

THE WELL-DEFINED PEDIATRIC ICU: ACTIVE SURVEILLANCE USING NONMEDICAL PERSONNEL TO CAPTURE LESS SERIOUS SAFETY EVENTS



The Joint Commission Journal on Quality and Patient Safety

This article, written by William A. White, BA; Kelly Kennedy, BS; Holly S. Belgum, BS; Nathaniel R. Payne, MD; and Stephen Kurachek, MD, appeared in the December 2015 issue of *The Joint Commission Journal on Quality and Patient Safety*[®]. Subscribe to *The Journal* regularly receive peer-reviewed articles that will help you promote quality and safety in health care.

Adverse events in pediatric care units (PICUs) are numerous, diverse, and costly.¹⁻⁷ Under the umbrella of patient safety events (“events not primarily related to the natural course of the patient’s illness or underlying condition”) a taxonomy of terms has emerged to differentiate the nature of events.⁸ Serious safety events (SSEs) or sentinel events, for example, result in severe patient harm (psychological or physical) or death. These events have obvious implications for care and attract attention from providers, payers, and press.⁹⁻¹¹ The Joint Commission Sentinel Event Policy differentiates events that reach the patient (sentinel, adverse, and no-harm events) and those that do not (“close call” or “near miss”; hazardous condition).⁸ Regarding events that do not reach the patient, Reason emphasized the importance of “latent conditions” within a system, which an active failure can trigger as an event resulting in patient harm.¹² Latent conditions exist at all organizational levels and can be recognized and remedied before an event occurs. Near misses or close calls can refer to events intercepted before patient harm occurs, and may or may not reach the patient; such potentially harmful events can be halted by chance, intervention, or patient resilience.¹³

Herzer et al. referred to the entire spectrum of undesirable patient events as “hazards” that range “from potentially unsafe conditions to events in which no harm occurred to events in which harm or death occurred.”¹⁴(p. 340) Similarly, Gabriel et al., in an effort to avoid negative connotations, referred to all events as “conditions.”¹⁵ In a pediatric cardiac surgical setting, Schraagen et al. borrowed the term non-routine events from the nuclear energy industry to describe any anomaly that could lead to serious harm.¹⁶ In the largest multicenter PICU study of adverse events, only events that reached a patient and required intervention were recorded.¹⁷ Subsequent PICU studies, however, revealed the profusion of nonroutine events that do not reach the patient but are valuable as demonstrations of latent conditions.¹⁸⁻²⁰

In the work that we describe in this article, we use the term less serious safety events (LSSEs) to describe incidents observed at the point of care that compromise safety but that do not result in severe patient harm; incidents may or may not reach a patient and cause minor or potential harm. We consider hazardous conditions and near misses, as well as other analogous terms, as LSSEs. Examples of LSSEs involving patients include, for example, failure to remove medications of a former patient before the admission of a new patient to the same room or the mistaken use of sterile water as a bronchoalveolar lavage fluid. LSSEs may reveal system defects and latent risks and can pre-cede serious events that result in patient or provider harm.^{21,22} Reason observed that the system conditions that result in latent risks are similar or identical to those that result in SSEs. Importantly, the latter are poorly predictable and the former more discoverable.¹² To capitalize on the value of LSSEs, effective detection, analysis, and a system for change are necessary.²³

Adverse events are underreported, as are SSEs and LSSEs, representing a lost opportunity to investigate defects before accidents occur.^{13,17,24,25} Analysis of events analogous to LSSEs is thought to have contributed to the reduction in catastrophic events in other industries.²⁵ Yet detection of LSSEs in health care usually has been time-limited and not incorporated into more comprehensive quality improvement (QI)/safety programs. For example, Kaushal et al., who used an intensive detection system entailing

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direct inquiry and order sheet, medication administration, and chart review to determine the rate of medication errors in a 36-day period, reported that the vast majority of errors did not result in harm.²⁶ LSSEs have been detected statewide by the Pennsylvania Patient Safety Authority for more than a decade through an online volunteer reporting system. During 2014, approximately 97% of 36,583 pediatric reports defined as “incidents” analogous to LSSEs have stimulated research and educational activities.²⁷

Investigators have exposed the deficiencies of standard hospital reporting systems,^{24,28–30} particularly for LSSEs.¹⁷ To combat underreporting, anonymous online forms, 24-hour “hotlines,” bedside cards, comprehensive chart audits, real-time safety audits, automated triggers, and retrospective trigger tools have all been used, with each method’s value defined in terms of its operational practicality and intervention to limit event recurrence.^{31–36} Prospective surveillance by specifically trained nurses or advanced practice nurses may be more effective by engaging bedside providers to report LSSEs.^{37,38} Surveillance for LSSEs may be of particular value in a PICU, where customization of care to accommodate critical illness, narrow therapeutic windows, and variation in development and weight are likely to increase their frequency.

At Children’s Hospitals and Clinics of Minnesota (CHC-MN), we sought to determine whether nonmedical personnel could cost-effectively perform prospective clinical surveillance for LSSEs in the PICU and use captured events to create quality/safety improvement projects. LSSEs were sporadically reported to the PICU leadership in the absence of a method to examine frequency and impact or prevent reoccurrence. In response, we created a unique program, the Well-Defined ICU (WICU) to complement the standard hospital reporting system for SSEs. The WICU quantifies and categorizes, and attempts to ultimately reduce, LSSEs.

