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## A Pilot Study to Determine the Incidence, Type, and Severity of Non-Routine Events in Neonates Undergoing Gastrostomy Tube Placement

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### Abstract

**Background**—Non-routine events (NRE) are defined as any suboptimal occurrences in a process being measured in the opinion of the reporter and comes from the field of human factors engineering. These typically occur well up-stream of an adverse event and NRE measurement has not been applied to the complex context of neonatal surgery. We sought to apply this novel

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Conflict of interest

The authors declare that they have no conflict of interest.

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safety event measurement methodology to neonates in the NICU undergoing gastrostomy tube placement.

**Methods**—A prospective pilot study was conducted between November 2016 and August 2020 in the Level IV NICU and the pediatric operating rooms of an urban academic children’s hospital to determine the incidence, severity, impact, and contributory factors of clinician-reported non-routine events (NREs, i.e., deviations from optimal care) and 30-day NSQIP occurrences in neonates receiving a G-tube.

**Results**—Clinicians reported at least one NRE in 32 of 36 (89%) G-tube cases, averaging 3.0 (Standard deviation: 2.5) NRE reports per case. NSQIP-P review identified 7 cases (19%) with NSQIP-P occurrences and each of these cases had multiple reported NREs. One case in which NREs were not reported was without NSQIP-P occurrences. The odds ratio of having a NSQIP-P occurrence with the presence of an NRE was 0.695 (95% CI 0.06 – 17.04).

**Conclusion**—Despite being considered a “simple” operation, >80% of neonatal G-tube placement operations had at least one reported NRE by an operative team member. In this pilot study, NRE occurrence was not significantly associated with the subsequent reporting of an NSQIP-P occurrence. Understanding contributory factors of NREs that occur in neonatal surgery may promote surgical safety efforts and should be evaluated in larger and more diverse populations.

**Level of evidence**—IV

## Keywords

Neonatal safety; perioperative; gastrostomy; non-routine events; NSQIP occurrences

## 1. Introduction

Non-routine events (NRE) – defined as *any* aspect of care perceived by clinicians or trained observers as a deviation from *optimal* care in that specific clinical context – comes from the field of human factors engineering (HFE). NRE reporting instruments are validated and have been used to study patient safety in operating rooms, intensive care units, emergency departments, and outpatient clinics [1–6]. NREs typically occur well up-stream from true adverse events, which are the more typical events captured in surgical safety reporting systems (such as the ACS NSQIP). Detecting potential safety concerns prior to the occurrence of an adverse events has obvious advantages and could lead to increased safety of surgical procedures.

In addition to the dichotomous measurement of an NRE occurrence (yes/no), NRE reports typically include the reporter’s (e.g., anesthesia provider, surgical team member, NICU clinician, or independent observer) assessment of the factors that contributed to each NRE. Contributory factors include both mutable factors (e.g., patient positioning, training in the operative technique, supervision) and non-mutable factors (e.g. patient anatomy or pathology) which can be used to facilitate learning and systems improvement [6].

NRE measurement and investigation of contributory factors has not been applied to neonatal surgery and offers a different perspective for evaluating the safety of various procedures and

different technical approaches to the same operation. Whether NREs are associated with the likelihood of developing a subsequent adverse event is unknown within the neonatal surgery context. These methods might provide a complementary approach to conventional clinical or health services research methodologies and may provide insight into malleable system and process opportunities to improve outcomes that are not otherwise apparent using more traditional methodology. HFE techniques are well-suited for perioperative safety research and include direct observation of surgical cases by trained research personnel, audio-video recording of cases for retrospective analysis by subject matter experts, and surveying and interviewing NICU and OR clinicians immediately after cases to collect perioperative safety-related events and their contributory factors [1, 7–9]. HFE data collected using these techniques provides richer contextual information than the data reported to incident reporting systems and/or extracted from electronic health records (EHRs) [10]. Analyses of these data can be used to identify upstream factors that precede and may contribute to perioperative harm events [11].

To simplify this pilot study of NRE measurement and identification of contributory factors to each NRE, which has never been applied to the neonatal surgery population, we restricted this analysis to infants undergoing gastrostomy tube (G-tube) placement without any other concomitant procedure. G-tube placement is among the most common operative procedures performed on infants admitted to the neonatal intensive care unit (NICU) [12–16] although reported studies in medically complex infants and neonates are sparse [17–19].

Our multidisciplinary research team recently completed a 4-year HFE study funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) to determine the incidence and severity of NREs in neonates requiring surgery and the association of NREs with 30-day post-operative NSQIP-P occurrences. The study was the first to collect NREs and their contributory factors across the phases of perioperative care (e.g., pre-operative through 24-hours post-operative). We employed both a 100% NSQIP-P case review and the hospital's standard sampled case review to determine and compare captured surgical outcomes in observed cases. G-tube was the most frequently observed procedure, occurring in approximately one-quarter of all cases. The primary purpose of this report is to determine the incidence and severity of NREs in neonates undergoing gastrostomy tube placement and present the methods and findings of the first HFE-based observational study in this population.

