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Defining the Epidemiology of Safety Risks in Neonatal Intensive Care Unit Patients Requiring Surgery

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Abstract

Objective: The aim of the study was to determine the incidence, type, severity, preventability, and contributing factors of nonroutine events (NREs)—*events perceived by care providers or skilled observers as a deviations from optimal care based on the clinical situation*—in the

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perioperative (i.e., preoperative, operative, and postoperative) care of surgical neonates in the neonatal intensive care unit and operating room.

Methods: A prospective observational study of noncardiac surgical neonates, who received preoperative and postoperative neonatal intensive care unit care, was conducted at an urban academic children's hospital between November 1, 2016, and March 31, 2018. One hundred twenty-nine surgical cases in 109 neonates were observed. The incidence and description of NREs were collected via structured researcher-administered survey tool of involved clinicians. Primary measurements included clinicians' ratings of NRE severity and contributory factors and trained research assistants' ratings of preventability.

Results: One or more NREs were reported in 101 (78%) of 129 observed cases for 247 total NREs. Clinicians reported 2 (2) (median, interquartile range) NREs per NRE case with a maximum severity of 3 (1) (possible range = 1–5). Trained research assistants rated 47% of NREs as preventable and 11% as severe and preventable. The relative risks for National Surgical Quality Improvement Program – pediatric major morbidity and 30-day mortality were 1.17 (95% confidence interval = 0.92–1.48) and 1.04 (95% confidence interval = 1.00–1.08) in NRE cases versus non-NRE cases.

Conclusions: The incidence of NREs in neonatal perioperative care at an academic children's hospital was high and of variable severity with a myriad of contributory factors.

Keywords

neonatal safety; perioperative; handovers; nonroutine events; morbidity

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The pursuit of highly reliable performance in health care delivery remains elusive.[1] Performance continues to be so uneven because high reliability relies on catching and correcting errors and unexpected events before they cause harm.[2,3] That is, high reliability is about the management of fluctuations,[4] especially non-routine events (non-NREs) or *any event that is perceived by care providers or skilled observers as a deviation from optimal care based on the clinical situation (e.g., accidental extubation, blood products delivered to the wrong OR, critical patient care information not communicated at patient handover)*.[5–7] High-reliability organizations (HROs) inside and outside health care are distinguished by their ability to detect and make sense of "weak signals" of danger and harm[8,9] and systemic vulnerabilities in the operational system that often manifest as NREs. To date, however, we know strikingly little about NREs and their causes. We know even less about NREs among the most vulnerable patients in the most difficult contexts that are likely to have the largest effects on morbidity and mortality—neonates requiring surgery.[10] What we do know often relies largely on data from voluntarily incident reporting systems, which have been shown to yield less than one-tenth the number of adverse events (AEs) than either retrospective chart review or prospective observation.[2,3,11–13] Trigger methodologies, including prospective electronic medical record-based systems, developed to address the shortcomings of retrospective chart review and voluntary incident reporting systems have not been sufficiently implemented or evaluated in neonatal intensive care units (NICUs) and pediatric operating rooms (ORs) or during care transitions between these settings to

determine their effectiveness in detecting adverse events and harm in neonates in these settings.[11,12,14–17]

Neonates are highly vulnerable to iatrogenic events due to their small size, fragility, immature organ systems, altered physiology, inability to communicate effectively, and exceptional sensitivity to environmental stressors.[12] These attributes increase care complexity and decrease neonates' ability to tolerate even small deviations in care. Adverse event rates in neonates are as much as eight times higher than that of hospitalized adults[13] with an incidence of 74 adverse events per 100 patients (0–11 AE/patient) discharged from the NICU. Of the AEs, 33% are severe.

