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Perioperative Emergency Manuals for Low-Incidence High-Risk Events

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Copyright Acknowledgement Statement

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10/27/2019

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10/27/2019

Disclaimer

Due to the impact of the COVID19 Pandemic, 2020 graduates of the Daniel K. Inouye Graduate School of Nursing were deemed critical to the mission of caring for the health of the nation. All phases of the DNP Project were complete, and met the standards and rigors of a quality DNP Project with an abbreviated dissemination timeframe.

Abstract

Phase II Site: Wright Patterson Air Force Base

DNP Project Title: Perioperative Emergency Manuals for Low-Incidence High-Risk Events

Authors: Ryan Abraham, Stacey O'Donnell

Background or Problem/Issue: There was a suspected case of malignant hyperthermia in the perioperative environment. It was identified that the cognitive aid currently used to manage malignant hyperthermia was challenging to follow for the implementation of best-practice interventions.

Clinical Question or Purpose: In perioperative teams (P), how does the implementation of the Stanford Anesthesia Emergency Manuals and safety training (I), compared with current practices (C), affect adherence to critical management steps in low-incidence high-risk events such as malignant hyperthermia (O)?

Project Design: The design was a quality improvement project utilizing simulation-based training on Stanford Anesthesia Emergency Manuals.

Analysis of the Results: One group failed to diagnose malignant hyperthermia in the PACU, leading to a statistical outlier resulting in a skewed distribution. The group deferred nonparametric testing as the difference would be the result of a failure to diagnose malignant hyperthermia versus a deficiency related to checklist utilization.

Organizational Impact/Implications for Practice: Two structured simulations of malignant hyperthermia in the operating room and post-anesthesia care unit were constructed and added to the Wright-Patterson Medical Center simulation database for future use and training.

Perioperative Emergency Manuals for Low-Incidence High-Risk Events

Introduction

A patient at a military treatment facility experienced a suspected episode of malignant hyperthermia (MH) during a surgical procedure. Post-event debriefing identified difficulty in following the current cognitive aid used to guide the management of MH with best-practice interventions. This perioperative emergency is just one of the many low-incidence high-risk events that providers may encounter. The rare and complex nature of these incidences can leave health care providers inadequately equipped to respond with best-practice standards shown to improve patient outcomes (Arriaga et al., 2013).

Significance

The incidence of MH is roughly 1 in 170,000 patients making it a rare occurrence in the surgical population (Aderibigbe, Lang, Rosenberg, Chen, & Li, 2014). Early administration of Dantrolene has decreased mortality rates from MH by 70% (Larach, Brandom, Allen, Gronert, & Lehman, 2014). Dantrolene reduces the incidence of MH related complications when given early (Aderibigbe et al., 2014; Larach et al., 2014). The cost savings associated with the proper administration of Dantrolene for MH versus supportive care is approximately $196,000 (Aderibigbe et al., 2014; Larach et al., 2014).

Perioperative providers in the military experience similar low-incidence high-risk events as their civilian counterparts. A method to enhance preparation for these high-risk perioperative events are emergency manuals. The use of emergency manuals in simulated settings demonstrated significant improvement in adherence to critical steps. (Arriaga et al., 2013; Balki, Cooke, Dunington, Salman, & Goldszmidt, 2012; Burden, Carr, Staman, Littman, & Torjman, 2012; Dagey, 2017; Hardy et al., 2018; Hubert, Duwat, Deransy, Mahjoub, & Dupont, 2014;

Lipps et al., 2017; Marshall, 2013; St. Pierre, Luetcke, Strembski, Schmitt, & Breuer, 2017; Ziewacz et al., 2011). Additionally, emergency manuals were viewed positively by study participants who also voiced interest in pre-implementation training for subsequent successful utilization (Arriaga et al., 2013; Balki et al., 2012; Burden et al., 2012; Dagey, 2017; Renna et al., 2016). Emergency manuals are not provided in the operating rooms (OR) or the Post Anesthesia Care Unit (PACU) at the project location.

The benefit of manual use in these high-risk events is improved patient outcomes via timely evidence-based standardized interventions. Improved patient outcomes, safer care , and reduced adverse and sentinel events translates into financial savings for the Department of Defense Military Health System. Improved training and practice guidelines support the Military Health System's mission to be a high-reliability organization while improving military readiness.

Clinical Question

In perioperative teams (P), how does the implementation of the Stanford Anesthesia Emergency Manuals and safety training (I), compared with current practices (C), affect adherence to critical management steps in low-incidence high-risk events such as malignant hyperthermia (O)?

Focus Areas

The specific focus areas for this evidence-based project include:

- identification of current response deficiencies to MH through simulation
- implementation of training on the Stanford Anesthesia Emergency Manual
- evaluation of staff response to MH through the use of simulation and availability of the Stanford Anesthesia Emergency Manuals
- provide a plan for manual implementation to the perioperative departments.

Relevance to Military Nursing

Studies suggest that the use of emergency manuals by all perioperative staff resulted in a 75% reduction in dosage and sequence errors associated with low-incidence high-risk events (Arriaga et al., 2013). Although not presently quantifiable, the overall impact of this evidence-based project, if implemented on a larger scale, could stem from faster provider response time resulting in improved patient outcomes. Two structured simulations of MH in the operating room and post-anesthesia care unit were constructed and added to the Wright-Patterson Medical Center simulation database for future use and training. These simulations are available for use by all perioperative personnel to maintain deployment and readiness skills training requirements.

Organizing Framework and Change Theory

We used the Revised Iowa Model for Evidence-Based Practice (EBP) (Figure 1) as an organizing framework to guide training and policy formulation for implementation of the Stanford Anesthesia Emergency Manuals. Pettigrew and Whipp's "Strategic Management of Change" theory was used to organize the clinical approach to emergency manual implementation.

The Iowa Model begins with the identification of five triggering issues and opportunities as potential gaps in healthcare resulting in a clinical question to be addressed (Buckwalter et al., 2017). Next, the model utilizes a flow diagram to prioritize a topic, formulate a team, synthesize the evidence available, ensure sufficient evidence for implementation, design/pilot change, evaluate results, integrate, sustain, and disseminate results (Buckwalter et al., 2017).

