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Purpose: Demonstrate patient education as a viable option for improving patient adherence.

Hypothesis: Patients information about their treatments. This knowledge about specific study treatments allows the patient to be more familiar with administering treatment, thus leading to greater treatment adherence.

Design: A presentation over the absorption and distribution of a sublingual medication and the importance of taking this medication properly for the subject to view. After viewing the presentation, the subject completed a short subjective survey. A survey regarding the subject's adherence was completed by the study coordinator.

Results: The subject and the study coordinator provided positive feedback and despite the lack of participants, this protocol was shown as a feasible method of patient education.

THE ROLE OF PATIENT EDUCATION IN THE PATIENT'S FAMILARITYAND UNDERSTANDING OF TREATMENT

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the

Graduate School of Biological Sciences

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In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

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CHAPTER I

INTRODUCTION TO THE INTERNSHIP PRACTICUM

My internship site was Baylor Research Institute at All Saints Medical Center in Fort Worth, where I worked as a clinical research coordinator. This research site is relatively new, as it has only been present at Baylor All Saints for a year and a half. The clinical research studies that this department coordinates include studies in the areas of women's health, cardiovascular health, pulmonary disease, and oncology. Studies involving both drugs and devices are coordinated by this site.

During my experience at All Saints, I had the opportunity to participate in all stages of a clinical research study. This included participating in site evaluations, IRB submissions, site initiation visits, patient visits, monitoring visits, reporting adverse events and site closeout visits. At the start of the internship, my role was mainly to help with regulatory documents and IRB submissions, but my clinical responsibilities progressed as my internship did.

Many of the studies conducted at this site involved the use of an experimental drug. It became apparent that subject adherence to the study plan is of utmost importance. If the subject is non-compliant with the treatment plan, the data can be skewed and the subject may not be receiving the most efficacious dose of their study drug. This study is designed to demonstrate whether patient education is a viable option for improving

patient adherence. It tested the hypothesis that patients want to learn more about their treatments and when educated about their specific study treatment plan, the patient will be more familiar with administering it, thus leading to greater patient adherence to the prescribed administration of the drug.

This project was designed to work in conjunction with an industry-sponsored sublingual breakthrough cancer pain study involving Drug X. A PowerPoint presentation was created that explained the absorption and distribution of a sublingual medication and the importance of taking this medication properly. After the subject veiwed the presentation, he or she completed a short survey on its content. The study coordinator for the study was approached after the next patient visit and asked to complete a survey on their perception of the patient's adherence to the study treatment since viewing the presentation.

CHAPTER II

INTERNSHIP SUBJECT

Background and Literature Review

Breakthrough Cancer Pain

Pain related to cancer fluctuates and patients often report periods of time during which the pain flares. Breakthrough pain is defined as when this flare is clinically significant and interrupts the background pain that is normally controlled by regular medication (Portenoy et al., 1999). The incidence of breakthrough pain in a prospective study was around 67% and is often a clinical challenge in patients with cancer (Portenoy & Hagen, 1990). Breakthrough pain events often fluctuate during the course of cancer treatment, often increasing towards the end of radiation therapy. This fact makes long acting pain medications inadequate to consistently relieve patient discomfort.

There is also a potential for adverse events when treating breakthrough pain. This has been the driving force behind the development of several drug strategies to help the patient cope with this event. A common strategy in opioid tolerant populations is the use of a short acting analgesic that the patient will use as needed to combat the effects of breakthrough pain (Portenoy et al., 1999). The guidelines for cancer pain management have focused on the use of pure μ-opioid agonists with short half lives and

time-action profiles. These drugs have rapid onset, early peak effect and duration of sufficient length to treat most breakthrough pain (American Pain Society, 1992; Jacox, et al., 1994).

Sublingual Medications

Drugs administered sublingually are absorbed via the buccal mucosa taken up by the blood circulation which provides direct systemic administration. (Stevens & Ghazi, 2000) This area of the mouth is relatively well vascularized, allowing drug to be rapidly absorbed. There are many factors that will either facilitate or impede sublingual absorption, including lipid solubility, the ionization and the molecular weight of the drug in question. Generally speaking, molecules of low molecular weight, low pH and higher lipid solubility will cross the buccal mucosa easier. Drug X has high solubility characteristics and is small in size making it easily absorbed via this method. (Stevens & Ghazi, 2000)

This method of administration completely bypasses the gastrointestinal system and liver. This ensures that the medication will completely bypass the first-pass effects imposed by the liver, providing early peak effects of the drug, which is very useful in fighting off sudden onset break through pain (Stevens & Ghazi, 2000). Sublingual administration also provides an alternative route of medication administration in patients that are too nauseated to tolerate oral medication or in patients who are incapable of swallowing. This is often the case of head and neck cancer patients, who have had tracheotomy and feeding tubes inserted. This form of administration is an alternative to

IV infusion, which may be appreciated in patients that have had to endure several needle sticks due to treatment and blood draws.

