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# Utilizing Human Factors to Improve Perioperative Adverse Event Investigations: An Integrated Approach

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## APPLYING SYSTEMS THINKING TO IMPROVE PERIOPERATIVE ADVERSE EVENT

### INVESTIGATIONS

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### Utilizing Human Factors to Improve Perioperative Adverse Event Investigations: An

#### **Integrated Approach**

## Abstract

**Objective:** Apply Human Factors (HF), systems engineering, and high reliability organizational principles to improve adverse event investigations in a regional hospital system. **Background:** Given the complexity of medicine and healthcare systems, innovative thinking is required to ensure these systems are resilient to error. Understanding the work system and its constituent parts is fundamental to understanding how errors begin and propagate. **Method:** This paper provides a discussion on employing a systems-based approach to improve perioperative adverse event investigations within a hospital system. **Results:** Data was collected across 13 investigations. The findings are summarized into 16 contributing factors, with 10 specific examples of critical/serious risks that were addressed by the hospital system. **Conclusion:** Modern medicine needs to look to HF to improve safety and reduce errors. This manuscript provides a systems-based approach grounded in HF and organizational theories to improve how

investigations are conducted and the approach to human error within a large hospital system.

Application: This work provides practical guidance for those who want to improve

postoperative investigations within their own units or hospitals.

**Precis:** This article describes research that evolves the approach to accident investigation to improve perioperative adverse event investigations in hospital settings.

**Keywords:** Accident analysis, anesthesiology/perioperative care, patient safety, communication and teamwork, care transitions and handoffs, organizational behavior/design

#### INTRODUCTION

Modern HF work in the medical setting focuses heavily on leveraging a systems-based approach to understanding and preventing the propagation of errors (Russ et al., 2013). Current estimates have deaths related to medical error as high as 250,000 per year in the U.S. (Makary & Daniel, 2016); although, others calculate deaths closer to 50,000 per year (Shojania & Dixon-Woods, 2017). According to Senders (1994), *"human error in medicine, and the adverse events that may follow, are problems of psychology and engineering, not of medicine."* Despite increased recognition of the value of the field of HF and, more importantly, systems thinking to prevent medical error, adoption has been "sluggish" (Gurses, Ozak, & Pronovost, 2012).

A systems-based approach to review cases to comprehend the contributory factors to adverse events in healthcare is lacking. Currently, patient chart reviews, grand rounds, incident reporting, and morbidity and mortality conferences all serve as means to investigate medical errors and safety events. Unfortunately, they often take a narrow approach. For example, task work (i.e., clinical topics) is typically the primary discussion, thereby, excluding teamwork even though it is critical to providing safe care (Mitchell et al., 2012). As another example, adverse

event reviews often target individual contributions as opposed to the understanding how other factors (e.g., organizational policies, equipment, or environmental layout) may have contributed to an event. These examples illustrate that while the medical community has certainly made strides regarding understanding and preventing errors, the mechanisms surrounding the analysis of adverse events need additional advancement for the discipline to progress towards providing consistent, quality, and safe care.

Therefore, the purpose of this paper is to examine an integrative approach utilizing a human factors/systems engineering perspective for investigation surrounding perioperative death (i.e., a death of a patient within 48 hours of a surgical procedure) in a hospital system: the Critical Event Response Team (CERT). Having this goal in mind, we will first discuss the background that served as the foundation to the investigation approach. Next, we detail the methods of the approach and the results of implementing the approach. We then conclude with a discussion of the limitations and the implications for theory and practice.

## **BACKGROUND: TAKING A SYSTEMS PERSPECTIVE**

## State of the Hospital System Prior to the Critical Event Response Team

A community hospital system using a root cause analysis (RCA) process expressed their desire for an alternative approach to adverse event investigation with the aim to further improve patient safety. The main impetus was that the hospital mortality review noticed that some patients who entered surgery with seemingly benign procedures expired unexpectedly. The system's RCA process facilitated some understanding of error in the context of perioperative deaths; however, the existing approach did not tie outcomes to actions, was narrow in scope regarding the topics covered, and had no HF expertise involved. The existing

RCA process also occurred over months rather than days and was generally inflexible. Further, there tended to be little, if any, direct communication or involvement of physicians to the outcome of RCA investigations. Mainly physicians gave insight into chart reviews but were left out of the process aside from this contribution.

