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# Effects of Percieved Treament Options on Compleation of Clinical Study Visits in an Obstetrics Study

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# **EFFECTS OF PERCEIVED TREATMENT OPTIONS ON COMPLETION OF CLINICAL STUDY VISITS IN AN OBSTETRICS STUDY**

## **THESIS**

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

University of North Texas  
Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements

For the Degree of

**MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT**

By:

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Fort Worth, TX

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## ABSTRACT

**Objectives:** To determine the effects of patient perception on perceived treatment options, and to determine whether distance traveled to receive treatment affects study visit attendance.

**Methods:** Prior to enrolling in the study, patient information was gathered using NextGen, an electronic medical records (EMR) program. Pregnant women between the ages of 18 and 35, inclusive, were selected to participate in the study. The subjects were presented with information about the pregnancy study at their clinic visits verbally and/or via a brochure. Any questions that the patients had were addressed by the clinical research coordinators. Subjects were randomly assigned to one of three different treatment groups – OMT, ultrasound, and standard care. A One-Way ANOVA was conducted to examine the relationship between the visit attendance and the treatment group, clinic group, and distance traveled to receive treatment.

**Results:** Subjects in the three different treatment groups, on average, completed about the same amount of visits and traveled about the same distance to their respective clinics to receive treatment. Research participants from the Harris clinic completed more study visits than research participants from the PCC, even though participants from Harris traveled a further distance from their homes to the clinic.

**Conclusions:** Patient perception of treatment options did not seem to have a significant effect on study visit attendance for the pregnant women involved in this study. Factors that could potentially hinder study visit attendance or clinical research enrollment were discussed; however, factors that effected study visit attendance for the participants were not examined.

**Keywords:** patient perception, attendance, OMT, ultrasound, standard care, study visit completion

**Abbreviations:** OMT, osteopathic manipulative treatment; PCC, Patient Care Center; OMM, osteopathic manipulative medicine; ORC, osteopathic research center; OB, obstetrics; gyn, gynecology; IRB, institutional review board

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## CHAPTER I

### SUMMARY

Obstetrics and gynecology is a rapidly growing practice in the health care field. It was one of the top 5 specialties with the largest number of active physicians in 2007 (AAMC). Even though it is a field that deals only with women, there is still a great deal of variety that can be found within this demographic subset. The majority of my practicum project will primarily cover obstetrics. There have been multiple research studies conducted on pregnant women; however very few of them pertain to osteopathic research.

The Osteopathic Research Center (ORC) is the research site where I completed my Internship Practicum. The goal of the ORC employees is to establish the evidence base for osteopathic manipulative medicine, and thus, increase its implementation in the health care setting. They hope to bridge the gap between science and the practice of medicine through the use of evidence based medicine. Through their efforts, the ORC staff hopes to provide data that supports osteopathic manipulative medicine (OMM) as an effective form of treatment. The long term goal would be that all patients would be able to benefit from osteopathic medicine.

During my internship, I worked with the project entitled, *Osteopathic Manipulative Medicine in Pregnancy: Physiologic and Clinical Effects* in which Dr. Kendi Hensel is the principal investigator. It is a prospective (cohort), randomized controlled trial examining the effects of OMT, ultrasound, or no care on treating low back pain in pregnant women. The clinical investigators are not blinded; however, one of the three study groups is partially blinded. The first group receives osteopathic manipulative treatment (OMT). The second group receives ultrasound treatment, but, this group is unaware that the ultrasound maybe a placebo, or sham,

treatment. The third group is the time control group, or the standard care group. This group does not receive OMT or the placebo ultrasound treatment.

I worked closely with Mrs. Mayra Rodriguez, a clinical research coordinator at the ORC. My major responsibility was to enroll subjects in the pregnancy study. There are two parts to the study – a clinical and sub study. The clinical study only involves treatment (i.e., receiving OMT or ultrasound treatment). The subjects may or may not receive treatment depending on which treatment group to which they are randomly assigned. The purpose of the sub study is to examine the physiological effect that an individual treatment has on a subject's body.

The goal of this practicum report was to investigate how patient perception of treatment options affects completion of study visits in a clinical trial. The report presents the demographics of the subjects that participated in the study. In addition, it examines the relationship between visit attendance and distance traveled to receive treatment.

## CHAPTER II

### Problem/Hypothesis

The field of clinical research is rapidly expanding and changing. The subjects that participate in clinical research studies are just as dynamic. Most studies enroll participants with a wide range of demographic information. In addition, treatment options available to them are different and are based on whether they receive genuine or placebo treatment, a combination of both, or neither. This project tested the hypothesis that patient perception of treatment options affects study visit attendance. For example, those subjects that felt standard care or ultrasound was not working for them did not feel the need to complete their visits; whereas, those receiving OMT completed most if not all of their visits when compared to the other two treatment groups. Likewise, because of the placebo effect, those receiving ultrasound treatment completed more visits than those in the standard care group. The placebo effect can be described as “nonspecific effects of treatment, attributable to factors other than specific active components” (i.e., physician attention, patient expectation of treatment effects) (14).

### CHAPTER III

#### SIGNIFICANCE

There has been little literature published regarding how subjects perceive their treatment options in clinical trials. The significance of this report is to provide clinical investigators with information regarding the role of patient perception of treatment options, which may affect a subject's willingness to complete a study visit. By using this information, physicians may then be able to establish innovative ways to improve study visit attendance. It is imperative that researchers understand these details so that they can maximize the results attained from the data collection. Investigators can reach better conclusions to support or refute hypotheses with a greater amount of accurate data.

## CHAPTER IV

### BACKGROUND

#### Osteopathic manipulative treatment and low back pain

Osteopathic manipulative treatment (OMT) has been in practice for a little more than one hundred years (5). It is a “distinctive modality commonly used by osteopathic physicians to complement their conventional treatment of musculoskeletal disorders” (5). One specific musculoskeletal disorder that is often treated by OMT is low back pain. Low back pain is the number two reason for scheduled doctor’s visits, preceded by the cold and flu (10). The majority of the American population will experience acute or chronic back pain within their lifetime. The Chicago Institute of Neurosurgery and Neuroresearch (CINN) states that lifetime prevalence of back pain in the United States is about 90%, with 30% - 60% experiencing some form of low back pain in any given year (10). In this case, the lifetime prevalence refers to the number of people [in the United States] who have [had] complaints of back pain throughout their life (10).

Many osteopathic physicians utilize manual manipulation to treat patients with low back pain. There are four crucial points to recognize when examining the affect of osteopathic treatment of low back pain – “1) the body is a unit; 2) the body possesses self-regulatory mechanisms; 3) structure and function are reciprocally interrelated; and 4) rational therapy is based on an understanding of body unit, self-regulatory mechanisms, and the interrelationship of structure and function” (6). These four points are the foundation for osteopathic medicine. The effectiveness of osteopathic manipulation in treating low back pain has been under investigation for several years. Some investigators have concluded that “many studies on the efficacy of OMT or other spinal manipulation for low back pain (LBP) have shown varying degrees of effectiveness” (3).

Advocates of OMT claim it is just as safe and effective as medical treatment with prescription drugs, but with fewer side effects. If found true by investigators, then the use of OMT would help reduce the over-prescription of many pain medicines used for low back pain. Desai and Patel explain that “osteopathic physicians tend to prescribe fewer medications than their allopathic counterparts in general and osteopathic physicians who use OMT prescribe fewer medications than osteopathic physicians who do not use OMT” (8). The reason for the difference in the amount of medications prescribed by allopathic physicians versus the amount prescribed by osteopathic physicians may lie in their method of handling disorders of the musculoskeletal system. In reference to low back pain, allopathic physicians use a broader approach to treat it, meaning they believe “an anatomic cause for the pain is often difficult to define with specificity and that only a small percentage of patients have an identifiable underlying cause” (3). In contrast, osteopathic physicians have a narrower approach for treating musculoskeletal disorders; osteopaths “establish a specific diagnosis, relating to a specific anatomic region, which can then be treated with OMT” (3).

#### Pregnancy and low back pain

A specific group of people that are more prone to suffer from low back pain are pregnant women. The female body experiences many morphological changes during pregnancy in order to contain the developing fetus (1). The back pain that most women experience during pregnancy is “caused by relaxation of the sacroiliac joint which is due to increased hormones (steroid sex hormone and relaxing) resulting in slight joint and muscle relaxation and increased mobility” (1). Pregnancy may cause problems such as lumbar lordosis and/or kyphosis, specific types of musculoskeletal disorders (1). Lordosis refers to an over exaggeration of the curve formed by the lumbar vertebrae, and kyphosis refers to the over exaggeration of the curvature of

the cervico thoracic vertebrae. The lumbar vertebrae are located towards the bottom of the spine around the low back and pelvic regions. The cervico thoracic vertebrae are located towards the upper part of the spine around the neck and chest region.

Another cause of the back pain experienced by women during pregnancy is weight gain. During a normal pregnancy, a woman may gain approximately 25 – 35 pounds (8). Carrying extra weight, such as during pregnancy, “worsens spinal [curvatures] and stresses the supportive structures of the pelvis, such as extremities” (7). Any excess curving of the spine can cause excruciating pain, and some of this excess curvature is due to changes in the center of gravity from enlarging abdomen and breasts (1). In addition, the pain is also a result of “pain signals and other sensory inputs [that] are amplified via central sensitization at the spinal cord level” (7). Therefore, the area around the spinal cord is particularly sensitive to painful stimuli, such as lumbar lordosis. Although weight gain is considered normal for a healthy pregnancy, “the weight changes [that a woman experiences] are modifying factors for posture, gait, and somatic complaints” (7). Somatic complaints are those that do not have a clear medical explanation; they include, but are not limited to heartburn, migraines, and back/neck aches (9).