Patients and Education

The Institute of Medicine (IOM) has called for a redesigned health care environment in which patients have more control over their medical treatments and has suggested the uses of shared decision making as the ideal model of treatment (Arora et al., 2008). Shared decision making has been advocated because it respects patients as persons, it may have a positive impact on health outcomes and clinical decisions should be consistent with patient values (Murray, et al., 2007). According to this model of physician care, patients and physicians discuss treatment options together and mutually decide the best treatment options. This is compared to physician paternalism where the physician makes all decisions based upon what he or she thinks is the best course of action for the patient. In a study to determine which model of treatment decision making patients preferred, 62% were in favor of shared decision making, 28% preferred consumerism (where the patient makes all the decisions) and 9% preferred paternalism (Murray et al., 2007).

This paradigm change has caused the patient to be a more active part of the decision making process and is the ideal situation, however it has been shown that about 50% of the American population has low health literacy skills (Bryan, 2008). As defined by the IOM "...health literacy is the degree to which individuals can obtain, process, and understand, the basic health information and services they need to make appropriate health decisions." (Institute of Medicine, 2006) This means that half of the patient

population of the United States does not have the skills necessary to make an informed healthcare decision. Poor health literacy is found across all socioeconomic, age, race and religion barriers. One cannot estimate a person's health literacy based solely on the comprehension of the English language or their cognitive abilities (Bryan, 2008). This is exacerbated by the fact that patient visits are often short and healthcare providers tend to have to hurry from patient to patient. The healthcare provider can lapse into medical jargon when feeling rushed. This further aggravates the issue because the patient is less likely to ask clarifying questions when their healthcare providers seems rushed, stressed or talk over their comprehension levels. Also, many times a healthcare provider may overestimate a patient's health literacy level if the patient does not ask questions or state that he or she understands when the patient does not (Bryan, 2008). It is important to remember that patients may not be forthcoming about areas of knowledge that they do not comprehend.

Patients will oftentimes access the internet if left to their own resources to gather information. The internet provides an easily accessible, vast database of information. The information that is posted on the web increases everyday, but it is becoming increasingly difficult to navigate concise and accurate data for both the healthcare provider and patient alike. The sheer volume of information can cause confusion and frustration (Arora et al., 2008). There is often conflicting information, information written at a very complex level or very dated information.

In a study conducted to investigate the ease of finding accurate information on colorectal cancer on the internet, it was shown that more than 27% of the websites on the

subject were delivering data that was 15 year old or older and only 1% of this information was being presented by professional societies (Sajid et al., 2008). The level of writing on these sites is often very complex and considering that as many as 32% of adults in the USA have less than a high school education, seeking information this way can seem an overwhelming task (Arora et al., 2008).

Another problem that is faced by patients who wish to seek out more information on their own is the lack of editing of articles that are posted. There is no law regarding posting false information on the internet. The general population may not be familiar with peer-reviewed databases such as PubMed, Ovid, or MDConsult and even if they are, they have limited access to the information that is posted there. Patients understand that not everything posted on the web is always accurate, and they have expressed frustration at trying to decide which information is accurate or not (Arora et al., 2008; Sajid et al., 2008).

The majority of patients agree that the best source of information about their illnesses and treatments is from their personal healthcare providers. This is a felt to be trusted source of information that is up to date and concise. They also express dissatisfaction regarding the amount of information they are receiving. They either are not receiving as much information as they would like, or the information presented is too complex and they do not fully comprehend it. Patients are often afraid to ask more questions or the questions they ask are not answered to their complete understanding (Arora et al., 2008).

