

TITLE PAGE

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

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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 1-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. 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 I L H R O principle scores.

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

I. PURPOSE

High-reliability organizations (HROs) such as aircraft carrier flight decks and nuclear power plants² 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 *the five C's*) 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 intensive care units (NICUs).

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 3-year pilot, we characterized CM behaviorally in NICU and OR teams and measure the 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:

Conduct a prospective observational pilot study of NICU and OR teams to a) estimate the prevalence of 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.

Determine the effects of perceived CM on the incidence and severity of NREs occurring during and across phases of neonatal perioperative care.

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) 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, tell

L Q G H S H Q e p o n t e M R E s and associated performance shaping (or contributory) factors. We also continuously audio D Q G 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 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 D Q G 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 Vogus⁹¹ 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 1 b, 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, in 2012 e/f @ sw 76.744m e a) 6e222 (a collected fj -0.036 Tw (0122Tw 31.796f24 Tw ((C Tw (s)Tj -0.0

D U H U H (i.e., ZMLC 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

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 QLI-QSOS Safety Organizing Scale (SOS) to providers in each team. The SOS was reworded to ask about ‘the care provided for baby during 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) were 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. 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 D 3) 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^{6,90}. NRE counts are reported as an overall rate (RE4 (c)

\$ O W K R X J K 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 generally¹⁰⁴⁻¹⁰⁷ 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 that views the contributions of individuals and teams embedc 0.048 Tw (/Reference <</MCID I382 -14.ams)Tj -0.06 T anganizationsa

Archived AV-recorded cases (i.e., from past research studies)

Y D U L D E a d d i n g i n t e r c e p t m o d e l , i n d e x e d b y c a s e , w a s u s e d t o a c c o u n t f o r c o r r e l a t i o n a m o n g N R E c o u n t a n d s e v e r i t y m e a s u r e m e n t s i n c a s e s w h e r e m u l t i p l e N R E s w e r e r e p o r t e d . A s e c o n d r a n d o m i n t e r c e p t m o d e l , i n d e x e d b y w o r k i n g s u r g e o n , w a s e m p l o y e d t o a c c o u n t f o r c o r r e l a t i o n a m o n g N R E c o u n t a n d s e v e r i t y a c r o s s c a s e s w i t h w o r k i n g s u r g e o n i n c o m m o n . ¹¹⁰¹¹¹ N a t u r a l c u b i c s p l i n e s w e r e u s e d t o m o d e l t h e e f f e c t o f c o n t i n u o u s I V s s u c h t h a t l i n e a r i t y w a s n o t a s s u m e d . R i d g e r e g u l a r i z a t i o n ¹¹² w a s u s e d t o a v o i d m o d e l o v e r f i t t i n g , l i m i t e d b y t h e d e g r e e o f f r e e d o m u n l i m i t e d b y f i n a l e f f e c t i v e s a m p l e s i z e . ¹¹³ B o o t s t r a p m e t h o d s w e r e e m p l o y e d f o r m o d e l v a l i d a t i o n . ¹¹³ A l l s t a t i s t i c a l a n a l y s i s w a s p e r f o r m e d u s i n g R (s t a t i s t i c a l s o f t w a r e) a n d t h e c o n t r i b u t e d p a c k a g e s r m s , n l m e , a n d l m e r . 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 kappa¹¹⁸¹¹⁹ 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 > 0.61 was considered substantial agreement

(e) [TJ2139y33 (r-6668080-16 (a) 8.988.3841 (e) ad (2.95383-660325 (a) 97.274 (a) 2) 429 (e) 6 (6848) 76 (a) 22]

A. Summary of accomplishments by Specific Aim:

\$ 1. Specific Aim 1

x We administered a REDCap version of

B. Results by Specific Aim

B.1. Specific Aim 1

Descriptive Statistics of Unit- /evel Collective Mindfulness at VUMC

Q9	363	5.00	6.00	6.00
SOS Score	354	4.00	5.00	6.00

Descriptive Statistics of CaseLevel 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 SOSscores.

Table 3. Descriptive Statistics for Pooled (N = 370 cases) Case- /evel
 Post Rperative SOS Responses at VUMC (N = 310) and PCH (N = 60)



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 VFR at VUMC found scores to be , and the greatest team-to-unit difference was found in NICU clinicians (mean SOS scores: Unit = 4.9 Y H U Team = 5.9).

