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Malignant Hypothermia Preparedness for Labor and Delivery Nurses

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MALIGNANT HYPERTHERMIA PREPAREDNESS FOR LABOR AND DELIVERY NURSES

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Doctor of Nursing Practice Final Scholarly Project

In Partial Fulfillment of the Requirements for the Degree

Doctor of Nursing Practice

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Executive Summary

Malignant Hyperthermia (MH) is a rare, inherited disorder of skeletal muscle triggered by general anesthesia in susceptible individuals. Although MH can occur later in the anesthetic course as well as post-operatively, it most frequently occurs shortly after induction of general anesthesia.

Operating room (OR) nurses receive extensive training in MH crisis management. On labor and delivery (L&D) units, neuraxial (spinal and epidural) blocks are the safest and most commonly used anesthetics during pregnancy. General anesthesia is utilized only when the life of the mother or infant is in jeopardy or when a neuraxial block is not possible. Under these circumstances, inhalational agents and succinylcholine, both MH triggering agents, are routinely administered.

Because general anesthesia is used infrequently in pregnancy, L&D nurses are less likely to encounter a MH crisis than OR nurses and are at risk of being unprepared for this rare, life-threatening event. At a medium sized, central Ohio trauma center, nurses are required to complete an online MH learning module annually. This learning module outlines the causes, signs, and symptoms of MH. In addition to the online learning module, OR nurses participate in a MH simulation drill where they practice hands-on MH crisis management skills. L&D nurses do not receive this additional training. Through close personal observation and informal question and answer sessions, it became clear L&D nurses could benefit from a MH simulation drill.

A hands-on MH simulation drill was created for the L&D environment to be utilized in conjunction with the online MH learning module. In the simulation drill, L&D nurses practiced skills not covered in the online learning module. The L&D nurses practiced their roles in the event of a crisis, located the MH cart, reconstituted drugs needed, and contacted appropriate help. The simulation drill afforded L&D nurses the opportunity to practice using low frequency,

high-risk skills to prepare for a MH crisis. After participating in the drill, paired T-test results show improved MH crisis management skills in L&D nurses.

Introduction

MH is a life-threatening event that can occur following the induction of general anesthesia. Succinylcholine, a depolarizing muscle relaxant, and/or an anesthetic inhalation agent, can trigger a hypermetabolic cascade of events in susceptible individuals that result in critically high temperature, extreme muscle rigidity, metabolic acidosis and renal failure. According to Rosenberg, Sambuughin, Riazi, and Dirksen, (2003), these individuals have a defective ryanodine (RYR1) receptor. The RYR1 receptor controls calcium release. MH triggering agents used in the induction of general anesthesia cause the uncontrolled release of intracellular calcium. Skeletal muscle damage, hyperthermia, and death occur if MH is unrecognized and untreated (Rosenberg, et al., 2003).

According to Gronert, Pessah, Muldoon, and Tautz, (2005), if MH is not recognized and treated quickly with the administration of dantrolene sodium (Ryanodex), the only known treatment for MH, it can have deadly consequences. The Malignant Hyperthermia Association of the United States (MHAUS, 2018), outlines recommendations on their website for training health care providers and the availability of dantrolene sodium in every anesthetizing location where MH triggering agents are used (https://www.mhaus.org/healthcare-professionals/be-prepared/) According to Mansur, (2018), The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) addresses the need for MH protocols in L&D. Traynor, (2005), postulates that an unprepared L&D unit can forestall JCAHO accreditation. For a medium sized, central Ohio trauma center with a thirteen-bed L&D unit, MH training for L&D nurses has become a high priority.

L&D nurses have been overlooked when it comes to MH training because the majority of pregnant patients receive a spinal or epidural (neuraxial) anesthetic for surgery. L&D nurses work primarily with pregnant patients, not surgical patients and although circumstances may necessitate an operative delivery, or other surgical procedures, the L&D nurse is involved in general anesthesia infrequently. Berghella, Baxter, and Chauhan, (2005), state "…cesarean delivery accounts for more than 30% of all births and is the most common surgical procedure performed in the United States with more than 1 million performed each year." According to Bloom, et al., (2005), the safest and most common method of anesthesia for cesarean section is a neuraxial anesthetic. Tsen, (2014), states "Neuraxial anesthesia has been used for more than 80% of cesarean deliveries since 1992." Tsen, (2014), supports the use of neuraxial anesthesia over general anesthesia during pregnancy because maternal morbidity and mortality is higher when general anesthetics are used. Even though neuraxial anesthesia is preferred, general anesthesia must always be anticipated in case of neuraxial anesthetic failure or maternal/fetal condition warrants the use of general anesthesia (Tsen, 2014). When general anesthesia is necessary, the drugs commonly used are those that can trigger a MH crisis. The infrequent exposure of L&D nurses to general anesthesia, combined with the infrequent occurrence of MH, implies that L&D nurses could benefit from a MH simulation drill.

A clinical needs assessment (See Table 1) identified a knowledge deficit in L&D nurse response to a MH crisis. The clinical needs assessment consisted of random, informal interviews with L&D nurses and included questions about how to manage a MH crisis, who to contact in a crisis, where the MH cart is located, and how to unlock the cart. All ten nurses interviewed, answered the four questions incorrectly. The answers revealed L&D nurses could benefit from additional MH skill training.

Training L&D nurses to respond to a MH crisis is important, much like training any expert nurse. Benner, (1984), developed her own theory on how nurses become experts. For example, Drumm, (2013), uses Benner's Novice to Expert Theory of Skill Acquisition to describe how nurse educators evolve into experts by developing clinical judgment and states that Benner's theory has been "incorporated into nursing curricula and used as a standard for nurses in various practice settings." If L&D nurses are to effectively care for the operative patient during a MH crisis, comparable training to OR nurses would be beneficial. MH simulation drills in a medium-sized central Ohio trauma center should help prepare L&D nurses to respond effectively in a MH crisis. After completion of the MH training and drill, L&D nurses should be able to recognize the onset of the MH crisis, identify medications that trigger MH, notify appropriate personnel for assistance, assist the anesthesia team, retrieve the MH supply cart, and administer rescue medications as needed.

Problem Statement

Does an online training module in conjunction with a simulation drill provide L&D nurses with more effective strategies to handle a MH crisis than an online training module alone?

Background and Significance of the Problem

MH is a low frequency, high-risk complication of general anesthesia (Hirshey Dirksen, et al., 2013). A literature review of the response to a MH crisis by operating room personnel reveals a need for better preparation. According to MHAUS, (2018), all locations utilizing drugs that can trigger a MH crisis need to have protocols in place in order to respond appropriately. MHAUS is an organization devoted entirely to the preparation for, and proper handling of a MH crisis. In addition, the MHAUS website provides healthcare personnel with useful information to assist in MH crisis intervention as well as a hotline phone number through which experts can be contacted during a crisis.

According to (Rosenberg, et al., 2003), MH occurs approximately once in 3,000 to 50,000 general anesthetics. Gronert, et al., (2005), postulate that if the MH syndrome is not recognized promptly and treated with the administration of dantrolene sodium, the only known treatment for MH, it can quickly progress to a life-threatening situation. When MH was first recognized as a complication of anesthesia, the mortality rate was 70-80%, (Britt & Kalow, 1970). The mortality rate is now estimated to be less than 5%, due to early detection of increasing end-tidal CO2, prompt use of dantrolene sodium, (Ryanodex), and diagnostic testing, (Rosenberg, Davis, James, Pollack, & Stowell, 2007). According to Larach, Gronert, Allen, Brandom, and Lehman, (2010), "Even though the mortality rates of MH are low, the morbidity rate of MH is relatively high at 34.8%...which emphasizes the need for continuing education of anesthesiologists on the most effective way to diagnose and treat MH." By utilizing MHAUS guidelines, lifesaving MH simulation drills, and protocols including the administration of dantrolene sodium, (Ryanodex); an MH crisis can be handled effectively or averted altogether.

