Reducing Hypotension in Elective Cesarean Section Patients with Administration of Ondansetron Prior to Spinal Anesthesia: A Retrospective Chart Analysis

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REDUCING HYPOTENSION IN ELECTIVE CESAREAN SECTION PATIENTS
WITH ADMINISTRATION OF ONDANSETRON PRIOR TO SPINAL
ANESTHESIA: A RETROSPECTIVE CHART ANALYSIS

by

Linsey Erin Phipps

A Capstone Project
Submitted to the Graduate School
and the Department of Advanced Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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December 2016
ABSTRACT

REDUCING HYPOTENSION IN ELECTIVE CESAREAN SECTION PATIENTS WITH ADMINISTRATION OF ONDANSETRON PRIOR TO SPINAL ANESTHESIA: A RETROSPECTIVE CHART ANALYSIS

by Linsey Erin Phipps

December 2016

The birth of a child is one of the most memorable moments in a woman’s life, and many women undergo an elective cesarean section, requiring spinal anesthesia. At this time, the patient and the unborn child’s well-being become the anesthetist’s main focus. The ultimate goal of anesthesia providers is to provide the safest care to the patient. Spinal anesthesia has many benefits, but has a common side effect of hypotension, which can also result in nausea. Hypotension, dangerous to mother and child, is often treated with vasopressors, but can also cause nausea, which is treated by the administration of ondansetron. A retrospective chart review (N=114) was performed to examine if the administration of ondansetron prior to spinal anesthesia in elective cesarean section patients reduced the occurrence of hypotension. Inclusion criteria consists of patients receiving spinal anesthesia for elective cesarean sections, ages 20-40 years, ondansetron only given prior to spinal anesthesia, ondansetron given in ten minutes or less before spinal anesthesia and met the American Society of Anesthesiologist’s (ASA) patient status classification I or II. Exclusion criteria includes patients presenting for cesarean section with epidural due to failure to progress, ASA patient status classification III, IV or V, emergent cesarean sections, multiple parities (twins/triplets), > 1,000 ml blood loss, > 6 mg ondansetron administered, patients presenting with a cardiac history (coronary
artery disease, myocardial infarction, congestive heart failure, murmur, mitral valve prolapse/regurgitation, dysrhythmias, aortic stenosis/regurgitation) and patients presenting with preeclampsia. A Chi Square test was performed, which indicated no significant association between administering ondansetron and the occurrence of hypotension (df=1, $x^2(1) = .035$, $p= .851$). A secondary analysis was performed, which did show a significant association between administering ondansetron and the reduced usage of vasopressors to increase blood pressure (df=1, $x^2(1) = 6.437$, $p= .011$). This evidence indicates that though ondansetron did not result in reducing hypotension, it did result in decreasing the amount of vasopressors used to maintain blood pressure, which in turn decreased vasopressor adverse side effects to mother and unborn child.
ACKNOWLEDGMENTS

I would like to convey my sincerest appreciation to my chair, Dr. Harbaugh. Her knowledge and guidance has allowed me to successfully complete this project. Thank you for all your patience and long hours spent helping with my project. I would also like to thank my committee members, Dr. Hayden and Dr. Rayborn. I could not have completed this project without your direction and encouragement.
DEDICATION

I would like to thank my parents, Patti and Dennis Phipps, for their support and love throughout the process of obtaining my Doctorate in Nursing Practice. I would also like to thank my significant other, Jay Butler, for all of his support and help throughout school. He has remained patient and loving throughout this whole endeavor. This capstone is dedicated to my parents, who have always told me to reach for the stars and never stop chasing my dreams. They have always pushed me to do my best in life and have had the utmost patience throughout this long journey. I can never thank them enough for everything they have done for me and given me throughout my life. This project is also dedicated to my significant other, Jay Butler, he has been my rock throughout this program. Without his positive attitude, patience and unfaltering love I would not be completing this project. Thank you for everything you have done for me over these three years.
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<table>
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<tr>
<td>ASA</td>
<td>American Society of Anesthesiologists</td>
</tr>
<tr>
<td>CE</td>
<td>Continuing Education</td>
</tr>
<tr>
<td>CRNA</td>
<td>Certified Registered Nurse Anesthetist</td>
</tr>
<tr>
<td>DAP</td>
<td>Diastolic Arterial Pressure</td>
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<td>DCI</td>
<td>Data Collection Instrument</td>
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<td>EPIC</td>
<td>Electronic Patient Integrated Care</td>
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<td>HR</td>
<td>Heart Rate</td>
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<td>MAP</td>
<td>Mean Arterial Pressure</td>
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<td>SAP</td>
<td>Systolic Arterial Pressure</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
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CHAPTER I - INTRODUCTION

When women enter the hospital for an elective cesarean section, they are given the option of general, spinal, or spinal/epidural combined anesthesia. The risk factors and benefits of each procedure are explained to the patient by the anesthesia provider. The primary anesthetic procedure used at this time is spinal anesthesia (Sirajuddin, Abbas, Murtaza, & Naqvi, 2013). Nagelhout and Plaus (2014) state “single shot spinal anesthesia is the most common used anesthetic technique for cesarean section deliveries because this technique offers many distinct advantages” (p. 1142). The advantages of spinal anesthesia include rapid onset, a more reliable block, and uses less toxic doses of local anesthetics compared to epidural anesthesia. Though there are many advantages that come from the use of spinal anesthesia, there are also some disadvantages. A few of the disadvantages when using spinal anesthesia include a chance of having a failure of the block, the fixed amount of time that a particular drug is effective, and sympathectomy with resultant hypotension and bradycardia. Farmawy and Rashad (2013) stated that hypotension represents the incidence of about 55-100%, making it the most frequent complication. Adults can walk around with low blood pressure every day, for a pregnant woman and her unborn child, hypotension needs to be treated. Hypotension in a pregnant woman can cause unconsciousness, which can lead to aspiration. It may also cause cardiac issues and decreased perfusion to the unborn child (Nagelhout & Plaus, 2014).