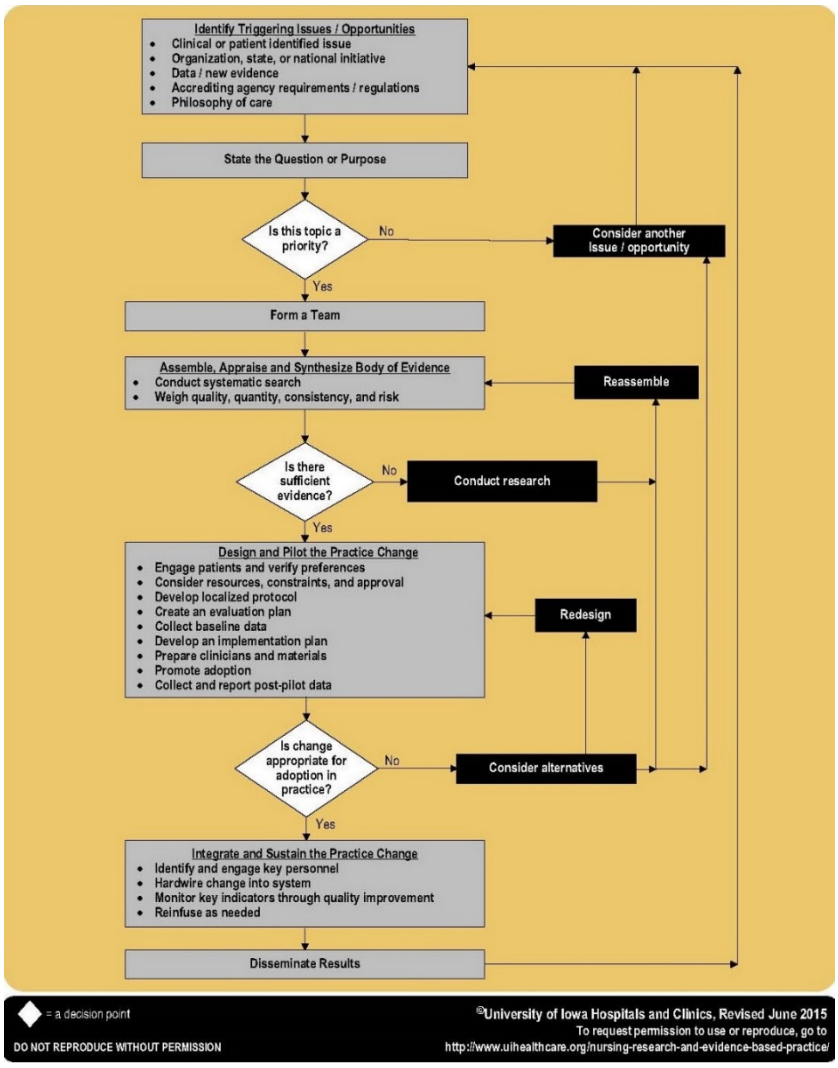

Figure 1. Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Healthcare. Reprinted from "Iowa model of evidence-based practice: Revisions and validation." by KC. Buckwalter et al., 2012. *Worldviews on Evidence-Based Nursing*, 14(3), p. 175-182.

We applied the Iowa Model framework to implement and evaluate the use of the Stanford Anesthesia Emergency Manuals. A systematic search of the literature was conducted to evaluate the quality, quantity, and consistency of current evidence, which was sufficient to address the clinical problem. We then utilized the Strategic Management of Change theory to guide practice implementation and then used simulation as a tool to train staff and evaluate emergency manual implementation.

Pettigrew and Whipp's model has three dimensions of strategic change utilized in a continuous interplay fashion (White, Dudley-Brown, & Terhaar, 2016). Content, process, and context are the factors that define objectives, purposes, goals, implementation, and the internal/external environment, respectively. Simplified, these entities are what (content), how (process), and why (context) (Stetler, Ritchie, Rycroft-Malone, Schultz & Charns, 2007).

The project focused on the lack of adherence to best practice interventions in low-incidence high-risk events by perioperative providers and how the Stanford Anesthesia Emergency Manuals could improve adherence. Implementation (process) involved simulation training focused on using emergency checklists. Providers were designated to a simulation team on MH, either with or without the emergency manuals, with a comparative evaluation on manual use and adherence to evidence-based interventions.

The importance of this project (context) revolved around improved patient safety, provider readiness, and cost-effectiveness. Evidence shows the use of emergency checklists and manuals improves patient health outcomes by reducing variability in treatment (Chen, Kan, Li, Qiu, & Gui, 2016).

Project Design

General Approach and Barriers

We implemented an evidence-based utilization of the Stanford Anesthesia Emergency Manuals and conducted a pre and post evaluation using the simulated low-incidence high-risk scenario of MH.

Potential barriers to our project were the opportunity costs of time associated with utilizing staff for simulations away from their primary work areas, simulation lab resources, the culture of the perioperative environment, and the allotted time for project completion. We

addressed the opportunity cost of time associated with simulations by holding simulations on scheduled hospital training days to avoid impacting staffing from the respective departments. We coordinated with simulation lab staff in the early stages of planning, which allowed us to maximize available lab resources and anticipate supply or funding gaps. We engaged the OR, anesthesia and PACU leadership team early in the project timeline, which aided in the recruitment of staff for simulation participation.

Setting

The setting of this project was the simulation lab at a military treatment facility. The simulation center was managed by a Certified Healthcare Simulation Operations Specialist who constructed simulations used to test the validity of the Stanford Anesthesia Emergency Manuals (Greiger, 2018). The center utilized a Laerdal SimMan 3G that was able to be programmed for customized neurological and physiological responses to mimic changes related to MH. The rooms were integrated with audio and video capability that gave the observers a multi-angled full range view of each room with sound allowing for real-time feedback between the participants and observers.

The PACU simulation room was set up to mimic a standard PACU bay consisting of a stretcher, monitor, oxygen and oxygen delivery devices, and bedside cart with supplies. The OR simulation room included a Drager Fabius anesthesia machine with full monitor and anesthesia circuit setup. Supplies included routine anesthesia medications, maintenance fluid and lines, and airway equipment. A malignant hyperthermia cart resembling the cart in stock at the facility was held in an adjacent room until requested by the simulation participants.

Procedural Steps

Evidence Evaluation

Methods.

We searched PubMed, Cumulative Index for Nursing and Allied Health Literature (CINAHL), and Excerpta Medica Database (EMBASE) to identify articles, abstracts, or dissertations for inclusion in this review of the literature. We specifically looked for implementation of standardized emergency manuals and safety training affecting patient outcomes in cases of OR fire, difficult airway, malignant hyperthermia, and perioperative cardiac arrest. The PubMed search utilized the Medical Subject Heading (MeSH) term “difficult airway”, “perioperative emergenc*”, “peri operative emergenc*”, “malignant hyperthermia”, “perioperative cardiac arrest”, “peri operative cardiac arrest”, “can’t intubate can’t ventilate”, “surgical suite”, “operating room[tiab]”, or “Operating Rooms[Majr]” and the MeSH terms “Checklist[Majr]”, “checklist*[tiab]", "manuals", "cognitive aid*", "algorithm", or the keywords "emergency", "crisis", or "crises". The CINAHL and EMBASE searches combined the keywords "Operating rooms", "Checklists", and "emergency". The group also performed an additional generic search using Google Scholar and these same key terms. These searches were retrospectively truncated at 2007 to ensure the accuracy of data acquired and included all articles published to present day. The search was limited to articles published in English.

As of 08 November 2019, this search strategy yielded 731 peer-reviewed articles and abstracts. The abstracts were reviewed, categorized, and entered into a database (EndNote) to allow for comparison and removal of 282 duplicates. Titles and abstracts of the remaining 449 articles were evaluated for inclusion in this review of the literature. Inclusion criteria were articles with a perioperative setting that utilized emergency manuals with operating room fire,

difficult airway, MH, and perioperative cardiac arrest. Exclusion criteria included: articles that only investigated hands-on training evaluations, utilized the terms emergency medical services/paramedics/pre-hospital, assessed scenarios/populations that were irrelevant to the major topics, utilized algorithms without emergency manual use, and only discussed results of original studies already included. A total of 386 articles were excluded using this method. A full-text review of the remaining 63 articles resulted in the further exclusion of 43 articles, leaving 20 articles for evaluation and synthesis (Appendix A).

Synthesis.

Quality.

The final 20 articles were appraised using the Johns Hopkins Research and Non-Research Evidence-Based Appraisal Tool and divided into levels of evidence (I-V) and quality (low, medium, or high). Of the final 20 articles, five were level I, eight were level III, three were level IV, and five were level V. According to the criteria in the appraisal tool, two of these articles were high quality, 17 were good quality, and one was low quality. The group included the low-quality article due to the limited number of articles directly addressing MH (Appendix B).