Preparation for a MH emergency is necessary for OR staff to respond appropriately in a MH crisis and the necessity of in-house drills is supported by literature according to Hirshey Dirksen, et al., (2013).

> "To give the best possible chance for a successful outcome, a swift, coordinated, multidisciplinary team response is necessary. MH occurs infrequently and, as such, details about its diagnosis, treatment, and management must be reviewed and reinforced during periodic education sessions." (Hirshey Dirksen, et al., (2013, p. 330).

The literature is lacking in specific MH protocols for L&D personnel. Cain, Reiss, Gettrust, and Novalija, (2014), state, "Many clinicians are unprepared to manage an MH crisis in the perioperative setting because it requires the use of low-frequency, high-risk skills and procedures." This is especially true of L&D nurses due to the infrequent use of general

anesthesia in the L&D environment. Cain et al., (2014), developed a quality improvement project "to provide simulation-based learning to perioperative personnel to educate them in the early recognition, treatment, and management of MH." According to Gaba, (2004), and Waxman, (2010), the use of simulation and real-life scenarios to facilitate learning are well-recognized educational techniques in high-risk industries. Crossman, (1919), reported that the military has trained pilots with flight simulators since World War I with great success. Additionally, Sleeper and Thompson, (2008), report that anesthesia educators have been using simulators since 1994 to optimize their skills and "with clearly defined scenario objectives, there were better ratings of problem solving and critical thinking of students during the simulation activity", and that problem solving and critical thinking skills improve with practice. Therefore, MH simulation drills should improve MH crisis management. Through education, simulation and practice, L&D nurses should improve their ability to manage a MH crisis, thereby increasing patient safety and outcomes.

Purpose

L&D nurses lack the necessary training and knowledge to respond appropriately to a MH crisis because they are focused on the pregnant patient rather than the anesthetized patient. Drugs used in the L&D operating room can trigger MH. L&D nurses must be prepared so that they can respond appropriately to a MH crisis. Proper training will increase patient safety and improve outcomes. The L&D unit is an area where nurses specialize in the care of pregnant and laboring women. Because general anesthesia is somewhat infrequent, L&D staff will rarely, if ever, experience a MH crisis. Using Benner's Novice to Expert Theory of Skill Acquisition, (1984), will enable the L&D staff to develop the competencies needed to respond appropriately to a MH crisis if one does occur. Utilizing the framework of Benner's Novice to Expert Theory of Skill

Acquisition, (Benner, 1984), L&D nurses will increase their skill level and knowledge through practice scenarios and MH crisis simulation.

Project Implementation

After obtaining Internal Review Board approval from Otterbein University (See Appendix A) and approval to implement a Quality Improvement Project at OhioHealth Grant Medical Center (See Appendix B), the Malignant Hyperthermia Preparedness for Labor and Delivery Nurses project was implemented.

Training L&D nurses to prepare for a MH crisis required planning an intervention, implementing the plan, and then evaluating the effectiveness of the intervention. The MH training at a medium size, central Ohio trauma center with a thirteen-bed L&D unit consists of an online learning module (Malignant Hyperthermia for RN's–CX5321.A1, OhioHealthUniversity/Healthstream.com). This online learning module is a yearly requirement for all nurses in the hospital. A series of random, informal interviews of L&D nurses included questions about how to manage a MH crisis, who to contact in a crisis, where the MH crisis cart is located, and how to unlock the cart (See Table 1). These interviews revealed the nurses could be better prepared for a MH crisis after completing the online learning module alone.

To effectively prepare the L&D nursing staff for a MH crisis, the nurses were asked to complete the annual online MH learning module. A ten-question pretest was then administered (See Appendix C). A PowerPoint presentation (See Appendix D) and question and answer session followed. Nurses were then given the opportunity to participate in a hands-on MH simulation drill, (See Appendix E). Simulation lab technicians set up a practice manikin and initiated monitoring events that mimicked a MH crisis. Staff was asked to participate in various activities during the simulation (See Appendix F). A team leader was identified and staff members were directed to call for help, obtain the MH cart (See Appendix G, Figure G1) from

the Main Operating Room (See Appendix G, Figure G2), start intravenous lines, assist with changing the anesthesia circuit, obtain bags of ice, and administer drugs. After the drill, each participant was asked to take a posttest (See Appendix C) identical to the pretest, to evaluate the effectiveness of the PowerPoint presentation and simulation drill. According to Galloway, (2009), "Compared with traditional education, which primarily includes verbal instruction and requires the participants to memorize presented material, a well-crafted simulation exercise promotes enhanced competency by incorporating kinesthetic learning." Participants then completed an evaluation of the program (See Appendix H). Effectiveness of the program has been determined by data analysis and descriptive statistics obtained through the pre and posttest scores (See Appendix I, Table I, 2 & I, 3).

Participant anonymity was maintained by using numbered pre and posttests. Each participant was given a number identifier for testing purposes and their names were not used. Each participant signed a consent form (See Appendix J).

Limitations

Limitations to this project included the availability of an OR to carry out the simulation. There are two OR's on the L&D unit and one must always be available for an emergency. An exceptionally busy schedule, staffing conflicts or an emergency on the L&D unit during the time set aside for the simulation could hamper the ability of the staff to participate. In fact, the first presentation was held in the simulation lab instead of the OR due to OR availability. Another limitation is the attitude and willingness of the staff. Staff may feel that because a MH crisis is rare, they shouldn't be required to participate. Additionally, according to Miller, (1956), if the staff feels the simulation is stressful, they may not absorb the information. A fourth limitation was staff availability. Poor staffing limited the number of participants.

MH training facilitators included the education coordinator on the L&D unit, Kate Ireland, RN, as well as the nurse manager, Susan MacAvoy, RN, and practice manager, Felicia Abercrombie, RN. Education coordinators in other areas also helped develop the simulation drills. The in-house medical library has been involved in this project from the beginning and was very helpful in accessing pertinent research articles. Dr. Norman Smyke, the director of anesthesia education, provided guidance, educational material, and helped coordinate the simulation drills. Hospital statisticians performed the statistical analysis. In addition, the hospital simulation lab personnel obtained imitation medication vials and instruments for simulation drills and assisted with implementation of drills.

The MH education and simulation drill was effective in that it promoted safety in an environment where every second counts. By bridging the knowledge gap between the online learning module and simulation drill, the L&D staff is better prepared for this unusual critical event.

Theoretical Framework

Patricia Benner's Novice to Expert Theory of Skill Acquisition is the theoretical framework for this project. Benner, (1984), identifies five levels of nursing practice; novice, advanced beginner, competent, proficient, and expert. Benner further classifies these levels into seven domains of nursing practice: The helping role, the teaching-coaching function, the diagnostic and patient-monitoring function, the ability to effectively manage rapidly changing situations, administration and monitoring of therapy, monitoring and ensuring quality of practice, and organizational and work-role competence. Benner's (1984) focus was "…to uncover meanings and knowledge embedded in skilled practice. By bringing these meanings, skills, and knowledge into public discourse, new knowledge and understanding are constituted".

Program Goals and Objectives

1. Participants will learn the signs, symptoms, and triggers of MH.
2. Participants will learn where the MH cart is kept.
3. Participants will learn where to obtain dantrolene sodium, (Ryanodex), and how to mix and dose it.
4. Participants will know how and where to obtain bags of ice.
5. Participants will learn the different tasks completed by medical personnel when responding to a MH crisis.
6. Participants will practice response to MH crisis by participating in a simulation drill.

