

The Use of Electronic Maternal Early Warning Criteria to Improve Treatment of Hypertension in
Hospitalized Obstetric Patients

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Approval Page

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Abstract

Background: It is difficult to recognize that an obstetric patient's condition is deteriorating because normal physiological changes in pregnancy generate significant shifts in maternal vital signs. Elevated blood pressures can be treated to prevent clinical deterioration. Electronic maternal early warning criteria (EMEWC) were set for *severe range* blood pressure parameters for a systolic blood pressure of 160 mm Hg and a diastolic blood pressure of 110 mm Hg in a cohort of inpatient obstetric patients diagnosed with hypertension.

Objective: Increase the rate of antihypertensive medication administration within one hour of the *severe range* blood pressure.

Methods: *Severe range* blood pressure parameters were set in the Cerner® FetaLink™ software and provided audible and visual alerts to nurses when the patient's condition deteriorated. Prompt recognition of the abnormal findings were evaluated by the timing of the administration of an antihypertensive medication.

Results: A total of 103 obstetric patients met study criteria. Pre-intervention, 15.5% of obstetric patients were treated with an antihypertensive medication within one hour of a *severe range* blood pressure. Post-intervention, the rate of treatment increased to 21.9%, although not significant ($p = .42$).

Conclusions: The use of EMEWC can assist with improving the recognition of clinical deterioration and prompt care interventions. Lessons learned from this quality improvement project can be applied to improving outcomes with other pregnancy complications.

Key Words: maternal early warning, electronic early warning systems, maternal clinical deterioration

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Chapter I: Introduction

Introduction to the Problem

Maternal mortality is infrequent in the United States, but when it occurs, has a devastating effect on both families and hospital staff. Although the World Health Organization (2015) announced a 44% reduction in worldwide maternal mortality since 1990, opportunity remains for improving obstetric health outcomes within our nation. Maternal deaths are attributed to delays in recognition, diagnosis, and treatment of patients' experiencing signs of clinical deterioration (Cantwell et al., 2011). Obstetric patients could benefit from the use of early warning systems that scan the electronic health record (EHR) for abnormal vital signs.

The Healthy People 2020 target goal of reducing the rate of maternal mortality from 12.7 to 11.4 maternal deaths per 100,000 live births is lofty, but achievable (Maternal, Infant, and Child Health, 2016). The Centers for Disease Control and Disease Prevention (CDC) (2016a) reports approximately 600 women die annually in the United States because of complications with their pregnancy or delivery. To assist in further reducing the maternal mortality rate, hospitals will need to evaluate their inpatient data on maternal illness and pregnancy complications. The CDC monitors maternal deaths in the United States through their pregnancy mortality surveillance system. In 2012, the pregnancy-related mortality ratio was 15.9 deaths per 100,000 live births with 7.6% of deaths caused by hypertensive disorders of pregnancy (Centers for Disease Control and Disease Prevention [CDC], 2016b). In-depth maternal death case reviews have identified diagnostic trends that include cardiovascular disease, pregnancy related hypertension disorders, hemorrhages, pulmonary and amniotic fluid embolisms, and infection

(Berg, C., Callaghan, W., Syverson, C. & Henderson, Z., 2010; CDC, 2016a). The search needs to continue to address the most common preventable cause of maternal deaths.

Background of the Problem

It is difficult to recognize that an obstetric patient's condition is deteriorating because normal physiological changes in pregnancy generate significant shifts in maternal vital signs. One of the major physiological changes that occurs during pregnancy occurs during the second trimester; The cardiovascular system is affected as blood volume doubles while systemic vascular resistance decreases. In turn, blood pressure drops and can cause dizziness or fainting. By the third trimester, blood pressure usually returns to pre-pregnancy ranges, but an abnormal rise during this time can be an indication of hypertensive disorders in pregnancy. Elevated blood pressures can be treated to prevent deteriorating clinical outcomes for mother and fetus.

The American College of Obstetricians and Gynecologists (ACOG) (2013) follows a four-category classification system, each with its own qualifiers, to describe hypertensive disorders in pregnancy: chronic hypertension, gestational hypertension, preeclampsia-eclampsia, and chronic hypertension with superimposed preeclampsia. The least severe hypertensive category, gestational hypertension, is diagnosed with the presence of a systolic blood pressure (sBP) 140 mm Hg or higher and/or a diastolic blood pressure (dBP) of 90 mm Hg or higher, on two separate measures, greater than four hours apart, before and after the 20th week of pregnancy (ACOG, 2013). As the categories progress in severity, preeclampsia blood pressure readings elevate to sBP 160 mm Hg or higher and/or dBP 110 mm Hg or higher, on two separate measures, greater than four hours apart, while the patient is on bed rest and include other organ involvement criteria (ACOG, 2013). Blood pressures meeting either of these parameters are referred to as *severe range*. Evidence suggests that treating *severe range* blood pressures with a

first line antihypertensive is needed to prevent repeated or sustained elevated blood pressure levels (ACOG, 2015; Clark & Hankins, 2012).

Regardless of the presence or absence of hypertension during pregnancy, blood flow to the placenta can be compromised—leading to poor neonatal outcomes. The maternal organs affected by hypertension during pregnancy include the kidneys, liver, and brain, and new evidence reveals that an increased risk of future cardiovascular disease exists. Causes of hypertensive disorders, and, more specifically, preeclampsia, are unknown; in fact, the only constant apparent is the presence of a placenta. At present, the only “cure” for hypertensive disorders during pregnancy is delivery of the baby, end of the pregnancy, and expulsion of the placenta. Treatment is comprised of managing blood pressure, monitoring organ involvement, and determining when the delivery needs to occur for optimum well-being of both mother and fetus. It is important to note that transition from the hypertensive condition to a non-hypertensive condition does not occur immediately during the postpartum period. Most patients’ blood pressures decrease after the placenta is delivered, but spikes in blood pressure can occur during the postpartum period, and they can continue to occur for up to six weeks after delivery.

Significance of the Problem

Preeclampsia is a frequently and widely researched condition, as it has been recurrently associated with “high rates of maternal and neonatal morbidity and mortality” (Moodley, 2011, p. 330). Hypertensive disorders are a common medical complication that affect approximately 10-13 % of pregnancies (Berg et al., 2010). The California Maternal Quality Care Collaborative (CMQCC) (2013) has been evaluating maternal morbidity and mortality in California for just over a decade. Their findings revealed an emerging theme relating to lack of timely treatment: “despite triggers that clearly indicated a serious deterioration in the patient’s condition, health

care providers failed to recognize and respond to these signs in a timely manner leading to delays in diagnosis and treatment” (California Maternal Quality Care Collaborative [CMQCC], 2013, p. 5). The American Heart Association joined with the American Stroke Association in recognizing urgency for, and importance in, future research for the prevention of strokes in women specifically because links have been identified between pregnancy and preeclampsia as gender-specific risk factors for future disease (Bushnell et al., 2014). Since high blood pressures in pregnancy present dangers for both the mother and the fetus, health care professionals must stay vigilant within their efforts to recognize and treat hypertension during pregnancy in a timely manner.

The project facility is a regional 457-bed, not-for-profit medical center located in the southern piedmont region of North Carolina. Statistics for hypertension in pregnancy rates at this facility parallel those found in field literature. Approximately 10% of obstetric patients are coded with a hypertensive diagnosis, and, of those, 40% are hospitalized to control their blood pressures and the progression of the disease. For the purposes of this project, *severe range* blood pressure is defined as an elevated sBP of 160 mm Hg or higher and/or dBP of 110 mm Hg or higher on two separate readings greater than 15 minutes apart.

The project facility’s rate of administration of an antihypertensive medication within an hour of a *severe range* blood pressure is 15.5% for the first nine months of the project year. Although no national benchmark exists, the healthcare system participates in the prestigious national Partnership for Patients Healthcare Engagement Network (HEN). The HEN goals for administering an antihypertensive medication within one hour of a *severe range* blood pressure for hypertensive patients have been set at 56% target and 65% stretch. During the HEN, focused improvements to assist with administering an antihypertensive within one hour of recognition

include standardizing blood pressure measurement education, building provider shared baseline protocols for antihypertensive medications, and placing medications on override in the medication dispensing systems to avoid a delay while awaiting pharmacy verification. There is no question that this disease needs a multifaceted approach to management, but recognizing signs of clinical deterioration, and notifying providers of these signs, specifically the presence of a *severe range* blood pressure, is a process measure that nurses can and should be responsible to.

Purpose with Aims and Objectives

Though there is evidence to support the use of computerized early warning systems in hospital settings, there is limited data on their use in hospitalized obstetric patients. The literature reveals there is not a specific validated instrument to detect a patient's clinical deterioration that can be built into the EHR; yet, research *does identify* detailed objective clinical signs that present prior to a patient's clinical deterioration. Within my research and subsequently, within this project, I propose implementing the use of electronic maternal early warning criteria (EMEWC) to evaluate the obstetric patient's clinical picture, and to alert nursing staff of the necessity for a bedside evaluation, in the event of abnormal parameters. The guiding Population/Problem-Intervention-Comparison-Outcome (PICO) question is: In hospitalized obstetric patients with a hypertensive diagnosis (P), will the use of the EMEWC (I), measured pre-and post-implementation (C), increase the rate of an antihypertensive medication administered within one hour of a patient's *severe range* blood pressure occurrence (O)? The purpose of this quality improvement project is to determine if the use of the EMEWC will increase treatment of *severe range* blood pressure—within one hour of recognition—in a cohort of hypertensive obstetric patients hospitalized in labor and delivery (L&D) and high risk obstetric (HROB) units. The long-term outcome measure for this Doctorate in Nursing Practice (DNP) scholarly project is to

examine if/whether early recognition and treatment of *severe range* blood pressures improve rates of treatment for *severe range* hypertensive crisis.

Practice Setting Support

Reducing mortality rates is a constant patient safety goal for the hospital, as well as its 13 sister facilities within the healthcare system that offer obstetric services. Recently, a sepsis warning system was implemented for inpatients outside of the obstetric setting, and favorable results ensued as evidenced by a decreased mortality rate. Due to the positive outcomes of the sepsis program, the hospital supports the evaluation and implementation of an electronic tool to assist with recognizing clinical deterioration in other service lines including those of obstetric, neonatal, and pediatric populations. The hospital's Assistant Vice President of Nursing Practice and the hospital's system's Chief Nursing Informatics Officer were approached regarding the need to incorporate the obstetric service line into quality initiatives that were being implemented. Both individuals offered support for this project to move forward including contacting our electronic health record (EHR) vendor, Cerner®, to see if they already had a program available for adoption.

As of the time of this writing, Cerner® does not have any programs available, but several other hospitals have also inquired about implementing maternal early warning systems, and they requested for the facility to participate in the product build. The project facility offered support through allowing distribution of the clinical nurse specialist workload to accommodate the evidence based project (Appendix A). The information systems department at the healthcare system level will assist with building and installing the electronic maternal early warning criteria through a program called Cerner® FetaLink™. Carolinas HealthCare System has two governing bodies that guide nursing evidence based projects. The Nursing Scientific Advisory Council

(NSAC) reviewed the proposal and offered approval to proceed with implementing the project (Appendix B). The Carolinas HealthCare System Institutional Research Board (IRB) deemed this project as Quality Improvement (Appendix C). East Carolina University's Institution Review Board deemed the project as quality improvement and not human subject research, so no further review was required (Appendix D). The overall time line (Appendix E) for this project spanned 18 months from idea conception to project completion.

Although there have not been any recent maternal mortality cases to prompt immediate action, the project facility's Perinatal Quality Committee (PQC), which is comprised of physician and nursing leaders, evaluated obstetric literature for trends in clinical parameters for maternal early warning systems. The maternal early warning criteria (MEWC) evaluated is not specific to a disease such as sepsis, but the criteria include parameters that mark clinical deterioration for many complications. ACOG Committee Opinion Number 590 (2014) recommends that "each health care setting should examine its own data to determine which events require evaluation of the early warning system" (p.2). The PQC discussed pros and cons of criteria found in literature, and it endorsed a set of high and low vital sign parameters. PQC recommendations were subsequently submitted to the Obstetrics (OB) Department where all inpatient obstetric providers discussed the selected parameters. Consequently, a unanimous vote of acceptance for EMEWC was established (Appendix F).

Project Hypothesis

EMEWC recognizes abnormal clinical parameters, and it provides an audible alarm that will prompt staff and providers to perform a bedside assessment of the patient. If a *severe range* blood pressure remains, nurses can initiate provider orders to prevent further clinical deterioration. The timely recognition of abnormal *severe range* blood pressures will increase the

rate of an antihypertensive medication administration within one hour of a *severe range* blood pressure in obstetric patients.

Assumptions

The proposed DNP scholarly project has been deemed a quality improvement initiative to evaluate whether the use of an electronic early warning system (EWS) can improve health outcomes. Prior to the implementation of the electronic EWS, vital signs are entered a patient's EHR in multiple ways: a nursing assistant enters the values, the current fetal heart monitoring program transfers them in automatically, or the nurse will enter them. A delay in recognition of the vital sign measurements in the past has, unfortunately, resulted in untimely patient interventions. Utilizing the new Cerner® FetaLink™ program features for setting vital sign parameters for *severe range* blood pressure, along with audible and visual alerts serves as an EWS for detecting a patient's clinical deterioration. Use of the electronic EWS in hospitalized obstetric patients should significantly improve the rate of administration of an antihypertensive medication within one hour of a *severe range* blood pressure.

Definition of Terms

- **Cerner®**- the data software company who developed and implemented the EHR utilized in this scholarly project.
- **Early Warning Systems**- a single, multiple, or aggregate-weighted scoring tool either print or electronic used to identify physiological parameters and track a patient's condition. Heart rate, respiratory rate, blood pressure, temperature, and oxygen level are common parameters monitored to assist with detecting clinical deterioration; when an abnormal value results, a trigger prompts appropriate intervention.

- **Electronic Health Record-** A digital version of a patient's medical history, assessments, interventions, provider orders, laboratory results, medications, and test results that assist the healthcare team in providing a thorough longitudinal approach to care.
- **Cerner® FetaLink™** - the Cerner® application for assessment of the fetus during pregnancy. The application is located at the patients' bedside, and it transfers assessments of both the mother's and fetus's condition into the EHR. Vital sign parameters for normal limits can be set, and audible (audio) and visual alarms will be enacted if a patient's clinical condition deteriorates outside of desired parameters. Notifications and patient interventions can be documented in this program to address alarms.
- **Hypertensive crisis-** severe systolic hypertension (greater than, or equal to, 160 mm Hg) or severe diastolic hypertension (greater than, or equal to, 110 mm Hg) that persist for 15 minutes or more.
- **Maternal Early Warning Criteria-** abnormal low and high physiological parameters that indicate the need for urgent bedside assessment by healthcare staff can escalate a response to care using diagnostic and therapeutic interventions.
- **Morbidity-** the condition used to describe a focus of death or how often a disease occurs in a specific region.
- **Mortality-** death of a large number of people used to describe health population trends.
- **Obstetric patient-** a time describing a pregnancy which includes any gestational age of a pregnancy during the antepartum period and the intrapartum period, as well as the time from birth until the 42nd day postpartum.
- **Severe range blood pressure-** elevation of a sBP to 160 mm Hg or higher and/or a dBP 110 mm Hg or higher.

- **Track and trigger systems-** this is a process that periodically measures observations (track) with predetermined action when certain thresholds are reached (trigger). The observations tracked in this project were blood pressure parameters. The trigger was programmed at sBP elevations to alert staff. The electronic fetal surveillance system allows for facilities to set track parameters and trigger frequencies.
- **Vital Signs-** physiological measurements of a patient's essential body functions including pulse (heart rate), respirations (respiratory rate), blood pressure, and temperature.

Summary

Hypertensive disorders complicate up to 10% of pregnancies, and they are a leading cause of maternal and perinatal morbidity and mortality worldwide. Preeclampsia, a subset of the hypertensive disorders, has increased by 25% in the United States during the past two decades; consequently, it is a risk factor for future cardiovascular disease and metabolic disease in women. Local hospital system data shows approximately 20% of patients are coded with a hypertensive disorder during pregnancy, and, of those, approximately 15% of patients experience an episode of *severe range* blood pressures. The recommended treatment to prevent long term complications is administration of an antihypertensive medication within one hour of the onset of a *severe range* blood pressure. The EMWEC will assist the staff with early recognition of signs of patient's clinical deterioration.

Chapter II: Researched Based Evidence

Introduction

Within the literature review, supporting evidence is divided into sections based on separate and distinctive themes. A literature search was performed utilizing CINAHL Complete, PubMed, and Nursing and Allied Health databases. Key terms included maternal early warning, electronic early warning systems, maternal clinical deterioration, maternal morbidity, and maternal mortality. Limitations within the scope of my search included literature published no earlier than the last 10 years, literature published in the English language, and that which utilized human subjects within their research in order to incorporate landmark studies and recommendations on the subject matter. In addition, I included a search for gray literature from professional organizations and national committees within my search. The following section outlines supporting literature in detail, while Appendix G offers highlights of current evidence related to the development of an electronic EWS to be subsequently implemented within this quality improvement project.