#### Pregnancy and osteopathic manipulative treatment

Because pregnant women cannot consume certain medications, they often seek alternative forms of treatment for their low back pain, and OMT is one of those types of treatments. A study involving pregnant women who experienced pain in the lumbar area concluded that the “use of osteopathic manipulative treatment to the lumbar area...resulted in significantly reduced pain; the conclusion of this study was measured by the need for analgesic medication during labor” (4). This is one of the few studies that have been able to demonstrate the effectiveness of OMT in treating low back pain. Many studies that have been conducted

have been too small to draw significant conclusions on the effect of OMT on pregnancy. A pilot study conducted by Christopher Caragan et al concluded that “OMT appears to be an effective therapy for immediate relief of pregnancy related low back pain and suggests a small possible longer term effect on improving functional capacity and bodily pain after three serial weekly treatments” (2). Despite the positive results of this study and others, more information needs to be collected to determine during which stage of the pregnancy process (i.e., conception to birth) osteopathic manipulation should be implemented and how many times during the pregnancy a woman should received OMT.

## CHAPTER V

### RESEARCH DESIGN AND METHODOLOGY

*The Osteopathic Manipulative Medicine in Pregnancy: Physiologic and Clinical Effects* project is a prospective, randomized control clinical trial in which one of the treatment groups (ultrasound) is blinded to the fact that they are receiving a placebo. Prior to enrolling in the study, patient information is gathered using NextGen, an electronic medical records (EMR) program. Pregnant women between the ages of 18 and 35, inclusive, are selected to participate in the study. Also, the patients' EMRs are reviewed to make sure they are not considered high risk pregnancies. The factors that were considered high risk include, but are not limited to gestational diabetes, hypotension, and third trimester bleeding. This information is also cross checked with the medical staff before a subject is enrolled. The subjects were presented with information about the pregnancy study at their clinic visits verbally and/or via a brochure. It was explained that participation was independent of the clinic visit and strictly voluntary. Any questions that the patients had were addressed by the clinical research coordinators.

The demographic data collected for this practicum study include the subject's age, race and/or ethnicity, educational level, address, and employment status. The database sampled was the obstetrics study database which was created at the ORC. This database includes the aforementioned demographic information, except the addresses, as well as visit dates, answers to the questionnaires, measurements from the sub-study, and delivery record information. The delivery record information was obtained from two University of North Texas Health (UNT Health) clinics – Harris Methodist OB/gyn and Patient Care Center (PCC). While working at the ORC, I created a delivery records form, which was used to obtain relevant information from the subject's actual delivery record. A release of records form that was signed by the patient was

faxed to the Harris Methodist records department in order to obtain labor and delivery (L & D) summaries. Once the L & D summary for the subject was received, the pertinent information was entered on the ORC delivery records form. The form was then reviewed by Dr. Hensel before the information was entered into the obstetrics database. All of the data used in this practicum report came from the demographics form that the subjects filled out or will be taken from the OB study database.

At the beginning of each visit the subjects were asked to fill out a set of questionnaires prior to receiving treatment. The subjects filled out the demographic information at the first visit. The research participants could either participate in the clinical study (receive clinical treatment – OMT, ultrasound, or no care) alone or participate in both the clinical study and sub-study. If a subject participated in only the clinical study, the visit lasted about forty minutes. If she happened to fall in the standard care group, the study visit lasted for the length of time it took for her fill out the paperwork. Subjects were compensated twenty-five dollars for their time and travel required to attend the clinical visit. If they participated in the physiological sub-study visit, they received an additional fifty dollars. The sub-study was only conducted at the first and fourth visit. The total time for a clinical and physiological sub-study visit was approximately two to two and a half hours.

When participating in the sub-study, the subject was asked to walk on a GaitRite® mat before and after completion of the physiological sub-study. The mat measures the pressure distribution in the subject's feet, how fast she walked, and the angles at which her feet landed while she walked. In the physiological sub-study room, the subject was required to lie on her left side for approximately thirty minutes. A string gauge was attached to the widest part of the subject's right calf to measure the edema, or swelling, in the leg. In addition, the following

circumferences were recorded in centimeters with a tape measure: 1) the widest part of the right thigh, 2) the area just above the right knee, 3) the area just below the right knee, and 4) the area just above the right ankle. The distances between 1) and 2), and 3) and 4) were also recorded. Their blood pressure and pulse were monitored via a finometer machine; heart rate was measured by an EKG machine. Within the 30 minutes of lying on the left, the subject was elevated to a 60-degree tilt and asked to perform heel raises. After the session, the patient received treatment in nearby room for approximately 30 minutes. If the woman was in the standard care group, the bed was lowered to a horizontal position, and the subject was asked to lie in the bed for ten to fifteen minutes for time control purposes. The physiological sub-study was resumed for another thirty minutes.

The statistical analysis of the data was performed using Excel and SPSS software. I first used excel to organize the information that I needed from the OB study. I then copied the data into SPSS and ran the analysis. A One-Way ANOVA was conducted to examine the relationship between the visit attendance and the treatment group, clinic group, and distance traveled to receive treatment. This test was conducted to see if there is variation between groups based on a specific variable. Any results with a p-value greater than .05 was considered significant.

A literature review was conducted to show that patient perception of treatment options does play a role in the outcome of a study. Furthermore, I have discussed three reasons that I felt hampered the enrollment process of the obstetrics study as well as affected study visit attendance. The three reasons are as follows: 1) lack of manpower, 2) protocol, and 3) location.

## CHAPTER VI

### RESULTS

Prior to enrollment the subjects were told that OMT and ultrasound were available treatment options. They were also told that those falling within the standard care group would not receive a treatment option.

Out of the 100 subjects that have completed the obstetrics study, 57 (57%) were never married, 39 (39%) were married, 1 (1%) was separated, 2 (2%) were divorced, and 1 (1%) was widowed. With respect to highest education level attained, 2 (2.1%) completed grade school, 51 (52.6%) completed high school, 25 (25.8%) had completed some college course work, 9 (9.3%) received an associate's degree, and 10 (10.3%) received a bachelor's degree. The education level was left unmarked by 3 of research participants. As per vocation of the participants, 5 (5.5%) were professionals, 18 (19.8%) worked in the services field, 21 (23.1%) worked in sales, 1 (1.1%) worked in construction, 17 (18.7%) were homemakers, and 27 (29.7%) unemployed. Nine research participants left this question blank. The majority of the research participants had some type of insurance coverage. Only 1 person left this question blank, and one other woman marked that she did not have insurance coverage.

The results were analyzed using a "One-Way ANOVA". Data are shown in Table 1. There was a significant difference seen between the subjects from Harris and the subjects from the PCC with regards to the number of visits completed. The mean percentage of visits completed for Harris subjects was about 91% and for PCC subjects was 82%, with a p-value of .06. The subjects from Harris tended to complete more visits than the subjects from the PCC even though the results also showed that the subjects from Harris had to travel a further distance to get to their appointments. There was no significant difference seen between travel distance

and treatment groups, which mean the treatment groups, completed more or less the same amount of visits regardless of the distance traveled. There was also no relationship seen between the percent of visits completed and distance traveled. With the results received from the analysis, I must reject my hypothesis about perception of treatment options playing a significant role in study visit attendance. However, other factors such as travel distance played a significant role.

**Table 1: Visits & Distance by Clinic**

	Harris	PCC	Both Clinics
Avg. # of visits completed	5.06	4.68	4.93
Avg. % of visits attended	90.9	82.3	88.0
Avg. distance traveled (mi)	13.6	9.4	11.8

**Table 2: Visits & Distance by Treatment Group**

	OMT	Ultrasound	Standard Care	All groups
Avg. # of visits completed	5.06	4.91	4.82	4.93
Avg. % of visits attended	87.0	90.3	86.6	88.0
Avg. distance traveled (mi)	11.8	11.8	11.7	11.8

I cannot solely base study visit attendance on patient perception of treatment options. Other factors such as distance traveled, socioeconomic status, and other life factors affect how many study visits will be completed.

## CHAPTER VII

### DISCUSSION

#### Protocol

One of the reasons as to why patient enrollment is hindered in a clinical trial and especially “Effects of OMM on Pregnancy” study is due to changes in procedure. There are many steps, or protocol, that needs to be followed to complete a task. For example, changes that are made to a consent form must be submitted to the Institutional Review Board (IRB) before those changes can be implemented in the study. Everything that pertains to the clinical trial must be submitted to the IRB for approval ranging from paperwork to personnel that will be working with the study. One setback that I experienced while working on the pregnancy study was a recruiting freeze. Every year the forms that are used in a study must be approved by the Institutional Review Board, and in this case, the IRB approval for the pregnancy study ended April 1, 2009. The consent forms for the study were not submitted and approved in a timely manner; thus, I could not recruit any new subjects for the study until after approval from the IRB office was received. As a result, I missed two patients that were interested in participating in the study. The study received special permission from the IRB office to continue treating patients that were already enrolled in the study.

Another factor that could delay enrollment in a clinical study is getting members of the research team together. One example, would be gathering the members of a Data Safety and Monitoring Board together in one place. A Data Safety and Monitoring Board (DSMB) meeting must be set up prior to the start of the research. Because everyone in the board has different schedules, getting them together is a difficult process. This plays a role as to when clinical study can officially begin. The purpose of a DSMB meeting is to ensure patient safety by examining

the clinical trial protocol. Also, the members discuss how to make the study as easy and efficient as possible. Members of the board usually consist of lay people and specialists in the particular field of research that is being studied.

