

Low-Dose Aspirin Use and Preeclampsia Prevention: A Quality Improvement Project

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Low-Dose Aspirin Use and Preeclampsia Prevention: A Quality Improvement Project

Over half a million women die each year from pregnancy related complications. Approximately 99% of these women live in low and middle-income countries and 10-15% of those deaths are associated with eclampsia and preeclampsia (Duley, L., 2009). Preeclampsia is defined as a disease process characterized by hypertension and proteinuria or one of the following features: thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or visual symptoms after 20-weeks of gestation (Leeman, Dresang, & Fontaine, 2016). Preeclampsia affects 2-8% of pregnancies (Auger, et al., 2016). Women who suffer from preeclampsia experience higher incidences of postpartum hemorrhage, placental abruption, HELLP syndrome, and heart failure; neonatal complications include low-birth weight, birth asphyxia, neonatal intensive care unit admissions, and neonatal resuscitation (Kongwattanakul, Saksiriwuttho, Chaiyarach, & Thepsuthammarat, 2018). Unfortunately, the only cure for preeclampsia is delivery (Bell, 2010). Initiation of low-dose aspirin (LDA) during pregnancy has been shown to prevent preeclampsia in women at high-risk for developing preeclampsia (Leeman, et al., 2016).

The United States Preventive Services Task Force (USPSTF) found a 24% risk reduction of preeclampsia in high-risk women taking LDA (LeFevre, 2014). As a result, the American College of Obstetrics and Gynecology (ACOG), in conjunction with the Society of Maternal-Fetal Medicine (SMFM), published a Committee Opinion in 2018 recommending the use of LDA prophylaxis in women at high risk of developing preeclampsia. LDA should be initiated between 12-28 weeks of gestation, preferably before 16 weeks, and taken daily until delivery (American College of Obstetrics and Gynecology, 2018).

The ACOG Committee Opinion (2018) sets the standard for best practice for providers

caring for pregnant patients. The purpose of this quality improvement (QI) project is to implement the ACOG recommendations of LDA use in high-risk women to prevent preeclampsia in pregnant women choosing to deliver in a free-standing birthing center.

Background

Eclampsia is defined as a condition where convulsions occurs in a pregnant woman with high blood pressure causing maternal and fetal complications (English Oxford Dictionary, 2018). Eclampsia was first described by Frenchman Francois Mauriceau in 1637 (Bell, 2010). According to Bell (2010), Mauriceau discovered that women with their first pregnancy were at greater risk for this disorder of convulsions compared to women who already had children and recommended two to three phlebotomies during the pregnancy for treatment and for prevention of eclampsia. Boissier de Sauvages distinguished eclampsia from epilepsy in the 18th century; while Dr. Thomas Denman, in 1821, hypothesized that convulsions came from the uterus (Bell, 2010). Another theory proposed that preeclampsia occurred during the evolution of the great apes into Homo sapiens (Elliot, 2016). One of the most significant theories was proposed in 1843 by Dr. Robert Johns who documented symptoms such as headache, temporary loss of vision, severe pain in the stomach, and edema of the hands, arms, neck, and face prior to the convulsions of eclampsia (Bell, 2010). This was the beginning of the understanding of preeclampsia.

Preeclampsia's etiology is still unknown; however, the pathophysiology is being uncovered layer by layer. In 1989, the endothelial cell disorder theory proposed that placental tissue without proper perfusion releases injury-causing factor(s) to endothelial cells setting into motion a cascade of coagulation, vasoconstriction, and intravascular fluid redistribution that results in preeclampsia (Roberts, et al., 1989). A more recent study combines the 1989-endothelial-cell-disorder theory with current research that maternal endothelial disorder is made

up of two stages: impaired placenta blood flow and development due to abnormal implantation of the placenta without sufficient invasion of the uterine spiral arteries; and the ischemic placenta, which releases factors, such as inflammatory cytokines, into the maternal circulation causing endothelial cell dysfunction and in turn causing preeclampsia symptoms (Aggarwal, Makris, & Hennessey, 2015). This theory found that circulating cytokines were a response to placental ischemia and were elevated in preeclamptic women, thus combining the two theories.

Hashemi et.al (2016) researched the effect of low-dose aspirin on endothelial dysfunction in preeclamptic patients. The study confirms the inflammation process and imbalance between vasoconstriction and vasodilation caused by endothelial dysfunction as the pathophysiology of preeclampsia. The study noted this endothelial disorder leads to activation of platelets and the clotting cascade, resulting in an imbalance of increased thromboxane and reduced prostacyclin levels that are associated with infarction and thrombotic vasculopathy. Therefore, low-dose aspirin (60–80 mg/day) may prevent preeclampsia by adjusting the thromboxane A₂/prostacyclin ratio optimizing placental blood flow and preventing placental thrombosis (Hashemi et.al, 2016).

Women who developing preeclampsia are considered high risk pregnancies and require higher levels of care. Preeclampsia would not be considered a low-risk condition because of the significant risk to the mother and infant. The preeclamptic mother would require a higher level of maternity care, such as hospital admission. This QI project will attempt to decrease the number of women who must transfer care from a birth center to a hospital by preventing the incidence of preeclampsia.

Problem Statement

Preeclampsia affects 2-8% of pregnancies (Auger, et al., 2016). It is also the cause of 10-15% of maternal morbidity and mortality (Kongwattanakul, Saksiriwuttho, Chaiyarach, &

Thepsuthammarat, 2018). Based on these staggering statistics, the nursing and medical community must apply their resources to prevent and treat this significant diagnosis. While the cure for preeclampsia is unknown, recent research has shown a reduction in incidence of preeclampsia in high-risk patients who take LDA during their pregnancy (LeFevre, 2014). ACOG and SMFM (2018) published a committee opinion encouraging providers to initiate LDA therapy between the weeks of 12 and 28 for women at risk for developing preeclampsia. This committee opinion contained the Clinical Risk Assessment for Preeclampsia (CRAP); this guideline is to be used in determining which patients are high risk and should initiate LDA therapy (see Appendix A). Therefore, it is the responsibility of the DNP-prepared nurse to identify these high-risk pregnant women and teach them the importance of utilizing LDA throughout their pregnancy.

The proposed DNP-project site is a birth center; birth centers care for healthy, low-risk women (Shaw, 2014). The birth-center patient that is diagnosed with preeclampsia is no longer considered healthy and low risk; therefore, she must transfer care to a location that cares for high-risk patients. If the providers at the birth center use the CRAP guidelines to identify women who are at risk for developing preeclampsia, then LDA therapy can be initiated and preeclampsia in this population of birth-center patients can be potentially prevented.

Purpose Statement

The aim of this evidenced-based DNP project is to implement the national guidelines for prevention of preeclampsia set by USPSTF, ACOG, and SMFM by identifying pregnant women at risk for developing preeclampsia and initiating LDA therapy between the gestational weeks of 12-28 (American College of Obstetrics and Gynecology, 2018).

Project Question

In pregnant women who are 12-28 weeks pregnant desiring to delivery in a birthing center, does the initiation of the CRAP guidelines identify women at risk for preeclampsia and allow for initiation of an LDA regimen compared to not using the CRAP guidelines for identification of women at risk for preeclampsia?

Project Objectives

In the timeframe of this DNP project, the host site will:

1. Improve knowledge and skills regarding identification of pregnant women at risk for developing preeclampsia through a multi-disciplinary training seminar.
2. Implement the use of ACOG's CRAP guidelines at the antepartum (AP) visits between 12-28 weeks to identify at-risk patients.
3. Initiate ACOG's LDA-therapy for at-risk patients between the weeks of 12-28.
4. Implement an automated progress note into the electronic health record (EHR) during the AP visits between 12-28 weeks to alert providers and nurses to utilize the Clinical Risk Assessment for Preeclampsia and initiate LDA therapy in women who qualify as high-risk for preeclampsia.

Significance

Because preeclampsia affects 2-8% of pregnancies (Auger, et al., 2016) and contributes to higher levels of maternal and infant morbidity and mortality (Kongwattanakul, et al., 2018), it is considered a significant health concern. Preeclampsia can also lead to long-term complications such as shorter maternal life-expectancy (Theilen, et al., 2018), decreased offspring cognition (Pineiro, Brunetto, Ramos, Bernardi, & Goldami, 2016), and higher systolic blood pressure in offspring (Tripathi, Rifas-Shiman, Hawley, Hivert, & Oken, 2018). Higher rates of preeclampsia

are seen in women in developing countries (Duley, L., 2009), lower socioeconomic status and African-American race (LeFevre, 2014). Therefore, an intervention for prevention of preeclampsia is imperative.

Search Terms

A systematic search was conducted on November 1, 2018 using these databases: Cochrane database, CINAHL, Clinical Key, ProQuest Health and Medical, ProQuest Nursing and Allied Health, and PubMed, with key words: preeclampsia, LDA, prevention, and pregnancy. On initial search, 3,308 studies were found. Duplicate studies were removed, and the search was narrowed down to 140 studies by adding these additional criteria: English-language only, articles published after 2012, and full-text articles. Bibliographies of relevant studies were searched. Evidence was narrowed down to 23 studies describing preeclampsia and LDA, as well as randomized control trials (RCTs) investigating the use of LDA and prevention of preeclampsia.

Review of Literature

A review of the current research yielded the following themes: condition, treatment, and prevention of preeclampsia. In addition, aspirin's role in preeclampsia prevention will be described, and risk factors for use of aspirin during pregnancy will be determined. National guidelines on the use of LDA to prevent preeclampsia will be evaluated and synthesized. And risk assessment for preeclampsia for women choosing to birth in a birth center will be reviewed.

Preeclampsia

Preeclampsia, the most common problem in pregnancy, occurs in 3-7% of nulliparous and 1-3% of multiparous women (Jido & Yakasai, 2013). Jido and Yakasai (2013) note that preeclampsia varies between developed countries and developing countries. In developed

countries, the incidence is 2-3 per 10,000 births; while in developing countries, the incidence is 13 per 1000 deliveries. The etiology, pathophysiology, clinical presentation, risk factors, and morbidity/mortality will be explored in this QI project.

Etiology/pathophysiology. In Jido and Yakasai's (2013) overview of the present understanding of preeclampsia, they believe the understanding of preeclampsia has progressed over the years, but the understanding of the etiology and pathophysiology of preeclampsia continues to be unclear. The authors describe several studies that suggest a genetic, immunologic factor; while other studies suggest preeclampsia is triggered by placental issues and failure of the trophoblasts to invade the myometrium and spiral arteries resulting in poor placentation. This poor implantation initiates the inflammatory response and causes vascular damage and dysfunction. The authors surmise that vascular endothelial damage manifests as hypertension, proteinuria and other systemic responses, leading to cerebral hypoxia, edema, then to seizures. The authors note that parenchymal damage in the liver results in elevated enzymes and hemolysis.

One study suggests that the gene ADAMTS-12 plays a role in the pathophysiology of preeclampsia (Gökdemir, Evliyaoğlu, & Çoşkun, 2016). The study suggests that ADAMTS-12 regulates the cell invasion of the trophoblasts. Therefore, when ADAMTS-12 is decreased, the invasion of the trophoblasts is decreased, and the spiral arteries are abnormal causing poor placentation (Gökdemir, et al., 2016). This study noted that in women with preeclampsia, ADAMTS-12 was tested and found to be deficient.

Another study suggests the pathogenic autoimmune factor, angiotensin II type 1 receptor antibody (AT1-AA), could be the cause of preeclampsia (Aggarwal, Makris, & Hennessey, 2015). The study describes preeclampsia as an endothelial disorder in which abnormal

implantation of the placenta leads to ischemia which releases factors into the maternal blood system. They propose that one of these factors is AT1-AA which causes vasoconstriction, endothelial cell damage, hypercoagulation, decreased fibrinolysis, and renal impairment. The study found that the antibody can cross the placenta and cause fetal growth restriction. They captured the antibodies in maternal circulation as early as 18 weeks (Aggarwal, et al., 2015).

Clinical presentation. The clinical presentation of preeclampsia can differ from one patient to the other; however, the most common complaints of preeclampsia are headache, visual disturbances, epigastric pain, or nausea and vomiting (Mol, et al., 2016). Neurologic symptoms of severe preeclampsia can include eclamptic seizures, stroke, reversible ischemic neurological deficit, cortical blindness, retinal detachment, and reversible encephalopathy; while cardiorespiratory symptoms can be myocardial ischemia or infarction and pulmonary edema (Mol, et al., 2016). Fetal characteristics of preeclampsia can include growth restriction, stillbirth, neonatal death, and prematurity-associated complications from preterm birth (Mol et al., 2016).

The diagnostic criteria for preeclampsia are hypertension of greater than 140/90 on two occasions that are four to six hours apart present after 20-weeks-gestation combined with other maternal organ dysfunction (i.e. renal insufficiency, liver involvement, neurological or hematological complications), uteroplacental dysfunction or fetal growth restriction (Magee, et al., 2014; McKenna et al., 2013). Laboratory changes include thrombocytopenia with a platelet count less than 100,000, serum creatinine level greater than 1.1 mg/dl, and elevated liver enzymes (Magee et.al., 2014).

One of the severe presentations of preeclampsia is hemolysis, elevated liver enzymes, and low platelets (HELLP) (Magee, et al., 2014). The development of HELLP syndrome can occur anytime during antepartum, intrapartum, or postpartum, and can progress to disseminated

intravascular coagulation (DIC), liver infarction or hemorrhage, renal failure, pulmonary edema, abruptio placentae or non-reassuring fetal testing (Jido & Yakasai, 2013; Magee, et al., 2014; McKenna et al., 2013).

Risk factors. Because the underlying cause of preeclampsia is still not completely understood, researchers are attempting to find identifiable risk factors in the attempt to predict who might develop preeclampsia. Rodriguez-Lopez et. al. (2017) conducted a study using the Swedish Birth Register to examine 626, 600 pregnancies between 2002-2010 to determine risk factors for preeclampsia. The study explains that traditional risk factors include previous preeclampsia, chronic kidney disease, autoimmune disease, diabetes, chronic hypertension, primiparity, age of mother ≥ 40 , obesity, family history of preeclampsia, or multiple gestation. This study also compared age (<40 , or >40), education, (<11 years, >12 years), and family situation (living with the father of the baby or not) to determine further risk factors.

Results of the study showed higher risk for primiparous women with lower education, not cohabiting with child's father, smoking before pregnancy and conception by artificial reproductive technology. Results also showed 35% of preeclampsia cases occurred without a known risk factor in multiparous women and in 64% of primiparous women. The study suggested that in order to accurately predict those at high risk for preeclampsia at least 3 moderate risk factors should be present, such as low education, maternal age greater than 40, previous preeclampsia, high blood pressure, chronic kidney disease, artificial reproductive technology, multiple gestation, diabetes and obesity (Rodriguez, et al., 2017).

The national standard recommended by USPSTF states that having one or more of the following risk factors makes a woman high-risk for developing preeclampsia: history of preeclampsia, multiple gestation, chronic hypertension, type 1 or 2 diabetes mellitus, renal

disease, and/or autoimmune disease (LeFevre, 2014). ACOG (2018) recognizes the USPSTF's risk factors for predicting high risk women, while adding the following risk factors as moderate risks: nulliparity, obesity (BMI greater than 30), family history of preeclampsia (mother or sister), sociodemographic factors (African American race, low socioeconomic status), age 35 or older, personal history factors (low birth weight, small for gestational age, previous adverse pregnancy outcome, more than 10-year pregnancy interval). ACOG (2018) states that having more than one of the moderate risk factors makes a woman high-risk for developing preeclampsia.

Morbidity/mortality. Maternal complications of preeclampsia consist of postpartum hemorrhage, need for blood transfusion, placental abruption, heart failure, DIC, intracranial hemorrhage, and intensive care admission (Kongwattanakul, et al., 2018; McKenna et al., 2013). Women with two or more pregnancies affected by preeclampsia have higher mortality rates and shorter life expectancy related to diabetes, ischemic heart disease, and stroke (McKenna et al., 2013; Theilen, et. al, 2018). Neonatal complications consist of low birth weight, prematurity, birth asphyxia, hypoxic neurological injury, neonatal intensive care admission, resuscitation, stillbirth and intrapartum death (Kongwattanakul, et al., 2018; McKenna et al., 2013). Offspring of women with preeclampsia have lower cognitive function (Pinheiro, et al., 2016) and higher systolic blood pressure (Tripathi, et al., 2018). Due to the short-term and long-term morbidity and mortality for mothers and infants, prevention of preeclampsia is crucial. The purpose of this QI project is to prevent preeclampsia by utilizing LDA.

Aspirin

Aspirin, the most widely prescribed treatment for the prevention of cardiovascular complications, has been used for 30 years in the prevention of preeclampsia (Atallah, et al.,

2017). The physiological effect of aspirin on preeclampsia and potential risks of aspirin use during pregnancy will be examined.

Physiology of aspirin on preeclampsia prevention. Aspirin inhibits prostaglandins, decreases thrombin, increases fibrinolysis, and prevents endothelial cell dysfunction (Atallah, et al., 2017) and inflammation (Hashemi, et al., 2016). Preeclampsia is an imbalance of thromboxane A2 (TXA2), responsible for vasoconstriction and increased platelet aggregation and adhesion, and prostacyclin, responsible for vasodilation and inhibition of platelet aggregation and adhesion (Atallah, et al., 2017). In women at high-risk for developing preeclampsia, increased TXA2 and decreased prostacyclin is found starting at 13-weeks' gestation (Atallah, et al., 2017). Aspirin inhibits TXA2 secretion, inhibiting platelet aggregation, but does not alter prostacyclin, allowing for vasodilation (Atallah, et al., 2017; Hashemi, et al., 2016). The TXA2/prostacyclin imbalance can be reversed after two weeks of aspirin therapy (Atallah, et al., 2017).