We describe the WICU’s design, creation, and early operation, with a focus on the use of nonmedical personnel. We attempt to demonstrate qualitatively and quantitatively that such personnel can effectively gather LSSEs, execute quality/safety improvement projects, and improve safety within a PICU.

SETTING

CHC-MN is an independent, not-for-profit children’s health care system with 410 licensed beds, that services 12,000 inpatients per year. CHC-MN is affiliated with the University of Minnesota Medical School and its pediatric residency program. Medical students and residents round on the general wards; residents and fellows are accommodated in the PICU for elective rotations. CHC-MN, a Level 1 pediatric trauma center, provides care for children requiring expertise from a variety of sub-specialties. Solid organ transplantation and bone marrow transplantation are not performed. CHC-MN has a total of 42 PICU beds on two campuses, not including 19 beds in a cardiovascular ICU. Patients are assigned to either PICU or intermediate care (IMC) status, depending on acuity. The provider staff (MD, RN, respiratory care practitioner, et al.) in the PICU attend to patients at both levels of care. The PICUs admit approximately 1,700 patients per year, with a Paediatric Index of Mortality 2 risk of mortality of 2.4% and a raw mortality rate of < 2%.³⁹ Low-admission acuity is due in part to step-down patients’ designation of IMC status.

Children’s Respiratory & Critical Care Specialists (CRCCS) is a private practice pulmonary and intensive care group of 20 board-certified or eligible critical care physicians and 12 pulmonary practitioners. CRCCS contracts with CHC-MN to provide critical care leadership, clinical services, and 24/7 in-house attending PICU coverage. CRCCS and CHC-MN are jointly responsible for the quality of medical care in the PICUs. The WICU represents a platform for a cost-sharing collaboration between a not-for-profit

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hospital and a private practice critical care group whose contract stipulates responsibility for the quality of care in the PICU.

Sidebar 1: Categorization of Events by Harm to the Patient and General Theme*

Harm Index

1. Event did not reach the patient; potential for minor harm
2. Event did not reach the patient; potential for major harm
3. Event reached the patient; minor or no harm resulted
4. Event reached the patient; potential for major harm
5. Event resulted in extra observation or monitoring
6. Event resulted in treatment or intervention
7. Event resulted in increased length of stay
8. Event may have contributed to disability or death

Theme Index

1. Medications
2. Physical Injury
3. Communication
4. Procedure/processes
5. Equipment/infrastructure
6. Patient movement
7. Suspected infection

**These indexes were adapted from Patient Safety Surveillance Unit. Clinical Incident Management System (CIMS) and Severity Assessment Code 1: Data Request Process. East Perth, Australia: Government of Western Australia, Department of Health, 2012., pp. 23–24. Accessed Oct 21, 2015. http://www.rph.wa.gov.au/~media/Files/Corporate/general%20documents/clinical%20assessment/PDF/CIM_and_SAC_1Data_Request_Guidelines.aspx. (Ref. 43, 559)*

STUDY DESIGN

We performed a prospective single-center, two-campus, observational study to determine whether daily surveillance and facilitated reporting of LSSEs in a PICU can be effectively performed by low-cost, nonmedical personnel. LSSEs and data were taken from both PICU and IMC status patient populations. CHC-MN's Institutional Review Board deemed this study, as a QI project, to be exempt from review.

THE WELL-DEFINED ICU

Origins and Development. The WICU was developed by CRCCS in collaboration with CHC-MN and launched in August 2012. Its conception followed a project in which a high school senior student participated in a successful two-campus effort to reduce central line–associated bloodstream infection (CLABSI) for 12 months.⁴⁰ The WICU, with its focus on LSSEs (Harm Index ≤ 6 [Sidebar 1, above]), was not intended to replace the hospital's electronic Safety Learning Report (SLR) system—a hospitalwide voluntary surveillance system—or its medication trigger tool—a retrospective system seeking adverse events reflected in the use of specific medications (for example, naloxone).

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Events detected by the WICU were used to drive quality/safety improvement projects (Figure 1, page 553). Oversight of the WICU was performed by CRCCS and the medical director of Quality and Research at CHC-MN [N.R.P.]. An intensive care physician [S.K.] served as quality safety officer (QSO), providing operational direction to and supervising two quality/safety analysts (QSAs). QSAs were nonmedical personnel (pre-medical college graduates). Funding of all personnel during this study was provided by CRCCS. The development of the WICU proceeded in conceptual phases.

Phase 1. This was a proof-of-concept phase to determine if we could capture and respond to events from two PICUs with two nonmedical personnel [W.A.W., H.S.B.], who were hired as QSAs and provided with a 40-hour (one-week) orientation to the hospital and the science of health care safety, including patient privacy and provider confidentiality. We emphasized creation of a safe reporting environment and a focus on events, not people. We used a paper-based system of documentation.

