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TITLE: Obstetric Simulation Training and Teamwork (OB-STaT) to Reduce Postpartum Hemorrhage

PRINCIPAL INVESTIGATOR:

CDR Joy A. Greer, MD

CONTRACTING ORGANIZATION: Naval Medical Center, Portsmouth, VA

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14. ABSTRACT

Introduction: Postpartum hemorrhage (PPH)–complicating 4-6% of all deliveries–remains a leading cause of treatable maternal morbidity and mortality in the US. PPH safety bundles may provide an opportunity to improve clinical skills and have been associated with improved patient outcomes. Additionally, military obstetric team members are expected to deploy and provide combat casualty care further necessitating the need for effective teamwork. This study aims to determine the impact of the Obstetric Simulation Training and Teamwork (OB-STaT) curriculum on PPH rates and associated clinical markers in continental United States (CONUS) U.S. Navy (USN) military treatment facilities (MTFs). The investigators hypothesize that OB-STaT will: (1) decrease PPH rates; and improve: (2) objective measures of hemorrhage management, (3) perceptions of teamwork, (4) team performance indicators and latent threat detection, and (5) overall patient satisfaction. **Methods:** This is a prospective cross-over cohort study of CONUS USN MTFs currently providing perinatal care. Baseline 6-month clinical data of all measures (clinical, team performance, and patient satisfaction) will be collected using medical records and validated questionnaires. Next, each site will be exposed to the OB-STaT curriculum over a 2-5 day period to ensure maximum participation. Each session is 4 hours in duration and begins with baseline knowledge and teamwork evaluation through a pre-test and in-situ simulation. Next, participants complete a multi-disciplinary debrief followed by independent practice on psychomotor skill work stations utilizing task trainers. Finally, a second simulation, debrief and knowledge post-test are administered. During simulations, teamwork and discipline specific PPH checklist assessments are completed by subject matter experts (SME). Clinical data, patient satisfaction, and teamwork measures will be collected in 6-month intervals following OB-STaT and compared within and between cohorts. Longitudinal simulation probes will occur in 3-month intervals to determine skill and teamwork decay. **Results To Date:** Thus far, 343 healthcare professionals from 5 sites have completed OB-StaT and 232 subjects enrolled in the study: 77 nurses, 54 physicians, 33 corpsman, 28 residents, 26 advanced practice nurses, and 4 students, 6 techs and 4 others. To support team training objectives, multiple specialties are included in the training such as nursing (n=84), OB/GYN (n=60), pediatrics (n=26), anesthesia (n=23), family medicine (n=13) respiratory (n=5) and other (n=21). 72% of participants report treating a PPH at least monthly further solidifying the importance of continued PPH teamwork training. Preliminary results indicate participants find value in the program as evident by the following Student Satisfaction and Self-Confidence in Learning subscales; Objectives and Information (4.43±0.81), Support (4.55±0.75), Problem Solving (4.44±0.82), Feedback (4.66±0.72) and Fidelity (4.48±0.83). **Conclusions:** Perinatal care is one of the largest services and high risk areas in the military health system. While PPH is relatively rare, it requires prompt recognition and effective teamwork to manage effectively. OB-STaT is poised to provide realistic multidisciplinary training, skills sustainment, and improve patient care. The results of OB-STaT will inform training algorithms policy and simulation requirements for obstetric care and traumatic hemorrhage control in military and civilian institutions.

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a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	16	19b. TELEPHONE NUMBER *(include area code)*

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1. **INTRODUCTION:**

Childbirth-related care accounts for almost half of the care provided to hospitalized female Military Health System beneficiaries. Worldwide, excessive bleeding or post-partum hemorrhage (PPH) occurs in about 4-6% of deliveries. Individual and team effectiveness is crucial to reduce the severity of consequences associated with PPH. The Obstetric Simulation Training and Teamwork (OB-STaT) curriculum provides a standardized and simulation based team training with the primary goal of decreasing PPH rates, improving objective PPH measures and increasing teamwork. The current prospective cross-over cohort study provides an opportunity to complete OB-STaT training at all US Navy Military Treatment Facilities (MTFs) in the continental United States and track patient outcomes and measures of teamwork. The timeline of this study allows for longitudinal tracking to determine if skills are maintained during follow up and provide additional insight into the effectiveness of simulation and the frequency with which it should optimally be implemented.