Critical Analysis of Literature

Hypertension in Pregnancy. Clark et al. (2008) performed a retrospective maternal death case review in order to examine trends in causes, prevention, and specific relationships with cesarean deliveries. They found that, of 17 deaths considered to be preventable, five cases involved the preeclampsia diagnosis. The authors determined that the “most preventable errors in preeclampsia management leading to maternal death involved inattention to blood pressure control and signs or symptoms of pulmonary edema” (Clark et al., 2008, p, 36e4).

Blood Pressure Control. Clark and Hankins (2012) researched recurrent errors that account for maternal deaths, and they offered 10 “clinical diamonds” that address key principles

to help reduce the possibility of errors in care that can lead to maternal mortality. One “diamond” centers around untreated blood pressures which often precede events of clinical deterioration.

“Any hospitalized patient with preeclampsia experiencing either sBP of 160 mm Hg, or a dBP of 110, should receive an intravenous antihypertensive agent within 15 minutes” (Clark & Hankins, 2012, p. 361). The authors recommend this single dose will not harm a patient, and they propose this should be an automatic response. The timing outlined in the article suggested a 15-minute window from recognition of elevated blood pressures to administration of the antihypertensive agent which is an aggressive administrative timeframe.

ACOG (2015a) presented a collective opinion on emergent therapy for the acute-onset, severe hypertension during both pregnancy and postpartum periods to aid in reducing adverse maternal outcomes. “Individuals and institutions should have mechanisms in place to initiate the prompt administration of medication when a patient presents with a hypertensive emergency” (ACOG, 2015a, p. 1). Central nervous system injury can occur at these parameters of elevated blood pressures. In the event of the hypertensive emergency, first-line therapy is recommended with an antihypertensive to prevent repeated or sustained elevated blood pressure levels.

Safety Measures. Many clinical emergencies are preceded by a period of instability in a patient’s condition; therefore, timely assessment and intervention are key to the improvement of clinical outcomes. ACOG Committee Opinion Number 590 (2014) encourages hospitals, specifically obstetric and gynecologic units, to prepare for clinical emergencies by recognizing changes in patients’ conditions that require immediate intervention. The Joint Commission (TJC) (2010) issued sentinel event alert #44 to assist with preventing maternal deaths. A suggested action for hospitals included “identify[ing] specific triggers for responding to changes in the mother’s vital signs and clinical condition and [to] develop and use protocols and drills for

responding to changes” (The Joint Commission [TJC], 2010, p.3). Obstetric patients with comorbid conditions, such as hypertension, could benefit from the use of early warning systems that scan the electronic health record (EHR) looking for abnormal vital signs and deteriorating conditions.

The Joint Commission’s Provision of Care, Treatment and Services chapter (2016) has a standard, PC.02.01.19, for each hospital to utilize an outlined process to recognize and respond to a patient’s deteriorating condition. The supporting rationale stems from evaluation of a vast number of critical inpatient events that were preceded by changes in the patient’s condition. Furthermore, hospitals standards require, in writing, early warning signs of clinical deterioration be determined and that a specific plan be in place for staff to call for assistance. Prior to this edition of standards, TJC (2010) issued a sentinel event alert #44 to assist with preventing maternal deaths. A suggested action for hospitals was to “identify specific triggers for responding to changes in the mother’s vital signs and clinical condition and develop and use protocols and drills or responding to changes” (TJC, 2010, p. 3).

Clinical Deterioration Recognition. Cantwell et al. (2011) report that new staff, of all levels, lack the clinical knowledge and skills needed to recognize signs of deterioration. This position is evidenced by healthcare providers failing to distinguish the signs and symptoms of certain pregnancy conditions and others who failed to identify when a female was becoming seriously ill. When the early warning signs of clinical deterioration are unrecognized in routine patients, it remains a challenge to implement early detection with severe illness especially in obstetric patients where physiological adaptations have occurred (Cantwell et al., 2011). The case reviews of maternal deaths in this expert consensus report revealed early warning signs of impending maternal collapse went unrecognized.

Lawton et al. (2010) performed a descriptive study of 29 charts of women who were admitted to an intensive care unit (ICU) who were coded to have a severe acute maternal morbidity. Ten percent of these cases were deemed preventable, and themes were identified that lead to poor patient outcomes which include inadequate diagnosis/recognition of high-risk status, inappropriate treatment, communication problems, and inadequate documentation. Although the number of patients monitored was small, and this study was conducted at a single site, the results can be utilized by other obstetric facilities to hone processes around these preventable events to improve the recognition of clinical deterioration.

After performing retrospective chart audits on 65 ICU admissions, Jonsson, Jonsdottir, Moller, and Baldursdottir (2011) found that an increased respiratory rate was the most common precursor to clinical deterioration. The study measured documentation of vital signs prior to clinical deterioration and subsequent transfer of a patient into the ICU, and it found that the respiratory rate was also the most poorly documented parameter. The authors urge nurses to be alert to the necessity of documenting early signs of deterioration of patients including, specifically, those pertaining to vital signs.

Early Warning Systems (EWS). The United Kingdom has led industrialized countries in promoting initiatives to decrease maternal mortality. The Confidential Enquiries into Maternal and Child Health (CEMACH) is an interprofessional team that meets every three years to review nations' maternal morbidity and mortality trends and to make recommendations, known as "Saving Mothers' Lives" reports, for practice. CEMACH's review of the trends from 2003-2005 culminated in the recommendation of the use an obstetric early warning system.

Swanton, Al-Rawi and Wee (2009) reported on the United Kingdom's efforts to develop a universally valid EWS that accommodates the obstetric patients' physiological changes during

pregnancy. A mail survey to members of the Obstetric Anesthetists' Association was conducted to ask for opinions on the value of an obstetric early warning system as well as how one could be implemented. Of the 71% of respondents, 89% thought it would be possible to implement an obstetric EWS if it was simple, "universal, validated, and relevant to obstetric physiology and disease" (Swanton, Al-Rawi & Wee, 2009 p. 254). Of note, 19% (30 hospital units) reported using various forms of an obstetric EWS (Swanton et al., 2009). Using these responses, the authors could develop a paper draft of an obstetric early warning tool, and they distributed it for validation. Swanton et al.'s (2009) persistence led to the alteration of the EWS triggers from adult services to incorporate the physiological parameters of pregnancy. The resulting Modified Early Obstetric Warning System (MEOWS) would develop into a paper, color coded tool designed to detect early signs of clinical deterioration through monitoring vital signs. The MEOWS soon became a useful tool, and, although it had not yet been validated, subsequently gained widespread acceptance.

The adoption of the use of an EWS gained momentum within a just few short years. Five years after evaluating the anesthetists' opinions of the implementation of an EWS, Isaacs et al. (2014) conducted a follow-up survey. By querying 205 lead obstetric anesthetists about the use of an EWS for their patients. These authors aimed to identify which EWS was currently in use within obstetric practice, exactly which physiological parameters were included, and authors asked for comments on problems associated with the EWS. With 130 completed surveys returned, all providers reported they used an EWS a significant numerical gain from the 19% that Swanton et al. (2009) originally reported. The respondents reported that MEOWS were used in 45% of the units, a modified version was in use in 50% of the units, and a different system was in place within 5% of the units (Isaacs et al., 2014). Of the lead anesthetists who completed the

survey, 118 (91%) agreed that the obstetric morbidity rate was improving since the implementation of an EWS. The six physiological parameters the respondents routinely utilized through various versions of obstetric EWS include the following: respiratory rate, heart rate, temperature, and oxygen saturation along with both the systolic and diastolic blood pressures readings. All versions of an EWS utilized in obstetric units evaluated in this study “track” parameters for trends, or they use a “trigger” system where single, multiple, or aggregate-weighted scoring systems identify the need for a patient evaluation by a provider.

Carle, Alexander, Columb, and Johal (2013) ventured to validate an aggregate-weighted early warning scoring system aimed for use outside of the ICU setting. A retrospective audit of direct obstetric admissions to ICU’s in the United Kingdom, Wales, and Ireland was performed. The charts were collected from the National Audit and Research Centre (ICNARC) Case Mix Programme (CMP), and the authors utilized a random allocation method of assigning direct obstetric intensive care admissions into a development (n=2240) or validation group (n= 2200). The statistical and clinical early warning scores were internally validated. The area under the receiver operating characteristic curve was 0.995 (95% CI 0.992-0.998) for the statistical score and 0.957 (95% CI 0.923-0.991) for the clinical score. This aggregate-weighted score was compared to other empirically designed early warning scores, and results indicate that this clinical obstetric early warning score can distinguish between survivors from non-survivors in this ICU data set. The authors’ next steps would be to validate this tool outside of the ICU for use on ward patients.

Singh, McGlennan, England, and Simons (2012) set out to validate the United Kingdom’s recommended MEOWS tool by measuring its sensitivity, specificity, and predictive value. They reviewed 676 consecutive obstetric admissions, through a retrospective audit, to

evaluate patient's MEOWS triggers. The MEOWS was 89% sensitive (95% CI 81–95%) and 79% specific (95% CI 76–82%), with a positive predictive value of 39% (95% CI 32–46%) and a negative predictive value of 98% (95% CI 96–99%). This study suggests that MEOWS is a useful bedside tool for predicting morbidity not mortality. The authors suggest further research should aim at evaluating adjusted trigger parameters to improve positive predictive value.

Mackintosh, Watson, Rance, and Sandall (2014) argue that the use of the MEOWS is “based on intuitive appeal and no validated system for use in the maternity population currently exists” (p. 26). Over the course of seven months, the authors completed an ethnographic study using observations, interviews, and documentary reviews, within two United Kingdom hospitals, in order to evaluate if the MEOWS was a valuable tool for managing maternal complications in the antenatal and postnatal period in women who had risks of morbidity. Observation and interview techniques were utilized to perform an ethnographic study to further understand the MEOWS. They worked with doctors, midwives, and managers to evaluate the complexities of managing risk/s and safety costs, as well as opportunity costs, associated with the tool. Results of the study revealed that the establishment of set triggers assisted healthcare providers to identify shared meanings for maternal complications; however, the use of the MEOWS with patients with low morbidity risks may not prove to be effective. They also call into question its role for routine use versus use solely for individuals with an established risk of morbidity.

The United Kingdom's recommendation/s for routine use of an EWS in obstetric patients began to spread to other regions as a testament to the improved maternal morbidity and mortality rates. Incidentally, the Australian and New Zealand obstetrics and gynecology community sought to perform their own studies. Austin et al. (2014) sought to determine whether the use of an EWS on a tertiary care maternity unit will improve the detection of severe maternal

morbidity, or lessen the severity of illness, among women with severe morbidity. The use of the tool may have reduced the seriousness of maternal morbidity within five cases. It was specifically noted that no patients had a complete set of respiratory rate, heart rate, blood pressure and temperature recordings at every time period.

In the United States, Mhyre et al. (2014) proposed, through the works of the National Partnership for Maternal Safety, that Maternal Early Warning Criteria (MEWC) would facilitate timely recognition, diagnosis, and treatment for patients exhibiting clinical deterioration. The suggested MEWC were extracted as the upper and lower boundary parameters, or “red” triggers”, outlined in the MEOWS presented by Singh et al. in 2012. The group evaluated records and results that trended in favor of a single-parameter risk assessment system that would offer simplicity and specificity. This system would also limit the multi-level scoring systems that “rely on nurses to document, calculate, and interpret the scores” (Mhyre et al., 2014, p. 783). The authors recognized that randomized control trials will be needed to validate the parameters of their suggested single parameter MEWC.

In India, the MEOWS chart emerged as a useful bedside tool for predicting maternal morbidity, and the authors support its routine use (Singh, Guleria, Vaid, & Jain, 2016). As mentioned in earlier studies, the MEOWS uses a “track and trigger” system to monitor physiological parameters which aid in recognition of clinical deterioration at an early stage, ultimately halting clinical deterioration and suffering maternal morbidity and mortality. Incidentally, the MEOWS chart was 86.4% sensitive, 85.2% specificity, 53.8% positive predictability, and 96.9% negative predictability. Parameters also had a significant correlation ($p < 0.05$) with obstetric morbidity.

Hedriana, Weisner, Downs, Pelletreau, and Shields (2015) had an objective to determine “whether predefined maternal early warning triggers (MEWT) can predict pregnancy morbidity” (p. 337), and the aim of the study was to evaluate the use of raw clinical vital signs, values, and clinical symptoms assessed over a period of time since there is no established best-practice early warning system. A retrospective case-control study followed 50 obstetric patients admitted to an intensive care setting throughout seven United States pilot hospitals and 50 obstetric patients that had normal delivery outcomes. Eligible patients were of term (and preterm) gestation, and they were evaluated in triage and subsequently admitted for treatment during antepartum, intrapartum or postpartum timeframes. The patients were admitted to the ICU for vaginal bleeding, hypertension, abdominal pain, labor, ruptured membranes, fever, gastrointestinal symptoms, and other symptoms that required evaluation. The six MEWTs evaluated were heart rate, mean arterial pressure, respiratory rate, oxygen saturation, temperature, and altered mental states. Of the 50 obstetric patients admitted to the ICU, 12% were diagnosed with pre-eclampsia.

Results showed that the presence of two or more MEWTs warranted further evaluation/or escalation of notification of the obstetric provider. The authors could conclude that MEWTs seemed to separate normal obstetric patients from candidates who presented with a clinical condition that warranted an intensive care admission for monitoring this indicates their use might reduce maternal morbidity (Hedriana et al., 2015). The strength of this study lies in its enabling normal vital sign values to be discriminated against abnormal values as evidenced by the fivefold lower rate of false-positives in the control group, as well as the 50 patients who had a normal delivery outcome. Limitations of the study include a/the small sample size, the nonrandomized design, and the lack of prospective data analysis (Hedriana et al., 2015).

Expanding on the benefits of EWS's here in the United States, Shields et al. (2016) assessed whether a reduction in maternal morbidity could occur through the implementation of a maternal early warning trigger (MEWT) tool that was designed as a clinical pathway tool. Sepsis, cardiopulmonary dysfunction, preeclampsia-hypertension, and hemorrhage, the four most common maternal morbidities, were the maternal conditions the tool addressed. Assessments and management recommendations for these conditions were also built into the pathway to streamline decision making. The pilot tool was implemented in 6 hospitals that are part of a large hospital system. The other obstetric sites for the system served as "non-pilot" sites during two of the study time periods. The CDC defined severe maternal morbidity, composite maternal morbidity, and ICU admissions were used as the outcome measures. The study was conducted with two time intervals to analyze the effect of the MEWT tool: a 24-month baseline control period and a 13-month MEWT study period. A total of 183,191 deliveries were involved in this study that subsequently resulted in significant reduction in maternal morbidity ($P < 0.01$) and composite morbidity ($P < 0.01$). The three most favorable components of the tool are identified as: low alarm frequency and reasonably good predictive value for patients admitted to intensive care units; also, it was tested in hospitals with a wide range of annual deliveries. There were no changes to ICU admissions. The authors report that the nonpilot sites were unchanged with the CDC severe maternal morbidity, composite morbidity, and ICU admissions between baseline and the post-MEWT testing period. The authors concluded that the "variation in hospital delivery services at the pilot sites suggests that this maternal early warning tool would be suitable for use in the majority of maternity centers in the United States" (Shields et al., 2016, p. 527).

Despite the benefits of the EWS mentioned in the above studies, there are still several obstacles to overcome. When designing the study, the paper scoring systems should use the "less

is more” approach, as suggested by Christofidis, Hill, Horswill, and Watson (2015). The authors report that the speed and accuracy within which chart-users determine patient’s early warning scores needed to be evaluated. Novice chart-users (n=47) were given vital signs to record on various types of charts. Their findings suggest that the fastest recordings—with fewest documentation errors—occurred while using a simple chart design without individual scoring rows. The data for complex patients yielded greater response times and greater error rates on all three of the chart designs.

Electronic Early Warning Systems. Behling and Renaud (2015) developed an Obstetric Vital Sign Alert (OBVSA) as their EWS that hinged on a points system derived by documentation in the EHR. The OBVSA uses 6 critical values which are assessed and scored per established ranges 2 deviations above or below normal ranges. A calculated risk score displays visual cues on a dashboard, so the obstetric staff can monitor the patients for postpartum hemorrhage. As a patient’s assessment changes, the values change on the display for constant review. The goal was to quickly identify women who are at risk for clinical compromise and to increase the staff’s critical thinking level in order to stimulate and encourage effectiveness in addressing clinical issues. The database consisted of women who were diagnosed with postpartum hemorrhage during the 8 months of pre-implementation of the OBVSA, and it yielded 44 charts for inclusion. The same inclusion criteria yielded 50 charts during the post-implementation time period. Results of the OBVSA resulted in reduced symptom-to-intervention time in the postpartum hemorrhage patient population. The implications for future practice include switching from EWS tools that were previously print/paper-based as well as to begin to let the EHR collect and display real-time data for patient assessment and improved outcomes.