Risk factors of aspirin use during pregnancy. Several trials studying LDA and prevention of preeclampsia have evaluated potential harmful side-effects aspirin could have on pregnancy, labor, and delivery. Results found aspirin was not associated with significant intrapartum risks, such as increase in placental hemorrhage, bleeding with epidural anesthesia, or increased bleeding in the fetus and newborn infant (CLASP: A randomised trial of low-dose aspirin for the prevention and treatment of pre-eclampsia, 1994). The use of LDA also posed no risk of increased bleeding or placental abruption during the antepartum period (Ohno, et al., 2014) Evidence of harm from other bleeding-related complications, such as postpartum hemorrhage, maternal blood loss, and neonatal intracranial or intraventricular bleeding was not found (Henderson, et al., 2014).

LDA and Preeclampsia Prevention

Evidence-based research. Roberge et al. (2017) conducted a large systematic review and meta-analysis resulting in the review of 45 RCTs that included 20,909 pregnant women who were randomized into groups between 50-150mg of aspirin daily and groups with initiation of LDA-therapy before and after 16-weeks-gestation. The analysis indicated that when aspirin was initiated at 16 weeks or less, there was a significant reduction in preeclampsia, severe preeclampsia, and fetal growth restriction. Further results showed higher doses of aspirin were associated with greater reductions of the three outcomes. When aspirin was initiated after 16 weeks, there was a smaller reduction of preeclampsia regardless of aspirin dose, and no reduction of severe preeclampsia or fetal growth restriction (Roberge, et al., 2017).

Meher et al. (2017) also conducted a meta-analysis that included 31 RCTs with 32,217 women and 32,819 babies comparing LDA or other antiplatelet agents with placebo or no treatment for prevention of preeclampsia. The study outcomes were preeclampsia, death of baby, preterm birth before 34 weeks, and small-for-gestational-age baby. The authors performed a subgroup analysis based on gestational age. Results found no difference in the effects of LDA or other antiplatelet agents on the four outcomes based on gestational age and recommended offering LDA or other antiplatelet agents regardless of gestational age.

The Cochrane Library Investigative Review of aspirin and prevention of preeclampsia included analysis of 59 RCTs and 37,650 women and showed a 17% reduction in the risk for preeclampsia with antiplatelet therapy (Duley et al., 2010). The authors concede that more information is needed to determine when to start treatment and at what dose.

According to Wright et al. (2017) compliance is important in the prevention of preeclampsia. The study showed that patients who were 90% or more compliant with the aspirin

regime had positive prevention of preeclampsia; however, if less than 90% compliant, the patient had similar results as the placebo group. This study shows that the positive effect of aspirin on prevention of preeclampsia is compliance dependent.

Current national guidelines. Several national health organizations have researched and published recommendations regarding the prevention of preeclampsia. The recommendations for prevention of preeclampsia all included the use of low-dose aspirin for women at risk of developing preeclampsia (American College of Obstetrics and Gynecology, 2018; Bushnell, et al., 2014; Henderson, et al., 2014; LeFevre, 2014; World Health Organization, 2011).

Recommendations for when to initiate LDA therapy range from the 12th week of gestation (Bushnell, et al., 2014; LeFevre, 2014), 12 to 28-weeks-gestation (American College of Obstetrics and Gynecology, 2018), less than 16 weeks-gestation (Roberge, et al., 2017) to less than 20-weeks-gestation (World Health Organization, 2011). The dose of aspirin recommended fluctuates from 60 to 160mg (Roberge, et al., 2017), 75mg (McKenna, et al., 2013; World Health Organization, 2011), and 81mg (American College of Obstetrics and Gynecology, 2018; LeFevre, 2014). Additional interventions included calcium supplementation of one gram per day in women with low dietary calcium intake (Bushnell, et al., 2014; World Health Organization, 2011) and magnesium sulfate administration in women with severe preeclampsia to prevent eclampsia (World Health Organization, 2011).

Birth Centers

The setting for this QI project is a birth center. This birth center only accepts low-risk women into their practice. Assessing risk and predicting preeclampsia is essential in out-of-hospital birth.

Risk assessment. Milne et al. (2005) published an evidence-based risk assessment to be

used in the community to ensure uniformity in assessment and referral for preeclampsia. This article was written for midwives seeing patients in the community. The authors listed 14 risk factors in which all women should be screened at the first prenatal visit, making note that this woman could be at risk for developing preeclampsia. After the initial risk assessment, a second risk assessment is made to determine when the woman should be assessed by a specialist. The following risk factors would constitute referral prior to 20-weeks-gestation: previous preeclampsia, multiple gestation, underlying medical conditions, or any two risk-factor from the initial assessment. According to the authors, this referral does not necessitate obstetrical care, only a referral to develop a plan-of-care. Transfer to obstetrical care would be made on an individual basis. After 20-weeks-gestation, every woman should be screened for new hypertension, new proteinuria, headache and/or visual disturbances, epigastric pain and/or vomiting, decreased fetal movement or small-for-gestational age, and referred to a specialist.

In the USPSTF and ACOG (2018) guidelines for prevention of preeclampsia, having one of the following conditions was considered high-risk for developing preeclampsia: previous pregnancy with preeclampsia, multiple gestation, chronic hypertension, type 1 or 2 diabetes mellitus, renal disease, or autoimmune disease (LeFevre, 2014). The guidelines state that if a woman has two or more of the following moderate risk factors, she is considered high-risk for developing preeclampsia: nulliparity, obesity (BMI >30 kg/m²), family history of preeclampsia in mother or sister, age 35 years or older, sociodemographic characteristics (African American, low socioeconomic level) or personal risk factors (history of low birth weight, small for gestational age, previous adverse pregnancy outcome, greater than 10-year pregnancy interval) (LeFevre, 2014).

Summary

The systematic review of literature provided evidence supported strategies regarding preeclampsia, LDA, guidelines and evidence for the prevention of preeclampsia, and risk assessment for preeclampsia for birth-center patients. Current literature concedes that the etiology and pathophysiology of preeclampsia is not completely understood and should continue to be researched (Jido & Yakasai, 2013). Researchers agree on the clinical presentation, risk factors, and morbidity and mortality of preeclampsia (American College of Obstetrics and Gynecology, 2018; Kongwattanakul, et al., 2018; LeFevre, 2014; Magee, et al., 2014; Mol, et al., 2016; Pinheiro, et al., 2016; Rodriguez-Lopez, et. al., 2017; Theilen, et. al, 2018; Tripathi, et al., 2018). Researchers agree that LDA can prevent preeclampsia; therefore, screening for risk factors in pregnant women have been suggested and guidelines have been published (American College of Obstetrics and Gynecology, 2018; Bushnell, et al., 2014; Henderson, et al., 2014; LeFevre, 2014; World Health Organization, 2011). A screening tool for preeclampsia for women planning to birth in a birth center has not been researched in the U.S. Therefore, future research could be aimed at developing a screening tool for preeclampsia similar to the community-based screening guideline used in the United Kingdom (Milne, et al., 2005).

Preeclampsia affects 2-8% of pregnancies and causes major complications for women and babies (Auger, et al., 2016). These high-risk patients utilize intensive-care nursing hours. Utilizing more nursing hours is significant due to the present and predicted nursing shortage; predictions state that 20% of the demand for nurses in 2030 will not be met (Texas Team Education Committee Task Force Membership, 2017). By using LDA to prevent preeclampsia, the burden of utilizing intensive-care nursing hours can be reduced. Utilization of health-care resources for these high-risk patients is also significant. Nurse administrators planning budgets

and staffing must consider higher costs related to use of supplies and nursing staff. Preventing preeclampsia could reduce the cost of care for these patients. Lastly, women in developing countries have higher rates of preeclampsia (Duley, 2009) along with women of lower socioeconomic status and African-American race (LeFevre, 2014). Nurses can play a pivotal role in decreasing the higher incidences in these populations by teaching these women to take LDA during pregnancy. LDA has been proven to be a cost-effective intervention (Roberge, et al., 2017).

Theoretical Framework

The theoretical framework of Avedis Donabedian's structure, process, and outcome will be utilized to guide this evidence-based DNP project. Donabedian's framework guides research for assessing and improving quality of health care by showing that good structure increases good processes, and good processes produce good outcomes (Donabedian, 1966). Because his framework encourages the researcher to attempt to improve quality of care through assessment of outcome measures, this framework is essential in QI studies such as this DNP project (Moran, Burson, & Conrad, 2017).

Historical Development of the Theory

In 1965, the Health Services Research Section of the U.S. Public Health Service asked Donabedian, a professor of medical care organization at the University of Michigan School of Public Health, to review the research on quality assessment at an important meeting of leaders from all health-related fields (Ayanian & Markel, 2016). In 1966, the research from all the leaders at the meeting were published including Donabedian's "Evaluating the Quality of Medical Care" (Ayanian & Markel, 2016). This article defined structure, process, and outcome for assessing medical quality of care and was the beginning of the Donabedian Framework

(Ayanian & Markel, 2016). In 1990, the Institute of Medicine's monumental report "Medicare: A Strategy for Quality Assurance" implemented this framework to assess quality (Ayanian & Markel, 2016). Donabedian defined quality by looking at health care as a system, i.e. performance of practitioners, the contributions of patients, and the health care system (Donabedian, 1997).

During Donabedian's career, he focused on defining and developing methods to measure the quality of health care, examining how clinical decision-making affected quality, and analyzing management of health care systems and resources (Ayanian & Markel, 2016). Donabedian's framework is one of the best-known frameworks in nursing research (Best & Neuhauser, 2004). Nurses have been researching patient safety for 115 years, and Donabedian's framework has been used in a great deal of nursing research whose aim is to develop a better quality of care (Kowalski & Anthony, 2017). Nurses work in areas that can affect structure and process; therefore, they play a large role in improving outcomes.

Applicability of Theory to Current Practice

The Institute of Medicine ([IOM], 2000) released a report that examined medical errors and introduced the Quality of Health Care in America Project. This report documented quality and safety issues in health care in the U.S. (DesHarnais, 2013). This report drove researchers to focus on quality and safety. Therefore, many of the researchers used Donabedian's framework to guide their studies on quality of health care.

A recent QI study attempting to reduce avoidable hospitalization of aged-care-facility residents by utilizing nurse practitioners implemented Donabedian's framework (Dwyer, Craswell, Rossi, & Holzberger, 2017). Another quality study using Donabedian's framework attempted to identify the difficulties preventing nurses and primary care providers in providing

nutritional counseling and child growth follow-up with the goal of preventing obesity (Palombo, et. al., 2017). Hiott, Phillips, and Amella (2018) used Donabedian's framework to evaluate adolescent-risk-screening instruments available to primary care providers in hopes of improving quality of care for adolescents. Sales et al. (2018) evaluated the use of standard operational protocols for nurses by utilizing Donabedian's framework to improve the quality of care provided.

A common theme with these and other studies utilizing Donabedian's framework is the use of structure, process and outcome to analyze an aspect of care in order to improve quality. Another common theme is analyzing the system of health care instead of health care providers only. Lastly, a common theme of studies using Donabedian's framework is the importance of identifying and respecting the patients' needs.

Major Tenets

Donabedian (1966) introduced three factors that could be used to evaluate the quality of care: Structure, process, and outcome. He stated that this three-part approach worked because good structure increases good processes, and good processes produce good outcomes (Donabedian, 1966). Donabedian stressed the need for valid measures of structure and process that could be associated with outcomes, as well as quality measures that could be reproducible (Ayanian & Markel, 2016). Donabedian's three tenets are the foundation of quality assessment (Ayanian & Markel, 2016).

Structure. The first tenet of the Donabedian framework is structure. Structure can be defined as the setting, qualifications of providers, administrative systems of care (Ayanian & Markel, 2016), and persons involved in the project (Moran, Burson, & Conrad, 2017).

Donabedian (1997) defined structure as the setting where care occurs, material resources, human

resources, and organizational structure. DesHarnais (2013) explained that structure was the resources available to provide quality care. Budget resources, staff training, reward systems, and payment methods have also been categorized as structure (Kajonius & Kazemi, 2016).

Process. Process is the second tenet of the Donabedian framework. Donabedian (1997) defined process as what is done while giving and receiving care, the patients' activities during care, and the practitioners' activities in making diagnoses and providing care. Others defined process as the components of care delivered (Ayanian & Markel, 2016) and how care is delivered (Moran, Burson, & Conrad, 2017); making a diagnosis and recommending or implementing treatment (Gulick, Halper, & Costello, 2007); and interaction, communication, and decision-making between caregivers and patients (Kajonius & Kazemi, 2016). Process variables have been noted to be more difficult to measure than structural variables because process variables are not always straightforward (Kajonius & Kazemi, 2016).

Outcome. Outcome is the final tenet of the Donabedian framework. Definitions of outcome are things that will be measured, reviewed, and assessed (Moran, Burson, & Conrad, 2017); recovery, restoration of health, and survival (Ayanian & Markel, 2016); the effect of care on the patient or population (Donabedian, 1966); patient knowledge and satisfaction (DesHarnais, 2013); and all the effects of care, such as health, and behavior (Kajonius & Kazemi, 2016). Using outcome measures decrease the probability of undesired outcomes (DesHarnais, 2013).

Theory Application to the DNP Project

Structure. Moran, Burson, and Conrad (2017) described structure as the setting and those who will be involved in the project. The structure for this QI project will be a birth center; the providers, Certified Nurse-Midwives (CNMs) and registered nurses (RNs); and birth-center

patients. The three tenets of the Donabedian Framework are defined and represented in Appendix B.

Process. The process for this QI project, what will be done and how, will begin with a pre-test (See Appendix C) of the knowledge of the risk factors for preeclampsia administered to the CNMs and RNs (Moran, Burson, & Conrad, 2017). After the pre-test, a presentation will be provided to the staff CNMs and RNs regarding ACOG's Clinical Risk Assessment for Preeclampsia, the guideline that will be used in diagnosing patients at-risk for developing preeclampsia. A post-test (See Appendix D) will be used to assess the knowledge of the CNMs and RNs regarding risk-factors for developing preeclampsia. The CNMs and RNs will implement the use of ACOG's Clinical Risk Assessment for Preeclampsia at the AP visits between 12-28 weeks gestation. Once a patient is identified as at-risk for preeclampsia, she will be provided an education form explaining the risks and benefits of LDA (See Appendix E) and begin ACOG's LDA-therapy. The CNM and/or RN will utilize an automated progress note in the electronic health record to alert other providers of the patient's at-risk status and LDA plan of care.

Outcome. The outcome, what will be measured, reviewed, or assessed, will be whether the CRAP guideline was utilized on each patient between the weeks of 12 to 28 during the project period, were high risk patients identified in accordance to the CRAP guidelines, and did those high risk patients initiate LDA therapy (Moran, Burson, & Conrad, 2017).

Project Design

The purpose of this QI project is to identify pregnant women at risk for developing preeclampsia in order to initiate LDA therapy between the gestational weeks of 12-28. The overall purpose of identifying risk and initiating LDA therapy is to prevent women from developing preeclampsia, allowing them to remain in a birth center environment. The project

design to address this issue is the QI model. A QI model includes four stages or cycles: planning for change, implementing, analyzing results, and acting on the results (Langley, Nolan, Nolan, Norman, & Provost, 2009). The model works on the premise that not all change will work as planned or in the planned timeframe (Langley, Nolan, Nolan, Norman, & Provost, 2009). The QI model allows participants to observe and identify what is and is not working, then plan and test new interventions to overcome problems recently identified (Mule, Evans, & Pollard, 2013). The QI model is the model for this project because of the following reasons: the DNP student is attempting to test a new evidence-based intervention to overcome the problem of preeclampsia, the student is observing the five-week process to determine if the project is working as planned, and the student will identify what worked and did not work at the completion of the project, following the steps of the QI model. The use of this model is supported by the following studies. Rogers, Saggaf, and Ziolkowski (2018) utilized the QI model for a project aimed to reduce perioperative hypothermia in patients with extensive burn injuries by utilizing a Bair Hugger warming system. Shepard, et al. (2018) developed a program based on the QI model to improve inpatient referrals by introducing an electronic referral system. The QI model has been utilized in other specialties as well. Chinman, Hunter, and Ebener (2011) used the QI model for a project involving counseling and substance abuse. Their project goal was to develop a continuous QI program for substance abuse prevention and treatment centers in community-based settings in order for program managers to improve service quality (Chinman, Hunter, & Ebener, 2012).

