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Evaluation of a Hypertension Bundle to Improve Maternal Outcomes

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Abstract

Problem: Hypertensive disorders of pregnancy continue to be on the rise in the United States, contributing to an increase in both maternal morbidity and mortality rates. These disorders not only have an effect on the pregnant women, but also the neonate. Early recognition and treatment of increased blood pressure findings can improve maternal and fetal outcomes.

Methods: This Quality Improvement (QI) project used a descriptive design and was comprised of a retrospective chart review, focused on the effectiveness of evaluating a hypertension bundle to improve maternal outcomes. The data collected for this project encompassed six months pre and post bundle implementation.

Results: Charts of those patients prior to bundle implementation (n=112) and post implementation (n=91) were reviewed for rate of hospital readmission, maternal deaths, Intensive Care Unit (ICU) transfers, and eclampsia rates. Hospital readmissions decreased from 4 % to 2% during post-bundle implementation even though not a statistically significant finding with a (P=.463). A maternal death did not occur in either pre or post bundle groups. Transfers to the ICU increased from 2% to 4% post bundle (P=.411) and eclampsia outcomes indicated a non-significant reduction with bundle implementation from 0% to 1% post activation (P=.448).

Implications: The use of the hypertension bundle did not improve maternal outcomes, but the care givers did have a greater awareness of the advantages of having a standardized practice and set of provider orders for patients who meet the hypertension bundle criteria. Extended study time periods pre- and post-bundle implementation could

possibly yield a larger sample size and show improvement in maternal outcomes with bundle activation.

Evaluation of a Hypertension Bundle to Improve Maternal Outcomes

Maternal morbidity and mortality have been on the rise in the United States (US) (Kilpatrick et al., 2014). According to Callaghan, Grobman, Kilpatrick, Main, and Alton (2014), embodied psychological and physical conditions that have an adverse effect on a woman's health or those aggravated by pregnancy are referred to as maternal morbidity. On the other hand, Hoyert, Uddin and Minino (2020), describe maternal mortality as the death of a woman during pregnancy or within 42 days of the end of a pregnancy, irrespective of the site and duration, excluding accidental or incidental causes. In the US, hypertensive disorders during pregnancy continue to be a leading cause of maternal morbidity and mortality. Hypertension is a diagnosis in one in every 12 to17 pregnancies among women ages 20 to 44 years(Centers for Disease Control [CDC], 2019). According to Kattha and Garovic (2013), hypertensive disorders represent the most significant complications of pregnancy and significantly contribute to both maternal and perinatal morbidity and mortality. Hypertensive disorders cover an array of conditions including chronic hypertension, gestational hypertension, preeclampsia/eclampsia, and preeclampsia superimposed on chronic hypertension (The American College of Obstetricians and Gynecologists [ACOG], 2019c; California Maternal Quality Care Collaboration [CMQCC], 2013; Kattha & Garovic, 2013; Roberts et al., 2013). Recognizing the risk factors and expediting treatment of hypertensive disorders with recommended medication can assist with decreasing morbidity and mortality when the treatment is implemented appropriately (ACOG, 2019b).

The severity of maternal hypertension has a direct correlation on maternal, fetal, and neonatal morbidity and is considered a life-threatening obstetric emergency

(CMQCC, 2013). Not only do these disorders affect pregnant women, but they can also harm the neonate, leading to fetal growth restriction, preterm delivery, and perinatal mortality. Early recognition and establishing a proper treatment regimen for hypertension during pregnancy can assist in improving outcomes for both the pregnant women and their neonates (Bernstein et al., 2017). Devising, implementing, and evaluating an evidence-based bundle for the treatment of hypertension is necessary for the US to improve maternal morbidity and mortality rates. The bundle structure offers a standardized approach for delivering evidence-based practices to be implemented with consistency for every patient. Hypertension bundles created should include but not be limited to: diagnostic criteria, a specific medication regimen, both maternal and fetal monitoring, and treatment implications.

