AWARD NUMBER: DM170467

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

PRINCIPAL INVESTIGATOR:
CDR Joy A. Greer, MD
Healthcare Simulation and Bioskills Training Center, Naval Medical Center, Portsmouth, VA
Women's Health Department, Naval Medical Center, Portsmouth, VA
Department of Obstetrics and Gynecology, Uniformed Services University of Health Sciences, Bethesda, MD

CONTRACTING ORGANIZATION: Naval Medical Center, Portsmouth, VA

REPORT DATE: SEPTEMBER 2020

TYPE OF REPORT: FINAL

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
SEPTEMBER 2020	Final Report	2JAN2018 - 30JUN2020

4. TITLE AND SUBTITLE
Obstetric **S**imulation **T**raining **a**nd **T**eamwork **(OB-STaT)** To Reduce Postpartum Hemorrhage

5a. CONTRACT NUMBER

5b. GRANT NUMBER
CDMRPL-17-0-DM17-0-467

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
CAPT Joy A. Greer, MD

E-Mail: joy.a.greer.mil@mail.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Medical Center Portsmouth, 620 John Paul Jones Circle, Portsmouth VA

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT **Introduction:** Postpartum hemorrhage (PPH) is a leading cause of treatable maternal morbidity and mortality in the US. 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: decrease PPH rates; and improve objective measures of hemorrhage management, perceptions of teamwork, team performance indicators, and overall patient satisfaction. **Methods:** This was 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) was collected using medical records and validated questionnaires. Next, each site received the OB-STaT curriculum over a 2-5 day period to ensure maximum participation. Each 4-hour session began with baseline knowledge and teamwork evaluation through a pre-test and in-situ simulation. Next, participants completed 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 were administered. During simulations, teamwork and discipline specific PPH checklist assessments were completed proctors. Clinical data, patient satisfaction, and teamwork measures were collected in 6-month intervals following OB-STaT and compared within and between cohorts. Longitudinal simulation probes occured in 3-month intervals to determine skill and teamwork decay. **Results To Date:** We trained 721 team members (45 teams), and 399 people (55%) enrolled in the study. Participants included nurses (n=129), pediatric team members (n=43), and providers from obstetrics (n=102), anesthesia (n=47), and family medicine (n=31). Over 70% of the participants treated PPH at least twice a year and 59% participated in simulations at least twice a year. Knowledge test scores were similar from pre- to post-training for Anesthesia (8 v 8.07), Family Medicine (8.74 v 8.23), Nursing (7.10 v 7.05), Obstetrics (8.23 v 8.31) and Pediatrics (7.03 v 6.48), all $p>.05$. Overall average CTS scores improved significantly between the two scenarios (6.14 ± 1.58 vs 7.75 ± 1.02, $p=0.008$) for all the training teams. The anesthesia training team demonstrated a significant increase (9%) in protocol adherence between the two scenarios as measured by the PPH protocol critical action score (12.4 ± 1.7 vs 13.5 ± 1, $p=0.001$), while both the nursing and OBGYN teams showed modest, but non-significant protocol adherence improvement between the two scenarios. Standardized patient satisfaction did not significantly improve between scenarios ($3.52 \pm .77$ v $3.73 \pm .72$, $p=.07$), but there was significant improvement noted in feeling well-informed by the medical team (3.40 ± 1 v $3.76 \pm .82$, $p<.01$). Follow up probes were completed on 328 people. Clinical outcomes measures were collected from 14,904 charts. Initial clinical outcome analysis included 9,980 deliveries: 5,059 before and 4,921 after OB-STaT. There was no significant difference in mode of delivery or birthweight between the groups. More subjects that delivered after OB-STaT were identified as being at risk for PPH (3.04% v 6.24%, $p<.001$). The PPH rate did not significantly decrease between the groups (5.5% v 5.1%, $p=.46$), associated PPH risk factors were associated with a 65% reduction in the likelihood of PPH after training (OR .35, 95% CI .33, .37). Other outcomes related to PPH significantly increased: median (range) uterotonic medication doses (0 (0-6) v 0 (0-8)), tranexamic acid use (8.4% v 10.5%), and hysterectomy (0 v 5), all $p<.05$. Massive transfusion (21 v 9, $p=.043$), length of stay (days) (2.1 v 2.0, $p=.04$) and composite maternal morbidity (6.2% v 5.2%, $p=.03$) decreased. On multivariate analysis, cesarean delivery, total doses of uterotonics, TXA use, and length of stay all increased odds significantly of PPH. During observed deliveries, patient satisfaction and team performance did not significantly change. **Conclusions:** While PPH is relatively rare, it requires prompt recognition and effective teamwork to manage effectively. OB-STaT, a standardized IPE program improved teamwork during simulated obstetric hemorrhage scenarios. Although overall rates of PPH did not significantly decrease, OB-STaT improved PPH management and contributed to decreased length of stay and composite maternal morbidity by increasing doses of uterotonic medications, use of TXA, and hysterectomy. Team performance and patient satisfaction were not significantly impacted. Ongoing analysis is continuing to determine presence of skill decay and effect on clinical outcomes as well as the benefit of simulation training to no training to further inform training algorithms policy and simulation requirements for obstetric care and traumatic hemorrhage control in military and civilian institutions.