Comparative Analysis %etween Team (&se) Level SOS Scores ta VUMC and PCH

CM self-reports were collected in 370 surgical cases at Vanderbilt (Ut case)

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 event in the perioperative care of neonates requiring surgery. This sub-analysis showed WICU nurses scored CM higher in their

teams decreased. This finding was not observed at VUMC. There was no association between composite SOS scores and NRE severity D I W H U 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)	S Value
Infant weight at surgery (kg), median (IQR)	3.2 (1.3)	2.8 (1.1)	S < 0.001
Age (days), median (IQR)	25.0 (72)	7.0 (46)	S = 0.002
Cases with at least one NRE, %	83%	98%	S < 0.002
NREs per case, mean (std)	3.4 (3.0)	7.8 (4.5)	S < 0.001
NRE Severity (1: minimum, 5: maximum), median (IQR)	2.2 (1.3)	2.0 (0.5)	S < 0.002
Safety Organizing Score (SOS) (1: min, 7: max), median (IQR)	5.9 (0.8)	5.8 (0.7)	p < 0.0001

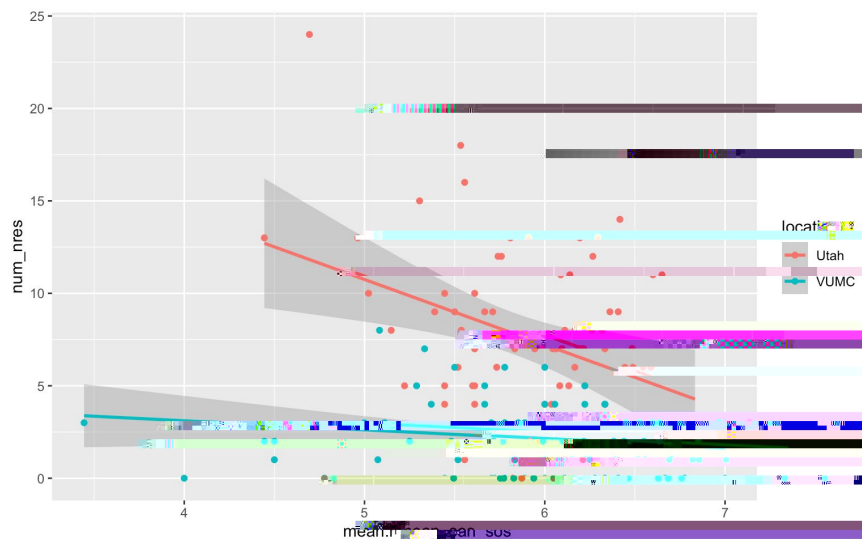


Figure 3. SOS Score versus number of NREs reported by hospital

Table 4. Results of Multiple Ordinal Regression

	$\hat{\beta}$	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

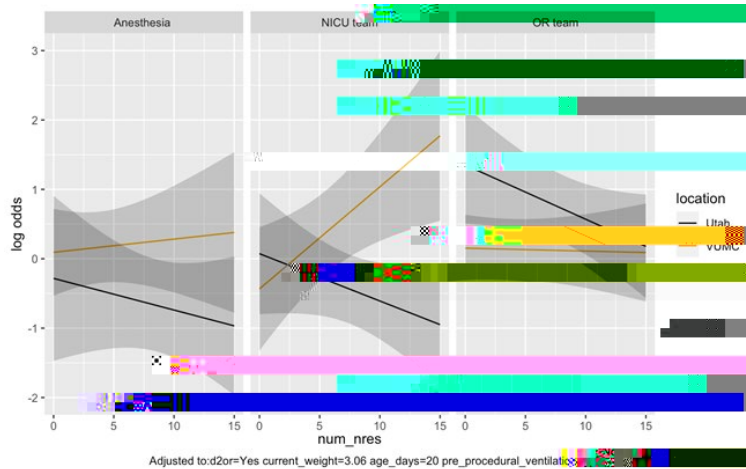


Figure 4. Interaction between clinical Micro-Team and location (+ospital)

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 D Q G video (AV) recorded 23 neonatal surgical cases in which we collected self-reports of CM from clinicians postoperatively. The dataset included 17 recordings of the preoperative phase, including NICU-to-OR handover, 17 recordings of the operative phase, and 17 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 R U perioperative care processes – used these tools to rate global CM and its I L Y H 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 Z D V conducted as a preliminary validation of the CM behavioral marker system.

Summary of Aim 3 findings

Eighteen cases of the 23 total *A/* cases had corresponding clinician-reported SOS data.

These 18 cases were used to Tw (A)Tj -0.02084 Tw Td (mplete the7 Tw ()TTj 0.0)TTj 0Td prelime /ry

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 measurability

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