Schmidt et al. (2015) performed a pragmatic, retrospective, observational study to see if the implementation of a specifically designed computerized program would improve the processes around the recognition of, and response to, patient deterioration. This study was not piloted with obstetric patients, but it did use three main specialties. However, within further studies, the results may be generalized as the “electronic physiological surveillance system (EPSS), was designed to improve the collection and clinical use of vital signs data, reduced hospital mortality” (Schmidt et al., 2015, p. 10). The findings suggest that a system like the EPSS can improve both processes and patient outcomes. Schmidt et al. (2015) do warn that a direct cause-and-effect relationship between the two cannot be established; yet, they confirm that results from two different sites support that the findings of the study are significant.

The United Kingdom has conducted hallmark studies and subsequently offered recommendations for maternity early warning systems through the use of national committees and the Obstetric Anaesthetists’ Association. After years of encouraging the use of a MEOWS, the United Kingdom’s recommendations have been implemented globally, albeit in different versions. Within the United States, vigorous ongoing research is occurring that examines the importance of the use of early warning systems and their ability to detect a patient’s clinical deterioration; however, this research trend does not include examination of obstetric patients. By 2014, The National Partnership for Maternal Safety gathered obstetric providers, here in the United States, to propose the use of maternal early warning criteria, and the committee made suggestions relating to parameters obstetric teams should consider. Collectively, within these studies, limited data exists to suggest that the use of these types of clinical assessment tools can reduce maternal morbidity (Mackintosh et al., 2014; Shields et al., 2016).

Freidman (2015) performed his own analysis of maternal early warning systems in order to document progress in improving maternal morbidity and mortality within the United States. The objective was to review the following strategies that improve maternal outcomes: clinical rationale for EWS including research literature from other specialties, clinical parameters and recommended care in maternal EWS's, research evidence to support use of a MEWS, and future directions for optimizing and validating MEWS's. Friedman (2015) recommends to the obstetric community includes optimization of the alert system performance to avoid false-positive results and to avoid nuisance alarms. Within the systematic review of research evidence, Freidman (2015) found that the United Kingdom's MEOWS alert parameters may detect hemorrhage, sepsis, preeclampsia, and cardiovascular complications. The simplified version of the MEOWS from the United States, the MEWC, offers a one-trigger prompt for bedside assessment. Maternal early warning systems are favorable for reducing severe maternal morbidity and mortality if identification of patients at risk for critical illness result without a high number of false-positive alerts (Friedman, 2015).

Synthesis of Evidence

Despite recommendations from the United Kingdom for use of a maternal early warning system, a validated tool geared specifically for the obstetric population does not exist (Isaacs et al., 2014; Swanton et al., 2009). Early warning systems are utilized, within other populations, with successful recognition of clinical deterioration (Edwards et al., 2016). The National Partnership for Patient Safety began to evaluate vital sign changes in the obstetric patient to develop a tool for recognizing deteriorating conditions for this population (Mhyre et al., 2014). To implement a MEWS in antepartum, intrapartum, and postpartum settings, a single-parameter scoring system may be more practical than an aggregate-weighted scoring system (Mhyre et al.,

2014). Parameters considered for the MEWS are specific to blood pressure, heart rate, respiratory rate, oxygen saturation, urinary output if an indwelling catheter is in place, and altered mental status. Additionally, a MEWS algorithm would identify patient conditions that would prompt a bedside assessment by providers who could activate resources required for diagnostic and therapeutic interventions. Improving systems to recognize and treat early indicators of maternal complications may prevent, or reduce, the severity of these situations (Mhyre et al., 2014).

Gap in Literature

Strong evidence exists highlighting the morbidity and mortality of hypertensive disorders of pregnancy, and that treating *severe range* blood pressures with an antihypertensive in a timely manner improves patient outcomes. Also, EWS have been in use in service lines outside of obstetrics with proven success. Utilizing the workflow and trends of EWS's, several formats of MEWS have been developed as paper tools for abnormal patient assessment parameters. Researchers agree that the MEWS standard should be simple, meaningful, and effective in promoting the avoidance of false-positive alerts. The literature was sparse relative to the evaluation of how the EMR, and real-time documentation by bedside staff, could be utilized as an EWS to detect a patient's clinical deterioration with the obstetric patient population. Notably, limited data exists for Level I-III evidenced based literature involving obstetric patients. This is certainly justified, as it is prudent to not withhold treatment or interventions that have proven or suspected favorable outcomes to conduct Level I-II studies. There remains the need for a national standardized and validated tool, whether in paper or electronic version, to be implemented for hospitals serving obstetric patients to positively impact morbidity and mortality rates.

Evidence Based Practice Model

The Iowa Model of Evidence Based Practice (Appendix H) was used to guide the project. Problem-focused triggers include process measures recognizing elevated blood pressures, administering an antihypertensive medication within one hour and outcome measures (hypertensive patients that experience a stroke or seizure, and hypertensive patients readmitted within 30 days). Incidentally, the clinical problem led to a comprehensive literature review on early warning recognition tools. The project will pilot the change for implementing an electronic early warning system to increase recognition of *severe range* blood pressures and subsequent treatment.

Theoretical Framework

The guiding framework for this evidenced based project is outlined by Avedis Donabedian, MD, MPH which is commonly referred to as “Structure, Process, Outcome” (Donabedian, 1983 & 1988). This model is frequently used when quality assessment is being measured, and it is useful in highlighting links between process and outcomes. Quality needs to be measured prior to, during, and post implementation of any health care practice change. As applied in this scholarly project, *structure* refers to the area within which care is monitored via the EMEWC and is delivered by a provider. *Process* refers to the interactions between parties in which change brings about a result. The EMEWC alarm trigger for elevated parameters and staff web-based training for the monitoring program, Cerner® FetaLink™, serve as processes in this project. *Outcomes* refer to the changes ultimately produced or the effects of the structure and process. Increasing recognition of severe hypertensive episodes, while decreasing time from recognition to medication administration, are this project’s ultimate outcomes. Gardner, Gardner, and O’Connell (2014) exemplify how the Donabedian framework remains applicable within

today's healthcare models. The authors found success with establishing relationships between structure, process, and outcomes through nursing service innovations which laid the groundwork for safe, effective, and patient-centered care. These three components are evaluated to draw conclusions about quality of care as summarized by Donabedian (1988): "good structure increases the likelihood of good process, and good process increases the likelihood of good outcome" (p. 1745).

Summary

It is difficult to recognize that an obstetric patient's condition is deteriorating, because normal physiological changes in pregnancy generate significant shifts in maternal vital signs. Literature reveals that 40-50% of maternal deaths can be attributed to delays in recognition, diagnosis, and treatment including deaths from hypertensive disorders (Cantwell et al., 2011; Lawton et al., 2010). ACOG (2015b) recaps and advises that adverse outcomes often occur because of failed system deficiencies or inadequate safety measures which are in place to prevent error/s. The use of EMEWC will assist with establishing standardization of care by decreasing variation in nurses' and providers' recognition and treatment plans.

The time has come to leverage the use of technology to improve clinical outcomes. Through bedside monitoring functionality of the Cerner® FetaLink™ program, clinical parameters can be established, and notifications can alert the nursing staff when patients present outside of the desired range. The healthcare system, overall, has experienced a reduction in adult mortality by utilizing Cerner® to recognize a patient's clinical deterioration through alerts designed to identify abnormal parameters established for sepsis recognition. The healthcare system is ready to share a variety of the lessons learned, via its use of Cerner®, to other disciplines and various other patient conditions. The purpose of this project is to evaluate

whether the use of the electronic maternity early warning criteria (EMEWC) improves rates of treatment of *severe range* blood pressures, within one hour, through the recognition of abnormal vital signs and notification prompts to providers.

Chapter III: Methodology

Needs Assessment

Prior to the implementation of this project, the hospital had been working to increase its compliance rate in treating patients' first *severe range* blood pressure. Provider and nursing education as related to the treatment standard, developing antihypertensive protocols in order for providers to have easy access to evidence based guidelines, and reporting outcomes at the hospital level have been implemented within the last eighteen months of this study. A literature search was performed/implemented to gain insight about the tools that are typically utilized to recognize deteriorating patient conditions and improve patient outcomes. The key stakeholders include the nursing staff, the providers, hospital administrators, the quality department, and, finally, the information services division.

Project Design

Purpose. The purpose of this evidence based project is to determine if the use of the EMEWC will increase treatment of *severe range* blood pressure—within one hour of recognition—in a cohort of hypertensive obstetric patients hospitalized in L&D and HROB units.

Question. The guiding PICO question follows: In hospitalized obstetric patients with a hypertensive diagnosis (P), will the use of the EMEWC (I), measured pre-and post-implementation (C), increase the rate of an antihypertensive medication administered within an hour of a patient's *severe range* blood pressure occurrence (O)?

Design. Data collection will occur on all obstetric patients in L&D and HROB units at the project facility with severe hypertension blood pressure readings. Pre-and post-implementation data will be evaluated.

Participant Setting and Sample. The project facility is a regional 457-bed, not-for-profit medical center located in the southern piedmont region of North Carolina, in the United States. The project facility delivers approximately 240 patients per month, and it serves patients of all races, ages, and pregnancy complications; additionally, it is a referral center for the surrounding five-county area. The labor and delivery (L&D) unit has 12 suites, 4 triage bays, and 2 operating rooms. The 8-bed high risk obstetric (HROB) unit admits antepartum and postpartum patients, as well as patients who are readmitted for a pregnancy complication within 30 days of discharge. Care is coordinated between obstetrics and gynecology (OB GYN) hospitalists, private practice OB GYNs, family practice attendings and residents, and two maternal fetal medicine providers as well as five neonatologists who accept patients into the Neonatal Intensive Care Nursery as early as 26 weeks' gestation.

All obstetric patients admitted to L&D and HROB with a *severe range* blood pressure (sBP 160 mm Hg or higher and/or dBP of 110 mm Hg or higher) will be included in this evidence based practice project. All the population will be measured; therefore, no random selection is required. Inclusion criteria are as follows: an inpatient obstetric admission to the L&D and HROB units regardless of the patient's pregnancy status; an ICD 10 patient diagnosis of any level of classification of hypertension in pregnancy; a patient's first severe blood pressure at any point during their inpatient admission; all maternal patients, regardless of age, parity, gestational age, insurance status, provider group, and/or any level of co-morbidity. Exclusion criteria are as follows: patients who deliver within one hour of the inpatient admit date and time, an obstetric patient in the operating room, or in an intensive care bed space. Patient data that is triggered by Cerner® FetaLink™ will be evaluated and confirmed through nursing assessment of the patient before interventions will be implemented.

Measures. The process measure for this project is to evaluate the percentage of patients who received an antihypertensive medication within one hour of the onset of a *severe range* blood pre-and post-implementation of the EMEWC. The goal, 3 months following post-implementation of the EMEWC, will be a 60% rate of administration of an antihypertensive medication within one hour of the onset of a *severe range* blood pressure.

Protocol. The steps of the project follow:

1. Information Services will coordinate the installation of the Cerner® FetaLink™ program on the hospitals nursing units of L&D and HROB in November 2016.
2. A web-based tutorial for the Cerner® FetaLink™ program will be secured, from Cerner®, to train all nurses hired on L&D and HROB units. The training module will be assigned to each staff through their *PeopleLink@CHS* talent management system that tracks educational requirements of staff.
3. This will be an interactive web-based training module that reviews the functionality of systems including how to address alerts and how/ways to document annotations (Appendix I) which will take approximately 30 minutes to complete.
4. The staff will be given a case scenario to complete, at the end of the module, that will demonstrate how the objectives of the program were met. Once the training objectives have been met, a certificate of completion will be printed, at the end of the module, that will be submitted to the manager. A roster will be kept, by the nurse management team, to ensure accountability of module completion by all nurses before they can work on the unit post-implementation of Cerner® FetaLink™.
5. The Project Lead will serve as a resource for staff, to encourage and support training, and he/she will be a resource post-implementation of Cerner® FetaLink™.

6. After training, the Cerner® FetaLink™ program will be “activated” on both L&D and HROB bed spaces.
7. Within Cerner® FetaLink™, the upper bound parameter alarms will be set for blood pressure readings: systolic greater than and equal to 160 mm Hg and diastolic greater than and equal to 110 mm Hg.
8. If a patient’s condition meets the upper bound limits of sBP 160 mm Hg or higher, and/or dBP of 110 mm Hg or higher, an audible alert will sound. The nurse will confirm the patient’s condition via a bedside assessment, and he/she will document appropriate annotations for monitoring and treatment interventions (Appendix J).
9. For a *severe range* blood pressure, the nursing staff will recheck the patient’s blood pressure to confirm the sustained elevation.
10. If the patient’s first *severe range* blood pressure remains elevated for greater than 15 minutes, the nurse will notify the provider of the patient’s condition and obtain an order for an antihypertensive treatment medication. This patient will be captured in the protocol, and she will be monitored for the medication administration time.
11. If the patient’s *severe range* blood pressure doesn’t not remain elevated for greater than 15 minutes, the nurse will continue to monitor the patient throughout her daily workflow. This patient would not be included in the measure due to the fluctuation in her blood pressure measurement.
12. The Cerner® EHR serves as the source of data. A SAP® BusinessObjects report, built by the Dixon Advanced Analytics team, within the healthcare system, will pull patient data medical records per the inclusion and exclusion criteria. The report highlights the date and time of the patient’s *severe range* blood pressure readings, as well as the date and

time of administration of the first antihypertensive medication. The reports developed by Dixon Advanced Analytics are validated against the medical record documentation at the time of the build.

13. A patient's date and time of a *severe range* blood pressure will be evaluated against the patient's medication administration record for timing of an antihypertensive medication.
14. A fallout will be assessed if the antihypertensive medication was administered greater than 1 hour of the first *severe range* blood pressure.

Analysis Support. The mentor for statistical support will be Dr. Julie Thompson from Duke University. As project lead, I calculated project statistics, and Dr. Thompson confirm the results. Professors at the East Carolina University College of Nursing were also available to help guide the statistical analysis upon request.

Data Collection and Analysis. Data collection occurred on all patients at the project facility with a diagnosis of hypertension during pregnancy. Descriptive statistics (N, %) were evaluated for patients who received an antihypertensive medication within one hour of a *severe range* blood pressure in order to determine if the goal (60 %) was met after three months. These patients were labeled as "treated". If the patient was not administered a medication within one hour of the elevated severe range blood pressure, the label of "not treated" was applied. A 2-x-2 Chi-Square Fisher's Exact test was conducted to compare the rate of administration of the antihypertensive medication for a *severe range* blood pressure, before and after implementing the electronic early warning system, through the Cerner® FetaLink™ program.

Baseline data for 2016 is a 15.5% rate for administering an antihypertensive within one hour of the onset of a *severe range* blood pressure. Data was collected, retrospectively, for three months' post implementation of the EMEWC. No demographic data will be collected for this

project, as *severe range* blood pressures can occur with any pregnant patient either pre-or post-delivery. The data will have patient identifiers that include the medical record number, and the patients account number, per the build of the data abstraction tool. The Hypertension Report that will be populated with data abstraction from the EHR that will have patient identifiers will be secured within the PI's Microsoft Office 365 password protected account; this account is provided by the healthcare system's Information Services department. No consents, tools, forms, or papers will be required for this project. IBM SPSS (2013) will be used for statistical analysis after patient identifiers have been removed. Alpha will be set to .05.

Limitations. The use of "non-equivalent" assignment acknowledges that the investigator did not control the assignment into the project; therefore, the groups' pre-and post-intervention participant's numbers may be different. Of specific note, here, is that any prior differences could potentially affect the project's analysis. This set up could lead to the conclusion that the EMEWC did not make a difference when it actually did, or the opposite could be true, and results could presume that the EMEWC did make a difference when it, in fact, did not.

Future Plans

A long-term set of outcome measures, that will not be realized during the specific timeframe of this project, will be used to evaluate the number of hypertensive patients that develop a stroke, hypertensive patients that experience a seizure, and 30-day readmission rate for postpartum patients with a hypertensive diagnosis. This data is currently monitored through the Quality Department with data abstraction occurring periodically. Should the result of this project implementation show valued increase in the use of EMEWC, Information Services, and the Nursing and the Quality Department, would like to expand the monitoring system to incorporate

several signs of clinical deterioration including quantitative blood loss measurements. The project has potential to expand to other obstetric facilities within the healthcare system.

