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Title: The Role of Collective Mindfulness in Delivering Reliable and Safe Perioperative Care to Neonates

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Period of Performance: 06/01/2018 – 05/31/2021

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Acknowledgement: Research reported in this progress report was supported by AHRQ under award number 1R03HS026069-01

Grant Award Number: 5R03HS026069-02 REVISED

STRUCTURED ABSTRACT

Purpose

The objective of this pilot study was to measure the prevalence of collective mindfulness (CM) or safety organizing in neonatal intensive care unit (NICU) and operating room (OR) teams and its association with non-routine events (NREs) during perioperative care.

Scope

This was a 2-year, two-site pilot study to characterize CM behaviors in NICU and OR teams to measure their impact on patient safety during perioperative care and to conduct a preliminary validation of a provisional behavioral marker system for CM.

Methods

We used a prospective, observational study and previously validated survey instruments to collect self-reports of CM and NREs after surgical cases. Validation of a provisional behavioral marker system for CM was conducted by retrospectively assessing the concordance between self-reported CM and expert ratings of observable CM behaviors in the same perioperative teams.

Results

CM self-reports were collected in 370 surgical cases at Vanderbilt University Medical Center (VUMC; N = 310) and Utah's Primary Children's Hospital (PCH; N = 60). Across observed cases, CM scores were nearly equivalent ($p = 0.6$) at VUMC (median 5.8, IQR 5.5-6.2) and PCH (median 5.8, IQR 5.5-6.3). Clinicians reported NREs in N = 256 (83%) and N = 59 (98%) of cases at VUMC and PCH, respectively. Significantly more NREs were reported per case at PCH ($p < 0.001$), but NREs were more severe at VUMC ($p = 0.005$). The number of NREs was negatively associated with CM at PCH. The concordance analysis did not find agreement between CM global scores or the five HRO principle scores.

Key Words: Collective mindfulness, non-routine events, behavioral marker, validation

I. PURPOSE

High-reliability organizations (HROs), such as aircraft carrier flight decks[1] and nuclear power plants,[2] are able to consistently operate hazardous technologies in a nearly error-free manner amidst complexity, interdependence, and time pressure. HRO case studies, including a few healthcare organizations,[3] suggest that a robust safety culture enables more reliable work processes and thus safer performance. More tangibly, safety culture can be seen 'coming to life' in HROs through specific behavioral processes observed in front-line employees, termed **collective mindfulness (CM)**.[3-6] These five inter-related behavioral processes (also called *safety organizing behaviors*) are 1) preoccupation with failure; 2) reluctance to simplify interpretations; 3) sensitivity to operations; 4) commitment to resilience; and 5) deference to expertise.[5] Healthcare is increasingly adopting CM as a way to improve care quality and safety.[7,8]

The critical need for higher reliability in healthcare is most apparent in neonatal perioperative care, which is among the highest-risk services hospitals provide.[9] Term (37 weeks gestation or greater) and premature (less than 37 weeks gestation) neonates are highly vulnerable to iatrogenic events due to their small size, fragility, and exceptional sensitivity to drugs and environmental stressors. Research in neonatal intensive care units (NICUs) shows that these attributes increase care complexity and decrease neonates' abilities to tolerate even small deviations in care. Neonates' adverse event (AE) rates can be eight times higher than that of hospitalized adults,[10] with an incidence of 74 AEs per 100 patients (0-11 AEs/patient) discharged from the NICU; 33% of these events are severe.[11,12] The risks may be greatest during surgery, yet there is very little perioperative (i.e., preoperative through postoperative) neonatal safety research. In our analysis of 2012 National Surgical Quality Improvement Program Pediatric (NSQIP-P) data, only 6% of all patients were neonates, but they accounted for 60% and 16% of the total observed 30-day postoperative mortality and morbidity, respectively.[13]

We proposed to measure the prevalence of collective mindfulness (CM) in NICU and operating room (OR) teams and its impact on non-routine events (NREs) – defined as *any event that is perceived by care providers or skilled observers as a deviation from optimal care based on the clinical situation*[14] – during neonatal perioperative care. This pilot study leveraged a large concurrent prospective observational study (IRB-approved NICHD R01) that defined the epidemiology of risk for neonates in the perioperative environment through an innovative analysis of NREs and contributory factors. During data collection, we audio and video (AV) recorded randomly selected eligible and consented cases, in which a case is defined as the period beginning 1 hour before the NICU-to-OR handover (i.e., preoperative) and ending 1 hour after the OR-to-NICU handover (i.e., postoperative). For this AHRQ-funded pilot study, we prospectively collected self-reported CM data from the NICU and OR teams using the validated Safety Organizing Scale (SOS; developed by Co-I Vogus) and merged these data with concurrently collected AV recordings (for domain experts to observe and score markers of the same behaviors) and NRE data (i.e., secondary use of R01 data) to conduct the

first comparative quantitative analysis of CM measures in healthcare teams. A final product of the study is the first empirical validation of a previously proposed behavioral marker system for CM.[6]

The long-term objective of our research program is to improve the reliability and safety of neonatal perioperative care. As a first step in this 2-year pilot, we characterized CM behaviorally in NICU and OR teams and measured their impact on patient safety, as measured by the incidence and severity of NREs during care transitions and subsequent care. For this project, we defined care transitions as the planning, preparation, and execution of handovers from the NICU to the OR. Our **Specific Aims** were to:

1. **Conduct a prospective observational pilot study of NICU and OR teams** to a) estimate the prevalence of *perceived* CM (i.e., self-reported using the SOS) during the perioperative period and b) delineate the relationship(s) between team attributes, case attributes, and perceived CM score.
2. **Determine the effects of perceived CM on the incidence and severity of NREs occurring during and across phases of neonatal perioperative care.**
3. **Conduct a preliminary validation of a provisional behavioral marker system by assessing the concordance of observed (expert ratings of AV recordings) and perceived (self-reported SOS scores) CM in the same perioperative teams.**

This project is laying the groundwork for a multicenter observational (Observational R01) study to measure the impact of CM in perioperative teams on NREs and, most importantly, 30-day postoperative morbidity and mortality. Findings from the pilot as well as the concurrent multisite observational study will be used by our research team to identify the team behaviors that are most critical for promoting and maintaining CM and neonatal safety in the perioperative environment, thereby allowing the development of tailored, team-based HRO interventions for widespread safety improvement. The development, implementation, and evaluation of these interventions will be the basis for a multicenter intervention study (Interventional R01).