Education, Patient Adherence, and Pain

Patient adherence is defined as "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice (Meichenbaum D and Turk, 1987). Currently, patient adherence often does not exceed 40-50% (Palmieri & Barton, 2007). There are many external aspects that will affect a patient's adherence. These include: a patient's perception of what the treatment will be able to accomplish and what the risks are that are associated with that treatment; their outlook on their disease; the patient's personal financial situation and how much the drug costs; their ability to tolerate the medication in respect to swallowing, absorption, gastrointestinal function and anxiety levels; the number of medications the patient will be concurrently taking; how this new medication will effect their current medication schedule; and the duration of their illness. (Palmieri & Barton, 2007)

Another challenge related to patient adherence is the fact that patients often do not understand the logic behind taking a drug in a specific manner or at a given time. When asked if the patient is taking his or her medication, the patient may say yes, but he or she may not be taking the medication in the prescribed manner. For example, medication that needs to be taken with food could be taken on an empty stomach. Also there is no guarantee that the timing to dosing will be correct. Common episodes of non-adherence are related to timing. A patient may skip a dose one day and then remember the next and take double the dose at that moment or a medication may be forgotten for several hours

until the symptoms have returned or something sparks the patient's memory. (Balkrishnan, 2005; M. D. Murray et al., 2007; Peterson, et al., 2003).

The patient's perception of their illness and their medication is also a very important factor in patient adherence. A patient's pain beliefs, according to the cognitive-behavioral pain theory, represent a patient's thoughts (cognition) about pain, and pain belief system reflects a person's appraisal of a pain experience (Meichenbaum and Turk, 1987). These beliefs may cause a patient to under-use or over-use their medications. Cancer patients may adopt a fatalistic outlook on their disease, especially if their pain is out of control, and come to the conclusion that cancer and death are inevitable and pain from their disease cannot be controlled. Patients may also have undue exaggerated concerns about the incidence and severity of adverse events that accompany their medications. There are also misconceptions about medications, especially cancer pain medications, causing immune suppression. Patients may be under the misconception that good patients do not report pain symptoms to their doctors and that reporting pain may in some way distract the doctor from treating the disease. (Ward et al., 2008)

Patients may be only partially informed about their medications and come to possess an undue fear of how easy they will become addicted to their medications. This is especially true in cancer analgesics which are oftentimes controlled substances (Ward et al., 2008) Another misconception that is common when a patient possesses a partial understanding of their medication entails patients who have developed unrealistic expectations of his or her medications. These patients may become discouraged with

treatment and stop adhering to the recommended treatment plan. (Balkrishnan, 2005; M. D. Murray et al., 2007; Palmieri & Barton, 2007; Peterson et al., 2003).

The other end of the spectrum, where the patient believes that if a little medication is beneficial than a whole lot will increase the effectiveness, is also a perception that leads to non-adherence. (Palmieri & Barton, 2007) This overuse can often lead to adverse events, thus, nullifying the therapeutic benefit the patient may have seen if they had been adherent to the therapy. It is crucial that the healthcare provider correct these misconceptions in order for the patient to receive the most efficacious treatment.

Effective spoken and written communication of information is crucial to the success of treatment. The effectiveness and safety of medicines cannot be maximized unless patients understand their role in the medicine-taking process. (Raynor, 2008) Patients who have received some medical education about their specific treatment or disease have a greater ability to communicate well with their healthcare provider (Syrjala et al., 2008).The patient better understands certain expected adverse effects and is more familiar with medical terminology after being instructed. This means less time is spent asking probing questions to find out if the patient is suffering from certain issues because the patient now knows how to verbalize what is occurring in his or her body.

Patient education is also an opportunity to inform patients about the advantages of drug adherence and the detrimental effects that can be associated with non-adherence (Balkrishnan, 2005). This is an opportunity for the healthcare provider to investigate if the patient has any false impressions about the proposed treatment plan and correct these misconceptions. This, too, increases the incidence of patient adherence because the

patient may learn something that makes them hopeful that they can actually do something to combat the pain or disease that they are experiencing (Balkrishnan, 2005) and assuage fears of addiction or intolerable side effects. It allows the healthcare provider to explain what symptoms are significant and that the patient should not feel ashamed about complaining about different symptoms they are experiencing.

Patient education also allows time to be spent with a patient and allows rapport to be developed between the patient and the healthcare provider. It is this rapport that will allow the patient to feel comfortable with their healthcare provider and cause them to be more willing to share any incidences of non-adherence or adverse events (Hartigan, 2003). This allows the healthcare provider to adjust medication appropriately. For example, if the patient is not taking his or her medication every single dosing period, it could lead to negative clinical results if their dose is increased.