Clinical Question

Does ondansetron, a 5HT3 antagonist used commonly to treat nausea, help reduce the hypotension associated with spinal anesthesia in women having a cesarean section? By understanding the effects ondansetron has on the body, healthcare providers
can capitalize on the benefits this medication can bring to pregnant women receiving the medication before the placement of spinal anesthesia. The use of ondansetron prior to spinal placement has been shown to reduce the excessive use of fluids and the need to use vasopressors to combat hypotension during the case (Farmawy & Rashad, 2013). Reducing the utilization of other medications and multiple bags of fluid will in turn reduce costs for the hospital and pharmacy. The proposed mechanism of ondansetron is the antagonism by the 5HT3 receptors in the intracardiac vagal nerve endings in the Bezold Jarisch reflex (Nagelhout & Plaus, 2014). Understanding the different responses activated by certain medications help make spinal anesthesia safer for pregnant women. Studies show that the use of opioid medications cause hypotension and that ondansetron can assist in reversing the hypotensive response. The opioid pathways in the brain are crucial in the hypotensive response detected after the 5HT3 antagonist receptor stimulation. By being more aware of the pain medications given to the patients, a better understanding of the side effects can be realized, and some may be able to be reversed by ondansetron.

Whether fluids, vasopressors or ondansetron are used to treat hypotension related to spinal anesthesia, hypotension must be treated to prevent further deterioration of the patient. Patient safety is the number one goal during the hospital stay. Evidence must be used to determine the most appropriate ways to increase patient safety and satisfaction. Ondansetron could be the most useful and cost effective way to maintain hemodynamics in pregnant women while undergoing spinal anesthesia.
Background and Significance/Problem Statement

Spinal anesthesia has the potential to produce several undesirable problems; the main one being hypotension. Nagelhout and Plaus (2014) state “when spinal anesthesia is used to produce the T4 (thoracic vertebrae 4) block needed for cesarean section, hypotension has been shown to occur in up to 80% of patients despite the patient being placed in left uterine displacement” (p. 1143). Typically, hypotension is treated with either large amounts of fluid therapy or vasopressors. Fluid therapy has been shown to provide positive outcomes in helping to reduce hypotension, but it can also lead to fluid overload and urinary retention. Patients with an underlying history of cardiac issues, such as congestive heart failure, will be unable to receive the typical one liter of fluid prior to spinal anesthesia. These patients are at a disadvantage and more prone to developing severe hypotension.

Ephedrine is the most common vasopressor used to treat maternal hypotension. Ephedrine is a synthetic, noncatecholamine sympathomimetic drug. Ephedrine is typically administered in doses ranging from five to twenty-five milligrams intravenously to treat acute decreases in blood pressure (Nagelhout & Plaus, 2014). According to Nagelhout and Plaus (2014), the effect of five to ten milligram intravenous doses usually persists for five minutes and the duration of ephedrine’s cardiovascular effects varies with each dose. Another drawback to the use of this medication is the possibility of tachyphylaxis. Tachyphylaxis can occur with repeated small dosing of ephedrine, which results in a decreased clinical effect after subsequent dosing. The issue of constant redosing and unreliability of duration of action show the drawbacks of using this medication to treat maternal hypotension. Nagelhout and Plaus (2014) state “recent
evidence suggests that ephedrine may cross the placenta and stimulate fetal β-adrenergic receptors, resulting in depression of fetal acid–base balance” (p. 1143). This makes its repeated use less than desirable.

Evidence of Problem/Local Need

Spinal anesthesia causes predictable and controllable physiologic changes that require minimal intervention if detected early. The spinal anesthetic causes a sympathetic nerve blockade, which in turn causes vasodilation, decreased venous return and decreased systemic vascular resistance. The changes that are caused by the sympathetic blockade in turn change the redistribution of blood and lead to hypotension. According to Nagelhout and Plaus (2014), “hypotension is immediately relevant to the perfusion of critical organs such as the heart and brain and is important to all organs in maintaining near homeostasis” (p. 1083).

When discussing the issue of spinal anesthesia and hypotension with anesthesia providers, there was a consensus that there is an issue in the obstetric population and a need to reduce the harmful side effects. In an interview with a local CRNA at my practice site (July 10, 2015), the issue of hypotension associated with spinal anesthesia was addressed as well as why he chose to administer ondansetron to help reduce this side effect. The CRNA stated he started using ondansetron in the obstetric population to help reduce hypotension after spinal anesthesia after he attended a Continuing Education (CE) meeting discussing this issue. After learning of its use he brought this information back to the practice site and started administering it to the obstetric patients receiving elective cesarean sections and spinal anesthesia. The CRNA stated approximately 70% of the patients receiving ondansetron required zero or a drastically decreased amount of blood
pressure support. Ondansetron, four milligrams, is given usually after the preoperative interview if the patient is being taken directly back to the operating room. The CRNA said he has seen a decrease in the amount of vasopressors being used during the procedure due to the administration of ondansetron prior to spinal anesthesia. Hypotension after spinal anesthesia for cesarean section patients has been an ongoing issue for this population, the ability to administer a medication that will help reduce this side effect and help make it safer for mother and child is of the utmost importance.