II. SCOPE

This project built upon a concurrent neonatal patient safety initiative (1R01HD086792-01), supported by the National Institute of Child Health & Human Development (NICHD; PI: France/Blakely), which is defining the epidemiology of non-routine events (NREs, defined as deviations from optimal care), contributory factors (CFs), and patient harm in surgical neonates. The R01 included a resource-intensive, 36-month, observational, single-site study of neonatal perioperative care (i.e., starting before NICU-to-OR handover and ending after OR-to-NICU handover). Trained research assistants (RAs) directly observed and captured NREs, while clinicians

independently reported NREs and associated performance shaping (or contributory) factors. We also continuously audio and video (AV) recorded randomly selected perioperative care episodes. Thus, the project leveraged this infrastructure of established study processes and tools, participant engagement (i.e., neonatologists, pediatric surgeons, NICU and perioperative nurses), and full institutional buy-in.

III. METHODS

Our 2-year research plan, as illustrated in **Figure 1,** included three **Specific Aims**: **Aim 1a,** to estimate the prevalence of *perceived* CM in NICU and OR teams; **Aim 1b,** to delineate the relationship between team attributes (e.g., clinician experience, etc.), case attributes (e.g., patient and procedural details), and perceived CM; **Aim 2**, to determine the impact of perceived CM on the incidence (count) and severity of NREs occurring during and across observed phases of perioperative care; and **Aim 3,** to conduct a preliminary validation of a behavioral marker system for CM by determining if safety organizing behaviors are observable, can be reliably scored by expert raters, and are concordant with SOS scores (i.e., self-reports) from the same teams.

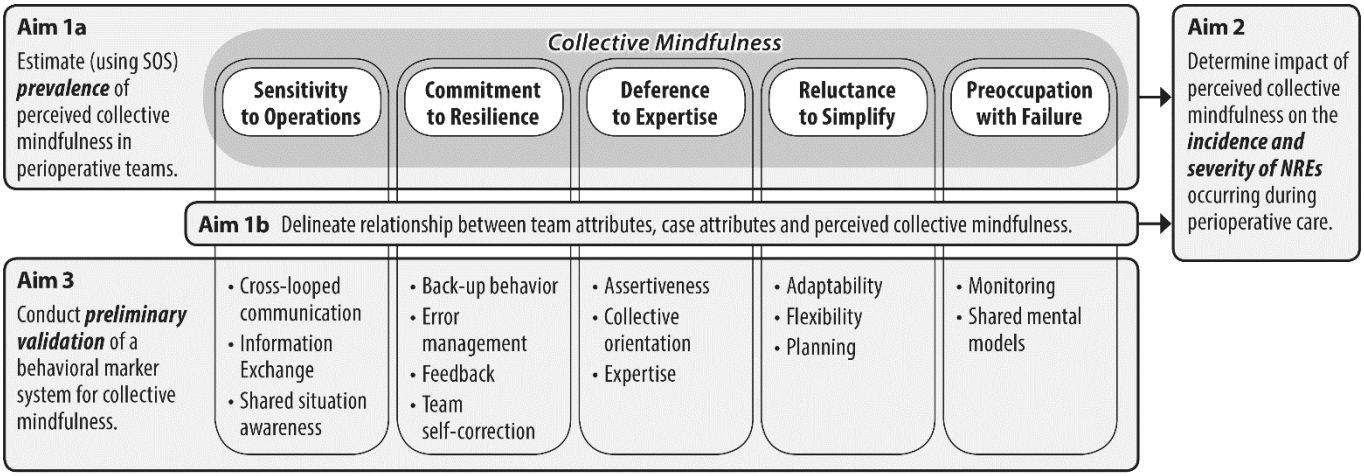

Figure 1. Conceptual Model[6]

To achieve these aims, we conducted an 18-month observational study of CM in perioperative teams that integrated HRO research methods developed by Vogus[91] with the patient safety research methods developed by our R01 team (see **Figure 2**). We used Vogus' validated SOS to prospectively measure perceived CM in NICU and OR teams in **Aim 1a**. In **Aim 1b**, we then merged SOS data with team and case attribute data collected for the R01 to model the relationship between team and case factors (independent variables [IVs]) and perceived CM (dependent variable [DV]). In **Aim 2**, we quantified the impact of perceived CM (IV) on NRE incidence and severity (DVs) using SOS data collected for **Aim 1a** and NRE data collected for our R01 safety study, including contributory factors (CFs). Finally, for **Aim 3,** expert raters (a pediatric surgeon [Blakely], a neonatologist [Grubb], and a pediatric anesthesiologist [Lorinc])

are reviewing (i.e., this work is ongoing) the AV recordings collected of the same teams for the R01 to evaluate a proposed behavioral marker system for safety organizing behaviors.[6]

A. Research Setting and Participants

The 18-month observational study was performed in the NICU and pediatric ORs of Vanderbilt's Children's Hospital in Nashville, Tennessee, and Primary Children's Hospital (PCH) in Salt Lake City, Utah. For **Aim 1** and **2**, we strived to include at least 120 eligible and consented cases. By enrolling 370 total surgical cases (i.e., infants; 310 at VUMC and 60 at PCH), we far exceeded this goal. To complete **Aim 3,** we used observational (AV) data from a subset of these cases. Eligible neonates had parental consent and received NICU care both before and after non-cardiac surgery. In total, 493 NICU providers (i.e., clinicians and staff) and 173 OR providers were eligible to participate in this study.

