

A Human Factors Approach for Event Analysis in a Pediatric Intensive Care Unit

Keywords: HFACS-Healthcare; Adverse Events; Pediatric Intensive Care; Human Factors

Abstract

Background: Medical management in the pediatric intensive care unit involves an increased risk of adverse events and near misses due to the complexity of the environment and patient acuity. Therefore, the feasibility of the Human Factors Analysis and Classification System for Healthcare was explored to identify underlying factors contributing towards adverse events and near misses in the pediatric intensive care unit.

Methods: Adverse events and near misses reported within the pediatric intensive care unit over five years were obtained from a nonprofit, tertiary care, academic medical center in Southern California. Researchers applied the Human Factors Analysis and Classification System for Healthcare framework to identify contributing factors.

Results: Using the Human Factors Analysis and Classification System for Healthcare framework, two trained human factors experts analyzed 272 events to identify contributing factors within the event narratives, resulting in identification of 340 causal factors. The top three contributing factors identified within the reports included skill-based errors (n=90, 26.47%), coordination breakdowns (n=70, 20.59%), and tools/technology breakdowns (n=49, 14.41%).

Conclusions: Adverse events and near misses in the pediatric intensive care unit can be addressed and improved with targeted human factors interventions by identifying areas of systemic weakness for the development of targeted patient safety interventions. The application of the Human Factors Analysis and Classification System for Healthcare framework to event reporting narratives bridges a gap in the understanding of safety events translating into a framework for clinical quality improvement.

Abbreviations

AE, adverse event; CF, contributing factor; HFACS-Healthcare, Human Factors Analysis and Classification System for Healthcare; MIP, medication infusion pump; NM, near-miss; PICU, pediatric intensive care unit.

Introduction

The pediatric intensive care unit (PICU) is a complex, high-acuity environment with increased potential for adverse events (AE). AE are unintended injuries that may result in temporary or permanent disability, death, or prolonged hospital stay [1]. Patients in the PICU setting often experience increased illness severity, more invasive interventions, and multiple interactions at the human-technology interface [2, 3]. A 2010 study [4] found that as many as 62% of PICU patients experienced at least one AE during their stay, where 10% were classified as life-threatening or permanent, and 45% were deemed preventable. A recent single centered study from Europe in 2020 found that of 842 patients admitted to the PICU, 142 (16.86%) experienced at least one AE during their stay, where 91.2% were considered preventable [5].



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AEs occur within a complex socio-technical healthcare system, in which systems components (humans, tools/technology, tasks, environments, organizations) [6] interact in ways that may contribute to AEs. One strategy for improving patient safety and reducing the likelihood of AEs involves exploring contributing factors (CF) associated with these incidents, leading to targeted solutions and improved patient safety [7, 8].

The reporting of near misses and unsafe conditions, by healthcare professionals who are directly or indirectly involved in the event, is vital for identifying and addressing latent safety issues to prevent AEs [9]. Near-miss (NM) events (unplanned events that did not result in injury, illness or damage, but had the potential to do so) present an opportunity to identify and correct flaws that jeopardize patient safety [10]. A continuum of cascade effects exists from apparently trivial incidents to near misses and full-blown adverse events [10, 11]. Consequently, the same patterns of causes of failure and their relations precede both adverse events and near misses. Incident reporting can provide interesting insights into the current state of the healthcare system; however, limitations exist with current incident reporting processes, including broad criteria for what to report, a general focus on quantity of quality of data, biased reports from the perspective of one person, the need for pragmatic and flexible taxonomies to classify patient safety problems, reporting pathways often involving reporting to supervisors, limiting what information is disclosed, and a lack of feedback [12].

These limitations constrain incident reporting from being used as a reliable epidemiological tool to measure the frequency of events and whether interventions are effective in improving patient safety [13]. The value of incident report data quickly diminishes without the application of a reliable, systemic framework to investigate and generalize CF reported across multiple events [7].

In prior work, researchers utilized the human factors analysis and classification system for healthcare (HFACS-healthcare) to analyze systems factors that may have contributed to surgery-related incidents across a hospital system [7]. The HFACS framework was developed based James Reason's Swiss-cheese model of accident causation and is organized by four tiers [7, 14]: 1) organizational influences; 2) unsafe supervision; 3) preconditions for unsafe acts; and 4) unsafe acts [7, 14, 15]. The HFACS framework was expanded upon to better fit specific healthcare-focused needs resulting in the HFACS-Healthcare framework [7]. The aim of this study was to investigate the feasibility of using the HFACS-healthcare framework to analyze previously reported events in a PICU over five years to identify underlying work-system factors related to the reported events.