Recognizing the limitations of the process that was being employed by the hospital, we sought to enhance the investigatory process by employing a systems-based approach rooted in human factors and organizational principles. The principles we leveraged strengthen the entire process from developing the investigatory team and process to collecting and analyzing the data as well as disseminating findings and sustaining change. For a list of these principles, refer

to XXXX.

Empower	Collect	Analyze	Inform	Change
Receive top-down support <sup>1,3</sup> Dedicate funds to investigations <sup>1,3,4</sup> Leverage a systems- based approach <sup>4</sup> Create a CERT <sup>7</sup> Employ an objective trigger system to mitigate potential bias <sup>3</sup> Trigger review within 48 hours of an event <sup>3</sup> Schedule interdisciplinary team interviews <sup>1,4</sup> Ensure a flexible schedule beforehand4 Avoid a blame culture <sup>1,3</sup> Reassure interviewees that the data will not be used for blame <sup>1,3</sup>	<ul> <li>Utilize systems-based interview questions (tasks, tools, technology, individuals and teams, environment, organization)<sup>3</sup></li> <li>Select individuals to be interviewed specifically staff on that floor about equipment, tools, and environmental factors<sup>1,3,4</sup></li> <li>Interview varied medical professionals1</li> <li>Conduct walk-throughs of the space of the event<sup>1</sup></li> <li>Examine tools involved (if applicable)<sup>2</sup></li> <li>Leverage a clinical and HF interview interview protocol<sup>2</sup></li> <li>Gather internal reports (EMR, shift reports, risk department report)<sup>3</sup></li> </ul>	<ul> <li>Include independent HF expert review<sup>3</sup></li> <li>Conduct a content analysis<sup>2</sup></li> <li>Categorize risk levels<sup>3</sup></li> <li>Identify key themes<sup>2</sup></li> <li>Create superordinate categories based on findings<sup>2</sup></li> <li>Aggregate HF findings into factors<sup>2</sup></li> <li>Include non-causal but problematic factors<sup>2,3</sup></li> <li>Reach consensus<sup>2</sup></li> </ul>	<ul> <li>Conduct debriefs after every investigative event<sup>1</sup></li> <li>Generate report of findings<sup>2</sup></li> <li>Distribute report from investigation to Chief Quality and Medical Officers for final review<sup>3</sup></li> <li>Distribute final report to interviewees and other relevant stakeholders<sup>1,3</sup></li> </ul>	<ul> <li>Identify actions and assign champions to lead post-review change<sup>2</sup></li> <li>Leverage the diverse expertise of your Human Factors specialists<sup>2</sup></li> <li>Involve hospital leadership in post- review decision making</li> <li>Cultivate a non-punitive culture by encouraging discussion on systematic issues<sup>3</sup></li> <li>Focus on measurement to understand longitudinal change<sup>2</sup></li> </ul>

Legend - 1. HRO, 2. Novel to CERT, 3. RCA2, 4. SEIPS

#### Figure 1. Review of how each investigative aspect was applied to the investigative process

#### METHOD

The following sections describe the methods relating to preparation, active case procedures, and data processing and synthesis. While the CERT method is a multidisciplinary approach including both medical personnel and Human Factors specialists, the Human Factors specialists guided the framework and process development and were integral to the implementation of the methods. Two of the human factors specialists (EHL & JRK) have extensive experience with both having worked for over 12 years in HF/E applied to medical systems. The third human factors specialist (EB) had approximately 20 years experience interviewing domain experts working in both military and commercial aviation complex systems.

A summary of the approach is delineated in Figure 1.

## **Interview Protocol**

A key component of the CERT approach is a retrospective interview protocol. To ensure that the interviews targeted all aspects of the system while still being clinically appropriate, the HF psychologists and medical experts developed a semi-structured, retrospective interview protocol. The SEIPS 2.0 model (Holden et al., 2013) was a primary driver for the question generation and organization process. The questions fall into categories: tasks, tools/technology, individuals and teams, the environment, and the organization. Leveraging the SEIPS 2.0

organizational schema ensured comprehensive coverage of the entire system surrounding an adverse event. Further, the clarity that SEIPS 2.0 focus on tasks, individuals, tools, or policy provides, also facilitates subsequent change (Stanton, 2017). Simply stated, the focus is on gathering information that will later point to solutions. See Table 1 for example questions.