## 2. Methods

### 2.1 Study Design and Setting

A prospective observational study was conducted between November 2016 and August 2020 in the Level IV NICU and the pediatric operating rooms at an urban academic children's hospital.

NREs were used to measure perioperative deviations from optimal care in observed G-tube cases. Clinicians voluntarily and anonymously reported NREs using a validated instrument, the Comprehensive Open-ended Non-routine Event Survey (CONES) [6]. To capture NREs across the phases of perioperative care, the CONES was administered immediately post-

operatively to all participating clinicians in the NICU and to those in the operating room and again 24-hours post-operatively to the NICU clinicians caring for the infant. NREs reported by clinicians immediately post-operatively were classified as “early post-operative NREs”. NREs reported by NICU clinicians 24-hour post-operatively were classified as “late post-operative NREs”.

The NREs were rated by SMEs for severity and their impact on the clinical team’s course of care for the infant using a 5-point Likert-like scales. The rating anchors for NRE severity were 1 (negligible), 3 (moderate severity), and 5 (catastrophic). The anchors for impact on course of care were 1 (minimal), 3 (temporary), and 5 (sustained). Ratings were subjective and based on clinical judgement. Contributory factors to each NRE were classified by SMEs using the following seven categories: clinical care processes (e.g., professional work, patient work, patient-professional collaborative work), equipment or supplies (e.g., availability, access, functional status, etc.), individual factors (e.g., patient, clinicians, staff), environment of care (e.g., design of workspace, noise, temperature, etc.), logistical and system factors (e.g., hospital policies, procedures, unit safety culture), team factors (e.g., teamwork, communication, and coordination), and patient factors (e.g. demographic and clinical) [6]. More than one contributory factor, if necessary, could apply to each NRE.

## 2.2 Participants

The study protocol was approved by the hospital’s Institutional Review Board (IRB # 050488). The project is registered as a clinical trial with [ClinicalTrials.gov](https://clinicaltrials.gov) (ID: [NCT02756195](https://clinicaltrials.gov/ct2/show/study/NCT02756195)). Eligible neonates had to be admitted to the NICU, receive pre-operative care in the NICU, undergo G-tube, and were expected to receive post-operative NICU care. Patients requiring concurrent surgical procedures were excluded (see Figure 1). All perioperative clinicians who deliver care to neonates including attending physicians, fellows, residents, nurses, nurse practitioners, nurse anesthetists, student nurses, therapists (respiratory, occupational, etc.), technicians, and clinical staff, were eligible to participate in the study. Written consent was obtained from parents or legal guardians and participating clinicians. Clinician participation was defined as completing the CONES immediately after observed surgical cases.

## 2.3 Perioperative Patient Outcomes

A 100% case review of 30-day mortality and the occurrence of post-operative major morbidities was completed using the NSQIP-P methodology [20, 21]. The comprehensive NSQIP-P review was conducted by a surgical resident and a research coordinator, who were trained by the hospital’s NSQIP-P reviewer and an attending pediatric surgeon study investigator with expertise in the NSQIP-P methodology. The results of the study’s 100% NSQIP-P case review were compared to the results of hospital’s standard sampled NSQIP-P review methodology. The hospital currently conducts a complete NSQIP-P review of approximately 40% of all eligible operations.

## 2.4 Data Analysis

Descriptive statistics, including percentages for categorical variables and medians and interquartile ranges (IQR) for continuous variables, were computed for patient demographics

and clinical factors, NRE characteristics, and NSQIP-P outcomes. Three logistic regression models were used to determine the distinct association between Any NRE (yes/no), NRE count (i.e., number of NREs per case), and maximum NRE severity and the outcome, NSQIP-P occurrence (yes/no)[22]. All regression analyses were adjusted for two following potential confounders: American Society of Anesthesiologist (ASA) Physical Status Classification System (dichotomized as <3 and ≥3) and pre-procedural ventilation (yes/no). The effect of NRE measures was summarized using the adjusted odds ratio (OR) with 95% CI and Wald-type test. P-values less than 0.05 were considered evidence of statistical significance.

### 3. Results

#### 3.1 Patients

A total of 36 G-tube procedures were observed - 17 cases of patients undergoing an open procedure and 19 cases of patients undergoing a laparoscopic procedure. Pre-surgical diagnoses included feeding difficulties, oropharyngeal dysphagia, and failure to thrive.