Phase 2. In this phase, LSSE and data capture was switched from a paper form to a Web application, accessed at the point of care on tablet computers. This expansion was planned from the onset of the program to enable provider and administrator access to the repository of LSSEs. The Web application was accessible by touch screen tablets, desktop computers, and other interfaces. A partial screenshot of the PICU Census Form is provided in Appendix 1 (available in online article), and a partial screenshot of the Core Event Form for a Tube/Line Event is provided in Appendix 2 (available in online article). The PICU census was updated to the Web application by an hourly feed of admission, discharge, and transfer data from the electronic health record system. The data were stored on a relational database management system—a secure SQL server (Micro-soft; Redmond, Washington). Daily, the data were loaded into QlikView®, an application for analysis and reporting (QlikTech International AB, Lund, Sweden).

LSSEs ascertained on this platform during the 15-month interval from June 1, 2013, through August 31, 2014, were formally reviewed.

Role of the QSAs. Two QSAs canvassed the PICUs for adverse events each morning at 6:30 a.m., seven days per week. The two PICUs averaged 21 nurses each night, who were queried by the QSAs. On any one night, an estimated 80% of the night nurses were interviewed, the remainder were unavailable, for reasons including acuity, handoff reporting, or time constraints. QSAs also queried the intensivist on night call, lead respiratory care practitioner, and day pharmacist. The QSA, with the assistance of the reporting provider, classified each LSSE by theme and harm. A summary of events was presented to the QSO weekly for review and was provided to the PICU leadership and director of Quality and Research.

Well-Defined ICU (WICU) Program Logic Summary

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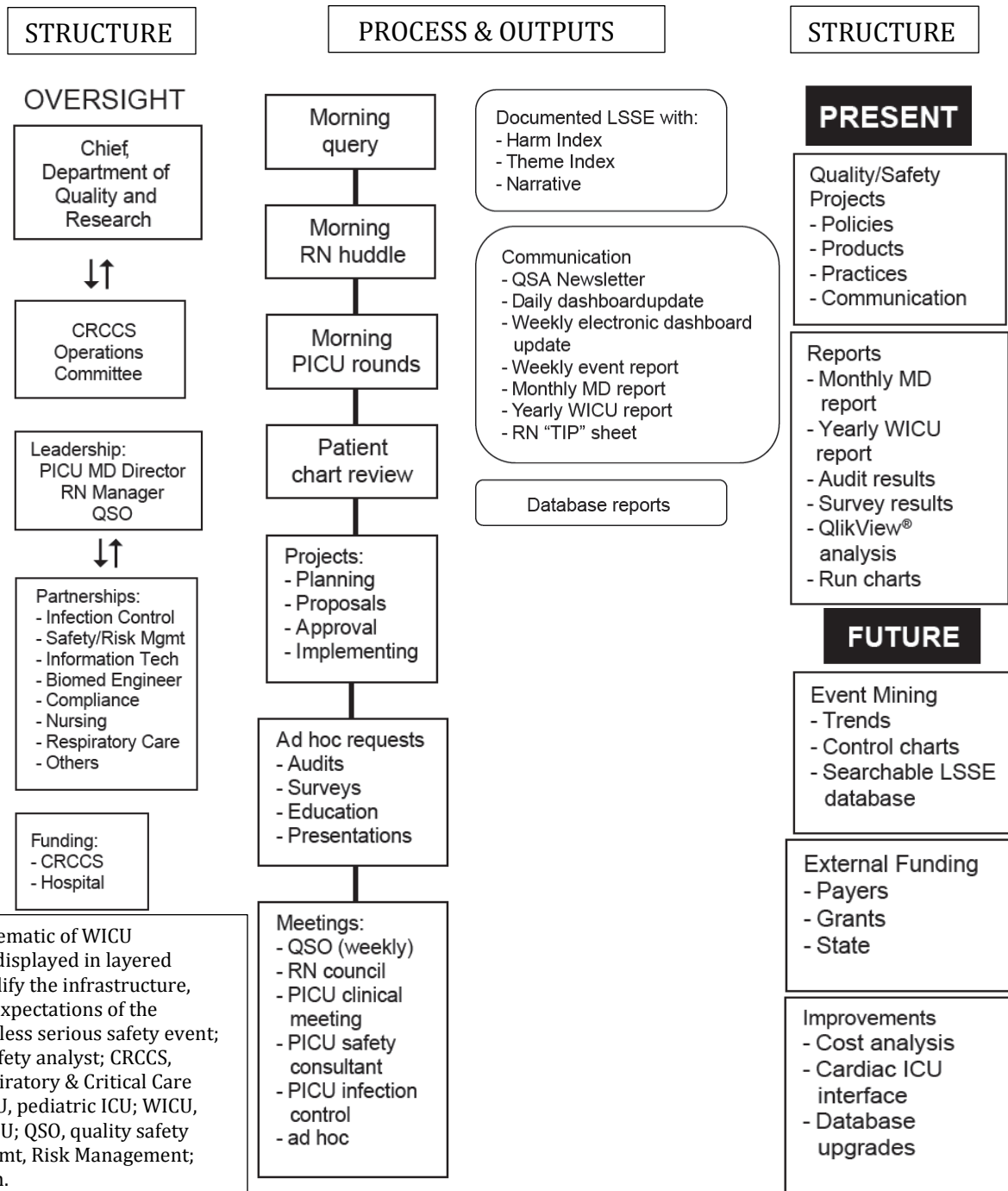


Figure 1. A schematic of WICU components is displayed in layered fashion to simplify the infrastructure, workings, and expectations of the program. LSSE, less serious safety event; QSA, quality/safety analyst; CRCCS, Children’s Respiratory & Critical Care Specialists; PICU, pediatric ICU; WICU, Well-Defined ICU; QSO, quality safety officer; Risk Mgmt, Risk Management; Tech, technician.

