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Retrospective Study on Factors that may Contribute to Cesarean Delivery in Induced Women

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RETROSPECTIVE STUDY ON FACTORS THAT MAY CONTRIBUTE
TO CESAREAN DELIVERY IN INDUCED WOMEN

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RETROSPECTIVE STUDY ON FACTORS THAT MAY CONTRIBUTE
TO CESAREAN DELIVERY IN INDUCED WOMEN

INTERNSHIP PRACTICUM

Presented to the Graduate Council of the Graduate School of Biomedical Sciences

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Master of Science

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Dan Nguyen, B.S., Fort Worth, Texas

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INTRODUCTION

Induction of labor is a method to help initiate or increase the rate of contractions in women who are near the end of their pregnancy. Over the years, the number of labor inductions has increased significantly for a variety of medical reasons, as well as, elective reasons (1). However, before the decision is made to have a woman induced into labor, there are several factors that should be considered, including the woman's gestational age, status of the cervix, and any medical indication that may cause complications. Labor induction is generally performed when the potential benefits outweigh the risks of continuing the pregnancy (1).

The consequence of a failed induction usually results in a cesarean section (C-section). Compared to vaginal birth, a C-section poses more potential health risks to the woman and the baby, as well as, a significantly longer recovery period for the woman. Therefore, a C-section should be recommended only when it is necessary.

Studies have shown that there is a correlation between induced nulliparous women, women who had never given birth, and the rate in C-section (2-4). Other studies have examined factors such as maternal age, body mass index (BMI), ethnicity, number of previous children or parity status, and gestational age to see how they relate to the increase of C-section (5-7).

This practicum examined a number of contributing factors and indications for C-section induced patients. The purpose of this study is to improve our understanding of why there is an increase in C-section deliveries among women whose labor is induced and what factors determine if a C-section is more likely.

BACKGROUND AND LITERATURE REVIEW

A. Labor Induction

According to The American Pregnancy Association, induced labor is defined as “the artificial start of the birth process through medical interventions or other methods (8).” During labor, the female body produces the hormone oxytocin to stimulate contraction. Pitocin is a brand name for oxytocin that is administered intravenously to induce labor. Although elective labor induction is not generally recommended, a mother may choose to induce labor if the distance to the hospital may prevent a problem with delivery; the mother has a history of rapid deliveries; or for the convenience of time (1). In 2010, reports from the National Center for Health Statistics (NCHS) find that 23% of all expectant mothers of all races were labor-induced. (6)

Although labor induction may be an elective choice, it is normally performed for medical reasons (1). Medical complications, such as gestational hypertension, gestational diabetes, prolonged artificial membrane rupture, or placental abruption, are several reasons that may require labor to be induced (8). Gestational hypertension or pregnancy-induced hypertension can cause the placenta to receive insufficient supply of blood flow resulting in lack of oxygen or nutrient delivery (8). Gestational diabetes may cause the fetus to have a greater birth weight and increased risk of death (8). An artificial membrane rupture without the start of contractions will increase the risk infection for the fetus, increase delivery complications with the change in fetus position, and increase the risk of the umbilical cord being delivered prior to the baby (8).

Placental abruption or the separation of the placenta from the uterus can be life-threatening to the baby as the placenta serves to transport oxygen and nutrients to the baby (8). Therefore, inducing labor may help speed up the delivery process in order to prevent further medical complications (9).

Inducing labor is also a common practice for women who have a prolonged pregnancy (5). The World Health Organization and International Federation of Gynaecology define prolonged pregnancy as “a mother who has not delivered after 42 completed weeks or more than 294 days since their last menstrual period (5).” Siozos and Stanley state that “prolonged pregnancy can be divided into two adverse outcome categories: those who have decreased uteroplacental function and those who have normal placental function (5).” With decreased uteroplacental function, the fetus exhibits reduced growth of the fetus, decreased availability of oxygen, deficiency in amniotic fluid, and a possibility for stillbirth. A fetus with continued normal placental function may have excessive birth weight that could lead to trauma during the delivery.

Induced labor may increase the risk of developmental problems for the baby. These can include difficulty breathing, feeding, or maintaining a normal temperature. Excessive concentrations of Pitocin or oxytocin may cause too many contractions, which can lower the fetal heart rate (10).

B. Cesarean Delivery

In 2010, reports from the National Center for Health Statistics (NCHS) state that 32% of all births in the United States are by cesarean delivery (6). A C-section is a surgical procedure

that involves incisions to the abdominal wall. If there is a complication during vaginal delivery, a C-section may be the preferable option.

There are many medical reasons that may call for a C-section. A placenta abruption may require an emergency C-section as the separation of placenta will stop oxygen transport to the baby (11). A tear in the uterus can result in hemorrhaging in the mother and will restrict the baby's oxygen availability (11). Pregnant women who had a prior C-section are usually advised to have a repeat C-section since vaginal birth after C-section (VBAC) can lead to uterine rupture (11). Similarly, a pregnant woman diagnosed with severe pre-eclampsia or high-blood pressure, which can lead to decreased oxygen transport from the placenta to the baby, might require C-section (11). Fetal distress or non-reassuring fetal status is an indication that the baby may not have enough oxygen. A significant change in the fetal heart rate can be a sign of fetal distress (12). The position of the baby is a key factor in determining whether a woman will have a C-section. According to the American Academy of Pediatrics, 3% percent of babies have a breech presentation, in which the baby is positioned with the feet or buttocks coming out first instead of the head (12). Breech presentation makes it difficult to delivery vaginally and a C-section is highly recommended. Cephalopelvic disproportion (CPD), which occurs when the baby's head is too large or the passage of the mother's pelvis is too narrow, will require a C-section as vaginal delivery will be difficult (11). In relation to CPD, gestational diabetes may lead to a large baby, which will cause complications for vaginal delivery. Multiple gestational deliveries may increase the chances of a C-section, depending on the size and weight of the babies (11).

There are risks associated with any surgical procedure, including C-sections. When comparing C-section with vaginal delivery, there is increased blood loss with the C-section, which may require a blood transfusion (13). An infection or inflammation might form at the sites

of incision (13). The risk of developing a blood clot inside a vein is greater with a C-section (14). A baby who is delivered through C-section before 39 weeks of gestation might be at risk of having problems with lung development. The lungs might not have fully matured, causing the baby to have breathing problems. With any surgical procedure, including C-section, anesthesia medication can have an effect (12). The effects of the anesthesia can cause the baby to have difficulty breathing initially (12). Not surprisingly, the increased risks and complications associated with C-section procedure will also result in an increased mortality rate for mothers compared to vaginal birth (13).