15. SUBJECT TERMS					
NONE LISTED					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	11	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

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.
        - Data collection was completed for all aims and analysis has been initiated.
        - Draft manuscripts have been prepared for Specific Aims 1 and 3.

- **Specific Aim 1 Conclusion:** This large-scale simulation study across a health system demonstrated initial impact of improved team performance and improved communication with a standardized patient. Knowledge did not improve within disciplines. Anesthesia teams demonstrated statistically significant improvements in adherence to algorithms for postpartum hemorrhage care. In the short-term, we can continue to encourage the use of interprofessional team training within a health system. The clinical outcomes and skill decay components of this study are still being analyzed.
- **Specific Aim 3 Conclusion:** Although overall rates of postpartum hemorrhage did not significantly decrease, OB-STaT, a standardized interprofessional education simulation-based curriculum, improved postpartum hemorrhage management and contributed to decreased length of stay and composite maternal morbidity by increasing doses of uterotonic medications, use of tranexamic acid, and hysterectomy in spite of an increased patient-baseline risk of PPH in the cohort.

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

  As described above, the OB-STaT curriculum trained 721 healthcare professionals from 8 sites. Study participants covered multiple specialties: 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. An additional 328 individuals participated in follow-on simulation probes to evaluate skill decay. Continuing educational units were offered to all those who were candidates and/or needed continuing education for ongoing professional certification and licensure during both the initial OB-StaT training and follow-up simulation probes.

- **How were the results disseminated to communities of interest?**
  - They will be disseminated through virtual presentations at the International Meeting for Simulation in Healthcare, January 2021 in New Orleans, Louisiana and via publications.

- **What do you plan to do during the next reporting period to accomplish the goals?**
  - N/A as this is final report
  - Continue to work with the biostatistician to complete the 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?**
     - **Specific Aim 1:** We trained 721 team members (45 teams), and 399 people (55%) enrolled in the study. Participants included nurses (n=129), pediatric team members (n=43), and providers from obstetrics (n=102), anesthesia (n=47), and family medicine (n=31). Over 70% of the participants treated PPH at least twice a year and 59% participated in simulations at least twice a year. Knowledge test scores were similar from pre- to post-training for Anesthesia (8 v 8.07), Family Medicine (8.74 v 8.23), Nursing (7.10 v 7.05), Obstetrics (8.23 v 8.31) and Pediatrics (7.03 v 6.48), all $p>.05$. Overall average CTS scores improved significantly between the two scenarios (6.14 ± 1.58 vs 7.75 ± 1.02, $p=0.008$) for all the training teams. The anesthesia training team demonstrated a significant increase (9%) in protocol adherence between the two scenarios as measured by the PPH protocol critical action score (12.4 ± 1.7 vs 13.5 ± 1, $p=0.001$), while both the nursing and OBGYN teams showed modest, but non-significant protocol adherence improvement between the two scenarios. Standardized patient satisfaction did not significantly improve between scenarios ($3.52 \pm .77$ v $3.73 \pm .72$, $p=.07$), but there was significant improvement noted in feeling well-informed by the medical team (3.40 ± 1 v $3.76 \pm .82$, $p<.01$).

