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Implementation and Evaluation of a Registered Nurse Pre-eclampsia Education Program Within a Women's Urgent Care Center

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IMPLEMENTATION AND EVALUATION OF A REGISTERED NURSE PRE-ECLAMPSIA EDUCATION PROGRAM WITHIN A WOMEN'S URGENT CARE CENTER

by

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ABSTRACT

Pre-eclampsia can be a serious development for both mother and fetus during pregnancy. Increased mortality and morbidity rates have been shown in women diagnosed with pre-eclampsia. Higher education for registered nurses on a Women's Urgent Care (WUC) center will help diagnose the mother more quickly and inevitably receive treatment sooner leading to better outcomes for the birth of her newborn. The educational tools used in the study were a pre-and post-test and an educational video for the registered nurses to watch. A retrospective chart review before and after the intervention will help to see if there is any decrease in the time of treatment for the patient.

With the tools used for the project, the post chart reviews indicated a decrease in compliance from the nurses, an increase in the times between when the patient presented to WUC and treatment. The times increased also from when nurse gave medication after getting the increased BP reading. Although the times increased, more education on the nurses' level and perhaps the providers level to help decrease the mortality rates of women. Monitoring and giving treatment to the patients when needed is the role of the registered nurses in a hospital setting. Education helps to keep them up to date on the best way to care for the patients. Pre-eclampsia is a major concern in a labor and delivery unit and needs to be addressed due to the increased mortality rate.

ACKNOWLEDGMENTS

I would like to thank my committee chair, Dr. Lisa Morgan, for helping me fulfill this degree. I appreciate her taking me on as a student and has not only helped me in my studies but also in life perspective and kept me on track.

I would also like to thank Yolanda Moore, BSN who helped me with the ins and outs of the computer system for parts of my research and just encouraged me throughout the process. She made my research much easier for me and I could not be more appreciative.

DEDICATION

I would like to dedicate my doctoral project to my children, Brendan, Makayla, and Nathan, who have always supported me throughout my educational endeavors. They were there for me and never let me give up hope. A special dedication to my parents, Michael and Corlyce Barth, for unconditional love, support, and encouragement through everything. I could not have gone through this journey without the support of every one of you and I love you all.

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LIST OF ABBREVIATIONS

AACN	American Association of Colleges of Nursing
BP	Blood Pressure
DNP	Doctor of Nursing Practice
EVT	extravillous trophoblasts
IRB	Institutional Review Board
mg	Milligram
mmHg	Millimeters of Mercury
RN	Registered Nurse
QR code	Quick response code
UMMC	University of Mississippi Medical Center
WUC	Women's Urgent Care
USM	The University of Southern Mississippi

CHAPTER I – INTRODUCTION

Background

The doctoral student was asked to perform education on pre-eclampsia in a Women's Urgent Care (WUC) unit to comply with the Joint Commission guidelines of 2020. The Joint Commission was founded in 1951 and works to continuously improve healthcare establishments by inspiring the organizations to excel in proving safe and high-quality healthcare (Lyons, 2019). The goal of this research was to measure the effectiveness of pre-eclampsia education using a pretest, posttest design. To comply with IRB guidelines for 2020, the doctoral student created an educational video to upload online for the participants in the study to view.

Significance

Labor and delivery is a specialized area of practice for registered nurses (RN). The RNs not only care for one patient but two, therefore, the RN should be educated on pathophysiology of the mother and the baby (Lyons, 2019). When a mother comes in and is experiencing high blood pressure (BP), she and the baby are affected and at increased risk for mortality and morbidity by the changes in the maternal system. The Joint Commission has started a project for maternal patient safety. The Joint Commission has created six requirements for the hospitals to follow:

> 1) detailing within the policy and procedure steps for accurately measuring and remeasuring maternal blood pressure 2) development of a policy and procedure for managing maternal patients with severe hypertension/preeclampsia 3) delivery of staff and provider education on maternal hypertension/preeclampsia 4) conducting OB severe hypertension/preeclampsia drills 5) performing OB severe

hypertension/preeclampsia case reviews 6) delivery of patient and family education. (McGolrick, 2020, para. 18-23)

The doctoral student's goal was to improve outcomes in pre-eclampsia patients by delivering education to the RNs. The doctoral student plans on educating RNs to assess their patients and interventions. At the facility where the doctoral student will be implementing the education, women present to an urgent care center before they are transferred to the labor and delivery floor. Educating RNs in the outpatient urgent care center will expedite care by identifying the problem before the patient is transferred to the labor and delivery unit.

Problem Statement

The Doctor of Nursing Practice (DNP) project PICOT question format is: Among registered nurses in a woman's urgent care center (P), will additional education in pre-eclampsia (I), instead of no continuing education (C), increase awareness (O) after one 10-minute educational video (T).

Available Knowledge

Pre-eclampsia is a condition characterized by an elevated systolic BP above 140 mmHg, an elevated diastolic BP above 90 mmHg along with proteinuria (>300 mg/day) after 20 weeks gestation. Along with the elevated blood pressure, the pregnant woman may experience "edema, epigastric pain, blurred vision, and a headache which will not subside after interventions are taken" (Royani et al., 2019, p. 1). Complications may arise from pre-eclampsia for the mother as well as the fetus. Maternal complications may include "cardiovascular disease, cerebral disease, liver and/or renal failure, placental abruption, seizures, or disseminated intervascular coagulation" (Royani et al., 2019, pp.

1-2). Fetal complications include “low birth rate, fetal growth restriction, preterm birth, severe birth asphyxia, and stillbirth” (Royani et al., 2019, p. 2).

Predicting who will develop pre-eclampsia during pregnancy is difficult due to the unknown nature of the syndrome, but certain risk factors involved may increase a woman’s chance. Risk factors include a history of pre-eclampsia in earlier pregnancies, family history, primigravida, multiple gestation, history of hypertension, diabetes, or kidney disease, obesity, advanced maternal age, young maternal age, in-vitro fertilization, African American descent, having an autoimmune disease (Lupus), or polycystic ovarian syndrome. Research has shown probable causes of pre-eclampsia. Genetic abnormalities, poor uterus perfusion, and an abnormally functioning placenta are all probable causes of pre-eclampsia. During pregnancy,

> … highly invasive extravillous trophoblasts (EVT) acquire vascular-like properties to remodel uterine spiral arterioles. This creates low-resistance, large-diameter vessels which promote uteroplacental blood supply to sustain fetal growth. It is widely accepted that inadequate trophoblast invasion and impaired uterine spiral artery remodeling is an initiating factor in the development of preeclampsia. (Winship et al., 2015, p. 15928)

Extravillous trophoblasts are what connects the placenta to the uterus wall and control the opening of the spiral arteries. Researchers conclude that when the spiral arteries are narrowed is a major cause of pre-eclampsia (Moser et al., 2016). Narrowing of the arteries impairs the ability for uteroplacental artery perfusion and restricts nutrients and oxygen to the fetus.