The population of interest for this project consists of the CNMs and RNs of a small birth center. The patients of the birth center will be an indirect population of interest. A pre- and post-test design will be utilized to evaluate the CNMs and RNs' knowledge of risk for preeclampsia. A similar study to this project used a QI design testing baseline and post-intervention periods to

evaluate if use of a computer-based decision-making program increased healthcare utilization and quality in India (Peters, Kohli, Mascarenhas, & Rao, 2006). Another similar study utilized the pre- and post-intervention QI design to determine if utilization of the World Health Organization's Safe Childbirth Checklist improved quality of care for mothers and babies (Spector, et al., 2012). This QI project will use the one-group pre- and post-test design to examine the variable of the clinical staff's knowledge of risk factors for preeclampsia (Grove, Burns, & Gray, 2013). A pre-test evaluation of clinical staff's knowledge of risks for preeclampsia will be administered, and data collected. A multi-disciplinary training seminar based on the use of the CRAP guidelines will then be presented. A post-test of clinical staff's knowledge will then take place, and data collected. A Wilcoxon Signed Rank Test (WSRT) will be used to assess the difference in CNMs and RNs' knowledge of risk factors for preeclampsia before and after the training program.

Readiness for change of the clinical staff will be evaluated by administering the Organizational Readiness for Implementing Change (ORIC) survey to the CNMs and RNs after the completion of the posttest (See Appendix F). The ORIC is a 12-item instrument designed to measure if members of the organization are confident in the commitment and ability of everyone in the organization to implement an upcoming change (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014). The data obtained from the ORIC tool will be calculated for the mean, allowing the DNP student to evaluate the staff's readiness for change and plan for obstacles related to resistance to change. The CRAP guidelines will be integrated into the AP visits of patients between the gestational weeks of 12 to 28 for the duration of the five weeks of the study. A template utilizing questions from the CRAP guidelines will be integrated into the EHR for all women between the gestational weeks of 12 to 28. The Preeclampsia Risk Audit (PRA), a chart

audit tool designed specifically for this project, will be conducted weekly during the project (See Appendix G). The PRA will examine the variables of process adherence of CRAP guidelines, diagnosis of high risk for preeclampsia, and initiation of LDA therapy. The variable of process adherence will be tabulated on the PRA, and a process adherence score will be given for that health record. To determine if adherence to the CRAP guidelines increase over time, a Kruskal-Wallis test will be completed analyzing the variables of process adherence weekly for five weeks. At the completion of the project, a chi-squared test for independence will analyze the portion of high-risk women who initiated LDA therapy with the high-risk women who did not initiate LDA therapy. The chi-squared results will allow the DNP student to determine if identifying women for risk for preeclampsia increased the use of LDA therapy.

Upon completion of the project, the results from the Kruskal-Wallis test and chi-square test for independence will be evaluated to determine if the QI project successfully identified women at risk for preeclampsia and allowed for initiation of LDA. The project design will accomplish the project objectives by allowing for improvement in the knowledge and skills regarding identification of pregnant women at risk for developing preeclampsia through a multi-disciplinary training seminar and pre-test/post-test evaluation. The implementation of the use of the CRAP guidelines at the AP visits between 12-28 weeks will identify patients at risk for preeclampsia and fulfill the objective of initiating LDA-therapy for at-risk patients (American College of Obstetrics and Gynecology, 2018). Lastly, the objective of implementing an automated progress note into the EHR to alert providers and nurses to utilize the CRAP guidelines and initiate LDA therapy in high-risk women will be accomplished through this project design.

The DNP student will present the data from the project via a power point presentation to

participants of the study and other staff at the project site. At that time, the DNP student will offer suggestions for change or future implementation of the guideline. The participants of the project will be encouraged to continue to assess for improvements in preventing preeclampsia. A copy of the power point presentations and data will remain in a password-protected folder in Drop Box accessible to the administrative director/owner.

Population of Interest

The population of interest is defined as all the elements that meet criteria for inclusion for the study (Grove, Burns, & Gray, 2013). The population of interest in this QI project will be the clinical staff of a small, out-of-hospital birthing center in Central Texas. Inclusion criteria will be RNs and CNMs on staff who attend the training seminar. Exclusion criteria will be any non-clinical staff or any clinical staff unable to attend the training seminar. Pregnant women between the gestational weeks of 12 and 28 at risk for developing preeclampsia are an indirect population of interest. Because the philosophy of birth center care is to involve women in planning their own pregnancy and birth care by providing flexible options, pregnant women 12 to 28 weeks pregnant will be screened for preeclampsia risk and offered LDA therapy (Lescure, Schepman, Batenburg, Wiegers, & Verbakel, 2017). Lescure, et al. (2017) noted that when women were asked why they chose a birth center, they gave the following answers: because of the safe and comforting feeling, nice atmosphere and knowledge that medical help is close and available; and they felt in control, which is desired by many women and is associated with higher satisfaction with the birth experience.

Setting

The setting of a QI project is defined as the location where a study is conducted (Grove, Burns, & Gray, 2013). The setting for the Boesveld, et al.(2017) study was a birth center,

described as a place where women with uncomplicated pregnancies give birth in a home-like setting. Women in the birth center were referred to a hospital maternity unit if complications occurred (Boesveld, et al., 2017). The aim of the study was to identify quality indicators to assess the quality of birth center care, demonstrating that the setting of a birth center is an appropriate setting for a QI project (Boesveld, et al., 2017). Similar to the Boesveld, et al. (2017) study, the setting for this QI project will be a two-bed out-of-hospital birth center in urban, Central Texas staffed by four CNMs and four RNs performing approximately 15 to 18 births per month. Permission to use this site was granted by the administrative director/owner of the birth center (Appendix H). Grove, Burns, and Gray (2013) define a partially controlled setting as an environment that the researcher manipulates or modifies. This QI project utilizes a partially controlled setting by manipulating the assessment process of AP patients during the gestational weeks of 12 to 28.

Stakeholders

The stakeholders involved in this QI project will be four CNMs, four RNs, the administrative director/owner, and the patients of the birth center. The CNMs and RNs are stakeholders because they are committed to caring for patients in a birth center setting. Birth centers are designed for low-risk patients, and the diagnosis of preeclampsia would necessitate a hospital birth (Boesveld, et al., 2017; Milne, et al., 2005). Therefore, they are invested in this QI project because preventing preeclampsia would prevent patients from transferring out of birth center care. The administrative director/owner is a stakeholder because he owns the birth center, and one of his quality indicators is the number of women who transfer to hospital care. According to the administrative director/owner, the women and the birth center are affected financially when a woman is transferred to another location for birth. Birth center patients are

stakeholders because they have chosen to receive care in a birth center instead of a hospital. In a study measuring satisfaction with birth, satisfaction was higher for women with vaginal births compared with caesareans deliveries, and higher for women who had both planned to deliver in a home or a birth center, and who had actually delivered in a home or a birth center (Fleming, et al., 2016). Furthermore, spontaneous vaginal birth and perineal integrity were higher for women beginning care in a birth center compared to women in hospital care (Alliman & Phillippi, 2016). The systematic review concluded that women planning to birth in a birth center had lower rates of cesarean birth; few severe maternal outcomes and no maternal deaths in any studies of the systematic review; and were satisfied with the comprehensive, personalized care that they received from birth centers (Alliman & Phillippi, 2016). They are also stakeholders because preventing preeclampsia could reduce the risk of dangerous complications associated with preeclampsia, such as postpartum hemorrhage, placental abruption, intracranial hemorrhage, etc. (Theilen, et al., 2018). Weekly meetings will be scheduled with the stakeholders during the development of the project to ensure all questions and concerns are addressed. Weekly email communication with results of each weeks' PRA results will be provided to all clinical staff. Upon completion of the project, results will be presented in a Power Point presentation at a staff meeting. Suggestions on areas of improvement will be provided in that presentation.

Recruitment Methods

The recruitment method will be a Power Point presentation explaining the purpose and benefits of the QI project (See Appendix I). The Power Point will be presented at a regularly scheduled quarterly staff meeting; therefore, all staff will be present. The administrative director has approved this presentation. The presentation will review reasons why women choose birth center care. A cross-sectional survey of 1,835 pregnant women in Australia revealed that women

choose their birth setting because of many factors, such as government and institutional policy, personal values, and economic situation (Steel, Adams, Frawly, Broom, & Sibbritt, 2015). Steel, et al. (2015) suggests that a clear understanding of what factors are important to each woman and access to the most appropriate birth environment will achieve the best maternal and fetal health outcomes. The presentation will also present the potential harmful effects of preeclampsia, such as eclampsia, HELLP, DIC, and maternal death (Kongwattanakul, Saksiriwuttho, Chaiyarach, & Thepsuthammarat, 2018). Finally, the presentation will explain that LDA therapy could potentially prevent preeclampsia, and in turn prevent maternal complications and hospital birth (American College of Obstetrics and Gynecology, 2018). The involvement in the project will be voluntary. A poster board advertisement of the QI project will be posted in the work area of the site to encourage staff members to participate. A lunch will be provided one month prior to the QI project to review the purpose and goals of the project. Another lunch will be provided at the start of the study after the pretest. Patients will not be recruited for this project. Instead, data regarding patients will be obtained from the project site's EHR and will be anonymous by assigning a number to the record and deidentifying the patient. The identification of clinical staff participating in the study will also remain anonymous by assigning each an identification number and deidentifying the participant . Data will be stored in a password-protected computer in the possession of the DNP student and in a password-protected folder in Dropbox shared only with the administrative director/owner.

Tools and Instruments

No validated clinical tools are available to predict preeclampsia early in pregnancy with sufficient sensitivity and specificity; therefore, USPSTF created the CRAP guidelines to identify patients with an absolute risk for preeclampsia until a validated tool can be created (LeFevre,

2014). The USPSTF is an independent group of national experts in prevention and evidence-based medicine working to improve health by making evidence-based recommendations about clinical preventive services (U.S. Preventive Services Task Force, 2018). In attempt to examine the research surrounding the CRAP guidelines, a systematic review of 525 abstracts were examined (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). The abstracts were narrowed down to 73 potentially relevant articles (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). The systematic review resulted in the inclusion of the following studies: one large U.S. study (n=2,539), one large United Kingdom study (n=9,364), and 13 smaller trials evaluating the benefits of aspirin (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). Six randomized controlled trials (RCTs) of women not at increased risk for preeclampsia were reviewed to discover the potential harm of aspirin use (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). Five of these RCTs were studies for prophylaxis on women at low to average preeclampsia risk: a multisite study in the United States (n=3,135), and a smaller U.S. study (n=606), a multisite study in France and Belgium (n=3,294), a study in Barbados (n=3,647), and a U.K.-based study (n=122) (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). Two observational studies were also included to review any harmful effects from aspirin on pregnant women: a cohort study of 47,400 women and a case-control study from a large prospective cohort study (n=3,129) (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). The conclusions of the systematic review were as follows: for women at elevated risk of preeclampsia, prophylaxis with LDA beginning after the first trimester of pregnancy reduced the risk of preeclampsia by 10 percent; studies found limited evidence of harm associated with low-dose aspirin use during pregnancy (Kaiser Permanente Research Affiliates Evidence-based

Practice Center, 2014). The systematic review also found that the most consistent risk factors for developing preeclampsia were previous preeclampsia, certain chronic medical conditions (e.g., diabetes, chronic hypertension, renal disease, and autoimmune diseases such as systemic lupus erythematosus and antiphospholipid syndrome), and multifetal pregnancy (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). These are the same risk factors listed in the high-risk category of the CRAP guidelines (LeFevre, 2014). The systematic review found the following factors consistently predicted moderately-increased risk for preeclampsia: first birth, maternal age ≥ 35 years, BMI ≥ 35 kg/m², family history of preeclampsia (mother, sister), and other personal history risk factors (e.g., pregnancy interval over 10 years, low birth weight) (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014). These risk factors are consistent with the moderately-high risk factors in the CRAP guidelines with the exception of BMI (CRAP recommends a BMI ≥ 30 kg/m²) (LeFevre, 2014). The systematic review noted that efforts to develop predictive tools for identifying women who will eventually be diagnosed with preeclampsia have been attempted but are not yet successful (Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2014).

The USPSTF guideline is broken down into three categories: high risk, moderate risk, and low risk (LeFevre, 2014). The diagnosis of high risk for preeclampsia requires the presence of one of the following risk factors: history of preeclampsia, multifetal gestation, chronic hypertension, type 1 or 2 diabetes, renal disease, or autoimmune disorder (LeFevre, 2014). The diagnosis of high risk for preeclampsia requires the presence of several of these moderate risk factors: nulliparity, obesity, family history of preeclampsia, sociodemographic characteristics, age ≥ 35 years, and/or personal history factors (LeFevre, 2014). The requirement for low risk for preeclampsia is the history of a previous uncomplicated full-term delivery (LeFevre, 2014).

ACOG (2018) adopted the CRAP guidelines but adjusted for more strict definitions of risk by making the requirement of more than one moderate risk factor to diagnose high risk instead of several. This QI project will use ACOG's (2018) version of the CRAP guidelines.

ACOG (2018) CRAP guidelines are used to identify women at risk for preeclampsia in order to initiate LDA therapy. ACOG (2018) recommends the initiation of 81mg of aspirin per day for women diagnosed as high risk for preeclampsia. The initiation of LDA therapy should be between the weeks of 12 to 28, with 16 weeks being the optimal initiation period, and should continue until delivery (American College of Obstetrics and Gynecology, 2018).

For this project, the clinical staff, including CNMs and RNs, will take a pre-test measuring their knowledge of risk-factors for preeclampsia in pregnant women according to 2018 ACOG Committee Opinion. The test will be confidential and will use only numbers to identify the staff member. The DNP student will present ACOG 2018 *Committee Opinion: LDA Use in Pregnancy* and highlight the CRAP guidelines in a 45-minute Power Point presentation (See Appendix J). The clinical staff will then take a post-test measuring their knowledge of risk factors for preeclampsia in pregnant women. Again, this test will be confidential and will only use numbers to identify the staff members. Both pre- and post-test were examined for content validity by experts, and questions were found to be highly relevant (content validity rating = 1; See Appendix C & D).

After the completion of the post-test, the ORIC will be administered to participants in order to assess readiness for change. The ORIC was developed to measure change commitment and change efficacy in individuals in order to determine organizational readiness for change (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014). The ORIC can assist healthcare leaders by understanding the climate of the organization while planning for change (Shea, Jacobs,

Esserman, Bruce, & Weiner, 2014). The ORIC has good validity (CFI = .98, RMSEA = 0.8, SRMR = .05) and inter-rater reliability (kappa = .94). This tool has been reproduced in Danish and maintained its validity (CFI=.95, RMSEA=.067, and CMNI/DF=2.32) and reliability (Cronbach's alpha 0.88) (Storkholm, Mazzocato, Tessma, & Savage, 2018). The ORIC has been used to measure preceptors' perceptions regarding readiness for student pharmacists to provide direct patient care (Sanders, et al., 2017). The ORIC has also been used to assess organizational readiness for change in a large dental care organization that was implementing a multi-faceted QI program (Cunha-Cruz, et al., 2017). Both studies utilized the ORIC to define areas of the organization that were ready for change and areas needing attention prior to change. This QI project will calculate the mean score of the ORIC to determine readiness for change of the participants. The DNP student will use this information to determine if any problems with readiness need addressing prior to implementing the project guidelines.

The CRAP guidelines will be incorporated into AP visits weeks 12-28 by developing a template that will be added to the EHR (See Appendix K). After the guidelines have been implemented, a chart review of pregnant women between the gestational weeks of 12 to 28 will be completed weekly using the PRA. The Agency for Healthcare Research and Quality (AHRQ) (2014) utilized a similar chart-audit tool in their obesity study. AHRQ's (2014) chart audit tool evaluated patients' medical history, weight-management visits, and required documentation of BMI and weight management recommendations to ensure all providers were assessing and providing consistent information. The PRA will evaluate patients' medical and family history, risk factors for preeclampsia, initiation of LDA therapy, and required documentation of risk and LDA therapy. A process adherence score will be tabulated based on the PRA for that health record. The process adherence score is calculated by assigning a grade of 0 or 1 (0= did not

follow CRAP guidelines, 1 = did follow CRAP guidelines; total score: 0-5) to questions 1, 2, 5, 6, and 7 of the PRA. The chart review for this QI project will not include any identifying information. Each chart will be assigned a number, and all information will be confidential. No statistician will be utilized. Data will be analyzed by the DNP student using SPSS.

Data Collection Process

The data will be collected by the DNP student using a pre-test/post-test of provider knowledge of risk factors for preeclampsia. Collected data will be recorded on Excel spreadsheets. All data for the DNP project will be de-identified before data analysis. All data will be stored on a password protected computer accessible only by the student. A WSRT will be utilized to analyze the difference in knowledge of risk factors for preeclampsia before and after the power point presentation using the pre- and post-test scores. Data from the ORIC tool will be collected, and the mean score of the test will help determine readiness for change of the participants.

At the end of each study week, the DNP student will examine records for patients between the gestational weeks of 12 to 28. The patients will be identified by using the EHR's search feature that allows search by estimated gestational age. The PRA, created for the study, will be utilized to collect data from approximately 50 charts from the site's EHR. Collected chart data will be recorded on an Excel spreadsheet. A process adherence score will be assigned to each record each week. The process adherence score is calculated by assigning a grade of 0 or 1 (0= did not follow CRAP guidelines, 1 = did follow CRAP guidelines; total score: 0-5) to questions 1, 2, 5, 6, and 7 of the PRA. At the end of each week, the DNP student can determine process adherence in order to assess if changes in the study protocol should be made. This process will be repeated weekly for five weeks. A Kruskal-Wallis test will be conducted to

determine if process adherence increased with time. At the completion of the study, the data will remain with the student for five years, and a copy of the data will be available to the practice site’s administrative director/owner through a password-protected file on Dropbox. In five years, the DNP student will delete the data from the computer.