#### 3.2 Surgeons

The 36 surgical procedures were completed by seven attending surgeons.

#### 3.3 NRE frequency, severity, and impact on team's course of patient care

A total of 109 NREs were reported ( $3.0 \pm 2.5$  per case). On average (Table 2), both NRE severity ( $2.0 \pm 1.1$ ) and their impact on patient care ( $2.3 \pm 1.1$ ) was minimal to temporary.

#### 3.4 NRE distribution by phase

NREs were present in all phases of care (Table 3), with the majority of NREs occurring intraoperatively. However, there was not a significant difference in the distribution of NRE reports by perioperative phase.

An examination of specific examples of NREs by perioperative phase is necessary to demonstrate the full breadth and depth of NREs and their contributory factors (Table 4). Pre-operative NREs mostly included patient clinical events, equipment issues, and failures in communication and coordination related to the NICU-to-OR patient handover. NREs with the highest severity in this phase were patient-related. One patient self-extubated during the night preceding the operation, requiring re-intubation in the NICU prior to the NICU-to-OR handover. Another infant exhibited agitation and progressive oxygen desaturation starting in the NICU that worsened in the OR prior to surgical incision. An NRE of moderate severity involved a difficult intubation by a student nurse anesthetist. Equipment- and handover-related NREs were generally rated as being lower severity. The most common pre-operative NREs involved uncoordinated patient handovers between the NICU and OR. On several occasions, key members of the patients NICU care team (a neonatologist, nurse practitioner or NICU nurse) were absent during patient handover. Two examples of equipment-related NREs were an anesthesia fellow forgetting a transport monitor during transport from the OR to the NICU and a separate incident involving the transport of an infant to the OR in a fixed-top isolette that drew concerns about patient access in case of emergency. In these

cases, the issues were resolved by retrieving the forgotten monitor and replacing the isolette with a more accessible model.

Operative NREs were the most frequently reported and severe, and occasionally changed the infant's planned course of care. Operative NREs included patient clinical events, equipment issues or malfunctions, and system failures. The most frequent severe clinical NREs were bronchospasm, difficult patient airways associated with oxygen desaturation, bradycardia or tachycardia, and hypotension. Equipment-related NREs included a leak in the endotracheal tube resulting in patient desaturation, unsterile G-tube (discovered before being passed to sterile field), the pulse oximeter tracing not displaying on the monitor, malfunction of a laparoscopic instrument (two separate cases), and an anesthesia monitor failure. System-related NREs included a 5-hour delay in starting a case, an operation moved to a different OR than usual that was not stocked with needed equipment, a case not boarded as laparoscopic, an operating table in the wrong position requiring patient re-positioning, the OR being short-staffed, lack of available beds in the post-anesthesia care unit (PACU) causing disruption at the end of the case, and significant delays in delivery of required equipment.

Post-operative NREs typically involved patient clinical events of moderate severity. They occurred either in the OR PACU soon after the case, or up to 24-hours post-operatively in the NICU. Examples of post-operative clinical NREs included bronchospasm, stridor and respiratory distress, apnea, prolonged paralysis, and an unplanned extubation. System-related post-operative NREs included a respiratory therapist (RT) not being available upon return to the NICU, delays in receiving medications from the pharmacy, a PACU nurse delivering the patient to the NICU without giving report to the NICU team, the NICU team not being present upon OR team's arrival, and RT equipment not being calibrated before the infant arrived back to the NICU.

### 3.5 NRE contributory factors

The leading contributory factors (Table 4) to NREs were patient factors, clinical care processes, and equipment - each were cited as contributors in over one-fifth of all reported NREs. Contributory factors are not mutually exclusive so their sum can exceed one-hundred percent.

### 3.6 Post-operative outcomes

Concordance between the NSQIP-P reviewers, computed using Kendall's coefficient (W), was 0.826 ( $P < 0.001$ ). Our 100% NSQIP-P case review (Table 5) identified 7 patients (19%) with post-operative NSQIP-P occurrences, no patients died within the 30-day post-operative period, and 3 patients died beyond one month after surgery. In comparison, the hospital's official sampled NSQIP-P review (40% of hospital cases; submitted to NSQIP) found 4 patients experienced NSQIP-P occurrences, no patients died within the 30-day post-operative period, and one patient died after 30 days post-surgery.

NSQIP-P occurrences included pneumonia, unplanned intubation, reintubation, cardiac arrest, and surgical site infection (SSI). Perioperative NREs were reported in 6 cases with NSQIP-P occurrences, all 9 cases where the infant remained in the hospital at day 30

post-operative, and all 3 neonates who died beyond one month after surgery. One case where NSQIP-P occurrences were absent had no NRE reports.