The purpose of this project is to evaluate evidence-based care and expedite the treatment of pregnant women who meet the hypertension bundle criteria. The project aims to improve maternal outcomes by decreasing the progression to eclampsia, readmissions to the hospital, transfers to the Intensive Care Unit, and maternal deaths. On completion, the project will answer the following project question:

1. In pregnant women aged 18-45, what is the effect of instituting a maternal hypertension bundle compared to not utilizing the bundle on the following maternal outcomes?
    a. Eclampsia
    b. Readmissions within 14 days of delivery
    c. Admissions to the Intensive Care Unit
    d. Maternal Deaths

Review of Literature

The literature review examined current research regarding the evaluation of hypertension bundles used to improve maternal outcomes, along with the effects of hypertension during pregnancy and the postpartum phase. An electronic search of the literature was

conducted using the following databases: CINAHL, ERIC, PubMed, GOOGLE Scholar, Science Direct along with the University of Missouri St. Louis library catalog. An initial search of the terms “hypertension” and “pregnancy” was used and revealed over 1,000 articles. The search was then narrowed using the terms “maternal hypertension,” “ACOG hypertension treatment,” “pregnancy outcomes with hypertension,” and “hypertension bundle.” Search limits were used to eliminate non-English articles. Articles were chosen based on their significance in the evaluation of hypertension and maternal outcomes. Due to the immense volume of literature returned by the search parameters, a total of 21 articles were used in this literature review based on relevance to the study criteria.

A leading cause of maternal morbidity and mortality in the US is hypertension and occurs in 6-8% of pregnancies in the United States (ACOG, 2019c; Bernstein et al., 2017; Burgess & Founds, 2016; Kattah & Garovic, 2013). According to The Missouri Pregnancy Associated Mortality Review (2020), the most common cause of death in 2017 during pregnancy was preeclampsia/eclampsia. The primary concern of having elevated blood pressure in pregnancy relates to the potentially harmful effects on not only the mother but the fetus (Mustafa, Ahmed, Gupta & Venuto, 2013). Both the National High Blood Pressure Education Program of the National Heart, Lung, and Blood Institute [NHLBI] and ACOG categorize hypertensive disorders of pregnancy into the following

categories: chronic hypertension, gestational hypertension, preeclampsia, and preeclampsia with superimposed preexisting hypertension (ACOG, 2019b, 2019d, 2020; CMQCC, 2013; Mustafa et al., 2012; Roberts et al., 2013). The risk factors that healthcare providers should note are obesity, first pregnancy, extremes in maternal age, previous history of preeclampsia, family history of preeclampsia, a new partner, the use of infertility treatment to become pregnant and multiple gestations (ACOG, 2019c; Burgess & Founds, 2016; Mustafa et al., 2012; Roberts et al., 2013). Additional risk factors include thrombophilia, kidney disease, system lupus erythematosus, antiphospholipid antibody syndrome, obstructive sleep apnea, and those with a diagnosis of diabetes (ACOG, 2019b, 2019c).

According to ACOG (2019a), a systolic blood pressure (SBP) of greater than 140 or diastolic blood pressure (DBP) greater than 90 occurring prior to pregnancy or before 20 weeks' gestation is described as chronic hypertension. It is important to note that chronic hypertension is accompanied with both maternal morbidities associated with severely increased blood pressure and fetal growth restriction (Roberts et al., 2013). Gestational hypertension is a diagnosis when the SBP is 140 mm Hg or more or a DBP of 90 mm Hg or more, or both, on two separate occasions at least 4 hours apart after 20 week's gestation, in a woman with previously normal blood pressure readings (ACOG, 2019b, 2019c; CMQCC, 2013; Mustafa et al., 2012).

Preeclampsia is a disorder of pregnancy-associated with new-onset hypertension and proteinuria occurring after 20 weeks of gestation. In the absence of proteinuria, the diagnosis of preeclampsia can still be made if the woman presents with any of the following complaints in addition to hypertension; cerebral or visual disturbances,

decreasing platelet count, pulmonary edema, and a serum elevation in creatine or liver enzymes (ACOG, 2019c; Bernstein et al., 2017; Burgess & Founds, 2016; Burgess, McDowell & Ebersold, 2019; CMQCC, 2013; Mustafa et al., 2012). Preeclampsia with superimposed preexisting hypertension complicates approximately 25% of pregnancies in women with a history of chronic hypertension and is defined as new-onset proteinuria in a woman who has already been diagnosed with chronic high blood pressure (ACOG, 2019c; CMQCC, 2013).