Safety risks may be the greatest during surgery,[10] yet there is very little published data on the perioperative (i.e., preoperative through postoperative) safety of surgical neonates. Besides the known risks common to all surgical patients (e.g., wrong patient, site or side errors, retained foreign bodies), neonates are more susceptible to harm from medication errors, gaps in monitoring, or the failure or misuse of technology (especially infusion pumps and ventilators).[12,18,19] An analysis of 2012 National Surgical Quality Improvement Program Pediatric (NSQIP-P) data found that neonates represented only 6% of all patients, yet accounted for 60% and 16% of the total observed 30-day postoperative morbidity and mortality, respectively.[20] Unadjusted mortality (2–3%) and composite morbidity (16–21%) rates are as much as two-fold higher for neonatal versus pediatric surgery patients in all specialties except orthopedics.[21,22] The relative contribution NREs to these outcomes remains largely unknown.

Neonatal safety research has largely been limited to a narrow catalog of error types (e.g., medication and diagnostic errors)[23–25] and interventions (error reporting, team training).[26–29] Few studies have investigated the etiology or effective prevention of all-cause harm in neonatal care.[12] Failing to do so incompletely maps the sources of potential harm and limits the range of interventions considered and, consequently, also circumscribes the efficacy of interventions for improving safety.

The primary objective of our study was to explore and define the epidemiology of neonatal safety risk in the perioperative environment using the NRE framework and methodology.[5–7] The NRE methodology was selected because it is an open-ended event detection methodology that does not predefine the nature or manner in which risks manifest in patient care. Thus, consistent with practice within highly reliable organizations,[9] the NRE methodology is tailored to capture the unique risks and threats in a particular context. As such, the methodology engages clinicians in active, prospective reporting, does not place constraints on what they report, and is flexible across care processes and settings. Examples of NREs in surgical neonates include unplanned extubations, inadequate postoperative pain management, and blood products sent to the wrong location. The NRE also captures contributory factors that provide insight into the conditions giving rise to NREs and how neonatal units can intervene to enhance reliability.

METHODS

Design and Setting

This 17-month prospective observational study was conducted at an urban academic children's hospital to assess the etiology of NREs during neonatal perioperative care and to obtain preliminary estimates of 30-day mortality and major morbidity in cases with and without NREs. We attempted to enroll all noncardiac surgical neonates and the clinicians who cared for them. Cardiac surgical neonates were excluded because the objective of the study was to define baseline neonatal risk in the *system* of perioperative care, defined by care delivery in the NICU and OR, and related care transitions. Neonates requiring cardiac surgery are typically admitted to the pediatric cardiac intensive care unit. Therefore, all eligible study patients were admitted to the NICU preoperatively and ultimately returned to the NICU postoperatively.

The primary unit of analysis was a "case," which consisted of the following four phases: (*a*) the preoperative phase, the period before the patient (i.e., neonate) left the NICU, which could last as long as 1 hour; (*b*) the OR phase, the period starting with the patient's entry into the OR and ending with their exit from the OR including all operative procedures; (*c*) the early postoperative phase, which included the patient's transport from the OR, any postoperative handovers, and the first hour of postoperative NICU care; and (*d*) the late postoperative phase, the 24 hours that followed the early postoperative phase. Trained research assistants (RAs) surveyed NICU and OR providers after *each* perioperative phase, using a previously validated data instrument to collect information on the incidence, severity, and preventability of NREs and their contributory factors.[7] Research assistants used a two-step interview process for eliciting NRE reports from clinicians: first, they asked clinicians tovoluntarily report NREs they observed or experienced; secondly, they prompted the clinicians about NREs they independently observed and documented but that the clinicians did not report. The NSQIP-P occurrences were identified through structured chart review.

Participants

The study protocol was approved by the hospital's institutional review board. Eligible neonates had to be admitted to the NICU, receive preoperative care in the NICU, be scheduled to undergo noncardiac surgery, and expected to receive postoperative NICU care. Eligible patients were excluded if we were unable obtain written informed consent from the parent/legal guardian, from at least one clinician in *each* perioperative phase, or if the infant's surgical procedure was not eligible for NSQIP-P review.