**Purpose of the Project**

The aim of this doctoral project is to examine clinical evidence to support a practice change to reduce the amount of vasopressors administered to cesarean section patients receiving spinal anesthesia by administering ondansetron, thereby reducing hypotension related to this particular population and increasing patient safety. Evidence of the relationship between the administration of ondansetron prior to spinal anesthesia in cesarean section patients and reduced hypotension, and decreased use of vasopressors will be done via a retrospective chart review. As healthcare providers, our duty is to provide care that is efficient and harmless to our patients. Healthcare providers must evaluate the medications and procedures used and determine if evidence supports enhancements in the care the patient receives during their stay. Patients come to the hospital wanting to feel safe and assume the safest, most current forms of treatment are being used. Through establishing the evidence linking ondansetron to hypotension, when administered prior to spinal anesthesia for a cesarean section, a change in current practice may be indicated. Findings will be presented to key stakeholders in an educational presentation. The educational presentation will disseminate the evidence of relationship
of ondansetron, administered prior to spinal anesthesia in cesarean section patients, to hypotension, and the use of vasopressors. See Appendix D and E for project logic model and SWOT analysis.

Theoretical Framework

The theory used that represents the concepts of preventing hypotension related to spinal anesthesia for a cesarean section is The Theory of Human Caring (Watson, 1979). This theory incorporates the human being, health, environment, and nursing; the nursing model is concerned with promoting the patient’s health, preventing illness, caring for the sick and restoring the patient’s health (Watson, 2008). The healthcare provider uses the nursing process to evaluate the patient. Care plans are developed to help the healthcare provider determine individual variables that would be included/examined and what data will be collected; this is the intervention phase. Evaluation of all data collected and analyzing the results may likely lead to a new idea regarding the problem. In this theory, caring is a key component that will result in the promotion of the patient’s health and satisfaction of their needs. Identifying the problem, building a relationship with the patient that promotes faith and hope in the provider, discussing the problem and options with the patient, developing a plan for the patient and the problem, all come together in covering Watson’s 10 carative factors and make her framework a good fit for this doctoral project.

Doctor of Nursing Practice Essentials

This doctoral project fulfills and applies the 8 practice essentials of the doctor of nursing practice essentials. This doctoral project meets all eight essentials (See Appendix B), but the main essentials addressed are Essential IV and VI. In looking at Essential IV,
there was a retrospective chart review and de-identified patient data was extracted from their electronic medical record and protected to avoid ethic/legal issues. Electronic databases were used for review of literature and to obtain information regarding ondansetron and spinal anesthesia on cesarean section patients. Essential VI was met by collaboration with anesthesia providers which is pivotal to bringing about a practice change. Each provider has vital information and suggestions that can help bring about a change and help in providing the safest care to the patient population. Another vital component in collaboration for this project, is that of the Electronic Patient Integrated Care (EPIC) technology staff and the researcher. Without this collaboration, the information for the project would not have been available.
CHAPTER II – REVIEW OF LITERATURE

A literature search was conducted to determine if the incidence of hypotension with spinal anesthesia is reduced if ondansetron is given prior to the procedure for women receiving an elective cesarean section. A comprehensive review of literature was performed. Article inclusion criteria were as follows: 1) articles must relate to spinal anesthesia and the use of ondansetron, 2) must be written in English 3) searches were limited to peer-reviewed articles appearing in scholarly journals in the past five years. The search consisted of multiple databases accessed through USM's online catalog. The databases used were PubMed, Cochrane, CINAHL with Full Text, and Medline. The search terms used were ondansetron, hypotension, spinal anesthesia and cesarean section. One hundred sixty-eight articles were found. Six articles met inclusion criteria. After an initial review, the final six articles consisted of systematic, meta-analysis and integrative reviews of control trials. Information from the articles was placed into a literature matrix. (See Appendix A)

Synthesis of Literature

Spinal anesthesia has become a safe alternative to general anesthesia for surgical interventions. Though the procedure has many advantages, the disadvantages such as cardiovascular effects can be detrimental. The most common issues expressed are hypotension and bradycardia. Spinal anesthesia decreases vascular resistance and stimulates the Bezold-Jarisch reflex. The responses in turn cause vasodilation and bradycardia, which result from the stimulation of the 5HT3 receptors in the vagal nerve endings (Owczuk et al., 2008).
Owczuk et al. (2008) implemented a study to validate their hypothesis that blocking type three serotonin receptors by introducing ondansetron intravenously would reduce hypotension and bradycardia induced by spinal anesthesia. Seventy-one adult pregnant patients participated in the study. Patients were randomly placed into two groups. The ondansetron group contained 36 patients who received 8 mg of ondansetron diluted in 10 ml normal saline. The placebo group included 35 patients who were administered 10 ml of normal saline. Baseline measurements were obtained five minutes prior to the spinal anesthetic and every five minutes throughout the procedure. There was a decrease in the mean arterial pressure (MAP), systolic arterial pressure (SAP), and diastolic arterial pressure (DAP) in both groups when compared to the baseline measurements with the heart rate (HR) values remaining unchanged. The ondansetron group showed a higher SAP when measurements were taken at the 10, 15 and 20-minute marks. The MAP, DAP, and HR had no significant changes in the two groups at these minute marks. A SAP drop below 90 mmHg was detected in 7 patients in the placebo group and 1 patient in the ondansetron group (20% vs. 2.8%) this difference was statistically significant (p=0.028) (Owczuk et al., 2008). The study concluded there was no definite evidence that the ondansetron had more advantages than administration of vasopressors, but its use may be more beneficial for particular groups of patients. One population of patients is pregnant women, in which the administration of vasopressors can have adverse effects on uterine blood flow, and may not be the optimal choice.