All cancer pain guidelines include a mandate for patient education within standard practices. Most recommend training the patient to reduce barriers of pain relief, use medications properly and communicate their pain needs (Syrjala et al., 2008). The challenge in the development of effective patient educational materials and situations is creating a uniform way of educating patients that does not become tedious for the healthcare provider and remains interesting to the patient. Studies have shown that a combination of different forms of information delivery is best received by patients (Peterson et al., 2003). The different formats commonly used in patient education or training include oral, written and audiovisual communications. Purely written communication, despite being shown as the least effective form of convening health

education, is often the format most utilized. (Bryan, 2008) Comprehension of material by the patient is increased significantly when text is combined in a multimedia approach. This allows complicated or confusing topics to be simplified by easy to use and concise diagrams. (Bryan, 2008) A multimedia approach also ensures that the training and teaching caters to more than one major learning style.

There have been several studies that have shown the important relationship between medical education and patient adherence (Balkrishnan, 2005; Murray et al., 2007; Palmieri & Barton, 2007; Peterson et al., 2003). Educational interventions with patients have been shown to improve their rate of adherence. In one such study the rate of adherence for a group of patients that received written and oral instruction about their medication was 78.8% while the control group had an adherence rate of 67.9% (. Murray et al., 2007).

There are limitations with studies such as these due to the difficulty that comes from quantifying patient adherence. There are many different methods of measuring patient adherence, but each one has their own deficiency. Adherence can be measured by pharmacy refill records. This allows an observation that is not known by the patient, but assumes that every time a prescription is filled, the prescription is taken and taken accurately. Medication can directly be detected by the concentration of the drug in the patient's blood or urine, but this is expensive and inconvenient, as it would require another clinic visit. Electronic monitoring can be employed for oral medications, but it again is expensive and assumes that the patient will take the medication every time the pill bottle is opened. This may not be the case, as a patient may open the pill bottle and

then be called away to do something else and forget to take their medication or just leave the bottle open between dosings to make access easier for him or herself (Balkrishnan, 2005).

Even though it is difficult to measure patient adherence, patient education has been shown to improve patient adherence no matter how the adherence itself is measured. This is because patient education can be used as a teaching tool to ensure the patient understands what his or her medications are, what the medications are treating, when to correctly take their medications, and why this timing or method is important.(Balkrishnan, 2005; Murray et al., 2007; Palmieri & Barton, 2007; Peterson et al., 2003).

Specific Aims and Hypothesis

Hypothesis: Patients want to learn more about their treatments and when the patient is educated about their specific study treatment, the patient will be more familiar with administration of the treatment, thus leading to greater patient adherence.

Specific Aim 1: Demonstrate that a patient wants to learn more about his or her treatment by asking whether patients would like to view a short PowerPoint presentation about the absorption and distribution of his or her medication

Specific Aim 2: Demonstrate that viewing this presentation results in a patient's familiarity with an understanding of a particular treatment plan. A patient's familiarity and understand of the treatment plan will be measured by responses to the patient questionnaire and perception of adherence by the study coordinator.

Specific Aim 3: Demonstrate that this increased knowledge and familiarity with a particular medication leads to the patient being more attentive in how he or she self-administers the medication by having the patient demonstrate how he or she has been administering the medication at the next scheduled study visit.

Study Rationale

Patient education has become increasingly important as medical care shifts from a paradigm of physician paternalism to patient directed treatment. Patients have shown more desire to become an active part of the decision making process when it comes to their treatment, creating a partnership between physician and patient. However, this partnership is limited by a patient's health literacy. In order to increase their knowledge base about their condition, patients often times will try to find information on their own. The internet is an easily accessible database of a vast amount of information and is often where patients look. The accuracy and readability of the material they access is sometimes questionable, as there are no filters on what can and cannot be posted (Arora et al., 2008). This study would allow patients to receive accurate and understandable information.

Patient education eliminates some preconceptions about a specific treatment or medication. This is especially true with novel treatments or novel administration routes. This will be important with regards to the proposed study drug, which is administered sublingually, a relatively uncommon route of drug administration when compared to oral or intravenous treatments. Patient education also allows the patient to be more

knowledgeable when talking to nurses or physicians about their treatments (Arora et al., 2008; Balkrishnan, 2005). This study is aimed at increasing this understanding with the assumption that increased comprehension will increase the patient's familiarity with their medication and thus increase the patient's adherence to their treatment plan.