Material and Methods

Data Collection

Following Institutional Review Board (STUDY00001911) approval, PICU event reports were collected from a nonprofit, tertiary care academic medical center in Los Angeles, California, between January 2016, and April 2021. The medical center's 12-bed pediatric intensive care unit (PICU) is combined with the congenital cardiac intensive care unit and admits patients with medical and surgical needs including congenital cardiac surgery, neurosurgery, orthopedic surgery, and renal transplantation.

The institution utilizes an anonymous electronic incident reporting system to promote patient safety and improve patient care [7]. The incident reporting system is available to all hospital personnel to document near misses, good catches, and safety events that affect patients, visitors, and staff. Upon submitting an incident report, users provide information on the demographics surrounding the event, a narrative review, and assess severity according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) classification [16]. Data obtained for this study included the event number, event type, specific event type, person affected, medical record number, patient age, event date, department, location of the event, level of harm, and a narrative describing the event details.

HFACS Classification

The HFACS-Healthcare classification system was used to classify identified factors into one of the 21 categories to analyze CFs associated with each event (see Table 1). Two trained human factors researchers analyzed the data in two stages as done similarly in other research [17]: stage one - each rater individually reviewed event narratives to identify CFs, coming to consensus on the number of CFs within each event; stage two - researchers individually categorized each CF into one of the 21 HFACS-Healthcare categories. Interrater reliability was assessed, and reviewers came to a consensus on any disagreements.

Subsequently the narratives within the three most populated HFACS-Healthcare categories were sub-classified using the methods above to further understand specific underlying issues contributing to the incident. The sub-classification was developed using themes that appeared throughout events within each category.

Data Analysis

Microsoft Excel was used to analyze the data. Contributing factors

were summed across events and by year and patient demographics and harm classifications assigned to each AE or NM were calculated and analyzed.

Results

Demographics

During the study period (January 2, 2016, to April 19, 2021), 1,676 patients were admitted to the PICU and 331 events were reported across 114 patients. Patient age ranged from under 1 year of age to 17 years of age, with most being under 1 year old (n=139, 41.99%), followed by 1-3 years of age (n=50, 15.11%), and 13-15 years of age (n=46, 13.90%).

Of the 331 events reported, 288 (87%) included an associated level of harm. Incidents most often involved the following classifications: 1) "reached patient, no harm" (n=133, 40.18%); 2) "did not reach patient" (n=46, 13.90%); and 3) "capacity for error (good catch)" (n=42, 12.69%). The remaining reports with associated level of harm classifications included: monitor patient, no harm (n = 28, 8.46%); intervention required, temporary harm (n = 28, 8.46%); death (n = 6, 1.81%); intervention to sustain life (n = 4, 1.21%); and extended stay, temporary harm (n = 1, 0.30%).

HFACS Classification

Inter-rater reliability among reviewers was 84.88% before consensus was made on disagreements. After removing duplicate entries (n = 13, 3.93%), a total of 272 events (82.18%) could be analyzed using the HFACS-Healthcare classification system. The 46 (13.90%) events that could not be analyzed did not include enough information to conduct a systemic analysis and only provided a brief factual description of the event type (e.g., "code blue").

Of the remaining 272 reports, 216 (79.41%) included one CF, 46 (16.91%) included two CFs, 8 (2.94%) reports each included three CFs, and the remaining 2 (0.73%) event reports included four CFs. Between 2016 and 2021 the number of incidents reported trended down with a total of 49 events reported in 2016 and 19 reported in 2020. The CF categories most often cited included skill-based errors (i.e., errors that occur in highly practiced tasks) (n=90, 26.47%), coordination breakdowns (i.e., breakdowns within teamwork, planning, assistance, etc.) (n=70, 20.59%), and breakdowns due to issues with tools and technology (i.e., usability issues, poor condition, functionality, etc.) (n=49, 14.41%) (see Figure 1 and Table 2).