Methodological Approach

L&D staff knowledge about MH was measured by using a quantitative clinical study with a quasi-experimental design. According to Melnyk, Morrison-Beedy, and Cole, (2015), "If the research question or hypothesis concerns itself with testing the effects of an intervention or treatment on (patient) outcomes, the study calls for an experimental design." For purposes of this project, a pretest, (quantitative research tool) was administered to the L&D staff to determine existing knowledge about MH. An educational intervention, including a PowerPoint presentation and simulation drill, was designed to teach L&D staff the functions they can perform to improve the team response to a MH emergency. Following the program, a posttest was administered to determine the program's effectiveness. Based on posttest answers, effectiveness of the program was evaluated and the program will be revised as needed.

Sample

The target population was the L&D nursing staff. There are approximately thirty-eight registered nurses employed on the thirteen bed L&D unit in a medium size, central Ohio trauma center. A convenience sample consisted of seventeen L&D nurses. Although the entire L&D

staff will benefit from participation in the simulation drill, the sample size of seventeen L&D nurses was used. The L&D nurses were recruited via email and fliers posted on the L&D unit (See Appendix K, Figure 3).

The inclusion criteria for this study were the L&D nursing staff. According to Segen, (2002), inclusion criteria for clinical research are the medical or social reasons why a person may or may not qualify for participation in a clinical trial. Because this doctoral project is designed to improve L&D staff response to a MH crisis, registered nurses employed on the L&D unit met the inclusion criteria. Nursing staff will be invited to participate in training as an annual requirement in subsequent years. A CME application was filed post program approval as a Quality Improvement project.

Data Collection

Several group educational sessions were conducted in a specific medium sized, central Ohio trauma center in a simulation lab, classroom, or OR. These sessions were forty-five minutes in length and included a PowerPoint presentation (See Appendix D), illustrating MH key educational targets. A MH drill immediately followed these sessions and a tour of the main operating room was conducted so that all participants could see where the MH cart is stored (See Appendix G, Figure 2). All participants took a pretest prior to the educational session and took a posttest after completion (See Appendix C). In addition, nurses who participated in the educational session and drill completed an evaluation of the program (See Appendix H).

Timeline

The target implementation date for the Malignant Hyperthermia Preparedness for Labor and Delivery Nurses training project was planned for September 24, 2018 (See Appendix L, Figure 4). The MH training project mirrors the training received by the OR staff with specific changes designed to meet the needs of L&D nursing staff.

The L&D MH project consisted of three parts. Part I was a pretest administered to the sample of seventeen L&D nurses. Part II was initiated following the pretest, and consisted of a lecture and PowerPoint presentation and hands-on simulation drill in the L&D OR (See Appendix M, Figure 5). The lecture and PowerPoint was initially planned as an on-line learning module to be administered through the hospital education website. However, this was found to be difficult to accomplish prior to the scheduled JACHO hospital visit in October 2018. Instead, four group face-to-face sessions of 3-6 nurses each was the most effective way to reach the staff. Part III was a posttest designed for L&D nurses.

The pretest and posttest were identical and consisted of ten questions that focus on MH causes, treatment, staff responsibilities, location of MH cart, and who, when, and how additional personnel are to be notified in the event of a crisis (See Appendix E). The first of four drills took place in the hospital simulation lab OR on 9/24/18 utilizing a manikin and a simulated MH crisis. The simulation lab was utilized because the L&D unit was too busy to accommodate the MH drill as originally planned for the L&D OR. The other three drills took place in the L&D OR based on availability before or after 7P-7A shifts so that as many L&D nurses as possible had the opportunity to attend.

L&D staff participated in a realistic MH crisis scenario (See Appendix F). Critiques and instruction was provided during the drill by anesthesia staff so that everyone could learn from the event. Nurses were then taken on a tour of the main OR so they could see where the MH cart is stored. The posttest followed the simulation to determine if information was understood and retained by participants. Evaluation of the project consisted of comparing the test results from the pre and posttests. The presentation and simulation and was completed by September 30, 2018. The participants evaluated the program after completing the posttest.

Budget

Budget for the project was over-estimated. Burson and Moran (2014), describe the cost management for a Doctor of Nursing Practice scholarly project in detail. Because the MH project was developed to benefit the hospital and staff as a safety measure for patients, the implementation of the project was not dependent on the budget. However, time spent on project design ranged from 25-50 hours at a rate of $100.00/hour for anesthesia personnel participation. Simulation lab personnel spent approximately 10 hours at $40.00/hour for set up and implementation of drills. Cost of materials: imitation dantrolene sodium (Ryanodex), $5.95 per ampule. Six ampules were needed for demonstration purposes. Other materials such as syringes, needles and IV tubing did not incur a cost, as expired items were utilized in the drills. Each L&D nurse was paid for one hour of participation at approximately $30.00-40.00/hour. Total cost for this life-saving project was less than the original budget of $6,000.00.

The Malignant Hyperthermia Preparedness for Labor and Delivery Nurses training is being planned to be included as part of the annual hospital skills training day that all L&D nurses in this medium size central Ohio trauma center are required to complete. As an incentive to participate, nurses were paid for their time and the hospital education department has processed a CME application so that nurses can receive a free CME.

Analysis and Outcome Evaluation

The goal of this quality improvement (QI) project was to develop and implement an educational program that teaches L&D nurses appropriate MH crisis management. Testing (See Appendix C), before and after participation in the training program was completed. Statistical analysis was performed by recording the rate of a particular response for each question before and after training (See Appendix I, Table 2 & 3). Grant Medical Center OhioHealth Research and Innovation Center used McNemar's test for paired proportions to compare pre and posttest

training responses (See Appendix I, Table 2 & 3). McNemar's test is a non-parametric (distribution-free) test that is used to determine if a statistically significant change in proportions has occurred on a dichotomous trait at two time points on the same population. It "is sometimes referred to as McNemar's Chi-Square test because the test statistic has a chi-square distribution" (Statistics How To, 2019). Response rates are recorded at time 1 and time 2 in a 2×2 contingency table (See Appendix I, Table 2 & 3). Comparing pre and posttest scores in this way assessed the success of the educational program. Results from the pre and post-training rates showed statistically significant data (P- value<0.05) (See Table 1 & Table 2) for two out of ten questions; question 3, "Which agent is not a MH trigger?" and question 9, "What is the initial dose of Ryanodex?" p=<0.05.

Conclusion and Recommendations

According to the pretest results, the online MH training utilized at a medium size central Ohio trauma center does not adequately prepare L&D nurses for a MH crisis event. Data obtained after L&D nurses participated in an additional MH educational training session and drill illustrate that L&D nurses increased their knowledge of MH crisis management. These findings show that a greater number of correct answers were obtained on the posttest than the pretest when L&D nurses participated in the MH Preparedness for Labor and Delivery Nurses educational program and simulation drill. One can conclude that these nurses are now better prepared for a MH crisis. In addition, according to the post-training assessment and debriefing, participants in the program felt better informed about MH and their ability to manage a MH crisis.

Based on the data, this author recommends a change in practice and training of L&D nursing staff. Including L&D nurses in MH training and drill simulations will benefit patients and improve response to a MH crisis event. This author advocates for MH training including

simulation drills to be utilized in all locations where MH triggering agents are used, including L&D units. By conducting a well-organized annual training session and simulation drill, management of MH can improve patient care and safety.

The MH simulation drill for L&D nurses can and should be implemented at other institutions where annual MH training is not a priority. Evidence of posttest scores points to personnel being better prepared for high acuity, low frequency events when they practice rescue measures needed for MH management. Utilizing Benner's Novice to Expert theory, (Benner, 1984), can help meet the growing demand for emergency preparedness and nursing excellence. In my own institution, as a result of the evidence identified, I have spearheaded MH training for the L&D department and have advocated for MH simulation drills to be included in annual training requirements. In the future, I plan to train others to manage MH drills so that this training will become a permanent component of L&D nursing skills.