The most common of these four categories of hypertensive disorders during pregnancy is preeclampsia. Preeclampsia rates have risen nearly 25% in the past two decades in the US (Burgess & Founds, 2016; Jeyabalan, 2013). In addition to rising rates, the evidence is now clear that preeclampsia is associated with development of cardiovascular disease later in life (Kattah & Garovic, 2013; Roberts et al.,2013). More specifically, the American Heart Association guidelines (2014) for the prevention of stroke in women, revealed that 18.2 % of women with a history of preeclampsia during that pregnancy had a cardiovascular event within the 10 years of delivery. What is unclear is the subsequent late-developing cardiovascular disease and the pathophysiologic relation with a diagnosis of preeclampsia. Some researcher's hypothesis that preeclampsia is an inflammatory disease, associated with immune and impaired endothelial function (Mustafa et al., 2012; Umbetov, Berdalinova, Tusupkalieyv & Zharilkasynov, 2016).

According to Bernstein et al. (2017) and ACOG (2020), hypertension-related complications can be significantly reduced with timely and appropriate, standardized treatment. A multidisciplinary group of the National Partnership for Maternal Safety,

within the Council on Patient Safety in Women's Health Care, developed a bundle to be utilized during pregnancy and the postpartum period in an effort to improve maternal morbidity and mortality due to a maternal crisis involving hypertension (ACOG, 2019c; Bernstein et al., 2017). The safety bundle can be described as a set of evidence-based guidelines to optimally manage a woman with hypertensive disorders during her pregnancy, thus improving the patient's outcome. The obstetric guidelines and checklist will facilitate both the timely recognition and treatment of hypertension (ACOG, 2020; Bernstein et al., 2017).

The Hypertension Bundle Algorithm used as standard practice makes careful note not to be overzealous with correcting maternal blood pressures. According to ACOG (2019b), the action of lowering the patient's blood pressure too quickly can cause decreased profusion to the maternal brain and heart and to the fetus via the placenta. Since the placenta does not autoregulate its own blood flow, the decreased perfusion to the placenta can cause fetal heart rate abnormalities (ACOG, 2019b). Therefore, based on evidence obtained during a systematic review of 35 randomized trials (3,573 women) assessing different medications to be used for acute antihypertensive therapy for blood pressures $\geq$ 160/110 medications were chosen based on their therapeutic modalities (ACOG, 2019b). The three medications added to the bundle order set are labetalol, hydralazine, and nifedipine (AGOG 2019b, 2020; Bernstein et al., 2017; CMQCC, 2013). Intravenous labetalol and hydralazine have been considered first-line medications for quite some time for the management of acute-onset hypertension in both pregnant and postpartum women (AGOC, 2019b, 2020; CMQCC, 2013). While each is effective, it is important to note that in a meta-analysis, hydralazine was more effective than labetalol in

lowering severe blood pressure in the pregnant patient but was associated with more adverse maternal and perinatal effects (placental abruption, prolonged hypotension, maternal tachycardia, oliguria, cesarean delivery, and low Apgar scores) (ACOG, 2019b; Mustafa et al., 2012). In addition to a medication regime, the bundle also provides guidelines for close monitoring of blood pressures as well as fetal monitoring if applicable (ACOG, 2019c, 2020).

The hypertension bundle was developed to reduce maternal morbidity that is associated with hypertensive disorders during pregnancy and the postpartum period. Knowing that this disease can progress rapidly and involve multiple organ systems, it becomes more evident that caregivers need to practice using the evidence and guidelines provided. The obstetric hypertension checklist and guidelines assist in facilitating timely recognition and treatment of hypertension to quickly reduce blood pressures, thus improving maternal outcomes and reducing cerebral complications (Bernstein et al., 2017). A common, preferred method that is used for quality improvement in healthcare is the Plan-Do-Study-Act model (PDSA). According to Taylor et al., (2013), this framework can provide a means for structuring the development of change and assist with understanding the impact and benefits of the interventions to be implemented. The improvements in outcomes are achieved by assessing what changes are needed, testing those changes, measuring the outcomes, adjusting interventions and goals, and repeating the cycle (Taylor et al., 2013). The PDSA cycle will be useful in evaluating the compliance of the Hypertension Bundle.

Method

Design

A descriptive study design was used in this quality improvement project, utilizing record reviews before and after the bundle was implemented. The study period prior to the implementation covered the months of April 1, 2019, to September 30, 2019. The months of November 1, 2019, to April 30, 2020, were used for the post-implementation data.