Quantity and consistency.

A total of 12 of the 20 articles included were research-based. Designs included: five randomized control trials, one exploratory sequential mixed-methods study, two one group pretest-posttest studies, two prospective cohort studies, three surveys, and one methodological study. The remaining eight articles were non-research and consisted of three literature reviews, one position statement, one expert opinion, and one case report.

Findings.

The most consistent theme amongst these studies was the use of cognitive aids in simulated settings, with the exception of OR fires, demonstrated significant improvement in adherence to critical steps in the management of low-incidence, high-risk events (Arriaga et al., 2013; Balki et al., 2012; Burden et al., 2012; Dagey, 2017; Hardy et al., 2018; Hubert et al., 2014; Lipps et al., 2017; Marshall, 2013; St. Pierre et al., 2017; Ziewacz et al., 2011). Adherence was consistently measured in a binary fashion. Additionally, a positive correlation between cognitive aid use and time-to-intervention was found by most studies. One study did not find a statistically significant difference in time-to-intervention with the use of cognitive aid (Renna et al., 2016). However, this was a pilot study being used to inform a future power analysis if findings supported the hypothesis.

Another consistent theme was the positive perception of the cognitive aid use by the study participants (Arriaga et al., 2013; Balki et al., 2012; Burden et al., 2012; Dagey, 2017; Renna et al., 2016). Participants also perceived the need for training on these cognitive aids as necessary to their successful utilization. These perceptions were assessed with the use of a five-point Likert scale.

Collect baseline data.

Baseline data was collected by having providers undergo a simulated MH crisis in both the OR and PACU environment. Overall completion of required evidence-based tasks, along with time to completion of time-sensitive tasks was recorded. These data points were used to compare post-checklist implementation data.

Design and implement evidence-based practice guideline pilot.

Identification of current response deficiencies to MH through simulation.

We worked with all departments to deconflict scheduling as staffing for simulations required four anesthesia providers, four OR nurses, four PACU nurses, and two PACU medical technicians. We then composed four separate MH simulations for the OR and PACU with and without Stanford Anesthesia Emergency Manuals. All groups, regardless of manual availability, received the same pre-simulation briefing on the simulation room, SimMan, and purpose of the exercise.

Two mock simulations were performed with clinical site senior anesthesia students to ensure interrater reliability before the rated simulations were conducted. The first set of simulations were without the Stanford Anesthesia Emergency Manuals. Two OR simulations were conducted with two groups of one anesthesia provider and two OR nurses. The standardized brief was given to all members from each OR simulation group. Afterward, the group was escorted to the simulation room and allowed a brief period of familiarization with the setting and SimMan before the simulation started. Two PACU simulations were conducted with two groups of one anesthesia provider, two PACU nurses, and one medical technician. All members of each group received the brief. Afterward, one nurse was taken to the simulation lab to allow for familiarization with the setting before the simulation started. The rest of the group remained in the briefing room and were made available to the nurse upon request. This setup simulated the real-life scenario of a PACU nurse recovering a patient alone until help is called to assist with the emergency.

The simulations were conducted by a certified simulation specialist along with two students and a phase II faculty member who coordinated appropriate mannequin physiologic

responses. This team monitored the simulations from outside the room and recorded time-to-intervention for critical steps in management and adherence to all evidence-based steps outlined in the Stanford Emergency Manual for MH (Appendix C). After each simulation concluded, the staff were excused to the briefing room while the results were discussed amongst the observers. Afterward, the staff were debriefed. Each participant was given a Likert-scale survey (Table 1) to record their perception of actual or potential manual use. This process was repeated until all four simulations concluded.

Table 1

Pre-Checklist Likert Scale Survey

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I would have used a best-practice checklist for this emergency if it was made available to me	1	2	3	4	5
I would use a checklist if I were presented with this emergency in real-life	1	2	3	4	5
I feel a checklist would improve my adherence to best-practice standards for this emergency	1	2	3	4	5
If I were having an operation and experienced this intraoperative emergency, I would want this checklist to be used	1	2	3	4	5

Implement training on the Stanford Anesthesia Emergency Manual/Evaluate staff response to MH through the use of simulation and presence of the Stanford Anesthesia Emergency Manual.

The same previously listed steps were used for the post-checklist groups. However, a 10-minute pre-simulation brief on familiarization and utilization with the Stanford Anesthesia Emergency Manual was conducted. This allowed all staff to look over the manual, familiarize themselves with the location of scenarios within the manual, and ask any questions about manual use. They were notified that a copy of the manual was available for use in their simulated perioperative emergency case. The post-simulation routine, including a Likert-scale survey (Table 2), was the same as pre-implementation days to maintain consistency.

Table 2
Post-Checklist Likert Scale Survey

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The checklist helped me feel prepared during the emergency scenario	1	2	3	4	5
The checklist was easy to use	1	2	3	4	5
I would use this checklist if I were presented with this operative emergency in real life	1	2	3	4	5
If I were having an operation and experienced this intraoperative emergency, I would want this checklist to be used	1	2	3	4	5

Evaluate processes and outcomes.

We used Cohen's Kappa to determine interrater reliability amongst student graders for both time-to-intervention and performance of key processes. The results were analyzed by the hospital statistician to determine any statistical significance between pre- and post-checklist implementation. Likert-scale responses were compiled to show the perception of the manuals with an average score of 4 or higher indicating agreement and positive correlation. These results were presented to our stakeholders for dissemination to all staff.

Institute change into practice.

After dissemination, the project stakeholders decided they wanted the manuals stocked in the operating suites as their perceived value outweighed the results of the project. The group had the printing office print a total of 24 manuals. Two copies were given to PACU to stock near both nursing stations for maximum visibility. Two copies were stocked in each OR suite with one copy positioned near the circulating nurses' desk and one copy attached to the anesthesia machine. Two copies were kept as extra stock in the event a copy was lost or misplaced.

HIPAA Concerns

Our doctorate of nursing practice (DNP) project was a quality improvement simulation-based training that did not incorporate research, making it exempt from institutional review board (IRB) approval. We collected voluntary survey information from hospital staff without personally identifiable information.

Project Results

Interrater reliability amongst the student and phase II faculty had a Cohen's Kappa of 0.82, indicating strong agreement. Participants in the pre-checklist simulation group completed a total of 41 of 50 key evidence-based interventions in four observations. Participants in the post-

checklist simulation group completed a total of 34 of 50 key evidence-based interventions in four observations. The decrease in the post-checklist group was due to a failure to diagnose malignant hyperthermia during one simulation, which largely skewed results due to a small sample size of eight groups.

Time to first Dantrolene dose, time to second Dantrolene dose, and time to call the Malignant Hyperthermia Association of the United States (MHAUS) were assessed from time zero, indicating the start of each simulation after familiarization with the simulated setting (Table 3). These measures were selected as Dantrolene is the definitive treatment for MH and calling MHAUS is considered the standard of care anytime MH is suspected. Evaluation of the OR pre-checklist group for these measures revealed an average of 300 seconds, 556 seconds, and 423 seconds respectively. Average OR post-checklist group times were 346 seconds, 616 seconds, and 411 seconds respectively. Average PACU pre-checklist times were 755 seconds, 1190 seconds, and 480 seconds respectively. Averages were unable to be calculated for the PACU post-checklist group due to an inability to diagnose MH in the second observation. However, times on the first PACU post-checklist simulation were 456 seconds, 773 seconds, and 481 seconds respectively.