All perioperative clinicians who deliver care to neonates (n = 269 of 634 total pediatric perioperative clinicians) including attending physicians, fellows, residents, nurses, nurse practitioners, therapists (respiratory, occupational, etc.), technicians, and clinical staff were eligible to participate in the study.

Epidemiology of NREs

The incidence and severity of NREs were the primary outcome measures in this study. Research assistants collected NRE reports from perioperative clinicians after *each*

perioperative phase using the Comprehensive Open-Ended Non-Routine Event Survey (CONES), which has been described previously.[7] Using the CONES, clinicians rated the severity of NREs on a 5-point Likert-like scale (1 [negligible], 3 [moderate severity], 5 [catastrophic]) and identified contributory factors. Contributory factors were categorized into the following eight distinct but not mutually exclusive categories: clinical care processes (i.e., individual actions or inaction related to care processes), individual factors (e.g., stress, fatigue, experience), logistical and system factors (e.g., staffing, scheduling, support policies and procedures, management decisions), patient factors (e.g., gross anatomy anomalies, pathology), equipment or supplies (e.g., unavailable or wrong blood, medication, or equipment, equipment failure); environment of care (e.g., noise, crowding, lighting, temperature); teamwork (e.g., lack of team cohesion or trust, lack of communication, mis-communication, coordination failures), and other (i.e., user specified). Nonroutine events could be attributed to one or more contributory factor, and clinicians were instructed to identify and describe all the factors that they believed contributed to each NRE. Trained RAs helped the clinicians select the appropriate category for each reported contributory factor during the administration of the CONES based on their description and characterization. Nonroutine event count and the maximum reported NRE severity were computed at the case and perioperative phase level.

Trained RAs used the same CONES to describe clinician-reported NREs and to provide their assessment of each NRE's preventability (yes, preventable/no, not preventable). Research assistants' ratings of preventability were subjective and based on prestudy training that included extensive observations in the NICU and OR, shadowing perioperative providers (e.g., surgeons, certified nurse anesthetists [CRNAs], NICU nurses, etc.), and case studies of audio- and video-recorded episodes of perioperative care that included NREs of variable severity and contributory factors.

Perioperative Patient Outcomes

We also collected data at the case level on 30-day mortality and the occurrence of postoperative major morbidities using the NSQIP-P methodology.[30,31] The NSQIP-P review was conducted by a surgical resident, who was trained by an attending pediatric surgeon study investigator with expertise in the NSQIP-P methodology.

Data Analysis

Descriptive statistics, including percentages for categorical variables and medians and interquartile ranges (IQRs) for continuous variables, were computed for patient demographics and clinical factors, NRE characteristics, and NSQIP-Poutcomes. Mann-Whitney U tests and χ^2 analyses were used to compare the distributions of continuous variables (e.g., gestational age) and proportions of categorical variables (e.g., anesthetic type), respectively, in cases stratified by NRE incidence (i.e., cases with ≥1 NRE versus cases without NREs). Kruskal-Wallis H test and Dunn test for post hoc pairwise comparisons were used to compare the NRE counts and severity by perioperative phase. Cohen κ was used to measure the agreement between RAs and a trained clinical subject matter expert (SME) in rating the preventability of reported NREs. A random sample of 30

NREs was used to estimate rater agreement. The SME was an anesthesiologist with more than 15 years of experience in rating NRE reports.

Risk ratios were used to compare the relative risk of 30-day mortality and the occurrence of major postoperative morbidities in patients stratified by NRE exposure (i.e., at case level). All statistical analyses were conducted in IBM SPSS 25.0 (IBM SPSS Statistics for Windows, Version 25.0., 2017; IBM Corp, Armonk, NY).