Setting

An inpatient women's service unit at a not-for-profit Catholic healthcare organization, located in a Midwestern, suburban hospital. This facility also receives transfers from outlying counties. In 2019, this healthcare facility delivered 8,598 babies and had the largest Level III Neonatal Intensive Care Unit (NICU) in Missouri. This service line employs 220 nurses, three nurse practitioners, eight nurse-midwives, 24 resident physicians, and 130 physicians as well as the Obstetric Anesthesia team. This unit cares for any woman who has a confirmed pregnancy through the second week of the postpartum period.

Sample

A convenience sample of 203 antepartum, intrapartum, and postpartum pregnant patients were reviewed. Inclusion criteria included pregnant females between the ages of 18-45 who had a confirmed pregnancy, or who are no greater than two weeks postpartum, and delivered in the hospital. The patients will have two recorded blood pressures of an SBP $\geq$ 160 or a DBP of $\geq$ 110 at least 15 minutes apart. Exclusion criteria included non-pregnant females greater than two weeks postpartum, a previous diagnosis of chronic

hypertension, pregnant females below the age of 18 and over the age of 45. Also excluded are pregnant females who did not have at least two recorded blood pressures of ≥ 160/110 at least 15 minutes apart or those who delivered outside of a hospital.

Approval Process

This project was approved by the Chair of the Department, Executive Director of Nursing, and Nurse Manager at the hospital. The Hypertension Bundle was approved for use by the Obstetrics Specialty Committee in October 2019 and was implemented that same month. Institutional Review Board (IRB) approval was obtained from the University of Missouri – St. Louis (UMSL) and additionally from the hospital facility. Additional approval was obtained from the UMSL College of Nursing Doctoral Committee and the UMSL graduate school. There are minimal risks or ethical considerations for this project.

Data Collection and Analysis

The Hypertension Bundle was implemented in October 2019. Data was collected via a retrospective chart review from April 2019 to September 2019 to determine the treatment of a patient with two recorded blood pressures of ≥ 160/110 received before the bundle was implemented. The following data was extracted from the medical record: the patient's age, gravidity, number of weeks' gestation, blood pressure readings, notification of the healthcare provider, medication name, time and dose(s) administered, follow-up blood pressure, and escalation of treatment if the blood pressure remained elevated. Additional information obtained included the number of patients that progress to having an eclamptic seizure, readmissions to the hospital within 14 days of delivery, transfers to the ICU, and maternal deaths. The same data was collected post implementation,

covering the months of November 2019 to April 2020. This time frame allowed for statistical analysis of pre-and post-intervention data (See Appendix A).

Data collection was coded and de-identified. A generated report from EPIC was run during the months previously indicated. Charts reviewed before the implementation of the bundle were labeled "P" before implementation or baseline beginning with P1. Charts reviewed following the implementation of the bundle were labeled with an "A" for after implementation, beginning with A1. All data was stored on a password-protected computer and an encrypted USB flash drive. This information was deleted after the completion of this project in May of 2021. Analysis of the data included descriptive statistics to determine if there is a significant difference in patient outcomes pre- and post- implementation of the hypertension bundle.

Procedures

A team of key stakeholders which included nursing management, members of the Perinatal Safety Committee, Women's Service department chair, nursing staff, obstetrician providers, obstetrician resident, and anesthesia providers was formed in January of 2019. The team reviewed evidence from ACOG and CMQCC on the advantages of having a standardized practice and set of provider orders for patients who meet the hypertension bundle criteria. Prior to the implementation, the patients were being treated with a non-standardized treatment plan and differed depending on the provider. The stakeholders determined the unit needed to implement the hypertension bundle to assist providers with recognizing patients who met the criteria and establish their plan for monitoring and treating hypertensive disorders. The team agreed that the Hypertension Bundle would was necessary and was implemented in October of 2019.

Prior to implementing the hypertension bundle the unit nursing staff was educated on the blood pressure parameters that would need to be reported to the provider, frequency of patient's blood pressures, and medications likely to be prescribed. A team was formed to ensure the provider orders were standardized in the electronic health record and the pharmacy was made aware so the medications could be ordered and available. Obstetrician providers, obstetric residents and obstetric anesthesia, were notified through email of the practice change and were provided the peer-reviewed articles used in the decision-making process. Templates with the order set were placed on each computer in the unit and staff were provided with a badge buddy containing the blood pressure parameters to report as well as the additional task to perform when implementing the hypertension bundle. Steps that were performed in order to complete this project are:

- successful completion of the proposal
- defense of the proposal
- IRB approval
- retrospective chart review (perform initial chart search of patients who meet inclusion criteria including two elevated blood pressures 15 minutes apart, validation of blood pressures, notification of provider on patient's assessment requiring additional orders, review if antihypertension medication was given within 60 minutes of increased reading, document demographic data for those patients who meet bundle order initiation and record if repeat blood pressure was performed)

- review of post-implementation charts (will be the same as above; see Appendix A for data information tool)

The above tasks were completed, an analysis of data was performed, and the presentation of the information was provided to the hospital facility.