Table 3

Time to Critical Intervention

Group	First Dantrolene	Second Dantrolene	Call MHAUS
OR Pre-checklist	300	556	423
OR Post-checklist	346	616	411
PACU Pre-checklist	755	1190	480

PACU Post-checklist	456*	773*	481*

Note. Times recorded in seconds
*Times from single group

Likert scale surveys were compiled with averages for questions calculated (Table 4). The pre-checklist group averaged 4.85, indicating a positive view on the utility of perioperative emergency checklists. The post-checklist average was 4.38, also a positive perception of perioperative emergency checklists.

Table 4

Likert Scale Survey Responses

Questions	Pre-checklist	Post-checklist
1	4.85	4.23
2	4.85	4.3
3	4.85	4.46
4	4.85	4.53
Total	4.85	4.38

Analysis of the Results

The second PACU post-checklist group failed to diagnose MH in their simulation, which resulted in the completion of only one of 12 key evidence-based interventions and failure to administer Dantrolene or call MHAUS. This outlier, coupled with a small sample size (N=8), resulted in a skewed distribution. The skewed distribution of the data set prevented statistical analysis using a conventional parametric t-test. Data analysis using the equivalent nonparametric

Mann-Whitney U test was not performed since the difference in rank between the pre-checklist and post-checklist group was due to a failed diagnosis versus a performance deficit from checklist utilization.

Likert scale surveys of a checklist for perioperative emergencies were positive amongst both the pre-checklist and post-checklist groups. However, the lower response scores in the post-checklist scenarios were from the PACU group that failed to diagnose MH and were unable to use the checklist. This lack of utility without an appropriate diagnosis was reflected in the literature (Hardy et al., 2018).

Organizational Impact/Implications to Practice Policy

Unfortunately, the authors are unable to quantify organizational impact due to the lack of clinically or statistically significant results from the project. However, the project requirement for an MH scenario in both the OR and PACU yielded two perioperative scenarios that satisfied the requirements for archival into the military treatment facility's simulation database. These simulations are now available for future use by all perioperative staff.

Future Directions for Research

Although not statistically significant, the recognition and performance of key interventions for MH were much slower in the PACU setting. Currently, there are only scattered case reports of MH in the PACU setting. A retrospective case series on the most common clinical presentation of MH in the PACU setting could inform future training and simulation construction. More realistic simulations can help promote early recognition of an MH crisis in the clinical setting and lead to improved patient care.

Conclusions

Improvement in provider adherence to best-practice interventions using standardized emergency manuals in perioperative low-incidence high-risk anesthesia events is supported in current literature (Arriaga et al., 2013; Balki et al., 2012; Burden et al., 2012; Dagey, 2017; Hardy et al., 2018; Hubert et al., 2014; Lipps et al., 2017; Marshall, 2013; St. Pierreet al., 2017; Ziewacz et al., 2011). However, the proper application of these manuals relies on the anesthesia provider making the correct diagnosis. Logistical limitations in staff availability for simulation coupled with a failure of an anesthesia provider to diagnose MH prevented the group from realizing a statistically significant improvement with the implementation of the Stanford Anesthesia Emergency Manuals.

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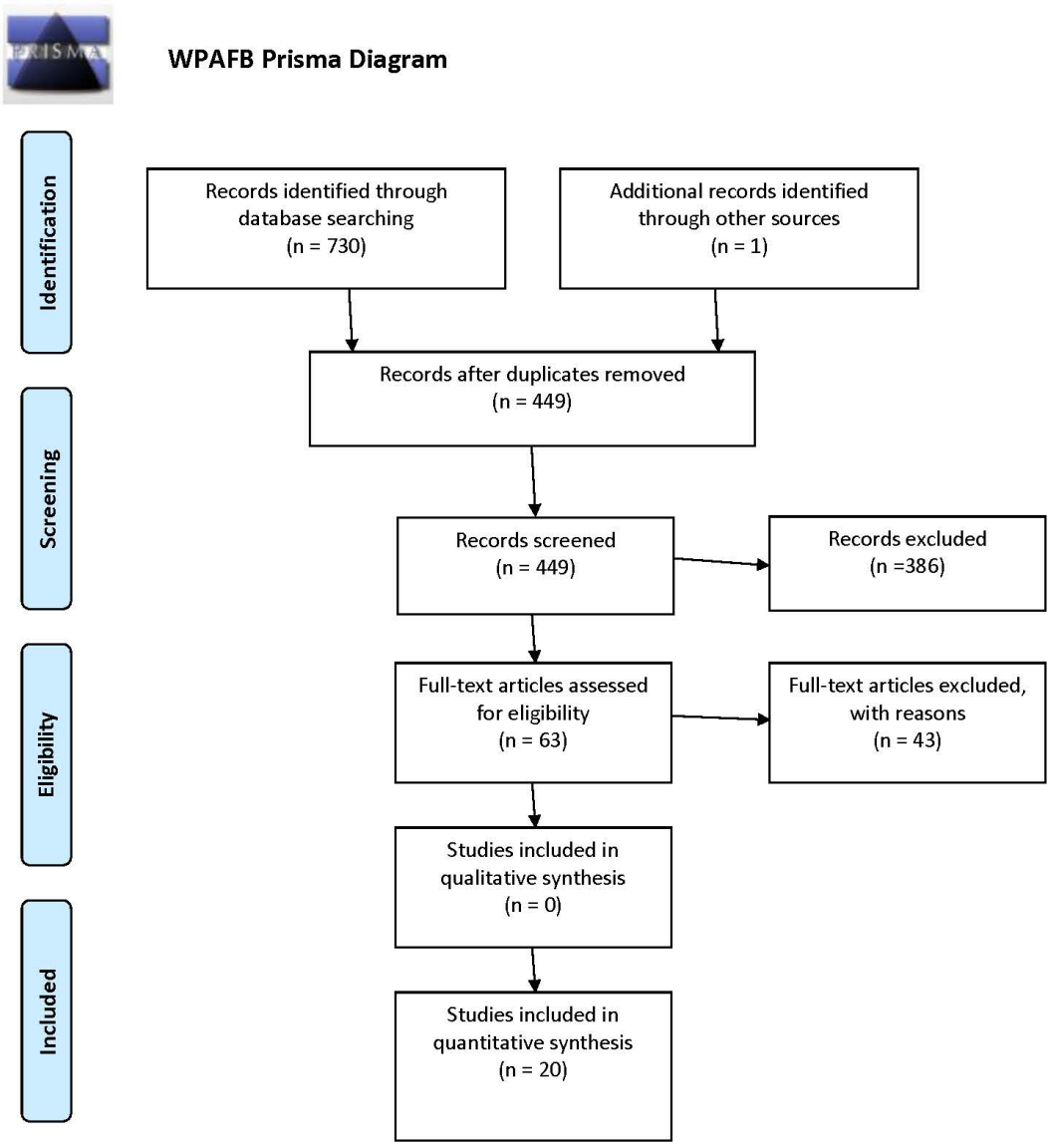
Timeline

Project Year 1 (2018)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval	**X**	**X**										
Site IRB Submission and Approval									**X**	**X**	**X**	**X**
Project Planning	**X**	**X**	**X**	**X**	**X**	**X**	**X**		**X**	**X**	**X**	**X**
Project Implementation/Data Collection												
Data Analysis												
Dissemination												