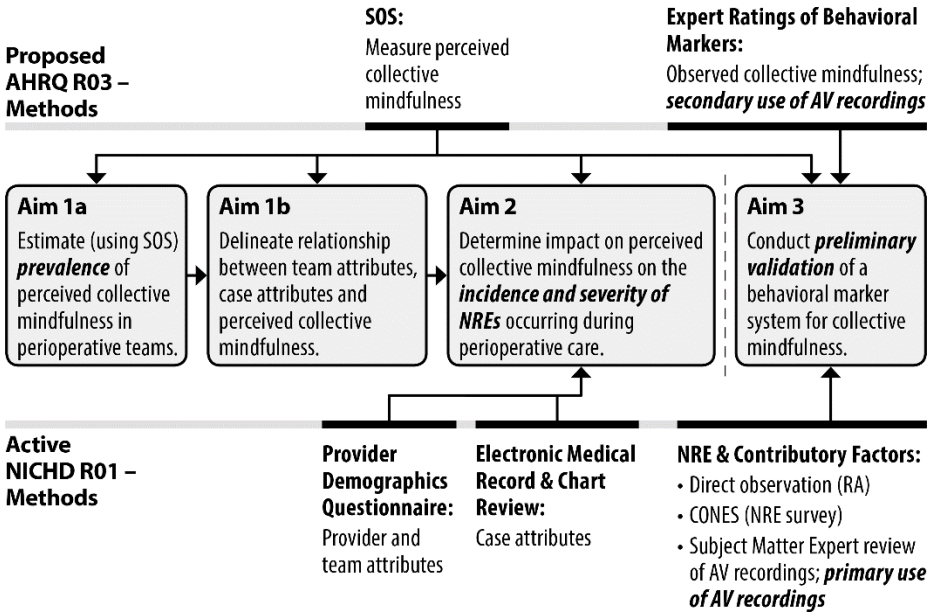

Figure 2. Methods for Proposed Study

We are analyzing self-reported CM and CM behaviors in three perioperative teams: 1) the Core NICU team that provides preoperative care, typically consisting of a neonatologist (attending or fellow), a NICU nurse, and a NICU and nurse practitioner (NNP); 2) the Care Transition team that conducts the NICU-to-OR patient handover, typically consisting of the Core NICU team plus the anesthesia provider (anesthesiologist or certified nurse anesthetist [CRNA]), surgeon (attending or fellow), and any additional clinician or staff participating (i.e., ECMO, RT, etc.) in the patient handover; and 3) the Core OR team that performs the surgery, consisting of at least one attending surgeon or surgery fellow, an anesthesia provider, an OR scrub nurse, and a circulating nurse. All participating clinicians provided written informed consent prior to each case to be eligible for inclusion and observation. The presence or absence of each type of perioperative provider was recorded for each observed care transition and surgery to allow differentiation between absence and non-response.

B. Procedures and Measures

Aim 1 – Conduct a prospective, observational pilot study of NICU and OR teams to a) estimate the prevalence of *perceived* CM and b) delineate the relationship(s) between team/case attributes and CM.

A trained RA measured CM in the interdisciplinary teams after two different perioperative care transitions – 1) after the NICU-to-OR handovers and 2) after surgery – by administering the validated nine-item Safety Organizing Scale (SOS) to providers in each team. The SOS was been reworded to ask about 'the care *you* provided for *this* baby during *this* care transition (or operation).' The SOS was administered to OR teams immediately after the surgery, because these teams disperse quickly after each case. The SOS was administered to Care Transition Teams no later than 1-hour after their handover (slightly delayed because, based on findings from our R01, the clinicians are too busy to complete surveys immediately after the handover). For **Aim 1a**, the median team SOS score (for stratified analysis of NICU transition and OR teams) or median case SOS score (for pooled analysis) was used to measure the prevalence of CM.

Prior to starting our pilot, we administered the SOS to all NICU and OR clinicians and staff using a web-based REDCap™ cross-sectional survey to measure baseline unit-level CM in both work groups. To maintain consistency between unit-level and team-level analyses, we excluded pediatric cardiac surgeons and cardiac anesthesia providers from these surveys, because neonates requiring cardiac surgery were ineligible for the study. Median NICU and OR unit SOS scores provided CM benchmarks.

SOS data collected in **Aim 1a** was merged with team, case, and patient attribute data collected during the R01 to enable analysis (see **Section D3**) of the relationship between these factors and perceived CM (**Aim 1b**).

Aim 2 – Determine the impact of perceived CM on the incidence and severity of NREs occurring during and across phases of neonatal perioperative care.

We merged the measurements of perceived CM (**Aim 1**) with detailed NRE, CF, and case data (e.g., team, surgical case, patient variables) collected on the same cases for our NICHD-funded patient safety study. This novel data set was used to build multivariable models for each phase of perioperative care observed in the pilot and also at the case level by pooling data across these phases of care.[26,90] NRE counts are reported as an integer count of the total number of NREs occurring in each phase or case. NRE severity was scored on a five-point Likert-type scale.

Aim 3 – Assess the concordance between expert-rated behavioral markers from the AV recordings (observed CM) and teams' self-reported SOS scores (perceived CM).

Although significant advances have been made in measuring perceived adherence to HRO principles and assessing its impact on organizational safety, less progress has been made in developing and validating reliable behavioral markers in healthcare generally[104-107] or for CM specifically.[6,9,92] Experts in teamwork and team training at the University of Central Florida (UCF) previously proposed a promising set of behavioral markers using a systems perspective[6] that views the contributions of individuals and teams embedded within an organization equally as important as organizational level values in obtaining and sustaining HRO status. The proposed behavioral markers for CM have high face and construct validity but may not be sufficiently specific or sensitive, as non-HRTs may exhibit them and they do not exclusively focus on error and unexpected events.[5]

In **Aim 3**, we conducted a concordance analysis of *perceived* versus *observed* safety organizing behaviors as a preliminary evaluation of the validity (i.e., accuracy, completeness, and observability) and reliability of a behavioral marker system adapted from UCF's HRT system. Data collection of AV-recorded cases for the NICHD R01 was paused during the early months of the COVID-19 pandemic, so we were unable to achieve our original target case sample. However, the sample obtained – 23 cases – was sufficient to complete the objectives of Aim 3.