RESULTS

A total of 312 eligible cases in 213 neonates occurred during the study period. No parents or legal guardians declined consent, but in 32 eligible cases (10%), they were unavailable to provide consent and these cases were excluded. The excluded cases did not differ from observed cases in terms of types or distribution of surgical procedures performed. Pediatric surgeons declined to consent in 6 (2%) of eligible cases. One hundred forty-one eligible cases could not be observed because of logistical constraints (e.g., concurrent cases, insufficient notice, etc.). Thus, we report on 129 cases with complete data involving 109 eligible neonates.

A total of 232 (86%) of 269 eligible perioperative providers associated with eligible cases consented to participate in the study. Twenty-three pediatric surgeons performed surgeries on the enrolled infants, with no single surgeon accounting for more than 15% of total observed cases (range = 1%–15%). One-hundred twenty-two unique clinicians reported one or more NREs. The leading reporters of NREs were NICU nurses (30%), OR nurses (21%), certified nurse anesthetists (13%), and attending surgeons (11%). These reporting rates broadly correspond with the distribution of clinician types. The NICU RNs accounted for 40% of the perioperative workforce eligible to report NREs in the study, whereas OR RNs accounted for 14% and CRNAs and pediatric surgeons each accounted for 5% of the eligible workforce.

Patient Demographics, Clinical, and Procedural Characteristics

As shown in Table 1, patient characteristics were nearly uniform across NRE and non-NRE cases. Significant differences were observed in procedural characteristics: (*a*) non-NRE cases had significantly higher proportions of emergency cases and laparoscopic gastrostomies than NRE cases and (*b*) NRE cases had a significantly higher proportion of otolaryngology cases than non-NRE cases.

Nonroutine Event Epidemiology and Contributory Factors

Nonroutine events were reported by clinicians in 101 (78%) of 129 cases, resulting in 247 total NREs. Nineteen percent of all cases had at least one report of a severe NRE. Table 2 summarizes the incidence, severity, and preventability of clinician-reported NREs across each perioperative phase.

In cases with one or more NREs (Table 2), the number and severity of reported NREs did not vary significantly across perioperative phase. The operative phase had the highest median NRE reports and highest median severity but also had the lowest percentage

of preventable NREs and preventable-severe NREs. The early postoperative and 24-hour postoperative phases accounted for the highest rates of preventable severe NREs.

Table 3 shows the contributory factors clinicians identified reported preventable NREs. The most frequently cited contributory factors to preventable NREs were patient factors (e.g., gross anatomy, anomalies, and pathologies) and clinical care processes, which were cited in 47% and 41% of all NRE reports. Table 4 provides vignettes of actual NREs reported by clinicians in the study.

Reliability of RAs' Ratings of NRE Preventability

The level of agreement obtained between our RAs and a clinical SME in rating the preventability of a subsample of NREs (n = 30) was moderate ($\kappa = 0.51$). The results showed that the RAs were much more conservative than our SME in rating NREs as preventable. The raters were most discrepant in rating the preventability of equipment-related NREs: the SME was six times more likely to rate an equipment-related NRE as preventable than a trained RA.

Perioperative Patient Outcomes

Structured NSQIP-P chart review found the overall incidence of 30-day major morbidity and mortality to be 28% (n = 30) and 2% (n = 3), respectively, in observed cases. The relative risks for 30-day major morbidity and mortality in cases with and without NREs were 1.17 (95% CI = 0.92–1.48) for morbidity and 1.04 (95% CI = 1.00–1.08) for mortality.

DISCUSSION

The pattern of findings in this study has clear implications for improving quality and safety performance in general and the pursuit of high reliability in specific. Namely, our findings suggest the prevalence of NREs as a potential source of learning, opportune moments in the care process to intervene, and a method to elicit reporting NREs. All of which provides concrete insight into how NICUs and ORs can cultivate two foundational behaviors of HROs —preoccupation with failure and sensitivity to operations[8,9]—in perioperative teams.