Project Year 2 (2019)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval												
Site IRB Submission and Approval												
Project Planning												
Project Implementation/Data Collection	**X**	**X**	**X**	**X**								
Data Analysis					**X**	**X**	**X**					
Dissemination								**X**	**X**	**X**		
Project Year 3 (2020)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval												
Site IRB Submission and Approval												
Project Planning												
Project Implementation/Data Collection												
Data Analysis												
Dissemination				**X**								

Appendix A



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Appendix B

Title	Citation	Purpose	Sample	Design	Independent Variable	Dependent Variable	Statistical Analysis	Results	Level of Evidence	Quality (JHP EBP	Scenario
ASA advisory addresses operating room fires: educate, assess risk prior to surgery	(2008) American Society of Anesthesiology	Development a practice advisory to address OR fires, best practices to reduce	N/A	Non-Research Expert Opinion	N/A	N/A	N/A	N/A	5	Good	OR Fire
Simulation-based trial of surgical-crisis checklists	(2013) Arriaga, Alexander F Bader, Angela M Wong, Judith M Lipsitz, Stuart R Berry, William R Ziewacz, John E Hepner, David L Boorman, Daniel J Pozner, Charles N Smink, Douglas S Gawande, Atul A	Evaluation of a tool to improve adherence to evidence-based best practices for eight operating room crises	N=67 (17 OR teams consisting of multiple perioperative specialties)	RCT	Checklist	Same scenarios for all	Multivariate, SAS, Cohens Kappa, Post hoc analyses	75% reduction in failure in failure to adhere to critical steps in management (6% missed with checklists vs. 23% without checklists)	1	High	All except OR Fire
Unanticipated difficult airway in obstetric patients: development of a new algorithm for formative assessment in high-fidelity simulation	(2012) Balki, Mrinalini Cooke, Mary Ellen Dunington, Susan Salman, Aliya Goldszmidt, Eric	Development of a consensus-based algorithm for the management of the unanticipated difficult airway in obstetrics, and to use this algorithm for the assessment of anesthesia residents' performance during high-fidelity simulation.	N=16 anesthesia residents (7 PGY4, 9 PGY5)	Prospective, observational cohort study, non-experimental	N/A (the algorithm was only used to assess resident performance, not actually implemented for use)	Tested use of 4 developed checklists in OR crisis via SIM center	Three raters, blinded to the residents' levels of training, independently evaluated the critical and crisis resource management skills on the videotaped sessions by use of our designed checklist and previously validated Ottawa Global rating scale (GRS), respectively. The checklist consisted of 15 items rated on an anchored ordinal scale (0 2; 0=action not performed, 1 =performed but not timely, 2 =performed timely). The GRS was rated on 7 point Likert scale (1–7; where 1=poor and 7=superior).	Checklist scores ranged from 64–80% and improved from scenario 1 to 4. Overall Global rating scale scores were marginal and not significantly different between scenarios. The intraclass correlation coefficient of 0.69 (95% CI: 0.58, 0.78) represents a good interrater reliability for the checklist. All participants agreed the algorithm would have been helpful in managing the different scenarios	3	Good	CD/CV in obstetrics
Does every code need a "reader?" improvement of rare event management with a cognitive aid "reader" during a simulated emergency: a pilot study	(2012) Burden, Amanda R Carr, Zyad J Staman, Gregory W Littman, Jeffrey J Torjman, Marc C	Determine if a cognitive aid "reader" improved adherence to critical actions in treatment of obstetric cardiac arrest and MH	N=28, resident physicians (mixed OB and anesthesia)	Quasi-experimental pretest-postest	Cognitive aid "reader"	Adherence to critical treatment steps in obstetric cardiac arrest and MH	Descriptive statistics were used to summarize overall scores, and results are presented as percentages and means +/- SD. Two-level nominal data extracted from the checklists were analyzed using the nonparametric Kruskal-Wallis test. For the Team and Leader interaction analysis, a two-way analysis of variance with repeated measures was used to identify significant differences among matrix variable scores across the pre- and post-Reader periods and between the two resident groups. The statistical analyses were performed using Systat version 11.00.01 (Systat Inc., Chicago, IL), and a P value <0.05 was set for statistical significance	OCA: No subjects performed all critical steps before introduction of the Reader. Twenty-two percent of Anesthesiology (AN) and 31% of Obstetrics (OB) trainees used the CA. MH: All subjects (AN) correctly diagnosed MH and administered the first dantrolene dose at 7.3 T 2.5 minutes (PETCO2 72 T 8 mm Hg, temperature 41.5-C T 1.3-C) but skipped critical treatment steps. Thirty-three percent of subjects used the CA. Reader introduction resulted in execution of all critical actions in both OCA and MH.	3	Low	Cardiac arrest in obstetrics and MH
The Development and Implementation of Cognitive Aids for Critical Events in Pediatric Anesthesia: The Society for Pediatric Anesthesia Critical Events Checklists	(2017) Clebone, Anna Burian, Barbara K Watkins, Scott C Galvez, Jorge A Lockman, Justin L Heitmiller, Eugenie S	Article reviews the developmental steps in producing the Society for Pediatric Anesthesia (SPA) crisis checklists, including creation of content, incorporation of human factors elements, and validation in simulation	N/A	Non-research, position statement	N/A	N/A	N/A	Critical-events checklists have the potential to improve patient care during emergency events, and it is anticipated that incorporating the elements discussed here will aid in the successful implementation of these essential cognitive aids.	4	Good	General
Using Simulation to Implement an OR Cardiac Arrest Crisis Checklist	(2017) Dagey, D.	Crisis checklists can assist teams to work more effectively during critical events in the OR.	CUSP team includes RN and surgical technologist unit champions, physician champions (i.e., surgeons, anesthesiologists), a facilitator, an executive member, an OR manager, and the director of perioperative services	Non-experimental simulation survey	N/A	N/A	N/A	80% of staff members who participated in the training expressed an increase comfort level using a cognitive aid while caring for a patient in cardiac arrest.	4	Good	Cardiac arrest