The QSAs, as not part of the hospital hierarchy and with no authority within the system, helped foster a reporting culture in which providers are encouraged to share their thoughts on improving care.⁴¹

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LSSE capture led to multidisciplinary quality/safety improvement projects, which the QSO and QSAs selected on the basis of the frequency and severity of events. Clinicians from multiple disciplines helped develop proposals, and outside inputs were pursued, such as a medical literature review, ad hoc calls to external PICUs, review of internal neonatal ICU (NICU) and cardiovascular ICU procedures, and use of Plan-Do-Study-Act (PDSA) cycles. QSAs were responsible for proposals, pre-and post-intervention metrics, and follow-up to help ensure sustained improvement. Proposals were formally reviewed by the PICU leadership (medical director and nurse manager) and other stakeholders, as indicated: infection control, PICU safety consultant, respiratory care practitioners, PICU Nurse Council, PICU physicians, and hospital compliance officers.

DATA ANALYSIS

Descriptive statistics were used to describe the primary out-come measure—ascertainment of LSSEs by QSAs. We defined success of the QSAs in terms of their capture of LSSEs in excess of the SSEs submitted through the traditional SLR system during the study period. QSA interrater reliability for PICU database elements, as determined by Cohen's kappa coefficient (which measures interrater agreement for qualitative [categorical] items⁴²), was performed quarterly.

The frequency of LSSEs was expressed per day and per patient-day. The number of SLRs submitted during the 15 months preceding the WICU were compared to the number submitted during the study period. The chi-square test was used to determine whether the number of SLRs reported during the two periods differed, with statistical significance defined as $p < .05$.

Table 1. Distribution of Core Events by Category in the Pediatric ICU in a 15-Month Period (June 1, 2013–August 31, 2014) for 1,535 Core Events

| Core Event Categories | n | (% of Core Events) |
|---|-----|--------------------|
| Accidental extubation | 8 | (0.5) |
| Catheter-associated urinary tract infection (CAUTI)* | 7 | (0.5) |
| Central line–associated bloodstream infection (CLABSI)* | 8 | (0.5) |
| Cardiopulmonary resuscitation (CPR) | 9 | (0.6) |
| Death | 35 | (2.3) |
| Emergent intubation | 9 | (0.6) |
| External ventricular drain infection (EVDI)* | 1 | (0.1) |
| Failed extubation | 16 | (1.0) |
| Line complication | 951 | (62.0) |
| Arterial line, central venous line (CVL) | 371 | (24.2) |
| Non-arterial line, non-CVL | 580 | (37.8) |
| Medication issues | 333 | (21.7) |
| Skin breakdown | 150 | (9.8) |

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| | | |
|--|---|-------|
| Ventilator-associated complication (VAC)† | 8 | (0.5) |
| <p>*The Well-Defined ICU (WICU) program reports all suspected health care–associated infections to the Department of Infection Control and Prevention for final adjudication using standard Centers for Disease Control and Prevention criteria.</p> <p>† Ventilator-associated complications (pneumonia/bronchitis) are under-estimated; a local surveillance tool is under construction.</p> | | |

LSSEs were divided into core and noncore events to separate generic outcome measures of a PICU from unexpected incidents. Core events reflected standard PICU metrics, such as airway-related events (for example, failed extubation), skin breakdown, noninfectious line or tube complications, and cardiopulmonary resuscitation (CPR) in the PICU. The number of patients of “monitor only” status was recorded, defined as patients admitted at ICU status who did not receive an ICU–specific therapy. Additional standard metrics, such as health care–associated infections, medication errors, and mortality, were captured by the hospital’s medication reporting and SLR systems. Noncore events—which cannot be categorized as core events—included “close calls” and incidents embedded in PICU practice and generally not recognized as LSSEs (“normalization of deviancy”). All events were categorized by theme and harm (Table 1, above). The Theme Index and Harm Index were modified from the Clinical Incident Management System of Western Australia, a comprehensive patient safety program that reviews contributory factors in assessing safety events.⁴³ We did not assess the impact of the program on frequency of events, themes, or harmfulness or the preventability of LSSEs.

Quality/safety improvement projects, completed by supervised QSAs, were enumerated and detailed by example as a secondary outcome measure and an indicator of QSA effectiveness. Broadcasting and sharing of LSSE data and interventions were summarized.

RESULTS

DEMOGRAPHICS AND PATIENT CHARACTERISTICS

There were 1,980 PICU admissions, representing 10,766 PICU patient-days during the 15-month study period (part of Phase 2, as detailed earlier). Of the 1,980 admitted patients, 678 required invasive mechanical ventilation (34% of admissions). During this interval, there were 4,993 mechanical ventilation–days, 6,280 central venous line (CVL)–days, and 35 deaths.