Intervention/Project Timeline

Dates	Project Actions
December 2018 to June 2019	Complete project proposal Obtain permission to use project site Meet weekly with stakeholders to maintain communication and collaboration
June 6, 2019	Present recruitment power point to project site staff Place recruitment poster in project site staff room Provide lunch for staff for recruitment
June 26, 2019	Administer pretest to staff Present project power point explaining guidelines and project Administer posttest to staff Administer ORIC survey Provide lunch for recruitment Install EHR template
July 1-5, 2019	Begin screening patients and initiating LDA End of the week, begin chart audits End of the week, present project stats to stakeholders
July 8-12, 2019	Continue project Continue audits End of the week, present project stats to stakeholders

June 17-21, 2019	Continue project Continue audits End of the week, present project stats to stakeholders
July 22-26, 2019	Continue project Continue audits End of the week, present project stats to stakeholders
July 29-August 2, 2019	Complete project Complete audits
August 2-5, 2019	Analyze data
August 5-7, 2019	Prepare presentation for project staff
August 9, 2019	Present outcomes of project to staff Make recommendations for future use of guidelines

When considering a timeline for the project, the DNP student prepared all sections of the proposal prior to setting the timeline for implementation. Approval from the project site was obtained with approval of the proposed timeline. Recruitment of participants was considered and began one month prior to implementation. Timeline describes the implementation of the project for five weeks. Time for collection and analysis of data were considered. Evaluation of the project and presentation of the results and evaluation to the project site was also considered.

Ethics and Human Subjects Protection

This DNP project is focused on the implementation of a screening tool to be utilized for the prevention of preeclampsia in a birth center setting. The CNMs and RNs volunteering for this project will benefit by being introduced to evidence-based practice guidelines, assisting patients to remain healthy and low-risk, and experiencing collaboration on a QI project. The indirect participants, the patients, will benefit by being screened for a potential serious complication that

could be prevented. The DNP student will protect the anonymity and confidentiality of participants by ensuring that the information being provided is not tampered with or shared by keeping all data on a password protected computer. Privacy for participants will be maintained by assigning numbers to data instead of provider or patient names, resulting in deidentified data. Individual patient data will be collected for statistical analysis based on a chart audit; however, the patient is not a participant and information will be anonymized utilizing a number and no identifiable personal information. Data will be collected only by the DNP student. The birth center owner/administrative director granted permission to allow the DNP student to recruit volunteers from the birth center and conduct the QI project at the site. No Institutional Review Board was required by the project site. Per IRB guidelines, the project meets exempt status because the activity involves no risk to the participants. No compensation will be provided to the participants volunteering in this project.

Plan for Analysis/Evaluation

A Wilcoxon Signed Rank Test (WSRT) will be utilized to analyze the difference in knowledge of risk factors for preeclampsia before and after a power point presentation using the pre- and post-test scores. According to Pallant (2016), a WSRT is a test used when data are collected on one group of people at two different times or under two different conditions and is appropriate for a pre-test/post-test design. The purpose of a WSRT is to determine whether there is a significant difference in the median scores for Time One and Time Two (Pallant, 2016). The WSRT, a non-parametric test, will be appropriate to analyze the project's data due to the small sample size (Pallant, 2016). Several statistical assumptions will be made: Random samples, independent observations, and one group of participants measured on two different occasions (Pallant, 2016). The research question being addressed by this WSRT is: Is there a significant

change in nurses' knowledge of risk factors for preeclampsia following participation in a power point presentation based on CRAP guidelines for diagnosing risk for preeclampsia and initiation of LDA? The pre- and post-tests are comprised of 10 questions each and will result in continuous variables, a score of zero to 10. These scores will be input into SPSS for analysis using the WSRT. The Z value and associated significance levels will be examined to determine if there is a significant difference in scores (Pallant, 2016). Effect size will also be calculated to determine how much of an effect the intervention made (Pallant, 2016).

Data from the ORIC tool will be collected, and the mean score of the tests will be determined. The ORIC tool is a 12-item survey using the Likert scale, producing ordinal data (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014). The DNP student has determined a mean score of 45 or greater will show readiness for change in the participants. Skewness, an indication of the symmetry of the distribution of scores, and kurtosis, an indication of the clustering of scores, will be tested by SPSS (Pallant, 2016). A histogram will also be produced to determine the distribution of scores. If the distribution of scores are skewed, the median will be reported instead of the mean (Pallant, 2016). A boxplot of the distribution of scores will be produced in order to find outliers (Pallant, 2016).

A process adherence score (PAS), a score to determine if the participants are following the project guidelines, is calculated at the end of each week of the project by assigning a grade of 0 or 1 (0= did not follow CRAP guidelines, 1 = did follow CRAP guidelines; total score: 0-5) to questions 1, 2, 5, 6, and 7 of the PRA. This process will be repeated weekly for five weeks. A Kruskal-Wallis test, a non-parametric test that allows for comparison of scores for three or more groups or time periods, will be conducted using SPSS to assess if process adherence increases over time (Pallant, 2016). The research question the Kruskal-Wallis test will answer is as

follows: Is there a difference in PAS scores across five weeks of testing? Several assumptions will be met: Level of measurement will be continuous; random sampling will be assumed; independence of observations will be valid because data will be collected strictly from chart audits; normal distribution will be determined by creating a histogram; missing data will be determined by running missing value analysis; and outliers will be determined by creating a boxplot (Pallant, 2016).

A Chi-square Test for Independence explores the relationship between two categorical variables (Pallant, 2016). A Chi-square Test for Independence will be used to answer the following question regarding the indirect population of interest, project-eligible patients: Is there a significant relationship in patients diagnosed as high-risk for preeclampsia and patients starting LDA therapy? Several assumptions will be met: Random sampling and independent observation assumptions will be met by utilizing data from the PRA, and the assumption of having more than five frequencies in each cell will be determined (Pallant, 2016).

Significance/Implications for Nursing

Women diagnosed with preeclampsia are at risk for postpartum hemorrhage, need for blood transfusion, placental abruption, heart failure, DIC, intracranial hemorrhage, and intensive care admission (Kongwattanakul, et al., 2018; McKenna et al., 2013). These high-risk patients utilize more nursing hours which is significant due to the present and predicted nursing shortage predicting that 20% of the demand for nurses in 2030 will not be met (Texas Team Education Committee Task Force Membership, 2017). The United States is predicted to experience a nursing shortage in the coming years due to aging baby boomers, insufficient numbers of nursing graduates, the aging population, and a rise in chronic care management needs (Snavelly, 2016). Another reason for the predicted nursing-shortage crisis is lack of nursing faculty; in 2014,

nursing schools denied almost 70,000 qualified applicants due to faculty shortages (Brown, 2015). By using LDA to prevent preeclampsia, the burden of utilizing intensive-care nursing hours can be reduced.

High-risk preeclamptic patients utilize more health-care resources. Nursing leaders who plan budgets and staffing must consider higher costs and expenditures related to use of supplies and nursing staff. Preventing preeclampsia could reduce the cost of care for these patients. Preventing preeclampsia for patients planning a birth center birth can save patients, insurance companies, and state-funded healthcare plans thousands of dollars. For example, the average hospital and provider charges for a vaginal birth in 2010 were \$22,734 (after insurance adjustments: \$12,520) and cesarean birth were \$32,062 (after insurance adjustments: \$16,673) (Truven Health Analytics, 2013; See Appendix L). In 2011, the average reimbursement from Medicaid for an uncomplicated vaginal birth in a hospital was \$3,998, compared with \$1,907 in birth centers; this alone saved \$27.2 million in the National Birth Study II conducted from 2007 to 2010 with 15,574 participants from 79 midwifery-led birth centers (Stapleton, Osborne, & Illuzzi, 2013). This cost difference is significant for health care resources and an incentive to prevent preeclampsia.

Racial disparities in pregnancy outcomes have been a problem for a great deal of the last century; a consistent two-fold increase in the infant mortality rate between African American and Caucasian infants have been documented (Kiely, et al., 2011). Much of the disparity in infant mortality is attributable to the higher rates of low birth weight and preterm birth; other disparities remain unknown (Kiely, et al., 2011). The number one risk factor for African American women for low-birth weight infants is preeclampsia (Kiely, et al., 2011). Women of African-American race are at higher risk for developing preeclampsia compared with Caucasian women and at

higher risk for cardiovascular disease (Breathett, Muhlestein, Foraker, & Gulati, 2014).

Cardiovascular disease is the leading cause of death of women in the U.S. (Breathett, Muhlestein, Foraker, & Gulati, 2014). Nurses can play a pivotal role in decreasing higher incidences of cardiovascular disease and preeclampsia by identifying African American women who are considered a candidate for LDA therapy and initiating the therapy during pregnancy (McKenna, 2013).

Current literature does not address prevention of preeclampsia in birthing-center patients. This DNP project will demonstrate that screening birthing-center patients using the CRAP guidelines, diagnosing women at risk of developing preeclampsia, and initiating LDA therapy can prevent preeclampsia and allow these patients to remain low-risk. This DNP project also provides a template for other birthing centers to adopt the CRAP guidelines in hopes of preventing preeclampsia in their population. The results of this project could also be adapted for utilization in other settings and add to the body of nursing knowledge.

Analysis of Results

The purpose of this QI project was to identify pregnant women at risk for developing preeclampsia in order to initiate LDA therapy between the gestational weeks of 12-28. The overall purpose of identifying risk and initiating LDA therapy was to prevent women from developing preeclampsia, allowing them to remain in a birth center setting. The population of interest for this project consisted of CNMs and RNs at a small birth center. The project-eligible patients of the birth center were an indirect population of interest. The demographics of the project participants are listed in Table 1, and the demographics of the patients eligible for the project are listed in Table 2.

Table 1

Demographics of Project Participants (Percentage in parentheses)

Characteristic	CNM Participant (n = 3)	RN Participant (n = 3)
Gender		
	0 (0)	0 (0)
	3 (100)	3 (100)
Ethnicity		
White	3 (100)	3 (100)
Hispanic	0 (0)	0 (0)
African American	0 (0)	0 (0)
Age in years		
18-25	0 (0)	1 (33)
26-39	2 (67)	1 (33)
40-59	1 (33)	0 (0)
≥ 60	0 (0)	1 (33)
Experience at facility in years		
1-3	2 (67)	2 (67)
4-7	0 (0)	1 (33)
≥ 8	1 (33)	0 (0)
Highest Level of Education		
Associate	0 (0)	2 (67)
Bachelor	0 (0)	1 (33)
Master	2 (67)	0 (0)
Doctorate	1 (33)	0 (0)

Chart 2

Demographics of Project-Eligible Patients (Percentage in Parentheses)

Characteristic	Project-Eligible Patients (N = 52)
Age in years	
21-29	24 (46)
30-39	26 (50)
≥40	2 (4)
Ethnicity	
White	40 (77)
Hispanic	7 (13)
African American	4 (8)
Asian	1 (2)
Relationship Status	
Single, living with partner	5 (10)
Single, not living with partner	0 (0)
Married, living with partner	45 (86)
Separated	0 (0)
Divorced or widowed	0 (0)
Other	2 (4)
Highest Level of Education ^a	
HS/GED	1 (2)
Some College	7 (14)
Associate	3 (6)
Bachelor	30 (60)

Master	7 (14)
Doctorate	2 (4)
Parity	
0	21 (40)
1	14 (27)
2	6 (11.5)
3	7 (13.5)
4	3 (6)
≥5	1 (2)
BMI	
<18.5 Underweight	1 (2)
18.5-24.9 Normal	29 (56)
25-29.9 Overweight	14 (27)
30-34.9 Class I Obesity	5 (9)
35-39.9 Class II Obesity	3 (6)

^a 2 data missing.

The clinical staff volunteering to participate in the project including three CNMs and three RNs. The participants took a pre-test measuring their knowledge of risk-factors for preeclampsia in pregnant women according to the 2018 ACOG Committee Opinion. Following the pre-test, the DNP student presented a 45-minute Power Point presentation (See Appendix J). The presentation presented ACOG's 2018 *Committee Opinion: LDA Use in Pregnancy* and highlighted the CRAP guidelines. The clinical staff then took a post-test measuring their knowledge of risk factors for preeclampsia in pregnant women. A WSRT was utilized to analyze the difference in knowledge of risk factors for preeclampsia before and after a power point presentation using the pre- and post-test scores. The following statistical assumptions were confirmed because the DNP student utilized the PRA to collect data: random samples, independent observations, and one group of participants measured on two different occasions (Pallant, 2016). No assumptions were violated. The research question addressed by this WSRT was: Is there a significant change in nurses' knowledge of risk factors for preeclampsia following participation in a power point presentation based on CRAP guidelines for diagnosing risk for preeclampsia and initiation of LDA? The WSRT revealed a statistically significant increase in

scores on the testing of knowledge of risk factors for preeclampsia following participation in a Power Point presentation, $z = -2.06$, $p = .04$, with large effect size ($r = -.065$) (Table 3). The WSRT showed that participants increased their test scores on the knowledge-of-risk-factors test from 60 (pre-program) to 100 (post-program). Results show the power-point presentation had a large effect on the increase in test scores.

Table 3

Wilcoxon Signed Rank Test^a Results for Pre- and Post-tests for Project Participants

	Pre-test Scores (%)	Post-test Scores (%)
Respondent 1	60	100
Respondent 2	50	80
Respondent 3	60	-- ^b
Respondent 4	70	100
Respondent 5	70	100
Respondent 6	50	70

^a $z = -2.06$ (based on negative ranks). $p = .04$ (Asymp. Sig. 2-tailed). $n = 5$.

^b Respondent 3 did not complete post-test.

To determine project participants' readiness for change, data from the ORIC tool was collected. The DNP student had pre-determined a mean score of 45 or greater would show readiness for change in the participants. Upon analysis of ORIC scores, skewness, an indication of the symmetry of the distribution of scores, indicated a skewness score of $-.95$ suggesting a clustering of scores at the high-end of the graph (Pallant, 2016). Kurtosis, an indication of the "peakedness" of scores, was -1.66 indicating a relatively flat distribution with cases in the extremes (Pallant, 2016, p. 57). Due to the skewed results, the median was reported instead of the mean (Table 4). The histogram showed an abnormal distribution of scores, and the boxplot of the distribution of scores found no outliers (Pallant, 2016). The median score of the tests was determined to be 59.5 out of 60 possible points. Therefore, the DNP student assumed the participants were accepting and ready for this guideline change and did not need further

presentations on the guideline changes.

Table 4

ORIC Scores for Project Participants

	Total ORIC Score	Median	Std. Deviation
Respondent 1	60		
Respondent 2	60		
Respondent 3	54		
Respondent 4	59		
Respondent 5	60		
Respondent 6	53		
		59.5	3.27

Note. Kolmogorov-Smimov: Test statistic = .33, Degree of Freedom = 6, Sig. = .05

A PAS score to determine if the participants were following the project guidelines was calculated at the end of each of the five weeks of the project by assigning a grade of 0 or 1 (0= did not follow CRAP guidelines, 1 = did follow CRAP guidelines; total score: 0-5) to questions 1, 2, 5, 6, and 7 of the PRA. A Kruskal-Wallis test, a non-parametric test that allows for comparison of scores for three or more groups or time periods, was conducted using SPSS to assess if process adherence differed over time (Pallant, 2016). The research question the Kruskal-Wallis test answers is as follows: Is there a difference in PAS scores across five weeks of testing? The Kruskal-Wallis test revealed no significant difference in PASs for the five weeks of testing (Wk1, n = 9, Wk2, n = 8, Wk3, n = 13, Wk4, n = 15, Wk5, n = 7), $\chi^2(4, n = 52) = 5.90, p = .21$ (Figure 1 and Table 5). The participants were consistent in following the CRAP guidelines throughout the five weeks of the project. Several assumptions were met: level of measurement was continuous; random sampling occurred; independence of observations were valid because data was collected strictly from chart audits; missing data was determined by running missing value analysis (0 missing cases); and outliers were determined by creating a boxplot (3 outliers) (Pallant, 2016). Normal distribution was analyzed by creating a histogram; normal distribution was not seen. The difference between the Mean (4.73) and the 5% Trimmed Mean (4.95),

however, was very small indicating that extreme scores did not have a strong influence on the Mean.