Estimated Resources and Costs

Cerner® FetaLink™ software has secured financial support for its purchase and installation, and for staff training, from the hospital system. The monitoring of data, and subsequent data analysis, will be performed by the Doctorate in Nursing Practice student, and relevant information will be incorporated into the Clinical Nurse Specialist role and responsibilities to improve patient care.

Chapter IV: Results

This chapter presents the results of the data analysis which includes sample characteristics and major findings. The quality improvement project spans 14 months. The nine-month pre-implementation period occurred during calendar months January through September. The installment, training, and utilization of Cerner FetaLink™ serves as the implementation phase which lasted for two months. The post-implementation phase is represented by three calendar months: December, January, and February. Data was collected using a report that analyzed obstetric patients' diagnosis code of hypertension and the date and time of the patient's first *severe range* blood pressure reading, as well as the date and time of administration of the first antihypertensive medication. Due to the automated monthly EHR Hypertension Report, there are no missing cases. The small sample size afforded the use of the 2-x-2 Chi-Square Fisher's Exact test to compare the rate of administration of the antihypertensive medication for a *severe range* blood pressure labeled in the data as "treated".

Sample Characteristics

The EHR Hypertension report recognized 103 obstetric patients diagnosed with a hypertensive disorder who met inclusion and exclusion criteria. The pre-implementation phase included 71 obstetric patients who met criteria in which 11 (15.5%) were treated within one hour of the *severe range* blood pressure. The post-implementation phase included 32 obstetric patients who met criteria in which 7 (21.9%) were treated within one hour of the *severe range* blood pressure. Table 1 offers a display of the obstetric patients who were included in the quality improvement project, and it denotes the pre-and post-intervention data compared for treatment groups. Data for treatment outcomes was collected monthly as noted in Appendix K.

Table 1

Antihypertensive Treatment Rates During Pre-and Post-Implementation Phase

			Implementation Phase		Total
			Pre	Post	
Treatment Outcome	No Treatment within 1 Hour	Count % Not Treated	60 84.5%	25 78.1%	85 82.5%
	Treatment within 1 Hour	Count % Treated	11 15.5%	7 21.9%	18 17.5%
Total		Count	71	32	103
		% Population	100%	100%	100%

Each subscript letter denotes a subset of PrePost categories whose column proportions do not differ significantly from each other at the .05 level.

Major Findings

The target goal for the project facility was to reach a 60% treatment rate of an antihypertensive for patients with a *severe range* blood pressure. There was a 71% rate of increase in patients treated from the pre-implementation phase (15.5%) to the post-implementation phase (21.9%). The Chi-Square Fisher’s Exact test (Table 2) was utilized to evaluate the two categorical variables study phase and treatment outcome from the single study population of antihypertensive obstetric patients. A 2-x-2 contingency table was established in IBM SPSS (2013) to compare the percentage of treated patients during pre-and post- intervention phases. The minimum expected cell frequency was five or greater, so the project did not violate any Chi-Square test assumptions. The Chi-Square Fisher’s Exact test indicated no significant associations between pre-and-post intervention and treatment timing with an antihypertensive medication, $\chi^2 (1, n = 103) = p = .42$. Although there was an increase in the treatment percentage from 15.5% to 21.9%, the improvement was not statistically significant.

Table 2

Chi-Square Tests for Project Significance

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.623 ^a	1	.430	.418	.300
Continuity Correction ^b	.259	1	.611		
Likelihood Ratio	.604	1	.437		
Fisher's Exact Test					
Linear-by-Linear Association	.617	1	.432		
N of Valid Cases	103				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5.59.

b. Computed only for a 2x2 table

Chapter V: Discussion

Despite efforts to reduce maternal mortality, opportunities remain for improved outcomes, as approximately 600 women die annually, within the United States, from complications of pregnancy and delivery (CDC, 2016a). Cantwell et al. (2011) find that delays in recognition, diagnosis, and treatment of patients experiencing signs of clinical deterioration remain significant contributing factors to maternal death/s. Hypertensive disorders complicate approximately 10% of pregnancies, and patients with hypertensive disorders often experience *severe range* blood pressures during pregnancy. ACOG (2015a, 2013) recommends treatment for the onset of a severe range blood pressure with an antihypertensive medication within one hour of recognition. Treating the hypertensive crisis in pregnancy can impact the complications that may lead to mortality.

Limited data exists on the use of EWS in hospitalized obstetric patients. It was proposed that the use of EMEWC can aid in the evaluation of the obstetric patient's clinical picture and alert nursing staff for a bedside assessment in the event of abnormal parameters. The purpose of this Doctorate in Nursing Practice quality improvement project is to determine if/whether the use of EMEWC will increase treatment of *severe range* blood pressure, within one hour of recognition, in a cohort of hospitalized obstetric patients with a diagnosis of hypertension. The project facility realized an increase in the rate of an antihypertensive within one hour of onset of a severe range blood pressure in the target population after the implementation of Cerner® FetaLink™ although the results are not statistically significant.

Project Results Relation to Theoretical Framework

The guiding “Structure, Process, Outcome” framework by Donabedian highlights links between the three phases for increased quality. *Structure* was applied in the obstetric units when the providers established a standard treatment approach for hypertensive patients with a *severe*

range blood pressure to receive treatment with an antihypertensive medication within one hour. Although the standard was in place, the nursing staff were unable to consistently recognize the elevated blood pressure specifically due to various forms of input of vital signs into the EHR.

Process was offered with the implementation of the Cerner® FetaLink™ program which served as an EWS for nursing staff. The program was set with an EMEWC alarm trigger (i.e. elevated blood pressures for sBP of 160 mm Hg or higher and dBP of 110 mm Hg or higher). The alarm has both distinct audible and visual alerts. The staff utilized a web-based interactive training program in order to familiarize themselves with the software. Throughout the two-month dates of implementation, staff were offered individual training on the use of the program, ways to address vital signs, and ways to pull the patient data from Cerner® FetaLink™ into the EHR.

Outcomes, the changes produced, or the effects of the structure and process, were improved for administering an antihypertensive within one hour of a patient's severe range blood pressure. Although not significant, the project facility experienced a 71% rate improvement during the three-month post-implementation phase. The staff could increase recognition of severe hypertensive episodes when the Cerner® FetaLink™ program alerted them to a change in a patient's condition. In turn, this decreased the time from *severe range* blood pressure recognition to that of medication administration. This quality improvement project supports the Donabedian framework, as relationships were established between structure, process, and outcomes.

Significance of Results to HealthCare

The implementation of the Cerner® FetaLink™ software allowed for patient's deteriorating clinical conditions to be monitored continuously, and it offered the capability to alert healthcare staff when parameters for assessments were outside of defined limits. For this

quality improvement project, the EMEWC of *severe range* blood pressures was evaluated although this was just one piece of the software's functionalities. Incidentally, other software functions are available to monitor clinical deterioration which include abnormal lab values, all aspects of vital signs, patient assessment's outside of normal defined limits, and fluid volume. This project's focus concentrated on administering a medication to improve outcomes; however, data from EWS can serve to improve mortality rates as well as to lower transfers to intensive care units from inpatient hospital beds. The key finding for this quality improvement project reveals that increasing trends in treatment within an hour for a *severe range* blood pressure should be noted by facilities that are evaluating the implementation of software that scans patient clinical conditions in the EHR to improve outcomes.

There are national programs that support healthy patient outcomes in obstetrics. Health People 2020 (Maternal, Infant, and Child Health, 2016) set target goals to reduce the rate of maternal mortality, as well as, the rate of maternal illness and pregnancy complications. The Institute for Healthcare Improvement (2017) aims to motivate and build the will for change in patient outcomes, identify and test innovative models of care delivery, and ensure the broadest possible adoption of proven practices that improve health. To prevent maternal deaths and complications that occur during the labor and delivery process, the EHR needs to function in partnership with healthcare professionals by utilizing alert functions when signs of clinical deterioration are recognized. As the obstetric community increases its adoption of versions of MEWS (Mackintosh et al., 2014; Mhyre et al., 2014; Singh et al., 2012) to identify abnormal assessment parameters, the rate of maternal deaths and poor pregnancy outcomes should decline. This scholarly project serves as a foundational study that adds to the body of knowledge for tools and interventions that improve pregnancy outcomes using electronic MEWS.

Project Strengths and Limitations

Strengths. Several strengths of the project were specifically identified. Cerner® FetaLink™ software allowed customization of within normal limits parameters. The project facility set the EMEWC for elevated sBP at 160 mm HG and for dBP of 110 mm Hg. If a patient's clinical data hit either elevated parameter, a visual cue appeared on the Cerner® FetaLink™, and it emitted a distinct audible alert that was both seen and heard in the patient's hospital room and at each nursing station. The parameter was easily agreed upon via support within the literature. The project facility's obstetric providers had also agreed upon a treatment standard of care of *severe range* blood pressures that included specific antihypertensive medications, dosages, and routes of administration. The pharmacy had also approved the standard of care treatment, and it had placed all the appropriate medications on override so that a nurse could administer them without any delay. The specific defined *severe range* blood pressure alerts, providers' approving one treatment standard of care, and the pharmacy's working with the team to accept nursing oversight for medication management allowed this quality improvement project to focus on the new tool: Cerner® FetaLink™ intervention to assess rates of improvement in the antihypertensive medication administration.

An additional strength can be attributed to the use of the Hypertension Report that pulled data from coding, then pulled blood pressures, followed by medication names with dates and times of administration. Objective data is "clean" and free of researcher bias. The patients in the population met all inclusion and exclusion criteria, and the results could be replicated by any other investigator.

Limitations. Limitations of the study may have impacted the less than significant outcome. The project's population was pulled by the EHR Hypertension Report which pulled

final diagnosis coding which occurs after a patient's discharge. The first *severe range* blood pressure may have occurred early into the patient's inpatient admission before a hypertensive diagnosis was suspected. In this case, nursing staff would not be following the hypertensive treatment standard of care and may have missed the one-hour window of administration time.

Cerner® FetaLink™ functions in a manner in which delays can occur. Although vital signs are automatically assessed by the software, the data must be recognized and verified by a nurse which allows the crossover from the program to the EHR for the date and time stamp the data was *collected*. At that point, the audible and visible alert would fire for abnormal parameters. Timing of data entry impacts alerts, and the subsequent care will be provided. Both delays in recognition of hypertensive coded patients, and data recognition and verification of vital signs, may have impacted the project's outcomes.

Limitations also occur in the form of lessons learned during a project's implementation. Staff training and go-live support on new equipment must be multifaceted. The web-based training was helpful but not realistic, and it could not identify every circumstance a nursing staff member may encounter with their patients. The training included information on hardware, software, functionality and charting; whereas, this project's focus was on the recognition, verification, and entering of blood pressures. Perhaps one function of an intervention could have been hard-wired instead of a large software upgrade where bits and pieces of training were remembered. Go-Live support was provided by Information Services staff for two weeks around the clock. Despite best efforts, each nurse was not able to use the Cerner® FetaLink™ software to its full potential during that time. Training was continued, with individual nurses, as requested by staff, and during shift-huddles to educate individuals and address frequently asked questions and quality reports pulled from the software.

Another lesson learned by this project lead is that projects may have set time criteria where pre- and post-intervention phases cannot be equal. In this project, the nine-month pre-intervention allowed for many points of data to be collected. Within time constraints to complete this Doctorate in Nursing Practice quality improvement project, only a three-month post-intervention phase was evaluated. The short time frame allows for a rate to be determined to meet project terms, but a longer post-implementation period may have lead statistically significant results.

Benefit of Project to Practice

The contribution of this quality improvement project is that it supports the growing need for utilizing EWS to improve patient outcomes. More specifically, EMEWC, within those EWS, can identify clinical deterioration in the obstetric population that is often omitted from quality initiatives. Although the project facility aimed to achieve a 60% rate of an antihypertensive medication within one hour of a *severe range* blood pressure, a 71% rate of increase of patients treated from the pre-implementation phase (15.5%) to the post-implementation phase (21.9%) was achieved. It is important to note that blood pressure is just one data point that was being evaluated which serves as a foundational study toward developing an electronic MEWS. There exists the ability, with EMEWC, to set parameters on assessments that include pain scale, temperature, heart rate, respiratory rate, quantitative blood loss, and lab values along with any documented nursing physical assessment detail. This could lead to assisting with other maternal mortality complications of pregnancy and delivery that include hemorrhage, seizures, and infections. It is important, now, to focus specifically on availability the EHR identify signs of clinical patient deterioration, alert the healthcare staff to intervene, and to conduct a bedside assessment as well as to develop a treatment plan.

The American Association of Colleges of Nursing Essentials of Doctoral Education for Advanced Nursing Practice (2006) outlines eight core competencies that programs must address. This scholarly project was conducted to assist with fulfilling the requirements of the DNP program at East Carolina University. In conjunction with other DNP didactic courses and objectives, each DNP essential was addressed as identified in Appendix L. I am obligated as a DNP to continue with a scholarly approach to the nursing discipline and will commit to advancing the profession through implementing additional quality improvement initiatives. This project serves as a training process so that I can continue to advance nursing practice and impact patient outcomes.

Recommendations for Practice

Practice. The results of this project trend, within a favorable direction, toward the use of EWS to aid in identifying clinical deterioration. Nursing staff need to incorporate trends in patient assessment findings, and apply critical thinking skills on how to intervene when a patient's condition warrants. As nurses grow professionally they often change positions which lends newly-hired staff to remain on the night or weekend shifts where fewer hospital resources and seasoned peers, are readily available for consultation and intervention. The EWS can well be an additional tool to assist with staff who are less experienced and often those who lack certain critical thinking skills.

Education. The nursing discipline can incorporate low or high-fidelity simulation into assessment and intervention training. This can be achieved in nursing schools as well as to hone skills of nurses already in the profession for ongoing training. Simulation training can incorporate changing patients' conditions to bring awareness to assessments and subsequent interventions for each. An EWC should aid in the identification of clinical deterioration, and, notably, it should not be the first line of assessment in patient care.

Policy. Depending on the use of an EWS, most parameters and alerts will need to be based upon evidence based standards and guidelines. Policy and clinical standards may need to be developed or approved to identify a standard of care or parameters for within defined limits. That policy or practice will be used by a facility's Information Services team to set software alerts for patient conditions that fall outside of normal values.

Research. The United Kingdom was the first nation to extend efforts to develop a national plan to address maternal mortality. It has taken years to develop, but this body of research is beginning to evaluate obstetric early warning systems and scores or tools that will assist with recognizing clinical deterioration. I believe future research should continue to work towards developing a national standard of care for identifying changes in conditions in obstetrical patients, and it should offer a subsequent set of standard interventions to that specific end. An example would be for an obstetrical patient with a hypertensive diagnosis who has a *severe range* blood pressure--not only would the EHR alert staff, but it would assist with ordering the antihypertensive medication and check lab values. If a liver function test had not been ordered, a task could trigger it to place an order to collect labs. Everything would be documented electronically. Finally, in the opinion of this researcher, it appears time the EHR works to coordinate all the entries to identify patient trends with a goal of improving each and every maternal outcome.

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Appendix A
Organization Letter of Support



Carolinus HealthCare System

July 21, 2016

To Whom It May Concern:

We at Carolinus HealthCare System NorthEast have reviewed Mary M. Bowers' DNP Scholarly Project titled "The Use of Electronic Maternal Early Warning Criteria to Improve Treatment of Hypertension in Hospitalized Obstetric Patients". Mrs. Bowers has organizational support and approval to conduct her project within our institution. We understand that for Mrs. Bowers to achieve completion of the DNP program, a poster presentation of the scholarly project will be required by the University.

Our organization has deemed this project as an evidenced based practice initiative that will be reviewed by our Nursing Scientific Advisory Council and submitted for expedited review by the institutional IRB.

Thank you



Rebecca H Dunlap RN, BSN, MHA, NEA-BC

Assistant Vice President, Patient Care Services

CMC-NorthEast, Nursing Administration

Carolinus HealthCare System

Office: 704-403-3219

Mobile: 704-591-4537

Mailing: 920 Church Street, North, Concord, NC 28025

Appendix B

Carolinas HealthCare System - NSAC Approval



Carolinas HealthCare System

Nursing Scientific Advisory Committee (NSAC)

October 3, 2016

Mary M. Bowers

Carolinas HealthCare System NorthEast

RE: Protocol: #025-16: Use of electronic maternal early warning criteria to improve treatment of hypertension in hospitalized obstetric patients

Dear Mary,

The Nursing Scientific Advisory Committee has considered your protocol, **Use of electronic maternal early warning criteria to improve treatment of hypertension in hospitalized obstetric patients** and elected to give your study *full approval*. You may initiate your project pending sanction by the IRB or IACUC, as required, and supportive funding. If you will be utilizing the lab, radiology or pharmacy for your research please contact the following (Lab: Pat O'Rourke 355-5596; Radiology: Jeff Aho 355-3612; Pharmacy: Ryan Bender 355-5142). If at anytime you wish to revise your protocol, please submit the revision for our review. We would also like to know when you have completed your project.