#### Lack of manpower

One major problem that the study dealt with was lack of man power. When I arrived, there was one clinical research coordinator that was recruiting at the two clinics. Harris Methodist has two obstetrics units – one composed of midwives and the other composed of physicians. In essence, one person was recruiting at three different clinics. With only one person recruiting, many potential subjects were not approached for enrollment. The Patient Care Clinic is smaller in size, and does not receive as high a patient volume as Harris Methodist. For this reason Mrs. Rodriguez concentrated most of her time at the Harris clinic.

#### Location

Clinical treatments were provided at the ORC or the Harris clinic. Subjects that attended the PCC for their OB visits came to the ORC to receive their treatment. The PCC and the ORC are in close proximity to each other, and thus, the subjects simply had to walk a few hundred feet to get to the ORC from the PCC. Most Harris patients received treatment in the Harris clinic; however, on rare occasions, they would have to travel to the ORC to receive their treatment. This would happen if the clinic visit with their obstetrician gynecologist occurred on a day in which the clinical research coordinator was not at Harris. This required them to drive about 2.64 miles to get to the ORC from Harris, or about eight to ten minutes. Many times subjects had difficulty locating the ORC, which caused some to not come to their study visit. Others either

could not or did not want the inconvenience of driving to multiple destinations to complete the study.

#### Aversions to or difficulties with participation in clinical research trials

Different subsets of the population have experienced the downside of unregulated clinical trials. The residual effects of the injustices faced by African American males in the notorious U.S. Public Health Service Syphilis Study at Tuskegee are still felt today. According to Grant, “There appears to be a lingering distrust in the research enterprise among some persons of color in the United States,” (731). The study commenced in 1932 in Tuskegee, Alabama. The clinical trial was conducted by the Public Health Institute and the Tuskegee Institute. It began with six hundred African American males, but grew to a much larger number as the years progressed. Of the 600 men that initially started the study, 399 had syphilis and the other 201 did not have the disease (CDC). The men were told that they were receiving treatment for “several ailments including syphilis, anemia, and fatigue” (CDC). Unfortunately, the African American male participants were not receiving any treatment to cure their illness. The Tuskegee experiments were to conclude approximately six months after the start study, but instead lasted for roughly another 40 years. The African Americans in this study were treated unjustly and taken advantage of. Consequently, many of them have apprehensions about enrolling in clinical trials, even today.

A different sub-group of the population that may be averse to participating in clinical trials is pregnant women. This may be because they want to protect the health of their fetus, and they feel that participating in a clinical study might harm the unborn child. In addition, the women have undergone physiological, emotional, and physical changes; therefore, performing a task outside of their routine, such as participating in a research study, may not appeal to them.

Like many African Americans, some pregnant women may be apprehensive to enrolling in a clinical trial because of the history of inclusion of pregnant women in previous studies. In the 1960s and 1970s thalidomide was an experimental drug that was used to treat nausea in expectant women (13). However, ingesting the drug led to disastrous effects on the growing fetus, which were not discovered until after the woman had given birth. Thalidomide caused abnormalities in the eyes, ears, heart, genitals, kidneys, digestive tract, (including lips and mouth), and nervous system (13). The most common anomaly related to the thalidomide drug was phocomelia, or seal limbs. This defect resulted in “shortening or missing arms with hands extending from the shoulders, absence of the thumb and the adjoining bone in the lower arms and similar problems with the lower extremities” (13).

One way to address the apprehensions of some patients may be to have minority research coordinators approach the patients. I suggest minority research coordinators because the minority patients may be able to relate to them better than someone that is a non-minority. In addition using advertisements with minority participants could ease the qualms that some may have about enrolling in a clinical research study.

The Hispanic population is a vastly growing minority group. Their participation in clinical research studies is greatly needed and highly beneficial. However, there is a major problem that prevents many Hispanics/Latinos from participating in clinical research – the language barrier. In general, clinical studies are conducted in English. In order to incorporate non-English speaking Hispanics into a study, bilingual consent forms and questionnaires must be available, as well as a professional interpreter. The bilingual forms must be submitted and approved by the IRB. Also, clinical research employees that speak and understand Spanish cannot act as translators unless they have approved certification to do so. Employing interpreters

and translating documents, costs extra money that many studies cannot cover, hence, enrollment of Hispanics and Latinos might be reduced. In a review on the language barriers in health care, it was found that “non-English speaking status was a marker for a population at risk for decreased access” (15). In addition, “six of seven studies evaluating the quality of care found a significant detrimental effect of language barriers” (15). These studies demonstrate the importance that language plays in the health care system, as well as the need to improve the assimilation of the Spanish language into the health care scene.

#### Patient perception

In a sickle-cell disease (SCD) study, patients were asked their perception of certain treatment option for the disease and their willingness to accept a transplant-related mortality (TRM) or graft failure (GF). As long as they perceived allogenic bone marrow transplantation (allo-BMT) as a curative treatment option, the majority of the participants that were surveyed, were willing to accept TRM, GF, life-long prophylaxis, or infertility in addition to a cure for the debilitating disease. However, if the curative option was perceived to lead to another chronic illness, in this case chronic graft-versus-host disease (GVHD), the margin of acceptance was quite narrow. In other words, “a majority refused to accept chronic GVHD in lieu of a cure of SCD” (12).

In a different study regarding the perception of OMT in a hospital setting, an overwhelming percentage of patients surveyed declared that they would recommend OMT in the treatment of future patients. Of the 160 responses, 28 were considered obstetrics patients (i.e., admitted for labor and delivery). In reference to the amount of pain, the level of stress and anxiety, the improved recovery and overall comfort, OMT had a tremendous positive effect on

those patients admitted for labor and delivery (11). The perceived benefits are as follows: 89% believed OMT decreased their pain, OMT caused a reduction in stress and anxiety in 96%, 93% felt their recovery was improved, and 100% perceived an improvement in overall comfort. On the other hand, in reference to the need for pain medication, only 29% declared a need for fewer analgesics. According to Licciardone, et al., “those open to receiving [osteopathic manipulation were] more likely to perceive the outcome of therapy as being beneficial” (11), which was acknowledged as a bias for this particular study.

## CHAPTER VIII

### LIMITATIONS

With every type of research, there are some factors that limit the interpretation of data. The major obstacle that the OB study faces is reduced subject retention. Some of the main causes are patient's developing high risk pregnancies or simply not completing all 9 study visits. This loss to follow-up decreases the validity of the data collected. An additional limitation of the data analysis conducted is the issue of missed subject visits. There are not any explanations recorded regarding why visits were missed, unless the subject delivered early. The means of transportation during the course of their participation in the study was not recorded either. Those variables would help with the analysis as to why some women completed their visits and others did not.

I was not able to obtain delivery records for some patients at the PCC. These patients' information was not available for retrieval on NextGen®, and had already been archived at a location outside of the clinic. Because I could not obtain some delivery records, I had to estimate the approximate date of delivery using the subjects' study visit dates. The problem with estimating the dates is that a study appointment falls within a range. For example, a woman is 32 weeks pregnant for approximately 6 days; thus I could have underestimated or overestimated delivery dates based on this factor.

An additional limitation was poor equipment recordings, such as improper calibration of the machines which could cause data distortion. Subjects answering questions incorrectly could pose as another limitation. Skipping a question, incorrect markings, or illegible writing are all examples of answering a question incorrectly. When this occurs, investigators cannot determine what this subject actually meant in her response. The investigator must leave the question blank

when entering it in the database. However, if the mistake is noticed before the subject leaves, he or she will be asked to clarify their answer. The final barrier that may limit the interpretation of data collected or arguments presented is a lack of follow-up questions for some of the questionnaires. As of now, only assumptions can be made as to why some subjects felt one treatment option was better than another.

## CHAPTER IX

### INTERNSHIP ACTIVITIES

While interning at the ORC, I was able to engage in many hands-on-activities with the pregnancy study. I recruited subjects from the PCC, and sometimes assisted Mayra with recruiting subjects at Harris. I entered all subject responses to the questionnaires into the obstetrics study database, which was kept for analysis after completion of the study. I provided explanations about the consent forms for new subjects that wished to enroll in the study. In addition, I had the privilege of sitting in on the DSMB meeting for the study. I conducted several sub-studies and had the opportunity to train a fellow in how to conduct a sub-study. I edited the protocol sheet that explained how to conduct a sub-study, created a delivery records template and a height/weight chart for the research study. I kept a journal to log all of my experiences.

As well as working on the obstetrics study, I assisted with the low back pain study. My duties for the low back pain study involved calling subjects to remind them of their visits and reviewing the questionnaires to make sure all questions were answered.