The only way to fully treat pre-eclampsia is to deliver the baby and the placenta, whether by vaginal delivery or cesarean section before the condition turns into eclampsia. Deciding if the risk outweighs the benefits of delivering the baby is ultimately up to the physician. Studies have shown Magnesium sulfate is a medication used to prevent eclampsia in the woman and severely elevated BP's. Magnesium sulfate is not used to lower BP, but to prevent seizures. High BP's, when the systolic BP is above 160 mmHg and the diastolic BP is above 110 mmHg, intravenous anti-hypertensives such as labetalol or hydralazine should be used to lower the BP to a safe level. Administration of intravenous labetalol for severe hypertension guidelines state to give 20mg of intravenous labetalol and check the BP after 20 minutes. If the BP is still elevated with systolic pressure at or above 160 and diastolic pressure at or above 110, give 40mg of labetalol intravenously. If the BP remains elevated after 20 minutes, give 80mg of labetalol intravenously. The total amount of labetalol given in 24 hours should not exceed 300mg. If the BP continues to be elevated after giving 80mg of labetalol intravenously, give 10mg of hydralazine intravenously. If the BP remains elevated wait for further orders from the physician. If the BP is below the threshold, continue to monitor the BP every 10 minutes for an hour, then every 15 minutes for one hour, followed by every 30 minutes for one hour, and then hourly (American College of Obstetrics and Gynecology [ACOG], 2019).

Needs Assessment

The rates of maternal mortality are rising, the numbers have almost doubled since 1987, reaching the rate of 29.6 maternal deaths per 100,000 live births in the United States. Maternal mortality numbers include deaths related to or aggravated by pregnancy

and the management of the pregnancy (excluding accidental or incidental causes), during pregnancy or childbirth, or within one year of termination of pregnancy. The number of 29.6 is well above the Healthy People 2020 goal of 11.4. Mississippi has a maternal mortality rate of 27.2 per 100,000 live births (United Health Foundation [UHF], 2020). Pre-eclampsia is accountable for 6.8% of pregnancy-related deaths in the United States. Although a woman has a 5-8% chance of experiencing pre-eclampsia, every patient should be screened and monitored for early warning signs (McGolrick, 2020). In Mississippi in the years from 2013-2016, there were 13 deaths associated with hypertension in pregnancy. Five were pre-eclampsia related and 5 were hypertension-related that was either synchronized with or related to hypertension during pregnancy (Mississippi State Department of Health [MSDH], 2019).

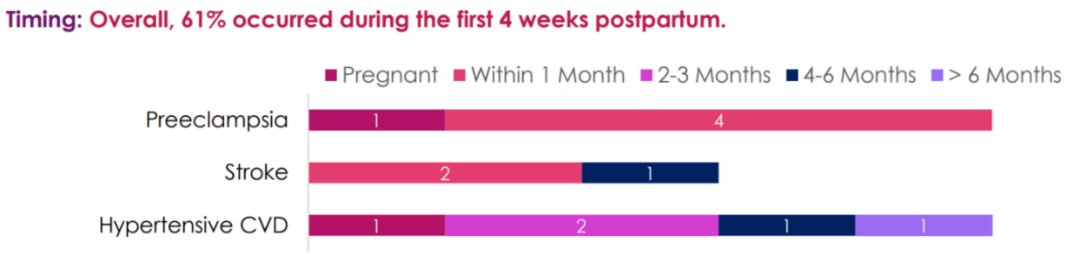


Figure 1. Pre-Eclampsia Rate

Synthesis of Evidence

Search

Five search methods were used: CINAHL with full-text, MEDLINE, PubMed, Google scholar, and google. The search aimed to locate capacity-building articles in public health records, evidence-based practice guidelines, pre-and post-test use, the pathophysiology of the placenta and maternal changes during pregnancy, and general

information on learning theories. Phrases were used with the text related to pre-eclampsia (preeclampsia and pre-eclampsia), maternal mortality (Mississippi and nationwide), joint commission guidelines preeclampsia, education for registered nurses, continuing education, reliability and validity in the questionnaire, and transformational learning (Mezirow's Theory). Other phrases for the pathophysiology of the placenta and maternal changes were trophoblasts, placenta attachment, kidney changes with pre-eclampsia, maternal changes in pre-eclampsia, and causes of pre-eclampsia. Articles were included if they were government organizations, peer-reviewed, guidelines, and/or healthcare-related.

Evidence-Based Findings

The cause of pre-eclampsia is unknown, but some theories suggest the reason why some women will develop the disorder and others do not. Zhang, Ye, and Chen (2013) state that pre-eclampsia is caused by a poor placenta, and the poor plantation of the placenta causes hypoxia and oxidative stress. Zhang et al. (2013) also state that evidence suggests that the maternal immune response and endocrine system cause shallow implantation. The shallow implantation causes an immune intolerance to pater-derived fetal antigens. The shallow implantation, in turn, causes inadequate spiral arteries, which is what connects the placenta to the uterine wall.

Winship et al. (2015) agree that there is poor placenta perfusion that causes pre-eclampsia, and they state that Interleukin 11 elevation is a major concern. "Interleukin11 (IL11) is a pleiotropic cytokine that regulates cell cycle, invasion, and migration in numerous cell types, all roles in critical placental development" (Winship et al., 2015, p. 15928). The elevated IL11 is what causes spiral artery remodeling and placentation.

Although the only true way to cure pre-eclampsia is to deliver the placenta, some scientists are saying that antiplatelet therapy can prevent women with high-risk factors from developing pre-eclampsia. Duley et al. (2019) state that using antiplatelet therapy can reduce the chance of proteinuric pre-eclampsia by 18%. Administering low-dose aspirin starting in the first trimester of pregnancy, can reduce the rate of pre-eclampsia, small for gestational age newborns, preterm births, and fetal death. Although low-dose aspirin lowered all these conditions, daily low-dose aspirin only slightly raised the chance of postpartum hemorrhage.