Results

A total number of 203 patients' charts (N = 203) were reviewed for this study. There were 112 charts pre bundle activation and 91 post bundle that were reviewed. The sample groups were found to be homogeneous, and the following demographics were obtained. Participants in the pre-bundle group ranged in age from 19 years old to 41 years old (M = 29.5, SD = 4.7). The post-bundle group ages were 18 to 41 years old (M = 29.7, SD = 5.6). The infants gestational age at the time of delivery pre bundle ranged from 24 to 41 weeks (M = 35.8, SD = 3.6) and post-bundle gestational age ranged from 18-41 weeks (M = 36.5, SD = 3.6). The patient's gravidity ranged from 1 to 8 pre-bundle (M = 2.1, SD = 1.6) and post bundle ranged from 1 to 5 (M = 1.7, SD = 1) (see Appendix B).

A Fisher's exact test analysis was performed on the four variables (eclampsia, intensive care transfers, maternal deaths, and readmissions to the hospital) both pre and post groups to determine if there was a statistical significance between the groups. Primary outcome results indicated a non-significant reduction in eclampsia pre-bundle=0% (0/112) compared to post bundle = 1% (1/91) P= .448. Transfers to the intensive care unit resulted in 2% (2/112) pre bundle and 4% (4/91) post bundle implementation with a P=.411. Hospital readmissions of the participants was 4% (5/112) prior to implementation and 2% (2/91) post bundle with a P= .463. The analysis could

not be run on the variable maternal death because no deaths occurred, and a comparison could not be made. Thus, there were no differences pre and post bundle when referring to maternal deaths since a maternal death did not occur (see Appendix C).

The data did satisfy two of the Pearson chi-square tests since the independent and dependent variables are categorical and all the data is independent, but a third assumption of chi-square test is all expected frequencies are greater than 5. Since this assumption was violated, a Fisher's exact test was run to account for the small group sizes to increase the statistical power**.**

Discussion

This quality improvement project reviewed six months of data pre-bundle implementation of participants with qualifying blood pressures (N=112) and six months post-bundle participants (N=91). The p-value or significance value yielded by the analysis was greater than .05. Therefore, there was no statistical significance noted in maternal outcomes pre and post bundle implementation when analyzing all four variables (eclampsia, readmissions, intensive care unit transfers, and maternal death). However, while not statistically significant, the readmission rate is clinically significant. The readmission rate went from 4% pre-bundle to 2% post-bundle implementation, showing a 50% reduction in post-bundle results. The Intensive Care Unit transfers was higher post bundle implementation. This increase could be explained by possibly more critical patients being admitted during this time due to participant condition or having a COVID-19 diagnosis. Perhaps, if the study was rerun once the pandemic stabilized, we could see a decrease in this variable.

There are other variables that could have been considered when developing the data tool. These variables include: was the pregnancy a multiple gestation, what was the route of the delivery (vaginal or cesarean section), what was the pregnancy outcome (live birth, stillborn, miscarriage), where there any complications during the pregnancy (placenta previa, placental abruption, diabetes, etc.).

Some limitations to this study include taking into account if the patient was receiving or received Magnesium Sulfate for the prevention of seizure activity, especially since there was only one patient with eclampsia and that occurred with a post bundle participant. When looking at the readmission rate, it is important to note that during the COVID pandemic, patient length of stay was decreased and thus patients could have been discharged prior to severe range blood pressures presenting themselves. Sample size may limit results of this improvement project, studying a larger sample size and for a longer time period may show improvement of maternal outcomes and statistical significance could be identified with further analysis.