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Index Distribution of 2,465 Less Serious Safety Events in a 15-Month Period (June 1, 2013–August 31, 2014)

Harm Index

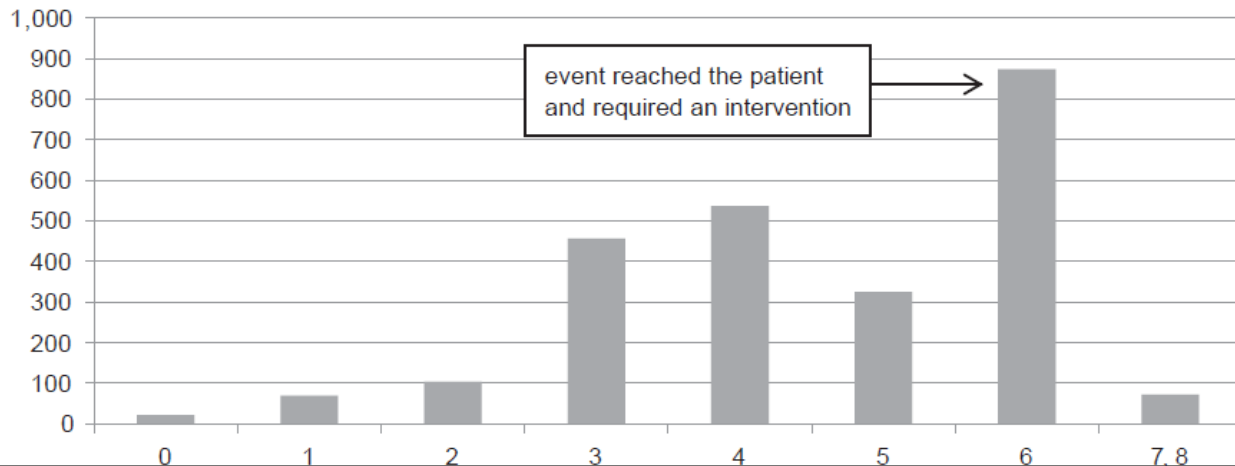


Figure 2. The Harm Index is a snapshot of event severity. Events graded 0–5 can be considered near misses; they had limited impact on the patient. Events graded 6 reached the patient and required an intervention. Events graded 7–8 are underrepresented in the Well-Defined ICU (WICU) database because incidents of this severity were encouraged to be reported through the hospital's Safety Learning Report reporting system.

ASCERTAINMENT OF LSSES AND SLRS

We identified 2,465 LSSEs in addition to 541 SSEs detected through the hospital SLR system, or 1.52 total events per patient (3,006 events/1,980 patients). The 2,465 LSSEs represented 1,535 core events (Table 1) and 930 noncore events—5.4 LSSEs/day or 0.23 LSSEs/patient–day. The 541 SLRs filed represented 1 SSE for every 4.6 LSSEs. The SLR reporting rate was 0.21 reports/patient (358 SLRs for 1,712 patients) at baseline, compared with 0.27 reports/patient (541 SLRs for 1,980 patients) after LSSE surveillance began. The increased reporting of SLRs was significant ($p < .0001$).

INTERRATER RELIABILITY

Across seven separate comparisons involving four event collectors and 103 patients, interrater reliability of 99.66% agreement was observed, with a kappa value of 0.949.

LESS SERIOUS SAFETY EVENTS AND PATIENT INTERVENTION

LSSEs resulted in treatment or intervention (Harm Index ≥ 6) 38% of the time (Figure 2, above) after excluding read-missions and transfers from the general wards, which were not assigned a Harm Index. An example of LSSEs that required patient intervention (Harm Index ≥ 6) is skin abrasion from tape requiring bacitracin ointment.

CORE AND NONCORE EVENTS

QSAs successfully captured detailed information about each LSSE. Core events required intervention more commonly (55.2%) than noncore events (10.8%). Core events of interest to critical care physicians

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included failed extubation rate, 4% of planned extubation trials; accidental extubation rate, 0.49 per 100 endotracheal tube–days; CLABSI rate, 0.33 per 1,000 line-days; and 38.5 monitor-only patients per month admitted at ICU status. These data were used to construct run or control charts to follow volume trends and process outcomes. LSSEs spanned a broad array of bedside problems, including 508 communication-themed events (Figure 3, page 555). The theme elements were broken down further to reveal qualitative trends. Among the 397 events related to physical injury, for example, 7 were secondary to securing medical devices (for example, endo-tracheal tube). On two occasions, providers incurred a limited injury from a violent or uncontrolled patient. Blisters and abrasions, with 62 events, were the most common physical injury.

