

AWARD NUMBER: CDMRPL-17-0-DM17-0-467

TITLE: **O**bstetric **S**imulation **T**raining **a**nd **T**eamwork (**OB-STaT**) To Reduce Postpartum Hemorrhage

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CONTRACTING ORGANIZATION: Naval Medical Center, Portsmouth, VA

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>			
<b>14. ABSTRACT</b>			
<p><b>Introduction:</b> 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. <b>Methods:</b> 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. <b>Results To Date:</b> 721 healthcare professionals from 8 sites completed OB-STaT and 423 subjects enrolled in the study. Clinical outcomes measures were collected from 14,904 charts and follow up probes were completed on 328 people. Participants had a positive impression of the program as indicated by Student Satisfaction and Self-Confidence in Learning subscales; Objectives and Information (4.49±0.88), Support (4.71±1.28), Problem Solving (4.56±1.13), Feedback (4.85±1.52) and Fidelity (4.65±1.18). Additionally, Clinical Teamwork Scales showed an immediate improvement in measures of teamwork following the training program. The mean for each item improved from a classification of 'average' (6.21 ± 1.12) to 'good' (7.69 ± 1.44). Overall, there was a significant improvement in total CTS score from scenario 1 (85.65 ± 20.10) to scenario 2 (106.54 ± 13.38) (p=0.008). <b>Conclusions:</b> While PPH is relatively rare, it requires prompt recognition and effective teamwork to manage effectively. OB-STaT provides a realistic multidisciplinary training and skills sustainment. Participants see value in the curriculum and immediate improvements in teamwork are noted after simulation training. Further OB-STaT results will inform training algorithms policy and simulation requirements for obstetric care and traumatic hemorrhage control in military and civilian institutions.</p>			

<b>15. SUBJECT TERMS</b>					
NONE LISTED					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			<b>19b. TELEPHONE NUMBER</b> <i>(include area code)</i>
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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?**
  - OBSTaT Training
    - OB-STaT training was successfully implemented at the remaining NMW sites and all NME sites
  - Simulation probes data collection
    - Completed baseline, interim and final simulation probes at designated NME and NMW sites.

- Observation data collection
  - Baseline and interim and final observation data collection completed at all NME sites and NMW sites.
  - Clinical outcomes data was successfully pulled from the electronic medical record including Essentris and MHS Genesis.
- Additional equipment was purchased to facilitate OB-STaT intervention including study laptops.
- Contract for standardized patient services was awarded and a standardized patient was hired for OB-STaT probes.

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

As described above, the OB-STaT curriculum has already trained 721 healthcare professionals from 8 sites including 115 nurses, 153 physicians, 51 corpsman, 45 advanced practice nurses, and 13 students. To help meet team training objectives, multiple specialties are included in the training such as nursing (n=128), OB/GYN (n=102), pediatrics (n=43), anesthesia (n=47), family medicine (n=31) and respiratory (n=9). While the OB-STaT training includes active duty, civilians and contractors, 74.8% of participants were active duty. Of those trained, almost 40% 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?**

- They will be disseminated through oral presentations at the International Meeting for Simulation in Healthcare, January 19-22, 2020 in San Diego, California.

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

- 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?**

Participants had a positive impression of the program as indicated by high scores on the Student Satisfaction and Self-Confidence in Learning subscales; Objectives and Information (4.49±0.88), Support (4.71±1.28), Problem Solving (4.56±1.13), Feedback (4.85±1.52) and Fidelity (4.65±1.18). This instrument is a Likert Scale of 1-5 with higher scores indicating a positive

impression of the program. The link between improved teamwork and improved patient outcomes has been shown across disciplines. However, prior to an improvement in patient outcomes, an associated improvement in teamwork is expected. The Clinical Teamwork Scale (CTS) scores were thus compared to determine changes in teamwork immediately following simulation. CTS scores showed an immediate improvement in measures of teamwork following the training program. The mean for each item improved from a classification of 'average' ( $6.21 \pm 1.12$ ) to 'good' ( $7.69 \pm 1.44$ ). Overall, there was a significant improvement in total CTS score from scenario 1 ( $85.65 \pm 20.10$ ) to scenario 2 ( $106.54 \pm 13.38$ ) ( $p=0.008$ ). Lastly, the standardized patients used in the simulations were given a chance to evaluate the medical team. These rating improved from 3.83 for the first scenario to 3.92 for the second scenario ( $P>0.05$ ). The largest improvement was noted in the team's ability to inform the patient via good communication.

- **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**
  - Successfully applied for a No-Cost Extension to ensure time for data analysis and results dissemination within the timeframe of the grant.
  
- **Changes that had a significant impact on expenditures**
  - Nothing to report.
  
- **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.**
    - “Obstetric Simulation Training and Teamwork (OB-STaT) to Reduce Postpartum Hemorrhage: A work in Progress. Orally presented at the International Meeting for Simulation in Healthcare, January 26-30, 2019. San Antonio, TX.
    - “Changes in Teamwork Immediately Following a Large Multidisciplinary Simulation” orally presented at the International Meeting for Simulation in Healthcare, January 18-22, 2020 in San Diego, California.
    - “Current State of Simulation Experience for Perinatal Team Members” orally presented at the International Meeting for Simulation in Healthcare, January 18-22, 2020 in San Diego, California.
    - “Unforeseen Challenges with Implementation of Nationwide Simulation Curriculum at Military treatment Facilities” orally presented at the International Meeting for Simulation in Healthcare, January 18-22, 2020 in San Diego, California.
    - “Simulation Team Training to Improve Standardized Patient Satisfaction in Emergent Situations”. Accepted for poster presentation at American College of Surgeons Surgical Simulation Summit, March 13-14, 2020 in Chicago, Illinois.
- **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**
  - Nothing to report.

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

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

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

	<i>support is provided from other than this award).</i>

- **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:**

- Nothing to report

○ **QUAD CHARTS:**



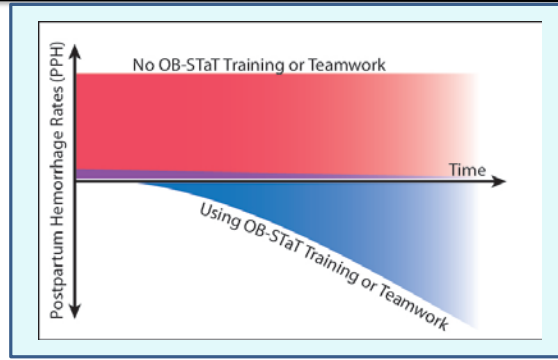
PI: Joy A. Greer, CAPT MC USN    Org: Naval Medical Center, Portsmouth, VA    Award Amount Requested: \$1,571,107

**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					
<b>Estimated Budget (\$K)</b>		<b>\$000</b>	<b>\$931.2</b>	<b>\$639.9</b>	<b>\$000</b>

Updated: 31DEC19

**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: \$1,206,682