In a study conducted by Sahoo, SenDasgupta, Goswami, and Hazra (2012) the authors hypothesized that spinal induced hypotension and bradycardia could be minimized with ondansetron in non-laboring obstetric patients undergoing a cesarean
section. This study consisted of 52 patients scheduled for cesarean sections who were randomly placed into two groups. Group O consisted of 26 patients receiving 4 mg of ondansetron. Group S consisted of 26 patients receiving 10 ml normal saline. Heart rate, blood pressure, and vasopressor use were measured with each group. Decreases in mean arterial pressure were significantly lower in Group O. Patients in Group O required significantly less vasopressor \( (p=0.009) \) (Sahoo et al., 2012). The use of ephedrine and the incidence of nausea were significantly decreased with the administration of ondansetron. The study concluded that administration of ondansetron 4 mg five minutes prior to the spinal anesthetic reduces hypotension and vasopressor use in patients undergoing a cesarean section.

Wang et al. (2014b) investigated the effects of administering ondansetron prior to spinal anesthesia by coloading crystalloid infusion after the administration with cesarean delivery. The research extended previous studies that investigated the effect of preloading with crystalloid on hypotension. Though there are benefits to this method, researchers concluded that delaying the spinal anesthesia for the nurse to deliver a fixed amount of crystalloid was not the best option.

Wang et al. (2014b) continued their investigation by administering ondansetron prior to the cesarean sections, which would not require a delay in onset of anesthesia. These authors hypothesized that administering ondansetron prior to the spinal and crystalloid after the spinal would decrease the incidence of hypotension. The study consisted of 62 women taking part in an elective cesarean section. The women were placed into two randomly selected groups. The group receiving ondansetron had a significantly lower incidence of hypotension and nausea than the placebo group \( (p=0.011 \).
vs. 0.004). The frequency of decreasing mean arterial pressure and systolic pressure were also lower in the group receiving ondansetron compared to the placebo group (\(p=0.008\) vs. 0.025). This group also required less phenylephrine administration throughout the case. The authors concluded the method used helped to significantly reduce maternal hypotension and nausea, and reduced the amount of vasoconstrictors used during the case.

While studies have shown the benefits of using ondansetron on maternal hypotension when administering spinal anesthesia, one drawback has been that the different amounts of the drug were not fully investigated. In Wang et al. (2014a) a dose-dependent study was set up to determine the optimal dose for ondansetron. One hundred and fifty women were divided up into five groups (n=150). The groups consisted of a control placebo and administration groups receiving 2mg, 4mg, 6mg and 8 mg of ondansetron. The group 4mg and 6mg showed a reduced incidence of maternal hypotension compared to other groups (\(p \leq 0.05\)). Minimal changes from baseline in the mean arterial pressure, systolic blood pressure, and diastolic pressure appeared in these two groups. The researchers concluded that while both doses provided the beneficial results, administration of 4mg ondansetron is the best option. Administering 6mg or greater of ondansetron is related to lactate acidosis in the fetus. The administration of less than 4mg ondansetron failed to show a reduced incidence of maternal hypotension. Four milligrams ondansetron was determined to be the optimal dose because of the dose ability to prevent maternal hypotension, decrease nausea and the reduced need for vasoconstrictors (Wang et al., 2014a).
The use of ondansetron for maternal hypotension is considered to be a newer intervention that is not entirely understood. Ortiz-Gomez et al. (2014) performed a double-blind, randomized study to observe the effects of ondansetron and determine the optimal dose. One hundred twenty-eight women undergoing elective cesarean sections receiving spinal anesthesia were involved in the study. The women were randomly placed into four groups (n=32) and received either a placebo or 2 mg, 4 mg, 8 mg ondansetron dosages prior to spinal anesthesia. The authors concluded there were no differences in the number of patients with hypotension: 14 patients (43.7%) in the placebo group, 17 (53.1%) in the 2 mg group, 18 (56.2%) in the 4 mg group, and 17 (53.1%) in the group receiving 8 mg ondansetron ($p=0.77$). There were also no differences found in the groups of patients requiring vasoconstrictors. The study did not support administration of ondansetron prior to spinal anesthesia to reduce maternal hypotension. The authors concluded that the findings showed there was little effect on the incidence of hypotension from administration of ondansetron in parturients undergoing spinal anesthesia. This effect might be due to differences in a particular population, sample size, study design, and anesthetic technique.

Farmawy and Rashad (2013), performed a study to observe the effects of giving ondansetron or granisetron to patients undergoing spinal anesthesia for their cesarean section. The authors investigated the effect of hypotension related to spinal anesthesia by observing the effects of the patient’s hemodynamics and sensory blockade. Sixty women undergoing elective cesarean section were divided into three groups (n=20). The first group, labeled O, had an injection of 4 mg of ondansetron mixed with 10 ml of normal saline. The second group, labeled G, had an injection of 1 mg granisetron mixed with 10
ml of normal saline, and the third group, labeled S, had an injection of 10 ml of normal saline. The results of the study concluded ondansetron was most effective in decreasing hypotension related to spinal anesthesia with lower vasopressor use ($p<0.05$) and granisetron was more efficient in allowing the motor functions to come back sooner ($p<0.05$). There was also a significant decrease in nausea in the groups administered ondansetron and granisetron ($p=0.008$).

The advancement of surgery and medicine has brought about new studies that will help in increasing positive outcomes of patients. The articles in this literature review had varying results on the administration of ondansetron to help decrease the incidence of hypotension associated with spinal anesthesia. Though the authors provided sufficient evidence to support the use of ondansetron, more studies and evidence need to be accumulated before making a final decision. Safety and efficiency are the main objectives when caring for our patients. Ondansetron has many beneficial uses in the clinical setting, to be able to use it to help prevent spinal anesthesia induced hypotension, as well as nausea and vomiting will be an added benefit. A medication having multiple benefits and few disadvantages will ensure the patient receives the best care possible.

