An Evidence Based Oxytocin Protocol for the Third Stage of Labor Decreases Postpartum Hemorrhage Rates

Quality Improvement Project

Statement by Executive Leader Supporting this Application:

Enclosed is an innovative multidisciplinary quality improvement project with far-reaching benefits to our obstetric patients in the third stage of labor. I am writing to provide my absolute endorsement of this project for consideration of the prestigious Hospital Quality Institute’s Vanguard Award. Those who contributed to this excellent work were: LCDR Judd Whiting, MC, LCDR Maureen Higgs, MC, LCDR Sara Gonzalez, MC, LCDR Patricia Butler, NC, CDR (ret) Jeff Budge, MC, and LCDR Monica Lutgendorf, MC and CAPT Lynn Bailey, MC.

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Several of the authors are military service members. This work was prepared as part of their official duties. Title 17 U.S.C. 105 provides that ‘Copyright protection under this title is not available for any work of the United States Government.’ Title 17 U.S.C. 101 defines a United States Government work as a work prepared by a military service member or employee of the United States Government as part of that person’s official duties.
Executive Summary:

Naval Medical Center San Diego (NMCSD) is a 272-bed, tertiary care Military Treatment Facility. Due to our large, young active duty population, obstetric care is one of our busiest product lines with over 3,000 deliveries a year. An analysis of the postpartum hemorrhage rate of 4% revealed that we were above the National Perinatal Information Center average.

With a strategic mission of providing safe, quality healthcare and a target of high reliability, NMCSD launched an initiative in 2016 to reduce postpartum hemorrhage and achieve zero patient harm. A multi-disciplinary team lead by the obstetric team created a bundle to standardize management and facilitate rapid response to postpartum hemorrhage. Implementation resulted in a 40% decrease in postpartum hemorrhage, and is currently being exported to military treatment facilities throughout the enterprise.

Background and relevance of the problem being addressed and effort undertaken:

Postpartum hemorrhage occurs in approximately 4-6% of deliveries, and remains an important cause of morbidity and mortality in the United States. Active management of the third stage of labor decreases the risk of hemorrhage following delivery, and includes administration of oxytocin, immediate cord clamping and cutting, controlled cord traction, and vigorous fundal massage. However, evidence based analysis of active management of the third stage of labor has confirmed only oxytocin administration as effective in decreasing postpartum hemorrhage. Though active management reduces the risk of bleeding after delivery, this reduction may be due to oxytocin alone, and prophylactic oxytocin is the prevention strategy of choice in high resource settings.

The literature supports the effectiveness of prophylactic oxytocin at decreasing postpartum hemorrhage and need for therapeutic uterotonics, however there is limited data regarding the most effective dose and timing after delivery. Recent studies have shown that the dose of oxytocin needed to contract the uterus after cesarean delivery is lower than previously used and there is a peak effect of bolus oxytocin. Additionally, there is limited data on the ideal oxytocin dosing after vaginal deliveries. Potential adverse effects have been associated with high dose oxytocin, including significant cardiovascular side effects. Our objective was to develop an evidence based protocol for administration of postpartum oxytocin that would decrease postpartum hemorrhage rates, and improve patient outcomes.

Description of the effort, including the scope, process, strategies and tactics utilized, challenges encountered and how they were addressed

This study was an approved clinical quality improvement project at Naval Medical Center San Diego. We convened a multidisciplinary working group to assess current practices, review the literature and develop an evidence based protocol. The working group consisted of representatives from the department of obstetrics and gynecology, maternal fetal medicine, and departments of anesthesia and nursing. A rigorous review of the literature was conducted,
and identified five published articles evaluating the use of oxytocin after both cesarean and vaginal delivery. Various oxytocin regimens were reported, as seen in Table 1.