C. Cesarean Delivery Rates Based on Various Factors

In 2007, the National Center for Health Statistics (NCHS) reported data on the rate of cesarean delivery (CD) across several categorical groups including maternal age, ethnicity, and gestational age (15). NCHS states that mothers from ages 40 to 57 years of age are twice as likely to have a C-section compared with mothers who are ages 20 or less (15). With regards to ethnicity, CD rates were highest for non-Hispanic black women (34%) compared with non-Hispanic white (32%), Asian or Pacific Islander (31%), Hispanic (30%), and American Indian or Alaskan Native (28%). Based on figures provided by NCHS, gestational age has an inverse relationship with the rate of C-section. Both early (34 weeks) and late preterm infants (34-36 weeks) had a higher C-section rate than term births (37 weeks and older). In a retrospective study, Caughey et al. also focused on the relationship between gestational age and cesarean delivery among women who were induced (7). The population that they studied was term births of 38 gestational weeks and older. They found that women who were induced at 38 weeks of

gestation had a lower CD rate (11.9%) compared with women who were induced after 38 weeks of gestation (13.3%).

Suzuki found that women who underwent CD during the night at 37 or more weeks of gestation had an increased risk for neonatal morbidity (16). He believes that the lack of anesthesiologists during the night shift might contribute to the delay in starting a CD procedure. In contrast, Bailit et al. state that “neonatal morbidities caused by cesarean delivery complications do not increase during the night shift (17).” Their findings show that there is no significant difference between day and night shift surgical outcomes. Compared to 567 women who participated in Suzuki’s study, Bailit et al has a significantly larger sample size of 18,900 women.

D) Relationship between Labor Induction and C-section

Sanchez-Ramos states that there are absolute and relative reasons to withhold labor induction (1). Absolute contraindications include prolapsed cord, prior cesarean delivery, genital herpes infection, or a transverse fetal lie (18). Labor induction may increase the risk of an umbilical cord prolapse (the umbilical cord comes out of the vagina prior to the delivery of the baby). Umbilical cord prolapse poses a very serious risk with the possibility of the baby’s head pressing on the umbilical cord and inhibiting oxygen transfer. For the contraindication of genital herpes, inducing labor may increase the risk of exposing the baby to the virus as the baby travels through the birth canal. A transverse fetal lie is where the position of the baby’s head is on one side of the mother’s body with the feet on the other side. If labor induction were to proceed under the presence of these contraindications, a C-section will likely occur in order reduce harm to the mother and the baby.

The mother has an increased chance of C-section if her cervix is not dilated enough when she has been induced. According to Sanchez-Ramos, “cervical ripening is the process that softens and increases the distensibility of the cervix (1).” If labor induction is to be pursued, certain pharmacologic or mechanical methods such as applying a prostaglandin gel or using a balloon catheter can help ripen the cervix in preparation for labor induction (19). Summers stated in her article that when labor is induced with an unripe cervix, prostaglandins can help decrease the number of failed inductions, decrease the probability of prolonged labor, and increase the chances for spontaneous delivery (19). She also states that many studies have been conducted that relate the ripening of the cervix to the likelihood of a vaginal delivery. Therefore, mothers who are induced with a soft and open cervix will have less risk of requiring a C-section (9).

In 1964, Bishop quantified the cervical ripeness with a score based on dilation, effacement, station, consistency, and position. A score between 0-3 was given for each category, and the sum of each category was considered the Bishop score (20). Using the Bishop score, Sanchez-Ramos states that nulliparous women with a score of 3 or less will have a 23-fold increase of a failed induction and two to four times more likely to have a C-section compared with a score of 4 or more (1). For multiparous women, a Bishop score of 3 or less increases the likelihood of a failed induction by six fold and twice as likely to have a C-section compared to a Bishop score of 4 or more. Similarly, Yeast et al. reported that nulliparous women had a twofold increase in cesarean delivery rate (4). With both groups undergoing labor induction, there was a 19% CD rate for nulliparous women compared with a 7% rate for multiparous women (4). Luthy et al. found that nulliparous women had a higher CD rate when they underwent induced labor (25%) compared with women who went into spontaneous labor (15%) (2). Luthy states that elective induction almost doubles the risk of CD in nulliparous women overall but can vary

based on the individual physician. They suggest that elective induction should be performed only when the physician and patient agree that there is a significant risk of C-section and that the implications will affect future labor and delivery. Out of 135 induced nulliparous women, the indications for C-section included cephalopelvic disproportion (70%), non-reassuring fetal status (15%), and failed induction (14%).

Ehrental et al. concluded that labor induction and obesity are the risk factors that contributed the most to the likelihood of cesarean deliveries (3). They state that labor induction may serve to avoid the risk of failed induction in populations with specific risks such as pre-pregnancy obesity, gestational diabetes, excess weight gain, and gestational hypertension. They also state that the increase in C-section within the United States can be attributed by the increase in elective labor induction and the increase in obesity in the population. Increased BMI was associated with increased rate of CD across all categories.

Alanis et al. states that labor induction is rarely successful for pre-eclampsia patients before 28 weeks of gestation (21). On the other hand, pre-eclampsia patients at 28 weeks or more had a high induction-success rate. Overall, when labor induction is not successful, fetal distress is accounted for half of pre-eclampsia patients. Their study concludes that induction of labor is not associated with adverse neonatal outcomes (21).

When comparing the relationship between induction of labor and the increase in number of C-section, Caughey et al stated that studies conducted on this topic were not randomized trials (7). A randomized trial would reduce the possibility of bias or influence that might alter the data. Women who are at 41 weeks of gestation or more have a lower chance of C-section after they have been induced. In addition, Caughey states that results from prospective randomized trials contradict prospective and retrospective cohort or case-control studies by showing a decrease in

C-section rate. They reason that the majority of cohort or case-control studies have failed to control for gestational age. This is important when considering data analysis since induction of labor is more likely to increase with gestational age and gestational age is a risk factor for C-section. They found that CD rate was lowest at 38 weeks and the rate increases in subsequent weeks. Although they focused their study on term births, they suggest that future studies on early and pre-term birth may show different results.

SPECIFIC AIMS

The specific aims of this practicum project are:

1. To collect patient information including body mass index (BMI), ethnicity, parity status, time of delivery, duration of delivery, and gestation age from 500 labor-induced vaginal-birth patients and 500 labor-induced C-section patients.
2. To assess whether there is a statistical significance between the values of BMI, ethnicity, parity status, time of delivery, duration of delivery, and gestation age between labor-induced woman having a vaginal versus C-section delivery
3. To evaluate the C-section indications on these patients.

SIGNIFICANCE

Cesarean deliveries pose greater health risks to the mother compared to the vaginal delivery (7, 9). The time for recovery is longer for mothers who have undergone a cesarean delivery (CD) compared to a vaginal delivery (VD). Risks to the mother may include increased blood loss, damage to the urinary bladder, and possible death (8). The risk for infection, including wound infection, urinary tract infection, and endometritis (infection in the inner lining of the uterus) is increased (9). Following CD, internal scarring, known as adhesions, can form between the abdominal organs including the uterus, fallopian tubes, gallbladder, and ovaries. Complications associated with adhesions include internal pain, bowel obstruction, and a decrease in fertility rate (8). With induced labor, the percentage of CD is higher than when labor begins spontaneously. This practicum study is designed to improve the understanding regarding why there is an increase in C-sections among women whose labor is induced and what factors determine why a CD will have more odds among this group. This data can be used to inform physicians and patients, who are considering labor induction, about the possible increased risk of C-section and the complications that follow.