Best of luck with your investigation. Please refer to the research policy dealing with research conduct (**ADM 240.01**) located in the CHS Policy and Procedure & Procedure Manual. Should you have any questions or concerns, please contact Dr. Gayle Casterline (704-355-0765, gayle.casterline@carolinas.org) or Dr. Maureen Fogle (704-355-1337, Maureen.fogle@carolinas.org).

Sincerely,



Gayle Casterline, RN, PhD
Chair, Nursing Scientific Advisory Committee

Appendix C

Carolinas HealthCare System IRB Determination

RECEIVED
 SEP 09 2016
 CHS IRB

CAROLINAS HEALTHCARE SYSTEM
 Institutional Review Board / Patient Privacy Board

IRB Review & Determination of QI vs. Research Projects

The form must be completed in entirety

Submission Date: 9/8/16	IRB Tracking #: (To be supplied by the IRB)
Project Lead: Mary M. Bowers	Dept.: Nursing Clinical Education Services Carolinas HealthCare System NorthEasy
Phone: 704-403-1416	E-mail: Marylou.bowers@carolinashealthcare.org

Project Title: The Use of Electronic Maternal Early Warning Criteria to Improve Treatment of Hypertension in Hospitalized Obstetric Patients

Is the project supported by funding?

Yes – Federal or Foundational funding, please provide copy of grant proposal with this form

Yes – Industry sponsored

Yes – CHS internal funding

No

Purpose of the project: Provide a 2-3 sentence description

The purpose of this project is to evaluate if the use of the electronic maternity early warning criteria improves rates of treatment of severe range blood pressures within one hour through the recognition of abnormal vital signs and notification prompts to providers. The project will include hospitalized obstetric patients that are admitted to two of the facility's nursing units: Labor and Delivery (L&D) and High Risk Obstetric (HROB).

Briefly describe project details, including how patients and/or providers will be involved:

All obstetric patients admitted to LD and HROB with a severe range BP will be included in this evidence based practice project, then, 100% of the population will be measured. Inclusion criteria are as follows: an inpatient obstetric admission to the L&D and HROB units regardless of the patient's pregnancy status; an ICD 10 patient diagnosis of any level of classification of hypertension in pregnancy; a patient's first severe blood pressure at any point of their inpatient admission; all maternal patients regardless of age, parity, gestational age, insurance status, provider group, and any level of co morbidity. Exclusion criteria are as follows: patients that deliver within one hour of the inpatient admit date and time, an obstetric patient in the operating room or in an intensive care bed space. Patient data that is triggered by Cerner FetaLink will be evaluated and confirmed through nursing assessment of the patient before interventions will be implemented. If a patient's condition meets the upper bound limits, an alarm will sound. The nurse will confirm the patient condition through a bedside assessment and document appropriate monitoring and or treatment interventions (Appendix D) which will silence and reset the alarm. For a severe range blood pressure, the nursing staff will recheck the patient's blood pressure to confirm the sustained elevation. If the patient's severe range blood pressure remains elevated for greater than 15 minutes, the nurse will notify the

*Adapted from the Stanford University Research Compliance Office Determination of Human Subject Research screening form

QI vs. Research Screening Form
v. 1.0
3.25.15

CAROLINAS HEALTHCARE SYSTEM
Institutional Review Board / Patient Privacy Board

IRB Review & Determination of QI vs. Research Projects

provider of the patient's condition and obtain an order for an antihypertensive treatment medication. A SAP® BusinessObjects report built by the Dixon Advanced Analytics team within the healthcare system will pull patients medical records according to the inclusion and exclusion criteria. The report highlights the date and time of the patient's severe range blood pressure readings as well as the date and time of administration of the first antihypertensive medication. A patient's date and time of a severe range blood pressure will be evaluated against the patient's medication administration record for timing of an antihypertensive medication. A fallout will be assessed if the antihypertensive medication was administered greater than 1 hour of the first severe range blood pressure. Providers will be involved when the nurse calls to report the severe range blood pressure.

Is this project Quality Improvement (QI)?

Quality Improvement includes activities that have purposes limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes. Improvement projects are limited to a setting of care and do not seek to make universal changes to evidence-based care.
 See CHS Policy http://documents.carolinas.org/Research/QI_vs_Research_Definition.pdf.

	Yes	No
Do you consider this project to meet the definition of QI as noted above?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the activity primarily designed to:		
1. Improve clinical care at CHS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Apply to patients or populations beyond your specific study population?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Is this project Research?

Research is "a systematic investigation, including research development, testing and evaluation that is designed to develop or contribute to generalizable knowledge".
 [45CFR46.102 and 45 CFR 164.501]
 See CHS Policy http://documents.carolinas.org/Research/QI_vs_Research_Definition.pdf.

	Yes	No
Do you consider this project to meet the definition of research as noted above?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the project involve a systematic investigation that may include a hypothesis, testing and evaluation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

*Adapted from the Stanford University Research Compliance Office Determination of Human Subject Research screening form

QI vs. Research Screening Form
 v. 1.0
 3.25.15

CAROLINAS HEALTHCARE SYSTEM Institutional Review Board / Patient Privacy Board		
IRB Review & Determination of QI vs. Research Projects		
Is the activity primarily designed to:		
1. Develop new knowledge?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Apply to patients of populations beyond your specific study population?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Activity Involves Human Subjects?		
Does your project involve:	protocol attached	Yes No
Interventions or interactions with patients, including manipulation of a person, or a person's environment through surveys, interviews, tests or observations? If yes, attach the document.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does your project involve:	Yes	No
Obtaining identifiable private information about living people?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If this project uses existing data, please answer the following:		
What is the source of the data (i.e., from whom/where): BusinessObjects report from DA2		
Are the data publicly available?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Can the individual associated with the data be identified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Are the data de-identified? If yes, who did (or will) de-identify the data? The name can be scrambled but the MRN and Acct Would still be available to visualize on the report	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were the data collected specifically for this project? We currently report this measure to HEN 2.0 But that contract ends at the end of the month. Antihypertensive medications within 1 hr of severe Range BP has also been a Perinatal QSOC goal since 2015.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were the data collected as part of clinical care?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical Investigation?		
Does your project include testing the safety and efficacy of a drug or device in a human subject, including analysis or comparison of outcome data about a drug or device?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does your project include a non-FDA-approved assay or In Vitro Diagnostic device?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Will any data resulting from this activity be submitted to the FDA?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
*Adapted from the Stanford University Research Compliance Office Determination of Human Subject Research screening form		
QI vs. Research Screening Form v. 1.0 3.25.15		

Appendix D

East Carolina University- IRB Determination



EAST CAROLINA UNIVERSITY

Office of Research Integrity and Compliance (ORIC)
 University & Medical Center Institutional Review Board (UMCIRB)
 Brody Medical Sciences Building, 4N-70 • 600 Moyer Boulevard • Greenville, NC 27834
 Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: Mary Bowers, ECU College of Nursing, DNP Program

FROM: Office of Research Integrity & Compliance (ORIC) 

DATE: November 7, 2016

RE: Doctor of Nursing Practice (DNP) Scholarly Project

TITLE: The Use of Electronic Maternal Early Warning Criteria (EMEWC) to Improve Treatment of Hypertension in Hospitalized Obstetric Patients

This activity has undergone review on 11/7/2016 by the ORIC. A Doctor of Nursing Practice candidate is planning an evidence based practice initiative/quality improvement project at Carolinas HealthCare System NorthEast. This project will examine the use of EMEWC to recognize hypertensive disorders in obstetric patients. The purpose is to evaluate if the use of warning criteria will improve rates of treatment within one hour through the recognition of abnormal vital signs and notification prompts to providers. Ms. Bowers will review medical record data before and after the use of the warning criteria to determine improvement. Carolinas HealthCare System IRB confirmed this project was quality improvement and the ORIC agrees.

This activity is deemed outside of UMCIRB jurisdiction because it does not meet the current federal descriptions for human subject research. Therefore, this activity does not require UMCIRB approval. Contact the office if there are any changes to the activity that may require additional UMCIRB review or before conducting any human research activities.

Relevant Definitions for Human Subject Research:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities
- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

Appendix E

DNP Scholarly Project Time Line

Date	Task	Complete/Incomplete/ Ongoing
January-June 2016	Explore project topic	Complete
May-June 2016	Review the literature for topic of interest	Complete
June 2016	Define project topic	Complete
June 2016	Explore and define theoretical framework	Complete
June 13, 2016	Establish project committee	Complete
June 30, 2016	Complete abstract for summer practicum	Complete
June 30, 2016	Complete timelines for summer practicum	Complete
July 7, 2016	Present Maternity Early Warning Criteria (MEWC) to CHS NorthEast Perinatal Quality Committee	Complete
July 12, 2016	Design and establish how the project will be built in CERNER with requested MEWC parameters-Meeting #1	Complete
July 13, 2016	Submit DNP 1 first 3 chapters draft of scholarly paper	Complete
July 21, 2016	Meet with CHS Center for Advanced Practice Director to review project, paper, and NSAC forms	Complete
July 21, 2016	Meet with CHS NorthEast AVP of Nursing Practice	Complete
July 22, 2016	Meet with CHS Chief Nursing Informatics Officer	Complete
July 25, 2016	Complete DNP 1 final draft of scholarly paper	Complete
July 29, 2016	Work with IS to map out parameter triggers pathways	Complete
August 4, 2016	CHS NorthEast OB Provider Department Meeting- finalize MEWC parameters	Complete
August 9, 2016	Design and establish how the project will be built in CERNER with requested MEWC parameters-Meeting #2	Complete
September 19, 2016	Carolinas HealthCare System (CHS) Nursing Scientific Advisory Council (NSAC) received proposal for review	Complete
October 3, 2016	CHS NSAC Approval Received	Complete
October 17, 2016	CHS IRB review received: Quality Improvement	
October 20, 2016	Drafted ECU IRB Papers in ePIRATE	Complete
November 3, 2016	DNP Project Chair submits drafted forms for ECU IRB for review	Complete
November 7, 2016	ECU IRB deems project as Quality Improvement	Complete
December 1, 2017	Begin data collection	Complete
February 28, 2017	End data collection	Complete
March-April 2017	Evaluate outcomes of project	Complete
May 31, 2017	Draft final chapters of paper for DNP IV	Complete
June 14, 2017	Development Poster and Presentation for Dissemination	Complete
July 13, 2017	Poster Presentation to ECU Faculty and Guests	Complete

Appendix F

Carolinas HealthCare System NorthEast Perinatal Quality Committee

Maternal Early Warning Criteria

CHS NE Perinatal Quality Committee and OB Department		
Parameters for EHR	Value	
	Low	High
Temperature	96.9	>100.4
Blood Pressure-systolic	<80	>160
Blood Pressure-diastolic		>110
Heart Rate	<50	>120
Respiratory Rate	<10	>30
Oxygen Saturation %-room air	<95%	
Oliguria (mL for >2 hours) for catheterized patient	<30	
Quantitative Blood Loss-C-Section		>1000
Quantitative Blood Loss-Vaginal		>500
Maternal agitation, confusion, unresponsiveness	if any present	
Preeclampsia, with patient reporting non-remitting headache or shortness of breath	if any present	

Appendix G

Evidence Table

The Use of Electronic Maternal Early Warning Criteria to Improve Treatment of Hypertension in Hospitalized Obstetric Patients

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Swanton et al. 2009	Descriptive Study Level VI	222 maternity units lead obstetric anesthesiologists N=158 completed, returned surveys	71% response rate 80% median usefulness score for standardized national obstetric EWS The survey supports CEMACH recommendations for a nationally agreed obstetric EWS. 30 units (19%) currently use any form of obstetric EWS		Survey to assess opinions on the value of an EWS validated for the obstetric population, how it could be implemented plus a comments section.	Obstetric Anaesthetists' Association (OAA) led the survey to address the recommendation by the United Kingdom's Confidential Enquiries into Maternal and Child Health (CEMACH) to improve patient care through the use of an EWS. AIM: to collate opinions on the value and ease of implementation of an obstetric-specific system to discover what systems are currently in use in facilities in the United Kingdom
Lawton et al. 2010	Descriptive Study Level VI	29 charts of women admitted to an ICU	10% of cases were deemed preventable Most frequent types of preventable events were: inadequate diagnosis/recognition of high-risk status, inappropriate treatment, communication problems, and inadequate documentation.	The sample was small and from a single site.	Case reviews of severe acute maternal morbidity (SAMM)	AIM-to conduct a retrospective audit of SAMM cases to describe clinical, socio-demographic characteristics, pregnancy outcomes, and preventability to measure the quality of maternal care

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Cantwell et al. 2011	Expert Consensus Level VII		<p>For many patients in this review, sepsis and hemorrhage modified early obstetric warning system (MEOWS) alerts had the potential to improve outcomes through early recognition.</p> <p>Combination of physiologic and neurologic parameters assist with identification of parameters of clinical deterioration in hypertensive disorders and other conditions leading to mortality.</p> <p>Case reviews of maternal deaths show that early warning signs of impending maternal collapse went unrecognized.</p> <p>Recommends hospital-based adoption of MEOWS as a “top ten” requirement and urges leadership and policy makers to introduce and audit MEOWS as soon as possible.</p>		Parameters for RR, HR, Pain, Oxygen Saturation, T, BP, & Neurologic Response are assigned abnormal values depending on severity a yellow alert or red alert is scored. A clinical response to urgently assess the patient’s status will fire for 2 yellow or 1 red trigger.	<p>8th report (2007) United Kingdom’s CEMACH’s triennial report (Saving Mothers’ Lives) on maternal death recommends adoption of the MEOWS</p> <p>Routine use in all pregnant or post-partum women who become unwell to facilitate more timely recognition, referral and treatment of women who have, or are developing, a critical illness.</p> <p>Parameters seek to identify hypertensive disorders, hemorrhage, thromboembolism, sepsis and cardiovascular complications.</p>

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Jonsson et al. 2011	Retrospective, Descriptive Level VI	ICU admissions at a university hospital Reykjavik, Iceland. 65 patient's records over 3-month period	<p>Observations were documented in the medical record in various percentages:</p> <p>Respiratory rate =14%, urinary output = 40%, level of consciousness = 48%; temperature= 69%, and oxygen saturation = 80%</p> <p>Increased respirations were the most frequent precursor to clinical deterioration in patients prior to admission to the ICU and was at the same time the parameter that was most poorly documented.</p> <p>With better monitoring and documentation of physiological parameters, emergency admission to the ICU might be avoided.</p>	<p>The sample was small and from a single site.</p> <p>Obstetric patients were not utilized</p> <p>Blood pressure measurements were not considered.</p>	Data collection, chart review for documentation of vital signs prior to clinical deterioration	<p>AIM: to estimate the accuracy of nursing documentation per parameters that comprise MEWS in patients prior to emergency admission to the intensive care unit (ICU).</p> <p>Nurses to need be alerted to the necessity of documenting early signs of deterioration of patients, particularly the respiratory rate.</p>

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Singh et al. 2012	Prospective Evaluation Level IV	676 obstetric admissions of gestational ages 20 weeks' to 6 weeks postpartum 200 (30%) triggered abnormal measured parameters 86 (13%) had a morbidity of hemorrhage, hypertension in pregnancy or infection	Modified Early Obstetric Warning System (MEOWS) was 89% sensitive (95% CI 81-95%), 79% specific (95% CI 76-82%) with a positive predictive value 39% (95% CI 32-46%) and a negative predictive value of 98% (95% CI 96-99%). Morbidity (94%) driven by 3 conditions: hemorrhage, preeclampsia, and infection A valuable screening tool is one that is cost effective, safe and validated The MEOWS demonstrated a much higher sensitivity than non-obstetric early warning systems that are in use in adult populations. Conclusion: Useful tool for predicting maternal morbidity Not designed to determine MEOWS efficacy in detecting acute critical illness, improving management of morbidity (time to administration of antihypertensives) or improving clinical meaningful outcomes.	Single center study The MEOWS triggers are set close to the values that define morbidity (a positive trigger that is associated with morbidity could become a self-fulfilling prophecy. Definitions for morbidity used nationally accepted criteria but there is not a universal definitions of obstetric morbidity.	Limits were set for MEOWS parameter for triggers: Temperature, BP, Heart Rate, Respiratory Rate, Oxygen Saturation, Pain Score, and Neurological Response. Each parameter documented at least every 12 hours; a trigger was assessed if an abnormal parameter was documented.	AIM: To evaluate the MEOWS as a tool for predicting maternal morbidity by measuring its sensitivity, specificity, and predictive value. The 2003-2005 triennial Confidential Enquiry into Maternal and Child Health (CEMACH) recommended the routine use of the MEOWS which is adapted for the obstetric population. Definition of morbidity included hemorrhage, severe preeclampsia, infection, and thromboembolism. This is a paper tool. No previous studies have validated the charts although the tool is in use in the United Kingdom. This is the first study attempting to validate an obstetric early warning chart.