Our team developed a CM guidebook for expert raters and an observational CM rating instrument based on past field work, the validated SOS, and published research. Expert raters (Vogus, Salwei, and Schremp) performed a secondary analysis of AV recordings collected for the R01 to rate the observed CM or safety organizing behaviors in the same perioperative teams observed and surveyed for **Aims 1 & 2**. Our expert raters were trained by Slagle (Co-I) using video-based training. Slagle used AV-recorded cases from our NICHD R01 archive of actual cases to build example sets for each of the five behaviors. Examples, such as the samples shown in **Table 1**, were used to exemplify the bulleted behaviors in **Figure 1.**

Table 1. Representative Examples of Behaviors Underlying Collective Mindfulness[6]

Collective Mindfulness Attribute	Description of Team Behavior *(one of many shown for each)*	Example of an Observed Behavior
Preoccupation with failure	*Performance Monitoring* - Team's ability to monitor team members' performances and provide constructive feedback	A nurse monitors a doctor's performance during a procedure to ensure steps are not omitted.
Deference to expertise	*Assertiveness* - The willingness of team members to communicate ideas and observations in a manner persuasive to other team members	A nurse questions a doctor's medication order because of a patient's known allergies.

Archived AV-recorded cases (i.e., from past research studies), partitioned by perioperative phase (i.e., preoperative care, care transition, and surgery), were selected to serve as training set from our video archive. Slagle assessed our experts' intra-rater reliability (IRR $\geq$ 0.7) using existing methods.[77,108,109,120] A review and rating of the AV recording was completed by three SME raters. Two SMEs raters observed the AV recording and rated each of the five safety organizing behaviors. The third reviewer was used to resolve disagreements when they occurred. The five behaviors that define CM were rated for each team using the same seven-point rating scale used for the SOS to facilitate concordance analysis of *perceived* versus *observed* behaviors. A global score of team CM was also rated by the expert reviewers.

D. Analysis Plan

Aim 1. Descriptive analyses, including unadjusted summary statistics with 95% confidence intervals ,when appropriate, were conducted on unit-level SOS (i.e., self-reported) scores and team-level SOS scores in the NICU and OR to estimate prevalence of CM. The baseline NICU and OR unit-level scores were summarized by computing the median and interquartile range (IQR) of SOS scores collected by cross-sectional REDCap survey. The cross-sectional survey was re-administered at the midpoint and conclusion of the NICHD R01 observational study.

Team SOS scores (also referred to as case scores) were computed as the composite score (i.e., mean or median) of the ratings of the nine SOS survey items provided by clinicians post handover or post case. SOS item scores were also summarized for each team by computing the median and IQR. 'Team score' calculations were stratified by perioperative phase (i.e., separate median [IQR] score calculated for each clinical micro-team: NICU team, Anesthesia team, and OR team).

Finally, we used multiple ordinal regression to model the association between attributes characterizing the perioperative team, surgical case, and patient's clinical disposition and the composite team CM scores. Team-related attributes were represented by micro-team affiliation (NICU, Anesthesia, OR). It was not possible to model team composition using gender, age, work experience, etc., due to high levels of missing data in these data fields. Case-related covariables included hospital (VUMC or PCH), surgical specialty, case complexity or ASA score (1-5 scale), direct transfer to OR (Y/N), etc. Patient-related covariables included gestational age at birth, current weight, and preprocedural ventilation (Y/N).

Aim 2. Multiple logistic mixed-effects regression and ordinal mixed-effects regression analyses were used to assess the association between NRE incidence and severity with CM within and between hospital sites. We adjusted for the case-related

variables. A random intercept model, indexed by case, was used to account for correlation among NRE count and severity measurements in cases when multiple NREs were reported. A second random intercept model, indexed by the attending surgeon, was employed to account for correlation among NRE count and severity across cases with the attending surgeon in common.[110,111] Natural cubic splines were used to model the effect of continuous IVs such that linearity was not assumed. Ridge regularization[112] was used to avoid model overfitting, in which the degrees of freedom were limited by final effective sample size.[113] Bootstrap methods were employed for model validation.[113] All statistical analysis was performed using R (statistical software) and the contributed packages rms, nlme, and lmer.[114-117]

Aim 3. The recording and analysis of SME-rated behavioral marker scores collected in Aim 3 mirrored the SOS analysis plan in **Aim 1** to facilitate the concordance analysis of the two measures. Cohen's kappa[118,119] was used to measure the concordance between the SOS scores (perceived CM) and expert-scored ratings of teams' safety organizing behaviors (observed CM). A kappa $\geq$ 0.61 was considered substantial agreement between these continuous ratings. Agreement was assessed using the concordance correlation coefficient.

IV. RESULTS

The Specific Aims of the project have been successfully completed despite significant interruptions and delays in patient (case) recruitment and accrual caused by the COVID-19 pandemic. We appreciate AHRQ's approval to extend our no-cost extension to complete Specific Aim 3's analysis. All aims were completed as proposed.

Major project accomplishments include 1) completing a prospective, observational study of CM in perioperative teams to estimate the prevalence of CM generally at the unit level (i.e., NICU and OR) and specifically in perioperative teams during neonatal surgeries (Aim 1); 2) delineating the relationship between team attributes, case attributes, patient attributes, and perceived CM as measured by the SOS (Aim 1); 3) determining the association between team CM and the incidence and severity of NREs during perioperative care (Aim 2); 3) developing a CM reviewer guide and behavioral observational rating instrument by adapting UCF's provisional behavioral marker system for CM (Aim 3); and 4) completing the concordance analysis of perceived versus observed CM behaviors in the same perioperative teams to validate a provisional behavioral marker system (Aim 3).