2. **KEYWORDS:**

Simulation, training, team, postpartum hemorrhage, continuing education, interprofessional, safety, obstetric, military, hospital, in situ.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**
  - **Specific Aim 1:** Determine the immediate impact of OB-STaT on team member knowledge in diagnosis and management of PPH via pre- and post-test scores, adherence to established protocols for PPH, and teamwork through simulation scenarios.
  - **Specific Aim 2:** Compare the change in PPH rates and associated clinical outcomes, team performance, and patient satisfaction six months after baseline assessment between the control cohort and the cohort receiving the initial OB-STaT intervention.
  - **Specific Aim 3:** Compare PPH rates and associated clinical outcomes, team performance, and patient satisfaction before and 6 months after OB-STaT across the entire USN cohort.
  - **Specific Aim 4:** Identify skill and teamwork attrition after OB-STaT implementation through unannounced longitudinal systematic simulation probes and change in post-training clinical outcomes to determine a potential interval on which to base ongoing PPH simulation training.
- **What was accomplished under these goals?**
  - The training curriculum was finalized by the research team and TATRC collaborators and a study initiation visit occurred to train and standardize members of the research team.
  - Additional resources were acquired including the purchasing of statistical software and consumables. Personnel including clinical research coordinators were hired. A trained active duty standardized patient was

used during the training curriculum and probes during this reporting period.

- OB-STaT training occurred at all Navy Medicine West (NMW) sites. 343 healthcare workers participated in the training and 232 consented to participate in the research study. Additionally, the first three month simulation probe was completed at the NMW sites and included 76 participants total.
- Baseline survey data was completed for all Navy Medicine East (NME) sites. Overall, the Clinical Teamwork Scale was completed on 32 deliveries, 23 patients completed a satisfaction survey and 11 members of the delivery team completed the TeamSTEPPS Teamwork Perception Questionnaire.
- Data collected from the trainings and teamwork observations has been compiled and coded.
- DSAA approval obtained to pull clinical outcomes data.

- **What opportunities for training and professional development has the project provided?**

  As described above, the OB-STaT curriculum has already trained 343 healthcare professionals from 5 sites including 80 nurses, 54 physicians, 36 corpsman, 28 residents, 26 advanced practice nurses, and 6 students. To help meet team training objectives, multiple specialties are included in the training such as nursing (n=88), OB/GYN (n=60), pediatrics (n=26), anesthesia (n=23), family medicine (n=13) and respiratory (n=5). While the OB-STaT training includes active duty, civilians and contractors, 79% of participants were active duty. Of those trained, 72% report treating a PPH at least monthly further solidifying the importance of continued PPH teamwork training.

- **How were the results disseminated to communities of interest?**

  - Nothing to report.

- **What do you plan to do during the next reporting period to accomplish the goals?**

  - For NME sites, an interim data collection will occur and then the OB-STaT training will commence. Six months following training, the final survey data collection will occur. Additionally, simulation probes will occur at approximately 3 and 6 months following OB-STaT for the designated NME sites only.

- For NMW sites, interim and final data collection will occur at all sites in addition to simulation probes.
- Complete data pull of clinical outcome data from the electronic medical records for baseline, interim, and final data collection points.
- Compile and code all data and send to the biostatistician for analysis.
- Disseminate findings via conference presentations and manuscript publication.

4. **IMPACT:**

   - **What was the impact on the development of the principal discipline(s) of the project?**
     - Please see appendix 1, unsolicited emails from study sites which describe the immediate impact of the training by clinical staff.

   - **What was the impact on other disciplines?**
     - Nothing to report.

   - **What was the impact on technology transfer?**
     - Nothing to report.

   - **What was the impact on society beyond science and technology?**
     - Nothing to report

5. **CHANGES/PROBLEMS:**

   - **Changes in approach and reasons for change**
     - Nothing to report.

   - **Actual or anticipated problems or delays and actions or plans to resolve them**
     - Hiring of the research coordinators was delayed. Because of this, very minimal baseline survey data at Navy Med West was obtained. At Navy Med East sites, baseline and interim survey data did not follow the

proposed timeline. Instead, the baseline and interim data occurred in a 3 month span (instead of 6 months) and the OB-STaT training was delayed by approximately 1 month. Moving forward, the research team anticipates following the proposed timeline. The final data collection point at some sites will extend into November 2019 so a no-cost extension will be requested to complete the study. No funds will be needed as this portion of the project will be completed by the clinical research coordinators and their funding will continue through June 2020 based on when the 2-year contract was awarded.

- Contract office was not able to proceed with purchasing study computers or compete the contract for the standardized patient due to fiscal year purchasing time constraints. A trained active duty standardized patient has been used to fulfill this role with only travel costs to the grant. Year 2 money was received the third week of January 2019 by the PI. The study computers can now be purchased and the standardized patient contract competed. It is anticipated to take 90 days to award and execute the contract. We will continue to request active duty support to fulfill the standardized patient role until the standardized patient contract is awarded.