Cognitive aids in medicine assessment tool (CMAT): preliminary validation of a novel tool for the assessment of emergency cognitive aids	(2015) Evans, D.	Development of a new tool called "CMAT" to assess the efficacy of existing cognitive aids. They tested this tool using difficult airway cognitive aids.	N/A	Methodological study	N/A	N/A	Cronbach's alpha & Inter-rater reliability assessed by Cohen's kappa, Two-tailed Pearson's coefficient was used to assess correlation between CMAT scores and global impression ranking from qualified anesthesia providers	The resultant CMAT provided a valid and reliable assessment tool of difficult airway cognitive aids, based on good-to-excellent internal consistency, fair-to-substantial inter-rater reliability and high levels of agreement with independent, expert assessment.	4	Good	Difficult Airway
Critical action procedures testing: a novel method for test-enhanced learning	(2009) Galvagno, S. Segal, S.	CAPS is cost-effective modality to augment both simulated & actual experimental learning	21 First-year anesthesiologists residents	Longitudinal/prospective/ observational cohort study	Four subjects: difficulty airway, fire protocol, dantrolene dosing for MH, and AHA ACLS.	CAPs test results	Kruskal-Wallis test- intergroup comparisons & Mann-Whitney U-test for independent samples	Likert based survey data indicated a positive report for attainment of knowledge p<0.001 & 20.5% vs. 80%	3	Good	Difficult Airway, Cardiac Arrest, OR Fire,
Emergency Manual Uses during Actual Critical Events & Changes in Safety Culture from the Perspective of Anesthesia Residents	(2016) Goldhaber-Fiebert, S.Pollock, J. Howard, S. Merrel, S.	Assess perspectives on local or safety culture regarding cognitive aid use before & after implementation of EM & describes early clinical uses of EM during critical events	Pre-survey 34/66 & Post-survey 42/74	Mixed Methods Survey	N/A	N/A	N/A	More residents agreed the culture in the ORs supports consulting a cognitive aid when appropriate	3	Good	General
Emergency Manuals: How Quality Improvement and Implementation Science Can Enable Better Perioperative Management	(2018) Goldhaber-Fiebert S.N. Macrae C.	How principles of implementation were applied by multiple teams in the development, testing, and systematic implementations of emergency manuals in perioperative care.	N/A	Non-Research Literature Review	N/A	N/A	N/A	N/A	5	Good	General
The Use of a Checklist Improves Anesthesiologist technical and non-technical performance for simulated MH management	(2018) Hardy, JB. Gouin, A. Damm, C. Compere, V. Veber, B. Dureauil, B.	Assess the usefulness of the French Society of Anesthesia and Intensive Care's (SFAR) "Malignant Hyperthermia" (MH) checklist on simulated MH	24 anesthesiologists	RCT	SFAR checklist	Completion of required tasks	Wilcoxon-Mann-Whitney test used for quantitative data & Fisher's exact test compared Qualitative demographic data	ANTS score 56.5 vs. 48.5 & Performance scores 24/30 vs 18/30 & admin of dantrolene 15.7 mins vs. 22.4 mins	1	Good	MH
Operating Room Crisis Checklists & Emergency Manuals	(2017) Hepner, D. Arriaga, A. Cooper, J. Gaba, D. Goldhaber-Fiebert, S. Berry, W.	Cognitive aids demonstrates to work to counter the effects of stress, ineffective teamwork, and inability to recall all evidence-based actions required for the optimal response in rare events.	N/A	Non-Research Literature Review	N/A	N/A	N/A	N/A	5	Good	General
Effect of simulation training on compliance with difficult airway management algorithms, technical ability, and skills retention for emergency cricothyrotomy	(2014) Hubert, V. Duwat, A. Deransy, R. Mahjoub, Y. Dupont, H.	Assess usefulness of short training course with high fidelity simulations on anesthesiology residents ability to adhere to difficult airway management guidelines at later intervals of 3m, 6m, 12m	N= 27 3rd year anesthesia residents at 3 different medical centers	Quasi-experimental Pre-post test study with randomized follow-up	Participation in 2 day simulation training session with high fidelity mannequins	Compliance with difficult airway management algorithm	Sample size estimated using McNemar testing (marginal homogeneity). Bonferroni-Holm used to control for multiplicity (method used to counteract familywise error rate [the probability that one or more Type I errors will occur]) Wilcoxon signed rank test used for pretest comparisons of paired, quantitative variables (cricothyrotomy duration, checklist score, global scale score) For quantitative variables in post test (3m, 6m, 12m) Kruskal-Wallis one-way ANOVA conducted. Due to small sample size of the post test participants, any equivalence test to assess for decay over time could not be performed	After training, all 27 residents (100%) complied with the airway management guidelines, compared with 17 (63%) in the pretest, Median time to cricothyrotomy went from 117 seconds to 62 seconds	3	Good	Difficult Airway
Physiologically triggered digital cognitive aid facilitates crisis management in a simulated operating room: A randomized controlled study	(2017) Lipps, J. Meyers, L. Winfield, S. Durda, M. Yildiz, V. Kushelev, M.	Determine if use of a digital cognitive aid improved time to begin pacing a patient that experiences 3rd degree HB in high fidelity simulation when automatically triggered at a set VS aberration	Convenience sample, N= 30 anesthesia residents	RCT	Digital cognitive aid	Time to commencement of pacing	Normality of data was assessed after visual inspection with Shapiro-Wilk test (the null is that population is normally distributed). Fishers exact or X2 test used to explore association between groups and other categorical variables. Student -T test or Wilcoxon rank sum test used to compare continuous variables. Log-rank test (non-parametric hypothesis test used to establish efficacy of new treatment in comparison with a control when the measurement is the time to event) used to compare intervention group and control group time to pace. Significance level set alpha </= 0.05	All participants in intervention group began pacing patient vs 6/14 in control group. Participants in intervention group also initiated pacing faster than control group (260seconds vs. 405 seconds). Pharmacologic interventions did not reach statistical significance between the 2 groups	1	Good	Cardiac Arrest
The use of cognitive aids during emergencies in anesthesia: a review of the literature	(2013) Marshall, Stuart	Determine 1) whether cognitive aids improve performance of individuals and teams . 2) whether recommendations can be made for future cognitive aid design, testing, and implementation	N/A	Non-Research Literature Review	N/A	N/A	N/A	Multiple studies suggested cognitive aids improved technical performance in anesthetic crises with differing results on improvement in communication/teamwork. Facilities should implement these aids in simulated scenarios for training in	5	Good	General

Awareness and use of a cognitive aid for anesthesiology	Neily, J. DeRosier, J. Mills, P. Bishop, M. Weeks, W. Baglan, J.	Used surveys to determine if newly developed cognitive aid for anesthesia providers in emergencies 1) reached providers, 2) was used in emergency situations, 3) was used for learning in non-emergent situations	Convenience sample, N=446 (CRNA=229, Resident=21, Attending=191)	Non-experimental survey	Cognitive Aid	Provider Awareness, Utilization in Emergent Situations, Utilization as Educational Tool in Non-emergent Situations	Chi-Square	87% had awareness of the aid, 50% used the aid as an educational reference during non-emergent situations, 7% used aid in emergent situation	3	Good	General
The use of cognitive aid checklist leading to successful treatment of malignant hyperthermia in an infant undergoing cranioplasty	(2014) Ranganathan, P. Phillips, J.H. Attaalah, A.F. Vallejo, M.C.	Show how emergency manuals helped quick treatment and resolution of MH	N/A	Case Report	N/A	N/A	N/A	N/A	5	Good	MH
Cognitive aids for role definition (CARD) to improve interprofessional team crisis resource management: An exploratory study	(2016) Di Renna, T. Crooks, S. Pigford, AA. Clarkin, C. Fraser, A.B. Bunting, A.C Bould, M.D. Boet, S.	1. Qualitatively assess OR team members perception of CARD (Cognitive Aid for Role Definition) when used in simulated intraoperative cardiac arrests 2. Explore quantitative effect of CARD on interprofessional team performance during simulated crises	Convenience sample, N= 16 teams, no explicit indication of number of participants	Exploratory Sequential Mixed Method	Cognitive Aid for Role Definition	Members perception of CARD, team performance measured by team score rating, time to initiate chest compressions, and hands off time	Thematic Qualitative Analysis using nVivo 10, repeated measures ANOVA for outcomes, Mann Whitney U for retention simulations	Qualitative- Participants felt the cards improved teamwork, had logistical issues associated with implementation to include training, and ability to perform role specified may vary among provider, Quantitative: no a significant difference in TEAM scores, time to chest compressions and hands off time	3	Good	Cardiac Arrest
The effect of an electronic cognitive aid on the management of ST-elevation myocardial infarction during caesarean section; a prospective randomized simulation study	(2017) St. Pierre, M. Luetcke, B. Strambski, D. Schmitt, C. Breur, G.	See if cognitive aide vs memory improved treatment for intraoperative STEMI management in cesarean section with spinal anesthesia	Convenience sample, N=83, anesthesia students, nurse anesthetists, and anesthesiologists	Single-blinded RCT	Cognitive Aid	Adherence to 15 checklist steps, perceived usefulness	Two tailed t-test for time intervals, Fischer's exact for adherence to steps, Chi-square for survey questions of usefulness	Cognitive aid improved performance in nine ESC task by 24% compared to control, and overall performance by 28.5% compared to control	1	Good	Cardiac Arrest
Crisis checklists for the operating room: Development and pilot testing	(2011) Ziewacz, J. Arriaga, A. Bader, A. Berry, W. Edmonson, L. Wong, J. Lipsitz, S. Hepner, D. Peyre, S. Nelson, S. Boorman, D. Smink, D. Ashley, S.	Development and pilot testing of the efficacy of checklists in life threatening operating room crises	Convenience sample, N=11, surgical attending, surgical resident, anesthesia attending, anesthesia resident, circulating nurse, surgical technologist	Pilot RCT	Checklists	Adherence to the critical processes for managing each emergency, and perceived usefulness of the checklist	Multivariate generalized estimating equations for adherence and Likert scales for perceptive usefulness	Failure rates fell from 24% (11 of 46 processes missed) in control group to 4%(2 of 46 processes missed)	1	High	Cardiac Arrest, Difficult Airway, MH