APPENDIX A:

TABLES 3-9

**Table 3: Treatment Group Division**

<b># of Subjects in Each Treatment Group</b>	
OMT	33
Ultrasound	34
Standard Care	33
<b># of Subjects in Each Treatment Group by Clinic</b>	
PCC	
• OMT	11
• Ultrasound	10
• Standard Care	13
Harris	
• OMT	22
• Ultrasound	23
• Standard Care	21

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**Table 4: Average Age**

<b>Average Age of Participants</b>	
PCC + Harris	23.1
• PCC	21.8
• Harris	23.8

**Table 5: Marital status frequencies****Statistics**

marital status

N	Valid	100
	Missing	0

**marital status**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Never Married	57	57.0	57.0	57.0
	Married	39	39.0	39.0	96.0
	Separated	1	1.0	1.0	97.0
	Divorced	2	2.0	2.0	99.0
	Widowed	1	1.0	1.0	100.0
	Total	100	100.0	100.0	

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**Table 6: Highest level of education frequencies****Statistics**

education level

N	Valid	97
	Missing	3

**education level**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Grade School	2	2.0	2.1	2.1
	High School	51	51.0	52.6	54.6
	Some College	25	25.0	25.8	80.4
	Associate's Degree	9	9.0	9.3	89.7
	Bachelor's Degree	10	10.0	10.3	100.0
	Total	97	97.0	100.0	
Missing	System	3	3.0		
Total		100	100.0		

**Table 7: Occupation frequencies**

**Statistics**

occupation

N	Valid	91
	Missing	9

**occupation**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Professional	5	5.0	5.5	5.5
	Service	18	18.0	19.8	25.3
	Sales	21	21.0	23.1	48.4
	Construction	1	1.0	1.1	49.5
	Production	2	2.0	2.2	51.6
	Homemaker	17	17.0	18.7	70.3
	Unemployed	27	27.0	29.7	100.0
	Total	91	91.0	100.0	
Missing	System	9	9.0		
Total		100	100.0		

**Table 8: Insurance frequencies**

**Statistics**

insurance

N	Valid	99
	Missing	1

**insurance**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	HMO/PPO/POS	20	20.0	20.2	20.2
	VA/Champus	1	1.0	1.0	21.2
	Medicare	2	2.0	2.0	23.2
	Medicaid	75	75.0	75.8	99.0
	No Insurance	1	1.0	1.0	100.0
	Total	99	99.0	100.0	
Missing	System	1	1.0		
Total		100	100.0		

**Table 9: Ethnicity and race frequencies**

**Statistics**

		ethnicity	race	other race
N	Valid	99	79	100
	Missing	1	21	0

**ethnicity**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Hispanic/Latino	32	32.0	32.3	32.3
	Non-Hispanic/Non-Latino	67	67.0	67.7	100.0
	Total	99	99.0	100.0	
Missing	System	1	1.0		
Total		100	100.0		

**race**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Black/African American	27	27.0	34.2	34.2
	Asian	2	2.0	2.5	36.7
	American INdian/Native American	1	1.0	1.3	38.0
	White/Caucasian	40	40.0	50.6	88.6
	Other	9	9.0	11.4	100.0
	Total	79	79.0	100.0	
	Missing	System	21	21.0	
Total		100	100.0		

APPENDIX B:

DELIVERY RECORDS TEMPLATE

<b>DR</b>	<b>Maternal Labor/Delivery Information</b>							<b>DB 1</b>	<b>DB 2</b>
	G:	P:	T:	Pt:	Ab:	L:			
	Anesthesia:	None <input type="checkbox"/> _0	Local <input type="checkbox"/> _1	Epidural <input type="checkbox"/> _2	Spinal <input type="checkbox"/> _3	IV Sedation <input type="checkbox"/> _4	General <input type="checkbox"/> _5		
	Oxytocin:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Post Placenta:		Yes <input type="checkbox"/>	No <input type="checkbox"/>		
<b>DR</b>	<b>Labor Summary</b>							<b>DB 1</b>	<b>DB 2</b>
	Anesthesia:	None <input type="checkbox"/> _0	Local <input type="checkbox"/> _1	Epidural <input type="checkbox"/> _2	Spinal <input type="checkbox"/> _3	IV Sedation <input type="checkbox"/> _4	General <input type="checkbox"/> _5		
	Length of Labor:	Stage 1:	hr	min	Prolonged Latent: Yes <input type="checkbox"/> No <input type="checkbox"/>				
					Prolonged Active: Yes <input type="checkbox"/> No <input type="checkbox"/>				
		Stage 2:	hr	min	Prolonged 2 <sup>nd</sup> Stage (>2.5hrs):		Yes <input type="checkbox"/>	No <input type="checkbox"/>	
		Stage 3:	hr	min					
		Total:	hr	min					
	Precipitous (< 3hrs):		Yes <input type="checkbox"/>	No <input type="checkbox"/>					
	Prolonged (≥ 20hrs):		Yes <input type="checkbox"/>	No <input type="checkbox"/>					
<b>DR</b>	<b>Delivery Information/C-Section Delivery</b>							<b>DB 1</b>	<b>DB 2</b>
	Episiotomy:	None <input type="checkbox"/> _0	Midline <input type="checkbox"/> _1	LML <input type="checkbox"/> _2	RML <input type="checkbox"/> _3				
	Perineal Laceration Ex:	None <input type="checkbox"/> _0	1° <input type="checkbox"/> _1	2° <input type="checkbox"/> _2	3° <input type="checkbox"/> _3	4° <input type="checkbox"/> _4			
<b>DR</b>	<b>Maternal Complications</b>							<b>DB 1</b>	<b>DB 2</b>
	Febrile (≥ 100.4°F/38°C):	Yes <input type="checkbox"/>	No <input type="checkbox"/>						
<b>DR</b>	<b>Baby A Delivery Information</b>							<b>DB 1</b>	<b>DB 2</b>
	Date:	Gestational Age:							
	Time:								
	Method:	Vaginal <input type="checkbox"/> _0	VBAC <input type="checkbox"/> _1	Converted to C-section <input type="checkbox"/> _2	Scheduled C-section <input type="checkbox"/> _3				
	Membranes:	Intact <input type="checkbox"/> _0	Bulging <input type="checkbox"/> _1	Ruptured <input type="checkbox"/> _2					
	Fluid:	Clear <input type="checkbox"/> _0	Bloody <input type="checkbox"/> _1	Meconium st. <input type="checkbox"/> _2					
	Odor:	Foul <input type="checkbox"/> _0	Normal <input type="checkbox"/> _1						
	Forceps used:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Type:					
	Vacuum:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>					
	Pre-term (≤ 37wks):	Yes <input type="checkbox"/>	No <input type="checkbox"/>						
	Post-term (≥ 42wks):	Yes <input type="checkbox"/>	No <input type="checkbox"/>						
	Presentation:	Unknown <input type="checkbox"/> _0	Face/brow <input type="checkbox"/> _1	Breech <input type="checkbox"/> _2	Frank <input type="checkbox"/> _3	Complete <input type="checkbox"/> _4	Vertex <input type="checkbox"/> _5		
		Single/double footing <input type="checkbox"/> _6	Trans. lie <input type="checkbox"/> _7	Back - up <input type="checkbox"/> _8	Back - down compd <input type="checkbox"/> _9				
<b>DR</b>	<b>Apgars</b>							<b>DB 1</b>	<b>DB 2</b>
	1 minute:								
	5 minute:								
<b>DR</b>	<b>Complications</b>							<b>DB 1</b>	<b>DB 2</b>
	None <input type="checkbox"/> _0	Preeclampsia <input type="checkbox"/> _1	Eclampsia <input type="checkbox"/> _2	Placenta previa <input type="checkbox"/> _3	Abruptio placenta <input type="checkbox"/> _4				
IN:	Date:								

Notes:

Subject ID #: \_\_\_\_\_ Date of entry 1: \_\_\_\_\_ IN: \_\_\_\_\_ Date of entry 2: \_\_\_\_\_ IN: \_\_\_\_\_

## APPENDIX C

### OB STUDY QUESTIONNAIRES

APPENDIX D  
ORC JOURNAL ENTRIES

Week 1: 2/2/09 - 2/6/09

Monday, February 2, 2009

- I was introduced to the people that I will be working with (Mrs. Debbie Lewis, Mrs. Dorothy Lindsey, Mrs. Mayra Rodriguez)
- I met Dr. Hensel - she is leading the OB study
- I met Dr. Stoll - he is leading the carpal tunnel study
- My main project will be the OB study; however, I will be cross-trained in the carpal tunnel and low back pain studies
- I received training on how to perform a DNA buccal swab
- There are 3 types of treatment for the OB study
  - OMT (Osteopathic Manipulative Treatment) - actual OMM treatment
  - Ultrasound care - placebo
  - Standard care - no treatment
- I observed 2 subjects that were enrolled in the clinical study as well as the sub-study
  - 1 standard care
  - 1 ultrasound
- I observed how to set-up the patients for the sub-study
- I watched how to operate the machines for the sub-study
  - Finometer (which uses the WINDAC program)
  - ECG (I watched how to put the EKG leads, the BP cuff, and the pulse cuff on)
  - Plethysmograph (string gauge) - measures edema; it is placed on the widest area of the patients right calf
- I signed a conflict of interest form for each of the studies

- Dr. Hensel signed the addition of key personnel to study form me

Tuesday, February 3, 2009

- I went to Harris for half a day with Mayra and observed how to recruit subjects for the study
- I was introduced to some of the staff at Harris
- We saw one potential subject and explained the study to her
  - She was given 2 consent forms (1 for the study and the other for the sub-study)
  - She was also given a map on how to get to the ORC (Osteopathic Research Center - the only site where the sub-study can take place)
- Drs. Stoll and Licciardone signed the addition of key personnel form to add me to their studies
- I met with Dr. Licciardone and some of the people he's working with
- I did some more observations on how to recruit patients and how to explain the study to them
- I helped prepare site for funder visit

Wednesday, February 4, 2009

- I had a meeting with Dr. Hensel and Mayra on how to read the delivery records from the clinic sites - this was so that we can analyze the results from the OB study (we compare the questionnaires with the patient records so that we can draw conclusions about the OB study)
- I was sorting through and organizing the delivery records
- I went to the Patient Care Clinic (PCC) with Mayra to recruit subjects for the study in the afternoon
- I had ITS issues all day so I was not able to access my e-mail or the UNTHSC portal from school or at home

Thursday, February 5, 2009

- I continued to work on organizing the delivery records.
- I continued to have ITS problems this morning.
- Mayra and I went to Harris in the morning until about 1:00pm - recruiting and a clinical study
- I watched Dr. Hensel perform an OMM treatment on the clinical study subject
- We had an appointment with a subject that was part of the sub-study
  - I had a little more hands-on experience → I set up the computers, enter necessary data in them