### 3.7 Unadjusted Analysis and Regression Analyses

The unadjusted analysis determined the odds ratio of having a NSQIP-P 30-day post-operative occurrence with the presence of an NRE was 0.695 (95% CI 0.06 – 17.04). Logistic regression analysis did not find an association between NRE incidence, NRE count, or maximum NRE severity and NSQIP-P occurrence, respectively, after adjusting for potential confounders (Table 6). There was a very large effect size in patients with pre-procedural ventilation (OR 5.4,  $p = 0.08$ ). However, the confidence interval was wide for this variable.

## 4. Discussion

This study demonstrates that NREs are prevalent in the perioperative care of infants requiring gastrostomy, varying in their severity and impact on the infant's course of care. All clinicians (i.e., neonatology, anesthesia, and pediatric surgery) and in all care settings (e.g., NICU, PACU, OR) readily reported NREs during all care phases (i.e., pre-operative, intraoperative, and post-operative). Approximately 8 out of 10 observed cases included at least one clinician-reported NRE; NRE-containing cases averaged 3 NREs per case. Our 100% NSQIP-P case review identified 5 cases (15%) with 30-day post-operative occurrences and each of these cases had multiple reported NREs. The 4 cases in which no NREs were reported had no NSQIP-P occurrences. The hospital's sampled NSQIP-P review (i.e., sub-sample of all available cases) did not capture one case that had post-operative occurrences, including +30-day mortality. In this pilot trial, NRE occurrence was not significantly associated with NSQIP-P occurrence (OR 0.695, (95% CI 0.06 – 17.04).

Research on NREs, contributory factors, and their association with major morbidity and mortality is limited. Prior NRE research in adult anesthesia has reported 22–30% intraoperative incidence rates in observed cases and NRE counts per case, comparable to those reported in this study [6, 11, 23]. Conversely, case studies in gynecological surgery and pediatric cardiac surgery did not report incidence rates at the case level (implied to be near 100%), but reported 12 and 15 NREs per case, respectively [24, 25]. There is no NRE research on neonates or medically complex infants.

The NRE approach used in this pilot study advances perioperative safety research in several important ways. First, our approach expands NRE analysis beyond a single clinical domain or environment by examining the continuum of perioperative care, the pre-operatively in the NICU (one-hour before the NICU-to-OR patient handover), transitioning to OR setting, and concluding 24-hours post-operation in the NICU. This is the first study to capture NREs longitudinally and explicitly across care transitions. Collecting clinician-reported NREs longitudinally captures both isolated events that may occur anywhere on this continuum and the accumulation of NREs over the entire course of perioperative care. This methodology aims to determine if either isolated NREs or the accumulation of many NREs is associated with post-operative major morbidity and mortality. Preliminary NRE research in anesthesia and surgery, including this study, has not established that link. Finding an association

between NREs and subsequent adverse patient outcomes would be significant as most NREs are not currently reported in conventional hospital reporting systems. NREs occur on an order of magnitude more frequently than reported hospital events [6]. Thus, the routine collection of NREs could provide greater opportunity to learn about patient risk, latent errors and systemic issues, clinical responses, and organizational resilience prior to catastrophic failures.

Second, our methodology invites open-reporting of NREs from *all clinicians* who are involved in each infant's care along this continuum. This includes neonatology, NICU nursing, anesthesia, and the entire surgical team and this inclusiveness is purposeful to obtain a diverse and thorough perspective of case quality. NRE reporting is intentionally subjective to encourage reporting of anything that registers in the clinician's mind as "off" or suboptimal. Each clinician's reporting threshold and behavior is calibrated by their cumulative clinical knowledge, expertise, and perception of optimal care for each patient and the clinical context rather than dictated by strict definitions, rules, or algorithms. Finally, the methodology further expands the view of surgical safety by pushing beyond the evaluation of the surgeon's technical skill and acumen to consider the broader impact of the system in which they work and deliver patient care [26–29].

Our findings and the current NRE methodology have several limitations. Our analysis was based on a small convenience sample of G-tube cases at a single academic medical center. While the study was a useful vehicle to demonstrate the NRE approach and its potential value in perioperative safety and comparative effectiveness research, it was not sufficiently powered to explore the relationship between G-tube surgical technique and post-operative outcomes. Replication of the NRE methodology in fully-powered, hypothesis driven studies is recommended. Adding HFE-based analyses to future multi-center, multi-technique studies would complement and advance previously published procedural efficiency and patient outcomes studies. Together, these data would produce granular safety profiles of each technique that would guide clinical decision-making in the OR.