Appendix C

MALIGNANT HYPERTHERMIA

By Stanford Anesthesia Cognitive Aid Group and Henry Rosenberg, MD

SIGNS

EARLY:
1. Increased $ETCO_2$.
2. Tachycardia.
3. Tachypnea.
4. Mixed Acidosis (ABG).
5. Masseter spasm/trismus.
6. Sudden cardiac arrest in young person due to hyperkalemia.

May be LATER
1. Hyperthermia.
2. Muscle rigidity.
3. Myoglobinuria.
4. Arrhythmias.
5. Cardiac Arrest.

1. CALL FOR HELP.
2. CALL FOR MH CART.
3. INFORM TEAM.
4. START PREPARING DANTROLENE or RYANODEX!

DDX

- Light anesthesia.
- Hypoventilation.
- Insufflation of CO_2.
- Over-heating (external).
- Hypoxemia.
- Thyroid Storm.
- Pheochromocytoma.
- Neuroleptic Malignant Syndrome (NMS).
- Serotonin Syndrome.

TREATMENT

1. **Discontinue** anesthetic triggers (volatiles and succinylcholine). Do **NOT** change machine or circuit.
2. Increase to **100% O_2, high flow** 10 L/min.
3. **Halt procedure** if possible. If emergent, continue with non-triggering anesthetic.
4. **Increase minute ventilation** (but avoid air trapping).
5. **Assign several people to prepare 2.5 mg/kg IV Dantrolene or Ryanodex bolus:**
   - **Dantrolene**: Dilute **each 20 mg Dantrolene vial in 60 mL** preservative-free **sterile water** (for **70 kg person give 175 mg so prepare 9 vials** of 20 mg Dantrolene each as above).
   - **Ryanodex** (new formulation of Dantrolene): Dilute **250 mg Ryanodex vial in 5 mL** preservative-free **sterile water** (for **70 kg person give 175 mg**).
6. **Rapidly give Dantrolene** or **Ryanodex**. Continue giving until patient stable (may need >10 mg/kg, call MHAUS 800-644-9737 for advice).
7. For metabolic acidosis, give **sodium bicarbonate** 1-2 mEq/kg.

MH Treatment continued on next page.

GO TO NEXT PAGE ➔

MALIGNANT HYPERTHERMIA
continued

TREATMENT

8. **Hyperkalemia** – or suspect from EKG, treat with:
   - **Calcium chloride** 10 mg/kg IV; Max dose 2000 mg or **Calcium gluconate** 30 mg/kg IV, Max dose 3000 mg.
   - **D50** 1 Amp IV (25 g or 50 ml Dextrose) + **Regular Insulin** 10 units IV (monitor glucose).
   - **Sodium Bicarbonate** 1-2 mEq/kg, Max dose 50 mEq.
9. Arrhythmias are usually secondary to Hyperkalemia. Treat as needed except **avoid calcium channel blockers. Go to ACLS events** as relevant and return.
10. Actively **cool patient** with ice packs, lavage if open abdomen. Stop cooling at 38°C.
11. Send **labs** for ABG, Potassium, CK, urine myoglobin, coagulation studies, lactate.
12. Place Foley catheter. **Monitor UO. Goal 1-2 mL/kg** per hour. Can give IV fluid and diuretics.
13. **Consider alkalinizing urine** if CK or urine myoglobin elevated (Sodium Bicarbonate 1mEq/kg/hour).
14. Arrange **ICU** bed. Mechanical ventilation usually required.
15. **Continue Dantrolene** or **Ryanodex**: 1 mg/kg every 4-6 hours or 0.25 mg/kg/hr infusion for at least 24 hours (**25 % of MH events relapse**). Observe patient in ICU for at least 24 hours.
16. Call **MH hotline** (below)for any suspected case with any questions.

Contact the Malignant Hyperthermia Association of the United States (MHAUS hotline) at any time for consultation if MH is suspected:

1-800-MH-HYPER (1-800-644-9737)

or see suggestions online at http://www.mhaus.org

END

Appendix D

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: Ryan Abraham (ID: 6532782)
- Institution Affiliation: Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- Institution Email: ryan.abraham@usuhs.edu
- Phone: 3217499317

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Basic Course

- Record ID: 24316684
- Completion Date: 25-Aug-2017
- Expiration Date: 24-Aug-2020
- Minimum Passing: 80
- Reported Score*: 87

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	25-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	25-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	25-Aug-2017	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	25-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 490)	25-Aug-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	25-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	25-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	25-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	25-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	25-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	25-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	25-Aug-2017	2/3 (67%)
FDA-Regulated Research (ID: 12)	25-Aug-2017	1/5 (20%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	25-Aug-2017	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	25-Aug-2017	No Quiz
Stem Cell Research Oversight (Part I) (ID: 13682)	25-Aug-2017	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kba65e385-2697-4dce-9593-1bb6302cd54c-24316684

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-6929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: Stacey O Donnell (ID: 6524075)
- Institution Affiliation: Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- Institution Email: stacey.odonnell@usuhs.edu
- Institution Unit: Uniformed Services University of the Health Sciences
- Phone: 3215918832

- Curriculum Group: OUSD P&R Human Research
- Course Learner Group: Biomedical Investigators and Research Study Team
- Stage: Stage 1 - Basic Course

- Record ID: 24287225
- Completion Date: 28-Aug-2017
- Expiration Date: 27-Aug-2020
- Minimum Passing: 80
- Reported Score*: 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	28-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	28-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2017	No Quiz
Cultural Competence in Research (ID: 15166)	28-Aug-2017	1/5 (20%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kc02c3e87-66cb-4ffb-b77d-21c761619729-24287225

Appendix E

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: GSN-61-1073 (VPR will assign)
Project Title: Perioperative Emergency Manuals for Low-Incidence High-Risk Events