METHODS

This practicum project was a retrospective study using data collected from Baylor's software databases called MIDAS and QS. Using MIDAS, a data report from January 2011 to July 2012 was compiled that listed labor-induced patients with vaginal delivery (VD). As well, a data report from January 2009 to July 2012 was requested for labor induced patients with C-section delivery (CD). Both reports share the same information on the patient including the patients' medical record number, maternal age, and ethnicity. Using the patients' medical record number as reference, QS was used to recover the patient's file from Baylor's electronic archive. From there, the patient's parity status, height, weight, time of delivery, duration of delivery, gestational age, and C-section indication was obtained. Patient information that had incomplete or missing data was not used. Data on 1,000 labor-induced women were collected. Medical records on these patients were selected based on numerical order of the medical record number. Half of these women were VD and the other half were CD. Factors including BMI, ethnicity, parity status, time of delivery, duration of delivery, and gestation age were examined to determine if they have any effect on the likelihood of CD. Cause of CD will be categorized by indication and assessed by percentage. Maternal age was assigned as less than 18, 18-34, 35-39, and 40 years and older. Gestational age was classified as less than 37 weeks, 37 weeks, 38 weeks, 39 weeks, 40 weeks, and 41 or more weeks. Delivery time was determined as day or night delivery. Delivery in the day was defined from 6 A.M. to 5:59 P.M. and delivery in the night was from 6 P.M to 5:59 A.M. Delivery methods were either vaginal or cesarean. Ethnicity

was categorized as black, white, Asian, and Hispanic. BMI was classified as less than 25, 25-29, 30-39, 40 and greater. BMI was based on the pregnancy weight. Labor duration was categorized as less than 5 hours, 5-10 hours, and more than 10 hours. Parity was categorized as 0, 1, 2 and 3 or more children.

After the collection of data, a binary logistic regression statistical analysis was performed to determine if the factors contributed to the increase number of women undergoing CD with induced labor. The dependent variable was the mode of delivery with the independent variables being the contributing factors. The relative risk assessment was used to assess how strongly each factor closely associates with CD or VD method. These results were derived from a statistical software program, SPSS. An analysis of C-section indications was done using the data on the 500 induced C-section patients. This simple analysis should allow the determination of the most common causes for induced C-section patients.

RESULTS

In this study, data was collected on 500 induced women who delivered vaginally and 500 induced women who had a C-section. Table 1 shows the association of contributing factors to the increased risk of cesarean delivery and the odds of an induced woman having a C-section delivery. Based on a p-value of 0.05, maternal age ($p = 0.004$), ethnicity ($p = 0.005$), gestational age ($p = 0.011$), BMI ($p = 0.000$), parity status ($p = 0.000$), and delivery time ($p = 0.000$) are shown to be statistically significant in representing an association with C-section. Mothers who are 40 years of age and older have five times the odds to have a C-section compared to mothers who are less than 18 years of age. Asians have six times the odds as whites to undergo a C-section. When comparing all induced women delivering at 37 weeks of gestational age to greater gestational age groups, women did not show a statistically significant increase in C-section rate. Body Mass Index (BMI) seems to have a positive relationship with C-section. Women with a BMI of 30 to 39, have a two to three times the odds for risk of cesarean delivery compared with a woman with BMI less than 25. Similarly, women with a BMI greater than 39 have nearly five times the odds of cesarean delivery compared with women with BMI less than 25. Women with no previous children have the greatest risk of having a cesarean delivery compared to women with multiple children. Night-time deliveries have three times the odds as day-time deliveries to undergo a cesarean delivery. Duration of labor was not statistically significant (0.767, $p > 0.05$) and therefore does not bear any effect to the method of delivery.

Table 1 Association of Contributing Factors with Odds Ratio of Cesarean Delivery and Vaginal Delivery

Factor	Sig (p<0.05)	OR	95% CI
Maternal Age (years)	0.004		
Less than 18		Referent	
18-34		0.63	0.28-1.39
35-39		1.20	0.43-3.36
40 and older		5.04	1.08-23.4
Ethnicity	0.005		
White		Referent	
Black		1.18	0.76-1.82
Asian		5.94	1.70-20.6
Hispanic		0.70	0.47-1.04
Gestational Age (weeks)	0.011		
Less than 37		Referent	
37		0.78	0.35-1.75
38		0.59	0.26-1.30
39		0.49	0.24-0.98
40		0.81	0.40-1.64
41 and over		1.23	0.53-2.80
Body Mass Index	0.000		
Less than 25		Referent	
25-29		1.54	0.76-3.11
30-39		2.71	1.38-5.33
Greater than 39		4.88	2.33-10.2
Parity Status	0.000		
0		10.0	4.92-20.4
1		1.53	0.73-3.21
2		1.11	0.47-2.62
3 or more		Referent	
Delivery Time	0.000		
Day		Referent	
Night		3.04	2.17-4.24
Duration of Labor (hours)	0.767		
0-5		Referent	
5-10		1.17	0.67-2.05
Greater than 10		0.60	0.60-1.83

OR, odds ratio; CI, confidence interval
Significance value (p<0.05)

Using the Hosmer and Lemeshow test, the model shows to be a good fit indicating that the number of deliveries that are observed is not significantly different from the number of predicted deliveries. The logistic regression model was evaluated to test its effectiveness in predicting the outcome values based on the observed values (Table 2). The ability of the model to predict the route of delivery was 70% for vaginal delivery, 81% for cesarean delivery, and overall correctly predicted 75% of all deliveries. Table 3 suggests that there were more C-section deliveries with nulliparous women and there were more vaginal deliveries with multiparous women.

Table 2 Ability to Predict the Mode of Delivery

Observed			Predicted		
			Delivery Type		Percentage Correct
			Vaginal	C-section	
Step 1	Delivery Type	Vaginal	350	150	70.0
		C-section	94	406	81.2
	Overall Percentage				75.6

Table 3 Parity Status for Vaginal and Cesarean Delivery

		Delivery Type		Total
		Vaginal	C-section	
Parity Status	0	186	417	603
	1	171	50	221
	2	87	17	104
	3 or more	56	16	72
Total		500	500	1000

Based on Table 4, the top five causes of C-section in the sample of 500 induced women are failure to descend (31.8%), non-reassuring fetal status (29.0%), failure to progress (18.8%), failed induction (18.0%), and cephalopelvic disproportion (14.4%). Table 5 suggests the indications for C-section in the sample of 418 nulliparous women. In comparison to Table 4, Table 5 shows that failed induction is slightly more common than failure to progress. Table 6 suggests the most common C-section indications for multiparous women. In comparison to Table 4 and 5, Table 6 suggests that non-reassuring fetal status is the most common indication (35.3%) for C-section followed by failure to descend (34.1%). As depicted in Tables 4-6, women may have more than one indication for C-section.