A. Summary of accomplishments by Specific Aim:

A.1. Specific Aim 1

- We administered a REDCap version of the SOS via the web to measure unit-level perceptions of CM in the NICU and OR at VUMC during three distinct phases of the NICHD R01 prospective patient safety study: pre-study, mid-study, and end-study. In total, we collected survey responses from 363 perioperative clinicians (**Table 2**). We conducted a repeated measures analysis of unit-level CM in the VUMC NICU and OR to examine how CM varied across each unit and by provider type over the course of a high-intensity patient safety study in the perioperative environment (concurrent NICHD R01 observational study).
- Concurrently, our research team conducted a parallel analysis of CM in observed perioperative teams. The repeated measures analysis included survey (SOS) responses from 392 unique providers collected during 370 observed cases at VUMC (N = 310) and PCH (N = 60). The sample size we have accumulated to date far exceeds the sample size of 241 cases we originally proposed for Specific Aim 1.
- Finally, we conducted a comparative analysis of unit-level CM and perioperative team CM at VUMC.

B.2. Specific Aim 2

- We conducted a comparative analysis of perceived CM, system factors, NRE incidence, NRE severity, and contributory factors at VUMC and PCH. The objective of this analysis was to highlight the variability in neonatal perioperative care processes at two sites and to elucidate their impact on perceived CM.
- Concurrently, we completed a comprehensive analysis of the relationships between perioperative team CM (measured as average of clinician SOS scores), case attributes, contributory factors, and NRE incidence and NRE severity at two academic medical centers.

C.3. Specific Aim 3

- We collected audio and video (AV) recordings of 23 neonatal surgical cases. The COVID-19 pandemic halted all clinical research, including AV recording of cases, and therefore significantly interrupted our accrual of recorded cases.
- We designed and developed a CM reviewer guide and a behavioral marker rating instrument for subject-matter expert (SME) reviewers.
- SME reviewers, who were experts in HRO and perioperative care processes, used the instrument to rate audible and observed high-reliability behaviors during the review of recorded patient handovers and surgical cases.
- SME ratings were compared with perceived ratings collected from clinicians immediately after the observed handovers and cases to evaluate concordance between perceived and observed collective mindfulness (i.e., behavioral markers).

B. Results by Specific Aim

B.1. Specific Aim 1

Descriptive Statistics of Unit-Level Collective Mindfulness at VUMC

Tables 1 and 2 show summary statistics for SOS data collected at VUMC at the **unit level** (i.e., NICU and OR) at three specific timepoints of the comprehensive observational study of neonatal perioperative safety: 1) pre-study (phase 1), 2) mid-study (phase 2), and 3) end=study (phase 3). The SOS was administered via REDCap for the unit-level analysis.

Table 1. Distribution of Unit-Level Responses by Project Phase and Clinical Setting at VUMC

	Pre-Study N (%)	Mid-Study N (%)	End-Study N (%)	Total N (%)
NICU	157 (78)	50 (63)	48 (59)	255 (70)
Operating Room	45 (22)	30 (37)	33 (41)	108 (30)
Phase Total	202 (100)	80 (100)	81 (100)	363 (100)

Table 2. Distribution of Unit-Level Survey Responses and SOS Item and Composite SOS Scores at VUMC

Survey Response		Interquartile Range		
Survey Item	N	25th (Q1)	50th (Median)	75th (Q3)
Q1	363	4.00	5.00	6.00
Q2	362	4.00	5.00	6.00
Q3	363	3.00	5.00	5.00
Q4	362	3.00	4.00	5.00
Q5	362	5.00	6.00	6.00
Q6	361	4.00	5.00	6.00
Q7	361	4.00	5.00	6.00
Q8	360	4.00	5.00	6.00

Q9	363	5.00	6.00	6.00
SOS Score	354	4.00	5.00	6.00

Descriptive Statistics of Case-Level SOS Scores at VUMC and PCH

Table 3 summarizes the Safety Organizing Scales (SOS) scores for 370 **perioperative teams** observed at the Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, Tennessee, and Primary Children's Hospital in Salt Lake City, Utah. Team SOS scores were calculated by averaging clinicians' self-reported SOS scores.

Table 3. Descriptive Statistics for Pooled (N = 370 cases) Case-Level Postoperative SOS Responses at VUMC (N = 310) and PCH (N = 60)

Survey Item (Response Scale: 1:Lowest; 7:Highest)	Site	Median (IQR)
Q1. We knew each other's talents and skills	VUMC	6.0 (0.8)
	PCH	6.1 (0.7)
Q2. We talked about any mistakes and ways to learn from them	VUMC	6.0 (2.3)
	PCH	6.0 (0.6)
Q3. We discuss our unique skills, so we know who knows what	VUMC	5.5 (1.0)
	PCH	5.5 (1.2)
Q4. We discuss alternatives as to how we go about our normal work activities	VUMC	5.5 (1.0)
	PCH	5.4 (0.9)
Q5. When handing off/giving report, we discussed what to look out for*	VUMC	6.2 (0.6)
	PCH	6.0 (0.8)
Q6. When resolving any problem [non-routine event], we took advantage of our unique skills	VUMC	6.0 (0.8)
	PCH	6.0 (0.6)

Q7. We spent time identifying activities we didn't want to go wrong	VUMC	6.0 (1.2)
	PCH	6.0 (0.6)
Q8. We discussed how we could have prevented any errors [or non-routine events] that occurred	VUMC	6.0 (1.0)
	PCH	6.0 (0.8)
Q9.We pooled our expertise to resolve any problem/crisis that occurred.	VUMC	6.3 (0.7)
	PCH	6.3 (0.4)
Overall Case SOS	**VUMC**	**5.9 (0.8)**
	PCH	**5.8 (0.7)**

*Statistically significant difference, p = 0.024

Figure 1 shows the density curves of SOS responses. The SOS is scored on a seven-point Likert-like scale, in which a score of '1' is the lowest score (low SOS item score) and a score of '7' is the highest score (high SOS item score). The composite SOS scores, computed as the mean item scores and displayed as the bottom curve, show that CM skews high or very positively at VUMC and PCH. Perioperative clinicians from two academic medical centers self-reported very positive perceptions of CM within the teams they worked.