Summary

The experience of designing and implementing the MH training session and drill for L&D nurses has been fulfilling because all of the L&D nurses who participated in this project achieved better scores on the posttest than on the pretest. This illustrates the MH project was beneficial to the nursing staff and may prevent a MH crisis from becoming a disaster for mother and infant.

The MH training and drill has been approved by OhioHealth Grant Medical Center to become part of L&D nursing annual training. This is important because MH training and the ability to manage a MH emergency is a lifesaving skill. Both nurses and patients will benefit from the additional training the L&D nurses receive. This new educational program will now bridge the knowledge gap that existed prior to its implementation.

Overall, the MH training sessions went smoothly and were well-received, however, through a debriefing session held after the training sessions, it became apparent the nurses wanted the training to take place in the OR rather than the simulation lab or classroom. This author observed better participation and engagement of the staff when the drill was conducted in the OR. Unfortunately, time, space and staffing will play a role in how, when and where future drills are conducted with patient safety being the priority. As long as staff and trainers are flexible, this issue can be overcome. In addition, better documentation and more detailed testing may have provided useful qualitative information rather than quantitative results alone.

Looking toward the future, additional research in how often MH is encountered in L&D, and how effectively it is managed would provide healthcare personnel with better tools to use to in case of a MH crisis. The knowledge that this quality improvement project will continue into the future, to benefit staff and patients, is rewarding.

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Table 1

Clinical Needs Assessment Questions

Question	Yes	No
Do you know how this L&D unit manages a MH crisis?	0	10
Do you know whom to contact in a MH crisis?	0	10
Do you know where the MH cart is located?	0	10
Do you know to unlock the MH cart?	0	10

Appendix A

Otterbein Internal Review Board Approval

INSTITUTIONAL REVIEW BOARD
RESEARCH INVOLVING HUMAN SUBJECTS
OTTERBEIN UNIVERSITY

X Original Review
_____ Continuing Review
_____ Five-Year Review
_____ Amendment

ACTION OF THE INSTITUTIONAL REVIEW BOARD

With regard to the employment of human subjects in the proposed research:

HS # 17/18-89
Prusinski & Rabinowitz: Malignant Hyperthermia Preparedness for Labor and …

THE INSTITUTIONAL REVIEW BOARD HAS TAKEN THE FOLLOWING ACTION:

✓ Approved
_____ Approved with Stipulations*
_____ Deferred
_____ Disapproved
_____ Waiver of Written Consent Granted

*Stipulations stated by the IRB have been met by the investigator and, therefore, the protocol is APPROVED.

It is the responsibility of the principal investigator to retain a copy of each signed consent form for at least four (4) years beyond the termination of the subject's participation in the proposed activity. Should the principal investigator leave the college, signed consent forms are to be transferred to the Institutional Review Board for the required retention period. This application has been approved for the period of one year. You are reminded that you must promptly report any problems to the IRB, and that no procedural changes may be made without prior review and approval. You are also reminded that the identity of the research participants must be kept confidential.

Date: 27 August 2018 Signed: Meredith C Frey
Chairperson

OC HS Form AF

Appendix B

OhioHealth QI Project Approval

September 13, 2018

Patricia Rabinowitz, CRNA, MSN Nurse Anesthetist Anesthesia Grant Medical Center

111 South Grant Avenue Columbus, Ohio 43215

RE: ***Malignant Hyperthermia Preparedness for Labor and Delivery Nurses***

Dear Dr. Rabinowitz,

The OhioHealth Quality Improvement/Research Determination Sub Committee has reviewed and approved your request to conduct the aforementioned QI project.

The activities proposed in the project are not considered human subjects research, as defined in 45CFR part 46 (see below); therefore does not meet the requirements for OhioHealth Institutional Review Board review nor oversight.

"Human subject means a living individual about whom an investigator conducting research obtains: (1) Data through intervention or interaction with the individual or (2) Identifiable private information."

"*Research"* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

This approval includes the following documents:

- Rabinowitz - Malignant Hyperthermia QI - Protocol 9-5-18
- Appx 4.1 - Participant Recruitment Notice & Goals
- Appx 4.2 - MH Lecture
- Appx 4.3 - MH Knowledge Eval

Thank you very much for notifying our office about this activity. We are always happy to assist with any questions you have concerning research activities.

Sincerely,

Adam J. McClintock, MBA, CIP Manager, Office of Human Subjects Protections OhioHealth Research & Innovation Institute 3545 Olentangy River Road, Suite 328 Columbus, OH 43214

Appendix C

Malignant Hyperthermia Knowledge Evaluation

Please answer the following questions about Malignant Hyperthermia (MH). Scores from this test will be used to measure the success of the training session. Your score will not be linked to you in any way, and we will not share your scores.

1. What is MH?	☐ Excessive calcium release triggered by Succinylcholine/or anesthetic gas ☐ Overdose of anesthesia ☐ Muscle spasms
2. Is MH an inherited disorder?	☐ Yes ☐ No
3. Which agent is not a MH trigger?	☐ Desflurane ☐ Propofol ☐ Succinylcholine
4. What drug is used to treat MH?	☐ Calcium ☐ Ryanodex ☐ Epinephrine
5. Where is the MH cart located?	☐ Main OR front desk ☐ OR B ☐ L&D supply room
6. What is an early sign of a MH crisis?	☐ Muscle spasms ☐ Increased end-tidal CO2 ☐ High temperature
7. What is a late sign of a MH crisis?	☐ Low temperature ☐ High temperature ☐ Muscle weakness
8. What is the first action when MH is suspected?	☐ Discontinue general anesthesia and switch to non-triggering drugs ☐ Continue surgery but alert patients family ☐ Administer Calcium
9. What is the initial dose of Ryanodex?	☐ 5 mg ☐ 10 mg/kg ☐ 2.5 mg/kg
10. Where are ice bags located?	☐ In the freezer ☐ In the MH cart ☐ In the main OR

FOR STAFF USE ONLY: ☐PRE ☐POST

Appendix D

Malignant Hyperthermia PowerPoint

Malignant Hyperthermia Preparedness for Labor and Delivery Nurses

Patricia Rabinowitz
MSN, DNP Candidate
Otterbein University
College of Nursing

Acknowledgments

- Final Project Committee
  - Regina Prusinski, DNP
  - Kacy Ballard, DNP
  - Donna Doyle, DNP

Acknowledgments

- Thank you to the Labor and Delivery Unit at Grant Medical Center
- Thank you to Dr. Norman Smyke who helped develop and implement this project
- Thank you to Kate Ireland, RN, Director of Education in Labor and Delivery at Grant Medical Center
- Special thanks to the statisticians at Grant Medical Center for the assistance in collection and analysis of data

Introduction

- CRNA certified 1994
- 24 years experience
- Specialize in labor and delivery anesthesia

Introduction to the Problem

- The clinical setting is the labor and delivery (L&D) unit at Grant Medical Center (GMC)
- Approximately 38 registered nurses are employed on the L&D unit
- MH training for L&D is limited to an online learning module

Introduction to the Problem

- L&D nurses specialize in care of pregnant and laboring women
- Spinal/epidural (neuraxial) anesthesia is the safest anesthetic in pregnancy, although general anesthesia (GA) is sometimes necessary (Tsen, 2014)
- Because GA is infrequent, L&D staff will rarely, if ever, experience a MH crisis
- MH is a high acuity, low frequency event (Cain, Riess, Gettrust, & Novalija, 2014) and as such, L&D nurses are at risk of being unprepared

Extent of the Problem

- Operating Room (OR) nurses complete an online MH training module and participate in a MH simulation drill annually
- Online module is the only MH training available for L&D nurses
- Low-frequency, high-risk events such as a MH crisis are best prepared for by a well-crafted simulation exercise (Galloway,2009). L&D nurses are at risk for mismanagement of MH due to infrequent, often unplanned GA, and inadequate MH training

PICO Question

- Does an online training module in conjunction with a simulation drill provide L&D nurses with more effective strategies to handle a MH crisis than an online training module alone?