Table 4 C-section Indications and Percentage of C-section Induced Women

Indication	Percentage (number)
Failure to Descend	31.8 (159)
Non-reassuring Fetal Status	29.0 (145)
Failure to Progress	18.8 (94)
Failed Induction	18.0 (90)
Cephalopelvic Disproportion	14.4 (72)
Failure to Dilate	7.00 (35)
Malpresentation	3.20 (16)
Pregnancy Induced Hypertension	2.20 (11)
Infection	1.60 (8)
Prolapsed Cord	1.00 (5)
Repeat C-section	0.80 (4)
Separated Placenta	0.80 (4)
Multiple Gestation	0.60 (3)
Primary Elective	0.60 (3)
Macrosomia	0.60 (3)
Diabetes	0.40 (2)
Prolonged Rupture of Membranes	0.40 (2)
Maternal Temperature	0.40 (2)
Meconium	0.20 (1)

Table 5 C-section Indications and Percentage of C-section Induced Nulliparous Women (n=418)

<u>Indication</u>	<u>Percentage (number)</u>
Failure to Descend	31.3 (131)
Non-reassuring Fetal Status	27.2 (114)
Failed Induction	19.1 (80)
Failure to Progress	18.8 (78)
Cephalopelvic Disproportion	15.3 (64)
Failure to Dilate	7.10 (30)
Malpresentation	2.60 (11)
Pregnancy-Induced Hypertension	2.40 (10)
Infection	1.20 (5)
Elective	0.71 (3)
Prolapsed Cord	0.47 (2)
Multiple Gestation	0.47 (2)
Separated Placenta	0.24 (1)
Macrosomia	0.24 (1)
Prolonged Rupture of Membranes	0.24 (1)
Meconium	0.24 (1)

Table 6 C-section Indications and Percentage of C-section Induced Multiparous Women (n=82)

<u>Indication</u>	<u>Percentage (number)</u>
Non-reassuring fetal status	35.3 (29)
Failure to Descend	34.1 (28)
Failure to Progress	15.8 (13)
Failed Induction	12.2 (10)
Cephalopelvic Disproportion	9.70 (8)
Malpresentation	7.30 (6)
Failure to Dilate	6.10 (5)
Repeat C-section	6.10 (5)
Prolapsed Cord	3.60 (3)
Separated Placenta	3.60 (3)
Macrosomia	2.40 (2)
Pregnancy-Induced Hypertension	1.20 (1)
Infection	1.20 (1)
Multiple Gestation	1.20 (1)
Prolonged Rupture of Membranes	1.20 (1)

DISCUSSION

Almost one-third of all births are by cesarean delivery (6). The logistic regression model used in this practicum study allows the prediction of the effect of contributing factors on the cesarean delivery rate. In agreement with the literature, the findings show that induced nulliparous women have more significant odds to have a C-section compared to induced multiparous women (Tables 1 and 3). Data show that 83% of women who underwent induced C-section deliveries did not have previous children (Table 3). These data support previous studies in the literature that induced nulliparous women have a significant risk of C-section (1-4). Another reason why the majority of the data were nulliparous women is that multiparous women with previous C-section deliveries are more likely to undergo another C-section and will not require labor induction. According to Shearer, one-third of women who have a C-section will undergo a repeat C-section (22). In accordance with NCHS, the data in this practicum also suggests that mothers 40 years of age and older are more likely to have a C-section compared with mothers who are less than 18 (15). Although this practicum shows to have a greater risk association, the difference may be attributed to how each study categorizes the maternal age group.

Interestingly, the percentage of indications on C-section induced woman (Table 4) remained almost constant with nulliparous (Table 5) and multiparous women (Table 6). In comparing the data with the literature, Luthy et al. performed a study where 135 electively induced nulliparous women underwent a C-section (6). Their data indicates that cephalopelvic

disproportion (70%) was most common, followed by non-reassuring fetal status (15%), and failed induction (14%). However, in this practicum study, non-reassuring fetal status was twice as likely to occur compared to cephalopelvic disproportion in induced nulliparous women overall.

This study fails to provide conclusive results in some areas. Although the statistics indicates that Asian women have almost six times the odds as white women to have a C-section, the data is based on a relatively small sub-section. An increase in the number of recorded deliveries for Asians may give a different result. NCHS reports their data to have CD rates highest for non-Hispanic black women and Asian women ranked third highest (15). Duration of labor was not statistically significant and this study could not be determined if it has any effect on the rate of C-section.

Although this study fails to address certain issues, it did show that night deliveries were related to a higher risk of C-section compared to day deliveries. The reason for this can be that inductions usually occur early in the morning so if they have a night delivery it is because they have had a long labor already. Consistent with the existing literature, this practicum study confirmed that women with greater body mass index (BMI) have more odds to have a C-section. In agreement with the literature, an increase in gestational age is related to an increase in C-section. However, the results of each study may vary based on how they categorize gestational age and define their reference group.

There are several limitations to this retrospective study. The findings for this study are based on a population at one medical center and may not be generalized for other studies. Methods of cervical ripening and labor induction are not controlled or recorded. Variables not included in this study such as Bishop's score or gravida status, was not considered and was not

measured with regards to their effect on the use of labor induction. There may be other variables that are not accounted for that could have changed the results of the study. Patients' medical records that have missing information were not used in this study. This study did not focus on the interaction and dependency between each contributing factor. The study assumes that each of these factors is independent from one another.

In summary, this practicum study collected patient information including body mass index (BMI), ethnicity, maternal age, parity status, time of delivery, duration of delivery, and gestation age on 500 labor-induced vaginal-birth patients and 500 labor-induced C-section patients. With exception to duration of delivery, all of these factors were shown to have an association with the increase risk of C-section in induced women. Women with a BMI of 30 to 39, have a two to three fold increased odds of cesarean delivery compared with a woman with BMI less than 25. Similarly, women with a BMI greater than 39 have nearly a five-fold increased odds of cesarean delivery compared with women with BMI less than 25. Asian women have almost six times the odds as white women to have a C-section. Mothers who are 40 and older have five times the odds in having a C-section compared to mothers who are less than 18 years of age. Nulliparous women have ten times the odds to have a C-section compared to women with 3 or more children. Night-time deliveries have three times the odds to undergo cesarean delivery compared to day-time deliveries. Women at 41 weeks of gestational age have a 23 percent increase in odds compared to women at 37 weeks of gestation age for risk of C-section. The findings of this practicum also suggest that non-reassuring fetal status and failure to descend was the most common indication for C-section for induced women. This practicum has important implications for physicians and patients and encourages the need for women to be counseled about the potential risk of C-section associated with labor induction.

INTERNSHIP EXPERIENCE

My last six months of the Clinical Research Program were spent at my internship site, Baylor All Saints Medical Center in Fort Worth. The U.S. News and World report that Baylor All Saints Medical Center is one of the best hospitals in the metropolitan area. The American College of Nurse-Midwives Benchmarking Program has labeled Baylor Fort Worth a "best practice" facility for operative vaginal births. The Paul and Judy Andrew Women's Hospital at Baylor All Saints Medical Center was recognized and given the 2009 Innovation in Women's Health Award.