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): Abraham, Ryan, T Student E-mail: ryan.abraham@usuhs.edu
2. Home Addres[redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Vance, Anna, LtCol
4. Telephone: 937-257-0569 Fax: N/A E-mail: anna.vance@usuhs.edu
5. USUHS Building/ Room No.: N/A

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number: _____
   Project Title: _____
   Project Start Date: _____ Project End Date: _____
8. Anticipated period of performance: Project Start Date: 8/1/2017 Project End Date: 5/30/2020
9. Performance Site(s): Wright Patterson Air Force Base
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☒ No ☐ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

The following signatures attest to the validity of the above information:

ABRAHAM.RYAN.T.[redacted]	VANCE.ANNA.M.[redacted]
Student (Project Point of Contact for the Group) (Signature and Date)	Chair/Senior Mentor (Signature and Date)
BONDS.RAYMOND.L.7[redacted]	
Chair/Program Director (Signature and Date)	Chair/Program Director (Signature and Date)
WANZER.LINDA.JEANNE.[redacted]	SEIBERT.DIANE.C[redacted]
DNP Project Director or PhD Director (Signature and Date)	Associate Dean for Academic Affairs, GSN (Signature and Date)
WASSERMAN.JOAN.E.66[redacted]	ROMANO.CAROL.A.294[redacted]
Associate Dean for Research, GSN (Signature and Date)	Dean, DKI Graduate School of Nursing (Signature and Date)

In light of the above signatures, the project is approved.

[redacted]
USUHS Vice President for Research

2 July 2019
Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix F

USU
Uniformed Services University

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number:	GSN-61-10703
Principal Investigator:	Abraham, Ryan
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Perioperative Emergency Manuals for Low-Incidence High-Risk Events
Project Period:	8/1/2017 to 5/30/2020

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0			To be Submitted	N/A

Remarks:
This Notice of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.

[redacted]

2 July 2019

Yvonne T. Maddox, Ph.D. Date
Vice President for Research
Uniformed Services University of the Health Sciences

cc: Abraham, Ryan
File

Appendix G

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Perioperative Emergency Manuals for Low-Incidence High-Risk Events

was completed at Wright Patterson Air Force Base by the following student(s):

(type student name)	*(signature)*	*(date)*
Ryan Abraham	[redacted]	03/29/2020
Stacey O'Donnell		03/29/2020

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

(type name)	*(signature)*	*(date)*	
Lt Col Anna Vance	[redacted]	31 Mar 2020	Senior Mentor
Lt Col Ronald Hodge		31 Mar 2020	Team Mentor
			Team Mentor
			Team Mentor & Phase II Site Director

***For RNA Students only** - add the following additional signature for final verification of project completion:*

CDR Kennett Radford	[redacted]	31Mar2020
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017

Appendix H

DEPARTMENT OF THE AIR FORCE
88TH MEDICAL GROUP (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE OHIO

30 June 2019

MEMORANDUM FOR RYAN T ABRAHAM, DNP

FROM: WPMC INSTITUTIONAL REVIEW BOARD

SUBJECT: Institutional Review Board (IRB) Research Determination

1. Your project proposal FWP20190001N entitled "Improving Adherence to Best Practice Standards in Malignant Hyperthermia Through the Implementation of Emergency Manuals," has been reviewed by the Wright-Patterson Medical Center (WPMC) IRB.

DoD Assurance: F50005
DHHS Federalwide Assurance: 00000609
DHHS IRB Registration: 00001357

2. The WPMC IRB has determined that this project does not meet the criteria to be considered research in accordance with 32 CFR § 219.102. This activity is considered an evidence-based practice initiative involving perioperative/anesthesia services staff at WPMC, and is not designed nor intended to contribute to generalizable knowledge. Therefore, research protocol approval and oversight by an IRB is not required. *Any changes to the activity may affect the study status and must be reviewed by the WPMC IRB.*

3. This determination does not grant permission to conduct the project; this authority lies with 88th Medical Group leadership.

4. If you have any questions regarding this determination please call me at (937) 257-4242, or e-mail frederick.h.funke.civ@mail.mil.

FREDERICK H. FUNKE, Civ, DAF, CIP
WPMC IRB Administrator

Appendix I

DEPARTMENT OF THE AIR FORCE
88TH MEDICAL GROUP (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE OHIO

2 March 2020

MEMORANDUM FOR 88 SGC/SGCJ
ATTN: CAPT RYAN ABRAHAM

FROM: 88 MDG/SGNE (Clinical Investigations)

SUBJECT: 88 ABW Public Affairs Security and Policy Review of Publications

1. The following publications submitted for Security and Policy Review have been cleared for unlimited distribution to the public domain by 88 ABW/PA:

a. Case Number 88ABW-2020-0766, "Perioperative Emergency Manuals for Low-Incidence High-Risk Events." (Briefing Charts)

b. Case Number 88ABW-2020-0786, "Perioperative Emergency Manuals for Low-Incidence High-Risk Events." (Poster)

c. Case Number 88ABW-2020-0820, "Perioperative Emergency Manuals for Low-Incidence High-Risk Events." (Thesis)

2. As these publications have been cleared for unlimited distribution, this includes all activites related to USUHS Research week, as well as archive of the manuscript in the "USU Archives."

3. Please direct questions or concerns to me at email frederick.h.funke.civ@mail.mil, or phone (937) 257-4242.

[redacted]

FREDERICK H. FUNKE, Civ, DAF, CIP
WPMC Human Protections Adminstrator

Appendix J

Operating Room

Intervention	Performed (1)	Not Performed (0)
Discontinue Volatiles		
FiO2 100%		
Stop Procedure if Able		
Increase Minute Ventilation		
Assign and Give Ryanodex		
Give Second Ryanodex		
Sodium Bicarb for Acidosis		
Hyperkalemia Treatment		
Actively Cool with Ice Packs		
Send ABG, K, CK, Urine Myoglobin, Coags, Lactate		
IVF for UO 1-2ml/kg		
Alkalinize Urine (Bicarb Drip)		
Arrange ICU bed		
Start Ryanodex Infusion		
Call MHAUS		
	Total	
	Total Percent	

	Times (Seconds)
Time to First Dantrolene	
Time to Second Dantrolene	
Time to MHAUS	

Post Anesthesia Care Unit

Intervention	Performed (1)	Not Performed (0)
FiO2 100%		
Assign and Give Ryanodex		
Give Second Ryanodex		
Sodium Bicarb for Acidosis		
Hyperkalemia Treatment		
Actively Cool With Ice Packs		
Send ABG, K, CK, Urine Myoglobin, Coags, Lactate		
IVF for UO 1-2ml/kg		
Alkalinize Urine (Bicarb Drip)		
Arrange ICU bed		
Start Ryanodex Infusion		
Call MHAUS		
	Total	
	Total Percent	

	Times (Seconds)
Time to First Dantrolene	
Time to Second Dantrolene	
Time to MHAUS	

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Perioperative Emergency Manuals for Low-Incidence High-Risk Events

was completed at Wright Patterson Air Force Base by the following student(s):

(type student name)	*(signature)*	*(date)*
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Verified by:

(type name)	*(signature)*	*(date)*	
Lt Col Anna Vance	[redacted]	31 Mar 2020	Senior Mentor
Lt Col Ronald Hodge	[redacted]	31 Mar 2020	Team Mentor
			Team Mentor
			Team Mentor & Phase II Site Director

For RNA Students only *- add the following additional signature for final verification of project completion:*

CDR Kennett Radford [redacted] 31Mar2020
RNA Project Director *(type name)* *(Date)*