Basic nursing knowledge about critical thinking, patient care, and pathophysiology of the human body is given during nursing school. Continuing education after school allows RNs to build on their evidence-based knowledge and critical thinking skills (Roney & Acri, 2019). Roney and Acri (2019) state that obtaining quality education can be more difficult for rural nurses due to the financial restraints of having to travel and they might not have ancillary support like nurses in a more urban setting would have. Roney and Acri state that online learning has opened the door for nurses to have quality education no matter their location. The medical field is forever changing, and continuing education gives nurses the knowledge to give their patients the best, safest care possible. Employers encourage continuing education for nurses "raised staff morale, increased motivation and staff retention" and nurses saw continued education beneficial for "enhancement of professional knowledge; advancing professionally; providing relief from routine; improvement of social relations; and acquirement of credentials" (Richards & Potgieter, 2010, p. 43).

Theoretical Framework

Many theories exist for adult education, ranging from a discussion, and finding their answers to telling the students what to learn. The Transformational Learning Theory describes one aspect of adult learning developed by Jack Mezirow in 1991. Transformational learning focuses on "critical reflection on personal assumptions, attitudes, and beliefs followed by discourse to understand and validate the new insights" of the learner (Matthey-Maich et al., 2010, p. 25). Transformational learning goes above the basic knowledge and focuses on the deeper and more constructive learning and focuses on the critical aspect of the learner. The doctoral student believes that by explaining why the recipients should learn the new protocol of treating pre-eclampsia and educating the participant as to what is happening in the body, the participant will remember the information better and be able to 1) enforce the education in their own nursing practice 2) educate the patients as to why the tests are being performed, what pre-eclampsia is, and why it is taken so seriously by the medical team. "Mezirow's initial research led him to theorize that adults don't apply their old understanding to new situations, instead they find they need to look at new perspectives to get a new understanding of things as they change" (Western Governor's University [WGU], 2020, para. 2). Transformational learning is not memorization, it is a firm understanding and knowledge base that increases actions and stimulates more critical thinking, and asking more questions to form more knowledge (Marrocco et al., 2014).

Western Governor's University (2020) states that there are different phases of transformative learning:

1) A disorienting dilemma

2) Self-examination

3) critical assessment of assumptions

4) planning a course of action

5) acquisition of knowledge or skills to carry out a new plan

6) exploring and trying new roles

7) building self-efficacy in new roles and relationships. (WGU, 2020, Phases of Transformative Leadership section)

The RNs that will be participating in the education will already know the basics but understand that there is more information that they can always learn, which is part of transformational learning. The act of learning and applying the new information to the workplace is steps three to five. By the participants signing up for the research and educational video, the participant is on steps three and four; step four being that they are signing up for the video to continue their learning.

The RNs involved in this study have experience in their field of expertise. The RNs know what to look for and what pre-eclampsia is, but do the RNs have a firm understanding of what is happening in the body? With this type of education, the doctoral student is hoping for an “aha” moment where the RNs understand what is happening in their patients' bodies and they are more aware of the seriousness of the situation and can remember treatment protocols because the RNs know what they are looking for and why.

Specific Aims

The goal of the study is to measure education on pre-eclampsia in a WUC unit. After researching the mortality and morbidity maternal rates, not only in Mississippi but

the United States, the doctoral student agrees with The Joint Commission. More education on pre-eclampsia for RNs is needed. The education not only should cover the correct treatment protocol, but also the pathophysiology to know what signs to look for in patients that present to the unit and to understand why the provider will order specific tests. When education is given and the "why?" is answered, RNs are more likely to remember the education and recognize signs and symptoms in a patient. By the participants completing the pretest and posttest, the doctoral student will be able to measure what the RNs learned from the educational material presented.

DNP Essentials

The American Association of Colleges of Nursing (AACN)(2006) recognizes the practice-focused DNP. The DNP is a terminal degree with a focus on the discipline of nursing practice. The AACN (2006) has comprised eight curricular and elements and competencies that need to be incorporated in all programs conferring the Doctor of Nursing Practice degree. The doctoral student can include four of these essential elements in the study:

- Essential I- Scientific Underpinnings for Practice
    - Addresses scientific knowledge concurrent with the complexity of practice
- Essential II- Organizational and Systems Leadership for Quality Improvement and Systems Thinking
    - Quality improvement project related to sustaining changes at the organization and policy level
- Essentials III: Clinical Scholarship and Analytical Methods for Evidence-based Practice

    - Integrates knowledge from diverse disciplines to apply to nursing practice
- Essentials IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care
    - Uses technology to obtain patient data and configure results
- Essentials VII: Clinical Prevention and Population Health for Improving the Nation's Health
    - Discusses a health problem that is population-specific

Summary

Little research has been done regarding the RN's knowledge about pre-eclampsia and regular practices with patients presenting with pre-eclampsia in a hospital setting. The doctoral student is suggesting an increase of knowledge at the RN's level will help reduce maternal and infant mortality. A pre-eclampsia educational video will be offered to the RNs in conjunction with the pre-test and post-test.

CHAPTER II - METHODS

Context

Little research has been done regarding the RN's knowledge about pre-eclampsia and regular practices with patients presenting with pre-eclampsia in a hospital setting. The doctoral student was suggesting an increase of knowledge at the RNs' level would help reduce maternal and infant mortality. A pre-eclampsia educational video was offered to the RNs in conjunction with the pretest and posttest.

Interventions

A retrospective chart review was performed 6-months before the beginning of the study to determine the times between when the patient that presents with symptoms of pre-eclampsia enters the WUC to when they received treatment. Timeliness is essential for the treatment of pre-eclampsia. The faster a diagnosis is determined, and treatment is given, the better outcome is for the mother and the baby. Performing a chart review before the education was given gave the doctoral student a baseline for the average time that the unit was first treating patients that present with pre-eclampsia. For the study, fliers were dispersed in the nursing breakroom and on the back of employee bathroom doors about the study being conducted. Information was given about the research and QR codes were listed for RNs interested in participating in the study voluntarily. Three QR codes on the page: one for the consent and the pretest, the second for the education about pre-eclampsia, and the third for the posttest. Qualtrics were used to access the consent, pretest, and posttest. The educational video was uploaded onto YouTube for the viewer. Each section of the study had its QR code and the participants could take them when they had time. If the participant was needing to do the pretest and then on her next break,

watch the educational video and take the posttest, that was an option. If the participant could do all three sections at once, that was allowed as well. Fliers were placed on the walls as well as copies on the breakroom table that the RNs could take home with them so that they had the QR codes available with them when they have the time to complete the sections of the study. The pretest contained 13 questions with the first four comprising of demographic information of the participant. The educational video was uploaded to YouTube and pertained to the pathophysiology of pre-eclampsia, signs, and symptoms the RN will look for, lab work that will be ordered, and information on medication and the protocol for treating pre-eclampsia, the video could have been watched more than one time. The posttest had the same questions as the pre-test, including the first four demographic questions. For each test, the participant put in the first four numbers of their birthdate for the tests to be evaluated evenly. The participants were instructed that the first two digits would be their month and the last four digits would be their day of birth, for example, if the participants birthday is August 4 their code number will be 0804. That way the participant would know and remember their code, but the doctoral student did not know who the participant was. The pretest and posttest took about five to ten minutes to complete, and the educational video took about 10 minutes to watch. A retrospective study was then be performed one month after the conduction of the study to monitor the times between when the patient with pre-eclampsia symptoms entered the WUC and when the received treatment to see if the times had improved when compared to the chart reviews performed before the interventions were started. If the times had improved, it shows that educating RNs on

signs and symptoms and the dangers of the effects of pre-eclampsia on a woman's body will help the women receive treatment faster and therefore, have a better birth outcome.