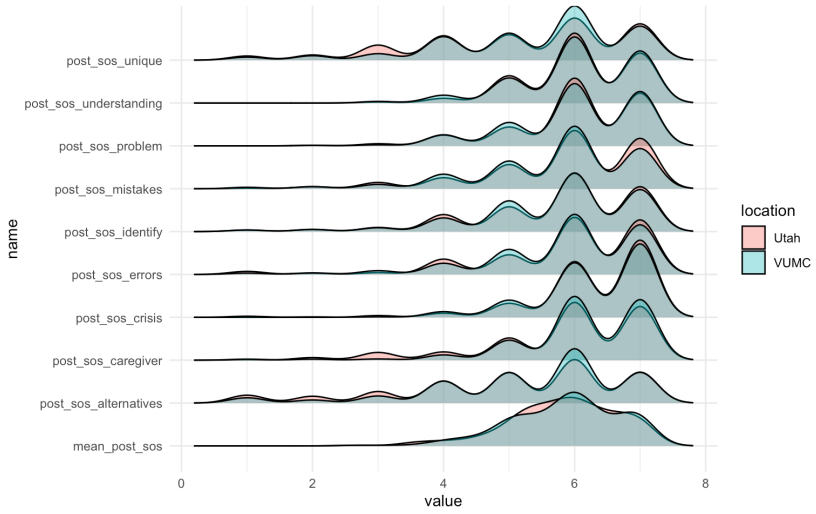

Figure 1. Density Curves of SOS Responses

VUMC Analysis: Comparative Analysis of Unit-Level and Team (Case)-Level SOS Scores

Three hundred sixty-three (N = 363) clinicians completed the unit-level SOS survey via REDCap, and 313 clinicians completed 966 post-case team-level surveys during 310 observed surgical cases at VUMC. Overall, mean SOS scores were moderately high at the unit (mean = 4.9) and team (mean = 5.8) levels. At the unit level, only OR nurses demonstrated changes in SOS. Nurses' SOS scores increased significantly from pre-study (diff. = -1.14, p = 0.02) to mid-study and sustained this gain post-study (diff. = -1.11; p = 0.02).

Within perioperative teams, NICU and surgical clinicians (i.e., excluding anesthesia) exhibited high SOS scores (mean 5.9 for both groups) and U-shaped trends in SOS scores over the three phases of the study; that is, SOS scores decreased significantly from pre-study (phase 1) to mid-study (phase 2; NICU: diff. = 1.20, p = 0.000; OR: diff. = 0.22, p = 0.04) and increased significantly from mid-study (phase 2) to post-study (phase 3; NICU: diff. = -1.40, p = 0.05; OR: diff. = -0.28, p = 0.04). However, team-level SOS scores never exceeded baseline scores.

Comparison of team- and unit-level SOS scores at VUMC found scores to be *significantly higher at the team level than at the unit level*, and the greatest team-to-unit difference was found in NICU clinicians (mean SOS scores: Unit = 4.9 versus Team = 5.9).

Comparative Analysis Between Team (Case)-Level SOS Scores at VUMC and PCH

CM self-reports were collected in 370 surgical cases at Vanderbilt University Medical Center (VUMC; N = 310) and Utah's Primary Children's Hospital (PCH, N = 60) using the SOS. A comparative analysis of SOS scores (Mann-Whitney U test) collected from perioperative teams at VUMC and PCH found statistically significant ($p < 0.001$) differences in survey completion behaviors and relative ratings of collective mindfulness. On average, perioperative teams at PCH submitted two more SOS responses per case than VUMC teams. Across observed cases, SOS (CM) scores were nearly equivalent (p = 0.6) at VUMC (median 5.8, IQR 5.5-6.2) and PCH (median 5.8, IQR 5.5-6.3). Clinicians reported NREs in N = 256 (83%) and N = 59 (98%) of cases at VUMC and PCH, respectively. Significantly more NREs were reported per case at PCH ($p < 0.001$), but NREs were more severe at VUMC (p = 0.005).

Modeling the Relationship Between Team, Patient, and Case Attributes and Composite SOS Score

Higher SOS scores were significantly associated with study site (VUMC, β=0.839, p = 0.018), clinical micro-team (OR, β=1.36, $p < 0.0001$), lower ASA score (β=-0.642, p = 0.0133), and the interaction between study site and OR team (β=-1.388, p = 0.0003). In summary, CM was most influenced by the acuity of the case and SOS score reporting by OR teams at PCH.

Summary of Aim 1 findings

Overall, SOS scores were found to skew high (i.e., positively) at two children's hospitals but did not differ significantly in data collected from perioperative teams post surgery.

However, deeper sub-analysis of unit and case or team-level SOS scores at VUMC revealed that CM varied significantly between hospital unit and perioperative teams, clinician type or role, and overtime during a large prospective study to determine the epidemiology of non-routine events in the perioperative care of neonates requiring surgery. This sub-analysis showed that clinicians scored CM higher in their perioperative teams than they did generally for their clinical units. NICU and OR teams exhibited U-shaped SOS trends (i.e., baseline CM, followed by decrease in CM, followed by return to baseline CM) during the study. At the unit level, OR nurses demonstrated increased and sustained CM (as measured by SOS) during the study period.

Modeling the relationship between team, patient, and case factors and the SOS scores at PCH and VUMC showed that higher SOS scores (CM) were associated with low-acuity surgical cases and showed a strong interaction between OR team and hospital. Specifically, the OR team at PCH reported significantly higher SOS scores.

B.2. Specific Aim 2

Modeling the Relationship Between Perioperative Team SOS Scores and NRE Incidence and Severity

To model the association between SOS scores (i.e., CM) and NRE incidence and NRE severity, hospital-level case matching (see Figure 2) was completed to create equivalent datasets from PCH and VUMC. First, the observational datasets were aligned, because data collection started at VUMC well before it started at PCH. In other words, the modeling of the association between SOS and NREs included cases in which the data collection period overlapped for VUMC and PCH. Second, gastrostomy-only cases were removed from the VUMC dataset, because PCH performs very few of those procedures in neonates.