Narratives involving skill-based errors, coordination breakdowns and tools and technology issues were sub-classified to identify the underlying issues that contributed to each event. Skill-based errors involved delayed or incomplete tasks (n=25, 27.78%), retrieving or administering incorrect medication (n=16, 17.78%), and incorrect, missing, or unverified orders (n=15, 16.67%). Coordination breakdowns involved problems with planning (n=26, 37.14%), coordinating lab samples (n=11, 15.71%), and teamwork (n=10, 14.29%). Finally, tools and technology breakdowns included issues with infusions and pumps (n=14, 26.53%), the flow of medication within a line or tube (n=7, 14.29%), pyxis errors (n=4, 8.16%), and problems with the design of the electronic health record (n=4, 8.16%) (Table 3).

Table 1: Definitions and associated examples for the Human Factors Analysis and Classification System for health care categories

HFACS-Healthcare Categories	Definitions	Examples
Organizational Influences		
Organizational culture	Organizational policies, structure, or culture that uphold the standards of safety	Staff concerns with speaking up for fear of retribution
Operational process	Organizational processes that aid in managing daily operations and procedures	Lack of protocols for how to complete a task, conflicting policies
Resource management	Management of organizational resources including staff, supplies, and budget	Shortage of supplies
Supervisory Factors		
Inadequate supervision	Guidance and mentorship related to policies, procedures, performance of duties, and training	Lack of supervision to trainees
Planned inappropriate operations	Management of staff schedules and work assignments	Assigning an untrained staff member to a role they cannot perform
Failure to correct known problem	Correction of problematic workplace issues	Inappropriate behavior unaddressed, inoperative equipment remains unfixed
Supervisory violations	Oversight of staff to ensure compliance of organizational practices and rules	Encouraging team members to cut corners
Preconditions for unsafe acts		
Situational factors		
Physical environment	Environmental factors that contribute to performance including lighting, temperature, noise, and organization and layout of the workplace	Dim lighting, cluttered environment, loud music or alarms/alerts
Tools/technology	Design, condition, usability, and functionality of tools	Error messages, contaminated instruments, confusing instructions
Task	Complexity, criticality, and consistency of tasks performed	Patient's unique anatomy creates challenges
Individual factors		
Mental state	Psychological factors that allow for successful performance including attention, attitudes, memory, and motivation	Boredom, fatigue, forgetfulness, confusion
Physiological state	Physiological factors that allow for successful performance including wellness and physical abilities	Illness, weakness, injuries
Fitness for duty	Activities performed outside of the workplace that affect performance within the workplace	Lack of sleep, consuming too much alcohol, poor diet
Team factors		
Communication	Ability to adequately provide, request, and confirm information related to the task	Miscommunication, lack of sharing, clarification, conflict
Coordination	Successful performance through adequate planning and preparation, monitoring, and support	Supplies are missing due to inadequate planning, waiting for team members to arrive
Leadership	Demonstration of appropriate leadership abilities such as professionalism, providing guidance, and maintaining cohesiveness within a team	Inappropriate use of authority, not reinforcing appropriate behavior/teamwork
Unsafe acts		
Errors		
Decision errors	Errors related to tasks that require conscious effort to gather appropriate information, maintain situational awareness, and execute appropriate actions	Selecting the wrong medication, incorrect diagnosis
Skill-Based errors	Errors related to highly-practiced tasks that require little to no conscious effort	Mistyping, miscalculation, spilling
Perceptual errors	Errors related to tasks that rely on human senses to successfully perform (visual, auditory, and haptic processing)	Misperceiving a visual result because of a glare
Violations		
Routine violations	Bending or deviating from organizational policies	Disabling alarms, ignoring instructions
Exceptional violations	An isolated, deviation from the rules (not indicative of an individual's behavior) and not condoned by the organization	Performing activities without credentials, excessive risk taking that threaten safety

Table 2. Breakdown of all contributing factors identified within the 272 event reports.

HFACS-Healthcare Categories	N	%
Organizational Influences		
Organizational culture	0	0.00%
Operational process	19	5.56%
Resource management	27	7.89%
Supervisory Factors		
Inadequate supervision	7	2.05%
Planned inappropriate operations	0	0.00%
Failure to correct known problem	0	0.00%
Supervisory violations	0	0.00%
Preconditions for unsafe acts		
Situational factors	0	
Physical environment	2	0.58%
Tools/technology	49	14.33%
Task	3	0.88%
Individual factors	0	
Mental state	1	0.29%
Physiological state	0	0.00%
Fitness for duty	0	0.00%
Team factors	0	0.00%
Communication	36	10.53%
Coordination	70	20.47%
Leadership	0	0.00%
Unsafe acts		
Errors		
Decision errors	30	8.77%
Skill-Based errors	90	26.32%
Perceptual errors	0	0.00%
Violations		
Routine violations	4	1.17%
Exceptional violations	2	0.58%
Total	340	