Materials and Methods

The following inclusion and exclusion criteria were used in the selection of subjects for this study.

Inclusion Criteria:

1. Must be willing to sign an Informed Consent document
2. Must be 18 years of age or older
3. Must qualify and be enrolled in a study of Drug X, a sublingual spray for breakthrough cancer pain.
4. Must be able to read a PowerPoint presentation

Exclusion Criteria:

1. Not willing to follow study directions
2. Cannot read a computer screen
3. Refuse to complete questionnaire at conclusion of presentation

The following procedures will be utilized during the conduction of this study.

Procedure:

1. Patients that qualified for the sublingual cancer pain medication, Drug X, were approached at one of their study visits and asked if they wished to receive more

information about how their medication works. They were told that if they agreed, then they would watch a short PowerPoint presentation and would be asked to fill out a questionnaire after viewing the presentation. The time it took to do both was estimated to be about 30 minutes.

2. Subjects that agreed were given a consent document. The document and the study were discussed and the patient was given the opportunity to ask any questions they had about the study.
3. Once consent was obtained, the subject was instructed to view the presentation on a Dell Inspirion e1505 laptop computer that had been brought to the study visit for the convenience of the subject. The student investigator was present to solve any technical difficulties and to instruct the subject on how to use PowerPoint if he or she was unfamiliar with the program.
4. Once the subject finished viewing the presentation, he or she was asked to fill out a short questionnaire consisting of 9 questions.
5. The subject was given a printed version of the PowerPoint for future reference. There was a bibliography included to give them the sources of the information in the presentation if they wished to seek more information.
6. The subject was thanked for their time and the questionnaire was collected.
7. The research coordinator for the breakthrough cancer pain study was approached after the subject's next study visit and asked if there was any notable difference in the subject's adherence to treatment. This was based upon both objective and subjective observations.

PowerPoint Presentation

The presentation that was reviewed by the subject consisted of twenty-two slides that presented information in lay terms. It began by defining the term 'sublingual' and described what a sublingual medication is. The presentation proceeded to explain why a subject would take a medication sublingually, including the advantages associated with this form of administration.

The presentation continued with an explanation of how the medication's absorption and distribution work. This explanation included several diagrams that have simple flash animations to assist in the visualization of these concepts. The subject was then introduced to the fact that the medication had to be held under the tongue for a prescribed amount of time. The concept of diffusion was then explained to demonstrate how the medication was absorbed and why the mechanism of diffusion was the reasoning behind holding the medication under the tongue for a given period of time. Diffusion is a more complicated topic to describe, so the presentation utilized similes to help clarify the more difficult concepts.

The presentation concluded by reiterating that the reasoning behind holding the medication under the tongue for the prescribed amount of time is due to the medication's absorption rate. The presentation also stated that it was extremely important to hold the medication under the tongue for the whole period of time in order for the patient to receive the full effects of the medication. The main objective of the presentation was to promote adherence by impressing upon the subject the logic behind the prescribed

medication administration directions. Therefore these concepts were reiterated in the presentation. A copy of the presentation may be found in the Appendix A.

Subject Survey

The subject survey consisted of nine questions pertaining to the patient's subjective opinions about the presentation and their knowledge of sublingual medication before and after viewing it. Seven of the nine survey questions were formatted as simple yes or no questions designed to gauge how useful the subject perceived the presentation to be; did the subject appreciate receiving supplemental information about his or her medication; had the subject ever taken a medication sublingually before; and whether or not the subject felt more familiar and comfortable with his or her sublingual study medication. The patient answered the remaining two questions by utilizing a 0 to 5 Likert scale. These questions were to ascertain the study patient's familiarity with the study medication before and after the material was presented to him or her. A copy of the patient survey may be found in the Appendix A.

Study Coordinator Survey

The survey the coordinator was given only consisted of one question. This question asked if the study coordinator observed a notable difference in the subject's adherence to the study medication. She was asked to score this difference on a 0 to 5 Likert scale. The scale recorded this change in behavior by having 0 represent a worsening in adherence, 3 represent no change and 5 represent a notable improvement in the subject's adherence to the application of the study medication. The coordinator quantified improvement based on two criteria: the subject demonstrating how he or she

administers the spray and the coordinator's subjective observations. A copy of the coordinator survey may be found in the Appendix A.