In the year 2020, COVID-19 became a health concern for people worldwide. Precautions were made to help keep the public safe. This study was done during the COVID-19 pandemic and precautions were incorporated to keep the doctoral student and participants safe. No personal contact was made between the doctoral student or the participants. When placing fliers in the nurse's breakroom, a face mask was worn by the doctoral student. All educational material was conducted online for the current study due to the pandemic restrictions.

Study of Interventions

The purpose of the project was to improve identification and responsiveness to patients presenting with pre-eclampsia symptoms. A retrospective chart review before and after the pre-and post-test for the RNs determined the impact of the education given to the RNs on the women's urgent care center. The retrospective chart review was to get a baseline time for when the patients received care because timing is an especially important aspect in caring for patients with pre-eclampsia. The purpose of the posttest was to assess if the RNs learned anything from the video. The questions and answers were found throughout the educational video. The education to the RNs was not only about the signs and symptoms and hazards of pre-eclampsia but also teaching the RNs the protocol of when the nurse should administer medications to women who present with these signs and symptoms of pre-eclampsia. The education overall would help the RN to understand more of the importance of monitoring the patient's BP, communicating with the provider, and expecting when and how much medication to give the patient. The

retrospective chart review after the post-test was to determine if the education helped the patients receive treatment sooner. If the times decrease from when the patient receives care in the chart reviews after the intervention, then the educational video helped the RNs assess and acknowledge the patient's diagnosis sooner than before.

Population of Interest

Purposeful sampling took place from the coordinated hospital for the current DNP project. The doctoral student used RNs currently employed by WUC in a central Mississippi hospital with 722 beds. The RNs were employed as full-time, part-time, or per diem, but any RN in orientation will be excluded from this study. These RNs are chosen due to their clinical expertise and the population they served. The RNs were the first providers the patients see when they go to the hospital. These RNs assessed, and the providers determined if the women needed to be admitted to the hospital or if they could be treated in the women’s urgent care center and then be able to go home.

Measures

Performing a pretest and posttest was a way of measuring the amount of education learned by the RNs from the educational video. Conducting a pretest and posttest was one of the best ways in evaluating interventions used for the type of research being used (Alessandri et al., 2017). Several factors could hinder the results of these tests: participants' poor level of monitoring of taking an assessment and the inability for the participant to complete all three of the interventions. In the pretest and post-test, different types of questions were asked. The doctoral student included multiple-choice, true or false, and select all that apply. Both the pretest and posttest have 13 questions and answers on the evaluation. The first four questions are demographic questions asking

how long the participant has been an RN, how long the RN had worked in a women's area, age, and educational level. By asking the same questions on both the pretest and posttest, ensures test-retest reliability. "Test-retest reliability involves administering the same measure to the same group of test-takers under the same conditions on two different occasions and correlating the scores" (Deniz & Alsaffar, 2013, p. 498).

Analysis

This project determined the quantitative measurement of the education the RNs on the WUC learned from the educational video with this quasi-experiment design. The results of the pre-test and post-test were entered into REDCap by the doctoral student to keep safe and secure and then be able to be downloaded into Excel for easier data analysis. The first four questions were not included in the analysis due to the demographic nature of the questions.

The doctoral student also determined the times before the intervention was conducted on the amount of time a patient presented to the WUC to when the patient received treatment. The average times were calculated in Excel [=AVERAGE()] and the difference determined if the times were better (a decrease in times) after the intervention or worse (an increase in times).

Ethical Considerations

A letter of support from the facility and approval of the Institutional Review Board (IRB) of The University of Southern Mississippi (USM) (Protocol #-21-272) and the IRB board from The University of Mississippi Medical Center (UMMC) (protocol #2020V0373) were obtained before any implementations were initiated. Any participants related to the study contributed by volunteer status. No participants were coerced or

persuaded into participating. All information was confidential, no identifying information was given during the study. The surveys were secured and only the doctoral student had access to the records of the results of the survey. Qualtrics had survey protection that was enabled for anonymity. The pre and post-tests did have demographic information and had an assigned number of the participant's birth month and day (August 4 will be 0804), but this was not enough information to give away any participant's identity. Information from Qualtrics was also be uploaded into REDCap along with the times collected from the retrospective chart reviews. Consents were electronically signed before the pretest and gave consent for the pretest, education, and posttest. The participant was allowed to drop out without any drawbacks from the surveyor anytime during the pretest, educational material, or the posttest.

Ethical considerations will also be taken with obtaining information from chart reviews. The doctoral student did not collect any protected health information for this study. Only the diagnosis and the time the patient presented to the women's urgent care and the time treatment was given. The information will be logged into the primary doctoral student's computer which was password protected and put into REDCap for 6 months after the requirements for graduation are complete.

Project Timeline

The project timeline will be 2 months. Two weeks for the fliers with the QR codes to be posted in the bathrooms and the nurse's breakroom for the RNs to participate in the research. The doctoral student will be performing the retrospective search and analysis of the chart reviews during the assigned time. The doctoral student will then wait 1 month and perform another retrospective chart review to determine if the times for the cases

have decreased. The doctoral student is allowed a week for the post-intervention retrospective chart review.

Summary

Although there is no definitive test to know who will develop pre-eclampsia, knowledge is available to help those women who do develop pre-eclampsia. Educating RNs and providers on the safest and best way to control a women's BP and how to test for pre-eclampsia is a crucial step in helping a woman and her baby if she should develop pre-eclampsia. Understanding the pathophysiology of what is happening in the body will help the RN remember what to expect for orders and signs and symptoms to look for in the woman.

CHAPTER III – RESULTS

Results

The goal of this project was to decrease mortality rates in pre-eclampsia patients and their babies by giving the RN's education and assessing their retention of the information and seeing if the RNs put the education into practice. The education gave the RNs information about who is at risk for pre-eclampsia, how it might be developed in the growing placenta, how and what organs are affected by this disorder, and reviewing the protocol of treatment. This project had two parts, chart reviews and the intervention that included the education for the nurses.