Thematic Categorization of 2,465 Less Serious Safety Events (LSSEs) in a 15-Month Period (June 1, 2013–August 31, 2014) Incident Themes

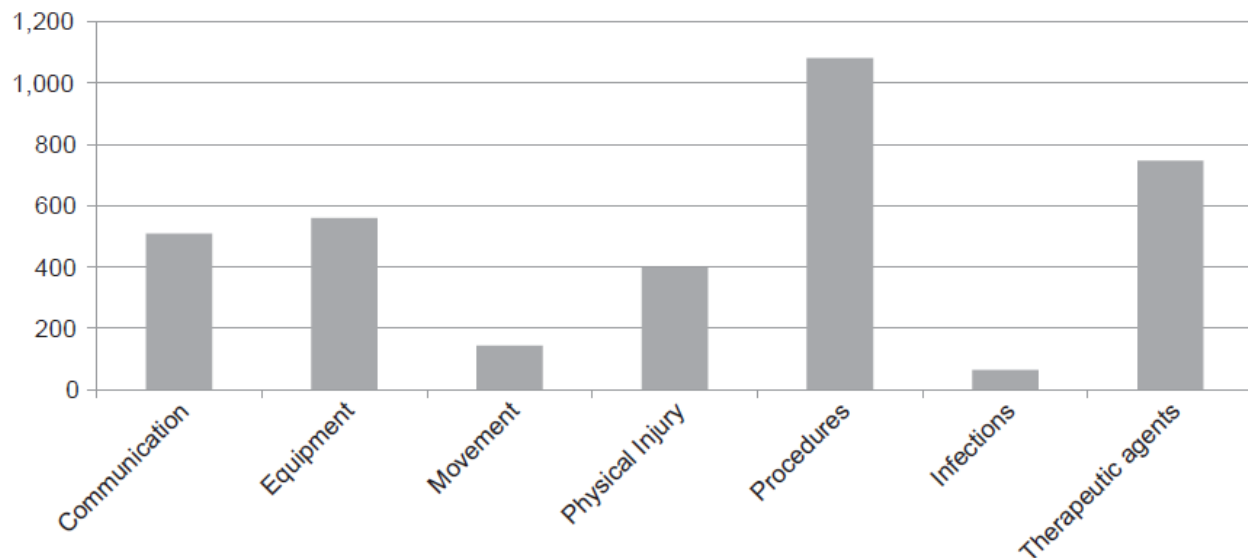


Figure 3. The total number of LSSEs, categorized into each of seven themes, is shown. Multiple themes may characterize a single event.

QUALITY/SAFETY IMPROVEMENT PROJECTS

Some 158 diverse quality/safety improvement projects were initiated on the basis of LSSEs during the 15-month interval, of which 74 were completed (Table 2, right). Most of the projects focused almost exclusively on PICU care, requiring a variable extent of QSO oversight. For example, changes in signage to improve hand hygiene or to clarify directions to the PICU were quickly accomplished by QSAs with limited supervision. Some projects had hospitalwide import and required supervision and advocacy from the QSO. For example, procurement of specimens from endotracheal and tracheostomy tubes was standardized and laboratory reporting of gram stains and cultures was changed to accommodate Centers for Disease Control and Prevention guidelines for the definition of ventilator-associated events.⁴⁴ Select

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projects required the purchase of new products, necessitating cost-benefit analysis, and/or changes in policy.

The bronchoscopy checklist, as an example, was developed following the accidental use of sterile water rather than saline for lavage. The tool required input from multiple PICU providers (physicians, nurses, respiratory care practitioners), as well as pulmonologists and otolaryngologists. Its development involved use of various QI tools (patient flow charts, cause- and-effect diagrams, stakeholder interviews, PDSA cycles) and successfully satisfied the American Board of Pediatrics maintenance of certification requirements for QI.45 It has been subsequently introduced to providers in the cardiac ICU and the neonatal ICU. A similar strategy was used to create reference tools or checklists for intubation, extubation, and transport for diagnostic or therapeutic procedures.

Table 2. Quality/Safety Improvement Project Categories Involving the Quality/Safety Analysts*

| Category | n | Example |
|------------------------|----|---|
| Audits | 25 | Improve rates of provider hand hygiene compliance. |
| Checklists/forms | 12 | Create PICU bronchoscopy checklist. |
| Education | 21 | Normal electronic imaging file for patient comparisons. |
| Environment | 14 | Repair medication drawer punch locks. |
| Information Technology | 26 | Add respiratory gas tank pressure to RCP assessment form. |
| Medication | 13 | Add phentolamine to infusion pump formulary. |
| Policy/Practice | 20 | Standardize procurement of ETT specimens for laboratory. |
| Products | 16 | Implement neutral caps and NJ securement device. |
| Signage | 11 | Install directional signs to the PICU. |

PICU, pediatric ICU; RCP, respiratory care practitioner; ETT, endotracheal tube; NJ, nasojejeunal.

* Categories of quality/safety improvement projects that were designed on the basis of less serious safety events (LSSEs) captured by quality/safety analysts (QSAs) and designed and executed by the QSAs, quality safety officer, and numerous other contributors, are shown. The number of projects initiated during the study period for each category is also shown.