## Table 1.

Example questions from Interview Protocol

1.	el Background:
	What is your position at the hospital?
2.	How long have you worked in the field? At this hospital?
3.	What shift were you working during the incident?
	thesiologists
1.	How many cases were you managing?
2.	Were you originally assigned to take care of this patient?
3.	Did you have adequate time to prepare?
Task:	
Critical I	
1.	In your own words, what happened?
	a. Can you give an overview of the incident?
	b. (after the interviewee gives an overview, we can begin probing questions below)
Prior to s	
1.	Were there any concerns in the preparation of this patient? (If so, please describe)
2.	Was the patient properly prepared to go to surgery?
3.	Did you have all the information you needed for this case going in?
During t	he surgery
1.	Where did the situation/case/ process go wrong? In your opinion, when did things start going south? What was
	happening?
2.	In your opinion, what were the causes of the incident? What steps or events were involved in (contributed to) the
	incident?
Provider	
	/Team:
Continui	/Team: ty/Teamwork/Training
Continui	<b>/Team:</b> ty/ <i>Teamwork</i> /Training What was the team size for the task?
Continui	/Team: ty/Teamwork/Training What was the team size for the task? a. Was it an appropriately sized team for this task?
<u>Continui</u> 1.	/Team: ty/Teamwork/Training What was the team size for the task? a. Was it an appropriately sized team for this task? b. Who do you view as the leader of the team?
<u>Continui</u> 1.	/Team: ty/Teamwork/Training What was the team size for the task? a. Was it an appropriately sized team for this task? b. Who do you view as the leader of the team? What were the tasks, roles, and responsibilities of team members/providers?
<u>Continui</u> 1.	/Team: ty/Teamwork/Training What was the team size for the task? a. Was it an appropriately sized team for this task? b. Who do you view as the leader of the team? What were the tasks, roles, and responsibilities of team members/providers? a. Were the tasks, roles, and responsibilities of each provider clearly defined?
<u>Continui</u> 1. 2.	<ul> <li>/Team: ty/Teamwork/Training</li> <li>What was the team size for the task?</li> <li>a. Was it an appropriately sized team for this task?</li> <li>b. Who do you view as the leader of the team?</li> <li>What were the tasks, roles, and responsibilities of team members/providers?</li> <li>a. Were the tasks, roles, and responsibilities of each provider clearly defined?</li> <li>b. To your knowledge is every team member aware of his or her role in the team?</li> </ul>
<u>Continui</u> 1. 2. 3.	<ul> <li>/Team: ty/Teamwork/Training</li> <li>What was the team size for the task?</li> <li>a. Was it an appropriately sized team for this task?</li> <li>b. Who do you view as the leader of the team?</li> <li>What were the tasks, roles, and responsibilities of team members/providers?</li> <li>a. Were the tasks, roles, and responsibilities of each provider clearly defined?</li> <li>b. To your knowledge is every team member aware of his or her role in the team?</li> <li>During the surgery, were there any changes in providers?</li> </ul>
<u>Continui</u> 1. 2. 3.	<ul> <li>/Team: ty/Teamwork/Training</li> <li>What was the team size for the task?</li> <li>a. Was it an appropriately sized team for this task?</li> <li>b. Who do you view as the leader of the team?</li> <li>What were the tasks, roles, and responsibilities of team members/providers?</li> <li>a. Were the tasks, roles, and responsibilities of each provider clearly defined?</li> <li>b. To your knowledge is every team member aware of his or her role in the team?</li> <li>During the surgery, were there any changes in providers?</li> <li>a. Was there a shift change during surgery?</li> </ul>
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Continui 1. 2. 3. <u>Workloa</u> 1.	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?       a.         was there a shift change during surgery?       d. Information and Distractions         Was all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.
Continui 1. 2. 3. <u>Workloa</u> 1.	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?       a.         a.       Was there a shift change during surgery?         d. Information and Distractions       Was all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.         What was the level of workload during this case?       To workload during this case?
Continui 1. 2. 3. <u>Workloa</u> 1.	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?       a.         a.       Was there a shift change during surgery?         d. Information and Distractions       Was all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.         What was the level of workload during this case?       a.       Do you think workload was a factor in this case?
<u>Continui</u> 1. 2. 3. <u>Workloa</u> 1. 2.	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?         a.       Was there a shift change during surgery?         d. Information and Distractions         Was all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.         What was the level of workload during this case?         a.       Do you think workload was a factor in this case?         b.       If so, what was the main source of high workload during this case?
<u>Continui</u> 1. 2. 3. <u>Workloa</u> 1. 2. 3.	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?       a.         a.       Was there a shift change during surgery?         d, Information and Distractions       Mas all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.         What was the level of workload during this case?       a.         b.       If so, what was the main source of high workload during this case?         b.       If so, what was the main source of high workload during this case?         a.       Describe these distractions/interruptions.
Continui 1. 2. 3. Workloa 1. 2. 3. Materia	/Team:         ty/Teamwork/Training         What was the team size for the task?         a.       Was it an appropriately sized team for this task?         b.       Who do you view as the leader of the team?         What were the tasks, roles, and responsibilities of team members/providers?         a.       Were the tasks, roles, and responsibilities of each provider clearly defined?         b.       To your knowledge is every team member aware of his or her role in the team?         During the surgery, were there any changes in providers?       a.         a.       Was there a shift change during surgery?         d, Information and Distractions       Mas all necessary information available, accurate, and complete? Any missing? Incomplete? Please describe.         What was the level of workload during this case?       a.       Do you think workload was a factor in this case?         b.       If so, what was the main source of high workload during this case?       Were distractions or interruptions a factor in this case?