Within this doctoral project’s clinical site, some providers administer ondansetron prior to spinal anesthesia and other providers do not. The medical field is ever changing, and advances are being made on a daily basis. Healthcare providers’ single goal is to provide the safest and most efficient care to patients. In providing care to women receiving spinal anesthesia for a cesarean section, there are many potential problems that need to be addressed. One of the main side effects of spinal anesthesia is hypotension (Farmawy & Rashad, 2013). This side effect can cause many problems for the mother
and the neonate that has yet to be born. The purposes of this doctoral project are to determine if ondansetron, a 5HT3 antagonist, helps reduce the hypotension associated with spinal anesthesia in women having a cesarean section, also if ondansetron use reduces the administration of vasopressors. These clinical questions will be answered using a retrospective chart review. In the sections that follow the method/data collection and analysis of the data will be discussed.
CHAPTER III - METHODOLOGY

The retrospective chart analysis took place at a hospital in the Southeastern United States. The facility has 512-inpatient beds. Patient information and record-keeping is accomplished by using EPIC software. Inclusion criteria consists of patients receiving spinal anesthesia for elective cesarean sections, ages 20-40 years, ondansetron only given prior to spinal anesthesia, ondansetron given in ten minutes or less before spinal anesthesia and met the American Society of Anesthesiologist’s (ASA) patient status classification I or II. Exclusion criteria includes patients presenting for cesarean section with epidural due to failure to progress, ASA patient status classification III, IV or V, emergent cesarean sections, multiple parities (twins/triplets), > 1,000 ml blood loss, > 6 mg ondansetron administered, patients presenting with a cardiac history (coronary artery disease, myocardial infarction, congestive heart failure, murmur, mitral valve prolapse/regurgitation, dysrhythmias, aortic stenosis/regurgitation), patients taking blood pressure medication and patients presenting with preeclampsia. After examining all data, a final inclusive data set was obtained. A sample size calculator determined the sample size, and the confidence level and confidence interval needed to produce a significant result. According to G power calculator with using a Chi square test the sample size will be 145, effect size 0.3 (medium), beta to alpha ratio .95, critical $x^2 = 3.841458$ and degrees of freedom 1. A Chi-Square test can determine if there is a significant relationship between two variables, those variables being the use of ondansetron and the incidence of hypotension after spinal anesthesia in women undergoing elective cesarean sections and the use of ondansetron and the administration of vasopressors. The independent variable consists of the usage of ondansetron and the non-usage of ondansetron. Dependent
variable are if hypotension does occur or does not occur, and if vasopressors are given or not.

Procedures/Methods

After IRB and hospital approval (See Appendix F), access to EPIC computer charting system was commenced. Patients at this time were de-identified. De-identifying the data was accomplished by deleting the patient identification number and substituting the number with a researcher generated unique identifier. A data collection instrument (DCI) was used to record patient data. (See Appendix C). The data collection instrument included subject number, age, ASA classification, diagnosis, previous cesarean sections, parity, hypotensive episodes, and administration of vasopressors. The hypotensive occurrences were defined as having more than a 20% decrease in blood pressure from baseline blood pressure prior to spinal anesthesia.

Analysis

Retrospective results and a presentation were compiled using the information/data collection from the literature review and chart analysis. This presentation was presented to the anesthesia providers at the facility where data were collected. Data hygiene and univariate analysis was used to look for outliers, miskeyed data and audits between data collection instrument (DCI) and every tenth subject ID. A Chi square analysis was used to analyze data between the independent and dependent variables stated earlier in the methodology section. All data collected were used to inform fellow anesthesia providers whether ondansetron reduced the incidence of low blood pressure in this hospital’s elective cesarean section patients, and also whether the use of ondansetron reduced the use of vasopressors.
CHAPTER IV – RESULTS

This DNP project determined if administration of ondansetron prior to spinal anesthesia in elective cesarean section patients reduces hypotension and the use of vasopressors. Variables examined were use of ondansetron, administration ten minutes or less prior to spinal anesthesia and usage of vasopressors up until the birth of the baby. A comprehensive literature review was conducted and results from the retrospective chart analysis were compiled within this doctoral project.

This project utilized the Chi Square test to assess the relationships in receiving ondansetron prior to spinal anesthesia and not receiving ondansetron prior to spinal anesthesia and the effect this drug has on reducing hypotension and on the use of vasopressors. The Chi Square test was executed by using SPSS (Statistical Package for the Social Sciences) by the researcher. Results were considered significant if the p value was equal to or less than .05.

Discussion of Results

There were 812 patient charts reviewed. Of the 812 charts, 57 met the inclusion criteria of receiving ondansetron ten minutes or less prior to spinal anesthesia, were between the ages of 20-40, and were an ASA class of I or II. Out of the 812 charts, 57 were also chosen that met all inclusion criteria except they did not receive ondansetron prior to spinal anesthesia, these charts were used to compare blood pressure values and vasopressor use to the prior 57 charts chosen. The 57 charts who did not receive ondansetron prior to spinal anesthesia were chosen on a first come, first serve basis. The first 57 available charts that met the criteria were used. Of the 114 charts used the minimum age was 20, maximum age of 39, with a mean age of 29. The minimum parity
was 0, the maximum parity was 10, with a mean parity of 1. There were 7 patients who fell into the ASA I class, with 107 patients in ASA II class.

A Chi Square test was conducted to examine hypotension in patients who did and did not receive ondansetron prior to spinal anesthesia in elective cesarean sections patients. The test determined there was not a significant association between the hypotension group and whether or not they used ondansetron, \( N=114, \text{df}=1, \chi^2 (1) = .035, p = .851 \) (Tables 1 & 2). These results show there is no significant benefit of using ondansetron prior to spinal anesthesia to help reduce hypotension. The second Chi Square test was done to investigate if less vasopressors were used up until the baby was born on those who received ondansetron. There was a significant association between vasopressor use and whether or not they used ondansetron, \( N=114, \text{df}=1, \chi^2(1) = 6.437, p = .011 \) (Tables 3 & 4).