BROADCASTING LSSES AND QUALITY/SAFETY IMPROVEMENT PROJECTS

We found that QSAs could effectively disseminate data and project results with providers and our network of hospital collaborators. Safety dashboards were placed at PICU entrances and updated daily with core event data, displaying the current and unit record “number of days since the last event.” An electronic dashboard displayed a slide presentation with weekly projects, run charts, safety tips, and current safety/quality activities. Weekly summaries of LSSEs were distributed to stakeholders, including the

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PICU leadership, the director of quality and research, and the director of safety and risk management. Monthly reports of PICU volume data and outcomes were distributed to intensive care physicians and PICU leadership. The QSAs also published a formal newsletter six times a year, which was posted and distributed electronically.

INITIAL DATA AND REVISIONS

We ascertained 679 LSSEs affecting 883 patients during the 6-month interval from August 1, 2012, through January 31, 2013,⁴⁶ the initial “paper” phase (Phase 1, a proof-of-concept pilot, as described earlier) for the WICU. We made adjustments to our methods on the basis of our findings, as we report in the Discussion.

COST

The total yearly cost of each QSA, a premedical college graduate, including an hourly wage of \$15.25 and benefits, was \$47,291.

DISCUSSION

We report the results of a prospective observational study on a unique prospective clinical surveillance program (WICU) designed to ascertain LSSEs in a PICU. We found that nonmedical personnel (QSAs) supervised by a PICU quality safety officer (QSO) could successfully capture LSSEs at the point of care and that these events occur at a high frequency. The true number of LSSEs in any system is undeterminable because of capture failure inherent in reporting systems; we provided prospective clinical surveillance once daily, in an attempt to maximize capture while acknowledging that it would be incomplete. LSSEs could be categorized according to general theme and harm and archived in a searchable electronic database for further analysis and review. QSAs were capable of participating in and completing safety/quality improvement projects generated by the exposure of LSSEs.

There were 2,465 LSSEs captured during a 15-month period—at a rate of 5.4 LSSEs/day. The ascertainment of LSSEs by QSAs exceeded SSE ascertainment by a ratio of 4.6:1, a quantitative demonstration of success in event capture and a proof of concept. High interrater reliability (99.66%) was observed, suggesting a repeatable, uniform method of event collection was achieved by QSAs/QSO. The WICU did not detract from reporting rates of SSEs through the hospital SLR system, which was an early concern. Implementation of the WICU was associated with a significant increase in reporting of SSEs during the study period, suggesting that the threshold for reporting SSEs decreased with the institution of the WICU.

A variety of adverse event reporting systems in PICUs have been described. For example, Larsen et al. performed a one-year retrospective chart review guided by a trigger tool, revealing an overall adverse event rate of 0.53 per patient-day in a single PICU.⁴⁷ Our lower rate of 0.28 (LSSEs and SSEs) may have in part reflected inclusion of PICU step-down patients of lower acuity. Silas and Tibballs compared voluntary electronic reporting by PICU nurses to systematic enquiry by two physicians; systematic enquiry captured 80% of all events, and electronic reporting 32%.³⁰ Overall, there were 0.71 adverse events of all severities per patient, compared to our finding of a total of 1.52 SSEs and LSSEs per patient. Importantly, their study did not include hazardous conditions, latent events, or near-miss events. More recently, Stockwell et al. used a sophisticated trigger tool with reviewer-physician teams in a multicenter pilot study to identify common causes of harm in the pediatric setting.⁴⁸ The tool’s capture rate of 0.05 instances of harm per patient-day and 0.4 instances per patient is comparable to the rate of SSEs at our

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institution but less than the rate of LSSEs detected by the WICU. Those three studies were all time-limited investigations to quantify adverse events in the pediatric setting. Prospective clinical surveillance programs in which event capture is prioritized, linked to analysis, and integrated into QI, as in the WICU, are found in the inpatient-adult literature.^{8,37,38} For example, Gabriel et al. described a comprehensive safety program in radiation oncology that recognized “low-level events” as precursors to more serious “conditions” and was intended to address them before they cause harm.¹⁵ Like the WICU, their approach combined safety culture improvement with implementation of surveillance systems.

Jefferies and colleagues cited specific barriers to reporting LSSEs: near misses regarded as harmless, fixable events too frequent to record, and bedside fixes regarded as the norm.³¹ Most reporting systems are heavily volunteer dependent, and associated barriers to reporting are well recognized: lack of familiarity with the system, time constraints, physician/provider disinterest, medical-legal concerns, lack of engaged leadership, and failure to provide feedback.^{6,49} In contrast to the barriers to reporting found for SSEs, LSSEs are less anxiety producing, and their content might be undervalued; SSEs may be colored by guilt, regret, and more severe medical-legal considerations. Despite more than a decade of QI focus on system defects and sincere efforts to reduce blame in our hospital cultures, blame is still with us.⁵⁰ Proximity to an error and fear of reprisal continue to be significant reporting barriers and a reflection of the fragility of safety cultures. A report on the Hospital Survey on Patient Safety Culture (653 hospitals) in 2014 revealed that fewer than half of the respondents felt secure in reporting mistakes.⁵¹

To help reduce barriers to reporting, the WICU uses facilitated reporting of adverse events, which has been demonstrated to be superior to chart review or volunteer provider reporting alone.^{30,52} Although facilitated reporting is known to be effective, the success of QSAs as nonproviders extracting LSSEs from health care personnel is unique, to our knowledge.