- **Changes that had a significant impact on expenditures**

  - Contract for standardized patient was not executed during year 1, and the contract for clinical research coordinators was less than originally budgeted. Furthermore the study computers have not been purchased, resulting in an execution of 73% of Year 1 money.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

  - Nothing to report.

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

  - **Journal publications.**

  - Nothing to report.

  - **Books or other non-periodical, one-time publications.**

  - Nothing to report.

  - **Other publications, conference papers, and presentations.**

  - Work-in-progress presented at the International Meeting for Simulation in Healthcare, January 26-30, 2019 in San Antonio, Texas.

- **Website(s) or other Internet site(s)**
  - Nothing to report.

- **Technologies or techniques**
  - Nothing to report.

- **Inventions, patent applications, and/or licenses**
  - Nothing to report.

- **Other Products**
  - The OB-STaT curriculum was completed as part of this project. This 4 hour curriculum is designed to provide the entirety of the delivery team and ancillary services the ability to practice skills required in obstetric emergencies. The program begins with a simulation which starts in a Labor and Delivery room and progresses to the OR. The simulated patient undergoes and emergency cesarean delivery, delivers a baby who is not crying, and experiences a postpartum hemorrhage. The team must care for both mom and newborn. The participants then debrief as a multidisciplinary team and then with a discipline specific expert. Next, participants are given time to complete a series of skills practice workstations. Finally, a second simulation and debrief occur.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	*CDR Joy Greer*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	0000-0002-3869-7574
Nearest person month worked:	*2*
Contribution to Project:	Curriculum design, research team training, regulatory support, data collection and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this*

	award).
Name:	CDR Monica A. Lutgendorf
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-1140-1507
Nearest person month worked:	2
Contribution to Project:	Curriculum design, research team training, data collection and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this award).*
Name:	CAPT Michael Spooner
Project Role:	AI
Researcher Identifier (e.g. ORCID ID):	0000-0003-3769-6008
Nearest person month worked:	2
Contribution to Project:	Curriculum design and administrative support.
Funding Support:	*(Complete only if the funding support is provided from other than this award).*
Name:	Lauren Welsch
Project Role:	AI
Researcher Identifier (e.g. ORCID ID):	0000-0003-1125-0630
Nearest person month worked:	3
Contribution to Project:	Research coordination services including regulatory activities, data collection/coding, and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this award).*
Name:	Adrian Modzik
Project Role:	AI
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Research coordination services including

	regulatory activities, data collection/coding, and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this award).*
Name:	Dominick Salas
Project Role:	AI
Researcher Identifier (e.g. ORCID ID):	0000-0003-4586-3101
Nearest person month worked:	3
Contribution to Project:	Research coordination services including regulatory activities, data collection/coding, and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this award).*
Name:	Jessica Fish
Project Role:	AI
Researcher Identifier (e.g. ORCID ID):	0000-0001-5565-582X
Nearest person month worked:	1
Contribution to Project:	Research coordination services including regulatory activities, data collection/coding, and administrative support.
Funding Support:	N/A *(Complete only if the funding support is provided from other than this award).*

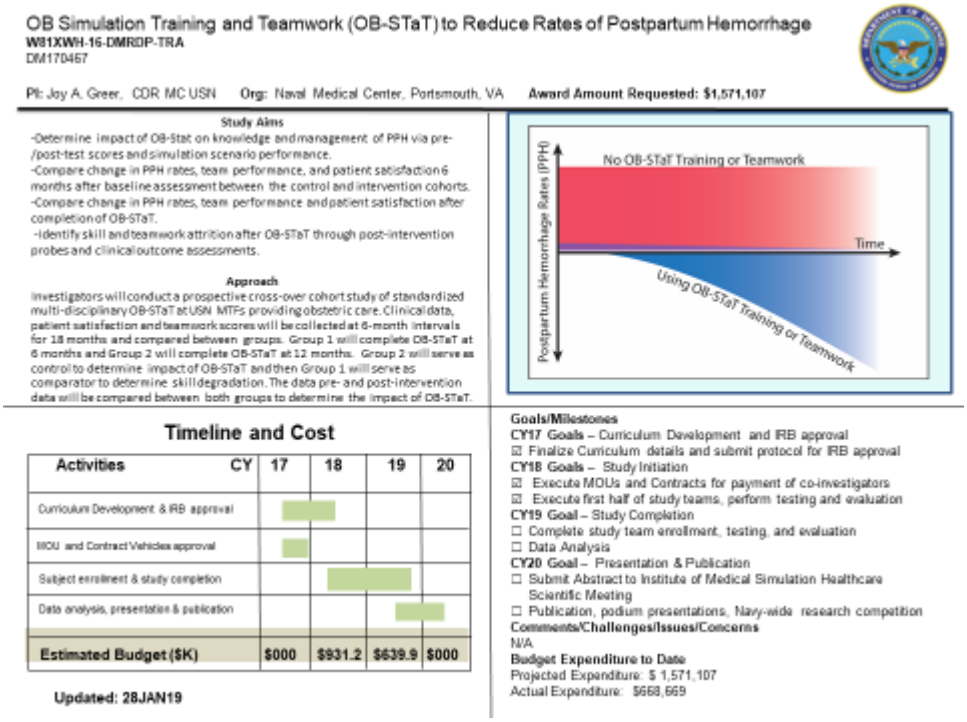
- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  - Nothing to report.
- **What other organizations were involved as partners?**
  - Nothing to report