Figure 1. Number of cases audited per week

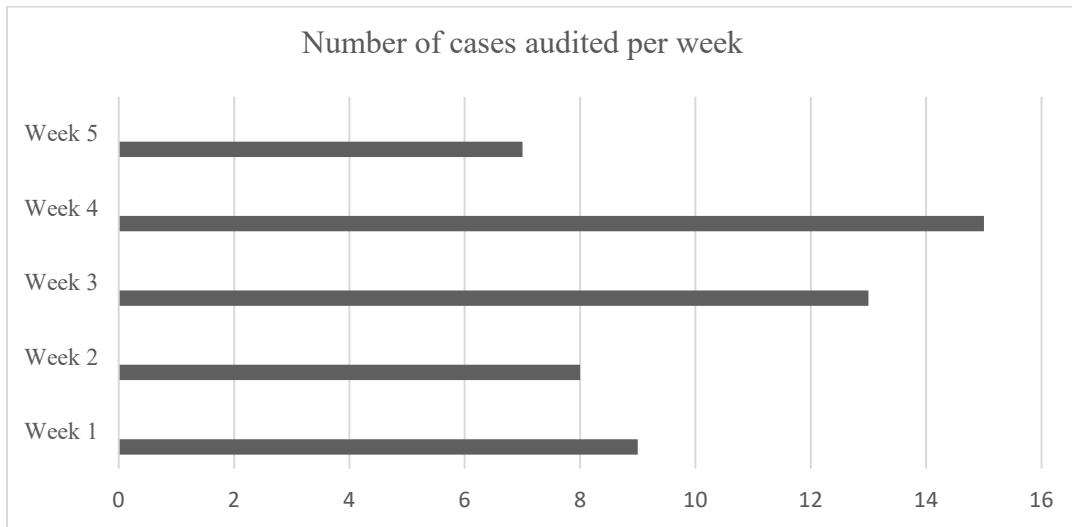


Table 5

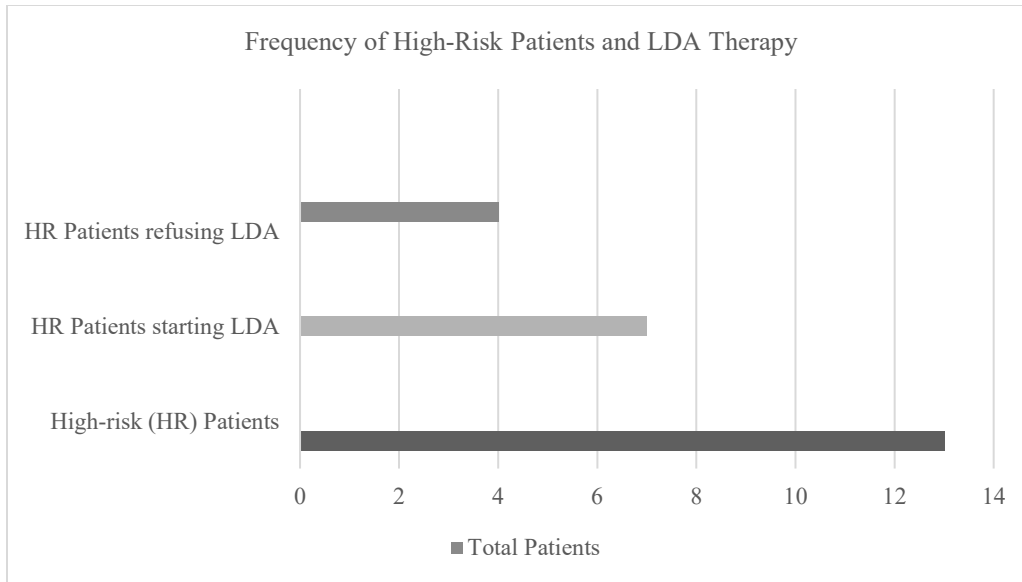
Kruskal-Wallis Test^a Results for Determining Differences in PAS Scores over 5 Weeks

Week of Project	Mean PAS Score	Standard Deviation
1	5.00	.00
2	3.75	2.32
3	5.00	.00
4	4.93	.26
5	4.57	1.13

^a n = 52. Test Statistic = 5.9. Degree of Freedom = 4. Asymptotic Sig. (2-sided test) = .21.

The indirect population of interest, patients of the birth center, were screened with the CRAP tool. Patients diagnosed as high risk were 13 out of 52, or 25%. Those patients diagnosed as high-risk were prescribed LDA therapy. Using the PRA, the DNP student recorded whether high-risk patients started LDA therapy (Chart 10). The reasons cited for declining therapy were a general refusal (n = 3) and allergy to aspirin (n = 1).

Figure 2. Frequency of high-risk patients starting LDA therapy



A Chi-square Test for Independence explores the relationship between two categorical variables (Pallant, 2016). A Chi-square Test for Independence was used to answer the following question: Is there a significant relationship in patients diagnosed as high-risk for preeclampsia and patients starting LDA therapy? The Chi-square Test for Independence (with Fisher’s Exact Test) indicated a significant relationship between being diagnosed as high-risk for preeclampsia and starting LDA therapy, $\chi^2 (1, n = 50) = 23.82, p = .00, \phi = .76$ (Table 7). Random sampling and independent observation assumptions were met by utilizing data from the PRA. The assumption of having more than five frequencies in each cell was violated by one cell; therefore, the Fisher’s Exact Test was reported (Pallant, 2016).

Table 7

Chi-square Test for Independence for High-risk Patients and LDA Therapy (Percentage in Parentheses)

Patients Dx High-risk	Patients Initiated LDA		Total Patients
	No	Yes	Total ^b
No	39 (100)	0 (0)	39
Yes	4 (36.4)	7 (63.6)	11
Total	43	7	50

Note. Dx = Diagnosed. LDA = Low Dose Aspirin.

^aFisher’s Exact Test = .00. Phi = .76.

^b2 patients lost to follow-up.

The project question answered was as follows: In pregnant women who are 12-28 weeks pregnant desiring to deliver in a birthing center, does the initiation of the CRAP guidelines identify women at risk for preeclampsia and allow for initiation of an LDA regimen compared to not using the CRAP guidelines for identification of women at risk for preeclampsia? The DNP student answered the project question by meeting the following objectives:

1. Made a statistically significant improvement in knowledge and skills regarding identification of pregnant women at risk for developing preeclampsia through a multi-disciplinary training seminar as evidenced by the increase of median scores from 60 to 100 after the seminar.
2. Implemented the use of ACOG's CRAP guidelines at the AP visits between 12-28 weeks to identify at-risk patients as evidenced by 13 out of 52 (25%) patients being diagnosed as high risk for developing preeclampsia.
3. Initiated ACOG's LDA-therapy for at-risk patients between the weeks of 12-28 as evidenced by 63.6% of high-risk patients initiating LDA therapy.
4. Implemented an automated progress note into the electronic health record (EHR) during the AP visits between 12-28 weeks to alert providers and nurses to utilize the CRAP guidelines and initiate LDA therapy in women who qualify as high-risk for preeclampsia as evidenced by 52 patients being screened by the CRAP guidelines, 13 patients being diagnosed as high-risk, and 7 patients initiating LDA therapy.

Discussion of Findings

The purpose of this QI project was to implement the national guidelines for prevention of preeclampsia by identifying pregnant women at risk for developing preeclampsia and initiating LDA therapy between the gestational weeks of 12-28. The 45-minute Power Point presentation

that was presented to the participants showed a statistically significant improvement in their knowledge of risk factors for preeclampsia as seen in median test scores improving from 60 to 100. Pre-test and post-test design has been used for training and evaluation in many studies. Petscavage-Thomas, Bruno, and Heather (2014) utilized the pre-test and post-test design to successfully train radiologic technologists signs of adverse reactions to contrast; they were then able to evaluate the effectiveness of the presentation with a pre-test and post-test comparison. In this QI project, the comparison of pre-test and post-test knowledge scores were significant at $p < .05$ with a large effect size, reinforcing the use of training and evaluation using the pre-test and post-test design.

Studies from different specialties of healthcare (e.g., pain management, pharmacological and dental care) have used the ORIC to document the perception of readiness for change among members of an organization (Ruest, Léonard, Thomas, Desrosiers, & Guay, 2019). The project participants of this QI project were assessed for their readiness for change in order for the DNP student to assess whether there was a need to provide more information regarding the utilization of the new CRAP guidelines. After analysis of the ORIC surveys, the project participants were determined to have a positive readiness for change. The DNP student determined a minimum mean score of 45 out of 60 to be positive readiness for change; however, due to the skewed results, the medium, 59.5 out of 60, was reported. The results were skewed to the higher scores. This could be a result of a small sample size. The high scores of readiness for change could also be a result of the midwives' and nurses' desire to adopt guidelines which would prevent patients from becoming high-risk and transferring to a hospital setting.

Chart audits are used to evaluate many aspects of healthcare, and research projects develop their own chart audit tools (Hogg, et al., 2010). The PRA was developed by the DNP

student to audit project-eligible charts. In order to determine compliance to the CRAP guidelines, a PAS score was calculated from the chart audits weekly for five weeks. By comparing the PAS scores using the Kruskal-Wallis Test, the DNP student determined no statistically significant difference in compliance from week to week was present ($p > .05$). These results implied that project participants' compliance to the CRAP guidelines to diagnose risk for preeclampsia and initiation of LDA therapy was consistent across the five weeks of the project.

Using the CRAP guidelines, project participants identified 13 out of 52 patients as high risk for developing preeclampsia. Participants educated these patients on the use of LDA to prevent preeclampsia and provided them with an education form. They were asked if they were willing to initiate LDA therapy. Five of the 13 stated they would consider initiating LDA therapy but wanted to think about it first. Two of the 13 declined therapy during the initial visit. Those seven patients were emailed a Power Point education presentation with more information regarding the prevention of preeclampsia using LDA (See Appendix M). At the completion of the study, two patients were still undecided on starting LDA therapy, seven initiated therapy, one was allergic to aspirin. The Chi-squared Test for Independence found a statistically significant relationship in patients diagnosed as high-risk for preeclampsia and patients starting LDA therapy. Therefore, this QI study supports the use of the CRAP guidelines in the birth center setting to diagnose patients at risk for developing preeclampsia and initiating LDA therapy to prevent preeclampsia.

Significance to Nursing

Little research has been done on out-of-hospital birth. When searching Pub-Med with the term "out-of-hospital birth," only 207 results were found. The majority of these results were studies on planned versus unplanned out-of-hospital births, safety of out-of-hospital births, and

outcomes for mother and baby. Very few studies have been conducted on strategies to prevent the transfer of birth center patients into the hospital setting. A birth-center patient diagnosed with preeclampsia is no longer considered healthy and low risk; therefore, she must transfer care to a location that cares for high-risk patients. This QI project is significant because it provides a set of guidelines to identify patients at high risk for developing preeclampsia and provides an opportunity for early initiation of ACOG's LDA-therapy. According to birth and death certificates in Oregon between 2012 and 2013, hypertension related to pregnancy was the second most common cause of transfer from home or birth centers into the hospitals (Snowden, et al., 2015). The CRAP guidelines not only identified those patients at risk for preeclampsia, but they also provided a way to potentially prevent the development of the dangerous disease (LeFevre, 2014). As shown in this project, birth-center providers can utilize the CRAP guidelines and potentially prevent a low-risk patient from becoming high-risk preventing transfer of care into the hospital setting.

A risk factor associated with developing preeclampsia is being African American (American College of Obstetrics and Gynecology, 2018). About 1.5% of births in the United States occur outside a hospital setting with the overwhelming majority being white women (Sperlich, Gabreil, & Seng, 2017). Sperlich, Gabriel, and Seng (2017) developed a survey to discover whether women felt safest giving birth in or out of a hospital and focused on the demographics of these women. Of the African American women surveyed, 24 (11.5%) said they felt safest giving birth out-of-hospital versus 42 (13.1%) of white women surveyed; however, only 2% of the 1.5% of birthing women who have an out-of-hospital birth in the United States and Canada are African American (Sperlich, Gabreil, & Seng, 2017). This difference in desire for birthing outside the hospital was not statistically significant between African American and

white women; however the actual number of births outside the hospital for African American women was a huge disparity (Sperlich, Gabreil, & Seng, 2017). This disparity is unexplained by the Sperlich, Gabriel, and Seng (2017) study. Therefore, it is vital for healthcare providers to develop ways to prevent African American women from developing preeclampsia, especially for African American women who desire to birth in a birth center setting.

It is well established that childbirth in multiparous and primiparous women differs in many respects: longer labors, increased risk of intrapartum complications, and more obstetric interventions are found in primiparous childbirth (Christensen & Overgaard, 2017). The use of interventions, especially assisted vaginal delivery and unplanned caesarean delivery, has been found to have a negative impact on women's birth experience, which may partly explain why primiparous birth experiences are viewed more negatively by mothers according to the Danish Birth Center Study (Christensen & Overgaard, 2017). Birth centers traditionally offer personalized, low-technological care supporting spontaneous vaginal birth without routine intervention to low-risk women in a family-friendly environment (Christensen & Overgaard, 2017). Therefore, for primiparous women desiring a birth center birth, it is important to prevent complications, like preeclampsia, that could make them high-risk and need to transfer care to a hospital where interventions are more routine. According to ACOG (2018), primiparous women are more at risk of developing preeclampsia. Therefore, using the CRAP guidelines to initiate LDA therapy for primiparous women would likely decrease the frequency of preeclampsia and subsequent transfer to the hospital. In this QI study, 8 of 21 primiparous patients (38.1%) were identified as high-risk for developing preeclampsia, allowing these women to initiate LDA therapy and potentially prevent transfer to the hospital and possible interventions.

An important philosophy of nursing is health promotion. Nurses work in many settings with the goal to improve the health of others, promote wellness, prevent illness and injury (Smalley, 2005). Ersin and Bahar (2017) used the Health Promotion Model (HPM) as the theoretical framework for their study on nursing interventions' effect on women choosing early detection for breast and cervical cancer. Their study showed that nurses had a positive effect on women choosing early detection methods (Ersin & Bahar, 2017). Erin and Bahar (2017) cited that nurses are providers who utilize the HPM to make positive changes. This DNP project is significant to nursing because it provides a guideline for disease prevention, thereby reinforcing the nursing philosophy of health promotion.

The USPTF issues recommendations on many areas of healthcare. Implementing those recommendations into clinical practice requires leadership, multi-disciplinary collaboration, and communication with shareholders. Several studies have discussed the implementation of preventative guidelines (Ayers & Griffith, 2007; Ramsey et al., 2015). Ramsey et al. (2015) describes the use of a multidisciplinary panel of experts to assist in developing a program for implementing USPSTF guidelines for lung cancer screening. Ayersd and Griffith (2007) discuss the barriers to implementing preventive guidelines along with the situations that help facilitate that implimentation. The 2007 study by Ayersd and Griffen cited the following as barriers to implementation: cost issues, time factors, legal issues, inconsistency among tools with various recommendations, tracking of patients who already received the education/intervention, lack of internalization of guidelines, and the patient-clinician relationship. Influences that helped to facilitate the implementation of guidelines were as follows: health plan/insurance support, patient materials, clinician awareness and sensitivity, and tool consistency (Ayers & Griffith, 2007). This DNP project demonstrated a successful way to implement USPTF guidelines by providing

patient and provider education tools, the CRAP guideline, an EHR documentation template, and the ORIC tool for measurement of readiness for change of staff and providers. In conclusion, this project contributed to leadership knowledge for nursing as supported by the findings examined in the discussion and significance subsections of this paper.

Limitations

Project Design

This DNP project had several limitations, including the single, private facility where the project was conducted and the small number of staff participants. The participant and project-eligible patients' demographics were not diverse in race. Therefore, the results of this project could be difficult to generalize to a population in a larger facility and more racially diverse. Another limitation to the project was the setting being a free-standing birth center. Birth center providers only care for low-risk women; therefore, the results of this study could be difficult to generalize to a higher risk population. The five-week timeframe for the study was also a limitation. Due to this limited timeframe, the student was unable to determine the long term compliance of the patients and the long term impact LDA made on prevention of preeclampsia. As Effkin (2016) pointed out, using different technology can be a hinderence to generalization. This DNP project used an EHR specifically made for home and birth center practices. For this project, a template was used to help participants screen clients on the correct weeks of gestation (12-28); using a different EHR could result in different consistency scores.

Data Recruitment and Collection Methods

A limitation regarding data recruitment and collection methods was the lack of a validated clinical tool available to predict preeclampsia early in pregnancy with sufficient sensitivity and specificity; therefore, USPSTF created the CRAP guidelines to identify patients

with an absolute risk for preeclampsia until a validated tool can be created (LeFevre, 2014). Another limitation to data collection was the hesitancy of patients to commit to taking LDA in pregnancy. Patients choosing a birth center are committed to natural birth and hesitant to take medications. Therefore, when patients were designated as high risk and encouraged to start LDA therapy, the majority replied that they needed to think about it and research LDA before they decided to initiate therapy. Due to this response, the DNP student created an additional power point presentation further explaining the benefit and lack of risk with use of LDA therapy in pregnancy. This presentation was emailed to all patients designated as high risk. Unfortunately, due to the five-week implementation period, two patients had yet to decide on whether to initiate LDA therapy.

Data Analysis

A limitation of the data analysis was the pre-determined mean score of 45 or greater on the ORIC showing readiness for change in the participants. Due to the asymmetry of the distribution of scores, it was necessary to report the median instead of the mean (Pallant, 2016). A limitation of the PAS analysis was the lack of normal distribution of scores necessitating reporting of the median instead of the mean. The difference between the Mean (4.73) and the 5% Trimmed Mean (4.95), however, was very small indicating that extreme scores did not have a strong influence on the Mean (Pallant, 2016). The limitation in analysis using Chi-square was violating the assumption of having more than five frequencies in each cell; therefore, the Fisher's Exact Test was reported (Pallant, 2016). Lastly, although there was a statistically significant relationship between being diagnosed as high risk and initiating LDA therapy, only 63% initiated therapy. This limitation is representative of a population of patients reluctant to use medication during their pregnancies.