Failure to provide feedback on reported events is a known barrier to reporting, particularly by physicians.^{53–55} The WICU provides feedback on actionable items through analog and electronic safety dashboards, the QSA newsletter, and individual conversation. Provider reporting time is reduced by having QSAs complete all documentation.⁵³ Systematic, direct inquiry at the point of care, such as that used by the WICU, has been shown to be successful in capturing LSSEs, possibly because of ease of reporting.^{30,37,38}

The PICU provider team's acceptance of the WICU is reflected not only in the sheer number of LSSEs reported but in the results of safety culture surveys (Safety Attitudes Questionnaire, Pascal Metrics®, Washington, DC) performed in 2011 and again in 2014. During this interval, when the WICU constituted the only new PICU quality/safety initiative, overall safety culture scores improved by 42% and 46% in the two PICUs, respectively, suggesting that the WICU may have been fundamentally changing the safety climate in our organization.

The ultimate purpose of the WICU, like any reporting system, is to use documented events to create safety/quality improvement.³⁴ Quantifying improvement is challenging when an isolated event is rectified by an isolated solution. For example, a parent recognized and a provider reported that a hallway call-light was obscured by a protruding wall. When the parent summoned help from inside the room, this delayed the response. The light was relocated within a day, providing systems improvement that was not readily quantifiable. Other projects were more amenable to demonstrating sustained improvement with longitudinal data, such as reducing CVL occlusion and associated risk of CVL infections, or reducing

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nasojejunal tube dislodgment with a new product.⁵⁶

LIMITATIONS

The limitations and biases of our method arise largely from using voluntary reporting. Fear of retribution could deincentivize reporting LSSEs relating to a provider's own mistakes; the WICU was intended to build trust by maintaining reporter anonymity and by ensuring that providers were never punished after reporting. Time pressure on clinicians can discourage reporting; we had QSAs complete all documentation to facilitate efficient reporting, often requiring less than five minutes of clinician time, less than existing SSE reporting tools. Facilitation of voluntary reporting was limited by our capacity to reliably reach all clinicians; we did not track the number or identity of providers who were unavailable at the time of the morning QSA rounds. Recording these data could undermine psychological safety in the reporting system and so was incompatible with our approach. Normalization of deviancy and apathy regarding change can decrease motivation to report; in response, we sought to create a subjective safety culture of pride, feedback, engagement, and empowerment by addressing as many clinician concerns as possible with quality/safety improvement projects. QSAs verbally reinforced a positive, improvement-oriented attitude with providers.

Distrust of nonmedical personnel was considered a possible limitation in the planning phase. We found that clinician trust was apparently sufficient; a large number of events were voluntarily reported, as described—which may be attributable to the WICU's focus on reporter anonymity and psychological safety in the reporting system.

LOGISTICAL ISSUES AND ADJUSTMENTS

We faced unexpected logistical issues related to the novel structure of the WICU and the context of collaboration between a children's hospital and a private practice critical care group. The WICU's design arose from its setting, so that a comparable quality/safety improvement initiative might not be successful in a different PICU model.⁵⁷ Funding for personnel salaries and information technology tools was creatively negotiated to the satisfaction of both parties. The WICU's functions were slowly integrated with hospitalwide systems by trial and error, with a focus on clear communication and deference to existing efforts. Over time we delineated WICU boundaries and differentiated local problems, such as PICU bronchoscopy checklist, from systemic issues, such as medication distribution system in the PICU. We strengthened connections to individuals and departments outside the PICU, providing a pathway for systemic issues; the WICU solicited expertise from the Department of Infection Prevention and Control on suspected health care-associated infections and worked in concert with the hospital's SSE reporting and medication trigger tool systems. Duplication of reporting was not likely, considering the divergent foci and quantitative asymmetry between reporting systems.

Timing of LSSE surveillance posed logistical problems. Although our QSAs canvassed the PICU seven days per week, as stated, we started with queries only between the night and day shifts, in the assumption that day and evening events would be verbally passed on through providers. Some LSSEs might not have reached the morning screening, so that our data necessarily would have underestimated the true frequency of LSSEs, as discussed earlier. In the future, QSAs will capture events between the day and evening shift on a regular basis. Having one QSA responsible for two locations over weekends proved difficult. We adjusted our methods to have the day nurse receiving report at one location collect and pass on events to QSAs.

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CONCLUSION

The WICU is a noncompulsory, no-fault, facilitated voluntary reporting system, with local providers engaged to solve local problems. The use of nonmedical personnel to anchor an adverse event reporting system is efficient and effective at capturing LSSEs from the point of care. The same personnel can complete quality/safety improvement projects and broadcast changes in practice resulting from provider reporting. The WICU captured a large number of LSSEs and completed numerous improvement projects; its institution was associated with an increase in SSE reporting and improved safety culture scores. The success of the WICU has prompted its extension to the cardiovascular ICU and the hiring of a third QSA after the period of this study. Inquiries into developing a similar system have come from the oncology, surgery, and emergency departments of our hospital. The applicability of the WICU to different settings is unknown, but PICU leaders should consider creating a program to capture LSSEs to improve patient care.

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