8. **SPECIAL REPORTING REQUIREMENTS**

COLLABORATIVE AWARDS:

- TATRC Medical Modeling and Simulation Innovation Center (MMSIC), Fort Detrick, Maryland. The TATRC Medical Modeling and Simulation Innovation Center (MMSIC) provided subject matter expertise regarding simulation-based education and assessment components of the project, including but not limited to, development and verification of hierarchical task analyses, task-load assessments and situational awareness assessments during the acquisition, retention and transfer phases of the study intervention. The MMSIC also provided instructional design and implementation science support for the overall research study effort. To date, TATRC staffing on this project has included Geoffrey Miller, MS, Research Scientist.

- **QUAD CHARTS:**



OB Simulation Training and Teamwork (OB-STaT) to Reduce Rates of Postpartum Hemorrhage

W81XWH-16-DMRDP-TRA
DM170467

PI: Joy A. Greer, CDR MC USN Org: Naval Medical Center, Portsmouth, VA **Award Amount Requested: $1,571,107**

Study Aims

-Determine impact of OB-Stat on knowledge and management of PPH via pre-/post-test scores and simulation scenario performance.
-Compare change in PPH rates, team performance, and patient satisfaction 6 months after baseline assessment between the control and intervention cohorts.
-Compare change in PPH rates, team performance and patient satisfaction after completion of OB-STaT.
-Identify skill and teamwork attrition after OB-STaT through post-intervention probes and clinical outcome assessments.

Approach

Investigators will conduct a prospective cross-over cohort study of standardized multi-disciplinary OB-STaT at USN MTFs providing obstetric care. Clinical data, patient satisfaction and teamwork scores will be collected at 6-month intervals for 18 months and compared between groups. Group 1 will complete OB-STaT at 6 months and Group 2 will complete OB-STaT at 12 months. Group 2 will serve as control to determine impact of OB-STaT and then Group 1 will serve as comparator to determine skill degradation. The data pre- and post-intervention data will be compared between both groups to determine the impact of OB-STaT.

Timeline and Cost

Activities / CY	17	18	19	20
Curriculum Development & IRB approval				
MOU and Contract Vehicles approval				
Subject enrollment & study completion				
Data analysis, presentation & publication				
Estimated Budget ($K)	**$000**	**$931.2**	**$639.9**	**$000**

Updated: 28JAN19

Goals/Milestones
CY17 Goals – Curriculum Development and IRB approval
☑ Finalize Curriculum details and submit protocol for IRB approval
CY18 Goals – Study Initiation
☑ Execute MOUs and Contracts for payment of co-investigators
☑ Execute first half of study teams, perform testing and evaluation
CY19 Goal – Study Completion
☐ Complete study team enrollment, testing, and evaluation
☐ Data Analysis
CY20 Goal – Presentation & Publication
☐ Submit Abstract to Institute of Medical Simulation Healthcare Scientific Meeting
☐ Publication, podium presentations, Navy-wide research competition
Comments/Challenges/Issues/Concerns
N/A
Budget Expenditure to Date
Projected Expenditure: $ 1,571,107
Actual Expenditure: $668,669

9. **APPENDICES:** Unsolicited Feedback from Participants

From: [redacted]
To: Greer, Joy A CDR USN NAVHOSP PORS VA (US)
Subject: Simulation questions (UNCLASSIFIED)
Date: Monday, December 10, 2018 11:40:27 AM

CLASSIFICATION: UNCLASSIFIED

Hi Dr. Greer!