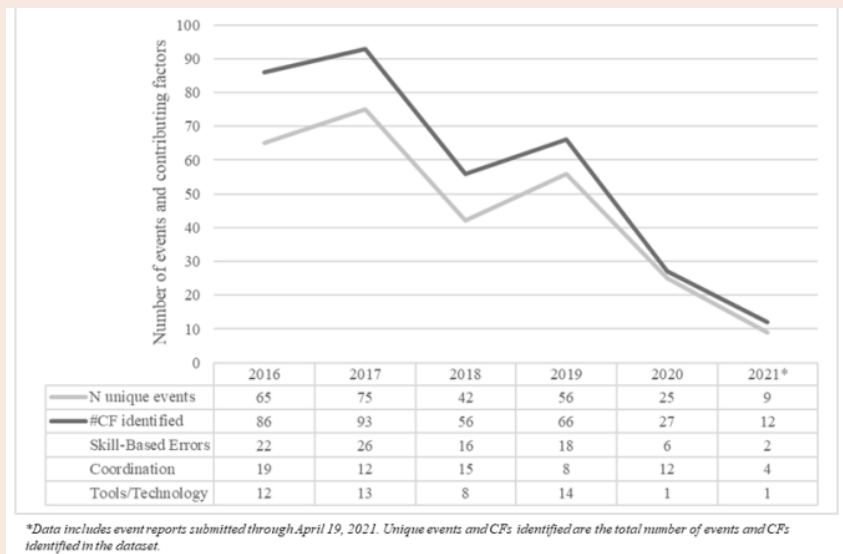


Figure 1: Breakdown of events, including the top three contributing factors.

Table 3. Top three contributing factors and their associated sub classifications.