Clinical Needs Assessment

Question	Yes	No
Do you know how this L&D unit manages a MH crisis?	0	10
Do you know whom to contact in a MH crisis?	0	10
Do you know where the MH cart is located?	0	10
Do you know to unlock the MH cart?	0	10

Nature of the project

- After a Clinical Needs Assessment was performed, a plan was devised to develop a MH simulation drill for L&D nurses
- 17 Nurses completed the online module and then took a simulation drill pretest
- After participation in the drill, a posttest was administered
- Pre and posttest scores were compared and statistically evaluated

Program Goals

- Participants will learn the causes, signs and symptoms of MH.
- Participants will learn where the MH cart is located.
- Participants will learn where to obtain dantrolene sodium, (Ryanodex), correct dose, and how to mix it.
- Participants will know how and where to obtain bags of ice.
- Participants will learn the different tasks completed by medical personnel when responding to a MH crisis.
- Participants will practice response to MH crisis by participating in a simulation drill.

Summary of Evidence Literature Review

- Minimal literature on MH protocols specifically for L&D
- "Many clinicians are unprepared to manage an MH crisis because it requires the use of low-frequency, high-risk skills and procedures." (Cain, et al.)
- The best chance for a successful outcome is a swift, coordinated response. Because MH is so rare, diagnosis, treatment, and management skills must be reviewed and reinforced periodically to maintain competency (Hirshey Dirksen, Van Wicklin, Ledrut, Mashman, Neiderer, and Merritt, 2013)

Summary of Evidence Literature Review

- Simulation and real-life scenarios to facilitate learning are well-recognized educational techniques in high-risk industries (Gaba, 2004, Waxman, 2010)
- Anesthesia educators have been using simulators since 1994 to optimize their skills and "with clearly defined scenario objectives, there were better ratings of problem solving and critical thinking of students during the simulation activity" (Sleeper and Thompson, 2008)

Malignant Hyperthermia

- Rare, often fatal complication of GA
- Occurs in approx. 1/3,000-50,000 anesthetics
- Genetic predisposition triggered by succinylcholine and/or volatile agents
- Susceptible patients have defective ryanodine receptor type 1 (RYR1) gene

(Rosenberg, Sambuughin, Riazi, and Dirksen, 2003)

Malignant Hyperthermia

- RYR1 controls the calcium ion channel in skeletal muscle
- In susceptible patients, succinylcholine and/or volatile anesthetic gases initiate uncontrolled calcium release
- High intracellular calcium causes hypermetabolic cascade of events

(Rosenberg, et al. , 2003)

SUCCINYLCHOLINE (Sux)

- Primary muscle relaxant used in emergency cesarean section
- Causes temporary paralysis of skeletal muscle and vocal cords to facilitate endotracheal intubation
- Sux with or without anesthetic gas can trigger MH crisis in susceptible individuals

(Rosenberg, et al. 2003)

Hypermetabolic MH response

- Hyper sympathetic response initiated by MH triggering agents
- Increased production of carbon dioxide, heat, and lactate
- Increased oxygen consumption
- Cell membrane disruption allows leakage of potassium, phosphate, magnesium and myoglobin into extracellular fluid

(Rosenberg, et al. 2003)

Clinical presentation

- Unexplained rise in end-tidal carbon dioxide
- Tachycardia, arrhythmias
- Muscle rigidity/masseter muscle spasm
- Hyperthermia
- Myoglobinuria
- Renal failure, cardiac arrest, death

(Rosenberg, et al, 2003)

Dantrolene sodium (Ryanodex)

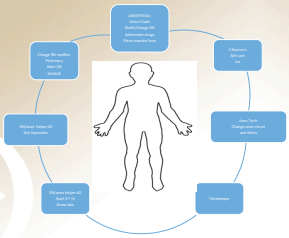
- RYR1 receptor antagonist
- Only known treatment for MH
- Must be given within first 10 min of crisis for best results
- 3 vials kept in hospital at all times
- Dose: 2.5 mg/kg
- 70kg patient=175 mg
- 250 mg vial + 5 ml sterile water
- Dose = 3.5 ml
- Administer over 1 minute

Theoretical Framework

- Patricia Benner's Novice to Expert theory of skill acquisition is the theoretical framework for this project
- Benner (1984) identifies 5 levels of nursing practice: novice, advanced beginner, competent, proficient, expert
- Benner further identifies ability to effectively manage rapidly changing situations as an advanced practice nursing domain

MH training and simulation drill for L&D

- On-line learning module completed by the 17 participants
- Pretest administered after the online module and prior to the additional training and drill
- PowerPoint presentation
- Simulation of MH crisis in L&D operating room by Sim Lab personnel, anesthesia and educators
- Team roles assigned
- MH cart obtained
- Dantrolene sodium (Ryanodex) mixed and administered
- Debriefing
- Posttest to evaluate program effectiveness



Timeline

Budget

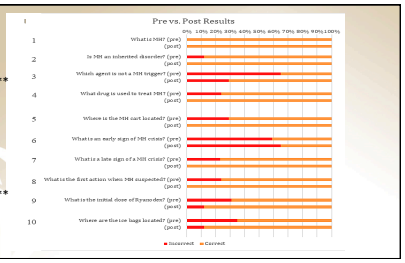
- Cost of project was less than $6000.00
- Includes 25-50 hrs. for project design
- 10 hours for set up and 4 scheduled MH drills
- 6 vials of imitation dantrolene sodium (Ryanodex) at $5.95/ each

Budget

- Budget was met, cost was less than anticipated
- QI project was approved as a simulation drill added to the online training module and all costs were absorbed by the hospital to improve nursing skills and patient safety

Outcome Analysis

- Instruments for evaluation of plan effectiveness:
  - Pre and posttest
  - Posttest scores compared with pretest
  - Data measured and analyzed through descriptive statistics
- McNemar's test for paired proportions used by Grant Medical Center OhioHealth Research and Innovation Center



Outcomes and analysis

- Grant Medical Center OhioHealth Research and Innovation Center used McNemar's test for paired proportions to compare pre and posttest training responses.
- McNemar's test is a non-parametric (distribution-free) test used to determine if a statistically significant change in proportions has occurred on a dichotomous trait at two time points on the same population. It "is sometimes referred to as McNemar's Chi-Square test because the test statistic has a chi-square distribution" (Statistics How To, 2019). Response rates are recorded at time 1 and time 2 in a 2×2 contingency table.
- Results from the pre and post training rates showed statistically significant data (P- value<0.05) for two out of ten questions, question 3, "Which agent is not a MH trigger?" and question 9, "What is the initial dose of Ryanodex?" p=<0.05.

Conclusions

- Utilizing the Novice to expert theory, L&D nurses increased skills and knowledge pertaining to MH
- Success of project was determined by comparing pre and posttest scores of online training vs hands on drill
- Project facilitators included education coordinators in L&D and anesthesia dept., L&D managers, pharmacy
- Limitations included scheduling the simulations to occur in the L&D OR so as not to conflict with surgeries and to accommodate nursing schedules

Recommendations

- Data obtained after participation in the MH training and drill illustrate that L&D nurses increased their knowledge of MH crisis management
- The MH simulation drill for L&D nurses can and should be implemented at other institutions where annual MH training is not a priority.
- Evidence of posttest scores points to personnel being better prepared for high acuity, low frequency events when they practice rescue measures needed for MH management.
- Utilizing Benner's Novice to Expert theory, (Benner, 1984), can help meet the growing demand for emergency preparedness and nursing excellence.
- In my own institution, as a result of the evidence identified, I have spearheaded MH training for the L&D department and have advocated for MH simulation drills to be included in annual training requirements. In the future, I plan to train others to manage MH drills so that this training will become a permanent component of L&D nursing skills.