Our approach used research personnel to survey clinicians about NREs during or immediately after critical perioperative care transitions. Having research personnel embedded in the NICU and OR is not a sustainable solution for NRE collection and may introduce the Hawthorne effect in observed teams. To minimize the Hawthorne effect, we conducted numerous pre-study observations as part of our training protocol to desensitize clinicians to the presence of the observers. Further, our team has a long history of observational research in the perioperative environment and has found little evidence that the Hawthorne effect influences clinician behaviors as demonstrated by the incidence, severity, and impact of NREs voluntarily reported by clinicians in this environment. For NRE reporting to be a more pragmatic approach, while still overcoming the limitations of conventional hospital incident reporting systems, processes must be developed to enable workflow-integrated NRE reporting. The CONES (i.e., our validated NRE survey) can usually be completed quickly, which would allow it to be easily integrated into a sign-out or surgical debriefing, completed post-case via a smartphone app. Improving proximity of event occurrence and event reporting through workflow integration of CONES or a similar instrument would increase the frequency and accuracy of reporting, thereby increasing



information to support system performance for feedback and safety improvement. For example, it is difficult to assess the severity or impact of a deficient patient handover in the moment. Patient safety research has shown that poor patient handovers can lead to downstream safety events and adverse patient outcomes [30, 31]. Comprehensive HFE studies of handover-related NREs, to and from the OR, and their impact on patient outcomes are needed.

Finally, we need to better understand any associations of NRE incidence and severity with patient outcomes [32]. Establishing a direct association between NREs and outcomes would, especially if directionality could be ascertained, provide a clear roadmap for safety improvement: prevent NREs to improve patient safety. Unfortunately, the NRE construct is likely more complex and nuanced. For example, one of the major principles of high reliability organization (HRO) theory – the study of organizations that perform safely and reliably in high-risk environments - is *pre-occupation with failure* [33]. HRO theory suggests that teams (e.g., NICU or surgical team) and organizations (e.g., hospitals) that enact or operationalize this principle would report more NREs during work and deliver better patient outcomes than organizations less attuned to potential failures and deliver better patient outcomes than organizations less attuned to potential failures. High NRE reporting rates, therefore, may be a positive organizational attribute and foundational to learning healthcare systems [34]. In contrast, future studies should evaluate type of NREs and their association with proximate (i.e., that case) and system outcomes.

## 5. Conclusions

The NRE methodology holds promise as a complementary approach to conventional clinical and health services research methods and may be particularly well-suited for comparative effectiveness research of clinic processes, tools, and interventions. Given the relatively low frequency of adverse outcomes in pediatric surgery and the difficulty of identifying actionable data with standard reporting methods, NRE methods may be especially well suited to pediatric surgery safety evaluation. Further, this approach facilitates the examination of interdisciplinary care processes that span physical space (e.g., NICU and OR) and time (e.g., phases of care). NRE reporting and analysis aims to expose risks inherent in our increasingly complex socio-technical systems of care delivery. Such risks are nowhere more evident than in the perioperative care of neonates and medically complex infants. Future comprehensive multi-center studies would help determine the relationship between NRE reporting behaviors and clinical team performance and if NRE measures (e.g., incidence, severity, patient impact) are associated with or predict post-operative major morbidity and mortality in children and neonates.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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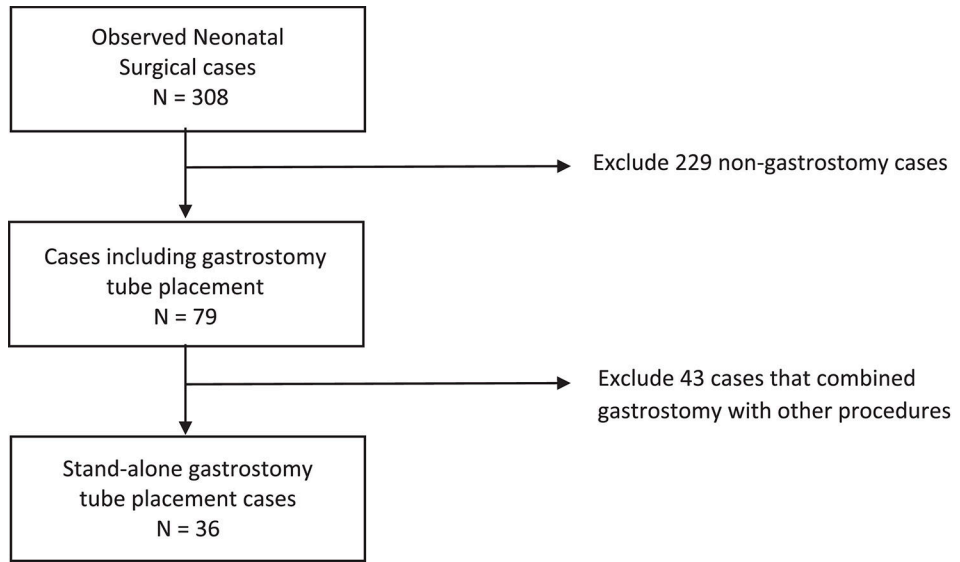
## REFERENCES