Conclusion

The study provided evidence that hospital readmissions rates were decreased post bundle implementation even though not a statistically significant finding. The results reveal there was no change in the number of maternal deaths pre and post bundle implementation. That value remained at zero cases of maternal mortality. Again, there were factors present which may have influenced the outcomes including the pandemic and decreased length of stay which is not a common occurrence. A recommendation would be to repeat the project using a longer time interval for the study and this could provide a larger sample size. This larger sample size could illicit statistical significance

in maternal outcomes as a result of implementing the hypertension bundle. Early recognition of severe range blood pressures and notification to the obstetric provider is essential in timely activation of the hypertension bundle. Activating the bundle offers a standardized approach of evidence-based practices allows for consistency in care for every patient meeting the bundle criteria.

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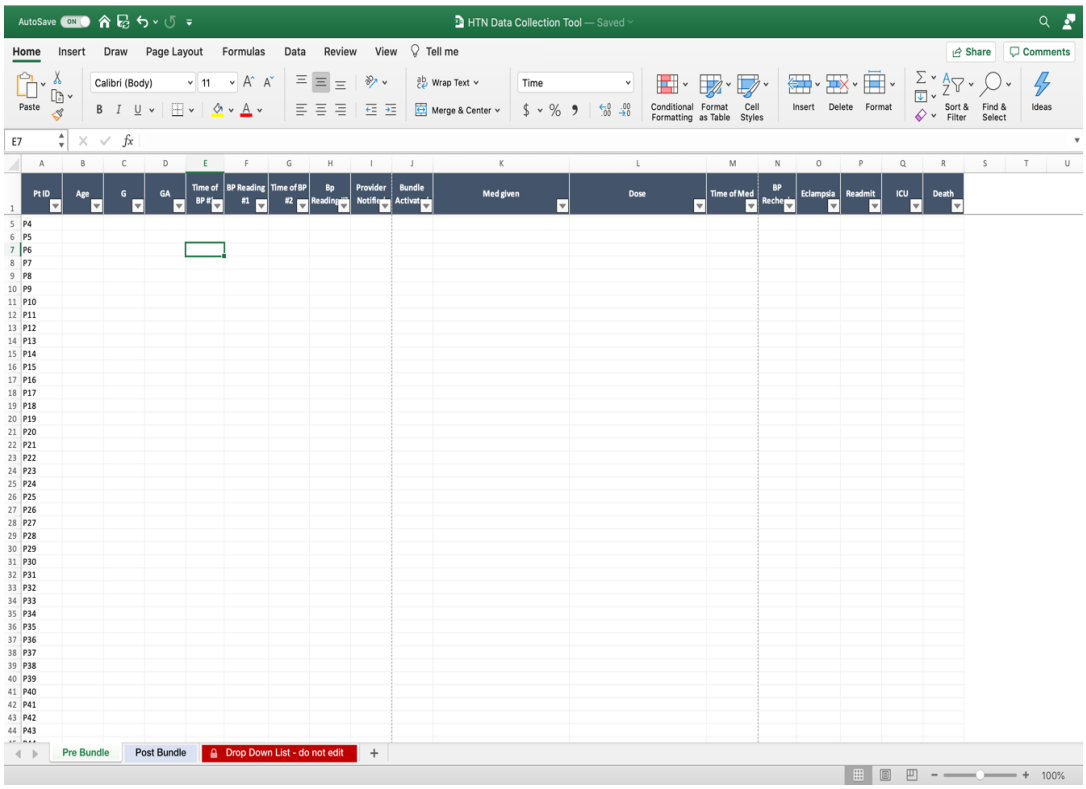
Appendix A

Figure 1. Data Collection Tool Evaluation Hypertension



Appendix B

Figure 2. Descriptive Statistics for Age, Gestational Age, and Gravidity

	Pre-Bundle						Post-Bundle				
Variable	*n*	Min	Max	*M*	*SD*		*n*	Min	Max	*M*	*SD*
	112						91				
Age		19	41	29.5	4.7			18	41	29.7	5.6
Gestational Age		24	41	35.8	3.6			24	41	36.5	3.1
Gravidity		1	8	2.1	1.6			1	5	1.7	1.0

Appendix C

Figure 3. Number of Patients with Examined Outcomes Pre- and Post- Bundle

Pre-Bundle *n=112*			**Post-Bundle** *n=91*		
Variable	Yes	No	Yes	No	*p*
Eclampsia	0	112	1	90	0.45
ICU Transfer	2	110	4	87	0.25
Maternal Death	0	112	0	91	—
Readmission	5	107	2	89	0.32