membership of the core consultation group would need to be reassessed before planning expansion.

Limitations

The virtual platform did not allow for automated data collection. Collection was a manual process where information was entered into an electronic database by members of the project team. This manual process was more likely to generate measurement system errors.

The project team did not collect data related to education processes. It would be valuable to understand process measures related to staff education.

Conclusions

Utilization of a virtual platform is effective for multidisciplinary collaboration and support when in-person rounding is not feasible. Virtual consultative technology can be applied to other acute care settings where in-person rounding is challenging. The next steps are to improve sustainability by fully integrating the CL Hotline into the EMR.

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About the Authors

Erin Lightheart (erin.lightheart@pennmedicine.upenn.edu) serves as master improvement advisor at the Hospital of the University of Pennsylvania (HUP), guiding quality improvement efforts within oncology and critical care teams. She has over 15 years of experience in quality improvement and specializes in statistical process control. Lightheart's purpose is to help teams accomplish their goals with ease, joy, and clarity.

Mary Guyton is currently an infection preventionist at the Hospital of the University of Pennsylvania (HUP). She seeks to improve care by fostering interprofessional, patient-focused teamwork within the oncology service lines. Guyton's work in healthcare stretches over 20 years and two countries. The impacts of intersectionality on individuals' and communities' health anchor her nursing practice and academic teaching.

Cheryl Gilmar is an infection preventionist at the Hospital of the University of Pennsylvania (HUP) covering the hematology oncology wards, with a focus on reduction of bloodstream infections. She enjoys collaborating with medical teams in supporting evidence-based practice and advocating for everyone's role in preventing healthcare-associated infections.

Jillian Tuzio is a clinical nurse specialist for an oncology unit at the Hospital of the University of Pennsylvania. Tuzio acts to influence the three spheres of impact, which are patient care, nursing, and systems. Tuzio serves as an expert clinician and assumes accountability for the patient outcomes on the unit.

Matthew Ziegler is an assistant professor of Medicine and Epidemiology at the University of Pennsylvania. His clinical research program focuses on the prevention of healthcare-associated infections in immunocompromised patients and the epidemiology of multidrug-resistant organisms (MDROs) within the hospital-built environment.

Colleen Kucharczuk serves as an oncology nurse practitioner and advanced practice manager at the Hospital of the University of Pennsylvania (HUP). She has her doctorate in nursing from The George Washington University and has 20 years of experience caring for oncology patients. Kucharczuk is a leader within oncology quality improvement, with a focus on care coordination, patient safety, and transitions in care.

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

By **Nirmal Joshi**, MD[†] & **Caitlyn Allen**, MPH*[◆]

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.

*Corresponding author
[◆]Patient Safety Authority
[†]Mount Nittany Health
Disclosure: The authors declare that they have no relevant or material financial interests.

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.

> "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

> "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.

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,

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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.

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?"

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

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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 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 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.

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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.

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.

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.

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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.

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

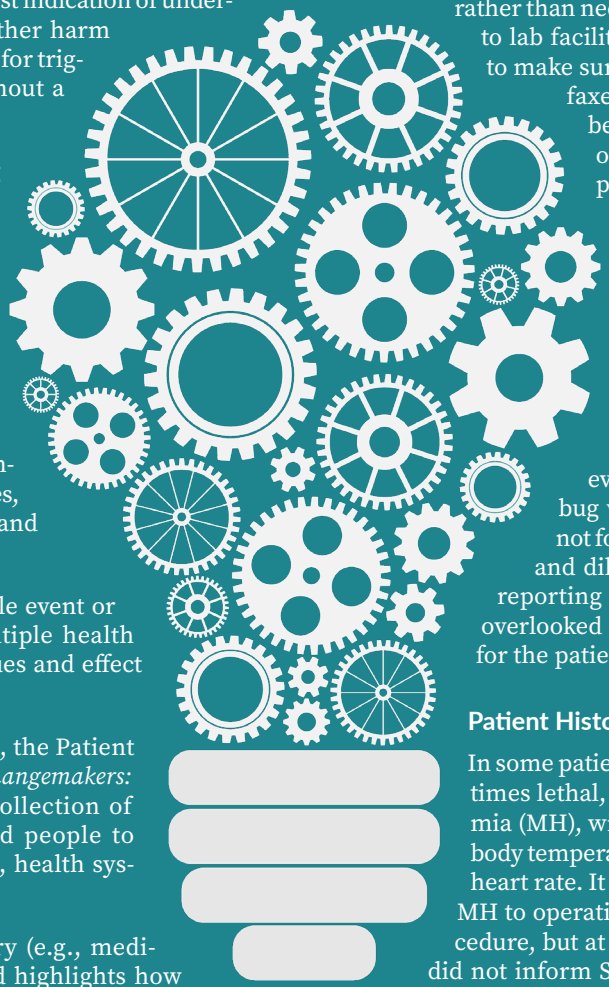
Nirmal Joshi is an experienced physician executive and internal medicine physician, with an extensive background in clinical quality and patient safety. *Becker's Hospital Review* recognized Dr. Joshi as one of their "100 Hospital and System CMOs to Know" in 2016. He currently serves as chief medical 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 foundedw two years ago with the intent of providing free care to those unable to afford care.