Currently, there are over 12 studies being conducted at this hospital. These include clinical trials in cardiovascular, diabetes, women's health, transplant, and oncology. There are seven clinical research coordinators and a director of clinical research who is employed at this facility. My on-site mentor was Claudia Mattil, who is the Director of Clinical Research. She helped me acquire access to the resources I need to perform my tasks. Every week she would keep track of the progress on my study and my responsibilities at the site. She was willing to help in any way she could. On the days that Claudia was not available, I would ask Theresa Cheyne, Research Supervisor, for her guidance and expertise. As a research nurse, Theresa was very helpful with explaining medical terminology and concepts on labor and delivery related to my study.

I am very grateful to have worked alongside Cathy Frisinger, a research coordinator who previously went through the same program at UNTHSC. On most mornings, I would copy

patient medical records for Cathy's study that comes from a software program, QS, installed only on computers located in labor and delivery area. This software program is the same one I use to collect data for my study. I would then collect the delivery summary and anesthesia records from the nurses charts. Around the same time I perform these daily tasks, Cathy was enrolling new patients for her study. Since Cathy had a high-enrolling study, I also contributed much of my time performing data entry and filling out case report forms. Occasionally, I was able to shadow Cathy and observe the process of how she enrolls patients for her study. At another time, I was given the chance to meet with the principle investigator (PI) and the monitor and to observe their role in the study. The coordinator usually contacts the PI for any significant changes, adverse events, clarifications, or required signatures. The monitor would review the data in the study and suggest changes that may be needed.

I was given the opportunity to observe a site qualification visit with Theresa for a diabetes study. Under the same study, I was assigned the task of helping write the informed consent. I followed the template that Baylor supplied in writing the informed consent. Most of the information in the informed consent was derived from the information provided by the sponsor. As the study progressed, I had a better understanding on the necessary steps for an initial start up of the study. I was able to follow Theresa and observe the process of how she enrolls patients for her study

I also learned much about the IRB and its involvement in clinical research. Their role is to assure that clinical research studies comply with the regulations and standards that ensure the safety and welfare of the patients. Any protocol deviations, adverse events, or changes that affect the patient must be reported to the IRB. Before I could start on my project, I had to submit my proposal and related IRB documents to both the Baylor and UNTHSC IRB committees. Both

IRB committees were very helpful and were detailed in what was needed. On one occasion, I was given the opportunity to attend an IRB meeting in Dallas to observe their process and discussion. Aside from the IRB members who were present in the room, there were also PIs, Sub-PIs, and research coordinators who participated. Anyone who was not able to physically participate could call in and listen to the conference. The IRB members discussed initial and continuing studies, with the purpose of approving or disapproving of the studies. Many of these approvals require changes within the protocol or informed consent. Before the committee votes, research staff who were involved in the study to be voted upon were asked to leave the room.

Overall, I had an enjoyable learning experience working alongside with the staff at Baylor All Saints Medical Center. For more detailed information on my internship experience, please refer to Appendix B.

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APPENDIX A: Data Collection

A	B	C	D	E	F	G	H	I	J	K	L
1 #	Mat Age (years)	Ethnicity	Gest Age (weeks)	BMI	Para	Delivery Time	Duration	Method	CD Cause		
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IRB APPROVED

AUG 2 2012

University of North Texas
Health Science Center

APPENDIX B: Daily Journal:

Monday June 4th 2012

In the morning, I looked over the employee handbook that contained information on defining what is research, the rules in regulating research, how drugs and devices are developed, the role of staff, and the policy of the Clinical Trial Office. I observed Cathy Frisinger fill out a patient and device accountability log.

After lunch with the staff, Cathy filled out a case report form (CRF) and explained to me what was on each page. Everything that was filled out in the CRF was highlighted from the data in the patient's file. This helps the monitor verify that the data was correctly translated into the CRF from the source data. With forms and documents, I learned that any mistakes should be single crossed out followed by the person's initial and date. Cathy also showed me how to submit and event report to the IRB. She had to notify the IRB of any deviation from the protocol.

Tuesday June 5th, 2012

I went over the protocol on the trial that I will work on in the future. In the binder, I also looked at the investigator agreement, financial disclosure agreement (form 14), confidentiality agreement, and the informed consent. The informed consent was thorough and easily understandable for the patient to participate. I assisted Jessica pipette blood from a patient's sample and package it to send to the laboratory.

I also observed Cathy perform data entry. The data from the CRF would be extracted and translated onto to the computer. There would be a primary and secondary input by different people to ensure validity of the CRF. If something does not match, then they would have to go back to the source data and verify.

Wednesday June 6th, 2012

I followed Theresa Cheyne to a site qualification visit. The meeting consisted of the Principle Investigator, Sub Investigator, the research coordinator, the sponsor representative, and me. The representative discussion of the study included the type of study, the type of drugs used on the patient, inclusion and exclusion criteria, and the number of enrolling patients, and number of sites participating. While the representative discussed the general protocols, any questions may be asked and will be addressed to the sponsor. Storage of records, investigational products, and study supplies was another topic of discussion. The representative had to make sure the site has enough storage space for all the factors above. After the discussion, the representative was given a tour of the facility to ensure that the equipment was up to date and available for the study. This included proper storage and equipment for the drug. After the representative inspected the facility, he spoke with the research coordinator. The PI and Sub PI tended to their clinic with the most of the questions left to be answered by the coordinator. For the rest of the day, I helped Cathy audit case report forms.

Thursday June 7th, 2012

I organized and prepared a binder for the standard operating procedures for one study. I emailed Baylor IRB to request an account for access to their IRB system. I continued to audit

case report forms for Cathy. I went to a nurse research presentation. I looked over different poster board presentations I attended one of their seminar presentations in one of the rooms.

Friday June 8th, 2012

I attended a grand rounds meeting. I continued to audit case report forms for Cathy. I made Xeroxed copies of the case report forms and filed them. I also made copies of any other forms that Cathy needed for her study.

Monday June 11, 2012

I continued to audit case report forms for Cathy. In order to begin working on any clinical study, I had to complete training required by Baylor Research Institute. I was trained on how the IRB process works, the responsibilities of the PI and staff, risk assessment in research, and how to care for vulnerable subjects. I helped Kristi Melvin with sorting laboratory files that needed to be reviewed and signed. I also began to discuss my research proposal with Cathy and Theresa. Using the data from the epidural study, I will find the factors that may cause patients to undergo a caesarean section after they are induced.

Tuesday June 12, 2012

I helped restock equipment for Cathy's study. I also helped Cathy carry patient files to be signed by the PI. I emailed the lady who worked in Baylor's research regulatory affairs about my research proposal topic. She stated that it would be a reasonable exempt study as long as I was given non-identifiable data on the patients. Also the sponsor should approve of the study. I helped format a document with inclusion/exclusion criteria. I continued to audit case report forms for Cathy.

Wednesday June 13, 2012

I continued to audit case report forms for Cathy. I observed Cathy make changes to by adding an additional two research staff members including myself to the study. Any changes were to be made and sent to notify the IRB. I made copies of the case report forms and filed them.

Thursday June 14, 2012

I read and completed an acknowledgment for Baylor's intellectual property agreement. I continued to audit case report forms for Cathy. I read through protocols for another study. The protocols included study objectives, study design, study population and recruitment criteria, study treatments, data collection methods, and adverse events. I also read information on the drug including adverse reactions, dosage of administration, indications, and target area.