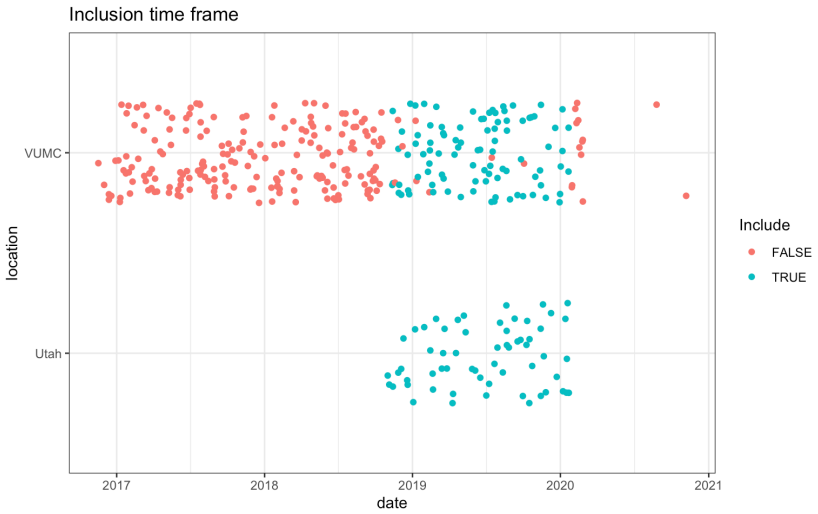

Figure 2. Hospital-Level Case Matching of Cases at VUMC and PCH

Multiple logistic (proportional odds) ordinal regression found a significant negative association between NREs and SOS scores at PCH only. That is, as composite SOS scores increased in perioperative teams at PCH, the number of NREs reported by those

teams decreased. This finding was not observed at VUMC. There was no association between composite SOS scores and NRE severity after adjusting for surgical case attributes and contributory factors (Table 4). Only study site (PCH) was significantly associated (OR = 5.4; $p < 0.0001$) with increased NRE incidence.

Table 4. Case Attributes, SOS Scores, and NRE Incidence and Severity in Observed Surgical Cases

Statistic	VUMC (N = 310)	PCH (N = 60)	p Value
Infant weight at surgery (kg), median (IQR)	3.2 (1.3)	2.8 (1.1)	$p < 0.001$
Age (days), median (IQR)	25.0 (72)	7.0 (46)	$p = 0.002$
Cases with at least one NRE, %	83%	98%	$p < 0.002$
NREs per case, mean (std)	3.4 (3.0)	7.8 (4.5)	$p < 0.001$
NRE severity (1:minimum, 5: maximum), median (IQR)	2.2 (1.3)	2.0 (0.5)	$p < 0.002$
Safety organizing score (SOS) (1:min, 7:max), median (IQR)	5.9 (0.8)	5.8 (0.7)	$p < 0.0001$

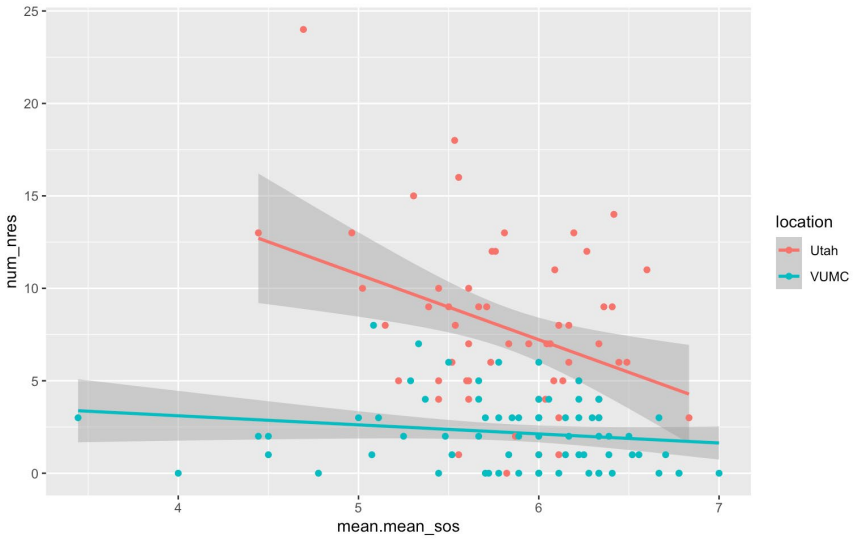

Figure 3. SOS Score Versus Number of NREs Reported by Hospital

Table 4. Results of Multiple Ordinal Regression

	β	S.E.	Wald Z	Pr(>|Z|)
SOS (mean)	-1.3452	0.5100	-2.64	0.0084
Location = VUMC	-9.0114	3.5358	-2.55	0.0108
SOS x location (mean)	0.9820	0.5956	1.65	0.0992

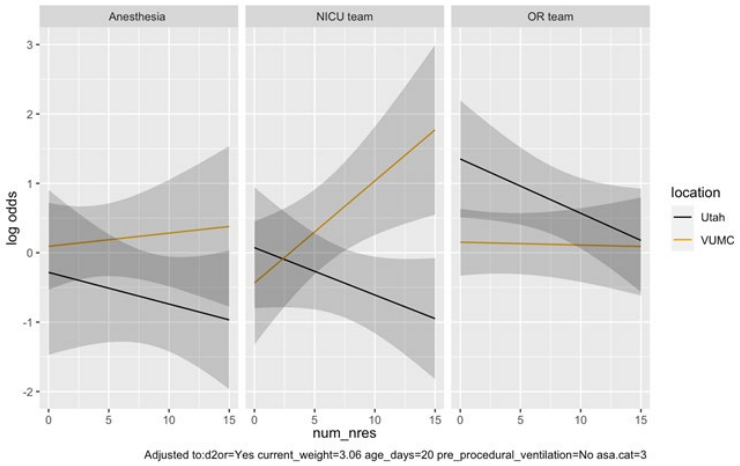

Figure 4. Interaction Between Clinical Micro-Team and Location (Hospital)

Summary of Aim 2 findings

SOS was negatively associated with the number of clinician-reported NREs at PCH. That is, teams with higher SOS scores reported fewer NREs per case. Both hospitals exhibited high rates of NRE incidence in neonatal surgeries. Clinicians at PCH reported significantly more NREs per case than clinicians at VUMC. However, the severity of clinician-reported NREs was significantly higher at VUMC than PCH. There was a significant interaction effect between NRE reporting by micro-team and hospital site. Higher SOS scores were significantly inversely related to the number of NREs reported by OR teams at PCH.