- [1]. Weinger MB, Slagle J. Human factors research in anesthesia patient safety: Techniques to elucidate factors affecting clinical task performance and decision making. *JAMIA* 2002;9(6 (supplement)):S58–S63.
- [2]. France DJ, Slagle J, Schreppe E, Moroz S, Hatch LD, Grubb P, et al. Impact of patient handover structure on neonatal perioperative safety. *Journal of perinatology : official journal of the California Perinatal Association* 2019;39(3):453–67. [PubMed: 30655594]
- [3]. Minnick AF, Donaghey B, Slagle J, Weinger MB. Operating room team members' views of workload, case difficulty and Non-Routine Events. *Journal for healthcare quality : official publication of the National Association for Healthcare Quality* 2011.
- [4]. Slagle JM, Anders S, Calderwood C, Weinger MB. Significant physiological disturbances in cases with and without non-routine events: An analysis of videotaped anesthetics. *Proc Human Factors Ergon Soc* 2009;53:674–8.
- [5]. Weinger M, Slagle J, Crimin K, Nwosu S, Feinleib J, Schroeder R, et al. Higher pre- and post-case workload ratings by anesthesiologists, surgeons, and OR nurses are associated with Non-Routine Events. *Proc Am Soc Anesthesiol Ann Mtg* 2011;115:A1728.
- [6]. Oken A, Rasmussen MD, Slagle JM, Jain S, Kuykendall T, Ordonez N, et al. A facilitated survey instrument captures significantly more anesthesia events than does traditional voluntary event reporting. *Anesthesiology* 2007;107(6):909–22. [PubMed: 18043059]
- [7]. Gurses AP, Kim G, Martinez EA, Marsteller J, Bauer L, Lubomski LH, et al. Identifying and categorising patient safety hazards in cardiovascular operating rooms using an interdisciplinary approach: a multisite study. *BMJ quality & safety* 2012;21(10):810–8.
- [8]. Gurses AP, Martinez EA, Bauer L, Kim G, Lubomski LH, Marsteller JA, et al. Using human factors engineering to improve patient safety in the cardiovascular operating room. *Work* 2012;41 Suppl 1:1801–4. [PubMed: 22316975]
- [9]. France DJSS, Schreppe E, Moroz S, Grubb P, Vogus TJ, Lehmann CU, Lorinc A, Robinson J, Crankshaw M, Sullivan M, Wallace T, Newman TA, Weinger MB, Blakely ML Defining the epidemiology of safety risks in NICU patients requiring surgery. *Journal of Patient Safety (In Review)* 2019.
- [10]. Hamilton EC, Pham DH, Minzenmayer AN, Austin MT, Lally KP, Tsao K, et al. Are we missing the near misses in the OR?-underreporting of safety incidents in pediatric surgery. *J Surg Res* 2018;221:336–42. [PubMed: 29229148]
- [11]. Liberman JS, Slagle JM, Whitney G, Shotwell MS, Lorinc A, Porterfield E, et al. Incidence and Classification of Nonroutine Events during Anesthesia Care. *Anesthesiology* 2020;133(1):41–52. [PubMed: 32404773]
- [12]. Fox D, Campagna EJ, Friedlander J, Partrick DA, Rees DI, Kempe A. National trends and outcomes of pediatric gastrostomy tube placement. *J Pediatr Gastroenterol Nutr* 2014;59(5):582–8. [PubMed: 24979479]
- [13]. Hatch LD, Scott TA, Walsh WF, Goldin AB, Blakely ML, Patrick SW. National and regional trends in gastrostomy in very low birth weight infants in the USA: 2000–2012. *Journal of perinatology : official journal of the California Perinatal Association* 2018;38(9):1270–6. [PubMed: 29925865]