At a large academic children's hospital, we found the incidence of clinician-reported NREs during neonatal perioperative care to be high with variable severity and myriad contributory factors. Nearly one-half of NREs and one-ninth of severe NREs were rated preventable by trained RAs. Additional research is needed to evaluate the reliability RAs' preventability ratings, but our sampled analysis found them to be much more conservative than an expert clinician reviewer. Comparing NRE rates across the four phases of perioperative care is challenging because the opportunity for NRE reporting was not uniform across each phase. Nonroutine event reporting is a function of the number of clinicians involved and the duration of each phase. In our study design, the preoperative and early postoperative phases were the most uniform in that observations were limited to 1 hour and CONES (i.e., NRE surveys) were administered to two clinicians. Conversely, the operative phase involved the most providers (i.e., "eyes on the infant") and varied from 10 minutes to 5 hours. Finally, the late postoperative phase limited CONES administration to the NICU nurse and neonatologist but allowed 24 hours for NREs to emerge postoperatively.

Despite the nonuniformity of NRE reporting opportunity, the study uncovered some important insights about perioperative NREs that will guide future research and quality improvement efforts. For example, the operative phase accounted for the highest amount of NRE reporting but the lowest rate of preventable NREs and preventable severe NREs (e.g., patient factors). The high rate of NRE reporting in the late postoperative phase and the high percentages of preventable NREs and preventable severe NREs in both the early and late postoperative phases both require additional research and suggest that systematic postoperative interventions that mirror the preoperative (e.g., structured NICU-to-OR handovers) and OR-centric interventions (e.g., checklists and standards of care) may be needed across postoperative care processes. This is supported by the findings that patient factors, equipment and supplies, and clinical care process were the most cited contributory factors for preventable NREs in the postoperative phases. The heightened mindfulness typically characteristic before and during surgical intervention is also needed postoperatively. Practically, standardized team-based handovers for all patient transfers from the OR to the NICU, regardless of patient acuity or source of transfer (OR or post anesthesia care unit) could enhance reliability (and reduce NREs) through standardization and by freeing up attention for more mindful processing. The findings may indicate moments where reliability is likely to break down and both when and what intervention may be most useful.

An important product of this work was to demonstrate the complementary nature of the NRE reporting methodology to conventional event reporting systems (e.g., voluntary event reporting). Our results show that the NRE reporting methodology captures events that are typically underreported in hospital voluntary reporting systems (i.e., lower severity, lower risk of patient harm) and thus holds promise as a complementary reporting channel and source of learning. The NRE approach has been promoted in the past as an interactive and less threatening approach to safety reporting than voluntary incident reporting systems that emphasize reporting medical errors and near misses associated with actual or avoided patient harm. Incident reporting systems tend to evoke fear from clinicians that system failures will be attributed to human error or even individual incompetence that can subsequently be misused to blame and punish.[6,7,32] The results of this study lend support to the argument that NRE reporting is psychologically safer[33] as clinicians of all job types and rank openly reported NREs in all phases of perioperative care. For example, CRNAs and pediatric surgeons who represented only 10% of the total workforce eligible for NRE reporting in this study accounted for nearly one-fourth of all NRE reports. Conversely, and in addition to general underreporting, voluntary incident reporting has historically been skewed toward high nurse participation and low participation by physicians.[34,35] However, this finding must be weighed against the lower signal to noise ratio inherent in NRE reporting versus incident reporting.

Although our approach does not necessarily point to a single intervention or point in time to resolve NREs and ensure safety, the method is both flexible and precise enough to produce an overarching sensitivity to operations characteristic of HROs that more accurately and fully captures current threats to safety in ways that motivate and shape action.[9] That is, NRE reporting reflects a preoccupation with failure where frontline caregivers are vigilant about current threats and avoid putting stock in past successes as an indicator of future safety performance. Nonroutine event reporting also suggests a more refined sensitivity to

operations that accurately characterizes the current state of the organizational system. Both preoccupation with failure and sensitivity to operations underpin the collective mindfulness exhibited in HROs.[36] As suggested by a preoccupation with failure, HROs are characterized by high rates of reporting low-severity NREs and a low incidence of preventable severe NREs and adverse system outcomes.[36] The pairing of NRE reporting behaviors and adverse safety outcomes, such as 30-day NSQIP occurrences, provides a more comprehensive picture of the state of reliability in the perioperative environment and other healthcare settings.