Summary

- This educational session and drill has been approved by OhioHealth Grant Medical Center to become part of L&D nursing annual training.
- This project was a fun and effective way for the L&D nurses to improve their skills and learn how to manage a rare life-threatening event. L&D nurses are experts at handling serious events pertaining to pregnancy, such as hemorrhage, uterine rupture, and DIC. After completion of the MH simulation training and drill, they are now better prepared for a MH crisis.

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Appendix E

Malignant Hyperthermia Drill for L&D Staff

Please join us for a Malignant Hyperthermia (MH) practice drill in L&D on September 24, 2018 as part of the L&D skills day. Drill will begin at 4pm and last approximately 30 minutes. Participation in the MH drill is entirely voluntary, however, skills learned could save lives!

Introduction

1. L&D staff will participate in a simulation/drill of a real-life MH crisis
2. Drill will take place in a L&D OR during skills day
3. Sim lab staff will set up scenario with mannequin, monitors, and slide show
4. 2 SRNA students will be assigned to help with set up

Goals

1. Participants will learn the signs and symptoms of MH.
2. Participants will learn where the MH cart is kept
3. Participants will learn where to obtain Ryanodex, and how to mix it
4. Participants will know how and where to obtain bags of ice
5. Participants will learn the different tasks completed by medical personnel when responding to a MH crisis
6. Participants will practice response to MH crisis by participating in a simulation drill

Session Plan (30 minutes)

1. Slide show will begin at 1600
2. Drill will start at 1615 and will last approximately 15 min
3. Debriefing

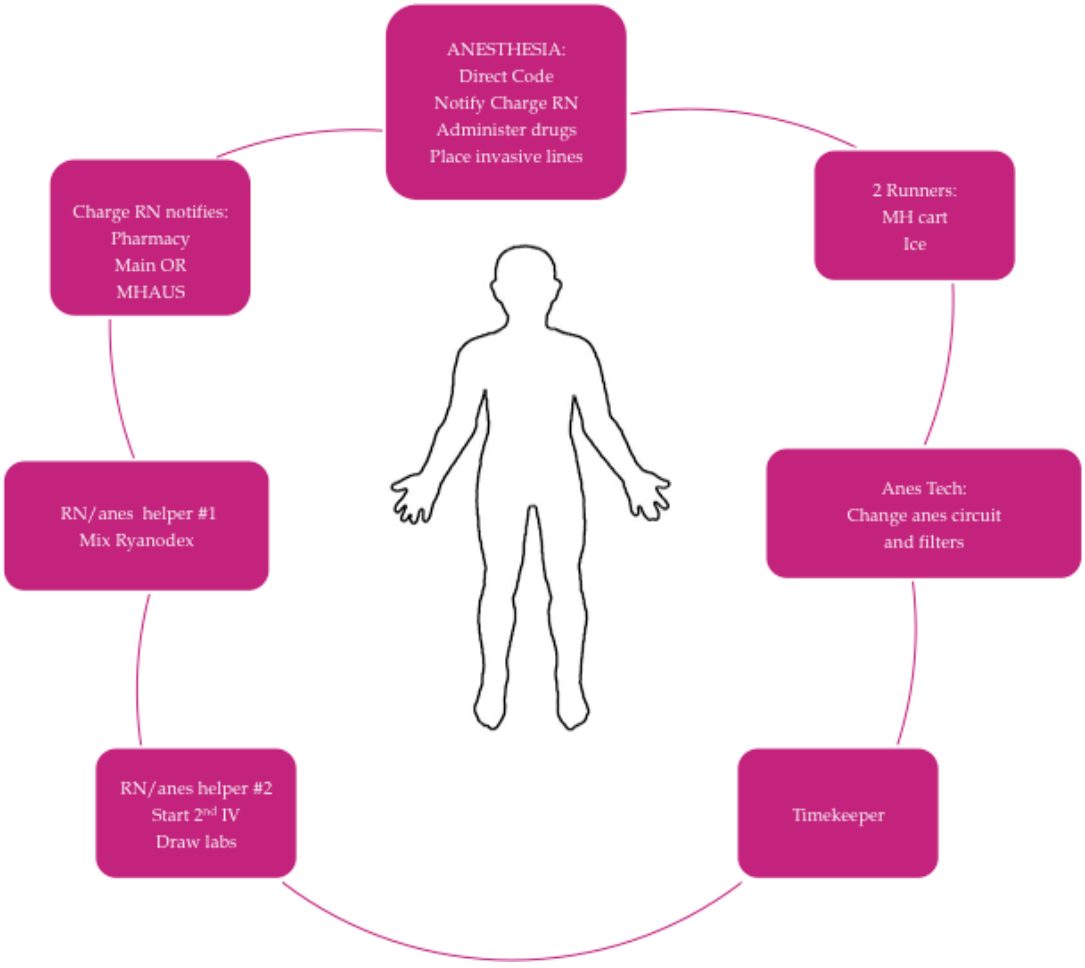
Debriefing (15 minutes)

1. What went well?
2. What can we do better?
3. How can we improve?
4. Any changes needed?
5. Suggestions

Appendix F

Staff Assigned Roles/script

1. Anesthesia provider will alert staff in room of suspected MH event
2. Surgeon will complete surgery as quick as possible
3. Anesthesia provider will alert attending anesthesiologist and anesthesia tech
4. Anesthesia tech will change circuit and soda lime and apply charcoal filters
5. Circulator will notify front desk and main OR and call for extra help
6. Front desk will notify pharmacy
7. 2nd RN will retrieve MH cart
8. 2nd RN will assist with mixing Ryanodex until pharmacy available
9. 3rd RN or anesthesia tech will obtain ice
10. Arterial line set up and extra IV set up to room
11. Runner/? Anesthesia tech will run stat labs



Appendix G

Malignant Hyperthermia Cart Contents

Item:	Par Level:	Order #:
Top of Cart		
Orange Medication Toolbox - locked by pharmacy		
Drawer #1		
Malignant Hyperthermia Reference Book	1	
Labels: STAT Stickers	10	
Biohazard Bags	10	CH6X9B10
Gold Blood Tube - Myoglobin, CK, SMA-19	5	8019904
Blue Blood Tube - PT, PTT, fibrinogen, FSP, D-dimer	5	8019827
Purple Blood Tube - CBC, diff, platelets	5	8019341
Gray Blood Tube - Lactic Acid	5	8019582
Sterile Specimen Containers	2	C13901
Drawer #2		
Alcohol Wipes	30	KC6818
18 GA x 1/2" Needles	15	BF305918
Insulin Syringes - 27 GA x 1/2"	4	BF305945
3 ml Syrginges	5	BF309657
5 ml Syringes	5	BF309646
60 ml Syringes	12	BF309653
Stopcocks	3	D500
ABG Kits	2	4649P-1
1 " Paper Tape	2	M1534
Chloraprep 3 ml Applicators	2	260415
Drawer #3		
Secondary Medication Set (more in pyxis)	1	2C7451
A-line Tubing	2	PX260
Extension Tubing	2	2C6227
Veni-gard Dressing	3	705-4431
Spring Wire Guides	2	AW-04025
Radial Artery Catheters - 20 GA	4	RA-4020
Esophageal Stethoscope - 18 Fr	1	VES400-18
Needle Holder - Sterile	1	SPD
Kelly Clamps - Sterile	2	SPD
Suture: 3-0 Silk SH PO	2	C013D
Ioban - 2	1	M6650EZ

Drawer #4		
Y Blood Tubing	2	2C7607
Cysto/Bladder Irrigation Tubing	2	2C4040
Toomey Syringe	2	OC3846
Betadine Prep Tray	1	41591
Medline Silicone Foley Catheter Kit w/ Urine Meter	1	
3-Way Foley Catheter, 16 Fr, 30 ml	2	167216
Suction Tubing	1	
NG Tube - 18 Fr	1	N612
Surgilube	1	CL000304A
Rectal Tubes 22 - Not Sterile	1	
Rectal Tubes 30 - Not Sterile	1	
Catheter Plugs	2	10743950

Drawer #5		
Sodasorb	1	00887D
Blue Basin - Large	2	
Plastic Bags - Small	5	
Plastic Bags - Large	5	

Fluids/Insulin	
Insulin - OR Pyxis	
Frozen Saline 1000 ml - Freezer outside of OR 5	4
Cold Saline 1000 ml bag - Frig across from OR 5	6
Cold Saline 3000 ml bag - Frig across from OR 5	2
Cold Saline 1000 ml bottle - Frig across from OR 5	4
Ice - Between OR 4 & OR 5, PACU, ASC	

Malignant Hyperthermia Cart

Figure 1. Malignant Hyperthermia Cart. Each drawer contains contents listed in Appendix G.