- [14]. Lin T, Pimpalwar A. Minimally invasive surgery in neonates and infants. *J Indian Assoc Pediatr Surg* 2010;15(1):2–8. [PubMed: 21180496]
- [15]. Holder TM, Leape LL, Ashcraft KW. Gastrostomy: its use and dangers in pediatric patients. *The New England journal of medicine* 1972;286(25):1345–7. [PubMed: 4554838]
- [16]. Greene NH, Greenberg RG, O'Brien SM, Kemper AR, Miranda ML, Clark RH, et al. Variation in Gastrostomy Tube Placement in Premature Infants in the United States. *American journal of perinatology* 2018.
- [17]. Clifford P, Heimall L, Brittingham L, Davis KF. Following the Evidence Enteral Tube Placement and Verification in Neonates and Young Children. *J Perinat Neonat Nur* 2015;29(2):149–61.
- [18]. Baker L, Beres AL, Baird R. A systematic review and meta-analysis of gastrostomy insertion techniques in children. *Journal of pediatric surgery* 2015;50(5):718–25. [PubMed: 25783383]
- [19]. Salazar JH, Spanbauer C, Sood MR, Densmore JC, Van Arendonk KJ. Variability in the Method of Gastrostomy Placement in Children. *Children-Basel* 2020;7(6).
- [20]. Raval M, Dillon P, Bruny J, Ko C, Hall B, Moss R, et al. American College of Surgeons National Surgical Quality Improvement Program Pediatric: a phase 1 report. *Journal of the American College of Surgeons* 2011;212(1):1–11. [PubMed: 21036076]
- [21]. Raval MV, Dillon PW, Bruny JL, Ko CY, Hall BL, Moss RL, et al. Pediatric American College of Surgeons National Surgical Quality Improvement Program: feasibility of a novel, prospective assessment of surgical outcomes. *Journal of pediatric surgery* 2011;46(1):115–21. [PubMed: 21238651]
- [22]. Liu Q, Shepherd BE, Li C, Harrell FE Jr. Modeling continuous response variables using ordinal regression. *Stat Med* 2017;36(27):4316–35. [PubMed: 28872693]
- [23]. Weinger MB, Slagle J, Jain S, Ordonez N. Retrospective data collection and analytical techniques for patient safety studies. *J Biomed Informatics* 2003;36:106–19.
- [24]. Law KE, Hildebrand EA, Hawthorne HJ, Hallbeck MS, Branaghan RJ, Dowdy SC, et al. A pilot study of non-routine events in gynecological surgery: Type, impact, and effect. *Gynecol Oncol* 2019;152(2):298–303. [PubMed: 30527338]
- [25]. Schraagen JM, Schouten T, Smit M, Haas F, van der Beek D, van de Ven J, et al. A prospective study of paediatric cardiac surgical microsystems: assessing the relationships between non-routine events, teamwork and patient outcomes. *BMJ quality & safety* 2011;20(7):599–603.
- [26]. Michaels RK, Makary MA, Dahab Y, Frassica FJ, Heitmiller E, Rowen LC, et al. Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations. *Ann Surg* 2007;245(4):526–32. [PubMed: 17414599]
- [27]. Adams-McGavin RC, Jung JJ, van Dalen A, Grantcharov TP, Schijven MP. System Factors Affecting Patient Safety in the OR: An Analysis of Safety Threats and Resiliency. *Ann Surg* 2019.
- [28]. Gawande AA, Zinner MJ, Studdert DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery* 2003;133(6):614–21. [PubMed: 12796727]
- [29]. Catchpole K, Mishra A, Handa A, McCulloch P. Teamwork and error in the operating room: analysis of skills and roles. *Ann Surg* 2008;247(4):699–706. [PubMed: 18362635]
- [30]. Barbeito A, Agarwala AV, Lorinc A. Handovers in Perioperative Care. *Anesthesiology clinics* 2018;36(1):87–98. [PubMed: 29425601]
- [31]. Segall N, Bonifacio AS, Schroeder RA, Barbeito A, Rogers D, Thornlow DK, et al. Can we make postoperative patient handovers safer? A systematic review of the literature. *Anesthesia and analgesia* 2012;115(1):102–15. [PubMed: 22543067]
- [32]. Lane-Fall MB, Bass EJ. "Nonroutine Events" as a Nonroutine Outcome for Perioperative Systems Research. *Anesthesiology* 2020;133(1):8–10. [PubMed: 32404772]
- [33]. Vogus TJ, Sutcliffe KM. The Safety Organizing Scale: development and validation of a behavioral measure of safety culture in hospital nursing units. *Medical care* 2007;45(1):46–54. [PubMed: 17279020]
- [34]. Medicine Io. In: Olsen LA, Aisner D, McGinnis JM, editors. *The Learning Healthcare System: Workshop Summary*. Washington (DC); 2007.

### Highlights

The measurement of non-routine events (NRE) is a safety methodology arising from the field of human factors engineering and is meant to detect potential safety alarms well up-stream of an adverse event (e.g., NSQIP-P occurrence). The NRE methodology has never been applied to neonatal surgery, which was our goal. To simplify this pilot study, we applied NRE measurement to G-tube placement in the NICU surgical population. We found that even in this “simple” operative procedure >80% of cases had an NRE reported by involved clinicians whereas only 19% had a NSQIP-P occurrence reported. NRE occurrence was not associated with an increased likelihood of an NSQIP-P occurrence, but this methodology does offer novel information that should be considered as we try to increase surgical safety. Application of this methodology to a broader array of operative procedures is needed.