Contributing Factor	2016 to 2021*	2016	2017	2018	2019	2020	2021*
Skill-Based Errors	n=90	n=22	n=26	n=16	n=18	n=6	n=2*
Delayed or incomplete task	27.78%	9.09%	30.77%	50.00%	33.33%	16.67%	0.00%
Incorrect medication retrieved or administered	17.78%	22.73%	23.08%	18.75%	5.56%	0.00%	50.00%
Incorrect/missing/unverified order	16.67%	9.09%	11.54%	18.75%	33.33%	16.67%	0.00%
Medication IV wasn't unclamped/clamped	6.67%	13.64%	3.85%	6.25%	0.00%	16.67%	0.00%
Missing/Incorrect ID band	6.67%	9.09%	7.69%	0.00%	11.11%	0.00%	0.00%
Label issue - medication or lab	4.44%	4.55%	3.85%	0.00%	5.56%	16.67%	0.00%
Chest tube issue	3.33%	13.64%	0.00%	0.00%	0.00%	0.00%	0.00%
Unused medication incorrectly stored	3.33%	0.00%	7.69%	0.00%	0.00%	16.67%	0.00%
Hand off issue	2.22%	0.00%	3.85%	0.00%	0.00%	16.67%	0.00%
Incorrect count	2.22%	0.00%	3.85%	0.00%	5.56%	0.00%	0.00%
Incorrect or missing weight documented	2.22%	0.00%	0.00%	6.25%	0.00%	0.00%	50.00%
Blood culture or specimen issue	1.11%	0.00%	0.00%	0.00%	5.56%	0.00%	0.00%
Incorrect reagent used for tests	1.11%	4.55%	0.00%	0.00%	0.00%	0.00%	0.00%
Incorrect phone number dialed	1.11%	4.55%	0.00%	0.00%	0.00%	0.00%	0.00%
Equipment setting unadjusted	1.11%	4.55%	0.00%	0.00%	0.00%	0.00%	0.00%
Incorrect room assignment	1.11%	0.00%	3.85%	0.00%	0.00%	0.00%	0.00%
Incorrect code button pushed	1.11%	4.55%	0.00%	0.00%	0.00%	0.00%	0.00%
Coordination	n=70	n=19	n=12	n=15	n=8	n=12	n=4*
Inadequate planning	37.14%	31.58%	33.33%	53.33%	37.50%	25.00%	50.00%
Lab sample - lost or not received	15.71%	5.26%	33.33%	6.67%	25.00%	16.67%	25.00%
Inadequate teamwork	14.29%	26.32%	8.33%	13.33%	12.50%	8.33%	0.00%
Radiology issue or delay	8.57%	15.79%	8.33%	6.67%	0.00%	8.33%	0.00%
Pharmacy order delay	4.29%	0.00%	0.00%	6.67%	0.00%	16.67%	0.00%
Galley delay	4.29%	0.00%	8.33%	0.00%	25.00%	0.00%	0.00%
Laboratory delay	4.29%	0.00%	8.33%	0.00%	0.00%	16.67%	0.00%
Blood bank order delay	2.86%	10.53%	0.00%	0.00%	0.00%	0.00%	0.00%
Neurosurgery delay	2.86%	5.26%	0.00%	0.00%	0.00%	0.00%	25.00%
Security request denied	1.43%	0.00%	0.00%	6.67%	0.00%	0.00%	0.00%
Pain team delay	1.43%	0.00%	0.00%	6.67%	0.00%	0.00%	0.00%
Special order not received	1.43%	0.00%	0.00%	0.00%	0.00%	8.33%	0.00%
MD delay	1.43%	5.26%	0.00%	0.00%	0.00%	0.00%	0.00%
Tools/Technology	n=49	n=12	n=13	n=8	n=14	n=1	n=1*
Infusion/pump issue	26.53%	16.67%	46.15%	12.50%	14.29%	100.00%	100.00%
Line/tube flow	14.29%	25.00%	7.69%	25.00%	7.14%	0.00%	0.00%
CS-Link issue	8.16%	8.33%	15.38%	0.00%	7.14%	0.00%	0.00%
Pyxis error	8.16%	8.33%	0.00%	12.50%	14.29%	0.00%	0.00%
Order entry issue	6.12%	0.00%	15.38%	0.00%	7.14%	0.00%	0.00%
iSTAT malfunction	6.12%	8.33%	0.00%	12.50%	7.14%	0.00%	0.00%
Barcode scan	4.08%	0.00%	0.00%	12.50%	7.14%	0.00%	0.00%
PICU door/elevator issue	4.08%	0.00%	7.69%	12.50%	0.00%	0.00%	0.00%
Dislodged trach/GT	4.08%	16.67%	0.00%	0.00%	0.00%	0.00%	0.00%
Electrical issue	2.04%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
Poor quality x-ray	2.04%	8.33%	0.00%	0.00%	0.00%	0.00%	0.00%
Device link or upload issue	2.04%	0.00%	7.69%	0.00%	0.00%	0.00%	0.00%
Medication label printing issue	2.04%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
Pump malfunction	2.04%	8.33%	0.00%	0.00%	0.00%	0.00%	0.00%
Galley documentation issue	2.04%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
Storz PICU Endoscope issue	2.04%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%
Paperless CMDR issue	2.04%	0.00%	0.00%	12.50%	0.00%	0.00%	0.00%
Alarm malfunction	2.04%	0.00%	0.00%	0.00%	7.14%	0.00%	0.00%

*Data includes event reports submitted through April 19, 2021

Discussion

In the present study, researchers assessed the feasibility and applicability of the HFACS-Healthcare framework to identify CFs associated with AEs and NMs reported in a PICU over five years. During the study period, 324 unique events were reported, where 272 provided enough contextual information about the event to be analyzed using HFACS-Healthcare. Ultimately 340 contributing factors were identified.

Over the course of the study the total number of events reported trended down from 65 events reported in 2016 to 25 events reported in 2020. While this finding could be indicative that safety in the healthcare system has improved overtime, it may also speak to factors influencing incident reporting including fear of retribution, usability challenges associated with event reporting, and even the COVID-19 pandemic influencing workload during 2020-2021 reducing the time available to submit incident reports. Thus, the discussion is focused on the CFs that were identified from this analysis and opportunities to improve the sociotechnical work system.

Most of the event reports cited one CF, many referenced two or more CFs. Consider the following example obtained from the study data:

["...Trauma patient that had several MDs in the room calling out medication orders...In the emergent situation of attempting to stabilize trauma patient no MD could place orders in the MAR resulting in confusion of rate of medication, no harm to patient... RNs to place orders under emergent verbal to link drips to the MAR"]

Although the identified error within this narrative is "incorrect medication rate" when analyzed using HFACS-Healthcare, three CFs emerge: 1) the patient had many attending and trainee physicians calling out medication orders (communication); 2) the physicians were unable to input orders into the medical record while stabilizing the patient (task); and 3) there was confusion in the rate of medication (skill-based error). Human factors analysis and aggregation of incident data provides novel insights into the system's current state.