Pursuing high reliability by learning from extreme events where harm occurs may provide an insufficient basis for learning from experience and may provide an overly positive picture of system safety that fails to catalyze action.[37] The incidence of clinician-reported NREs found in neonatal perioperative care (78% of cases, two per case) was substantially higher than NRE rates reported in adult surgery (27%–31%)[6,7] and for medication-related NREs in medical-surgical intensive care (35% in two adult ICUs and one pediatric ICU)[38] and at the lower end of the range previously reported for pediatric cardiac surgery and trauma resuscitations (77%–100%). An independent NRE study in pediatric cardiac surgery at the study hospital found a 77% NRE incidence (2 per case), whereas studies in trauma resuscitation and pediatric cardiac surgery at other hospitals reported 100% incidence rates (8 and 15 NREs per case, respectively).[32,39] Taken together, these findings show that NRE rates are high and increase with care complexity (e.g., pediatric versus adult, intensive care versus surgery, cardiac versus noncardiac surgery, etc.).

Nonroutine events may be especially useful because they represent a wide range of deviations that enlarge the set of experiences used as inputs for learning.[40] By providing opportunities for learning from experience, capturing and processing NREs mindfully may simultaneously reduce caregiver emotional exhaustion.[41] Future research is needed to determine which NRE types and contributory factors predict adverse clinical outcomes and to elucidate the processes reliable clinical teams use to manage and mitigate risk in NRE-prevalent settings and procedures.

Our analysis of contributory factors highlights the importance of efficient, safe, and standardized care processes for neonatal care in the high-risk perioperative environment due to the elevated baseline risk factors of the patients and the discontinuities in communication, coordination, and workflow created when patient care is transferred between one or more distinct clinical settings (e.g., NICU, OR, post anesthesia care unit, etc.). However, we also identified a set of preventable, largely organizational, contributory factors including equipment failures, mishaps in logistics and patient transport, and poor teamwork that reflect the challenges of coordinating neonatal care across the phases and settings of perioperative care. The NRE vignettes provide insight on how NREs can “snowball” such that the occurrence of one NRE can trigger subsequent NREs by disrupting workflow, communications, team cohesion, and creating uncertainty. The erosion of essential team processes has been shown to create conditions for adverse patient outcomes.[42,43] The next step in this line of research is to determine whether isolated and/or cascading NREs shift perioperative care toward and even beyond the boundary of safety in vulnerable patient populations.[44] We also recommend that future research should focus on evaluating NRE

reporting as an observable, intermediate behavioral outcome of collective mindfulness and high reliability at the team level. The perioperative environment is an especially promising setting for this work because patient care requires the interdisciplinary teamwork that is a hallmark of HROs. Interventional studies are also needed to address persistent known preventable threats to neonatal patient safety.[12]

Limitations

Our findings should be considered in light of the limitations of the current study. First, because the NREs and their severity ratings were made by clinicians who were participants in the cases, these measures were susceptible to reporter biases. To address this concern and otherwise reconcile discrepancies in NRE reports among different clinicians for the same patient, trained RAs performed a secondary review. Secondly, RAs, rather than involved clinicians, rated the preventability of reported NREs in attempt to remove reporting bias. To evaluate the appropriateness of this strategy, we compared the level of agreement between the preventability ratings provided by the RAs and a clinical SME using a random subsample of the total reported NREs. Finally, because of sample size constraints, we were unable to statistically model the relationship between NREs and 30-day NSQIP-P occurrences, including mortality. However, the results of this study do provide suggestive estimates of 30-day postoperative mortality and major morbidity. Future research could build upon these findings with a larger single-site or a multisite study.