Friday, February 6, 2009

- I was not at the ORC site

Week 2: 2/9/09 - 2/13/09

Monday, February 9, 2009

- I renewed the SPSS license on my computer so that I would be able to have access and create data bases that pertain the OB study
- I filled in my calendar
- I was organizing the delivery records (numbering them, putting them in order) so that they would be ready for us when we start extracting data from them
- I typed up the computer/equipment protocol sheet so that I could have step-by-step details of how to use the computers/equipment and how to run the clinical and sub- studies.
- I attended the ORC research meeting; many topics were discussed:
  - New and upcoming research
  - Progress of current research (Mayra, Debbie, and Dorothy discussed the OB, low back pain, and carpal tunnel studies, other people discussed theirs too)
  - IRB approval
  - Possible phlebotomy training for all

Tuesday, February 10, 2009

- I went to the PCC in the morning and again in the afternoon with Mayra; observed how to recruit subjects for the study
- I continued working on the protocol/equipment sheet → very tedious
- I did some practice runs with the GaitRite machine to get an idea of how the process works and to make sure that my protocol sheet was correct

Wednesday, February 11, 2009

- I continued working on the protocol/equipment sheet.
  - I used the GaitRite again to get more comfortable using it
  - I used the Finopress machine so that I could get an idea of how to configure it and to make sure my protocol sheet was correct
  - I used the Plethysmograph machine also so that I could get an idea of how to calibrate it and to make sure my protocol sheet was correct
  - I was not able to use the Finometer laptop because it was not available
- Mayra allowed me to screen for potential subjects (patients at the PCC) in her office using the EMR program, NextGen
- I had a meeting with Mayra concerning the OB study IRB
  - She discussed documents needed to complete the continuing review
  - She also explained the different types of forms that need to be filled out and why they are necessary
- I attended an electronic medical records (EMR) training session so that I could get access to NextGen and learn how to use it
- I worked on creating my own personal screening chart for the PCC
  - I was trying to figure out how I was going to organize it
  - I tried to make it into an excel spreadsheet

Thursday, February 12, 2009

- Today was an extremely busy day
- Mayra and I went to the PCC and Harris in the morning and we went back to Harris in

afternoon

- While we were at Harris in the morning, I was able to practice recruiting
  - I explained the purpose of the study and what it entails to a potential subject
- We spoke to a potential subject, but she declined to participate in the study, when she discovered that she may or may not receive treatment (i.e. receive standard care instead of OMT or ultrasound) → Harris
- At Harris, one subject was suppose to come in for treatment (OMT), but left her appointment because the midwife was taking to long to see her; therefore, she was not able to come in for treatment (which would violate the OB study protocol)

Friday, February 13, 2009

- There was no clinic today.
- I worked on completing the delivery records template form all day.
- We need the template so that we can transfer the information that we want from the patient's delivery records onto the form and eventually into our database on SPSS.
- In the afternoon, I assisted Dorothy with her low back pain study.
- I picked up a drying rack from the EAD so that we could use them to dry the buccal swabs
- I observed Dorothy perform a few buccal swabs
- I performed a buccal swab on one of the low back pain subjects
  - She gave me constructive criticism on how to improve my technique
- I cleaned the rooms after use
  - I used alcohol wipes to wipe down the beds, equipment and changed the pillow cases
  - I explained the new consent form (including the buccal swab addition) to an existing

study subject

- I also helped Dorothy with collecting the consent forms after they have been filled out

Week 3: 2/16/09 - 2/20/09

Monday, February 16, 2009

- Today I screened patients at the PCC to see if we could recruit anyone for the study
  - We didn't go to the PCC today because no one qualified for the study (NO CLINIC)
- I helped Mayra prepare for the arrival of a subject that was to receive treatment
  - She was an ultrasound subject and Dr. Hensel performed the treatment
  - Myra explained to me what documents were necessary for this visit
- Mayra explained to me how to prepare a new chart
- Mayra showed me how to access the money to pay subjects, as well as the protocol to adhere to when paying subjects
- I made minor changes to the delivery records protocol sheet that I created
- Mayra and I met with Dr. Hensel about the delivery records sheet that I created
  - We discussed any changes that needed to be made
  - We also asked her some questions that we had concerning the patient's actual delivery records and how to incorporate that into the protocol sheet

Tuesday, February 17, 2009

- I accompanied Mayra to Harris
  - We were able to recruit one subject
  - I explained the study to a potential subject so that I can get used to doing it on my own
- I worked on adjusting the delivery records template
- We went to the PCC to try to recruit the 2 subjects that I had screened for yesterday

Wednesday, February 18, 2009

- There was a new OB patient that we tried to recruit at the PCC; she didn't seem too interested in the study
- I spent most of the morning organizing my ORC binder and inputting data in the computer
  - I am recording the patients that I've seen in the computer along with some of their personal info for statistics reasons
- I screened for patients at the PCC
- I practiced my recruitment speech with Mayra and Dorothy
- I spent most of the afternoon getting my ORC binder together.
- We went to the PCC to try to recruit another new OB patient

Thursday, February 19, 2009

- We met with a potential subject this morning at the PCC. She was very interested, and she would have been the first enrollment from the PCC in a while. However, we found out that she has gestational diabetes after we spoke to her. ☹
- I was at Harris all morning and most of the afternoon. We had some subjects (1 new, 2 old) come in to get treatment and we just were running late because of a problem that we encountered when we got to Harris. There was a non-OB patient in our treatment room so we were not able to start on time. Eventually, things got going. However, one of our subjects overslept for her morning appointment with us so we had to schedule her later this afternoon. She came to her appointment last week, but was never seen by a midwife because she said that they were taking too long. So she rescheduled for yesterday and came in to see us today.

- I screened for patients at the PCC
- I organized my ORC binder

Friday, February 20, 2009

- There was no clinic today – no one qualified for the study
- I was organizing my binder (creating tabs, etc) and creating my PCC subject list template in excel
- I screened for potential subjects at the PCC
- I entered my patient encounters in excel
- I worked on transferring data from delivery records onto the templates that I created

Week 4: 2/23/09 - 2/27/09

Monday, February 23, 2009

- This was my first day on my own as a “research coordinator”. I went to the PCC in the afternoon to try to recruit a subject. I was nervous, but I think that I will get better with time.
- I worked on my journal entry today
- I was suppose to see an OB patient today, however, I assumed that she was not going to show up to her appointment because when I checked her status on NextGen, she was more than 30 minutes late and still hadn't checked in with the front desk, and would thus be labeled as a no show. I checked her status some minutes later and saw that she had been checked out. I am thinking that maybe the front desk didn't update her status when she arrived to her appointment, or maybe she arrived really late and maybe the front desk allowed her to still be seen by a physician.
- I spent time updating my PCC enrollment chart on excel
  - I created a new spreadsheet for extracting data from the PCC enrollment chart also (i.e. who is interested vs. who is not, who qualifies vs. who doesn't, etc)
- I filled in numbers for the PCC clinic on Mayra's enrollment chart for the bi-monthly meeting that we had
  - The chart basically keeps track of the progress that we have made, I.e. subjects we have enrolled or not and enrolled and the reasons why
- I attended the meeting, it was mainly based on IRB protocol and what we should and should not do when it comes to human research
  - Dr. Gladue was the guest speaker → he was the one that was explaining the IRB information to us

Tuesday, February 24, 2009

- I screened for potential subjects at the PCC.
- I was supposed to try to recruit a new OB patient in the morning, but she was a no show to her appointment.
- I filled out delivery records
- I went to go recruit at the PCC in the afternoon. The patient that I spoke to seemed interested in the study.
- I went to the CBH building to go get some conflict of interest forms filled to be turned in with the continuing review packet for the OB study

Wednesday, February 25, 2009

- I did not go to the PCC today because everyone that I screened did not qualify for the study
- We had a new subject come in for her first visit. She started filling out paperwork around 8:15am (when she got here). I performed the sub-study. I had difficulty starting, but eventually got the hang of it. We had problems with the equipment so the study took much longer than necessary. We were having problems with the leads (the ECG machine was not reading the leads), BP and pulse cuffs registering on the computer, etc. I basically ran the study by myself, which is good practice for me. I was happy with that. Mayra was guiding me through it all also. She is a standard care subject.
- I spent time untangling the wires in the sub-study room, because when they were tangled, they were decreasing the efficiency of the sub-study
- I had GroupWise difficulties; I took my laptop to ITS. They had to uninstall then re-install GroupWise
- I filled out delivery records
- I screened for potential subjects at the PCC

Thursday, February 26, 2009

- I did not go to the PCC because all of the patients that I screened did not qualify for the study

- I completed filling out all of the delivery records today.
- Mayra showed me how to input the data for the OB study in SPSS
  - I was able to do a couple of entries

Friday, February 27, 2009

- There was no clinic today – no one qualified for the study
- I did data entry for most of the afternoon. I was inputting data into SPSS for the OB study
- I helped Mrs. Lindsey with the low back study.
  - I collected buccal swabs from subjects and I paid them. I think that I have gotten better at performing buccal swabs thanks to Mrs. Lindsey's direction
  - I cleaned the rooms after the subjects left
- I screened for potential subjects at the PCC

Week 5: 3/2/09 - 3/6/09

Monday, March 2, 2009

- I went to the PCC to recruit subjects all morning.
- Mayra and Dorothy helped me practice my OB sub-study skills.
  - Dorothy was the patient and Mayra observed.
  - Both of them gave me constructive criticism.
- I made changes to the OB protocol sheet that I created
- I worked on the delivery records.
  - I addressed the comments/changes that Dr. Hensel made on the delivery records
  - I met with Dr. Hensel in the afternoon to discuss them. She liked my work.