- **Specific Aim 3:** Analysis included 10,043 deliveries: 5,059 before and 4,921 after OB-STaT. There was no significant difference in mode of delivery or birthweight between the groups. More subjects that delivered after OB-STaT were identified as being at risk for PPH (8.7% v 41.7%, p<.001). The PPH rate did not significantly decrease between the groups (5.5% v 5.1%, p=.37), associated PPH risk factors were associated with a 65% reduction in the likelihood of PPH after training (OR .35, 95% CI .33, .37). Other outcomes related to PPH significantly increased: median (range) uterotonic medication doses (0 (0-6) v 0 (0-8)), tranexamic acid use (8.4% v 10.4%), blood transfusion (27 v 43), and hysterectomy (0 v 5), all p<.05. Length of stay (days) (2.1 v 2.0, p=.04) and composite maternal morbidity (6.2% v 5.2%, p=.03) decreased. No other significant differences were observed in the assessed outcomes. During observed deliveries, patient satisfaction and team performance did not significantly change (14.4 v 14.3 and 93.6 v 99.6, respectively, all p>.05).
- OB-STaT, a standardized IPE program focused on management of obstetric hemorrhage, improved a participant's ability to communicate and work as a team during simulated obstetric hemorrhage scenarios. Although overall rates of PPH did not significantly decrease, OB-STaT also improved PPH management and contributed to decreased length of stay and composite maternal morbidity by increasing doses of uterotonic medications, use of tranexamic acid, and hysterectomy even in the setting of increased patient-level risk for PPH. Team performance and patient satisfaction was not significantly impacted.
- Further study is needed to determine skill decay as assessed through longitudinal probes and resulting impact on clinical outcomes.

- **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**
     - No-Cost Extension received. There have been delays with statistical analysis due to the data complexity and COVID19 which have prevented completion of data analysis for all specific aims.
   - **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. Please see attached initial drafts of two publications.
        - **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. CANCELED DUE TO COVID19
            - "Obstetric Simulation Training and Teamwork (OB-STaT): Immediate Impact on Knowledge, Teamwork and Adherence to Hemorrhage Protocols." Accepted for virtual presentation at International Meeting for Simulation in Healthcare, January 2021.
            - "Obstetric Simulation Training and Teamwork (OB-STaT) to Reduce Postpartum Hemorrhage: Short-term Clinical Outcomes." Accepted for virtual presentation at International Meeting for Simulation in Healthcare, January 2021.

    - **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:	*CAPT 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:	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:	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).*

- **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:**

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

W81XWH-16-DMRDP-TRA
DM170467

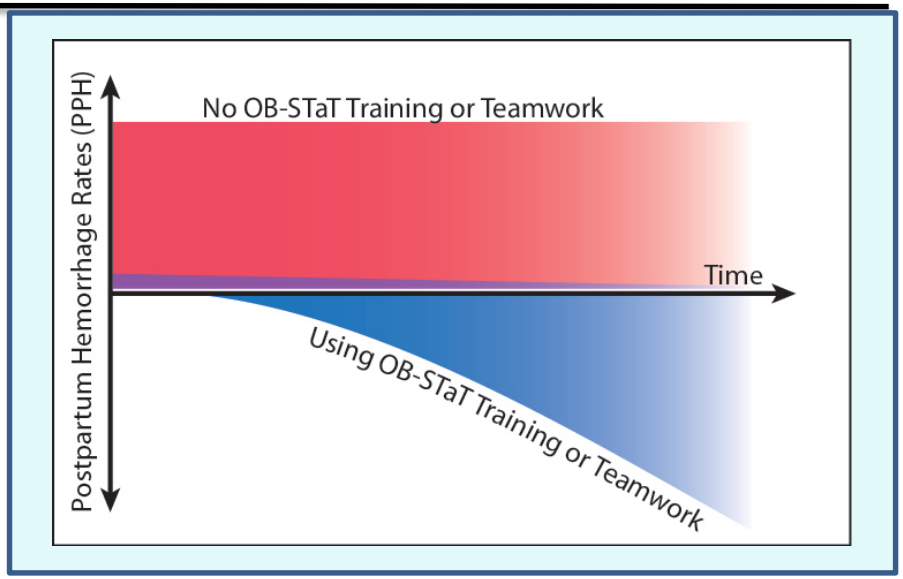
PI: Joy A. Greer, CAPT MC USN **Org:** Naval Medical Center, Portsmouth, VA **Award Amount Requested: $1,571,107**

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				
Estimated Budget ($K)	**$000**	**$931.2**	**$639.9**	**$000**

Updated: 27SEP2020

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