B.3. Specific Aim 3

Our research team audio and video (AV) recorded 23 neonatal surgical cases, in which we collected self-reports of CM from clinicians postoperatively. The dataset included four recordings of the preoperative phase, including NICU-to-OR handover; 17 recordings of the operative phase; and two recordings of the postoperative phase, including OR-to-PACU or NICU handover. Dr. France, Dr. Slagle, and Dr. Vogus created a behavioral marker observational checklist and rater guidebook for CM in neonatal perioperative care. SMEs – experts in HRO or perioperative care processes – used these tools to rate global CM and its five domains in the AV-recorded cases. The raters exhibited very high (>0.80) inter-rater reliability after independently reviewing a sample of cases. A concordance analysis comparing the SME ratings to clinicians' self-reported SOS scores collected after key perioperative care transitions was conducted as a preliminary validation of the CM behavioral marker system.

Summary of Aim 3 findings

Eighteen cases of the 23 total AV cases had corresponding clinician-reported SOS data. These 18 cases were used to complete the preliminary concordance analysis. Table 5 shows Kendall's W and its p values for global CM score and each of the scores of the five HRO principles. The results of this initial pilot study do not show significant agreement between either the global score or the principle scores.

Table 5. Results of Concordance Analysis of SME CM Rating Versus Clinician Self-Reported Ratings

Measure	Kendall's W	p value*
Global CM Score	0.568	0.311
CM Principle Scores		
Preoccupation with Failure	0.684	0.141
Reluctance to Simplify	0.704	0.121
Sensitivity to Operations	0.733	0.097
Commitment to Resilience	0.566	0.314
Deference to Expertise	0.642	0.191

*Level of Significance, $p < 0.05$

C. Discussion and Conclusion

This study successfully adapted the Safety Organizing Scale (SOS) for application to the perioperative domain. The SOS was modified and made available in two formats – a REDCap web-based survey to measure CM at the hospital unit level and a paper-based version designed to collect perceived CM after acute care episodes (i.e., NICU-to-OR handovers and neonatal surgeries). Our results show that perceptions of CM did not vary on average in surgical cases observed at two academic medical centers but did vary across hospital units, clinical teams, and clinician types or roles. Our study found a direct inverse relationship between team SOS scores and NRE count at one hospital (PCH) that was characterized by high NRE reporting rates and low incidence of severe NREs. The study did not find a significant relationship between CM and NRE incidence or severity, or 30-day postoperative outcomes, at VUMC. Finally, we developed a new CM behavioral marker checklist for prospective use in the perioperative environment or for retrospective AV review. The concordance analysis in this initial pilot study did not establish agreement between SME CM ratings and self-reported clinician ratings. However, the pilot study was not powered to be definitive. Future research is needed to (1) further translate and map the SOS survey for other clinical settings and applications; (2) further validate the relationship between observed and perceived CM using the CM behavioral checklist; and (3) elucidate the complex relationships between SOS, teamwork, team dynamics, safety reporting, and patient safety outcomes.

D. Significance

This AHRQ-funded pilot study was the first to study collective mindfulness or safety organizing in interdisciplinary clinical teams that provide patient care that spans time (preoperative to postoperative) and crosses clinical settings (NICU to OR and

back to NICU). Additionally, the study is to first to examine the relationship between safety organizing and event reporting in healthcare.

E. Implications

There is ample opportunity and need to advance education and team training in safety organizing to measurably improve patient safety. The relationship between collective mindfulness (safety organizing) is complex and is worthy of additional research and investigation. For example, our research findings may lend weight to the argument that highly reliable, safe perioperative teams report more NREs but experience few severe NREs that result in adverse patient outcomes. VUMC and PCH were characterized by high NRE case rates and high SOS scores. Subsequent research at VUMC has demonstrated that high NRE case rates were not associated with adverse 30-day postoperative outcomes, as measured by the National Surgical Quality Improvement Program – Pediatric (NSQIP-P). Finally, there is a need to understand the factors that determine how clinicians perceive and rate their own clinical teams.

F. List of Products

1. France DJ, "The Impact of Non-Routine Events on Neonatal Safety in the Perioperative Environment," Vanderbilt Department of Biomedical Informatics Lecture Series, April 26, 2018

2. France DJ, "The Impact of Non-Routine Events on Neonatal Safety in the Perioperative Environment," University of Utah, Departments of Pediatrics (Neonatology) and Pediatric Surgery, June 11 & 13, 2018

3. Schremp E, France DJ, Grubb P, Blakely M, Lorinc A, Lehmann CU, Vogus T, Evaluation of safety organizing behaviors in perioperative teams, *IARS 2019* Annual Meeting and International Science Symposium, Montreal, Quebec, May 20, 2019

4. France, DJ; Slagle, J; Rhodes, E; Schremp, E; Moroz, S; Grubb, P; Hatch, L; Lorinc, A; Newman, T; Shotwell, M; Robinson, J; Weinger, M; Blakely, M. The Association between Non-Routine Events and 30-Day Post-Operative Morbidity and Mortality in Neonates Requiring Surgery. Pediatric Academies Society, 2021

To-Be-Published Data Collection Instruments: Collective Mindfulness Behavioral Marker Observational Checklist and Rating Guidebook

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