The most common CFs identified were skill-based errors, coordination breakdowns, and issues with tools and technology. Medication errors related to incorrect, missing, or unverified orders and the incorrect retrieval or administration of medication were important contributors within the sub-categories of skill-based errors. The underlying factors contributing to skill-based errors may be related to a complex interaction amongst organizational factors such as inadequate staffing during busy census with high acuity patients assigned to a single health care provider leading to errors in task execution or poorly designed equipment and ergonomics leading to "workarounds" [18] and inefficiency. Prescribing errors in PICUs have been found to relate to the increased cognitive demand required for completing tasks associated with prescribing medication [19]. In a tertiary care center with a mix of adult and pediatric patients, the providers must navigate through multiple electronic health record interfaces to complete a medication order leading to a cognitive disconnect and information overload [20].

Coordination issues identified involved inadequate planning or inadequate teamwork related to supporting services such as

nutrition, handoffs to the pediatric ward or emergency department, or communication with the blood bank. The importance of teamwork within the intensive care unit cannot be overstressed - the ICU has emerged to be a team sport with patient outcomes being related not only to individual knowledge, skills, and attitudes, but the collective wisdom of the entire team [21]. Strategies to improve coordination issues include the use of checklists, crisis resource management principles, and teamwork training [22-25].

The third most common challenge cited involved issues with tools and technology. Medication infusion pump (MIP) errors were common along with issues concerning the flow within a line or tube and pyxis errors. The FDA-sponsored Infusion Pump Summit (2010) identified poor human-machine interface design as a critical shortcoming of current MIP [26, 27]. Clinicians often find themselves adapting their workflow to the designs of the MIP, as opposed to having access to MIP that are designed to meet their needs and workflow. However, several studies have concluded that implementing smart pumps in units treating critically ill patients had no impact on the number of severe medication errors prevented [28-30]. Enabling the interception of infusion programming errors could be used to improve patient safety to avoid the potential for severe injury to pediatric patients [31]. Being aware of the CFs involved with MIP-related AEs or NMs allows for the design of systemic solutions that may reduce repeat events.

Other work exploring event reporting in pediatric medicine has included single-site studies focused on PICUs [32-34], multicenter studies involving children's hospitals [35] and the Pediatric Emergency Research Network (PECARN) [36]. Although there are differences in the methodologies [3, 4], objectives [5], study periods, and taxonomies for classification [37, 38], the findings presented here demonstrate similar themes including noncompliance with established procedures, process failures, and communication failures [35, 36].

This study adds to the existing literature supporting the value of exploring healthcare-related events with a human factors' lens. A human factors approach will explore problems by looking at the humans within a system, their interactions with one another and various system components, and redesigns the tasks, interfaces, and system to make lasting improvements [39]. Exploration of the underlying CFs by trained individuals is key to the development of targeted patient safety solutions. Other studies have also found value in applying human factors methods to critical care patient safety as it helps us to understand 'work as done' in the clinical environment versus "work as imagined" [40]. Moreover, these approaches redirect quality improvement efforts to focus on redesigning systems (e.g., environments, tasks, tools and technology, and organization) [6] to improve human performance. Rather than developing more policies, channeling resources to compliance of policies as a reaction to AE and NM (retroactive), investigation into the CFs in a systematic manner with a system like HFACS-Healthcare (proactive) leads to a better understanding of poorly designed systems and unmet needs within the PICU [40].

Limitations

It is important to note that the retrospective data utilized for

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analysis originates from a single institution and is not necessarily generalizable across hospitals or pediatric centers, or units with different team compositions (trainees, advanced practice providers etc.). The study site's unique setting involves a PICU in the pediatric department located within a tertiary academic institution that is a non-children's hospital; hence the case-mix (acuity, type of patients) could be different from a free-standing children's hospital.

Additionally, the event data utilized relies heavily on untrained frontline health care providers to enter events and assign a level of harm voluntarily. Healthcare providers rarely receive guidance on what type of information should be included in the report (e.g., contributing systemic factors) to make it useful.

Conclusion

Applying the HFACS-Healthcare framework to event reporting in the PICU may aid in rethinking solutions that may positively impact provider workflow and patient safety. With further research applying the HFACS-Healthcare framework to other settings (academic children's hospital or the community pediatric intensive care unit), unique CFs could be explored, prompting the proactive application of targeted patient safety solutions for the unique environments with interventions for longitudinal sustainment.

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