**Figure 1.**  
Patient Selection

**Table 1**

## Patient demographics.

Variable	Observed Cases ( <i>N</i> = 36)
Gestational Age (Weeks)	
-Median (Q1, Q3)	34.6 (30.1, 38.3)
Female	
-Yes (% of cohort)	29 (80.6%)
Weight (Kilograms)	
-Median (Q1, Q3)	3.6 (2.9, 4.36)
Postnatal age (Weeks)	
-Median (Q1, Q3)	57.5 (25.5, 97.2)
Postmenstrual Age (Weeks)	43.9 (41.1, 46.4)
Pre-Procedural Ventilation	
-Yes (% of cohort)	11 (30.6%)
ASA Level	
2 (% of cohort)	4 (11.1%)
3 (% of cohort)	29 (80.6%)
4 (% of cohort)	3 (8.3%)

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**Table 2**

Frequency, severity, impact of non-routine events.

<b>Variable</b>	<b>Observed Cases (N = 109)</b>
# of NREs per Case	
Mean ± SD	3.0 ± 2.5
Cases containing NREs	
Yes	30 (83%)
No	6 (17%)
SME-rated NRE Average Severity (1–5)	
Mean ± SD	2.0 ± 1.1
SME-rated NRE Average Impact on Patient Care (1–5)	
Mean ± SD	2.3 ± 1.0

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**Table 3:**

NRE distribution by phase

Variable	Clinician-Reported NREs (N=109)
Pre-operative NREs	19 (16.5%)
Operative NREs	72 (66.1%)
Early post-operative NREs	14 (12.8%)
Late post-operative NREs	4 (3.7%)

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**Table 4:**

## Contributory Factors for Non-routine Events

Variable	Contributory Factors (N=109)
<b>Patient Factors</b>	
-Yes (% of cohort)	29 (26.6%)
<b>Clinical Care Processes</b>	
-Yes (% of cohort)	26 (24.1%)
<b>Equipment</b>	
-Yes (% of cohort)	22 (20.2%)
<b>Teamwork</b>	
-Yes (% of cohort)	10 (9.2%)
<b>Logistical &amp; System Factors</b>	
-Yes (% of cohort)	10 (9.2%)
<b>Individual Factors</b>	
-Yes (% of cohort)	9 (8.3%)
<b>Environment of Care</b>	
-Yes (% of cohort)	4 (3.7%)
<b>Other</b>	
-Yes (% of cohort)	3 (2.8%)

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**Table 5:**

## Results of 100% NSQIP-P Case Review

Variable	Cases(N=36)
<b>Post-Op Occurrences</b>	
-Yes (% of cohort)	7 (19.4%)
<b>30 Day Status</b>	
-Discharge to Home (% of cohort)	27 (75.0%)
-Hospital (% of cohort)	9 (25.0%)
-Death (% of cohort)	0 (0%)
<b>Mortality (31+ days post-op)</b>	
-Yes (% of cohort)	3 (8.6%)
<b>Re-admit</b>	
-Yes (% of cohort)	3 (11.5%)
<b>Unplanned Re-Op</b>	
-Yes (% of cohort)	0 (0.0%)
<b>Planned Re-Op</b>	
-Yes (% of cohort)	0 (0.0%)

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**Table 6:**

Logistic Regression Analyses: Association between NRE measures and NSQIP-P Occurrence

<b>ANY NRE (yes/no)</b>						
term	estimate	std.error	statistic	p.value	conf.low	conf.high
(Intercept)	0.435	1.498	-0.555	0.5786	0.0113	7.05
Pre-procedural ventilation (Yes)	5.457	0.974	1.743	0.0814	0.8673	46.47
ASA score >=3	0.334	1.392	-0.787	0.4315	0.0224	8.77
Any NRE (Yes)	0.695	1.326	-0.274	0.7839	0.0586	17.04
<b>NRE Count</b>						
term	estimate	std.error	statistic	p.value	conf.low	conf.high
(Intercept)	0.301	1.345	-0.894	0.3715	0.0110	3.43
Pre-procedural ventilation (Yes)	5.437	0.973	1.741	0.0817	0.8656	46.20
ASA score 3	0.318	1.375	-0.832	0.4052	0.0219	8.11
NRE Count	1.031	0.202	0.153	0.8783	0.6731	1.53
<b>Maximum NRE Severity</b>						
term	estimate	std.error	statistic	p.value	conf.low	conf.high
(Intercept)	0.375	1.358	-0.722	0.470	0.014	4.55
Pre-procedural ventilation (yes)	5.362	0.975	1.723	0.085	0.849	45.70
ASA score 3	0.323	1.381	-0.817	0.414	0.022	8.31
Maximum NRE severity	0.948	0.325	-0.163	0.870	0.501	1.87