Tuesday, March 3, 2009

- I screened for potential subjects at the PCC.
- I worked on the OB protocol
- I entered delivery records into the SPSS database.
- I went to go recruit at the PCC in the afternoon.

Wednesday, March 4, 2009

- I went to the PCC to recruit for subjects in the morning and afternoon.
  - In the morning, one turned out to be high risk, the other seemed interested. I will most likely follow up with her at her next visit.
  - The afternoon subject did not show up to her appointment.
- I had an initial review with Debbie in the afternoon.

- She highlighted my good qualities and provided me with constructive criticism on some things that I needed to work on. I was very pleased with the meeting. I didn't expect to get so many compliments!



Thursday, March 5, 2009

- I did not go to the PCC because all of the patients that I screened did not qualify for the study.
- We had a 36wk sub-study scheduled for today, but she canceled.
- I worked on entering the delivery records information into the SPSS data base

Friday, March 6, 2009

- Today was Research Appreciation Day (RAD)
- I did data entry for the OB study all day
- I helped Dorothy through out the day, mainly with taking buccal swabs from subjects.
- I attended the keynote speaker luncheon.
  - Dr. Josephine Briggs was the speaker. She gave an excellent presentation on the National Center for Complimentary and Alternative Medicine (NCCAM) and its projects/progress
- I had one OB subject come in for her 2 weeks post-partum visit; the other subject was suppose to come in for her visit 3 appointment, but never showed up.

Week 6: 3/9/09 - 3/13/09

Monday, March 9, 2009

- I was out sick. ☹

Tuesday, March 10, 2009

- I spent most of the day at the PCC trying to recruit subjects.
- I met a subject at the PCC and had her fill out her visit 2 questionnaires. She is standard care and therefore does not receive any treatment
- Dorothy watched me perform a buccal swab on a patient in the afternoon and provided me with constructive criticism. I'm getting better! ☺

Wednesday, March 11, 2009

- I worked on my journal and entered data into the OB study database for most of the morning.
- I had a meeting with Mayra about the SPSS entries that have been made thus far for the OB study. We discussed what we needed to do to be more efficient and what corrections needed to be made.
- I spent most of the afternoon updating my excel spreadsheet on the encounters that I have had at the PCC. I've met about 50+ pregnant women and more than half do not qualify for the study☹, but I still many that I need to hear back from, so there is hope! ☺.
- In the afternoon I went to the PCC and spoke with a patient that I have already talked to about the study. I wanted to follow-up to see if she had made a decision yet. She still hasn't made a decision, but she seems interested. I'll keep my fingers crossed! The doctors pushed her due date back so she has more time to make a decision.

Thursday, March 12, 2009

- I spent the morning at the PCC trying to recruit subjects for the study. I met two potential subjects – one was interested, and the other was not interested
- I spent the afternoon working on the OB study database.

Friday, March 13, 2009

- I did not go to the PCC today because none of the patients that I screened qualified for the study.
- I did data entry for the OB study all day
- I spent the afternoon creating labels for the OB study folders and entering data into the SPSS OB study database.
- I helped Mayra with a sub-study subject that came in for her 36wks visit (visit 4).

Week 7: 3/16/09 - 3/20/09

Monday, March 16, 2009

- There was no clinic today because of Spring Break
- I spent a few hours in the morning on my paper
- The rest of the day was spent working on the slew of corrections that needed to be made in the OB database.
- We sent the database to Dr. Bae and he compared them to see if there were any discrepancies between the two.

Tuesday, March 17, 2009

- There was no clinic today because of Spring Break
- Mayra and I were suppose to go to Harris today so that we could get some delivery records, but ended up canceling the trip. We ended up not going to Harris because we realized the there were way too many corrections that needed to be made in the OB database...we have a deadline to meet.
- I spent all day making corrections on the OB study database

Wednesday, March 18, 2009

- There was no clinic today because of Spring Break
- I spent all day making corrections on the OB study database

Thursday, March 19, 2009

- I did not go to PCC because all of the patients that I screened did not qualify to participate in the study
- I spent most of the day working on the OB study database
- I worked on my journal for a couple of hours

Friday, March 20, 2009

- I was not at the ORC.

Week 8: 3/23/09 - 3/27/09

Monday, March 23, 2009

- About half of my day was spent working OB study database, and the other half of the day was spent recruiting subjects at the PCC.

Tuesday, March 24, 2009

- I spent the first half of my morning organizing my ORC binder, the latter half of the morning was spent updating my PCC screening list on excel
- I worked on my paper in the afternoon
- I also went to the PCC to recruit subjects
- When I got back to the PCC, I screened patients to see who I would approach the following day

Wednesday, March 25, 2009

- I spent most of the day making corrections to the OB study database
- I went to the PCC for a couple of hours to recruit

Thursday, March 26, 2009

- Half of my day was spent working on the OB database and the other half was spent recruiting at the PCC

Friday, March 27, 2009

- I went to the PCC for a few hours in the morning to recruit
- The rest of my day was spent organizing the OB study files in the records room
- I gave each file a folder and inserted delivery records to their corresponding file.

Week 9: 3/30/09 – 4/3/09

Monday, March 30, 2009

- I had intentions to give one of my OB patients from the PCC her visit 3 questionnaires but she ended up rescheduling her appointment.
- I spent most of the morning at the PCC trying to recruit subjects for the OB study.
- I screened subjects for tomorrow's encounters and worked on my journal in the morning.
- I spent the afternoon recruiting at the PCC.

Tuesday, March 31, 2009

- I spent all day organizing the IRB folders for the OB study.
- As of April 1, 2009, the IRB approval for the OB study will expire; therefore there can be no further activity (i.e. recruiting) until after we get approval.
- At the end of the day I had to figure out what patients at the PCC would be affected by the recruiting freeze. I typed them up and sent them to Mayra so she could relay the information to the IRB.

Wednesday, April 1, 2009 (April Fool's Day)

- There was no recruiting today.
- I spent the morning helping Dorothy with the LBP study. I made reminder phone calls to her subjects. I also helped one of her Spanish speaking subjects fill out questionnaires.
- I spent all afternoon creating line graphs reflecting the visit rates of the OB study. This information will be presented at the Data Safety Monitoring Board (DSMB) meeting, which will be held April 8, 2009.
- I fooled Debbie and Mayra this morning, but I got fooled by the whole bunch (Debbie, Dorothy, Mayra)

later on that day. ☺

Thursday, April 2, 2009

- I worked on my proposal all day today.

Friday, April 3, 2009

- I worked on my proposal all day.
- I was expecting one of Mayra's subjects to come in to the ORC for a treatment, but she ended up canceling. I was waiting to give her the questionnaires that she needed to fill out since Mayra was still at Harris.
- There was another one of Mayra's subjects that I was to wait for, but Mayra ended up coming back from Harris in time for the patient so I didn't need to wait anymore.

Week 10: 4/6/09 – 4/10/09

Monday, April 6, 2009

- I had a 36 week (visit 4) sub-study patient come in. I completed the sub-study without the assistance of anyone. Yay! ☺
- I am extremely frustrated today because I am still not able to recruit anyone today. A patient that I spoke to 2 weeks ago came in to participate in the study. She was 28 weeks when I spoke to her and came in to enroll. As luck would have it, this is the only patient that has tracked me down at the ORC to participate in the pregnancy study. Unfortunately, we had to tell her that she could not be enrolled because our IRB approval was expired. All of this would have been avoided if the communication between us and the IRB was better. All of our papers were turned in on time but technicalities led us to this predicament. All-in-all, I will miss two potential OB subjects (including this one), because of the recruiting freeze.
- I did a lot of catching up with paper work.

Tuesday, April 7, 2009

- I spent most of the day organizing IRB folders for the carpal tunnel study.
- I attended Su Lee's internship practicum defense on: EVALUATION OF THE TEMPORAL ARTERY THERMOMETRY TO ASSESS ACCURACY WHEN COMPARED WITH BODY CORE TEMPERATURE IN THE OPERATIVE ENVIRONMENT

Wednesday, April 8, 2009

- I attended the Data Safety and Monitoring Board (DSMB) meeting this morning. It lasted for about 4 hours. It was very interesting. It was a very formal meeting. Various topics were discussed including: serious

adverse events (SAEs), how to deal with missed visit data (i.e. carry forward method), board recommendations, etc. I have to start collecting height and weight information for all of my subjects – recommendation from DSMB

- The rest of the day, I entered data into the OB study database.
- We received our IRB approval at the end of the day, so I went to the IRB office to pick the newly approved documents! I can start recruiting again. Yay! ☺

Thursday, April 9, 2009

- I was suppose to escort Mayra to Harris today so that we could start collecting delivery records from subjects that have already delivered; however, because we received IRB approval late yesterday afternoon, I went to the PCC to recruit instead.
- In the afternoon, I worked with the low back pain subjects. I gave them their questionnaires, escorted them to a room for treatment, and paid them at the end of their visit.

Friday, April 10, 2009

- I did not go to the PCC today because there weren't any subjects to be seen. There no doctors at the PCC today.
- I worked on data entry all day. I was inputting new subjects' and catching up on old subjects' data.
- I also worked on my journal.

Week 11: 4/13/09 – 4/17/09

Monday, April 13, 2009

- There was an ORC meeting scheduled for 9:00am, but it was canceled because a few were not going to be able to attend the meeting.
- I the whole day working on the OB data base.