I hope your holiday season is going well and things at NMCP are moving smoothly! I was recently tasked by our Chief Medical Officer to lead a team to improve our High Fidelity Simulation for Code Blue and Code Purple! After y'alls big sim visit, a lot of people were impressed by the utility of very realistic simulation. (That very next week, I had a severe PPH on a Friday night that resulted in a C-hyst. The patient did well and is fine now. Our L&D's response was very good and the blood bank did really well!)

Anyway, I need to present to the command our plan and vision to improve our simulation experience at [redacted] in the next coming year. I know there is tremendous literature out there about the effectiveness of simulation in leading to better patient outcomes. I was hoping that you may have some recommendations on recent studies that that might apply to a small command on the importance of simulation. I am also going to talk to risk management to try to get some estimates on how often we have code blues and code purple to put it into better perspective as well.

I would also love if you have insight into how to start a sim program at a small command. Do other small military hospital have any robust simulation programs that you are aware of? We just have an ER nurse who runs code blue drills periodically as his collateral duty and 1 midwife who does that same for code purple. It is not very organized so that everyone is participating, just sort of who is available that day. Lots of room to improve. We have the Mega Code Kelly for code blues and our wonderful OB sim maniquin as well.

Thank you so much! If talking on the phone is easier that typing, let me know and we can chat whenever is convenient for you!

V/R,
[redacted]

CLASSIFICATION: UNCLASSIFIED

Greer, Joy A CDR USN NAVHOSP PORS VA (US)

From: [redacted]
Sent: Sunday, September 2, 2018 5:17 PM
To: Lutgendorf, Monica A CDR USN NAVMEDCEN SAN CA (US); Greer, Joy A CDR USN NAVHOSP PORS VA (US)
Cc: [redacted]
Subject: FW: outstanding teamwork on [redacted] and from [redacted] charge
Signed By: [redacted]

Team,

Please see a quick message from the NOD below. I discussed with her in more detail this morning when I took over as NOD. She complimented all members of the team and said that the team seemed so calm and was able to handle all three situations that were happening at once. (There was also a vaginal delivery happening..) I hope that this highlights the importance of the simulation drills for all members of the multidisciplinary team. I heard from the nursing staff that the MOR nurse was able to jump in and help as well, because she, too had done the drills earlier in the day. Thanks for all the hard work making this training happen whether you participated, facilitated, or scheduled your staff to join the team!

Thanks

[redacted]

[redacted] Labor and Delivery Division Officer

[redacted]

-----Original Message-----
From: [redacted]
Sent: Friday, August 31, 2018 6:04 AM
To: [redacted]
Cc: [redacted]
Subject: outstanding teamwork on [redacted] and from [redacted] charge

Good morning,

I just wanted to briefly highlight some outstanding performance and teamwork I observed last night on [redacted] during a MTP and simultaneous crash

OR. The individuals who did an outstanding job both in knowledge of situation, leadership, communication and best attitude I have seen on [redacted] were: [redacted]. I can go into more detail if you would like.

Have a great day!

Very Respectfully,

[redacted]

Greer, Joy A CDR USN NAVHOSP PORS VA (US)

From: [redacted]
Sent: Friday, August 31, 2018 2:41 PM
To: Lutgendorf, Monica A CDR USN NAVMEDCEN SAN CA (US); Greer, Joy A CDR USN NAVHOSP PORS VA (US); [redacted]
Subject: FW: RE: MTP 8/30/18
Signed By: [redacted]

Please see below from one of the L&D nurses... this is good validation for all the hard work!!

[redacted]
Labor and Delivery Division Officer
[redacted]

[redacted]

-----Original Message-----
From: [redacted]
Sent: Friday, August 31, 2018 7:09 AM
To: [redacted]
Subject: RE: [redacted]

I wanted to drop you an email and let you know I appreciate having been through the simulation training before the MTP we called 8/30/18. The patient we had was symptomatic with a heart rate up to the 170's. In order to get the blood on board quickly, we activated the MTP. We had the floorwalker come down, they started an ART line so we could more accurately monitor the pt's BP's. I feel like having gone through the SIM training, we were more cohesive, our closed loop communication was effective and jobs were delegated. I knew while [redacted] and I were in the room, our coworkers at the desk were also working hard to make sure we had what we needed. (ordering labs, running labs, bringing in equipment and supplies as needed)

Thank you again for the opportunity to fine tune our skills and our teamwork in a safe setting so that we could be more efficient and effective in a real life situation.

[redacted]