3. Was everything that you needed (equipment and tools) available in a timely fashion? (E.g., blood products, rapid transfusion equipment, surgical devices, additional personnel, and etc.).

#### Organization/Process:

- 1. Describe the culture of the hospital.
- 2. How was the continuity of care?
- 3. Describe the handoff process used when giving and receiving a handoff.

#### Preparing the Critical Event Review Team (CERT)

Next, the Human Factors specialists developed and implemented two 4-hour training sessions for the medical personnel on the CERT. The purpose of this training was to familiarize the medical domain experts with the approach, rationale, and the cognitive interviewing procedures. Two training sessions occurred. The first training session described and discussed basic principles of Human Factors, systems engineering, and healthcare Human Factors research in general. Once the medical personnel were familiar with these concepts, the Human Factors specialists conducted a second training session to explain effective interviewing techniques and demonstrated the interview procedure.

## **Establishing a Trigger for Investigations**

The primary trigger for the investigation team was a perioperative death; the trigger was any patient death within 48 hours of a surgical incision. Two exclusion criteria were used, based on following: 1) the patient's preoperative rating/health score according to the American Society of Anesthesiologists (ASA) physical classification system (also known as the "ASA score") and 2) the patient's Preoperative Score to Predict Postoperative Mortality (POSPOM) score (Le Manach, 2016). The ASA score is a global assessment conducted by the attending anesthesiologist that relies on both objective values (e.g., laboratory tests) and subjective data (e.g. patient interviews). This data is utilized to categorize the overall health of a surgical

patient into one of six categories for living patients. The range is from "1" (normal healthy patient) to "6" (brain-dead patient). Although use of the ASA physical class assignments/scores is ubiquitous, the rating systems suffers from a lack of scientific reliability (Owens, 1978). In contrast, POSPOM, a highly sensitive and specific risk calculator, is based on validated 17 variables out of three domains: Age, co-morbidities and surgery type (Le Manach, 2016). Generally, the reviews focused on individuals who had low ASA (<4) and POSPOM scores (<20% risk of mortality from surgery) that were considered to be at minimal risk for perioperative death by the domain experts.

## **Investigation Method**

The CERT team aimed to conduct the investigations within 72 hours of the event to reduce interviewee memory decay from impacting the results. Furthermore, each investigation used three channels of information: 1) organization internal reports related to the case (e.g., electronic medical record, shift reports, risk department report), 2) physical walkthrough inspection and examination of technology/devices where the incident occurred, and 3) interviews with providers and other staff surrounding the perioperative event procedure.