Friday June 15, 2012

I filed and copied papers necessary for one of the study's Cathy was working on. I did online training to learn about Microsoft Access. I emailed my research committee to remind them of a meeting on Monday. I read articles on PubMed that were related to one of the studies I will be working on.

Monday June 18, 2012

I began to do a layout of my background from my project. I looked through Science Direct for articles pertaining to my research hypothesis. I organized and recycled supplies from

lab kits from certain studies. I met with my committee meeting to discuss my project. We discussed the format of how the project will go and what I needed to do. I need to work with a statistician to find out my sample size needed for my project.

Tuesday June 19, 2012

I read through different articles from Science Direct including “Labor Induction and the Risk of a Cesarean Delivery among Nulliparous Women at Term” and “Recent Trends in Cesarean Delivery in the United States”. I worked on finding other articles that pertained to my research hypothesis. I signed form 14 which is the annual financial interest report form to ensure that I list any financial interest (if any) related to the clinical trial that I will work on. I filed patient folders in order and placed them back into the drawers accordingly. I went to parking services to obtain my parking permit. I made copies of certain forms for Cathy’s trial.

Wednesday June 20, 2012

I printed copies of forms Cathy needed for her trial. I read through different articles from Science Direct including “Cesarean delivery after elective induction in nulliparous women: The physician effect”, “Induction of labor and cesarean delivery by gestational age”, and “Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions” I worked extracting relevant information that pertained to my research hypothesis/problem. I assisted Cathy with attaching and sending files over email.

Thursday June 21, 2012

I read through different articles from Science Direct including “Methods of cervical ripening and labor induction” and “Induction of labor”. I worked citing my sources and revising my background on my research project. I read over the informed consent form for a drug study. I listened to an IRB meeting on the phone. The order of the meeting was annual reviews of the studies, any revisions to the current studies, and then discussions of new studies.

Friday June 22, 2012

I reorganized source documents for Cathy and filed them in proper order. I went to my committee members Dr. Gwartz and Dr. Cammarata to have my degree form and advisory committee form signed. I spoke with a biostatistician about my sample size. Considering the factors that affect the number of induced patients with C-sections, my sample size is too small. Therefore, I need more patient data in order to make my statistical analysis of the study significant.

Monday June 25, 2012

I copied source documents from the patient’s chart. I discussed my project with my mentor about my sample size and where I would obtain my data. I realized I may need a bigger sample size to make my study’s statistical analysis significant. I updated my major professor, Dr. Cammarata, on where I am with the research proposal.

Tuesday June 26, 2012

I observed Cathy obtain informed consent from the patient. She gave the patient sufficient time to read over the consent and came back to answer any questions that the patient may have. She went over the procedures and made sure the patient understood the study. Later, I made copies

of source data from patient charts. I performed data entry using case report forms and source data. I filled out case report forms.

Wednesday June 27, 2012

I observe Cathy follow up with the patient's treatment by surveying their response. I filled out case report forms. I observed Cathy enter a protocol deviation online to the IRB. I made copies of the revised informed consent. I made copies of the source data from the patient's charts. I made copies of the case report forms. I met the PI of the study to have him verify and sign the case report forms.

Thursday June 28, 2012

I observed Cathy follow up with the patient's treatment by surveying her response. I copied source documents using patient's chart data. I helped fill out case report forms using source documents. I helped Cathy make copies of forms needed for the study. I called technical support to obtain access to network drive.

Friday June 29, 2012

I went down with Cathy to medical records to meet the person in charge of filing electronic records. I was given two patient charts and was asked to call those two patients the next day to follow up and survey with their response to treatment. I filled out case report forms using source documents.

Monday July 2, 2012

I filled out case report forms using the patient's chart data to verify. I went down to medical records to request a copy on a patient's data. I requested for network access in order to be able to do data entry for clinical studies. I spoke to a person along with Claudia and Theresa on getting an idea of what type of variables and data I will be looking for in my research project. I contacted someone who has access to patient database that may help me with my sample size limitation.

Tuesday July 3, 2012

I filled out case report forms using the patient's chart data to verify. I went down to medical records and made copies of the patient's data. I made copies of certain documents needed for the study. I researched on how to increase the sample size of my research project.

Thursday July 5, 2012

I helped enter data on the financial disclosure form (form 14) for the PI, sub PI, and the research coordinators who will be working on the study. They will then add any financial interest that they may have and sign the form. I observed Theresa figure out the study budget. This is important because all the cost within the study needs to be calculated and reported to the sponsor. The sponsor then pays for the study's expenses including study equipment and staff salary.

Friday July 6, 2012

I finished inputting data into the financial disclosure form (form 14). I helped fill out the investigator commitment document. I also helped fill out the scientific review approval

document. I read over the sponsor's informed consent on one of the trials. I formatted and edited in a way that matches ICH GCP and Baylor's guidelines.

Monday July 9, 2012

I helped fill out case report forms. I emailed a person in regards to obtaining data from Baylor's electronic database for my project. I needed to verify where my source of data will be coming from. I printed consent forms for Cathy's study. I called tech support for network drive access to do data entry.

Tuesday July 10, 2012

I helped fill out case report forms. I began to do data entry on the computer by verifying the data presented on the case report forms. Since Theresa will be working on a new study, I assisted in filling out an IRB supplemental application that summarized the main points of a study's protocol and consent form. For Cathy's study, I helped organize patient files in proper order. I also helped organize source documents in patient's file.

Wednesday July 11, 2012

I continued working on the IRB supplemental application for Theresa's study. While I waited for my research proposal to be reviewed by my committee members, I began working on my project's IRB application to Baylor as well as the school. I helped Cathy with her study by performing data entry. I also arranged the source documents in proper order so the monitor will have an easier time verifying the data.

Thursday July 12, 2012

I continued working on my project's IRB application to Baylor as well as the school. For Cathy's study, I performed data entry on the computer using case report forms as my source of input. I also arranged the source documents in proper order so the monitor will have an easier time verifying the data.

Friday July 13, 2012

I filled out IRB supplemental application form that summarizes my project and states that the study will be chart review. My project will fall under IRB expedited review. I also filled out financial disclosure agreement form, the PI attestation agreement, review of scientific and scholarly validity form, and administrative approval confirmation signature form. I worked on entering data on the computer for Cathy's study.

Monday July 16, 2012

I made copies of informed consent for Cathy's study. I made copies of blank case report forms. I assembled survey source documents for Cathy's study. I performed data entry as a secondary for Cathy's study.

Tuesday July 17, 2012

I worked on entering data on the computer using case report forms. I helped carry patient study files to be signed by the PI

Wednesday July 18, 2012

I worked on entering data on the computer using case report forms

Thursday July 19, 2012

I worked on entering data on the computer using case report forms. I emailed the IRB on what type of IRB review application would I have to fill out. I asked if there were any other forms that the student investigator needs to submit. I also asked what was required to prove that I am granted access to the data.

Friday July 20, 2012

I worked on entering data on the computer using case report forms. I called the Baylor IRB for questions on who the PI will be. Also, I asked questions about “master’s list” in order to identify patients.