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Carle et al. 2013	Retrospective Review Level IV	Intensive Care Units in the United Kingdom, Wales and Ireland submit data to the National Audit and Research Centre (ICNARC) Case Mix Programme (CMP). 71, 108 females aged 16-50 were randomly divided into Set 1 and Set 2. Set 1 became the model development set and used 2240 direct admissions to ICU. Set 2 became the validation set with 2200 direct obstetric admissions to the ICU.	<p>The new clinical obstetric early warning score has an excellent ability to discriminate survivors from non-survivors in this critical care data set.</p> <p>Compared the statistical EWS and clinical EWS with Swanton et al.'s empirically designed MEOWS; the Confidential Enquiries into Maternal Deaths obstetric EWS and the Royal College of Physicians' non-obstetric National EWS</p> <p>Mortality rates are presented with Clopper-Pearson 95% CI and the effects of predictor variables as odds ratios with 95% CI. Statistical significance was defined for two-sided $p < 0.05$.</p> <p>Swanton et al. Modified Early Obstetric Warning System, 0.937 (95% CI 0.884-0.991) for the obstetric early warning score suggested in the 2003-2005 Report on Confidential Enquiries into Maternal Deaths in the United Kingdom, and -0.973 (95% CI 0.957-0.989) for the non-obstetric National Early Warning Score.</p>	Missing data details on respiratory rate due to mechanical ventilation	<p>Physical variables collected during the first 24hrs of critical care admission</p> <p>Logistic regression for mortality in the model development set was used to create a statistically based early warning score.</p> <p>Physiologic variables that could be presented by a patient outside an ICU were selected: heart rate, blood pressure, respiratory rate and temperature.</p>	<p>AIM: to design and validate an aggregate weighted early warning scoring system for obstetric patients</p> <p>Used EWS parameters to predict death for patients with obstetric diagnosis admitted to ICUs.</p> <p>Pre-existing empirically designed early warning scores were also validated for comparisons</p>

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Austin et al. 2014	Retrospective Cohort Level IV	<p>Large tertiary maternity unit in Auckland City Hospital in New Zealand</p> <p>Random sample of women pregnant or within 6 weeks postpartum and admitted to ICU or CVICU or obstetric high dependency unit.</p> <p>N=42 admissions to ICU</p> <p>N=71 admissions to obstetric high dependency unit</p>	<p>The EWS might have reduced the seriousness of maternal morbidity in five cases (7.6%) including 3 admissions due to sepsis and 2 due to hemorrhage.</p> <p>Findings can advocate for the introduction of an EWS in the maternity service line</p> <p>Interpretation of validity and generalizability is limited.</p>	<p>Severe maternity morbidity patient charts reviewed and the EWS was applied to determine if care could have been improved.</p> <p>The sample was small and from a single site.</p> <p>This study did not allow the determination of how often an EWS might have led to either delayed escalation due to low scores or unnecessary escalation due to high scores</p>	<p>Case review and transcribed observation charts, group consensus determined whether EWS might have hastened the recognition and or escalation and effective treatment</p>	<p>AIM: to determine whether as EWS may have improved the detection of severe maternal morbidity or lessened the severity of illness among women with severe morbidity</p> <p>This study demonstrates that there is incomplete recordings of basic clinical parameters in particular respiratory rate.</p> <p>An EWS may address the issue of incomplete recordings, especially attention to the importance of measuring respiratory rate and reducing severe morbidity.</p>

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Isaacs et al. 2014	Descriptive Study Level VI	205 Lead Obstetric Anesthetists invited N=130 completed surveys	<p>Tools in use:</p> <ul style="list-style-type: none"> MEOWS-58 (45%) Modified Version-65 (50%) Different System-7 (5%) <p>Consistent Physiologic Parameters Monitored:</p> <ul style="list-style-type: none"> T, HR, RR, BP, Urine Output, Proteinuria, Lochia, Capillary Refill <p>This study deemed 4 parameters as essential in recognizing clinical deterioration: HR, RR, BP and T</p> <p>Suggested Updates to Physiologic Parameters:</p> <ul style="list-style-type: none"> Blood Sugar, Responds to Voice, Alert, Responds to Pain, Unconscious, Oxygen Saturation <p>Barriers to Implementation:</p> <ul style="list-style-type: none"> Staffing pressures, lack of support from midwives and lack of education, training and audit <p>MEWT tool in this study included recommendations for patient assessment and treatment.</p>	The tool was sent to Anesthetists only. The United Kingdom utilizes midwives who should be included in evaluations of morbidity and which tools help with improving communication with the health care team members.	Survey (adapted from 2007 survey previously administered) that included free text comments and requested a copy of the facilities currently used EWS	<p>AIM: The Modified Obstetric Early Warning Systems (MObs) Research Group (United Kingdom) aimed to identify which EWS are currently in used in obstetric practice and which physiological parameters are included, and to describe problems associated with EWS.</p> <p>100% of the facilities reported use of an EWS in maternity wards which is in an increase from the 19% reported in 2007.</p>

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Mackintosh et al. 2014	Ethnographic Study Using Observations Level IV	N=45 2 United Kingdom hospitals Doctors, Midwives and managers	MEOWS enabled communication about vital signs Trigger prompts helped shape shared understandings of maternal complications. Conflicting results of the effectiveness of early warning systems exists; value in MEOWS in structuring the surveillance of hospitalized women with an established risk of morbidity has to be weighed with opportunity costs of MEWOS and variation in implementation		Semi-structured interviews and documentation review performed in the maternity services	AIM-to explore implementation of the MEOWS in practice to further understand the influence of contextual factors
Mhyre et al. 2014	Expert Consensus Level VII		MEWC is triggers a prompt bedside alert with 1 abnormal parameter. Single scoring system Benefits: minimize false alarms, facilitate implementation, retain sensitivity MEWC is required for use in all New York hospitals with obstetric services		Used a consensus-based approach to define MEWC, a list of abnormal parameters that include the need for urgent bedside evaluation by a clinician.	Authors urge randomized control trials to evaluate whether the MEWC help teams achieve timely diagnosis and treatment thus limiting severity of morbidity.

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Behling et al. 2015	Cohort Study Level IV	5 EPIC EHR facilities	<p>Obstetric Vital Sign Alert (OBVSA) uses 6 critical values which are assessed and scored per established ranges, 2 deviations above or below normal ranges.</p> <p>Variables are updated in real-time in EPIC and display on electronic dashboard</p> <p>Aggregate scores are automatically calculated based on documentation, then display as a visual on a dashboard</p> <ul style="list-style-type: none"> • Normal = ≤ 2 • Modest Deviation = 3-4 • Severe Deviation = ≥ 5 <p>Protocols guide nursing documentation and interventions</p> <p>Nurses discuss score at each handoff</p>	Actual sample could be affected by factors not controlled for: experience level of nurses, volume and acuity of patients in labor and delivery and mother baby units, attention to the new tool, attendance at the learning module, and buy-in and compliance of the nursing and physician groups. Scoring as there is limited pulse oximetry on the mother baby unit.	<p>OBVSA- aggregate weighted electronic scoring system that is embedded into the EPIC HER.</p> <p>Dependent variables before and after implementing OBVSA:</p> <ul style="list-style-type: none"> • Response time • Time to intervention • Total estimated blood loss • PRBA units transfused • Maximum pulse • Lowest hemoglobin • Lowest sBP • Lowest dBP • Length of stay 	<p>Built on work of MEOWS by seeking to automate the scoring and trigger tools, and optimize the use of the HER and the team response to changing patient conditions.</p> <p>Measurements pertained to obstetrical hemorrhage but principles can be applied to all obstetrical clinical deterioration.</p>
Christofidis et al. 2015	Cohort Study Within-subjects experimental design Level IV	47 novice chart users Undergraduate psychology students	<p>Participants responded fastest and made the fewest errors when using the chart design without individual vital-sign scoring-rows.</p> <p>Participants were faster when the rows for scoring individual vital signs were separated (vs. grouped), but accuracy did not differ.</p> <p>Significantly more time-points were affected by scoring errors compared with adding errors. Early-warning scoring systems may be more effective without individual vital sign-scoring rows.</p>		<p>Within subjects, with “scoring-system design” as independent variable and participants’ response times and error rates as the main outcome measures.</p> <p>Participants response times and error rates for determining the overall scores were measured for 54 time-points per design.</p>	AIM-to evaluate the effect of early-warning scoring system design on speed and accuracy of scoring.

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Edwards et al. 2015	Retrospective Cohort Study Level IV	Single tertiary unit Sepsis patients N=364 cases of patients with chorioamnionitis with complete data for all physiological parameters in analysis	Modified Obstetric Early Warning Scoring Systems (MOEWS) were searched from global literature and scores were derived for each set of vital sign recordings during presentation of chorioamnionitis. Six MOEWS evaluated: <ul style="list-style-type: none"> • Ability to predict severe deterioration= 40-100% • Specificity varied from 4-97% • Positive predictive value from 2-15% Result-MOEWS with simple designs tended to be more sensitive, where as the more complex MOEWS were more specific but failed to identify some of the patients who developed severe sepsis.	The study only focus on the use of MOEWS with the sepsis morbidity	Hospital databases and patient records	AIM-to compare predictive power of MOWES for the development of severe sepsis in women with chorioamnionitis Six MOEWS were identified for use in maternity care each with different physiological thresholds, clinical triggers, and ability to predict severe worsening of obstetric sepsis.

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Freidman 2015	Synthesis of Evidence Level IV		<p><i>EWS</i>-other specialties-goal is to identify patients who may become critically ill and intervene early to improve outcomes. Method is a “trigger” or “scoring” system where a parameter or value is placed on the patient’s condition. Commonly used in pediatrics, general medical surgical wards. Systematic review shows overall impact on health outcomes and resource utilization is unclear. Major concern-various scoring systems and lack of consistency in detecting deterioration. Take home-Optimizing alert system performance to avoid false-positive results and avoid nuisance alarms.</p> <p><i>Maternal EWS</i>-specifically designed to incorporate physiologic changes that occur during pregnancy and the small number of conditions responsible for most maternal severe morbidity and mortality. The United Kingdom’s MEOWS alert parameters may detect hemorrhage, sepsis, preeclampsia, and cardiovascular complications. Simplified version from United States offered as MEWC where 1 trigger prompts bedside assessment.</p> <p><i>Supporting Evidence</i>-Singh et al., Carle et al., Austin et al,</p>			<p>AIM: Review the following strategies that improve maternal outcomes:</p> <ul style="list-style-type: none"> • Clinical rationale for EWS including research literature in on early alerts in other specialties • Clinical parameters and recommended care in maternal EWS • Research evidence supporting maternal EWS • Future directions in optimizing and validating maternal EWS <p>Maternal early warning systems are favorable for reducing severe maternal morbidity and mortality if they identify patients at risk for critical illness and not result in high number of false-positive alerts</p>

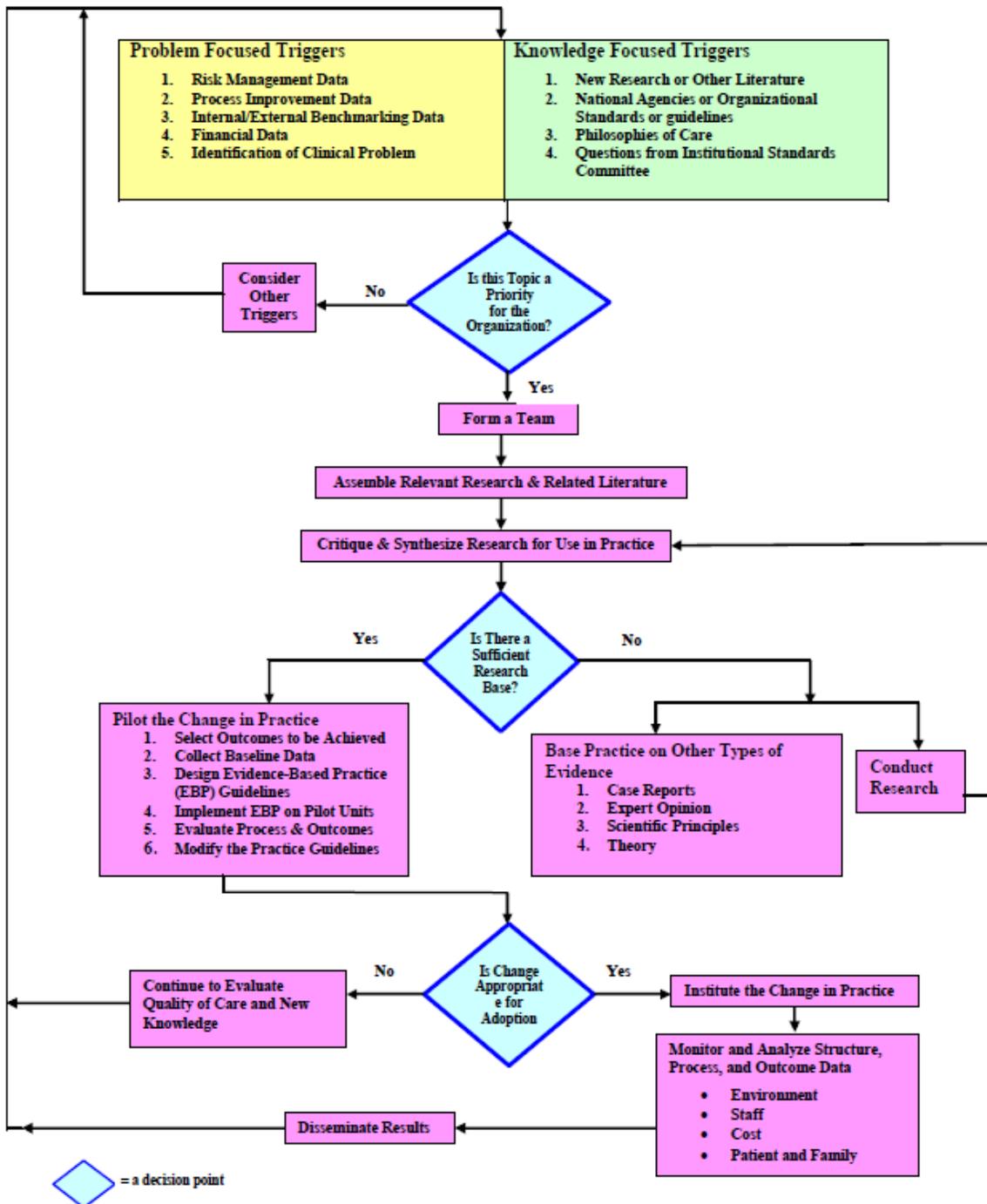
Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Schmidt et al. 2015	Retrospective, Observational Study Level IV	2 acute care general hospitals' mortality rates for 3 main specialties each	<p>During electronic physiological surveillance system (EPSS), crude mortality fell</p> <ul style="list-style-type: none"> • Hospital #1: 7.75% to 6.42% • Hospital #2: 7.5% to 6.15% <p>Both hospitals had abrupt and sustained mortality reductions during EPSS implementation</p> <p>The use of technology specifically designed to improve accuracy, reliability and availability of patients' vital signs and early warning scores is associated with reduced mortality in this study.</p>	Hard to prove a direct cause-and-effect relationship between EPSS and decreased mortality rates.	<p>Study of seasonally adjusted in-hospital mortality rates before, during and after the sequential deployment and ongoing use of a hospital-wide EPSS</p> <p>EPSS uses wireless handheld computing devices, replaced a paper-based vital sign charting and clinical escalation system.</p>	AIM-to determine whether introducing an EPSS specifically designed to improve the collection and clinical use of vital sign data, reduced hospital mortality.
Hedriana et al. 2016	Retrospective Case-Control Study Level IV	<p>50 Obstetric patients admitted to ICU; 50 normal birth outcomes</p> <p>7 pilot US hospitals</p>	<p>Persistent MEWT were present in most obstetric ICU cases; their use might reduce maternal morbidity.</p> <p>Case and control groups each contained 50 patients with pre-eclampsia (6/50, 12%) reason for admission to ICU.</p> <p>Significant associations Mean arterial pressure less than 65mm Hg (OR 4.5, 95% CI 1.9-10.8)</p>	<p>Used Mean Arterial Pressure (MAP) instead of blood pressures</p> <p>Small sample size; Lack of prospective data analysis</p>	<p>6 MEWTs were assessed:</p> <p>HR, MAP, T, Mental State, RR, and Oxygen Level</p> <p>Odds ratio and 95% CI were generated for each of the 6 MEWTs, P<0.05 was considered significant</p>	MEWT in this cohort seemed to separate normal obstetric pts from those whom ICU admission was indicated

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Shields et al. 2016	Controlled Trial without Randomization Level III	6 out of 29 hospitals in large hospital system 24-month baseline control period at pilot and non-pilot facilities 13-month MEWT study period at pilot and non-pilot facilities 36,832 deliveries at pilot sites during baseline and MEWT study periods 146, 359 deliveries at non-pilot sites during baseline and MEWT study periods	Pilot site, screened patients-sensitivity for ICU admission was 96.9%, predictive positive value of 12%, and negative predictive value of 99.99% Significant reduction in both the Centers for Disease Control and Prevention defined severe maternal morbidity (-18.4%, P = .01) and composite maternal morbidity (-13.6%, P = .01) when comparing baseline and after implementation of the MEWT tool. Use of the MEWT tool resulted in significant reductions in CDC severe maternal morbidity (P < 0.01) and composite morbidity (P < 0.01). Use of the MEWT, designed to address 4 common causes of maternal morbidity, as well as, provide assessment and management recommendations, resulted in significant improvement in maternal morbidity.	During the study, guidelines for management for severe blood pressure from the American College of Obstetricians and Gynecologists and California Maternal Quality Care Collaborative were implemented at pilot and non-pilot facilities. The reduction in severe maternal morbidity noted at pilot sites may have been greater if the pilot sites were compared to other hospitals without the recommendations in place.	To determine if maternal morbidity might be reduced with the utilization of a MEWT The tool addressed sepsis, cardiopulmonary dysfunction, preeclampsia-hypertension, and hemorrhage. To be considered positive, triggers needed to be sustained for >20 minutes and were defined as severe (single abnormal value).	Obstacles to address with development of early warning systems: ease of use by staff, the alert frequency must be low enough to prevent “alarm fatigue” and the positive predictive value must be high enough clinicians value the alert.