Caitlyn Allen (caiallen@pa.gov) is director of Exernal Affairs for the Patient Safety Authority and managing editor for *Patient Safety*, the PSA's peer-reviewed journal. Before joining the PSA, she was the project manager for Patient Safety at Jefferson Health, where she also was the only nonphysician elected to serve on the House Staff Quality and Safety Leadership Council.

Events That Inspired Change: The Importance of Sharing What Happened to Stop It From Happening Again

By **Eugene Myers**, BA*◆ & **Caitlyn Allen**, MPH◆

Reporting events that caused harm or could have caused harm to patients is not just a law in Pennsylvania, it's also one of the best ways to improve patient safety. Event reports can be the first indication of underlying problems, regardless of whether harm occurs. They also are essential tools for triggering widespread change throughout a facility—and beyond.



Event reporting isn't about pointing the blame at someone, but about explaining what went wrong so that next time, and every time thereafter, it goes right. When we know what happened, we can understand why it happened, and figure out how to prevent it from happening again. Sharing details about these events—telling the stories behind them—helps other healthcare facilities and staff avoid mistakes, learn from proven best practices, and better care for patients.

These details, whether from a single event or across multiple reports from multiple health systems, can uncover systemic issues and effect widespread change.

With this powerful impact in mind, the Patient Safety Authority (PSA) launched *Changemakers: Stories That Made a Difference*, a collection of stories about events that inspired people to improve care across their hospital, health system, or even nationwide.

Each story is classified by category (e.g., medication, equipment, pediatrics) and highlights how a reported event, whether through the Pennsylvania Patient Safety Reporting System (PA-PSRS) or an internal system, catalyzed improvements. Below are some of the dozens of stories that can be found in our new, searchable microsite.

System Malfunction Results in Incomplete Lab Orders

When a nurse coordinator found out that lab orders could be faxed directly from the Epic electronic health record system, rather than needing to be printed and faxing a hard copy to lab facilities, she decided to test the functionality to make sure it worked correctly and accurately. She faxed orders to her hospital's own fax number, but only received the first page of each order. Since sending incomplete orders puts patients' safety at risk by delaying treatment, she contacted the EpicCare systems analyst for support. He discovered that her Epic department wasn't the only one experiencing the issue—it extended to all departments throughout the hospital. However, he couldn't resolve it internally, so he elevated the problem to the software manufacturer. The nurse coordinator emailed the systems analyst every few weeks for status updates until the bug was finally fixed several months later. If not for her commitment to patient-focused care and diligence in testing a software feature and reporting an issue, this problem might have gone overlooked for much longer, with adverse outcomes for the patients affected.

Patient History Alerts Keep Staff Prepared

In some patients, anesthetics can cause a severe, sometimes lethal, reaction known as malignant hyperthermia (MH), with symptoms such as a dangerously high body temperature, rigid muscles or spasms, and a rapid heart rate. It is important to communicate a history of MH to operating room (OR) staff before a surgical procedure, but at one hospital in 2017, the surgeon's office did not inform Scheduling, Anesthesia, or the OR of the patient's history of MH. Fortunately, it was identified immediately preop and the team took appropriate precautions, resulting in no harm to the patient. However, the near miss prompted the Preadmission Center clinical leader and the OR operations

*Corresponding author
◆Patient Safety Authority
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manager to investigate the incident to prevent this from happening again, and the clinical risk coordinator referred the issue to the health information technology (Health IT) team and requested an alert to fire when a patient with a history or family history of MH is being planned for surgery. As a result, a multidisciplinary team comprised of Anesthesiology, Preadmission Testing, OR, Health IT, and Risk Management developed new case alerts in the electronic health record for MH. These alerts fire warnings in the form of a patient alert banner ("Patient has a history of malignant hyperthermia.") when a documented history of MH is entered for the patient, whether during scheduling or pre-anesthesia testing or visit, or by OR nurses, the surgeon, or Anesthesia, with reminders to follow the facility's procedures for notifying OR and Anesthesia leadership and update the case comments and medical record.