A retrospective chart review was conducted six months before the beginning of the planned intervention of the pre-test, educational video, and post-test. The doctoral student recorded the times from when a patient presents to the WUC to the time of treatment for increased BP (systolic 160 or higher and/or diastolic 110 or higher). While looking at the chart reviews, the doctoral student noticed not all women who received hypertension treatment, presented with symptoms, some women came in for other concerns and upon taking vital signs, the women's BP was elevated and needed treatment. Taking the women who presented to the unit without known BP issues into consideration, the times are not a reliable source of measurement to see if the interventions were successful. The average time discovered between entering the clinic and receiving treatment was 58 minutes. Since some women did not have an elevated BP at the beginning of the visit at WUC, the better way to measure would be to know the difference between the time of the elevated BP and the time of treatment. Calculating this information showed the average time from elevated BP to treatment was 7.6 minutes.

This unit is very well equipped for high-risk patients and many times if they are warned by the provider sending a patient over to be monitored, the RN will go ahead and insert an IV when the patient is admitted to keeping the times down for if they do have an elevated BP and need treatment.

The doctoral student first looked at the Unit Report Algorithm to get a baseline for the compliance rate for the WUC. The retrospective chart review revealed a 37.44% compliance with giving the patient any hypertension medication with an elevated BP. Looking at the Unit Report Algorithm, the system would record when the patient was put into the system on WUC, the times of an increased BP and the result of the BP measurement, and the time and medication that was given. So if a patient had 4 elevated blood pressures (systolic pressure at or above 160mmHg and/or diastolic pressure at or above 110mmHg) those four would be put in the report along with the time the BP was taken. If the same patient was treated with medication, it also shows what medication and time that the medication was given. The Unit Report Algorithm did not take some factors into account. Some patients would have a randomly elevated BP and the nurse would assess and note an inaccurate BP reading due to an inaccurate BP cuff because too small a cuff can produce a high BP reading, or the patient was moving when the BP was being taken. These instances, of course, will cause a falsely elevated BP and must be retaken. Other times, the patient was being taken up to be admitted to Labor and Delivery, and the medication was given on that floor. The protocol for elevated BP that WUC follows, states that after the medication is given for increased BP, to wait 20 minutes before obtaining another BP reading. On more than a couple of patients, the BP was taken before the 20-minute timeframe. After the 20-minute time limit was reached, the patient's

BP was out of the extreme range and fallen below 160/110mmHg. With all the calculations taken correctly by the doctoral student, the compliance rating for the WUC before interventions were 69%.

The results of the pre-test and post-test are inconclusive. The doctoral student received 4 participants that completed the pre-test, the educational video, and the post-test. One participant answered all the questions correctly on the pre-test and post-test, one participant answered the same questions wrong on both the pre-test and post-test thus getting them the same grade, another made a worse grade on the post-test than the pre-test, and one improved their grade on the post-test than the pre-test after watching the educational video. The results showed 100% of the participants were over the age of 30 and 75% of the participants had 10+ years of experience in women's health as an RN, either in Labor and Delivery, working on WUC, or in postpartum.

Table 1

Pre-test and Post-test Correct Answer Percentages

	Pretest Scores				Posttest Scores			
	Correct		Incorrect		Correct		Incorrect	
Question	N	Percent	N	Percent	N	Percent	N	Percent
Q6	2	50%	2	50%	3	75%	1	25%
Q7	4	100%	0	0%	4	100%	0	0%
Q8	4	100%	0	0%	4	100%	0	0%
Q9	4	100%	0	0%	4	100%	0	0%
Q10	4	100%	0	0%	4	100%	0	0%
Q11	3	75%	1	25%	3	75%	1	25%

Table continued

Q12	1	25%	3	75%	4	100%	0	0%
Q13	3	75%	1	25%	3	75%	1	25%
Q14	4	100%	0	0%	4	100%	0	0%

*Actual questions are shown in appendix B

The WUC is accustomed to seeing high risk pregnancies and are well equipped for emergencies and have done much education for pre-eclampsia. The RNs who work on this unit are mostly well seasoned Labor and Delivery nurses who have dealt with these high-risk patients and how to treat their ailments, which is probably why there was not a huge change in compliance. The tools used for the intervention were created by the doctoral student due to no tools available for this situation. If these tools were implemented at a less critical hospital and unit, they might have shown a different outcome than inconclusive.

Table 2

Results

Compliance before intervention	Compliance after intervention	Times from entering the unit to treatment before intervention	Times from entering the unit to treatment after the intervention	Times from increased BP before intervention	Times from increased BP after intervention
69%	50%	58min	77 min	7.6min	9.75min

The post retrospective chart review was completed for the month after the intervention was finished. Due to the restricted time frame, not many encounters of elevated BPs were presented when compared to the six months before the before retrospective chart review. The compliance rate for this month was 50%. Looking at the

charts, several patients that had elevated BP readings and were taken to be admitted to labor and delivery before medication was administered. When comparing the two compliance rates, the compliance got worse after the interventions. The average time from entering the WUC and receiving treatment increased as well, increasing to 77minutes. The times in between when the patient had a high BP reading and when she received treatment also increased to 9.75minutes.

Discussion

While pre-eclampsia is a very serious diagnosis, the results of this project were not reassuring in helping decrease the times that women received treatment. The results displayed that the educational intervention did not help with the times between when the women presented to the unit with pre-eclampsia symptoms and when the patient received treatment, nor did the intervention help with compliance in the protocol being implemented on the WUC unit for when to administer medication after increased BP readings, which caused a gap in nursing practice and when giving the treatment needed. Looking through the charts, the women who were being transferred to labor and delivery for preeclampsia should be treated before being sent to the next unit to help reduce inequalities in their care.

Considering the results of the project, certain situations could have changed the results to where at least the compliance rates could have increased. First, there were not enough participants to make a difference. Only 4 participants out of a total of 18 completed the pre-test, educational video, and post-test. Secondly, more time was needed after the intervention to do more chart reviews over several months. The best and most accurate way to measure compliance and times would have been to monitor at the same

time next year. The summer months have been shown to have more women present with symptoms of pre-eclampsia and high BP. Performing chart reviews over the same six months would be more reliable due to the same environmental setting due to the same time of year. Third, this doctoral project was created to verify if more education for nurses over pre-eclampsia would help in lower times for treatment. At the facility in which the project was performed, the times from the time of elevated BP to the time of treatment were already satisfactory. Implementing this education at another hospital whose times were not adequate, might have achieved better outcomes. If these three challenges were faced and resolved, the outcomes might be in favor of improving times for the patients.