CONCLUSIONS

The incidence of NREs in neonatal perioperative care at an academic children's hospital was high, of variable severity, and preventability with a myriad of contributory factors. Neonates may be as susceptible to preventable risks during postoperative care, which does not currently share the heightened mindfulness characteristic of preoperative and intraoperative care processes.

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TABLE 1.

Patient Demographics, Clinical, Procedural Characteristics, and Outcomes by NRE Incidence*

Variables	NRE(n_{Case} = 100)	No NRE (n_{Case} = 29)	*P*	Total (N_{Case} = 129)
Male sex, n (%)	52 (52)	17 (60)	0.87	69 (53)
White race, n (%)	82 (82)	23 (80)	0.88	105 (81)
Non-Hispanic ethnicity, n (%)	91 (91)	22 (76)	0.49	113 (88)
Weight, median (IQR), kg	3.3 (1.2)	3.1 (1.6)	0.69	3.2 (1.2)
Gestational age, median (IQR), wk	35 (11)	37 (8)	0.37	36 (10)
Day of life, median (IQR), d	35 (89)	26 (75)	0.26	29 (84)
Preprocedural mechanical ventilator support, n (%),	52 (52)	17 (59)	0.56	69 (53)
Inhaled nitric oxide, n (%)	2 (2)	1 (3)	0.65	3 (2)
Extracorporeal membrane oxygenation, n (%)	2 (2)	0 (0)	0.44	2 (2)
Direct NICU-to-OR transfer, n (%)	44 (44)	11 (39)	0.66	55 (43)
Direct OR-to-NICU transfer, n (%)	55 (55)	13 (46)	0.42	68 (53)
Emergency surgery‡, n (%)	11 (11)	10 (34)	0.003	21 (16%)
Anesthetic, n (%)				
General	93 (93)	28 (97)	0.17	121 (94)
General with regional	7 (7)	1 (3)	0.43	8 (6)
ASA score, median (IQR)	3 (1)	3 (1)	0.85	3 (1)
OR time in minutes, median (IQR)	74 (91)	85 (79)	0.36	79 (80)
Surgical specialty, n (%)				
General	68 (68)	22 (76)	0.42	90 (70)
Otolaryngology†	18 (18)	1 (4)	0.05	19 (15)
Neurosurgery	7 (7)	3 (10)	0.55	10 (8)
Other: ophthalmology, plastic, urology	7 (7)	3 (10)	0.55	10 (8)
Plastic (grouped as “other”)	1 (1)	0 (0)	0.55	1 (1)
Urology (grouped as “other”)	2 (2)	3 (10)	0.55	5 (4)
Primary surgical procedure, n (%)				
Gastrostomy, open (CPT: 43830)	12 (12)	4 (14)	0.80	16 (12)
Laparoscopic procedure on stomach† (CPT: 43653)	8 (8)	6 (21)	0.05	14 (11)

Variables	NRE(n_{Case} = 100)	No NRE (n_{Case} = 29)	*P*	Total (N_{Case} = 129)
Repair procedure on the diaphragm (CPT: 39503)	9 (9)	2 (7)	0.72	11 (9)
Endoscopy procedure on larynx (CPT: 31525)	9 (9)	2 (7)	0.72	11 (9)
No. procedures per case, median (IQR)	2 (2)	2 (1)	0.34	2 (2)

[*] Median and interquartile range shown for continuous variables.

[†] $P < 0.05$.

[‡] $P < 0.01$.

ASA, American Society of Anesthesiologists Classification.

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TABLE 2.