Monday July 23, 2012

I performed data entry on the computer while I verified the information on the case report form. I filled out the intent to graduate form. I spoke to my committee members at school about my project

Tuesday July 24, 2012

I performed data entry on the computer while I verified the information on the case report form.

Wednesday July 25, 2012

I performed data entry on the computer while I verified the information on the case report form. Deborah showed me how drugs were tightly packaged and that some boxes contain temperature tracking devices.

Thursday July 26, 2012

I submitted my research proposal to school. I performed data entry on the computer while I verified the information on the case report form

Friday July 27, 2012

I performed data entry on the computer while I verified the information on the case report form. I helped Cathy with installing printer ink cartridge.

Monday July 30, 2012

I performed data entry on the computer while I verified the information on the case report form. I made copies of the informed consent form for Cathy’s study.

Tuesday July 31, 2012

I performed data entry while I verified the information on the case report form. I organized the folders containing case report forms that are archived. I helped organize source data to facilitate the verification of data by the monitor.

Wednesday August 1, 2012

I made corrections after comparing different inputs of data entry and verifying that the data is accurate. I worked on obtaining letters of agreement to show that I have access to electronic

database for my project. I helped Cathy bring files to be signed by the principle investigator. I organized the folders containing case report forms that are archived.

Thursday August 2, 2012

I made corrections after comparing different inputs of data entry and verifying that the data is accurate. I worked on obtaining letters of agreement to show that I have access to electronic database for my project. I assisted in helping set up data entry process for another person. I made corrections and revisions to IRB form 15. I submitted my IRB application.

Friday August 3, 2012

I organized the folders containing case report forms that are archived.

Monday August 6, 2012

I restocked the investigator device for Cathy's study. I organize patient folders and stored them in proper order. I made copies of the case report forms. I submitted application to IRB.

Tuesday August 7, 2012

I performed data entry on the computer while verifying the data on the case report form was correct. I organized source data in a certain order to facilitate the verification process by the monitor. I made copies of source documents using nurse charts. I updated one of my committee members on my project.

Wednesday August 8, 2012

I performed data entry on the computer while verifying the data on the case report form was correct. I made copies of source documents using nurse charts.

Thursday August 9, 2012

I performed data entry on the computer while verifying the data on the case report form was correct. I created a page of subject exclusions to record how many patients were not enrolled and the total amount that was. I made copies of source documents using nurse charts. I placed patient files in the cabinet in chronological order. I made a label for a page divider that will be used for the regulatory binder.

Friday August 10, 2012

I attended a grand rounds presentation. I made copies of source documents.

Monday August 13, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source documents that the nurses use to fill out. I spoke with the committee member about how the method used to collect data. I read over the Code of Federal Regulations Title 21 Part 11 to ensure electronic data integrity. I made copies of source documents from nurse charts.

Tuesday August 14, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source documents from nurse charts. I made copies of blank informed consent. I made changes after comparing and verifying primary and secondary data. I had my PI sign off on

protocol synopsis form and the retrospective chart review form. I watched Cathy fill out a protocol deviation as she submits it to the IRB.

Wednesday August 15, 2012

I made copies of source docs from nurse charts. I submitted my IRB application to UNTHSC. I made revisions to Baylor's expedited review form, protocol synopsis, and HIPPA waiver form. I performed data entry on the computer while verifying the data on source documents.

Thursday August 16, 2012

I made copies of source docs from nurse charts. I verified data from the protocol for Cathy. I performed data entry on the computer while verifying the data on source documents.

Friday August 17, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents.

Monday August 20, 2012

I made copies of source docs from nurse charts. I prepared changes to certain variables on the case report form for Cathy's study. I made revisions to UNTHSC expedited review form. I had a meeting with the on-site mentor. I made changes to the protocol to state that I will not be using paper charts as a source of data. I made revisions to HIPAA waiver application

Tuesday August 21, 2012

I made copies of source documents from nurse charts. I made changes to variables of the case report form. I performed data entry on the computer while verifying the data on source documents.

Wednesday August 22, 2012

I performed data entry on the computer while verifying the data on source documents. I received IRB approval from Baylor and UNTHSC. I emailed a person to help set up data collection. I organized study patient files in numerical order within storage,

Thursday August 23, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents. I submitted the conflict of interest form from my PI and myself. I made changes to data collection sheet and submitted the changes to Baylor's IRB and UNTHSC's IRB. I met with someone to help set up MIDAS. Emailed tech support for access to applications within MIDAS

Friday August 24, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents. I made copies of case report form template,

Monday August 27, 2012

I met with on-site mentor to discuss the status of data entry performed in Cathy's study. We discussed what is needed to start data collection on project. I performed data entry on the computer while verifying the data on source documents.

Tuesday August 28, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I met the manager who is in charge of the medical records department.

Wednesday August 29, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I made copies of case report form templates. I made copies of documents needed for Cathy's study.

Thursday August 30, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts.

Friday August 31, 2012

I performed data entry on the computer while verifying the data on source documents.

Tuesday September 4, 2012

I filed revision forms in the regulatory binder for Cathy's study. I performed data entry on the computer while verifying the data on source documents

Wednesday September 5, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents. I made copies of informed consent templates for Cathy's study. I filed patient charts in storage room. Pick up RN form from labor and delivery. Enter date of IRB approval onto the log sheet.

Thursday September 6, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents.

Friday September 7, 2012

I made copies of source docs from nurse charts. I performed data entry on the computer while verifying the data on source documents. I received access to MIDAS software access that I need to get access to patient records.

Monday September 10, 2012

I performed data entry on the computer while verifying the data on source documents. I have set up a date for my Defense meeting. I began to gather data for my project through MIDAS and QS

Tuesday September 11, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I gathered patient data through QS system

Wednesday September 12, 2012

I performed data entry on the computer while verifying the data on source documents. I gathered patient data through QS system. I replaced one of the regulatory binders that were damaged for Cathy's study. I went through patient files to look for any missing documents and recorded those that are missing.

Thursday September 13, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I gathered patient data through QS system. I made copies of source documents for Cathy's study.

Friday September 14, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I gathered patient data through QS system.

Monday September 17, 2012

I performed data entry on the computer while verifying the data on source documents. I gathered patient data through QS system.

Tuesday September 18, 2012

I performed data entry on the computer while verifying the data on source documents. I gathered patient data through QS system. I listened to CRC conference. They began with the initial study review followed by continuing reviews. It was hard to hear on the phone and I believe it would be more helpful if one was present to physically participate. I made copies of the informed consent template.

Wednesday September 19, 2012

I made copies of source docs from nurse charts. I gathered patient data through QS system. I arranged the folders in the cabinet so that the folders were not too packed on one side.

Thursday September 20, 2012

I made copies of source docs from nurse charts. I gathered patient data through QS system. I attended an IRB meeting in Dallas. The conference was designed where the tables were centered in the room. Two additional tables were placed on the side for viewing but not participation. There was one person who introduced each study and the IRB members who were in charge of the study. These two people would then discuss the study and would eventually decide to approve or disapprove the study. They began with the initial study review followed by continuing reviews. Anyone who was present in the room had the chance to ask a question or pose a comment on any of the discussed studies. Those that were not present were able to call in to listen to the discussion.