When a perioperative death occurred within 48 hours of surgery, two CERT medical domain experts (e.g., surgeon, anesthesiologist) were alerted. These two individuals reviewed the internal reports, the patient's ASA and POSPIM scores, and made the determination if the case was appropriate for the CERT team to investigate. The reviews focused on individuals who had low ASA and POSPOM scores that were at minimal risk for perioperative death by the domain experts. Once the case was approved for CERT investigation, the CERT team members were notified, and within 24 hours, the team members discussed the case via conference call to

select interview participants. While the medical personnel discussed clinical diagnostics, the HF specialists maintained the systems perspective. Maintaining a systems perspective helped to ensure that a broad range of providers and personnel were considered for selection in in the subsequent interview process. After identifying the desired interviewees, CERT team members of the same expertise reached out to the respective individuals, explained CERT, and invited them to be interviewed. For example, if the CERT team desired to interview an anesthesiology who had worked on a case, then an anesthesiologist on the CERT team would contact that individual. The purpose of the expert-to-expert conversations and interview invitations was to increase trust, buy-in and participation in the interview process.

When the Human Factors scientists arrived on-site for the interviews, they participated in a walkthrough of the area(s) in which the case occurred. The purpose of the walkthrough was to provide the HF specialist and other team members the opportunity for a visual inspection of the physical layout. Having a conceptualization of the physical layout was important for the CERT team to understand subsequent interviewee responses related to descriptions of the physical space and to consider layout related factors. Since the Human Factors specialists were not familiar with the locations, they could provide unbiased views of the surroundings

#### **Interview Procedure**

After the initial review of the related internal reports and the walkthroughs, the team conducted the retrospective, semi-structured interviews. A HF scientist led the interview process and was present for all interviews for that case. The purpose of having the HF specialist lead the interviews was to maintain a systems perspective, to establish a non-threatening

environment to help interviewees feel comfortable, and to ensure a valid and reliable datacollection process that comes with an experienced interviewer. Additionally, the HF scientist was joined by at least one provider with relevant domain expertise for the respective interviewee (e.g., an anesthesiologist was on the interview team when an anesthesiologist was being interviewed; a surgeon was on the interview team when a surgeon was interviewed). The domain expert would ask additional questions and clarify jargon and relevant terms as needed. Lastly, individuals from the hospital's risk management department, including a scribe, joined the interviews and provided background information about the timeline and patient history. At the beginning of each interview, the interviewe was briefed on the procedure and purpose of the interview and asked if they were willing to be audio recorded.

#### Post-processing and final report creation

Following the interviews for each respective case, the scribe transcribed the audio recordings (and/or prepared for review any written/typed interview notes for those individuals who did not consent to be recorded) and delivered the interview data to the HF scientists. The content analysis involved reading the transcribed interviews and identifying key themes that occurred (e.g., more than one interviewee stating that a distraction had occurred). The scientists performed the work independently to minimize any potential bias based on the perspectives of the other scientists. After all three HF scientists finished content analyzing the transcripts, the scientists aggregated the findings into factors contributing to the incident. The scientists resolved any disagreements through consensus meetings. The HF scientists then synthesized the findings into a report and submitted the aggregated findings/report to the team's domain experts for review. Following, the entire CERT team (HF scientists and domain

experts) conducted a debrief. During the debrief, the HF scientist led in-depth discussions about the factors that the report highlighted. During this debrief, the CERT team would rank issues uncovered during the case into one of four categories based on how widespread the issue is and how much risk it introduced into the system (Table 2). Classifying issues into these severity ratings provides guidance to the organization on which areas to apply resources and a reasonable timeline for completion. This research complied with the American Psychological Association's Code of Ethics and was approved by the hospital systems Chief Quality and Safety Officer and offices of Risk Management and Patient Safety. As such, this study qualified as Quality Improvement and did not necessitate an approval from the Institutional Review Board.

Overall, the entire process takes approximately 20 hours of time in total for the HF researchers, approximately 15-30 hours for the transcriptionists, and approximately 1-8 hours for each provider depending on the number of individuals in their profession that were involved in the interviews.