Methods of Data Analysis

Quantitative data was to be analyzed using descriptive statistics. The yes/no questions were to be analyzed by looking at percentiles and the analysis visualized by pie charts and histograms. The Likert scale questions were to be analyzed by calculating the mean, median, mode and quartiles for these data. These data were to be visualized with box and whisker graphs. A t-test was also to be performed to see if there is any statistical difference between the subject's familiarity with the medication before and after viewing the PowerPoint presentation. However, I was only able to enroll one subject on my thesis project as there has only been one subject to date enrolled on the breakthrough pain clinical research trial at this site. Therefore these analyses were not preformed.

Results and Discussion

Results

This thesis project was held in conjunction with a clinical research trial and this trial had some difficulty locating subjects that met all of the inclusion and exclusion criteria. Some of the potential subjects decided against participation in the study because they did not want to start another pain medication. Due to these factors, only one study subject was enrolled in the clinical trial and thus only one subject was eligible for my thesis project.

This potential subject was approached about this project and agreed to participate. The subject was given informed consent and was given an opportunity to ask any questions relating to the project. Once the subject understood the purpose and the procedures of the study and had signed the consent form, he was given a laptop computer and viewed the PowerPoint presentation. After the completion of the presentation the subject was given the study subject survey. The subject indicated that he had never taken a sublingual medication before and that the presentation was helpful and easy to understand. The subject also specified on the survey that he liked receiving information from his health care provider and would like to get more information in a similar form in the future. The subject marked 1 (Not at all) as his familiarity with sublingual medications prior to the presentation and a 5 (Very Familiar) as his familiarity with sublingual medications after the viewing the presentation. The study coordinator was given a survey the next day that asked her to indicate the subject's improvement in administrating the sublingual medication. One on the study coordinator's Likert scale signified no improvement, while a five indicated great improvement. The study coordinator selected four as this subject's improvement on this scale.

Discussion

This value of this thesis study was not in the results per se, although they were positive and do indicate that this would be a feasible protocol, but was in the process of getting this protocol from idea to reality. There were many challenges that arose when creating and instituting this project. The process began with creating the research proposal. This process started with portraying my idea as a concise hypothesis and set of

specific aims. The literature search was a learning experience, as I had not quite mastered utilizing PubMed in the most efficient way. This was also the first time that I had utilized the program Refworks for citing references in a document as well and using it properly meant training myself on its functions.

The presentation also proved to be a great learning experience because it had to be accurate and on a reading level that was easily understandable to the lay person. The 8th grade level is chosen by the Baylor Research Institute IRB and the UNTHSC IRB as the maximum reading level at which patient materials should be written at. The principles of drug absorption and distribution are difficult concepts to portray on an 8th grade reading level or below. In order to assure that the patient would be able to easily understand the information, I had to employ various visual aids along with the written text. The presentation had diagrams and animations as well as the written text to provide a multimedia display of the material. The animations had to be timed to create a smooth flow from one concept to the next. The text and the diagrams that supplemented the message were synched to appear at the same time. Similes were used to help clarify the text as well. Thus, creating this presentation took a great amount of trial and error to create an educational piece that flowed smoothly from concept to concept and emphasize the appropriate themes while not presenting material that was above the potential study subject's comprehension level.

Another challenge was developing patient surveys that contained questions that were written at an appropriate reading level. Creating a survey that would accurately capture the information I wanted to obtain from the patient yet still be at an 8th grade

reading level was much more difficult than I initially thought. It took several drafts to create the survey that satisfied both of these criteria.

Creating a feasible and concise protocol was the next step in this process of the study project. This protocol not only had to meet UNTHSC requirements, but also those of Baylor Research Institute due to the fact that I would have to submit this protocol to both of institution's respective Institutional Review Boards. The dual submission was definitely a novel experience. Just coordinating how to properly accomplish this was difficult.

Both applications were completed and were attached to the appropriate materials in a packet. These packets were sent to both institutions' IRBs. UNTHSC returned the submission with approval needing very minor corrections. This IRB then approved my study application and I received an approval letter, stamped consent and stamped surveys. However, this was prior to a decision by the BRI IRB, and, thus I had to send an amendment to the BRI IRB. The BRI IRB approved the application with some other slight modifications. I resubmitted the changes and then received the approval letter and stamped consent from the BRI IRB. This created an issue because I had two different consents that were stamped so I took the Baylor approved consent to have it reviewed by the UNTHSC IRB chair and to have it reviewed and the UNTHSC stamp added as well.