Dissemination

The target population of this DNP project are providers caring for pregnant women: nurses, nurse midwives, obstetricians, family practice physicians, women's healthcare nurse practitioners, family nurse practitioners, nursing managers, and administrators developing prenatal guidelines. To reach this target population, the DNP student has applied to present this project to the American College of Nurse-Midwives' 2020 Annual Convention in Austin, Texas. At this convention, the DNP student would present to nurse-midwives, obstetricians, and student nurse-midwives. The DNP student will also submit an abstract to the *Maternal and Child Health Journal*, a peer-reviewed journal addressing maternal-child health practice, policy, and research; innovative service initiatives; implementation of maternal-child health programs; policy analysis and advocacy and maternal-child health professional development (Springer, 2019). The target audience for this journal is practitioners and academics in public health, obstetrics, gynecology, prenatal medicine, pediatrics, and neonatology (Springer, 2019). Lastly, the DNP student will submit this project to the Doctoral Project Repository at <https://doctorsofnursingpractice.org/> (Doctors of Nursing Practice, 2015).

Sustainability

The project site was a small birth center staffed by four CNMs. At the completion of the project, data and results were shared with the birth center staff. Plans for sustainability were discussed. Because research has shown that LDA therapy is most effective if started prior to 16-weeks' gestation, the DNP student recommended utilizing the CRAP guidelines at every patient's initial prenatal visit (Roberge, et al., 2017). It was recommended to utilize the EHR template utilized in the project to help providers identify high-risk patients. It was also recommended to utilize the EHR's "alert" feature that tags the patient's chart to alert all

providers of the high-risk status and whether LDA therapy was initiated. The birth center staff requested the DNP student's educational power point presentations in order to continue to email patients identified as high risk. The power point presentations and PRA forms were provided to the administrative director. Lastly, the DNP student recommended the staff member responsible for QI at the birth center continue to audit charts using the PRA and record outcome data to determine if the CRAP guidelines and LDA therapy were successful in preventing preeclampsia in those high-risk patients. The staff members and administrator chose to continue to utilize the guidelines of the project with audits and continued QI.

Conclusion

The number of out-of-hospital births in the US increased from 35,578 in 2004 to 62,228 in 2017 (1.61% of births); 19,878 of those 2017 births (0.52%) occurred in birth centers and 38,343 births (0.99%) were planned-home births (MacDorman & Declercq, 2019). CNMs delivered 56.6% of birth center births and 29.4% of planned-home births in 2017 (MacDorman & Declercq, 2019). Women with planned home and birth center births were less likely to have poor pregnancy outcomes, teen births, smoking during pregnancy, obesity, preterm infants, low birthweight infants, and multiple births (MacDorman & Declercq, 2019). Birth center patients were less likely to have a pre-pregnancy body mass index of 30 or more compared to planned hospital patients (13% v. 27.3%), and 97.5% of birth center patients initiated breastfeeding at delivery compared to 82% of hospital patients (MacDorman & Declercq, 2019). These results suggest that more women are seeking birth center and home births, and these women are low risk. Home birth providers could replicate this project by utilizing the CRAP guidelines to help prevent preeclampsia in the home-birth population and allow low-risk patients to remain low-risk, allowing them to deliver in the home setting.

The care provided during pregnancy and birth should focus on the needs of the new mothers, their rights, and their active participation in the process (Reis, Padoin, Toebe, Paula, & Quadros, 2017). Expanding the vision of childbirth beyond the biological aspects of care to focusing on the recognition of women's autonomy is important to women's rights (Reis, Padoin, Toebe, Paula, & Quadros, 2017). The growing dependence on technological interventions and the wide use of cesarean sections as a way of birth has decreased women's autonomy (Reis, Padoin, Toebe, Paula, & Quadros, 2017). This literature review found that non-traditional practices, such as vertical positions during delivery, are more closely related to the active participation of the patient (Reis, Padoin, Toebe, Paula, & Quadros, 2017). The literature also found that women preferred to be assisted by professionals, like CNMs, who believe in the potential of the female body to give birth, favor natural and physiological childbirth, and respect women's autonomy with shared decision making (Reis, Padoin, Toebe, Paula, & Quadros, 2017). CNMs could replicate this project in the hospital setting by utilizing the CRAP guidelines to identify women at risk for developing preeclampsia, educate them on the role of LDA therapy in the prevention of preeclampsia, and allow these women to choose whether or not they will initiate LDA therapy. By initiating the CRAP guidelines, women would have the opportunity for shared decision making and, in turn, more autonomy. If preeclampsia was avoided, those women would also have a better chance of a more natural childbirth with less interventions.

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Appendix A

Clinical Risk Assessment for Preeclampsia (American College of Obstetrics and Gynecology, 2018).

Table 1. Clinical Risk Assessment for Preeclampsia*

Risk Level	Risk Factors	Recommendation
High ¹	<ul style="list-style-type: none"> ● History of preeclampsia, especially when accompanied by an adverse outcome ● Multifetal gestation ● Chronic hypertension ● Type 1 or 2 diabetes ● Renal disease ● Autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome) 	Recommend low-dose aspirin if the patient has one or more of these high-risk factors
Moderate ²	<ul style="list-style-type: none"> ● Nulliparity ● Obesity (body mass index greater than 30) ● Family history of preeclampsia (mother or sister) ● Sociodemographic characteristics (African American race, low socioeconomic status) ● Age 35 years or older ● Personal history factors (eg, low birthweight or small for gestational age, previous adverse pregnancy outcome, more than 10-year pregnancy interval) 	Consider low-dose aspirin if the patient has more than one of these moderate-risk factors ³
Low	<ul style="list-style-type: none"> ● Previous uncomplicated full-term delivery 	Do not recommend low-dose aspirin

*Includes only risk factors that can be obtained from the patient’s medical history. Clinical measures, such as uterine artery Doppler ultrasonography, are not included.

¹Single risk factors that are consistently associated with the greatest risk of preeclampsia. The preeclampsia incidence rate would be approximately 8% or more in a pregnant woman with one or more of these risk factors.

²A combination of multiple moderate-risk factors may be used by clinicians to identify women at high risk of preeclampsia. These risk factors are independently associated with moderate risk of preeclampsia, some more consistently than others.

³Moderate-risk factors vary in their association with increased risk of preeclampsia.

Modified from Lefevre, ML. U.S. Preventive Services Task Force. Low-dose aspirin use for the prevention of morbidity and mortality from preeclampsia: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 2014;161:819–26.

Appendix B

Figure 1: Donabedian Framework

Donabedian Framework

Structure

Setting: Birth Center

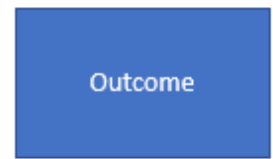
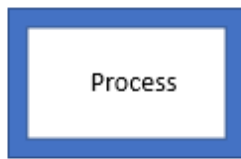
Participants: CNMs, RNs, Patients

Process

Interventions: Pre-test, Presentation, Post-test, ACOG's Clinical Risk Assessment for Preeclampsia, LDA-therapy, Automated Progress Note

Outcome

Measured: the clinical staff knowledge of high risk for preeclampsia, the clinical staff's readiness for change, the process adherence to CRAP guidelines, the implementation of LDA therapy for high risk patients



Appendix C

Pretest for Preeclampsia

Purpose

The purpose of this training session is to improve the certified nurse-midwives' and registered nurses' knowledge of potential risk factors for developing preeclampsia in order to initiate low-dose aspirin therapy. The course will also provide education on documentation responsibilities in the care of patients at risk for preeclampsia. It will also evaluate if the learners' knowledge led to changes in practice behaviors (documentation of EHR preeclampsia screening and initiation of LDA therapy between the gestational weeks of 12-28 in patients at risk for developing preeclampsia) after course completion. Documentation and change in practice behaviors will be measured using retrospective chart audits.

Learning Objectives

Upon successful completion of this course, you will be able to:

- Differentiate low, moderate, and high-risk factors for developing preeclampsia
- Describe low-dose aspirin therapy (LDA)
- Recognize findings that may be consistent with risk for preeclampsia
- Apply the Clinical Risk Assessment for Preeclampsia's (CRAP) guidelines for initiating LDA therapy

Population

The population is a group of clinical staff in an out-of-hospital birthing center.

Length of the Test

The optimum length of this test is 10 questions.

Difficulty and Discrimination Levels of Test Items

According to Pham, et al. (2018), students in medical school are required to answer higher-level cognitive-skill questions on exams; the type of written test instrument best suited to test higher order cognitive skills is undetermined by experts. Pham, et al. (2018) compared multiple-choice questions to short-answer questions in order to determine which type of question measures higher order cognitive skills (synthesis, analyzing, and application of knowledge). Study results revealed that multiple-choice questions can effectively measure the same cognitive level concepts as short-answer questions when testing higher order cognitive skills (Pham, et al., 2018). Therefore, this project will use multiple-choice questions written to mostly test comprehension, application, and analysis of knowledge.

Scoring Procedures to be Used

The goal is to use a separate answer sheet that will then be used to develop a computer-generated item analysis report.

Item Format

The test will be a selected response multiple choice format.

Test Blueprint

Content	Level of Cognitive Skill				
	Knowledge	Comprehension	Application	Analysis	Total
High-risk factors for developing preeclampsia	1		1		2
Moderate-risk factors for developing preeclampsia	1			1	2
Diagnosis of risk of preeclampsia			1	1	2
Low-dose aspirin therapy: benefits and risks		2			2

Low-dose aspirin therapy: evidence-based use			1	1	2
Total	2	2	3	3	10

Questions

1. The majority of randomized-control trials (RCTs) have shown that low-dose aspirin (LDA) use during pregnancy causes:

- A. Increased cases of hemorrhage after delivery
- B. Decreased risk for placental abruption
- C. Increased cases of hypertension
- D. Decreased risk of preeclampsia

Answer: D

Comprehension-LDA therapy benefit

Rationale: Low-dose aspirin therapy has been shown to decrease the risk of preeclampsia in high-risk patients. RCTs have shown no significant increase or decrease in cases of postpartum hemorrhage, placental abruption, or hypertension (American College of Obstetrics and Gynecology, 2018, pp. e45-46).

2. The majority of RCTs have shown the following impact to the fetus when the mother takes LDA:

- A. No fetal risk for congenital anomalies
- B. Increased risk for cardiac anomalies
- C. Increased risk for intracranial hemorrhage
- D. Decreased risk for fetal hypertension

Answer: A

Comprehension: LDA risk

Rationale: RCTs have found no increased risk to the fetus when the mother is taking LDA therapy (American College of Obstetrics and Gynecology, 2018, p. e46)

3. A pregnant woman is in clinic for her first prenatal visit. She says she's heard something about taking aspirin during pregnancy. What do you tell her about LDA therapy?

- A. Everyone should take LDA because it won't hurt you or the baby.
- B. Taking LDA can be used to help prevent stillbirth.
- C. LDA can be used to help prevent preeclampsia.
- D. LDA should be taken every day to prevent fetal growth restriction.

Answer: C

Application: LDA therapy: evidence-based

Rationale: Prevention of preeclampsia is the only indication that is evidence-based. B, C, and D were discussed specifically stating that use for these indications have been proposed but are not evidence-based (American College of Obstetrics and Gynecology, 2018, pp. e48-49)

4. When evaluating a pregnant woman at her 16-week prenatal visit, what in her history would encourage you to diagnosis her as high risk for preeclampsia?

- A. Type 1 or 2 diabetes
- B. First pregnancy
- C. Age 35 or greater
- D. Obesity

Answer: A

Application: High risk factor for preeclampsia

Rationale: According to the CRAP guidelines, Type 1 or 2 diabetes is a high-risk factor; B,C, and D are moderate risk factors (American College of Obstetrics and Gynecology, 2018, p. e46)

5. A pregnant woman is in clinic at 20 weeks for a routine prenatal appointment. Her BMI is 33. What moderate risk factor would make her at risk for preeclampsia?

- A. History of postpartum hemorrhage
- B. More than 10 years between her last birth
- C. Father of this baby is different from first partner

D. New onset asthma

Answer: B

Analysis: Moderate risk factor for preeclampsia

Rationale: According to the CRAP guidelines (American College of Obstetrics and Gynecology, 2018, p. e46), more than one moderate risk factor makes a woman at risk for developing preeclampsia. In the above scenario, she has a BMI greater than 30 and has (B) more than 10 years between her last birth. A, C, and D are not risk factors for preeclampsia.

6. How many high-risk factors are required to consider a patient at risk for preeclampsia?

- A. 1
- B. 2
- C. 3
- D. 0

Answer: A

Knowledge: High risk factor for preeclampsia

Rationale: According to the CRAP guidelines, having one risk factor from the high-risk category places a patient at risk for preeclampsia (American College of Obstetrics and Gynecology, 2018, p. e46).

7. How many moderate risk factors are required to consider a patient at risk for preeclampsia?

- A. 1
- B. More than 1
- C. More than 2
- D. More than 3

Answer: B

Knowledge: Moderate risk factors for preeclampsia

Rationale: According to the CRAP guidelines, more than one moderate risk factor places a patient at risk for preeclampsia (American College of Obstetrics and Gynecology, 2018, p. e46).

8. A woman is pregnant with her second pregnancy. Her first pregnancy was uncomplicated. She lives in a house with her husband and child. She works as a nurse. What level of risk for preeclampsia would you diagnose her?

- A. Low
- B. Moderate
- C. High
- D. Potential

Answer: A

Analysis: Diagnosis of risk for preeclampsia

Rationale: Low risk for preeclampsia is defined as a woman who has had an uncomplicated pregnancy and no other risk factors. A moderate risk factor is socioeconomic factors (i.e. unemployment, low socioeconomic status); therefore, it is important to know that she is employed, lives in a house, and is married. This shows that more than likely she is not in the low socioeconomic category (American College of Obstetrics and Gynecology, 2018, p. e46).

9. A woman is pregnant with her first pregnancy. She is African American. What interventions would you recommend?

- A. No intervention
- B. Begin LDA therapy at 12 weeks
- C. Begin LDA therapy at 36 weeks
- D. Begin LDA therapy postpartum

Answer: B

Application: Diagnosis of risk for preeclampsia

Rationale: The patient in this scenario has two moderate risk factors, first pregnancy and African American. According to the CRAP guidelines, she should be started on LDA therapy at 12 weeks gestation (American College of Obstetrics and Gynecology, 2018, p. e46).

10. A woman is seen in clinic for her first prenatal visit at 10 weeks gestation. During her history, you discover that she has Systemic Lupus Erythematosus. What will you discuss with her today?

- A. You are at risk for preeclampsia and should start LDA today
- B. You are at risk for stillbirth and should start LDA today
- C. You are not at risk for preeclampsia or stillbirth and evidence shows that you do not need LDA
- D. You are at risk for preeclampsia but will not start LDA therapy until 12 weeks gestation

Answer: D

Analyze: LDA therapy: evidence-based use

Rationale: The woman in the above scenario is at high risk for preeclampsia due to her SLE. She is only 10 weeks pregnant, and according to research described in ACOG's Committee Opinion (2018, p. e47), LDA should be initiated at or after 12 weeks gestation.

Content validity pretest

Content Validity Index Table

Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	4	4	4	4
3	4	4	3	3.67
4	4	4	4	4
5	4	4	4	4
6	4	4	4	4
7	4	4	4	4
8	4	4	4	4
9	4	4	3	3.67
10	4	4	4	4

The content validity index is calculated using the following formula:

$CVR = [(E-(N/2)) / (N/2)]$ with E representing the number of judges who rated the item as **Moderately Relevant or Highly Relevant** and N being the total number of judges.

The mean total of all of the means was 3.93 indicating that most of the questions were **highly relevant**.

The calculation is as follows:

$$CVR = [(3-(3/2)) / (3/2)]$$

$$CVR = [(3-1.5) / 1.5]$$

$$CVR = 1.5/1.5$$

$$CVR = 1$$

Appendix D

Posttest for Preeclampsia

Purpose

The purpose of this training session is to improve the certified nurse-midwives' and registered nurses' knowledge of potential risk factors for developing preeclampsia in order to initiate low-dose aspirin therapy. The course will also provide education on documentation responsibilities in the care of patients at risk for preeclampsia. It will also evaluate if the learners' knowledge led to changes in practice behaviors (documentation of EHR preeclampsia screening and initiation of LDA therapy between the gestational weeks of 12-28 in patients at risk for developing preeclampsia) after course completion. Documentation and change in practice behaviors will be measured using retrospective chart audits.

Learning Objectives

Upon successful completion of this course, you will be able to:

- Differentiate low, moderate, and high-risk factors for developing preeclampsia
- Describe low-dose aspirin therapy (LDA)
- Recognize findings that may be consistent with risk for preeclampsia
- Apply the Clinical Risk Assessment for Preeclampsia's (CRAP) guidelines for initiating LDA therapy

Population

The population is a group of clinical staff in an out-of-hospital birthing center.

Length of the Test

The optimum length of this test is 10 questions.

Difficulty and Discrimination Levels of Test Items

According to Pham, et al. (2018), students in medical school are required to answer higher-level cognitive-skill questions on exams; the type of written test instrument best suited to test higher order cognitive skills is undetermined by experts. Pham, et al. (2018) compared multiple-choice questions to short-answer questions in order to determine which type of question measures higher order cognitive skills (synthesis, analyzing, and application of knowledge). Study results revealed that multiple-choice questions can effectively measure the same cognitive level concepts as short-answer questions when testing higher order cognitive skills (Pham, et al., 2018). Therefore, this project will use multiple-choice questions written to mostly test comprehension, application, and analysis of knowledge.

Scoring Procedures to be Used

The goal is to use a separate answer sheet that will then be used to develop a computer-generated item analysis report.