We utilized the Plan-Do-Study-Act cycle for quality improvement. At the beginning of the project, the postpartum hemorrhage rate at our institution was 4%, higher than the postpartum hemorrhage rate reported by the National Perinatal Information Center (NPIC), a voluntary obstetric quality improvement database. During the plan phase, we identified this increased postpartum hemorrhage rate as an opportunity for quality improvement. We identified that postpartum oxytocin was administered in a non-standardized fashion, with an unspecified and uncontrolled rate. Surveys of physician and nursing staff revealed that timing of postpartum oxytocin was variable with some administering with delivery of the baby, while others initiated oxytocin after delivery of the placenta. The amount and timing of oxytocin was also variable, with the most common dose being 20 units oxytocin in one liter of intravenous fluid. This was administered at a variable rate, with some providers administering the oxytocin as a bolus, while others administered oxytocin at a rapid rate until adequate uterine tone was achieved, and then the rate was slowed. We also reviewed the literature on the benefits of oxytocin in the management of the third stage of labor, and the data supporting a maximal effective dose of oxytocin following cesarean delivery. Thus, we set our project objectives to decrease our postpartum hemorrhage rate, with the plan to create an evidence-based postpartum oxytocin protocol.

As we wanted to standardize the process for both vaginal and cesarean deliveries, we compiled a protocol using components of oxytocin regimens that were proven effective in both labored vaginal and cesarean delivery patients. The oxytocin concentration used was 30 units of oxytocin in a 500 mL bag, administered on an Alaris pump, and was administered with delivery of the baby. We chose an initial oxytocin bolus of three units over three minutes, which was the minimum effective dose of oxytocin to produce uterine tone in 90% of women who labored and then had a cesarean delivery. At the end of this bolus, (after three minutes) the nurse and/or anesthesiologist communicated with the delivering provider to determine if uterine tone was adequate. If uterine tone was deemed inadequate, a second three unit bolus was administered over three minutes. After one or two three unit boluses, the pump was set at 18 units per hour for one hour, and then set to 3.6 units/hour for three hours to complete a four hour infusion (Figure 1). This dosing was based on DaGraca et.al., who studied their postpartum oxytocin protocol in women undergoing both vaginal and cesarean deliveries. If there was inadequate tone after the second three unit bolus, the oxytocin infusion was initiated at 18 units per hour and patients were treated for uterine atony using other uterotonic interventions such as uterine tamponade balloon or other surgical interventions as needed.

During the Do phase, we initiated the protocol on Labor and Delivery and the postpartum wards. This process involved training nurses, obstetricians and anesthesiologists on the new protocol. We reviewed the evidence supporting the change, as well as institutional data to encourage individual buy-in and support. As oxytocin was to be administered on a pump, additional training was completed to ensure that all nurses and providers responsible for administering oxytocin were trained on the new protocol. We retrospectively reviewed all charts coded with postpartum hemorrhage for six months prior to implementation and
prospectively evaluated charts for six months after implementation. Charts were abstracted for mode of delivery, postpartum hemorrhage (defined as EBL ≥ 1,000 mL at delivery), delayed postpartum hemorrhage (occurring more than 24 hours after delivery), and use of additional uterotonics, uterine tamponade balloon and other surgical interventions.

During the “Study” phase, we analyzed the data collected. Categorical data was analyzed using the Chi square or Fisher’s exact test, and continuous data was analyzed using the Mann-Whitney U test. A proportion chart (P-chart) was created to compare proportion of postpartum hemorrhages before the new protocol to after the new protocol. SPSS was used for statistical analysis.

Description of the results of the effort

A total of 2,350 patients delivered between April 2015 and Feb 2016, with a total of 68 cases of postpartum hemorrhage recorded. The average age of patients with PPH was 29.4 years (Figure 2). Of the 62 patients with BMI recorded on admission, the mean BMI was 32.7 kg/m² (Figure 3), and the mean EBL for postpartum hemorrhage was 1,585 mL (Figure 4).

Following the introduction of our evidence based postpartum oxytocin protocol, we demonstrated a decreased rate of postpartum hemorrhage. This is shown graphically in Figure 3. Using a control chart, we graphically present the reduction in mean postpartum hemorrhage, with a 40% decrease from a proportion of 0.033 over the 12 months prior to the protocol to 0.019 over the eight months after implementation of the protocol (Figure 6). The rate of delayed postpartum hemorrhage also decreased by 16.5%; from a proportion of 0.44 before the protocol to 0.27 after the protocol (Figure 7).