Tuesday, April 14, 2009

- I went to the PCC in the morning to recruit subjects.
- I enrolled a subject into both the clinical and sub studies; however I did not realize that she was 29 weeks and 2 days until the sub study was well under way. I was very disappointed with how I missed her gestational age. The earliest that we will enroll a subject is 29 weeks and 4 or 5 days. I reported it to Dr. Hensel and Mayra; we thought that it might be a protocol violation. However, Mayra spoke to the IRB office and it turns out that it was ok. Lesson of the day: Be more observant the gestational age of new subjects.
- I had another subject come in for her visit 5 appointment.
- In the afternoon, I conducted a sub-study for one of Mayra's patients. Mayra had to stay at the Harris clinic to recruit.
- I also made address labels for some of Dorothy's low back patients, so that she could mail letters asking them to return to have a buccal swab performed on them. I didn't realize that she wanted me to handwrite the addresses on the labels.

Wednesday, April 15, 2009

- I spent most of the day handwriting addresses on envelopes for Dorothy.

- I organized the OB study charts.
- I was supposed to talk to a patient about the OB study in the afternoon, but she did not show up to her appointment with Dr. Robles.

Thursday, April 16, 2009

- There were 3 patients in the morning that I wanted to talk to about the OB study. Of the 3: one was not interested, one I had previously encountered and she turned out to be high risk, and the last one seemed very interested, but she still had time before she turned 30 weeks.
- I spent the rest of the day filling out the new delivery records that Mayra gave me and entering them into the OB study database.
- I called a subject that was interested in the OB study today to remind her that tomorrow would be the first day of her participation in the study. I was able to get a hold of her, but I left a message on her voice mail.

Friday, April 17, 2009

- I spent the morning trying to gather height and weight information from previous subjects that had already completed the study. It was difficult because many of them were not on NextGen or if they were, their information from the pregnancy was not available. This is because these patients were enrolled about 2 years ago and the PCC has switched from paper charts to electronic charts. Some of the patient information has not been uploaded onto NextGen or has already been archived and can no longer be accessed at the PCC.
- I enrolled a new subject for the OB study. She only wanted to participate in the clinical study. She actually came in early to her appointment (about 2 hours early) so I missed 2 women that I wanted to approach about the OB study.

Week 12: 4/20/09 – 4/24/09

Monday, April 20, 2009

- I spent the whole morning recruiting at the PCC.
- I spent the rest of the day updating my PCC screening list.
- I also e-mailed Dr. Hensel with a list of my encounters (approached, missed, high risk, etc) at the PCC of the past 2 weeks.

Tuesday, April 21, 2009

- I spent the morning looking through old patients' archived files on NextGen to get their heights and weights from all of the OB visits that they had when they were enrolled in the study. This was a long and tedious task. I reformatted the height and weight template that we will use to collect the subjects' height and weight.
- I had an OB standard care subject to see in the afternoon.
- I spent the afternoon recruiting at the PCC
- Afterwards, I attended Dr. Hensel's dissertation! It was great, she did an excellent job presenting and answering the questions that the audience asked.

Wednesday, April 22, 2009

- I did not go to the PCC today because there weren't any doctors available today.
- I spent the day assisting Dorothy with the low back pain study. I took about half of her patients. I gave them their questionnaires, took them to a room to be treated, and paid them at the completion of the study.
- I also entered chart information into the OB study database.

- Mayra and I figured out a way to communicate with each other on GroupWise in terms of keeping each other accountable for tasks that need to complete.

Thursday, April 23, 2009

- I did not go to the PCC today because there weren't any doctors available.
- I entered information into the OB study data base on SPSS.
- I worked on my journal for most of the afternoon.
- I created hanging folders for the OB study charts.

Friday, April 24, 2009

- I came in late to the ORC due to car troubles.
- I screened for patients to go talk to on Monday (4/27/09) about the OB study.
- I worked on delivery records for the majority of the afternoon. I was copying information from the faxed delivery records that Mayra gave me on to the delivery template that I made.
- I continued gathering height and weight information for patients that had already completed the OB study. I was getting this information from the scanned documents on NextGen.

Week 13: 4/27/09 – 5/1/09

Monday, April 27, 2009

- I called Dorothy's low back study patients to remind them of their appointments for the next day (4/28/09).
- I spent the afternoon at the PCC trying to recruit patients. OF the patients that I met, one was interested in the participating in both the clinical and sub studies and would be ready to be enrolled at her next doctor's appointment. Another patient was already 30 weeks and I told her to let me know as soon as possible if she wanted to be in the study so she could start the study at the latest tomorrow.
- I had one OB standard care appointment today, too.

Tuesday, April 28, 2009

- I did not go to the PCC today because there weren't any doctors available at the clinic today.
- The subject that I met yesterday that was 30 weeks in gestation did not contact me so I have to assume that she does not want to participate in the study.
- I completed filling out one subject's delivery record form.
- I went to Harris with Mayra to help her recruit subjects for the OB study; I spent most of the day there
- I organized the IRB charts for the low back pain study.
- I screened NextGen for patients that I would approach tomorrow at the PCC.
- I updated my excel spreadsheet with the old and new encounters that I have had with patients at the PCC.
- I entered information into the OB study database.

Wednesday, April 29, 2009

- I spent the morning at the PCC trying to recruit patients for the OB study.
- I was supposed to meet with an OB that was to receive ultrasound treatment today, but she rescheduled her appointment with us for tomorrow (4/30/09) because she was in a lot of pain. She claims that she did not know what she did to her back, but it started hurting a few days prior to this appointment.
- I did more data entry – entering information into the OB study database.
- I created a folder to hold extra height and weight sheets. The height and weight sheets were created in order to calculate BMIs for the patients that enroll in the study. This decision was made at the DSMB meeting which was held on 4/8/09.
- I continued gathering the height and weight information for subjects that have completed or are currently enrolled in the OB study.
- I also continued with the organization of the low back pain IRB charts.

Thursday, April 30, 2009

- I did not go to the PCC today because there were only two OB patients (to be seen by Dr. Robles) and both were over the gestational requirement necessary to participate in the study.
- I gathered information (CV, personal statement, resume, etc) that Dr. Hensel wanted from me so that she could submit her grant. She approached me last week to talk about possibly working for her as a research coordinator after I complete my master's program! ☺
- I called the OB that needed to reschedule her appoint to today to see what time she could come in for her treatment. She came in around mid-morning and was treated.
- I entered data into the OB database and worked on retrieving height and weight information for past and present OB study subjects.

Friday, May 1, 2009

- I did not go to the clinic today because there weren't any doctors available at the clinic.
- I spent all day helping Dorothy with the low back pain study. I took half of her subjects. I gave them their questionnaires, took them to a room for treatment and paid them upon completion of the study visit.

Week 14: 5/4/09 – 5/8/09

Monday, May 4, 2009

- I met with an OB standard care patient to give her the questionnaires for her visit.
- I spent the morning recruiting patients at the PCC. I missed 1, another was a no show for her doctor's appointment, and the rest (4) seemed interested to participate in the study.
- The second part of my day was spent entering information in the OB study database.
- I also provided Dr. Hensel with an update of my enrollment numbers from the PCC.

Tuesday, May 5, 2009

- I spent most of the morning updating my excel spreadsheet with the encounters from the PCC. I also decided to include dates on which I did not recruit at the PCC and the reasons for not recruiting (i.e. recruiting freeze, no physician available, etc.)
- I screened for patients to approach at the PCC on Wednesday.
- My afternoon was spent recruiting patients at the PCC.

Wednesday, May 6, 2009

- There weren't any doctors available at the clinic today so I did not recruit anyone.
- I had a meeting with Debbie and Mayra this morning. It pertained to the future of the OB study.
- I worked on collecting height and weight information on all the OB subjects from the PCC currently and previously enrolled in the study. It was easy for me because all of their information is has been transferred from paper charts to EMR. I was able to finish collecting all of the information today. However, there are a few charts that I need to go back and edit.
- I entered information into the OB study database, and started on the task that Mayra had assigned to me.

Thursday, May 7, 2009

- There weren't any doctors available at the clinic today so I did not recruit anyone.
- I was anticipating on meeting with an OB patient this morning to see if she would be interested in participating in the study. She turned 30 weeks today; however, her appointment was rescheduled.
- I met with one OB patient, spoke to her about the study, and provided her with a brochure.
- I spent time organizing my ORC binder.

Friday, May 8, 2009

- There weren't any doctors available at the clinic today so I did not recruit anyone.
- I prepared the PCC enrollment numbers for the week and sent them to Mayra, Dr. Hensel, and Debbie. We have to start preparing them every Friday so that they can be ready by Monday morning.
- I worked on my ORC journal entries.

Week 15: 5/11/09 – 5/15/09

Monday, May 11, 2009

- There was suppose to be an ORC staff meeting this morning but it was cancelled.
- I spent the morning updating my excel spreadsheet with my PCC encounters.
- I spent all afternoon trying to recruit patients at the PCC. One of the patients that I needed to see canceled her appointment. I was able to speak with everyone else.

Tuesday, May 12, 2009

- I was out sick today – pink eye.
- Mayra was able to conduct my 2 OB treatment visits today. She saw one OB that is already enrolled in the study, and a new OB that I had confirmed her interested in the study weeks ago. Yay! ☺ - a new OB subject

Wednesday, May 13, 2009

- There weren't any OB patients to see at the clinic so I stayed at the ORC today.
- I entered information into the OB study database.
- I began entering all the OB patients that have ever been encountered in to an OB recruitment database on SPSS. Mayra had already started on this task, but she passed it on to me. – very tedious.

Thursday, May 14, 2009

- I spent the afternoon recruiting patients at the PCC.
- I met with an OB standard care subject so that she could fill out the questionnaires for her visit. There was a

little confusion as to whether or not she would show up today – ultimately the staff at the PCC had made a mistake on the schedule.