## Table 2.

Risk level and description adapted from the RCA2 process

Risk Level	Description
Critical Systemic	Issue is widespread and could lead to immediate adverse events
Serious Systemic	Issue is widespread and could lead to adverse events if not resolved soon
Systemic Risk	Issue is widespread, risk is uncertain, issue should be investigated
Unrelated systemic	Potential issue that was unrelated to investigated event but that could lead to adverse events in other circumstances

#### RESULTS

The team reviewed 13 cases between 2016 - c2020. One case was removed from the results due to issues surrounding recruitment of relevant interviewees involved in the case. The team conducted 89 interviews across the 12 retained cases. Among the 89 interviews, interviewees included a variety of provider types (e.g., medical doctors, nurses, and technicians). Although the majority of our sample was registered nurses and anesthesiologists (48% and 15%), we interviewed other professional roles and specialties as well. See Table 3 for the type and frequency of providers interviewed. Individuals had a wide range of experience ranging from less than a year to over 45 years working in their respective field.

## Table 3.

Types of	providers	and	averaae	vears	of	experience
1900305	providers	ana	average	years	σj	experience

Provider Type	Number of providers interviewed	Average Years of Experience (Range)
Anesthesiologist	14	17.5 (.5 – 32)
Anesthesia Technologist	1	8(NA)
Certified Registered	9	3.1 (1 – 7)
Nurse Anesthetist		
Surgeon	6	13.7 (3 – 20)
Surgical Technician	3	7.2 (5.5 – 9)
Surgical Resident	1	1.2 (NA)
Registered Nurse	43	14.8 (1 – 45)
Intensivist	2	17 (4 – 30)
Hospitalist	2	11.25 (2.5 – 20)
Cardiologist	2	8.5 (7 – 10)
Nephrologist	1	6 (NA)
Medical Oncologist	1	10(NA)
Critical Care Physician	1	1(NA)

Gastroenterologist	3	12.2 (5.5 – 20
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Across the 12 investigations, 87 contributing issues were discovered. Using content analysis, the HF specialists organized these 87 issues into thematic areas which resulted in 16 categories. These categories are listed in Table 4 with their respective frequency of instances that issue appeared during the 12 reviews. Of the factors that appeared in our reviews, the three most prevalent were machine/equipment issues (13 instances), patient health (12 instances), and teamwork (11 instances). All cases included multiple categories.

## Table 4.

## Contributing factor categories and frequency

Category Name	Description	Frequency
Machine/Equipment Issues	Issue with poorly designed or difficult to use machinery or equipment	13
Patient Health	Issues surrounding aspects of the patient's diagnosis/comorbidities	12
Teamwork	Issues with shared knowledge, skills, and attitudes amongst the perioperative team	11
Information Loss	Issues surrounding information flow or disruptions	8
Code Response	Issues with activities surrounding code blue events	6
Error Prone Processes	Issues surrounding highly risky or error susceptible processes	5
Organizational Culture	Issues related to organizational policy or standards	5
Scheduling/Staffing	Issues surrounding schedules, time of day, or understaffing	5
Workload/Fatigue	Issues with provider's being tired, overworked, or fatigued	4
Alerts/Alarms/Distractions	Issues related to extraneous alerts, noises, or other distractions in the environment	3
Bias	Issues related to bias in provider decision making	3

Care Continuity	Issues in the care transitions and patient movement	3
Multi-Team System	Issues with coupling between different units, floors, or hospital systems	3
Training Issues	Issues related to under-trained staff	3
Drugs	Issues due to effects of drugs or medications used in the perioperative setting	2
Results/Tests	Issues surrounding results/tests of the patient	1

#### Major findings and interventions from reviews

Across the twelve reviewed cases, we categorized 77 issues as *systematic* risk or *unrelated systematic* risk and ten issues as *critical systemic* or *serious systemic*. Due to the criticality and urgency inherent within the critical systemic and serious systemic ratings, these ten issues led to interventions. Refer to the previously mentioned Table 3 for definitions of the risk level ratings. These included a variety of issues with the most common issue surrounding machine/equipment and code blue responses. A list of the specific issue, the thematic factor and the subsequent recommendation or organizational actions after they were uncovered are presented in Table 5.