Friday September 21, 2012

I made copies of source docs from nurse charts. I gathered patient data through QS system. I drove to a study site that was enrolling patients. This was the initial visit for the patient and will be longer than the other visits. Theresa went over the informed consent form in detail with the patient. The patient was then given the chance to ask questions and to give consent on their participation to the study. Following the informed consent process, the patient was asked his/her medical history including symptoms, allergies, medication use, as well as their basic information. This was to better understand the patient as well as see if they are qualified for the study. A blood sample was taken, packaged into the boxes that was provided by the sponsor, and sent to the proper designated lab for testing. The patient was given the investigational drug and equipment. This was followed by instructions on how to use and chart their information.

Monday September 24, 2012

I gathered patient data through QS system. I discussed and went over with Theresa how to separate the C-section indications into different categories for my project. I calculated BMI for my data and I converted the units for duration of labor to minutes.

Tuesday September 25, 2012

I performed data entry on the computer while verifying the data on source documents. I made copies of source docs from nurse charts. I gathered patient data through QS system. I calculated BMI for my data and I converted the units for duration of labor to minutes. I brought Cathy some equipment that she needed for her study.

Wednesday September 26, 2012

I made copies of source documents from nurse charts. I filed patient folders in numerical order. I brought Cathy more catheter kits from the storage room. I went to speak with my statistician about my project.

Thursday September 27, 2012

I made copies of source documents from nurse charts. I scanned copies of the case report forms to another person to perform secondary data entry.

Friday September 28, 2012

I made copies of source documents from nurse charts. I worked on my thesis. I made copies of the case report forms. I made copies of study documents for Cathy's study.

Monday October 1, 2012

I spoke with Claudia and Theresa on the status of my project. They asked if I needed any other assistance in any way and made sure I had everything I need. They will try to request for me to observe a surgical procedure since I have not had any experience doing so.

Tuesday October 2, 2012

I went upstairs to get more catheters to bring to Cathy downstairs in labor and delivery. I opened supply boxes to stock up on the catheters in the storage. I collected data for my project. I made copies of source documents from nurse charts. I performed data entry on the computer while verifying case report forms.

Wednesday October 3, 2012

I worked on looking for more articles for my thesis. I made copies of source documents from nurse charts. I began writing the materials and methods section for my thesis. I collected data on induced vaginal births using QS.

Thursday October 4, 2012

I found out that Cathy's study is currently on hold with her project. Therefore, my duties and responsibilities will also be on hold. I will utilize this time to work on my thesis and will be helpful to the Baylor staff with anything else they need me to do.

Friday October 5, 2012

I collect data on induced vaginal birth patients for my project. I am almost half way done on collecting the data I need for this project. I finished writing the materials and methods part of my thesis.

Monday October 8, 2012

I attended Baylor's staff meeting. They spoke about how to improve care for the patients and how they were doing compared to other hospitals. I met with Claudia and Theresa to have our weekly discussion about my responsibilities and the progress of my project. I discussed my preliminary results based on what I collected from induced C-section patients.

Tuesday October 9, 2012

I finished collecting data on induced vaginal births. I wrote about my internship experience at Baylor in my thesis. I also finished writing my acknowledgements and worked on the layout of my thesis. I began to write the background and literature review section of my thesis.

Wednesday October 10, 2012

I began to write my introduction to my thesis. I continued to write my background and literature review of my thesis. I went to talk to several people about my data and how to perform the proper statistics. I left early to go to school to analyze my data.

Thursday October 11, 2012

I finished writing my introduction of my thesis. I continued to write about my background and literature review of my thesis. I have finished analyzing my data at school the night before. I wrote about my interpretation of the statistics. I had Claudia sign my intent to defend form and I went to school to have my other committee members sign my intent to defend form.

Friday October 12, 2012

I attended the grand rounds presentation. The presentation was based on surgical errors that physicians make. This consisted of recorded surgical videos. The doctor who presented the information then explained of methods on how to avoid these types of errors. I begin to write my results and discussion of my project. I spoke to Theresa about my results from the data and we discussed if the statistics matched up with what she knew.

Monday October 15, 2012

I had a weekly meeting with Claudia and Theresa. The meeting was to ensure that I was on track with my thesis and to make sure that all the resources I needed was provided to me. I told them that I was still working on my thesis and should have a rough draft completed soon. I spent most of the day writing and revising my thesis.

Tuesday October 16, 2012

I applied to various research jobs in Fort Worth and Houston area. Each job opening has different requirements in terms of experience. I applied to job opening titles including research assistant, clinical research assistant, clinical research coordinator, data entry specialist, and research enrollment analyst.

Wednesday October 17, 2012

I made the necessary corrections on my thesis based on Cathy's feedback. I applied to various research jobs in Fort Worth and Houston area. Each job opening has different requirements in terms of experience. I applied to job opening titles including research assistant, clinical research assistant, clinical research coordinator, data entry specialist, and research enrollment analyst.

Thursday October 18, 2012

I went to a presentation on enneaagrams and how to figure out what type of person I am. This was located in Baylor Sammons Cancer Center in Dallas. The event was all day and the lady was very outgoing and was a great speaker. She went through each type of personality that a person may have. This would be useful to know what kind of person you will be working with and how to deal with the person. Also, it helps to know what type of person you are in order to overcome your weaknesses and emphasize on the strengths. I thought the presentation was useful and interesting.

Friday October 19, 2012

I applied to various research jobs in Fort Worth and Houston area. Each job opening has different requirements in terms of experience. I applied to job opening titles including research assistant, clinical research assistant, clinical research coordinator, data entry specialist, and research enrollment analyst.

Tuesday October 23, 2012

I helped create source documents for a diabetes study. This included the first patient visit to the close out visit. I had to make sure that everything that was included in the protocol was included in the source document. I had to read the protocol in order to better understand what was needed for each visit.

Wednesday October 24, 2012

I performed data entry for Cathy's epidural study. I continued to work on creating source documents for the diabetes study.

Thursday October 25, 2012

I performed data entry for Cathy's epidural study. I went to school to contact my major professor. I went with Cathy to a site nearby on a heart study. I was able to observe how she was to obtain consent from each patient. Cathy thoroughly explained the whole process of explaining

the study to the patient and answered any questions that they may have. It was interesting to learn about a new type of study.

Friday October 26, 2012

I performed data entry for Cathy's epidural study. I made corrections on my thesis from Dr. Gwartz corrections. I also made corrections based on suggestion that Theresa and Claudia provided.

Monday October 29, 2012

I performed data entry for Cathy's epidural study. I scheduled a meeting time with Dr. Cammarata for suggestions on my thesis.

Tuesday October 30, 2012

I met with Dr. Cammarata to talk about my thesis. He states that I need to make changes on the order of references and that I need to reduce the amount of redundancies in my paper. Other suggestions include reorganizing my tables to make it easier to follow and to discuss more about the results.