Placement of Malignant Hyperthermia Cart in the Main Operating Room

Figure 2. Malignant Hyperthermia Cart located in the Main Operating Room.

Appendix H

Program Evaluation

This presentation improved my knowledge about Malignant Hyperthermia and I am likely to apply this knowledge.

- o Strongly Disagree
- o Disagree
- o Neutral
- o Agree
- o Strongly Agree

The presentation prepared me to care for patients experiencing a Malignant Hyperthermia crisis on the L&D unit.

- o Strongly Disagree
- o Disagree
- o Neutral
- o Agree
- o Strongly Agree

I believe Malignant Hyperthermia is a treatable medical condition.

- o Strongly Disagree
- o Disagree
- o Neutral
- o Agree
- o Strongly Agree

The information presented has positively influenced my opinion about caring for L&D patients experiencing a Malignant Hyperthermia crisis.

- o Strongly Disagree
- o Disagree
- o Neutral
- o Agree
- o Strongly Agree

I understand that knowing where the Malignant Hyperthermia cart is kept, drugs used in a crisis, and universal Malignant Hyperthermia protocols can improve care and decrease serious complications in L&D patients.

- o Strongly Disagree
- o Disagree
- o Neutral
- o Agree
- o Strongly Agree

Please provide us with suggestions for improving the content, facilitation, delivery, environment and/or utility of this event.

_____

_____

_____

Appendix I

Pre and Post test Results

Characteristic		Statistic/Category	Results
1. What is MH?	Pre	Excessive calcium release ttriggered by Succinylcholine and/or anesthetic gas	17 / 17 (100.0 %)
	Post	Excessive calcium release ttriggered by Succinylcholine and/or anesthetic gas	17 / 17 (100.0 %)
2. Is MH an inherited disorder?	Pre	No	2 / 17 (11.8 %)
		Yes	15 / 17 (88.2 %)
	Post	Yes	17 / 17 (100.0 %)
3. Which agent is not a MH trigger?	Pre	Desflurane	4 / 17 (23.5 %)
		Propofol	6 / 17 (35.3 %)
		Succinylcholine	7 / 17 (41.2 %)
	Post	Propofol	12 / 17 (70.6 %)
		Succinylcholine	5 / 17 (29.4 %)
4. What drug is used to treat MH?	Pre	Calcium	4 / 17 (23.5 %)
		Ryanodex	13 / 17 (76.5 %)
	Post	Ryanodex	17 / 17 (100.0 %)
5. Where is the MH cart located?	Pre	L&D Supply Room	3 / 17 (17.6 %)
		Main OR Desk	12 / 17 (70.6 %)
		OR B	2 / 17 (11.8 %)
	Post	Main OR Desk	17 / 17 (100.0 %)
6. What is an early sign of a MH crisis?	Pre	High temperature	1 / 17 (5.9 %)
		Increased end-tidal CO2	7 / 17 (41.2 %)
		Muscle spasms	9 / 17 (52.9 %)
	Post	Increased end-tidal CO2	6 / 17 (35.3 %)
		Muscle spasms	11 / 17 (64.7 %)

		Muscle spasms	11 / 17 (64.7 %)
7. What is a late sign of a MH crisis?	Pre	High temperature	13 / 17 (76.5 %)
		Low temperature	3 / 17 (17.6 %)
		Muscle weakness	1 / 17 (5.9 %)
	Post	High temperature	17 / 17 (100.0 %)
8. What is the first action when MH is suspected?	Pre	Administer Calcium	4 / 17 (23.5 %)
		Discontinue general anesthesia and switch to non-triggering drugs	13 / 17 (76.5 %)
	Post	Discontinue general anesthesia and switch to non-triggering drugs	17 / 17 (100.0 %)
9. What is the initial dose of Ryanodex?	Pre	10 mg/kg	2 / 16 (12.5 %)
		2.5 mg/kg	11 / 16 (68.8 %)
		5 mg	3 / 16 (18.8 %)
	Post	10 mg/kg	2 / 17 (11.8 %)
		2.5 mg/kg	15 / 17 (88.2 %)
10. Where are ice bags located?	Pre	In the MH cart	11 / 17 (64.7 %)
		In the main OR	6 / 17 (35.3 %)
	Post	In the MH cart	15 / 17 (88.2 %)
		In the main OR	2 / 17 (11.8 %)

Table 2

Pretest Verses Posttest

Q1 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**17**	**0**	
Incorrect	**0**	**0**	**n/a**

Q2 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**15**	**0**	
Incorrect	**2**	**0**	**n/a**

Q3 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**6**	**0**	
Incorrect	**6**	**5**	**0.01**

Q4 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**13**	**0**	
Incorrect	**4**	**0**	**n/a**

Q5 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**12**	**0**	
Incorrect	**5**	**0**	**n/a**

Q6 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**5**	**2**	
Incorrect	**1**	**9**	**0.56**

Q7 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**13**	**0**	
Incorrect	**4**	**0**	**n/a**

Q8 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**13**	**0**	
Incorrect	**4**	**0**	**n/a**

Q9 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**11**	**0**	
Incorrect	**4**	**2**	**0.045**

Q10 pre vs. post

	Post		
Pre	**Correct**	**Incorrect**	**P-Value**
Correct	**10**	**1**	
Incorrect	**5**	**1**	**0.10**

Table 2. Pretest results verses posttest results.

Table 3

Table 3. Graphic results of pre verses posttest.

Appendix J

Informed Consent

The Department of Nursing at Otterbein University supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You should be aware that even if you agree to participate, you are free to withdraw at any time without penalty.

We are interested in determining if participation in a Malignant Hyperthermia (MH) drill will prepare labor and delivery (L&D) nurses for a MH crisis. You will take a 10-question pretest prior to the drill that will consist of a PowerPoint presentation, and hands-on simulation of a MH crisis. This will be followed by a posttest. It is estimated that this will take no more than 30 minutes of your time. Although it is not likely, there is a chance that you might feel slightly uncomfortable with some of the questions and parts of the simulation. Although participation will not directly benefit you, we believe that the information will be useful in helping the labor and delivery unit prepare to manage a rare, life-threatening malignant hyperthermia crisis.

Your participation is solicited although strictly voluntary. We assure you that your name will not be associated in any way with the research findings. Only a code number will identify the information.

If you would like additional information concerning this study before or after it is complete, please feel free to contact me by phone or mail.

Sincerely,

Dr. Regina Prusinski, Patricia Rabinowitz, Principal Investigator

Campus Address: Science, 435D
Campus Phone: 614-823-8311

_____ Signature of subject agreeing to participate

With my signature I affirm that I am at least 18 years of age.