Uncovering a Widespread, Unidentified Supply Issue

A facility called the PSA with a concern regarding misplacements of nasogastric feeding tubes. Several veteran staff members were suddenly inserting them in patients' lungs instead of their gastrointestinal tract, and the facility wanted to know if anyone else had reported the same issue. Through a review of PA-PSRS, the PSA was able to identify that two other facilities had reported similar scenarios, assist in determining the root cause, and alert others about the issue.

Further investigation revealed that a popular manufacturer had stopped producing the enteral devices, forcing facilities to find an alternative quickly. This facility had ordered a replacement of the same size and type, but communication of the change did not reach frontline staff who were placing the feeding tubes. The staff continued to place the tubes as they always had—without knowing they were using a different product. Once the staff became aware of the change, they commented that the new tubes seemed less pliable and slicker than the previous ones.

Identifying Unanticipated Equipment Failure

An organization reported several heparin infusion events over a year, which prompted several process changes in the electronic health record with the acknowledgement of orders, views within the medication administration record, and labeling of intravenous lines. These events and subsequent changes also led to greater awareness around management of heparin infusions within the organization, as well as more emphasis on hourly rounding to ensure patient safety. As a result, staff was better equipped to recognize problems as they are happening and act quickly to prevent patient harm.

As just one example of the positive impact of reporting adverse events: A patient arrived from the emergency department where a heparin infusion had been initiated. The nurse receiving the patient from the ED checked the infusion pump to make sure that all the settings were correct. Thirty minutes later, she noticed that the 500 mL bag of heparin only had 100 mL remaining; as the infusion had only been running for about 60 minutes, she realized that something was wrong and that the patient had received more heparin than ordered. She called the charge nurse in to look at the pump. The charge nurse immediately stopped the infusion, removed the pump from service, placed an order for a stat partial thromboplastin time (PTT, a blood test to see how long it takes for the blood to clot), notified the night hospitalist, and called the nursing supervisor. They also brought the adverse event to the attention of the nursing director on-call and the patient safety officer.

Ultimately, an investigation of the event revealed a broken hinge inside the pump had caused it to malfunction and alternate between free flow and a regulated drip rate. Because the harsh chemicals used to clean the pumps make the plastic hinges brittle over time, the facility educated and trained staff to look for potential defects, such as small hairline cracks that typically precede this type of break. Any pumps they identify with these cracks are removed from service before the hinge breaks, and the hinge is repaired for the pump is placed back into use.

Changing Procedures for Changing Trachs

Three safety events involving bedside tracheostomy (trach) changes—downsizing and occasionally upsizing—occurred at a hospital in one year, one of which was self-reported by a respiratory therapist to the respiratory manager. In response, the respiratory manager met with the patient safety manager and initiated a review with the respiratory staff. Through this review, they learned that there was no consistent practice for changing trachs and every staff member performed the procedure differently. They also identified other issues: there was no clear place for physicians to order a trach change, and sometimes no order was placed. These findings resulted in process improvements, which included a time-out procedure before a trach is changed, performed by two clinicians (a registered nurse [RN], another respiratory staff member, or a physician) and confirming the correct patient, correct trach and size, and presence of a physician order in the chart. A huddle sheet created for education was provided to the RN, physician, and respiratory staff; a policy was created to outline procedures for trach changes; and sections were added to the physician order for specific information related to the trach change, such as trach type and size. The time-out is documented in the patient's medical record and the respiratory manager frequently reviews the data to ensure compliance. No events related to this error have been documented since the new procedures were implemented.

Be a Changemaker

Visit patientsafety.pa.gov/EventReporting to read and share more stories like these demonstrating the impact of event reporting. If you have a story about how an event inspired staff to make changes that improved patient care and safety at your facility, please consider sending it to the PSA for inclusion in this site.

About the Authors

Eugene Myers (eugemyers@pa.gov) is the associate editor of Engagement and Publications for the Patient Safety Authority. He previously served as the editor-in-chief of Communications, Office of Institutional Advancement, at Thomas Jefferson University and Jefferson Health.

Caitlyn Allen is director of External Affairs for the Patient Safety Authority.

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