- I called her today and left a message on her answering machine letting her know that the PCC did not have any appointments scheduled for her. They last time that they saw her was May 4th (which was the last time that I saw her).
- I called her yesterday (5/13/09) and spoke with her. I told her to call the clinic and ask about her appointment and call me back but she never did.

Friday, May 15, 2009

- All of the patients were rescheduled because Dr. Robles was attending a conference.
- I worked on my journal entries.
- I updated my excel spreadsheet with PCC encounters.
- I worked on the enrollment numbers for the PCC and sent them to Mayra, Dr. Hensel, and Debbie.
- I also updated the OB study recruitment database.

Week 16: 5/18/09 – 5/22/09

Monday, May 18, 2009

- I spent the morning updating my excel spreadsheet with my PCC encounters and updating enrollment numbers.
- I spent all afternoon trying to recruit patients at the PCC.

Tuesday, May 19, 2009

- I went to the PCC to recruit subjects. I missed 2 patients, but was able to speak with everyone else. One of the women seemed interested and the other one enrolled in the clinical and sub studies! Yay! ☺ She will come in tomorrow because there wasn't any room on the schedule for her to come in today to participate in the sub study.
- I conducted two sub studies, which took up the rest of the day.
- I entered information into the OB database

Wednesday, May 20, 2009

- There weren't any doctors available at the PCC so I did not recruit today.
- I entered information into the OB study database.
- My new subject came in today to participate in the clinical and sub studies. Everything went well.

Thursday, May 21, 2009

- There weren't any doctors available at the PCC so I did not recruit today.
- I entered information into the OB study database.

- I conducted a new sub study for one of Mayra's subjects.

Friday, May 15, 2009

- I worked for half a day today.
- I spent the morning recruiting subjects at the PCC.

Week 17: 5/25/09 – 5/29/09

Monday, May 25, 2009

- HOLIDAY!!!

Tuesday, May 26, 2009

- I did not go to the PCC today because there was only one patient for the entire day. She was seen by Dr. Buchanan and was not an OB patient.
- I entered information into the OB study database.
- I worked on my patient encounters and enrollment numbers.
- I created a document for how to put together an OB folder.
- I conducted a 36 week sub-study today. She was one of Mayra's patients.

Wednesday, May 27, 2009

- I spent the morning trying to recruit subjects for the OB study. Two patients did not show up to their appointment, 1 was Spanish speaking only (SSO), and I was able to speak to 2 and gave them a brochure.
- I saw an OB standard care subject today.
- I entered information into the OB database.

Thursday, May 28, 2009

- I went to the PCC for about 30 minutes this morning to try to recruit a subject.
- We (Mayra, Dorothy, Cathy, and I) had a meeting with Debbie for about an hour. Debbie gave us an update on all of the studies that are currently going on at the ORC. She also talked about the future of the ORC and

the direction that it is headed.

- I went back to the PCC to try to recruit another subject, and conducted a sub study.

Friday, May 29, 2009

- There weren't any doctors available, but a nurse practitioner was available so I was still able to recruit.
- There was a new sub study today – one of Mayra's subjects. Everything that could go wrong went wrong. The Finometer stopped taking measurement during the sub-study and the bed fell apart. Dr. Minotti was able to tighten a screw and made sure the bed was in proper working condition.
- I had OB standard care patient come in today.

Week 18: 6/1/09 – 6/6/09

Monday, June 1, 2009

- I did not go to the PCC today because there weren't any doctors available.
- I called Dorothy's subjects to remind them of their upcoming appointments since she was out today.
- I worked on the PCC enrollment numbers.

Tuesday, June 2, 2009

- I tried to recruit subjects in the morning; however, 2 were SSO, 1 rescheduled, and the last one did not show up for her appointment.
- I entered information into the OB study database.
- One of my subjects came in for her clinical study visit.
- I went back to the PCC in the afternoon to recruit subjects. One woman that I encountered was not interested in participating. ☹

Wednesday, June 3, 2009

- I made labels for the clinical trial file cabinets. The charts were moved to different locations and thus file cabinets needed new labels.
- Dr. Hensel returned some delivery records that I asked her to look over, and I entered the delivery record information into the OB database.
- I organized my ORC binder and updated my excel spreadsheet.

Thursday, June 4, 2009

- We received some more delivery records so I copied the relevant information onto the delivery record template.
- I went to the PCC to recruit, but neither of the subjects that I went to go see showed up to their appointment.
- I printed delivery records dividers so that I could insert them into the OB folders.

Friday, June 5, 2009

- I went to the PCC to recruit this morning. I met with a patient that wanted to participate in the clinical and sub studies so I gave her consent forms to look over and sign. She would be eligible to start at her next appointment. Another subject that I was hoping to enroll rescheduled, but I was hoping that she'd reschedule her appointment for Monday so that she would meet gestational age requirement for the study.
- I entered information into the OB database.
- I conducted 2 sub studies and one of my standard care subjects came in to fill out questionnaires.
- There were a few patients that I wanted to meet with in the afternoon. Two of them were new OB (NOB) patients and out of those 2, one was SSO. The other did not seem too interested in the study. The last patient rescheduled and she fell in the 30 week range for starting the OB study.

Week 19: 6/8/09 – 6/12/09

Monday, June 8, 2009

- I went to the PCC to recruit subjects.
- I conducted a sub study for one of Mayra's subjects.
- I entered information into the OB database.
- I attended the ORC full staff meeting in the afternoon.

Tuesday, June 9, 2009

- I did not go to the clinic today because none of the patients that I screened qualified to participate in the study.
- I worked on creating/organizing the IRB binder for the low back pain study.
- One of my standard care subjects came in for her final visit of the OB study.
- I worked on my journal entries.

Wednesday, June 10, 2009

- There weren't any doctors available today so I did not recruit.
- I completed putting together the low back pain binder today.
- We received more delivery records so I transferred information onto the delivery record templates.

Thursday, June 11, 2009

- I went to the PCC to recruit subjects in the morning and the afternoon.
- One of my subjects came in for the clinical study.

- I worked on the enrollment numbers for the PCC.
- Two of my standard care subjects came in to fill out questionnaires.

Friday, June 12, 2009

- There weren't any doctors available at the clinic so I did not recruit.
- I went out of town.

Week 20: 6/15/09 – 6/19/09

Monday, June 15, 2009

- There weren't any doctors available today so I did not recruit.
- I worked on putting together/organizing the pregnancy study and the carpal tunnel study (CTS) IRB binders. I was able to complete the CTS IRB binder today.
- I entered delivery records information into the OB database and places the templates in their corresponding folders.
- There was an OB sub study; however we were not able to get a hold of Dr. Hensel so we had to let the subject go home without being treated.

Tuesday, June 16, 2009

- I did not go to the clinical today because there were not any physicians available.
- I spent all day putting together the OB IRB binder.

Wednesday, June 17, 2009

- There weren't any doctors available today so I did not recruit.
- I screened for patients to approach tomorrow.
- I entered information into the OB study database.
- I re-attached a metal clip that was broken on one of the sub study machines.
- I made some changes to the sub-study instructions that were written on the white board in the sub study room.

Thursday, June 18, 2009

- I did not go to the clinic today because none of the patients qualified to participate in the study. Some of them I had approached previously, and mentioned that they were not interested in participating in the study.
- I called one of my subjects to confirm that she was coming tomorrow to meet with the nurse practitioner. Her next appointment was scheduled for Monday. I asked her to schedule this appointment (and also keep her Monday appointment) so that she would not miss her study visit with us.
- I updated my excel spreadsheet with patient encounters and screened for subjects to approach tomorrow.

Friday, June 19, 2009

- I went to the PCC to recruit subjects.
- Two of my subjects and one of Mayra's subjects came in for their OB treatment.

Week 21: 6/22/09 – 6/26/09

Monday, June 22, 2009

- I screened for subjects to approach today at the clinic and then went to go recruit.
- One of my subjects came in for an OB treatment

Tuesday, June 23, 2009

- I did not go to the clinic today because there were not any physicians available.
- I spent all day putting together the OB IRB binder.
- There were 2 patients that I wanted to approach this afternoon – 1 rescheduled and the other was a no show.
- The standard care patient that was supposed to come in today to fill out questionnaires did not show up.

Wednesday, June 24, 2009

- I approached one patient at the PCC; she was 30 weeks; however she was not interested in participating in the study. Another patient did not show up for her clinic appointment.
- I missed 2 patients that I was going to approach today because I was conducting the sub study for one of Mayra's patients.
- I entered information into the OB study database.
- Height and weight columns were added to the database so I spent most of the day entering that information for all of the charts.

Thursday, June 25, 2009

- I conducted a sub study for Mayra. A DO fellow shadowed me during the sub study.

- There were 2 patients that I wanted to approach today, but was not able to because of the sub-study.
- One of Mayra's subjects came in for her 2 weeks post partum visit.

Friday, June 26, 2009

- One of my standard care subjects came in for her sub-study visit.
- I updated my excel spreadsheet (patient encounters).

Week 22: 6/29/09 – 6/30/09

Monday, June 29, 2009

- I did not go to the PCC today because there weren't any physicians available.
- I called 2 new subjects to reschedule their first appointment with us.
- I worked on the enrollment numbers for the PCC
- I made new charts for the OB study.
- I went to lunch with Mayra, Debbie, Dorothy, and Chai (the new intern at the ORC).

Tuesday, June 30, 2009

- I did not go to the clinic today because there were not any physicians available.
- One of Mayra's subjects came in for her sub study visit. I ran the study.
- I enrolled a new subject and her first visit was today. She decided to participate in the clinical study only.
- I met with Dr. Licciardone to discuss how to analyze the data for my practicum report.
- Today was my last day at the ORC. It was an exciting, yet sad day. I LOVED working there!

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