Looking at the times of treatment from when the patient had a high BP reading and when they received treatment, were good and reasonable from the beginning. This is due to the high critical care that the staff is accustomed to and the years of experienced nurses on the unit. The range of times the patients received treatment on WUC was from 1 minute to 15 minutes, with the higher times due to not being able to obtain an intravenous line. Implementing this project at a different hospital, perhaps a hospital that does not treat many pre-eclamptic patients, the times to treatment may have improved. The beginning average time of 7.6 minutes from increased BP to treatment is an exceptionally good average for as many patients that they treat, which is approximately 10,000 patients a year.

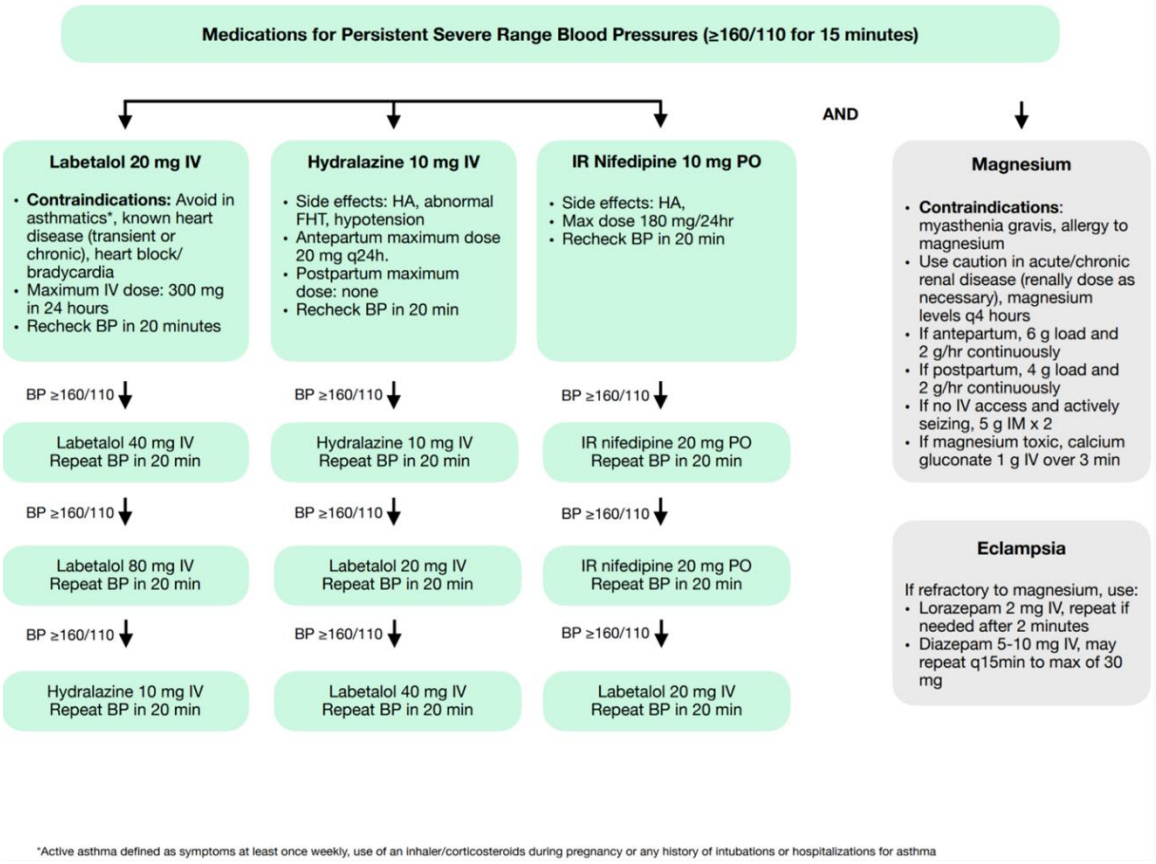
Although the results showed an increase in times of treatment and the compliance rating decreased, the project unveiled some areas that need improvement on the unit. The nurses need to always treat patients for hypertension before transferring to another floor

unless a true emergency develops, and the risk outweighs the benefit in treatment. Another aspect that needs addressing is some areas of charting. Looking at the Unit Report Algorithm which showed the times the patient would have elevated blood pressure, some of the patients would have an elevated BP, the nurse would take another BP within five-10 minutes and the BP would be below the parameters of getting treatment, but some of the nurses are not documenting if there was a reason for the increased blood pressure. When the patient has elevated blood pressure, the nurses will not give hypertensive medication, but not documenting the reason for the falsely elevated BP is another gap in the care of the patient due to not communicating with the providers and other staff why the patient had a false BP reading or what was happening in the room at the time of the BP reading.

The results of the project were not expected when planning and implementation began. The outcomes were expected to decrease the times between presenting to the WUC and treatment for the patient. The nurses on WUC are experienced in this area and see many patients throughout the year with pre-eclampsia which keeps them familiar with the protocol and treatment plans. Although the compliance rates decreased and the times of treatment increased, helpful information was learned to help increase compliance rates for WUC such as treating the patient when they have an increased blood pressure before moving the patient to another unit. Addressing pre-eclampsia for yearly competencies is important in any labor and delivery unit. Knowing the protocols for treatment, helps nurses feel more comfortable with these patients. Limited information is available about how and what type of education for nurses and/or providers can help decrease mortality

rates in women with pre-eclampsia. This project is a good preliminary step that needs further investigation.

APPENDIX A – Pre-eclampsia Treatment Protocol



(University of Mississippi Medical Center, 2020)

APPENDIX B - Pre- and Post-test Questions

How long have you been a nurse? (select one)

- 0-5 years
- 5-10 years
- 10-15 years
- 15-20 years
- more than 20 years

How long have you worked in a women's care setting (i.e.- labor and delivery, postpartum, women's urgent care)?

- 0-5 years
- 5-10 years
- 10-15 years
- 15-20 years
- more than 15 years

What is your age?

- 20-30 years old
- 30-40 years old
- 40-50 years old
- 50-60 years old
- 60+ years old
- prefer not to answer

What is your education level?

- ADN
- BSN
- MSN
- Other

Some high-risk factors for pre-eclampsia are: (select all that apply)

- ☐ chronic renal disease
- ☐ diabetes
- ☐ vascular disease
- ☐ chronic hypertension
- ☐ women of young age

Magnesium Sulfate is used to help reduce blood pressure in severe hypertension.