There was also a negative correlation between cesarean delivery and postpartum hemorrhage, $r^2 = 79.4\%$ (Figure 8), and between vaginal delivery and PPH, $r^2 = 20.6\%$ (Figure 9). The use of additional uterotonics was reduced by 50% after the implementation of the new protocol, from a median of 46 to a median of 22, however this was not statistically significant, $p = 0.15$.

Discussion of the significance of the results. How do the results demonstrate outstanding achievement?

With the implementation of a standardized postpartum oxytocin protocol, we achieved our goal of a significant decrease in the postpartum hemorrhage rates at our institution. This protocol also resulted in a decrease in the delayed postpartum hemorrhage rates, and these improvements were seen in both cesarean and vaginal deliveries. The results of this study are consistent with previous studies that have shown that comprehensive maternal hemorrhage protocols improve treatment of maternal hemorrhage. Though the benefit of oxytocin in the management of the third stage of labor in preventing postpartum hemorrhage is well recognized, substantial variation exists between national guidelines on the prevention and
management of postpartum hemorrhage. The most specific guidelines are from the Association of Women’s Health, Obstetric and Neonatal Nurses, with the recommendation for an initial 10 unit bolus over 30 minutes followed by administration of an additional 10 units of oxytocin for a total time of four hours. 

Ultimately, the optimal dose, route, and timing of the administration of oxytocin for the prevention of postpartum hemorrhage has not been determined. However evidence suggests that there is a maximum effective dose of oxytocin at time of cesarean delivery. The evidence regarding relative benefit of bolus administration versus infusion of oxytocin is mixed, with some studies supporting a benefit of bolus administration and others finding no benefit. In this case we chose to incorporate both a bolus and infusion of oxytocin based on the available literature and published guidelines. With the paucity of studies on the optimum dosing of postpartum oxytocin in women who delivered vaginally, it is important to emphasize that our improvements in postpartum hemorrhage were seen in both vaginal and cesarean deliveries, though the improvement was stronger in the cesarean delivery group. The fact that our protocol is standardized after delivery for all women is a benefit, and the robust use of standardized checklists and protocols has been shown to improve outcomes and is recommended by the American College of Obstetricians and Gynecologists.

Our project has several strengths and weaknesses. The limitations of our project include the wide variation of the studies on which this protocol is based. The lack of clear evidence to base decisions is challenging, however in the interest of process improvement, a process or protocol does not need to be superior to produce a benefit. If a protocol has demonstrated equivalence, a benefit will be realized when applied in a standardized fashion across a population. Another limitation of our project is the fact that this evidence based protocol was implemented in the setting of increased attention and focus on postpartum hemorrhage with a comprehensive postpartum hemorrhage bundle. Such bundles and comprehensive safety programs have been shown to produce improvements in outcomes, and we are unable to specifically prove that other factors did not also contribute at least in part to the improved outcomes we note after initiating this protocol. However, we do note that this bundle was adopted over 12 months prior to implementation of our oxytocin protocol, and ongoing improvements related to the bundle are possible.

The strengths of our project are that this is a robust process improvement project that has decreased postpartum hemorrhage rates in our institution. As we continue to monitor our data, we can further refine and improve the project. Additionally the clear process standardized across our institution and consistency, regardless of mode of delivery, are potential factors contributing to the positive effect of this protocol. Another strength of this protocol is the ability to efficiently move on to other uterotonic medications and interventions for the management of atony after the initial two boluses of oxytocin (six minutes). This clear delineation allows providers to quickly administer an effective dose of oxytocin and then move on to other agents without wasting time on an intervention that is not working.

With this data we propose that similar benefit and improvements may be realized in decreasing postpartum hemorrhage on a large scale with the application of similar standardized
evidence based dosing of oxytocin in the third stage of labor. Such improvements are important to improve outcomes and decrease hemorrhage related morbidity and mortality.