Author & Date	Evidence Type	Sample, Sample Size, & Setting	Study findings that help answer the EBP question	Limitations	Measurement	Other notes
Singh et al. 2016	Prospective Observational Study Level IV	Labor wards of a single hospital in India N=1065 study subjects	<p>Maternity Early Obstetric Warning System (MEOWS) “track and trigger” of physiological parameters can aid in recognition of maternal morbidity at an early stage, ultimately halting clinical deterioration and suffering maternal morbidity and mortality</p> <p>26.6% triggered an abnormal parameter</p> <p>16.61% fulfilled criterial for obstetric morbidity</p> <p>MEOWS chart was 86.4% sensitive, 85.2% specificity, 53.8% positive predictability, 96.9% negative predictability. Parameters also had a significant correlation (p<0.05) with obstetric morbidity.</p>	Single study site	MEOWS chart adopted from CEMACH 2003-2005	<p>MEOWS is based on principle that abnormalities in the physiological parameters precede critical illness.</p> <p>AIM-to evaluate MEOWS chart as a bedside screening tool for predicting obstetric morbidity and to correlate each physiological parameter individually with obstetric morbidity</p> <p>Findings: MEOWS chart is useful tool at bedside for predicting maternal morbidity and mortality and should be used in every obstetric unit.</p> <p>Strict monitoring and documentation of physiological parameters should be a part of a patient’s assessment to pick up acute illness</p>
The hierarchy of levels of evidence follow recommendations from Melnyk and Fineout-Overholt (2015).						
<p>BP-Blood Pressure</p> <p>CI-Confidence Interval</p> <p>HER-Electronic Health Record</p> <p>EWS-Early Warning System</p>			<p>HR-Heart Rate</p> <p>ICU-Intensive Care Unit</p> <p>MAP-Mean Arterial Pressure</p> <p>MEOWS-Maternal Early Obstetric Warning System</p>		<p>MEWC-Maternal Early Warning Criteria</p> <p>MEWT-Maternal Early Warning Triggers</p> <p>RR-Respiratory Rate</p> <p>T-Temperature</p>	

Appendix H

IOWA Model of Evidence Based Practice



(Titler et al., 2001)

Appendix I

Cerner FetaLink™ Web-Based Training Module

Cerner FetaLink™ Web-Based Training Module

Target Audience: Acute Care Nurses in Labor and Delivery and High Risk Obstetric Units
Purpose: Provides instructions on how to successfully navigate and utilize FetaLink
Training: A self-paced, web-based module is available in PeopleLink@CHS, which is a talent management suite. This module will be assigned by the manager for required implementation of objectives as determined by the developer, Cerner. The training program will continually be available as a references and can be accessed from any CHS computer at any point in time.

Completion: Cerner FetaLink™ Web-Based Training is developed by the company to ensure consistency among end users at instillation sites across the globe. The course material includes various educational modalities including the requirement for participants to utilize the computer mouse to document in the program. Once the required learning objectives are successfully met, a certification of completion can be printed.

Course Content: **Table of Contents:**

Instructions
• How to Launch FetaLink and Sign in
• How to Navigate the Census View
▪ How to Associate Patient to FetaLink
○ Retroactive Associations
○ Reason for Monitoring
▪ How to View Fetal Monitoring Episode
○ Central Monitoring View
○ Extended View
▪ How to Enter and Sign Annotations *
• How to Modify/Remove Annotations *
• Annotations Summary
▪ How to View Patient’s Archived Episodes
▪ How to Manage Alerts *
• Alert Parameters *
▪ How to Transfer Patients
▪ How to Finalize and Disassociate
▪ How to Disassociate Patient from Monitor
▪ Trouble Shooting Key Points
▪ Setting the Location
▪ Printing Fetal Strips

* Indicates Content with Screen Shots Attached

How to Enter and Sign Annotations

1. After you have **Signed in**, open the desired episode.
2. Double click on the fetal tracing in the spot you wish to place an electronic annotation.
3. The **Annotations** box displays.
4. You can select from the quick choices below.
5. Or, within the top free text box, you can type up to 255 characters. This is not easy to see once in **IView** so a short, quick annotation or going to **IView** to chart would be better.
6. You can hide the annotations by clicking the **Hide Annotations** box at the bottom left of the screen.
7. Be sure to click **Sign** to place your electronic signature on the Annotation.
8. Annotations will post directly onto the fetal monitoring tracing, as well as in the **IView Maternal Fetal Monitoring Data** section.

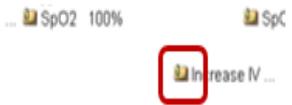
The screenshot shows the 'Annotations' window with the following elements:

- Free Text:** A large text area for entering up to 255 characters.
- Quick pick choices:** A list of 12 checkboxes for common clinical events, including:
 - Oxytocin infusion decreased
 - Oxytocin infusion discontinued
 - Oxytocin infusion increased
 - Turn to left side
 - Turn to right side
 - Primary Provider notified
 - Primary Provider at bedside
 - Increase IV fluids
 - Vaginal Exam
 - Hands and Knees
 - Pushing
 - Up to Bathroom
 - ROM
 - Ephedrine Given
- Buttons:** 'Sign' (highlighted with a red box) and 'Cancel'.
- Other fields:** User Name: dgray3, Annotate: 9/27/13 13:19:23 EDT, Now.

(Cerner FetaLink™, 2016)

How to Modify/Remove Annotations

To Modify

1. Double click on the annotation icon. 
2. Deselect undesired components or select additional components, Sign. OR

To Remove or Delete

1. Double click on the annotation icon. 
2. Deselect or erase undesired components, in the free text window type 'Clerical Error' and Sign.



3. Annotation Revision History allows user to view the history of any annotation changes for a [particular annotation](#).



- To view, double click on the already documented annotation icon.
- Click Revision History tab

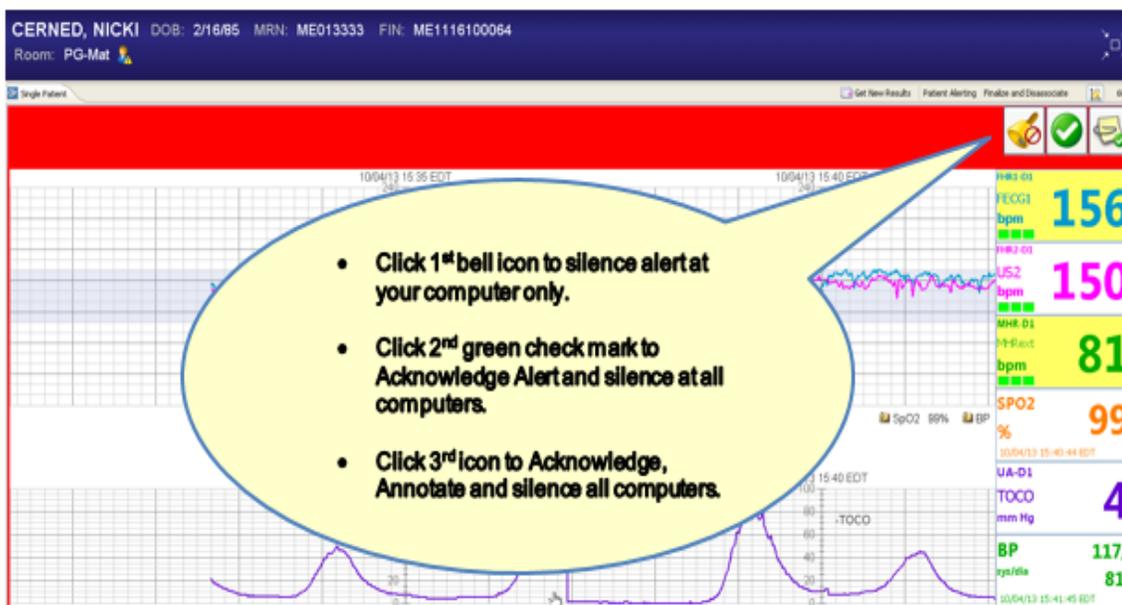
 BP 119/79,

Date	Annotation	User Id	Revision Date
10/04/2013 13:51:31 EDT	BP 119/79, MHR 82	system vitals	10/04/2013 13:51:32 EDT

(Cerner FetaLink™, 2016)

How to Manage Alerts

- Alert parameters define the normal range of patient data. If data falls outside of normal range, an alert will be triggered.
- When an alert fires
 - Bell will sound
 - Patient chart border will turn **RED**
 - Alerting vital sign box will change to yellow
- Three alert icons will appear for you to address the alert
 - Silence the alert**
 - Click on bell icon to silence the auditory alert and remove red banner *for this computer only for 30 seconds*.
 - The yellow box remains in view to show that this alert is still triggered.
 - After 30 seconds, the alert will sound again until the triggered alert is either Acknowledged or Annotated.
 - Acknowledge the alert**
 - Click on check mark to cancel and silence the alert on **all computers** within the FetaLink application.
 - Once acknowledged, the alert will not fire again until the results fall outside of the Alert Parameters.
 - Annotate and acknowledge the alert**
 - Click on this icon to cancel and silence the alert on all computers, as well as annotate an intervention onto the strip.
 - After entering the annotation, click **Sign** and the Alert will disappear.

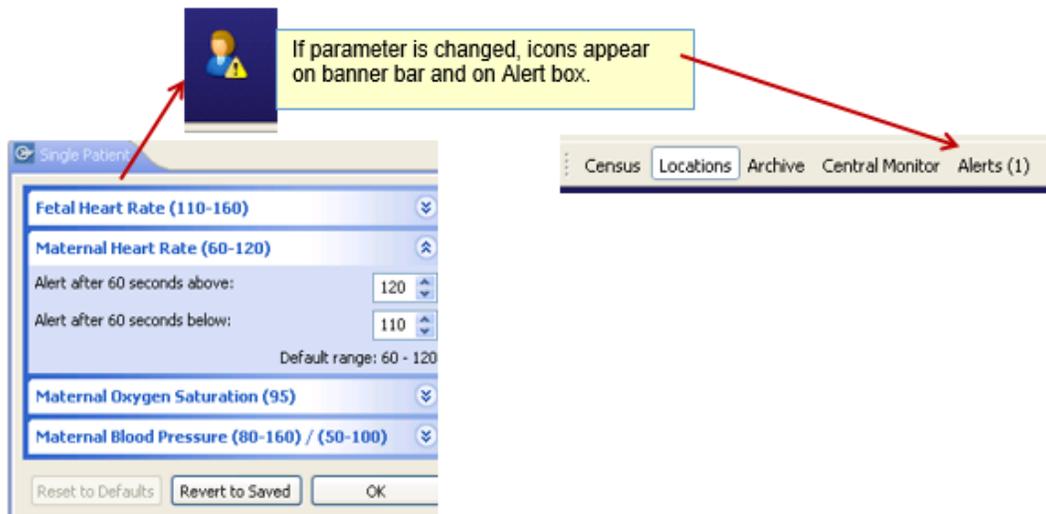


(Cerner FetaLink™, 2016)

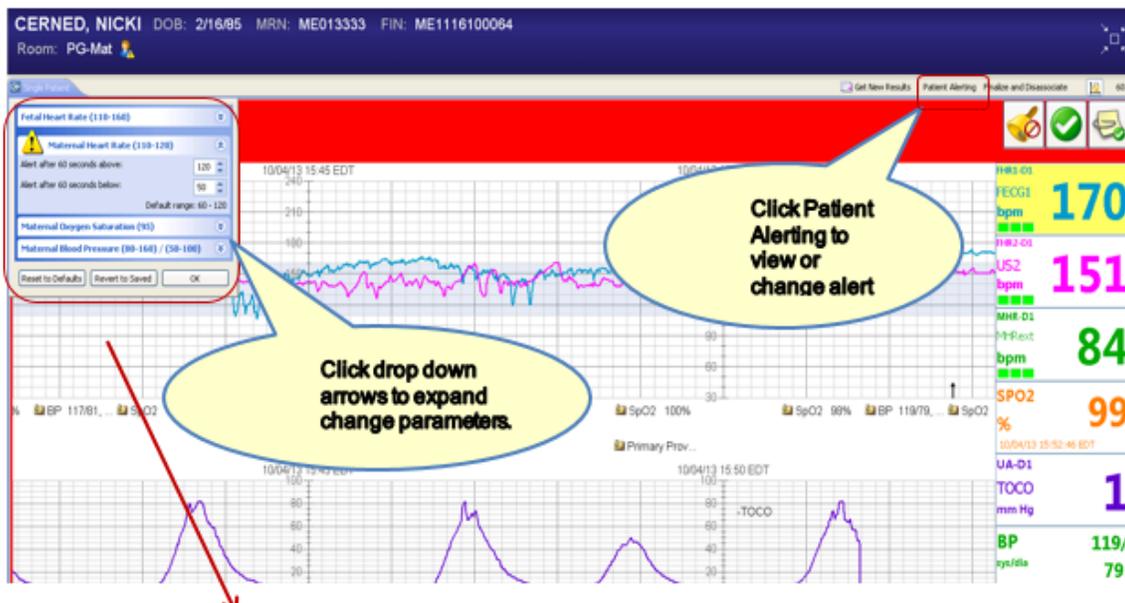


Alert Parameters

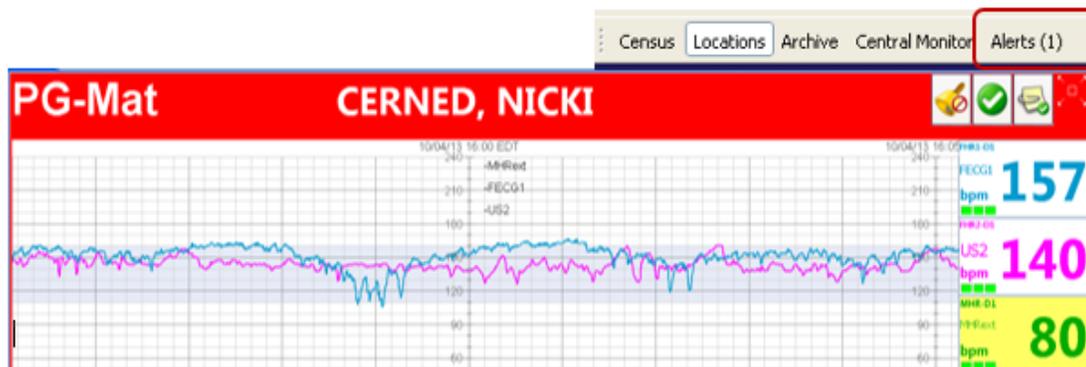
1. To set alert Parameters for a specific patient, click on the Patient Alerting button within the single patient view.
2. The *Alert Parameter* box will open to the left of the fetal strip.
3. Default parameters will be in view next to the specific vital sign.
4. Click the down arrow to the right of the vital sign parameter you wish to change.
5. The specific vital sign section, such as Fetal Heart Rate, will open to show the high and low range default settings.
6. Click the up/down arrows to change the parameters.
7. Click OK.
8. To show that the Patient Level Alerts have been saved, a yellow triangle displays in the alerting section, and an icon will display on the FetaLink demographic bar.
9. New alert parameters will override any default parameters and will apply to all devices associated to the patient.
10. A visual reference for the defined parameter range is displayed on the waveform as gray shading.
11. After the episode is finalized, the Patient Level Alert parameters reset to the default settings.