**Table 1 Ondansetron and Hypotension Crosstabulation**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Ondansetron Administered</th>
<th>No Ondansetron Administered</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>Count</td>
<td>Count</td>
</tr>
<tr>
<td></td>
<td>Hypotension</td>
<td>No Hypotension</td>
<td>Hypotension</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>32</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>25.5</td>
<td>31.5</td>
<td>57.0</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>63</td>
<td>114</td>
</tr>
</tbody>
</table>
Table 2 *Pearson Chi-Square Test Ondansetron and Hypotension*

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymptotic Significance (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>.035</td>
<td>1</td>
<td>.851</td>
</tr>
</tbody>
</table>

Table 3 *Ondansetron and Vasopressor Crosstabulation*

<table>
<thead>
<tr>
<th></th>
<th>Vasopressor</th>
<th>No Vasopressor</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Some Vasopressor</td>
<td>No Vasopressor</td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>Count</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td>Ondansetron Administered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>30</td>
<td>27</td>
<td>57</td>
</tr>
<tr>
<td>Expected Count</td>
<td>36.5</td>
<td>20.5</td>
<td>57.0</td>
</tr>
<tr>
<td>Count</td>
<td>43</td>
<td>14</td>
<td>57</td>
</tr>
<tr>
<td>Expected Count</td>
<td>36.5</td>
<td>20.5</td>
<td>57.0</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>73</td>
<td>41</td>
<td>114</td>
</tr>
<tr>
<td>Expected Count</td>
<td>73.0</td>
<td>41.0</td>
<td>114.0</td>
</tr>
</tbody>
</table>

Table 4 *Pearson Chi-Square Test Ondansetron and Vasopressor*

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymptotic Significance (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>6.437</td>
<td>1</td>
<td>.011</td>
</tr>
</tbody>
</table>
CHAPTER V – SUMMARY

The main goals of this retrospective chart analysis were to show whether the administration of ondansetron prior to spinal anesthesia would help reduce hypotension, or the use of vasopressors. After performing Chi Square tests through SPSS, it was determined the use of ondansetron was not significant in reducing hypotension related to spinal anesthesia. However, it was found that patients receiving ondansetron prior to spinal anesthesia were requiring less vasopressor use during their cesarean sections.

Limitations

There were limitations to this doctoral project. If I had expanded inclusion criteria by increasing the amount of time prior to spinal anesthesia that ondansetron was given it may have increased the numbers of patients available for the study, thus providing more charts to review and increasing the study’s power. Increasing the sample size could have been what the study needed to meet the power analysis and show a significance between ondansetron usage and reduction in hypotension. Increasing the amount of time prior to the spinal anesthetic could have also been beneficial in that it would allow the medication longer to take effect and could have possibly made more of a change in hypotension. Use of a randomized sample could have been used to reduce bias when performing a retrospective chart review. Another possible limitation to this project is the fact that the medication could have been given outside the measurement period, which in turn would skew the study’s results.

Barriers

One of the main barriers to this project are the multiple definitions in hypotension. The literature states “hypotension being defined as a blood pressure of less than 20% of the
baseline or preoperative blood pressure” (Nagelhout & Plaus, 2014, p. 1229). Literature also states that the practitioner should look at clinical signs, such as, nausea and loss of consciousness, and not just look at numeric signs of hypotension (Nagelhout & Plaus, 2014). Clinically most practitioners will treat a systolic blood pressure less than 100 regardless if it is 20% of baseline or not. This causes a barrier to the study, because some practitioners may be treating the blood pressure with vasopressors before a 20% drop is ever detected, they may just be treating based off of clinical signs.

Future Directions

This doctoral project can definitely be expanded in the future. Taking into consideration the limitations and possible changes that can be made to the project there is room to show more possible benefits of using this medication prior to spinal anesthesia. A closer examination of the decreased usage of vasopressors could be a major benefit in the use of ondansetron and bring about a possible practice change.

Conclusion

Spinal anesthesia is the most common anesthetic used when performing elective cesarean sections. Hypotension is one of the most common side effects experienced after performing spinal anesthesia. This side effect can be harmful to mother and the unborn child if gone untreated. This doctoral project was performed to look at administering ondansetron prior to spinal anesthesia in elective cesarean section patients in helping to reduce hypotension. In trying to determine if ondansetron will help in reducing the incidence of hypotension with spinal anesthesia associated with cesarean sections, scholarly databases and peer-reviewed articles were used to obtain the evidence. A spread matrix was constructed to bring together all information discussed in the literature.
The project results showed that there was no significant association between ondansetron and hypotension, but did show a significant association between ondansetron and decreased vasopressor use in this clinical setting. Decreasing the use of vasopressors helps in reducing the chance of causing issues to the unborn child and decreases the amount of medications being given to mother and baby before birth. Ondansetron is a medication that is typically given at some point during the cesarean section to help with nausea. This project has shown that giving it prior to spinal anesthesia can help decrease medication usage and can in turn still help with the unwanted nausea during the case.