Nonroutine Event Count, Severity, and Preventability by Perioperative Phase*

Variable	Statistic	Perioperative Phase				Total (n_{NRE} = 247)
		Preoperative (n_{NRE} = 41)	Operative (n_{NRE} = 140)	Early Postoperative (n_{NRE} = 28)	Late POSTOPERATIVE (n_{NRE} = 38)	
No. Reported NREs	Median (IQR)	1.0 (1.0–1.0)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.3)	2.0 (1.0–3.0)
Maximum NRE severity	Median (IQR)	2.0 (1.0–3.0)	3.0 (2.0–3.0)	2.5 (2.0–3.0)	3.0 (2.0–4.0)	3.0 (2–3)
NREs rated severe	n (%)	10 (24)	39 (28)	6 (21)	13 (34)	69 (28)
NREs rated preventable	n (%)	21 (51)	50 (36)	19 (68)	13 (66)	115 (47)
NREs rated severe and preventable	n (%)	5 (12)	10 (7)	5 (18)	6 (16)	27 (11)

*n_{NRE} is the number of NREs reported per perioperative phase.

TABLE 3.

Clinician-Reported Contributory Factors for Preventable NREs by Operative Phase

Contributory Factor	Definition	Statistic	Preoperative (n = 19)	Early Operative (n = 47)	Postoperative (n = 16)	Late Postoperative (n = 24)	Total (n = 102)
Patient factors	Gross anatomy anomalies, pathology, positioning	n (%)	10 (53)	23 (49)	9 (56)	6 (25)	48 (47)
Equipment or supplies	Unavailable, failure, wrong, incomplete/ parts missing (including blood and medications)	n (%)	3 (16)	13 (28)	4 (25)	7 (29)	27 (26)
Clinical care processes	Individual actions or inactions related to case processes before and during the procedure	n (%)	9 (47)	21 (45)	5 (31)	6 (25)	41 (40)
Logistical and system factors	Staffing, scheduling, lack of nonclinical staff support policies and procedures, management decisions	n (%)	5 (26)	10 (21)	1 (6)	1 (4)	17 (17)
Teamwork	Breakdowns in team processes including communications, trust, coordination leadership, and conflict resolution	n (%)	5 (26)	11 (23)	2 (13)	3 (13)	21 (21)
Individual factors	Stress, fatigue, experience, supervision, judgment, time pressures	n (%)	4 (21)	10 (21)	1 (6)	1 (4)	16 (16)
Environment of care	Noise, crowding, lighting, temperature, distractions	n (%)	1 (5)	7 (15)	0 (0)	3 (13)	11 (11)
Other		n (%)	1 (5)	0 (0)	0 (0)	1 (4)	2 (2)

TABLE 4.

Examples of Reported NREs

Example Number and CF	Vignette
Example 1 NRE#1 CF: Clinical care NRE #2 CFs: Clinical care, individual factors NRE #3 CF: Equipment and supplies	"During emergence, intravenous (IV) infiltration [NRE #1] was discovered. After removing [the IV] and bandaging the site, an Anesthesia Fellow continued to remove plastic drape from the head of patient, but the drape got caught on the endotracheal tube and accidentally extubated patient [NRE #2]. Patient was reintubated. On the way back to the NICU, the patient's bed and ventilator hit a wall which caused the NeoPuffto lose pressure [NRE #3]. Patient had to be manually ventilated until return to inpatient room."
Example 2 NRE #1 CFs: Teamwork, logistics NRE #2 CFs: Teamwork, individual factors NRE #3 CF: Logistics	"Patient with tracheoesophageal fistula. Prior discussions between anesthesia and surgery were that the patient was to be intubated in the OR. NICU team not aware of this plan [NRE #1]. Their protocol was to intubate in the NICU prior to surgery. After the patient was intubated, surgery team arrived. Argument between surgery and NICU teams whether the protocol for the NICU should be observed in this case or protocol for surgery should be observed [NRE #2]. The case start was delayed by two hours [NRE #3]."

CF, contributory factor.

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