Click Alerts will provide the following display

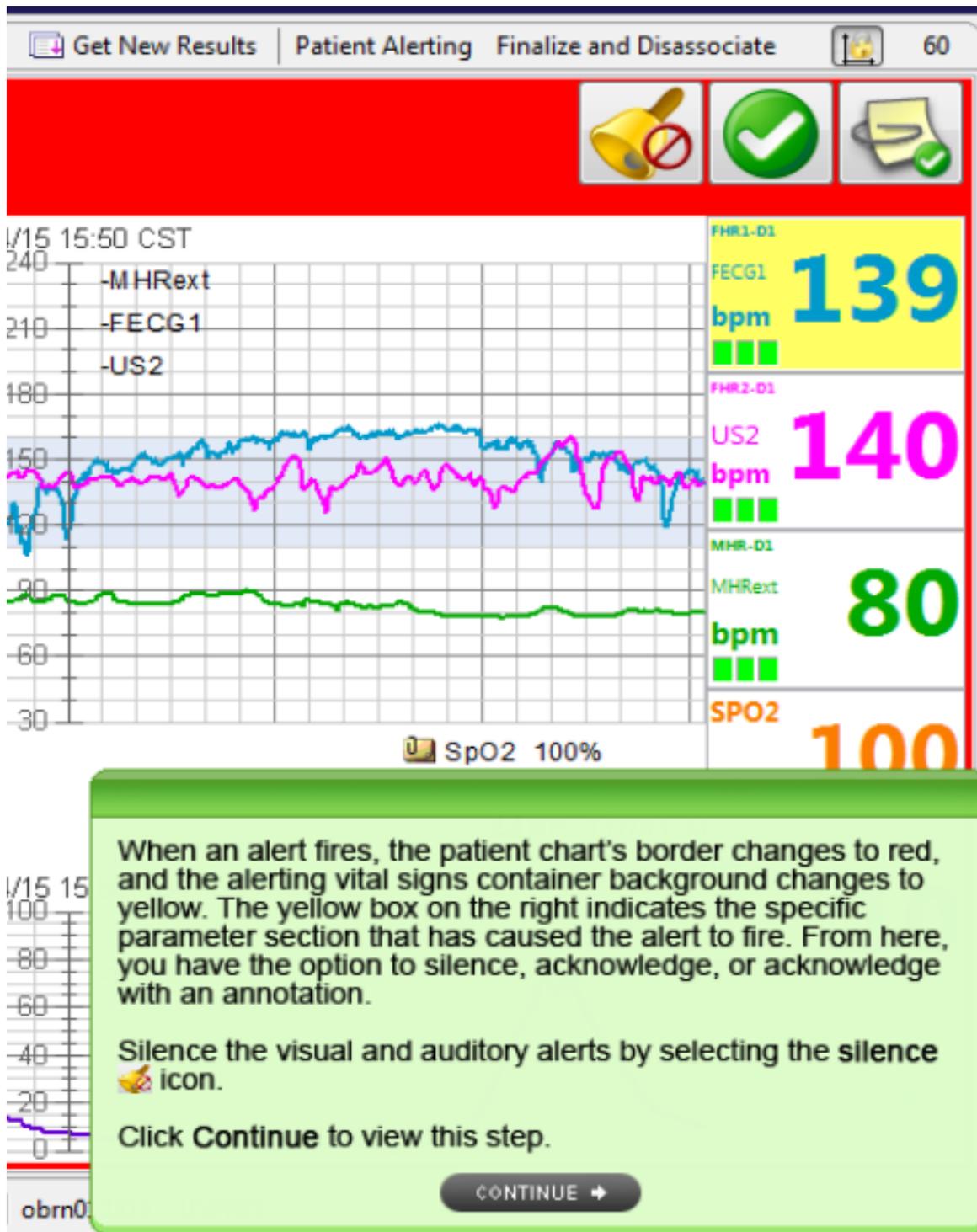


Click Alerts for the following view.



Appendix J

Cerner FetaLink™ Blood Pressure Alarm Notification



Annotations

User Name: Annotate: CST

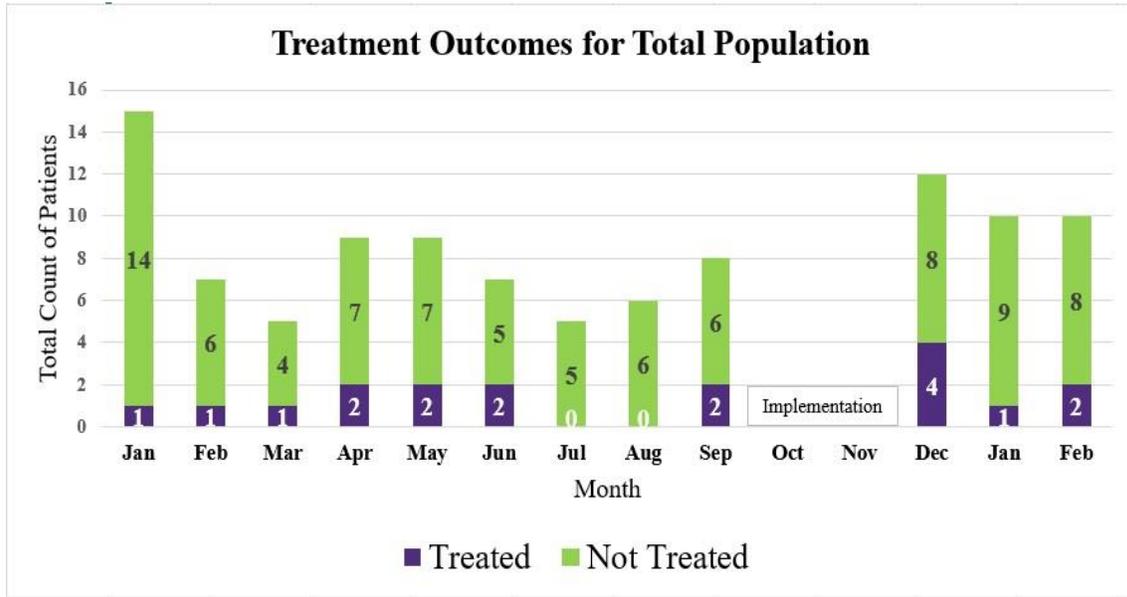
<input type="checkbox"/> RN at bedside	<input type="checkbox"/> OB Provider at bedside	<input type="checkbox"/> Call/Page OB provider
<input type="checkbox"/> Strip reviewed	<input type="checkbox"/> Up to bathroom	<input type="checkbox"/> Turn to left side
<input type="checkbox"/> Turn to right side	<input type="checkbox"/> Hands and knees	<input type="checkbox"/> Oxygen applied
<input type="checkbox"/> IV fluids increased	<input type="checkbox"/> Oxytocin off	<input type="checkbox"/> Vaginal Exam
<input type="checkbox"/> Pushing	<input type="checkbox"/> ROM	<input type="checkbox"/> Anesthesia at bedside

Hide Annotation

(Cerner FetaLink™, 2016)

Appendix K

Treatment Outcomes for *Severe Range* Blood Pressures



Appendix L

DNP Essential Competency and Demonstration Method

DNP Essential	DNP Competency	Demonstration Method
<p>Essential I</p> <p><i>Scientific Underpinning for Practice</i></p>	<p>Integrate nursing science with knowledge from ethics, the biophysical, psychosocial, analytical, and organizational sciences as the basis for the highest level of nursing practice.</p> <p>Use science-based theories and concepts to:</p> <ul style="list-style-type: none"> • Determine the nature and significance of health and health care delivery phenomena; • Describe the actions and advanced strategies to enhance, alleviate, and ameliorate health and health care delivery phenomena as appropriate; • Evaluate outcomes. <p>Develop and evaluate new practice approaches based on nursing theories and theories from other disciplines.</p>	<ul style="list-style-type: none"> ○ Concept Mapping ○ Concept Analysis ○ Synthesis Flow ○ Synthesis Literature Matrix (p. 70) ○ Theoretical Framework Identification (p.32) ○ CITI Modules ○ Good Clinical Practice Modules ○ IRB Process at Hospital & ECU (p. 13) ○ Community Assessments
<p>Essential II</p> <p><i>Organizational & Systems Leadership for Quality Improvement & Systems Thinking</i></p>	<p>Develop and evaluate care delivery approaches that meet current and future needs of patient populations based on scientific findings in nursing and other clinical sciences, as well as organizational, political, and economic sciences.</p> <p>Ensure accountability for quality of health care and patient safety for populations with whom they work.</p> <ul style="list-style-type: none"> • Use advanced communication skills/processes to lead quality improvement and patient safety initiatives in health care systems. • Employ principles of business, finance, economics, and health policy to develop and implement effective plans for practice-level and/or system-wide practice initiatives that will improve the quality of care delivery. • Develop and/or monitor budgets for practice initiatives. • Analyze the cost-effectiveness of practice initiatives accounting for risk and improvement of health care outcomes. • Demonstrate sensitivity to diverse organizational cultures and populations, including patients and providers. <p>Develop and/or evaluate effective strategies for managing the ethical dilemmas inherent in patient care, the health care organization, and research.</p>	<ul style="list-style-type: none"> ○ Organizational Assessment ○ Quality Improvement Plan ○ Scholarly Project ○ Cost Benefit Analysis ○ Grant Writing ○ Financial Statement Review ○ Estimating Costs ○ Budget Development ○ Redesigning a System of Care ○ Analysis of Quality Improvement ○ SQUIRE 2 ○ Innovation Analysis ○ Social Determinants of Health

DNP Essential	DNP Competency	Demonstration Method
<p>Essential III</p> <p><i>Clinical Scholarship & Analytical Methods for Evidence-Based Practice</i></p>	<p>Use analytic methods to critically appraise existing literature and other evidence to determine and implement the best evidence for practice.</p> <p>Design and implement processes to evaluate outcomes of practice, practice patterns, and systems of care within a practice setting, health care organization, or community against national benchmarks to determine variances in practice outcomes and population trends.</p> <p>Design, direct, and evaluate quality improvement methodologies to promote safe, timely, effective, efficient, equitable, and patient-centered care.</p> <p>Apply relevant findings to develop practice guidelines and improve practice and the practice environment.</p> <p>Use information technology and research methods appropriately to:</p> <ul style="list-style-type: none"> • collect appropriate and accurate data to generate evidence for nursing practice • inform and guide the design of databases that generate meaningful evidence for nursing practice • analyze data from practice • design evidence-based interventions • predict and analyze outcomes • examine patterns of behavior and outcomes • identify gaps in evidence for practice <p>Function as a practice specialist/consultant in collaborative knowledge-generating research.</p> <p>Disseminate findings from evidence-based practice and research to improve healthcare outcomes.</p>	<ul style="list-style-type: none"> ○ Concept Mapping ○ Literature Review ○ Concept Analysis ○ Concept Application ○ Analysis of Project Data (p. 45) ○ Analysis of Quality Improvement ○ SQUIRE 2 ○ Innovation Analysis ○ Social Determinants of Health ○ Community Assessment ○ Cultural Competency Modules ○ Critical Analysis of Literature (p. 18) ○ Synthesis of Evidence (p.30) ○ Gap in Literature (p.31) ○ Scholarly Project Review at Facility ○ Abstract Submission of Scholarly Project
<p>Essential IV</p> <p><i>Information Systems – Technology & Patient Care Technology for the Improvement & Transformation of Health Care</i></p>	<p>Design, select, use, and evaluate programs that evaluate and monitor outcomes of care, care systems, and quality improvement including consumer use of health care information systems.</p> <p>Analyze and communicate critical elements necessary to the selection, use and evaluation of health care information systems and patient care technology.</p> <p>Demonstrate the conceptual ability and technical skills to develop and execute an evaluation plan involving data extraction from practice information systems and databases.</p> <p>Provide leadership in the evaluation and resolution of ethical and legal issues within healthcare systems relating to the use of information, information technology, communication networks, and patient care technology.</p> <p>Evaluate consumer health information sources for accuracy, timeliness, and appropriateness.</p>	<ul style="list-style-type: none"> ○ Utilization of Excel (p. 93) ○ Utilization of SPSS (p. 43) ○ Theoretical Framework Identification (p. 32) ○ SQUIRE 2.0 ○ PDSA ○ SWOT ○ Maternal Early Warning Systems ○ Cerner® FetaLink™

DNP Essential	DNP Competency	Demonstration Method
<p>Essential V</p> <p><i>Health Care Policy of Advocacy in Health Care</i></p>	<p>Critically analyze health policy proposals, health policies, and related issues from the perspective of consumers, nursing, other health professions, and other stakeholders in policy and public forums.</p> <p>Demonstrate leadership in the development and implementation of institutional, local, state, federal, and/or international health policy.</p> <p>Influence policy makers through active participation on committees, boards, or task forces at the institutional, local, state, regional, national, and/or international levels to improve health care delivery and outcomes.</p> <p>Educate others, including policy makers at all levels, regarding nursing, health policy, and patient care outcomes.</p> <p>Advocate for the nursing profession within the policy and healthcare communities.</p> <p>Develop, evaluate, and provide leadership for health care policy that shapes health care financing, regulation, and delivery. Advocate for social justice, equity, and ethical policies within all healthcare arenas.</p>	<ul style="list-style-type: none"> o ANA Code of Ethics o ANA Strategic Plan o NC Division of Medical Assistance o SWOT o Maternal Early Warning Systems (MEWS) o Needs Assessment for MEWS (p.35) o Scholarly Project: Evaluated as Quality Improvement through ECU IRB, Hospital IRB and NSAC (p. 13) o Recommend use of Electronic Health Record to detect Signs of Clinical Deterioration
<p>Essential VI</p> <p><i>Interprofessional Collaboration for Improving Patient & Population Health Outcomes</i></p>	<p>Employ effective communication and collaborative skills in the development and implementation of practice models, peer review, practice guidelines, health policy, standards of care, and/or other scholarly products.</p> <p>Lead interprofessional teams in the analysis of complex practice and organizational issues.</p> <p>Employ consultative and leadership skills with intraprofessional and interprofessional teams to create change in health care and complex healthcare delivery systems.</p>	<ul style="list-style-type: none"> o Benefit of Project to Practice (p. 50) o Change Theory o Motivational Interviewing with Interprofessional Teammates o Collaborated with Information Systems Department, Quality Department, Nursing Informatics Officer, Perinatal Quality Committee (p.13) o Scholarly Project: Evaluated as Quality Improvement through ECU IRB, Hospital IRB and NSAC (p. 62)

DNP Essential	DNP Competency	Demonstration Method
<p>Essential VII</p> <p><i>Clinical Prevention & Population Health for Improving the Nation's Health</i></p>	<p>Analyze epidemiological, biostatistical, environmental, and other appropriate scientific data related to individual, aggregate, and population health.</p> <p>Synthesize concepts, including psychosocial dimensions and cultural diversity, related to clinical prevention and population health in developing, implementing, and evaluating interventions to address health promotion/disease prevention efforts, improve health status/access patterns, and/or address gaps in care of individuals, aggregates, or populations.</p> <p>Evaluate care delivery models and/or strategies using concepts related to community, environmental and occupational health, and cultural and socioeconomic dimensions of health.</p>	<ul style="list-style-type: none"> ○ Determinants of Health ○ Community Assessment ○ Cultural Competency Modules ○ Critical Analysis of Literature (p. 18) ○ Synthesis of Evidence (p.30) ○ Gap in Literature (p.31) ○ IHI Triple Aim and Healthy People 2020 Application for Improving Patient Outcomes (p. 47)
<p>Essential VIII</p> <p><i>Advanced Nursing Practice</i></p>	<p>Conduct a comprehensive and systematic assessment of health and illness parameters in complex situations, incorporating diverse and culturally sensitive approaches.</p> <p>Design, implement, and evaluate therapeutic interventions based on nursing science and other sciences.</p> <p>Develop and sustain therapeutic relationships and partnerships with patients (individual, family or group) and other professionals to facilitate optimal care and patient outcomes.</p> <p>Demonstrate advanced levels of clinical judgment, systems thinking, and accountability in designing, delivering, and evaluating evidence-based care to improve patient outcomes.</p> <p>Guide, mentor, and support other nurses to achieve excellence in nursing practice.</p> <p>Educate and guide individuals and groups through complex health and situational transitions.</p> <p>Use conceptual and analytical skills in evaluating the links among practice, organizational, population, fiscal, and policy issues.</p>	<ul style="list-style-type: none"> ○ Introduction to the Problem (p. 8) ○ Background of the Problem (p.9) ○ Significance of the Problem (p.10) ○ Needs Assessment (p.35) ○ Project Design (p.35) ○ Innovation Analysis ○ Analysis of Quality Improvement ○ SQUIRE 2.0