Description of sustainability and scaling of the achievements

Following implementation of the postpartum oxytocin protocol at our institution with the significant decrease in postpartum hemorrhage rates, the protocol was subsequently reviewed and incorporated as part of a regional quality collaborative postpartum hemorrhage bundle for both Navy Medicine West and Navy Medicine East. Thus the protocol is now in the process of being implemented Navy-wide at all Military Treatment facilities, with over 6,000 deliveries annually. The protocol has been in use at our facility for over 2 years and providers and nurses feel the protocol is helpful, both at improving postpartum hemorrhages and also increasing communication regarding uterine tone at all deliveries.

Description of key lessons learned and any advice to colleagues who might try to undertake a similar effort.

Key lessons learned:

- Multidisciplinary involvement and thorough evidence based literature reviews are critical for implementing this type of project.
- Recommend leadership and provider/nursing buy-in and effective change management to increase acceptance.
- With significant protocol changes, recommend in-depth training and robust support during implementation process to ensure adherence to protocol and real-time adjustments and clarifications as needed.
- Recommend robust data analysis to ensure outcome and process metrics are followed.
- Standardization of processes with large degrees of variance can be accomplished on a large scale, and can lead to improvements in outcomes when an equivalent process is applied to a group.
- Ongoing reassessment and stakeholder involvement in continuous process improvement can realize important improvements in patient care.
References:


Table 1. Comparison of published third stage of labor oxytocin regimens for the prevention of postpartum hemorrhage.

<table>
<thead>
<tr>
<th>Study</th>
<th>Mode of Delivery</th>
<th>Start</th>
<th>Bolus</th>
<th>Infusion</th>
<th>Postpartum Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tita(^7) (2012)</td>
<td>SVD</td>
<td>After placenta</td>
<td>—</td>
<td>10 units/500mL x 1 hour</td>
<td>—</td>
</tr>
<tr>
<td>Carvalho(^8) (2004)</td>
<td>Unlabored CD</td>
<td>With delivery</td>
<td>0.35 units</td>
<td>20 units/L @ 120/h in PACU</td>
<td>—</td>
</tr>
<tr>
<td>Munn(^9) (2001)</td>
<td>Labored CD</td>
<td>With cord clamp</td>
<td>—</td>
<td>80 units/500mL x 30 min</td>
<td>20 units/L @125mL/hr x 8h</td>
</tr>
<tr>
<td>Balki(^10) (2006)</td>
<td>Labored CD</td>
<td>With delivery</td>
<td>3 units + 0.5 units</td>
<td>—</td>
<td>20 units/L @120mL/hr x 8h</td>
</tr>
<tr>
<td>King(^11) (2010)</td>
<td>CD with risk factors</td>
<td>With cord clamp</td>
<td>5 units</td>
<td>40 units/500mL X 30 min</td>
<td>20 units/L @125mL/hr x 8h</td>
</tr>
<tr>
<td>DaGraca(^12) (2013)</td>
<td>SVD and CD</td>
<td>With delivery</td>
<td>—</td>
<td>18 units/h x 1h, double if atony</td>
<td>3.6 units/h on L&amp;D</td>
</tr>
</tbody>
</table>
Figure 1. Oxytocin Protocol

1. Oxytocin 3 units over 3 minutes
   - Adequate tone?
     - NO: Oxytocin 3 units over 3 minutes
       - Adequate tone?
         - NO: Oxytocin 18 units/hr x 1 hour
           - Treat PPH/Atony
         - YES: Oxytocin 3.6 units/hr X 3 hours
     - YES: Oxytocin 18 units/hr x 1 hour
Figure 2. Box plot of age for postpartum hemorrhage cases
Figure 3. Box plot of BMI for postpartum hemorrhage cases
Figure 4. Box plot of EBL
Figure 5. Trend in number of postpartum hemorrhage cases

Trend Analysis Plot for PPH Cases
Linear Trend Model
\[ Y_t = 10.45 - 0.682 \times t \]

PPH Cases
Month

Postpartum oxytocin protocol
Figure 6. Proportion of postpartum hemorrhages before and after implementation of evidence based postpartum oxytocin protocol
Figure 7. Number of days between delayed postpartum hemorrhage
Figure 8. Negative correlation between cesarean delivery and postpartum hemorrhage
Figure 9. Negative correlation between vaginal delivery and postpartum hemorrhage