- ○ true
- ○ false

Pre-eclampsia is "cured" by (select one)

- ○ labetalol
- ○ magnesium sulfate
- ○ delivery of baby
- ○ there is no cure

What is considered severe blood pressure? (select one)

- ○ 154/94
- ○ 161/112
- ○ 159/100

After giving labetalol 20mg IV for severe hypertension, how long should you wait to repeat the blood pressure? (select one)

- ○ 5 minutes
- ○ 10 minutes
- ○ 20 minutes

What is the cause of pre-eclampsia? (select one)

- ○ the placenta
- ○ the liver

- it's just something that happens

What lab work would be anticipated for the doctor to order for someone with symptoms of pre-eclampsia? (select all that apply)

- CBC
- CMP
- Uric Acid
- CRP
- TSH
- UA

What organs can be affected by pre-eclampsia? (select one)

- kidney, liver, brain
- kidney, lungs, heart
- thyroid, liver, pancreas

What are some medications to help in the reduction of blood pressure? (select one)

- labetalol, nifedipine, hydralazine
- labetalol, magnesium, hydralazine
- metoprolol, Lasix, hydralazine

APPENDIX C - Transcript for Educational Video

Hello! My name is Amber and I am going to review pre-eclampsia with you today and update you on the protocols for treatment.

Let's first talk about patients that could present to your unit with higher risk factors than others. It is difficult to predict who will experience preeclampsia during their pregnancy due to the unknown nature of the syndrome, but certain risk factors involved could increase a woman's chance. Patients who have chronic hypertension, are of advanced age, have chronic renal disease, are obese, have vascular disease, of young age (less than 17 years old), have a personal or family history of pre-eclampsia, have diabetes, used in-vitro fertilization to become pregnant, nulliparity, multifetal pregnancy, or have lupus are some that have a higher risk for developing pre-eclampsia than other patients.

The exact etiology of pre-eclampsia is unknown but let us talk about what could be possible causes of pre-eclampsia. Studies are suggesting that the placenta can be the cause of pre-eclampsia. Genetic abnormalities, poor uterus perfusion, and an abnormally functioning placenta are all probable causes of pre-eclampsia.

So, what exactly is happening to the body during pre-eclampsia? We have 3 key factors in pre-eclampsia: the spiral arteries, the placenta, and the mother's body (specifically the endothelial cells). The spiral arteries are found in the uterus and they play a big role in supporting the pregnancy. The trophoblasts that bed into the uterus and need good blood flow to the placenta through the spiral arteries. At 20 weeks gestation, these vessels will widen for more blood flow to nourish the baby. In pre-eclampsia, the vessels do not widen like they are supposed to and therefore cause vasoconstriction.

Vasoconstriction of the vessels in the placenta and the mothers' body will cause the blood pressure to rise. Picture a garden hose and you put your thumb over the opening and the pressure of the water increases and comes out with more force, this is what is happening inside of the vessels with increased blood pressure.

With decreased blood flow to the placenta and it will become ischemic and the baby will not be able to grow and develop properly. When the placenta experiences ischemia, it will release toxic substances into the endothelial cells in the mothers' body and become damaged.

Endothelial cells line the inside of the blood vessels throughout the whole body, they line the organs like the kidneys, brain, and liver. They control the tone of the blood vessel which causes vasoconstriction and causes high blood pressure in the patient. These endothelial cells that are damaged also allow fluid to leak due to less permeability of the blood vessels. The kidneys, particularly the glomerulus, are what filter out your blood, usually, they do not let large molecules. Protein is one of the large molecules that is allowed to leak out of the vessels when the endothelial cells are damaged. Protein regulates oncotic pressure and when protein is being leaked out of the vessels, water is going to follow. So protein is going to leave the blood and it is going to go into the urine.

The kidneys are not functioning as they should, vasospasms are happening and decreasing the profusion to the kidneys. Water is leaving the blood throughout the body and so it is letting the blood volume drop. When blood volume drops, blood flow cannot effectively reach organs in the body. So the kidneys are not functioning as they should. Kidneys usually can regulate uric acid and are no longer able to do this, so uric acid is going to increase which is a waste product. Creatinine levels are going to rise as well and

urinary output is going to decrease because the kidneys are not functioning as they should.

Edema is going to happen because of the permeability problem in the vessels and water leaking into the interstitial tissues. You will notice puffiness in the face and around the eyes and edema in the extremities.

The lungs can be affected because fluid is getting trapped in her lungs causing pulmonary edema and so she will complain of shortness of breath. Edema can also happen in the brain causing cerebral edema. Remember there are endothelial cells in the head that are also leaking. This is where symptoms can be severe and start turning into eclampsia. When there is swelling in the brain, you will see the CNS symptoms of severe headaches, vision changes, or hyperreflexia. We always want to be checking those deep tendon reflexes and checking for clonus in the ankles. When they are experiencing these symptoms, they are at high risk for convulsion episodes.

The liver is also going to be damaged, so the liver enzymes are going to increase, so you are wanting to look at the ALT and the AST. The patient could complain of upper right quadrant pain.

Diagnosing a patient with pre-eclampsia comes down to lab work and objective information found in the physical assessment. The patient must have increased blood pressure, protein in the urine, and signs of organ injury of either the brain, kidneys, or liver. The patient must be over 20 weeks to be diagnosed with pre-eclampsia.

Accurate blood pressure readings are important in treatment. Make sure that the right size cuff is on the patient (too small with give an artificially high number and too large of the cuff will give an artificially low number). The patient should be supine in a

semi-reclining position or a sitting position without their legs crossed. There need to be at least 2 separate readings of increased blood pressure or diastolic number above 90 and systolic above 140.

Vitamin C, vitamin D, or calcium are not effective at stopping the development of adverse effects of pre-eclampsia. The only way to treat preeclampsia is to deliver the baby.

Immediate-release oral nifedipine may be given if IV access is not available. Magnesium sulfate is not used as an antihypertensive agent but used for seizure prophylaxis. Be prepared to give Celestone to your patient if the gestational age is under 34 weeks.

Severe hypertension would be systolic pressure equal to or above 160 mmHg and diastolic equal to or above 110 mmHg.

The degree of systolic hypertension may be the most important predictor of cerebral injury and infarction in the mother.