Information from this study was compiled and presented to anesthesia providers at a local hospital. There was a definite interest in the findings and a possible practice change indicated verbally among some of the providers. As with any new finding and educational material, there are still some who are hesitant to change, especially when dealing with an unborn child. Hopefully the disseminated information will be passed on so providers will see the benefits of using ondansetron in their practice.
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Design</th>
<th>Framework</th>
<th>Sample</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rashad and Farmawy</td>
<td>2013</td>
<td>Quantitative</td>
<td>None</td>
<td>60 pregnant woman (20 per group), ASA I-II, aged 20-40, scheduled for elective cesarean</td>
<td>1. 4mg ondansetron significantly decreased hypotension and vasopressor use; IV granisetron induced faster sensory recovery 2. MAP were significantly lower in group O (n=20, ( P &lt; .05 )) than groups G (n=20, ( P &lt; .05 )) and S (n=20, ( P &lt; .05 )) with lower vasopressor use 3. Faster sensory recovery in group G (n=20, ( P &lt; .05 )) than groups O (n=20, ( P &lt; .05 )) and S (n=20, ( P &lt; .05 )) 4. Significant decrease in nausea in groups O (n=20, ( P = 0.008 )) and G (n=20, ( P = 0.008 )) than S (n=20, ( P = 0.008 ))</td>
</tr>
<tr>
<td>Wang, M. et al.</td>
<td>2014</td>
<td>Dose-dependent study</td>
<td>None</td>
<td>150 pregnant women (30 per group), ASA I-II, aged 18-35, 37-42 weeks of gestation</td>
<td>1. Compared to group S (placebo), the incidence of maternal hypotension was significantly lower in groups O4 (n=30, ( P &lt; 0.05 )) and O6 (n=30, ( P &lt; 0.05 )) 2. The umbilical venous pH was significantly higher in O4 (n=30, ( P &lt; 0.05 )), O6 (n=30, ( P &lt; 0.05 )) and O8 (n=30, ( P &lt; 0.05 )); and the bicarbonate and base excess in extracellular fluid were significantly lower in groups O6 (n=30, ( P &lt; 0.05 )) and O8 (n=30, ( P &lt; 0.05 )) 3. Minimal changes of systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure were observed in group O4 (n=30, ( P &lt; 0.05 ))</td>
</tr>
<tr>
<td>Owczuk et al.</td>
<td>2008</td>
<td>Double-blind, placebo controlled study</td>
<td>None</td>
<td>71 individuals, 2 groups (36 in ondansetron group, 35 in placebo group), ASA I-II, age 20-70</td>
<td>1. Decreases in mean, systolic, and diastolic arterial pressure as well as in heart rate, compared with baseline values values were observed in both groups 2. Minimal systolic and mean blood pressure values obtained over a 20 minute observation period were significantly higher in the ondansetron group 3. There were no significant differences in diastolic blood pressure and heart rate values between the groups</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Study Design</td>
<td>Comparator</td>
<td>Participants</td>
<td>Results</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------</td>
<td>------------------</td>
<td>------------</td>
<td>---------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Sahoo et al.                  | 2011 | Double-blind, randomized, placebo-controlled study | None       | 52 pregnant women having a cesarean section (Group O=26, Group S=26), ASA I, age 20-40 | 1. Decreases in mean arterial pressure were significantly lower in Group O than Group S.  
2. Patients in Group O (n=26) required significantly less vasopressor (P=0.009) and had significantly lower incidences of nausea and vomiting (P=0.049). |
| Ortiz-Gomez et al.            | 2014 | Double-blind, randomized, placebo-controlled trial | None       | 128 healthy pregnant women having a cesarean section, 4 groups (n=32 per group), ASA I, age 20-45 | 1. There were no differences in the number of patients with hypotension in the placebo (43.8%, n=32, P=0.77) and ondansetron 2mg (53.1%, n=32, P=0.77), 4mg (56.3%, n=32, P=0.77), and 8mg (53.1%, n=32, P=0.77). |
| Wang, Q. et al.               | 2014 | Quantitative     | None       | 66 women having a cesarean section, 2 groups (n=33 per group), ASA I-II, age 18-35, 37 to 42 weeks gestation | 1. Maternal hypotension and nausea were significantly lower in ondansetron treated patients (n=33, P=0.011) versus placebo (n=33, P=0.004).  
2. Decreases in maternal systolic and mean arterial pressures were significantly lower in ondansetron treated patients (n=33, P=0.008) versus placebo (n=33, P=0.025), with less requirement of phenylephrine administration compared with controls (P=0.029). |
## APPENDIX B – Doctor of Nursing Essentials

<table>
<thead>
<tr>
<th>DNP ESSENTIALS</th>
<th>CLINICAL IMPLICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essentials I - Scientific underpinnings for practice</td>
<td>Using the most up to date and safest evidence to prevent injury to the patient while using spinal anesthesia</td>
</tr>
<tr>
<td>Essentials II - Organizational and systems leadership for quality improvement and systems thinking</td>
<td>The administration of ondansetron may reduce hypotension related to spinal anesthesia, without the negative effects of other medications. This in turn will bring about implementation of policies to improve patient outcomes</td>
</tr>
<tr>
<td>Essentials III - Clinical scholarship and analytical methods for evidence based practice</td>
<td>Using a Chi square test to analyze data between two groups, involving independent and dependent variables</td>
</tr>
<tr>
<td>Essentials IV - Information systems or technology and patient care technology for the improvement and transformation of healthcare</td>
<td>Performing a retrospective chart review patient data will be removed from their electronic medical record and protected avoid ethic/legal issues. Electrical databases will be used for review of literature and to obtain information regarding ondansetron and spina anesthesia on cesarean section patients</td>
</tr>
<tr>
<td>Essentials V - Healthcare policy for advocacy in healthcare</td>
<td>If information from this doctoral project indicates ondansetron does help in the reduction of hypotension related to spinal anesthesia in cesarean section patients, then a practice change can be implemented to provide better patient safety and increase overall patient satisfaction</td>
</tr>
<tr>
<td>Essentials VI - Interprofessional collaboration for improving patient and population health outcomes</td>
<td>Collaboration between anesthesia providers is pivotal to bringing about a practice change. Each provider has vital information and suggestions that can help bring about a change and help in providing the safest care to the patient population. Collaboration between the EPIC staff and the researcher in being able to gather information needed for this study.</td>
</tr>
<tr>
<td>Essentials VII - Clinical prevention and population health for improving the nation’s health</td>
<td>The use of such medications as ephedrine though effective, can cause decreased uteroplacental perfusion. This project will evaluate using ondansetron in helping reduce the incidence of hypotension to help in either decreasing or alleviating the use of pressors such as ephedrine all together in the pregnant patient population, which in turn would improve patient outcomes</td>
</tr>
<tr>
<td>Essentials VIII - Advanced nursing practice</td>
<td>Applying evidence based practice and advanced clinical knowledge to maintain and provide the safest care to patients receiving anesthesia</td>
</tr>
</tbody>
</table>
## APPENDIX C – Data Collection Table