## Table 5.

#### Critical/Serious Systemic Risks and Recommendations/Actions

Issue	Factor(s)	Recommendation Given or Action Taken
Equipment issue with SURGINET software	Machine/Equipment Issues	Chief information officer was notified day of interview. Action plans were escalated and issue was resolved shortly after.
Lack of information sharing between separate hospitals	Multi-team system/Care continuity	Began investigation of methods for communicating between local regional hospitals
Lack of pre-operative care plan	Error prone process	Instituted need for using calculations to better understand

considering deep vein thrombosis		deep vein thrombosis risk
Lack of consideration of pulmonary hypertension as a serious perioperative risk	Patient Health	Anesthesia involved in development of pre-testing algorithm including pulmonary hypertension for surgical patients.
Too many individuals present during code blue	Code response	Teams should be limited in size of approximately 8 individuals. Individuals on code team should know what their responsibilities are. Due to bystander effect and social loafing extraneous individuals should be asked to leave the room/site of code. Shared with Code Blue committee
Staff unfamiliar with code blue process	Code Response/Training	Code Blue simulation should be consistently conducted in hospital, especially for newly on boarded staff. Debriefs should be conducted after codes. Shared with Code Blue committee
PYXIS machine failed to represent patient in its interface	Machine/Equipment Issues	Medication safety officer was notified and all machines/processes were put under review.
Sparking defibrillator	Machine/Equipment Issues	Shared with patient safety office
Delay in treatment due to inability to move patient through lobby	Care continuity/Organizational Culture	Chief Nursing Officer was notified to investigate and resolve
Confusing packaging for defibrillator pads/sponges	Machine/Equipment Issues	Immediate change in stocking procedure for crash carts

## DISCUSSION

Medicine is a complex system comprised of many dynamic, interdependent factors, and the occurrence of errors and adverse events is inevitable. However, how institutions detect, examine, and rebound from errors and adverse events can vary. To ameliorate the egregious consequences of adverse events, a systems-based approach is necessary.

To that end, we employed a unique approach compared to the more traditional patient chart reviews, morbidity and mortality conferences, and a root cause analysis that are typically performed when an adverse event arises. Specifically, the investigatory techniques synthesized the systems engineering in patient safety model (Holden, et al 2013), the root cause analysis

and action model (NPSF, 2015), and the principles underpinning high reliability organizational theory (Sutcliffe, 2011). By leveraging the systems engineering in patient safety model (Holden, et al, 2013), our investigative tools relied upon queries that targeted the tools and technology, the person (and teams), the organization, and the environment. By utilizing RCA<sup>2</sup> (NPSF, 2015) we categorized issues and risk levels to identify problems to determine the appropriate course of action for remediation. Additionally, we leaned heavily on the idea that any investigation should be void of blame and punitive actions as that hinders the discussion on errors and halts the advancement towards a safer system. Finally, our systems-based approach helps the organization move towards high reliability through pre-occupation with failures and errors, deferring to experts, having better sensitivity to the from line operations of the organization, using complex and intensive methods to understand complex problems, and maintaining resilience through innovative methods and interventions (Weick, Sutcliffe, & Obstfeld, 2008).

The theory driven methodology has several contributions compared to more traditional error investigative techniques. One contribution was the interdisciplinary nature of CERT that included both healthcare experts and HF specialists. One example of the importance of the interdisciplinary nature of CERT is the interview process. For an effective systems approach interview, it is essential to have interviewees who can speak to *all* the various facets of the case. As most researchers experienced in interviewing domain experts can attest, however, finding and engaging the necessary experts in a timely manner can be an onerous task. This is where the healthcare expert CERT members come in. That is, integrating aspects of Empower, Integrate, and Change (shown in Table1), the CERT process had healthcare experts on the CERT team reach out directly to the desired interviewees to explain the process and invite the

individuals for interviews. This simple, yet crucial step in the approach resulted in comprehensive interview participation in most of the cases.