Item Format

The test will be a selected response multiple choice format.

Test Blueprint

Content	Level of Cognitive Skill				
	Knowledge	Comprehension	Application	Analysis	Total
High-risk factors for developing preeclampsia	1		1		2
Moderate-risk factors for developing preeclampsia		1		1	2
Diagnosis of risk of preeclampsia			1	1	2
Low-dose aspirin therapy: benefits and risks		2			2
Low-dose aspirin therapy: evidence-based use			1	1	2
Total	1	3	3	3	10

Questions

1. Researchers have shown the benefits of low-dose aspirin use during pregnancy to be:

- E. Decreased fetal weight loss
- F. Decreased risk for placental abruption
- G. Decreased cases of placenta accreta
- H. Decreased risk of preeclampsia

Answer: D

Comprehension-LDA therapy benefit

Rationale: Low-dose aspirin therapy has been shown to decrease the risk of preeclampsia in high-risk patients. RCTs have shown no significant changes in placenta abruption or accrete or fetal weight loss (American College of Obstetrics and Gynecology, 2018, pp. e45-46).

2. A mother taking LDA during pregnancy should watch for what fetal complication or abnormality?

- E. Increased risk for vascular anomalies
- F. Increased risk for intracranial hemorrhage
- G. No fetal risk for congenital anomalies
- H. Increased risk for fetal hydrops

Answer: C

Comprehension: LDA risk

Rationale: RCTs have found no increased risk to the fetus when the mother is taking LDA therapy (American College of Obstetrics and Gynecology, 2018, p. e46)

3. You are performing a history and physical on pregnant woman in clinic for her first prenatal visit. She said she read about aspirin on Google. What do you tell her about LDA therapy?

- E. No woman that is pregnant should take any type of aspirin.
- F. Taking LDA can help prevent early pregnancy loss.

- G. LDA should be taken every day to prevent fetal growth restriction
- H. LDA can be used to help prevent preeclampsia.

Answer: D

Application: LDA therapy: evidence-based

Rationale: Prevention of preeclampsia is the only indication that is evidence-based. A is not true. B and C were discussed specifically stating that use for these indications have been proposed but are not evidence-based (American College of Obstetrics and Gynecology, 2018, pp. e48-49)

4. A pregnant woman comes to clinic for her 14-week prenatal visit, what one indicator in her history would encourage you to diagnosis her as high risk for preeclampsia?

- E. Chronic hypertension
- F. Low socioeconomic factor
- G. Age 35 or greater
- H. BMI greater than 30

Answer: A

Application: High risk factor for preeclampsia

Rationale: According to the CRAP guidelines, chronic hypertension is a high-risk factor; B,C, and D are moderate risk factors (American College of Obstetrics and Gynecology, 2018, p. e46)

5. A pregnant woman is in clinic at 22 weeks for a problem visit. She is 37 years old. What moderate risk factor would make her at risk for preeclampsia?

- E. History of premature rupture of membranes
- F. Her sister had a history of preeclampsia
- G. Late entry into prenatal care
- H. New onset asthma

Answer: B

Analysis: Moderate risk factor for preeclampsia

Rationale: According to the CRAP guidelines (American College of Obstetrics and Gynecology, 2018, p. e46), more than one moderate risk factor makes a woman at risk for developing preeclampsia. In the above scenario, she has is over the age of 35 and has (B) her sister had a history of preeclampsia. A, C, and D are not risk factors for preeclampsia.

6. Multifetal gestation is what type of risk factor for preeclampsia?

- E. None
- F. Low
- G. Moderate
- H. High

Answer: D Knowledge: High risk factor for preeclampsia

Rationale: According to the CRAP guidelines, having a multifetal gestation places a patient at risk for preeclampsia (American College of Obstetrics and Gynecology, 2018, p. e46).

7. A husband asks you why his wife is at risk for preeclampsia even though her risks are in the moderate category. You answer would be?

- E. She's not at risk because her risks are only in the moderate category.
- F. She's at risk because she has more than one moderate risk factor.
- G. She's not at risk. She has to have a risk factor from the high-risk category.
- H. She's at risk because she has one moderate risk factor.

Answer: B Comprehension: Moderate risk factors for preeclampsia

Rationale: According to the CRAP guidelines, more than one moderate risk factor places a patient at risk for preeclampsia (American College of Obstetrics and Gynecology, 2018, p. e46).

8. Your patient is pregnant with her third pregnancy. She has had 2 uncomplicated pregnancies. She is white, non-Hispanic. She works as a bank teller. What level of risk for preeclampsia would you diagnose her?

- E. Low
- F. Moderate
- G. High
- H. Potential

Answer: A

Analysis: Diagnosis of risk for preeclampsia

Rationale: Low risk for preeclampsia is defined as a woman who has had an uncomplicated pregnancy and no other risk factors. A moderate risk factor is socioeconomic factors (i.e. unemployment, low socioeconomic status); therefore, it is important to know that she is employed. This shows that more than likely she is not in the low socioeconomic category. The white, non-Hispanic race is not a risk factor for preeclampsia (American College of Obstetrics and Gynecology, 2018, p. e46).

- 9. You are seeing a patient for her first prenatal appointment. She has had a previous adverse pregnancy outcome and a low-birth-weight baby. What treatment, if any, would you recommend?**

- E. No intervention
- F. Begin LDA therapy at 12 weeks
- G. Begin LDA therapy at 36 weeks
- H. Begin LDA therapy postpartum

Answer: B

Application: Diagnosis of risk for preeclampsia

Rationale: The patient in this scenario has two moderate risk factors, a previous adverse pregnancy outcome and a low-birth-weight baby. According to the CRAP guidelines, she should be started on LDA therapy at 12 weeks gestation (American College of Obstetrics and Gynecology, 2018, p. e46).

- 10. Your patient is in clinic today for her 16-week prenatal appointment. You discover that she has renal disease. What will you discuss with her today?**

- E. You are at risk for preeclampsia and should start LDA today
- F. You are at risk for stillbirth and should start LDA today
- G. You are not at risk for preeclampsia or stillbirth and evidence shows that you do not need LDA
- H. You are at risk for preeclampsia but will not start LDA therapy until 28 weeks gestation

Answer: A Analyze: LDA therapy: evidence-based use

Rationale: The woman in the above scenario is at high risk for preeclampsia due to her renal disease. She is already 18 weeks pregnant, and according to research described in ACOG’s Committee Opinion (2018, p. e47), LDA therapy is most effective if started by 16 weeks gestation.

Content validity posttest

Content Validity Index Table

Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	4	4	4	4
3	4	4	4	4
4	4	4	4	4
5	4	4	4	4
6	4	4	4	4
7	4	4	3	3.67
8	4	4	4	4
9	4	4	4	4
10	4	4	4	4

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$CVR = [(E-(N/2)) / (N/2)]$ with E representing the number of judges who rated the item as **Moderately Relevant or Highly Relevant** and N being the total number of judges.

The mean total of all of the means was 3.97 indicating that most of the questions were **highly relevant**.

The calculation is as follows:

$CVR = [(3-(3/2)) / (3/2)]$

$CVR = [(3-1.5) / 1.5]$

$CVR = 1.5/1.5$

$CVR = 1$

Appendix E

Patient education form

Preeclampsia, high blood pressure of 140/90 or greater in pregnancy, affects 2-8% of pregnancies and contributes to higher levels of maternal and infant morbidity and mortality. The most common complaints of preeclampsia are headache, visual disturbances, upper abdominal pain, or nausea and vomiting. Symptoms of severe preeclampsia can include seizures, stroke, neurological deficits, and cardiorespiratory symptoms. Fetal characteristics of preeclampsia can include growth restriction, stillbirth, neonatal death, and prematurity-associated complications from preterm birth.

The understanding of the cause of preeclampsia is unclear; however, a review of 45 research studies that included 20,909 pregnant women who were randomized into groups and given low-dose aspirin (80mg) daily before 16-weeks-gestation indicated there was a significant reduction in preeclampsia, severe preeclampsia, and fetal growth restriction. Several trials studying low dose aspirin and prevention of preeclampsia have found aspirin was not associated with significant risks to the mother or infant in pregnancy, labor, or postpartum.

The American College of Obstetrics and Gynecologists has recommended screening all pregnant women between the weeks of 12-28 to determine their risk for developing preeclampsia. For at-risk women, it is recommended to start low-dose aspirin and continue the aspirin until after delivery.

Table 1. Clinical Risk Assessment for Preeclampsia*

Risk Level	Risk Factors	Recommendation
High ¹	<ul style="list-style-type: none"> • History of preeclampsia, especially when accompanied by an adverse outcome • Multifetal gestation • Chronic hypertension • Type 1 or 2 diabetes • Renal disease • Autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome) 	Recommend low-dose aspirin if the patient has one or more of these high-risk factors
Moderate ²	<ul style="list-style-type: none"> • Nulliparity • Obesity (body mass index greater than 30) • Family history of preeclampsia (mother or sister) • Sociodemographic characteristics (African American race, low socioeconomic status) • Age 35 years or older • Personal history factors (eg, low birthweight or small for gestational age, previous adverse pregnancy outcome, more than 10-year pregnancy interval) 	Consider low-dose aspirin if the patient has more than one of these moderate-risk factors ³
Low	<ul style="list-style-type: none"> • Previous uncomplicated full-term delivery 	Do not recommend low-dose aspirin

Allen Birthing Center is committed to practicing evidence-based care and is invested in your and your baby's health. We want to prevent anything that would put you or your baby at risk. Therefore, we are adopting this recommendation with the hope of preventing preeclampsia and maintaining your low-risk status. Please feel free to ask any questions regarding this new practice. We support any decisions you make regarding your care.

References for research studies can be found in your Client Portal.

Appendix F

Organizational Readiness for Implementing Change (Shea, Jacobs, Esserman, Bruce, & Weiner, 2014)

Additional file 1 Organizational Readiness for Implementing Change (ORIC)

	1	2	3	4	5
	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree
1. People who work here feel confident that the organization can get people invested in implementing this change.	1	2	3	4	5
2. People who work here are committed to implementing this change.	1	2	3	4	5
3. People who work here feel confident that they can keep track of progress in implementing this change.	1	2	3	4	5
4. People who work here will do whatever it takes to implement this change.	1	2	3	4	5
5. People who work here feel confident that the organization can support people as they adjust to this change.	1	2	3	4	5
6. People who work here want to implement this change.	1	2	3	4	5
7. People who work here feel confident that they can keep the momentum going in implementing this change.	1	2	3	4	5
8. People who work here feel confident that they can handle the challenges that might arise in implementing this change.	1	2	3	4	5
9. People who work here are determined to implement this change.	1	2	3	4	5
10. People who work here feel confident that they can coordinate tasks so that implementation goes smoothly.	1	2	3	4	5
11. People who work here are motivated to implement this change.	1	2	3	4	5
12. People who work here feel confident that they can manage the politics of implementing this change.	1	2	3	4	5

Appendix G

Preeclampsia Risk Audit

Patient ID #: _____

Review Period:

1. Week 1
2. Week 2
3. Week 3
4. Week 4
5. Week 5

Age: _____

Blood pressure at screening appointment

1. $\leq 120/80$
2. 121/81-139/89
3. $\geq 140/90$

Race:

1. White Non-Hispanic
2. White Hispanic
3. African American
4. Asian
5. American Indian/Alaskan Native
6. Native Hawaiian/other Pacific Islander

Employment status

1. Employed
2. Unemployed

3. Stay at home mom

Relationship status

1. Single, living with partner
2. Single, not living with partner
3. Married, living with partner
4. Separated
5. Divorced or widowed
6. Other

Education status

1. High school/GED
2. Some college
3. Associate degree
4. Bachelor's degree
5. Master's degree
6. Doctor degree

Gravida:

1. 1
2. 2
3. 3
4. 4
5. 5
6. 6 OR MORE

Para:

1. 0

2. 1
3. 2
4. 3
5. 4
6. 5 OR MORE

Pre-pregnancy BMI:

1. < 18.5 underweight
2. 18.5-24.9 normal weight
3. 25.0-29.9 overweight
4. 30.0-34.9 class I obesity
5. 35.0-39.9 class II obesity
6. ≥ 40.0 class III obesity

*1. Is the patient between the weeks of 12-28? PA: ____

0. No

1. Yes

*2. Was she screened using the CRAP tool? PA: ____

0. No

1. Yes

3. What gestational age was she screened?

1. 12
2. 13
3. 14
4. 15
5. 16
6. 17

7. 18
8. 19
9. 20
10. 21
11. 22
12. 23
13. 24
14. 25
15. 26
16. 27
17. 28

4. CRAP tool

One or more of the following: 1=yes, 2=no

Which one or more does she have:

1. History of preeclampsia, especially when accompanied by an adverse outcome
2. Multifetal gestation
3. Chronic hypertension
4. Type 1 or 2 diabetes
5. Renal disease
6. Autoimmune disorder (Lupus, Anti-phospholipid antibody)

More than one of the following: 1=yes, 2=no

Which ones does she have?

1. Nulliparity
2. Obesity (BMI >30)
3. Family history of preeclampsia (mother or sister)

4. Sociodemographic characteristics (African American race, low socioeconomic status)
5. Age 35 or older
6. Personal history factors (low birthweight, small for gestational age, previous adverse pregnancy outcome, more than 10-year pregnancy interval)

*5. Did she qualify as high risk: PA _____

0. No

1. Yes

*6. Was she prescribed the LDA regimen: PA _____

0. No

1. Yes

*7. Did she start the LDA regimen: PA _____

0. No

1. Yes

2. Refused therapy

3. Allergic to aspirin

8. Process Adherence Score (1 point each for correctly identifying Q 1, 2, 5, 6, 7) (#0-5)

Scale: _____

Appendix H

Site Approval Letter



406 West Main Street
Allen, TX 75013
214.495.9911
Fax • 214.495.9918
info@allenbirthingcenter.com

12/18/2018

To Whom it May Concern:

I have discussed the DNP project that Lana Giles has proposed and her desire to use Allen Birthing Center as the setting of her project. I have discussed this proposition with my staff. We all agree that we would be pleased for Ms. Giles to use our birthing center for the setting of her project.

Thank you,

A handwritten signature in black ink, appearing to read "Jeffrey Giles".

Jeffrey Giles
Administrative Director
Owner

Honoring the spirit of birth!

Appendix I

Recruitment Power Point

4 Why Do Women Choose Birth Centers
Lescure, et al. (2017)
• The safe and comforting feeling
• Also atmosphere
• Knowledge that medical help is close and available
• They felt in control, which is associated with higher satisfaction with the birth experience.

5 Preeclampsia: Birth Center Client
• Transfer to hospital
• Higher risk for operative birth
• Higher risk of maternal and fetal morbidity and mortality
• Lower satisfaction with birth due to not delivering in planned setting (Flanagan, et al., 2016)

6 Preeclampsia: Morbidity/Mortality
• Postpartum hemorrhage
• Placental abruption
• Heart failure
• DIC
• Intra-cranial hemorrhage
• ICU admission
• Maternal death

7 Preeclampsia: Treatment
Deliver baby

8 What if we could prevent it???
Low-dose aspirin therapy for women at risk for preeclampsia reduces incidence of preeclampsia

9 Reduce Preeclampsia: Reduce Transfer
• Low risk = low transfer rate = patient satisfaction with their birth

10 Preeclampsia Prevention Project
5 week study using guidelines to identify women at risk for preeclampsia
Women between 12 – 28 weeks gestation
Initiate low-dose aspirin therapy

11 THANK YOU

Appendix J

Power Point presentation of CRAP guidelines

Slide 1: Risk Factors for Preeclampsia
Lana A. Giles
Touro University Nevada

Slide 2: Incidence of Preeclampsia
- Preeclampsia affects 2-8% of pregnancies (Auger et al., 2016)
- 10-15% of maternal deaths are associated with eclampsia and preeclampsia (Delegy, L., 2009)

Slide 3: Diagnosis of Preeclampsia
Preeclampsia is a disease process characterized by hypertension and proteinuria or one of the following features after 20 weeks of gestation:
Thrombocytopenia, renal insufficiency, elevated liver enzymes, pulmonary edema, cerebral symptoms (headache, blurry vision, etc.)
Blood Pressure $\geq 160/90$ after 20 weeks gestation (James, Downing, & Costello, 2010)

Slide 4: Treatment of Preeclampsia
- The only treatment for preeclampsia is **delivery**
(Mull, 2010)

Slide 5: Prevention of Preeclampsia
Women diagnosed at risk for preeclampsia
Start low-dose aspirin (ASA) between weeks 12-28
Continue LDA therapy until delivery
• (American College of Obstetrics and Gynecology, 2018)

Slide 6: Clinical Risk Assessment for Preeclampsia

Slide 7: Diagnosis of Risk for Preeclampsia
- High Risk Factors:
- History of Preeclampsia, especially when accompanied by an adverse outcome
- Multiple gestation
- Chronic hypertension
- Type 1 or 2 diabetes

Slide 8: Diagnosis of Risk for Preeclampsia
- High Risk Factors (continued)
- Renal disease
- Autoimmune disorder
- Genetic thrombophilias:
- Antiphospholipid antibody
(American College of Obstetrics and Gynecology, 2018)

Slide 9: Diagnosis of Risk for Preeclampsia
- Only **ONE** high risk factor is needed to diagnose risk for preeclampsia
- That patient should be started on LDA therapy between 12-28 weeks gestation
(American College of Obstetrics and Gynecology, 2018)