Appendix K

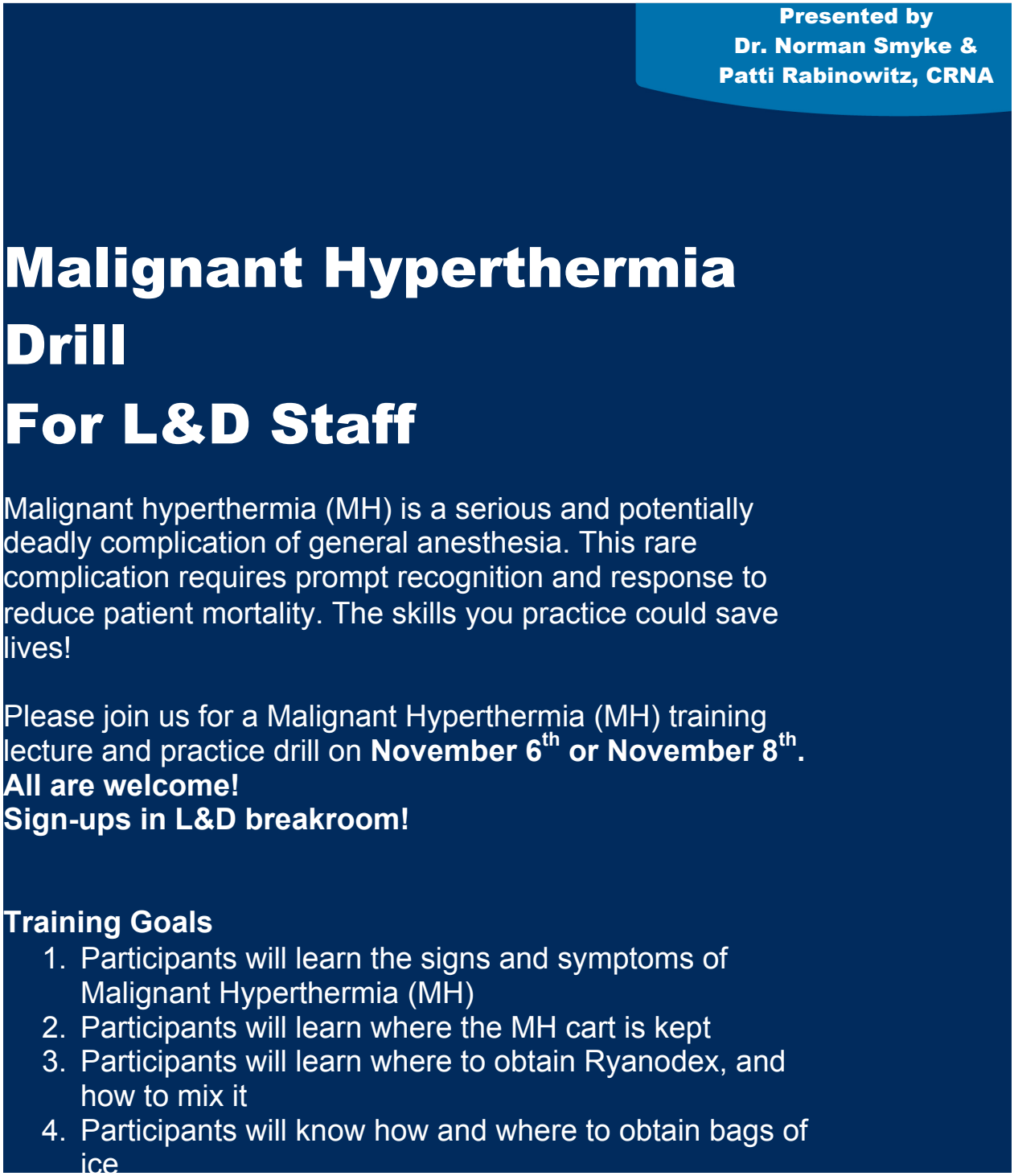


Figure 3. Invitation to nursing staff.

Appendix L

Malignant Hyperthermia Drill Timeline

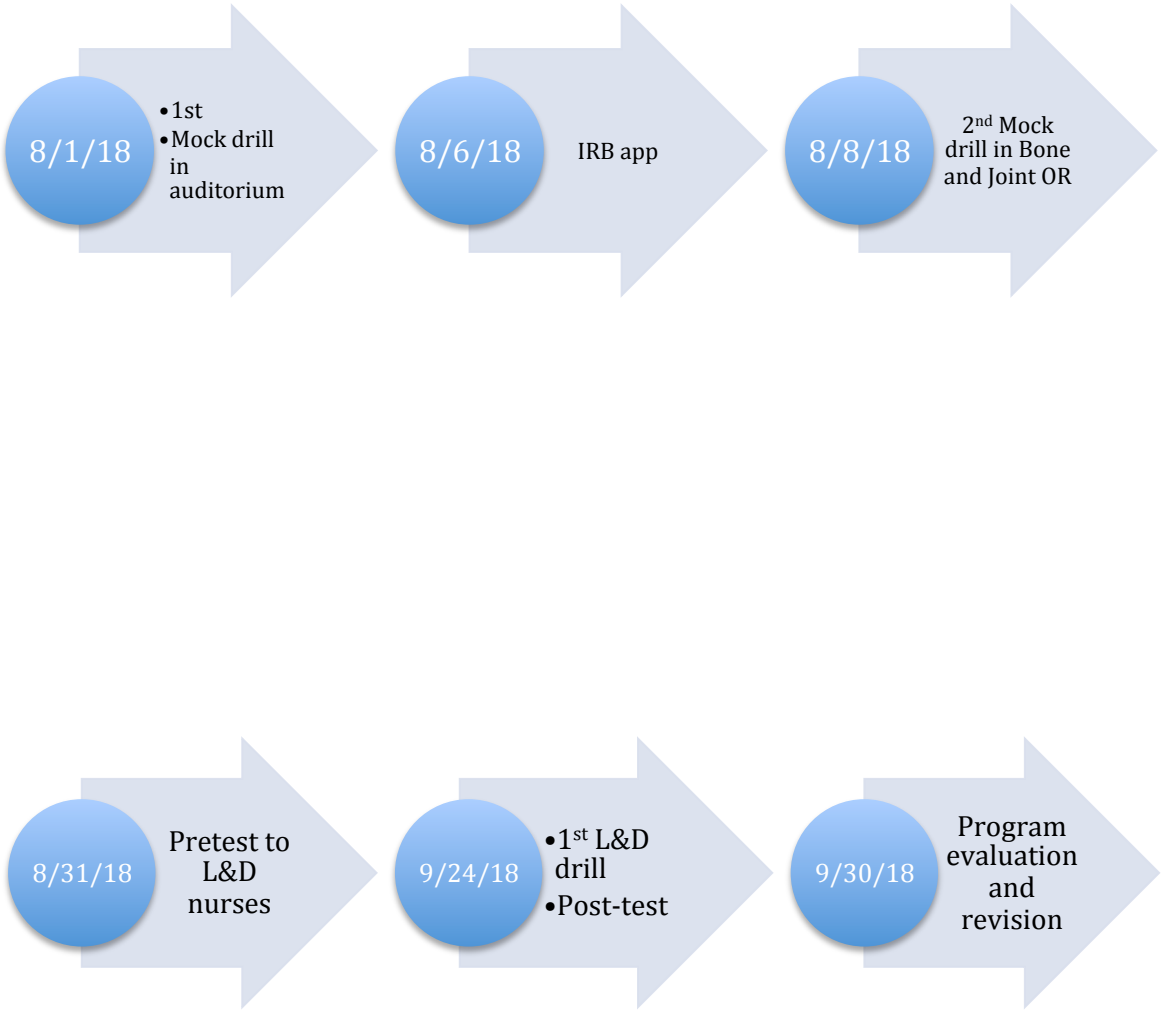


Figure 4. Proposed project timeline.

Appendix M

Figure 5. Operating room showing anesthesia machine with monitors.