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>ASA</th>
<th>Diagnosis</th>
<th>Elective C-section</th>
<th>Parity</th>
<th>Hypotension</th>
<th>Vasopressor Use</th>
<th>Ondansetron Use Prior to Spinal</th>
<th>Ondansetron Given 10 min or Less Before Spinal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject3</td>
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<td></td>
<td></td>
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</table>
# APPENDIX D - Logic Model

<table>
<thead>
<tr>
<th>Assumptions</th>
<th>Resources</th>
<th>Activities</th>
<th>Outputs</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reducing the incidence of hypotension related to spinal anesthesia is important to healthcare personnel.</td>
<td>• Research Articles</td>
<td>• Use of literature reviews involving evidence based practices</td>
<td>• Educational material</td>
<td>• Initial&lt;br&gt;• Decrease incidence of hypotension&lt;br&gt;• Provide knowledge to staff about the use of ondansetron</td>
</tr>
<tr>
<td>• Preventing unwanted side effects and issues with hypotension related to spinal anesthesia is important to healthcare workers and patients.</td>
<td>• Time needed to review articles and literature reviews</td>
<td>• Selecting articles best suited for the project based on evidence based practice and incidence of hypotension in cesarean section patients receiving spinal anesthesia</td>
<td>• White paper proposal</td>
<td>• Intermediate&lt;br&gt;• Shorter recovery time/hospital stay&lt;br&gt;• Decreased incidence of syncope, nausea/vomiting, and heart related issues</td>
</tr>
<tr>
<td></td>
<td>• Time needed to comb through patient information to include in data collection</td>
<td>• Reviewing and assessing records</td>
<td>• Literature review</td>
<td>• Long-Term&lt;br&gt;• Decreased incidence of ischemia&lt;br&gt;• Decreased costs for long term care&lt;br&gt;• Changing of hospital policy regarding medication used for spinal anesthesia</td>
</tr>
</tbody>
</table>
## APPENDIX E - SWOT

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No additional costs or extra work for the clinical site</td>
<td></td>
</tr>
<tr>
<td>• Retrospective chart review</td>
<td>• Inadequate documentation by the provider</td>
</tr>
<tr>
<td></td>
<td>• Variables cannot be controlled in a retrospective chart analysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Change in practice for the facility</td>
<td>• Ondansetron having no effect on decreasing hypotension in patient population</td>
</tr>
<tr>
<td>• Increases patient satisfaction scores and overall experience</td>
<td>• Anesthesia providers unwillingness for practice change</td>
</tr>
</tbody>
</table>
APPENDIX F – IRB Letters of Approval

INSTITUTIONAL REVIEW BOARD
118 College Drive #5147 | Hattiesburg, MS 39406-0001
Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional-review-board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 20, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months. Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16081505
PROJECT TITLE: Reducing Hypotension in Elective Cesarean Section Patients with Administration of Ondansetron Prior to Spinal Anesthesia
PROJECT TYPE: New Project
RESEARCHER(S): Linsey Phipps
COLLEGE/DIVISION: College of Nursing
DEPARTMENT: Advanced Nursing Practice/Nurse Anesthesia Program
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Exempt Review Approval
PERIOD OF APPROVAL: 08/16/2016 to 08/15/2017
Lawrence A. Hosman, Ph.D.
Institutional Review Board
DATE: August 2, 2015
TO: Linsey Philps
FROM: Honza Institutional Review Board
STUDY TITLE: R29125-11REDUCING HIPOTENSION IN ELECTIVE CAESARIAN SECTION PATIENTS WITH ADMINISTRATION OF ONDANSETRON PRIOR TO SPINAL ANESTHESIA: A RETROSPECTIVE CHART ANALYSIS
SUBMISSION TYPE: HIPAA IRB Waiver of Authorization
ACTION: APPROVED
APPROVAL DATE: July 23, 2016
EXPIRATION DATE: July 13, 2017
REVIEW TYPE: Full Committee Review

The [redacted] Hospital Institutional Review Board [IRB] has reviewed and approved the Waiver of Authorization for use of protected health information (PHI) for this research study as outlined in the approved research protocol.

In approving the Waiver of Authorization, the IRB has determined the following criteria have been met:

The use or disclosure of the requested information involves no more than minimal risk to the privacy of individual based on, at least, the presence of the following elements:

- An adequate plan to protect the identifiers from improper uses and disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
- Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule
- The research could not practicably be conducted without the waiver or authorization
- The research could not practicably be conducted without access to the use of the requested information

In making the determination, the IRB has followed the requirements of the Common Rule using Full Board Review procedures. If you have any questions, please contact Michael Stanley at 801-585-1740 or mstanley@genene.org. Please include your study title and reference number in any correspondence with this office.

Sincerely,

[Signature]
Lewis [redacted], M.D.
Chairman, Institutional Review Board
REFERENCES