Once the domain experts had secured the interviewees, we utilized HF specialists to lead the interviews. Just as the domain experts were key to obtain interviewee participation, the HF specialists were key to an effective data collection process. The benefits are twofold. First, the HF professionals were not employed within the organization, which empowered interviewees to be forthcoming since the HF professionals had no authority to influence interviewee's job security. Second, HF professionals did not have any established relationships with the interviewees, limiting the bias associated with familiarity. Additionally, the use of individual interviews rather than focus groups avoided potential for issues such as groupthink (i.e., a mode of thinking where unanimity overrides individuality; Whyte, 1989) and power distance (i.e., the degree of power over subordinates; Lee, Pillutla, & Law, 2000) which can influence responses.

Another key contribution was the timing of the investigative process. The investigative process entailed interviews that occurred within 72 hours of the event with the goal to limit memory decay. RCA2 investigations tend to suffer from time lags. Similarly, morbidity and mortality conferences are held monthly (e.g., Ksouri et al., 2010). Morbidity and mortality conferences can still have utility regardless of their frequency; however, limiting them to be conducted monthly does leave them susceptible to information loss. The emphasis on the guiding principles of HRO theory made timeliness a major goal of this approach -- a piece that has thus far appeared absent from other adverse event investigations.

Moreover, the investigative tool (i.e., semi-structured interview protocol) was also key. This interview protocol included questions regarding the tools and technology, the person (and teams), the organization, and the environment. The interview protocol targeted all facets of the system and ensured that the interview does not overly emphasize one area. To illustrate, an interviewer that concentrates on the technical expertise of a provider involved in the event may not uncover any equipment issues, the storage of medications, the process to obtain necessary equipment, the standardization of the handoff between providers and units, or distractions occurring in the unit but unrelated to that case, to name a few examples. Finally, we have created a change column in Figure 1 that describes the impactful effects this type of process can have on the organization. This included 1) identifying actions and assigning champions for leading post-review change; 2) leveraging diverse expertise of human factors specialists; 3) involve hospital leadership in post-review decision making; 4) cultivating a nonpunitive culture that focuses on systemic issues; and 5) focusing on measurement to understand organizational change longitudinally.

Despite these contributions, this effort had limitations. The first limitation is the small sample of cases reviewed. The limited cases were due to availability of resources (e.g., workload of CERT members) and to the pre-established inclusion criteria. On the flip side, the pre-determined criteria provided a systematic means to determine the case review as opposed to simply relying on interest, complexity, or other personal biases. Even though only twelve cases were reviewed, this included a relatively large sample of providers and, in particular, a variety of registered nurses. This leads to the second limitation: a low number of surgeons (~50%) that were willing to be interviewed. Although that number may be low, it was an

improvement over previous RCA processes in this hospital system. Additionally, many interviewees participated in each case, which resulted in the rich dataset due to their varied perspectives. Future work will need to focus on recruitment methods and interview scheduling strategies to encourage a higher participation rate for the surgeons involved in this type of review.

#### CONCLUSION

This paper detailed a process that leverages techniques and knowledge from the field of HF and Systems Engineering – a process that can guide healthcare organizations to better understand their own safety needs. This paper includes guidance for healthcare organizations to identify vulnerabilities within a particular system and areas for remediation. The process is grounded in the theoretical work of high reliability organizations, systems engineering in patient safety, and root cause analysis and actions. These theories provided a systems-perspective while minimizing bias and punitive culture. Consequently, organizations can benefit from providers discussing critical events and adverse events more openly. By providing insights regarding the critical events surrounding perioperative deaths, healthcare organizations will be better equipped to be resilient—rather than being debilitated--when critical events and adverse outcomes occur.

**Key Points:** 

This manuscript summarizes a novel HF approach for a set of 12 perioperative adverse event investigations.

Of the cases reviewed, 77 issues emerged. Of these, 10 were considered high enough risk for the hospital system to devise interventions. Some of these were enacted immediate changes to the system, while others are ongoing aspects of the systems process improvement efforts.

There is a benefit to using a systems-based approach rooted in HF and organizational theories when conducting adverse event investigations. These benefits range from a change in philosophy (e.g. don't blame the human) to methods and techniques to acquire data that can uncover issues and lead to positive systems change.

This manuscript provides a set of methods, techniques, and guidance that can be used to support other similar efforts, within medicine and potentially in other high risk domains.

#### **Declaration of interests**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

□ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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