Administration of IV labetalol for severe hypertension guidelines is to give 20mg of IV labetalol and check blood pressure after 20 minutes. If blood pressure is still elevated with systolic at or above 160 and/or diastolic at or above 110, give 40mg of labetalol IV. If blood pressure is still elevated after 20 minutes, give 80mg of labetalol IV. The total amount of labetalol given in 24 hours should not exceed 300mg. If blood pressure is still elevated after giving 80mg of labetalol IV, give 10mg of hydralazine IV. If you start the protocol by giving 10mg hydralazine IV, check the blood pressure after 20 minutes. If blood pressure is still equal to or above 160/110 give another 10mg hydralazine IV. Wait another 20 minutes and if the blood pressure is still out of range,

give 20mg of hydralazine IV. If your patient is still experiencing severe hypertension, give 40mg of labetalol IV. If you do not have any IV access and you are needing to give your patient immediate care for their severe hypertension, immediate-release 10mg nifedipine should be given. Recheck the blood pressure after 20 minutes and if the systolic or the diastolic pressure is out of range give 20mg of immediate-release nifedipine. Recheck the patient's blood pressure after 20 minutes and if still elevated above 160 or 110, give another 20mg of immediate-release nifedipine. You need to attempt to obtain IV access during this time and if you recheck the blood pressure after 20 minutes after giving the second dose of 20mg of nifedipine, give 20 mg of labetalol IV. Once BP is below the threshold, continue to monitor BP every 20 minutes for an hour and if the BP is still below threshold, monitor every 30 minutes for one hour, and then hourly.

Start with the labetalol protocol if possible because the antepartum maximum dose of hydralazine in 24 hours is only 20mg. There is no maximum amount for those not pregnant. Do not give labetalol to asthmatics. Magnesium should be given with caution in patients with acute or chronic renal disease. When giving magnesium for seizure prophylaxis in antepartum patients, give a 6g loading dose and 2g/hr. continuously. If giving magnesium to postpartum patients, give a 4g loading dose and then 2g.hr.

APPENDIX D - Consent to Participate in Study

The University of Mississippi Medical Center

Study Title: Pre-Eclampsia Evidence-Based Registered Nurse Staff Education Project

Principal Investigator: Amber Vetter

_____

Introduction

You are being invited to be in this experimental research study because you are a key player in the treatment of women with pre-eclampsia that present to the hospital. Please ask us about anything in this document or that we tell you that you do not understand.

Purpose

We are doing this study to learn if educating nurses about the signs and symptoms of pre-eclampsia and the dangers to the mother and baby, would make a difference in treating the mother quicker.

Procedures

If you agree to participate in this study, you will be asked to answer a few questions about pre-eclampsia, watch a short 15-minute educational video on pre-eclampsia, and then answer a few questions about the information that you might have learned from the educational video. The entire process should take around 15-20 minutes.

Benefits

You will not receive a direct benefit from being in this research study. We hope to learn information that may help others in the future.

Costs

There will not be any costs to you if you participate in this study.

Compensation

You will not be paid for participating in this study. **Voluntary Participation**

Your participation is voluntary. If you decide not to participate in this study, you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Withdrawal

You may choose to stop your participation in this study at any time. If you decide to withdraw the information already collected about you may still be used in this study but additional information will not be collected. Your decision to stop your participation will not affect the quality of medical care you receive at the University of Mississippi Medical Center.

Confidentiality

Your answers to the questions will be stored initially with Qualtrics in a password-protected electronic format via The University of Southern Mississippi. Data will later be downloaded and stored on a computer that will be password protected. We will not collect any protected health information about you for this study. Confidentiality will be maintained. All data will be deleted six months after all graduation requirements have been met.

Protected Health Information

Protected health information is any personal health information through which you can be identified. Your name and signature will be on this document, but we will not collect any other identifiable health information for this study. By signing this consent document, you authorize Amber Vetter and her study staff to collect this information and use your records as necessary for this study.

The information collected for this study will be kept *until the study is complete* and may be combined with information collected through other research studies or used in other studies, but no information will identify you. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

This authorization has no expiration date. If you do not sign this consent document, you will not be allowed to participate in this study.

Number of Participants

We expect 18 participants to enroll in this study here.

Questions

If you have questions about this study or need to report any problems please call Amber Vetter at 575-520-0853.

You may discuss your rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi 39216; telephone, 601 984-2815; facsimile, 601 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.

You will be given a copy of this consent document for your records.

Statement of Participation

I have been told about this study and the possible risks and benefits. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

Electronic Consent

By clicking the button below, you acknowledge:

- You have read and agree with the above information.
- Your participation in the study is voluntary.
- You are 18 years of age or older.
- You are a full-time, part-time, or PRN registered nurse for Women's Urgent Care of UMMC.
- You are aware that you may choose to stop your participation at any time for any reason.

APPENDIX E –IRB Approval Letters

Office *of*
Research Integrity

THE UNIVERSITY OF SOUTHERN MISSISSIPPI

118 COLLEGE DRIVE #5125 • HATTIESBURG, MS | 601.266.6576 | USM.EDU/ORI

NOTICE OF INSTITUTIONAL REVIEW BOARD ACTION

The project below has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services regulations (45 CFR Part 46), and University Policy to ensure:

- The risks to subjects are minimized and reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered involving risks to subjects must be reported immediately. Problems should be reported to ORI via the Incident template on Cayuse IRB.
- The period of approval is twelve months. An application for renewal must be submitted for projects exceeding twelve months.

PROTOCOL NUMBER: IRB-21-272
PROJECT TITLE: Pre-Eclampsia Evidence-Based Registered Nurse Staff Education Project
SCHOOL/PROGRAM: Leadership & Advanced Nursing, Professional Nursing Pratice
RESEARCHER(S): Amber Vetter, Lisa Morgan

IRB COMMITTEE ACTION: Approved
CATEGORY: Expedited

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

PERIOD OF APPROVAL: July 30, 2021

Donald Sacco Jr.

Donald Sacco, Ph.D.
Institutional Review Board Chairperson

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board
Telephone (601) 984-2815
Facsimile (601) 984-2961

DHHS FWA # 00003630

Approval Notice
Initial Application

05/28/2021

Yolanda Moore, RN, BSN
Amber Vetter, RN, BSN
University Of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 2020V0373
Pre-eclampsia evidence-based registered nurse staff education project

Your Initial Application was reviewed and approved by the Expedited Review process on 05/28/2021. You may begin this research.

Please note the following information about your approved research protocol:

- Protocol Approval period: 05/28/2021 – 05/27/2022
- Approved Enrollment #: 18
- Performance Sites: UMMC - Women's Urgent Care
- Expedited Category(ies): (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
  (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Please remember to:

- Use the IRB file number (2020V0373) on all documents or correspondence with the IRB concerning your research protocol.
- Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, if this study involves an intervention (whether or not it involves a drug or device) you (or the "responsible party") must register the study before enrollment begins and report results within 12 months of study closure through Clinicaltrials.gov http://www.clinicaltrials.gov/. Penalties for responsible parties who fail to register applicable clinical studies are significant and include civil monetary penalties and, for federally-funded studies, withholding or recovery of grant funds. For additional information please go to http://irb.umc.edu/GuidanceInfo/ ClinTrialRegistry.htm.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

IRB 2

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