Slide 10: Diagnosis of Risk for Preeclampsia
- Moderate Risk Factors
- Multiparity
- Obesity (BMI >30)
- Family history of preeclampsia
- Insulin
- Race

Slide 11: Diagnosis of Risk for Preeclampsia
- Moderate Risk Factors (continued)
- Sociodemographic characteristics
- African American race
- Low socioeconomic status
- Age ≥ 35

Slide 12: Diagnosis of Risk for Preeclampsia
- Moderate Risk Factors (Continued)
- Personal history factors
- Gestational hypertension or gestational diabetes
- Adverse infant or pregnancy outcome
- ≥ 10 year interval between births
(American College of Obstetrics and Gynecology, 2018)


Diagnosis of Risk for Preeclampsia

- **MORE THAN ONE** moderate risk factors are needed to diagnose risk for preeclampsia
- The patient should be started on LDA therapy between 12-28 weeks

(American College of Obstetrics and Gynecology, 2018)

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Diagnosis of Risk for Preeclampsia



Low Risk Factor:

- Previous uncomplicated full-term delivery
- Do not recommend LDA therapy for this patient

(American College of Obstetrics and Gynecology, 2018)

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LDA Therapy



- Contraindicated reasons for LDA therapy
 - Prevention of stillbirth
 - Prevention of fetal growth restriction
 - Prevention of spontaneous preterm birth
 - Prevention of early pregnancy loss

(American College of Obstetrics and Gynecology, 2018)

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Appendix K

Electronic health record template

1. Is the client between 12-28 weeks?

No: stop assessment/Yes: continue assessment

2. Does she have a history of ANY ONE of these risk factors?

Yes: stop and diagnose as high risk, initiate LDA therapy/No: continue

- History of preeclampsia, especially when accompanied by an adverse outcome
- Multifetal gestation
- Chronic hypertension
- Type 1 or 2 diabetes
- Renal disease
- Autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome)
- Recommend low-dose aspirin if the patient has one or more of these high-risk factors

3. Does she have a history of MORE THAN ONE of these risk factors?

Yes: diagnose as high risk, initiate LDA therapy/No: not at high risk for preeclampsia

- Nulliparity
- Obesity (BMI ≥ 30)
- Family history of preeclampsia (mother or sister)
- Sociodemographic characteristics (African American race, low socioeconomic status)
- Age ≥ 35 years
- Personal history factors (low birthweight, small for gestational age, previous adverse pregnancy outcome, more than 10-year interval between last pregnancy)

Appendix L

(Truven Health Analytics, 2013)

Table 6: Average Total Maternal Health Care Charges and Payments among Commercial and Medicaid Beneficiaries, 2010

	Total	Vaginal Childbirth	Cesarean Childbirth
Commercial			
Provider Charges	\$24,921	\$22,734	\$32,062
Allowed Paid Amount	\$13,494	\$12,520	\$16,673
Medicaid			
Provider Charges	\$24,227	\$21,247	\$31,259
Allowed Paid Amount	\$6,673	\$6,117	\$7,983

Note: Commercial results are weighted to reflect the national employer-sponsored insurance population. Because the Medicaid database is comprised of a small convenience sample of 7 states and 5 Medicaid managed care plans, the results are not weighted to the national Medicaid population. Maternal costs include the 9-month prenatal, childbirth, and 3-month postpartum period.


Appendix M

Power Point Emailed to High-Risk Patients

WOMEN CHOOSE BIRTH CENTERS BECAUSE:

According to the study by Stead, Adams, Frenn, Brown, and Skarife (2015):


- Feel more comfortable taking to a midwife than a doctor
- Consider themselves "prepared for childbirth"
- Desire non-pharmacological pain management
 - Breathing techniques
 - Massage
 - Acupuncture/Chiropractic
- Desire vitrous oxide for pain management



Why Do Women Choose Birth Centers?

LEWIS, et al. (2017)

- The safe and comfortable feeling of a home environment
- Knowledge that medical help is close and available
- They feel in control, which is associated with higher satisfaction with the birth experience.

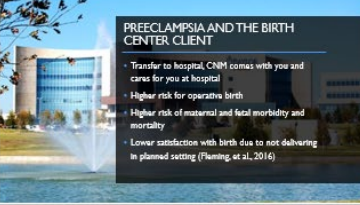


FROM LOW RISK TO HIGH RISK

- Women delivering in a birthing center must be low risk
- Preeclampsia is a high risk condition
- If diagnosed with preeclampsia, a birth center birth is no longer a possibility
- Preeclampsia, a condition of high blood pressure during pregnancy, affects 2-8% of pregnancies (Auger et al. 2016)


PREECLAMPSIA AND THE BIRTH CENTER CLIENT

- Transfer to hospital, CNM comes with you and cares for you at hospital
- Higher risk for operative birth
- Higher risk of maternal and fetal morbidity and mortality
- Lower satisfaction with birth due to not delivering in planned setting (Flaming, et al. 2016)



POSSIBLE SIDE EFFECTS OF PREECLAMPSIA

- HYPERTENSIVE ENCEPHALOPATHY
- PLACENTAL ABRUPTION
- HEART FAILURE
- DIC BLOOD CLOTTING DISORDER
- ICU ADMISSION
- STROKE




TREATMENT FOR PREECLAMPSIA

Delivery of the baby

Once the baby is delivered, most cases of preeclampsia resolve

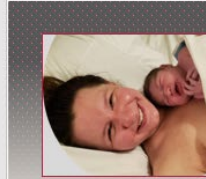
Small percentage of women have postpartum preeclampsia and must remain in the hospital for several more days

WHAT IF WE COULD PREVENT PREECLAMPSIA?



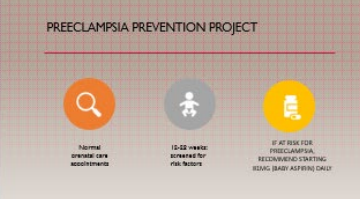
REDUCE PREECLAMPSIA; REDUCE TRANSFER

- Low risk = low transfer rates = patient satisfaction with birth
- If we prevent preeclampsia, we can prevent transfers to the hospital.
- We can prevent poor outcomes for mom and baby.




PREECLAMPSIA PREVENTION PROJECT

- Normal prenatal care appointments
- 10-12 weeks screened for risk factors
- If at risk for preeclampsia, recommended starting 80MG LOW DOSE ASPIRIN DAILY



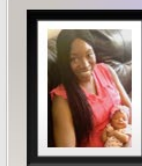
DIAGNOSIS OF RISK FOR PREECLAMPSIA

- High Risk Factors if you have One of these:
 - History of Preeclampsia
 - Twins with current gestation
 - Chronic hypertension
 - Two or more of these:
 - First time pregnant
 - Autoimmune disorder
- (American College of Obstetrics and Gynecology, 2014)



MODERATE RISK FACTORS FOR PREECLAMPSIA

- High Risk Factor if you have TWO OR MORE OF THESE:
 - 1st pregnancy
 - Obesity (BMI >30)
 - Birth history of preeclampsia
 - Partner
 - Sister
 - Age >40
- Sociodemographic characteristics
 - Urban/inner city
 - Low socioeconomic status
- Personal History Factors
 - Current weight at time of previous visit
 - Preeclampsia
 - Hypertension
 - 1-10 year interval between visits



TREATMENT TO PREVENT PREECLAMPSIA



- Between 12-28 weeks if you are diagnosed as high risk for developing preeclampsia, you can decrease your risk for having a low-birth-weight baby by taking 81mg Aspirin (Baby Aspirin) daily until delivery.

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IS BABY ASPIRIN SAFE FOR ME AND MY BABY

- Several trials have evaluated potential harmful side-effects aspirin could have on pregnancy labor and delivery:
 - Aspirin posed no risk of increased bleeding or obstetric abortion during the pregnancy period (2014, w.w. 2014)
 - Results found aspirin was not associated with significant risks in babies such as increase in placental hemorrhage, bleeding with abnormal methemoglobin, or increased bleeding in the fetus and newborn babies (2013). Increased risk of an abortion for the pregnancy was minimal at approximately 17%.
 - Other bleeding-related complications, such as ectopic pregnancy, maternal blood loss, and increased hemorrhagic or hemorrhagic bleeding, was not found (2014, w.w. 2014).

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Appendix N

DNP Project: Statistics Plan Worksheet

Please provide a brief description of each section. Attach supporting documents (instruments) to the end of this form as appendices.

Name: Lana A. Giles

Date: 4/25/2019

Section	Description
Project Title	Low-Dose Aspirin Use and Preeclampsia Prevention: A Quality Improvement Project
Project Purpose	The aim of this evidenced-based DNP project is to implement the national guidelines for prevention of preeclampsia set by USPSTF, ACOG, and SMFM by identifying pregnant women at risk for developing preeclampsia and initiating low dose aspirin therapy (LDA) between the gestational weeks of 12-28.
Project Question	In pregnant women who are 12-28 weeks pregnant desiring to deliver in a birthing center, does the initiation of the Clinical Risk Assessment for Preeclampsia (CRAP) guidelines identify women at risk for preeclampsia and allow for initiation of an LDA regimen compared to not using the CRAP guidelines for identification of women at risk for preeclampsia?
Project Outcomes	<p>In the timeframe of this DNP project, the host site will:</p> <ol style="list-style-type: none"> 1. Improve knowledge and skills regarding identification of pregnant women at risk for developing preeclampsia through a multi-disciplinary training seminar. 2. Implement the use of ACOG’s CRAP guidelines at the antepartum (AP) visits between 12-28 weeks to identify at-risk patients. 3. Initiate ACOG’s LDA-therapy for at-risk patients between the weeks of 12-28.

	<p>4. Implement an automated progress note into the electronic health record (EHR) during the AP visits between 12-28 weeks to alert providers and nurses to utilize the Clinical Risk Assessment for Preeclampsia and initiate LDA therapy in women who qualify as high-risk for preeclampsia.</p>
<p>Project Design (general description how treatments are assigned/observational/repeated measures of X # of people, etc.)</p>	<p>The QI model is the model for this project because of the following reasons: the DNP student is attempting to test a new evidence-based intervention to overcome the problem of preeclampsia, the student is observing the five-week process to determine if the project is working as planned, and the student will identify what worked and did not work at the completion of the project, following the steps of the QI model.</p> <ul style="list-style-type: none"> • A pre- and post-test design will be utilized to evaluate the CNMs (4) and RNs' (4) knowledge of risk for preeclampsia, evaluated by a 10-question pre-test and post-test for the 8 participants. • Readiness for change of the clinical staff will be evaluated by administering the Organizational Readiness for Implementing Change (ORIC) survey (12-item survey) to the CNMs and RNs (8) • The Preeclampsia Risk Audit (PRA), a chart audit tool designed specifically for this project, will be conducted weekly during the project (5 weeks) to evaluate process adherence of CRAP guidelines, diagnosis of high risk for preeclampsia, and initiation of LDA therapy
<p>Population of Interest</p>	<p>The population of interest for this project consists of the CNMs and RNs of a small birth center.</p>
<p>Variables</p>	<ol style="list-style-type: none"> 1. Clinical staff's knowledge of risk factors for preeclampsia 2. Readiness for change of the clinical staff 3. Process adherence of CRAP guidelines 4. Diagnosis of high risk for preeclampsia 5. Initiation of LDA therapy
<p>Sample Size</p>	<p>Approximately 8 clinical staff</p> <p>Approximately 20 chart audits</p>

<p>Recruitment Methods</p>	<ul style="list-style-type: none"> • Power Point presentation explaining the purpose and benefits of the QI project • A poster board advertisement of the QI project • A lunch will be provided one month prior to the QI project to review the purpose and goals of the project
<p>Instruments/Tools (Validity/Reliability)</p>	<ul style="list-style-type: none"> • Pre-test and Post-test measuring their knowledge of risk-factors for preeclampsia in pregnant women according to 2018 ACOG Committee Opinion (CVR=1) • The Organizational Readiness for Change has good validity (CFI = .98, RMSEA = 0.8, SRMR = .05) and inter-rater reliability (kappa = .94) • Preeclampsia Risk Audit
<p>Proposed Statistical Tests</p>	<ul style="list-style-type: none"> • Wilcoxon Signed Rank Test will be utilized to analyze the difference in knowledge of risk factors for preeclampsia before and after the power point presentation using the pre-and post-test scores • Data from the ORIC tool will be collected, and the mean score of the test will help determine readiness for change of the participants. • The process adherence score is calculated by assigning a grade of 0 or 2 (0= did not follow CRAP guidelines, 2 = did follow CRAP guidelines; total score: 0-10). This process will be repeated weekly for five weeks. A one-way repeated groups analysis of variance will be conducted to determine if process adherence increased with time.

Statistics Review of Project Design

C. Vanier, Ph.D., Touro University Nevada

cheryl.vanier@tun.touro.edu

I reviewed your proposed data collection and statistical analysis. Some of the text below is my effort to paraphrase your study as I understand it, while in other instances there are some recommendations for clarifying or improving the design or statistical approaches. If I get something wrong, consider whether it was a miscommunication or if you haven't completely thought through that piece of the study. Please contact me if anything is unclear.

Student response in red: Giles

My responses in blue- Dr. V

Dr. Vanier,

Thank you so much for the time you spent reviewing my project. I really appreciate your suggestions. I have added a few comments and questions. If I need to address these with my project mentor instead of you, please let me know. Thank you again for your time. It is really a great help.

Here's my understanding of your design:

1. You are using a convenience sample (volunteers) of medical professionals. They will receive information, bracketed by a knowledge quiz on ACOG recommendations. For this piece, you might consider splitting your quiz to have different questions for before/after, or at least consider rewording some or all of the questions to guard against your students simply memorizing the quiz. I have a pre and post test with different questions but obtaining the same information. That will be great. Does everyone get the same test pre and post, or is it split? Everyone will get the same pre and post test.
 - a. A Wilcoxon signed rank test for quiz scores sounds like a good idea. What descriptive statistics will you use? Perhaps mean or median change within person (SD or IQR)? That's a great idea. So I would calculate the mean/median change in each person. Then would I calculate the mean/median change of the group, or just keep the individual results? The variable of interest is really change within person, so if you calculate (post-test score – pre-test score), then you can show the mean (SD) or median (IQR) of those numbers to characterize your population.
 - b. Showing overall pre and post averages can obscure improvement, but those number can help you understand how much was known before and after.
2. Students (providers) will also be given the ORIC. It sounds like this is providing context about your population? Yes, I want to determine if my population of health care providers are accepting of change. The only other way to use it would be to keep track of the professional when you do the chart review and use ORIC as a predictor or as a covariate, but the sample size requirements might be rather large to take that approach. I considered keeping track of each provider, but different providers will see all of the patients. Therefore, one might diagnose risk and initiate the intervention while another provider follows up to determine if patient is actually taking the aspirin. Does that make sense? And if that part does not matter, then I CAN use the ORIC as a predictor. It sounds like maybe you can't use it as a predictor in a meaningful way. I think it's great context, though- it can go in your basic demographics table (usually Table 1).
3. Chart review to rate process adherence for 5 weeks. Dependent variables: adherence to CRAP guidelines, diagnosis of high risk for preeclampsia, initiation of LDA. A few questions here:
 - a. Are you doing any chart reviews before, or only after? I thought of doing chart reviews before the intervention but wasn't sure what I would review because the providers have never diagnosed risk for preeclampsia. I thought of reviewing the percentage of patients diagnosed with preeclampsia in the past with the percentage after the intervention. However, the intervention is at 12-28 weeks and preeclampsia is not diagnosed until around 36 weeks. So, my project would have to last at least 12- 24 weeks. Do you have any other suggestions on what I could compare? Hmm. Would it be noted in the charts 'before' that someone had high risk of preeclampsia? If not, I think you'll just have to do

'after' and assume the 'before' number was effectively zero. The risk assessment is fairly new so none of the "before" charts will have any notes of someone being at risk.

- b. You expect adherence to increase over time? I think it is typical after training that adherence spikes and then drifts downward, one hopes to a 'new normal'. Think carefully about how often you are sampling, at what intervals, and why. My thoughts were to look at adherence over time because I didn't have a before intervention and after intervention to compare. I was hoping adherence would increase over time. I think it's fine to track it, but it may very well spike and then equilibrate.
- c. The analysis: Make sure that the 'time' element of the repeated measures ANOVA is not forced to be a linear function (unless it is- look at a graph of time vs adherence in a scatterplot). I wouldn't expect it to be. Also, you will most likely want to compare certain pairs of time points using a post-hoc test. Help me understand "certain pairs of time points using a post-hoc test." Which one? I was thinking you might be interested in the differences between the first time point and the last, or possibly adjacent time points. The 'time' p-value in the ANOVA will tell you whether you have change over time, but think about how you'll interpret that? If you want to document whether it went up or down, and when, you may want to compare specific time points. When you compare a subset of levels of your variable, that's a post-hoc test (after the fact). It lets you dig into the data a little deeper to interpret the result. That makes sense! Thanks.
 - i. In your scoring system, is '1' partial adherence? If not, why 0 and 2 vs 0 and 1? Are you looking at each facet of adherence separately, or are you only interested in the sum? If the former, you'll need to use an analysis which can handle categorical data. I changed the scoring to 0 and 1. And I am only interested in the sum. Sounds good.