In retrospect, the best approach to this situation would have been to submit one application to one IRB and wait for approval. This would allow any changes to be made to the consent or application without interfering with the other IRB's submission process. Then the approved consent and other approved patient material could be included in the

submission to the other IRB. This would have eliminated some of the repetitive steps that occurred during my submission process.

What one needs to be aware of is the different turnaround times for the respective IRB's. The UNTHSC IRB returned the application a couple of weeks earlier than the BRI IRB. It would be advantageous to submit the first application to the IRB that has the longer return time because this would allow the more time intensive submission and resulting modifications to be completed first. Also, one should be aware of the different IRB policies towards exemption status and what the IRB will stamp and not stamp. It is up to the IRB to designate if a study qualifies for exempt status and one IRB may interpret the qualifications differently. In this case both IRB committees determined my thesis project met the exempt criteria so this was not an issue. However, a difference in IRB policies was seen on the surveys. The UNTHSC IRB policy is to stamp the consent as well as the survey given to the study subject, but the BRI IRB does not stamp subject surveys. It is important to be aware of these differences to ensure that the patient is getting appropriately stamped material that is compliant with both IRB requirements.

Once both IRB approvals were received it was time to enroll patients. This proved a special challenge because the clinical research study this thesis project was attached to had not been able to enroll any subjects. In an effort to resolve this issue, the research coordinator, the principal investigator, the nurse manager, a recruiting specialist and I sat down for a meeting to evaluate ways to facilitate enrollment. This was a wonderful opportunity to see what happens when there is trouble enrolling patients and what steps can be taken to remedy this problem. This was not a study where public advertisement

would have been appropriate because of the specificity of the inclusion/exclusion criteria. Instead, it was decided that the study coordinator would spend time in the clinic every Monday when the principal investigator conducted his treatment checks. This allowed her to be easily accessible if the investigator realized a patient might be eligible during one of these check-ups. The coordinator also was to meet with the principal investigator every Wednesday to go over the next week's patient schedule to mark patients that the principal investigator may deem ready to be pre-screened. This approach appeared to keep the research study on the investigator's mind, and, thus led the consenting and enrollment of the current study subject.

Learning how to approach potential subjects and talk about my thesis project and conduct the consent process was also a new experience. The questions that the patient raised during my explanation of the project allowed me to realize what sections of the project needed to be explained in more detail and which were easily understood. It also ensured that I was explaining the process on a level that was understandable to the lay person and when to breakdown words that were too technical. Observing the subject as they reviewed the study was also very helpful. It gave me an opportunity to see how easily the presentation flowed as well as observe how easily the patient was able to navigate through the PowerPoint. This was the point where it became obvious that the subject did not have too much difficulty reviewing the PowerPoint. Also it appeared that this method of conveying information to the patient would be a feasible option in the future.

Summary and Conclusions

Despite the fact that this thesis project only enrolled one patient, it was an invaluable training tool. It was an opportunity for me to go through all of the steps necessary for creating a study project and exposed me to both the regulatory and the clinical side of clinical research management. The process of creating and executing this project gave perspective on the amount of work that goes into creating clinical studies and integrated the roles of the investigator and the research coordinator. Learning to create documents for the study subjects that were not only comprehendible but also accurate and kept the subject's attention was another great exposure to the considerations that have to be made to the patient during a clinical research study. The protocol also proved to be feasible and efficient. The feedback from the subject and the study coordinator was very positive. In this specific case, the subject wanted to learn more information about their treatments and this knowledge made them more familiar with their study medication. This in turn did increase the subject's adherence to the study protocol specified administration of the study medication.

CHAPTER III

INTERNSHIP EXPERIENCE

Internship Site Activities

My internship site was located at Baylor All Saints Medical Center where I worked for Fort Worth division of Baylor Research Institute as a clinical research coordinator. During my internship I participated in many different aspects of the research process. I learned various aspects of coordinating a study from the initial site evaluation through the site closeout visit. I also helped the Nursing Research department perform studies and create protocols. This often entailed working with a relatively research naive group of people. I also worked on several industry sponsored studies, including oncology studies, gynecology studies, a cardiovascular study and a pulmonary study. The following are descriptions of my responsibilities and experiences while working as an intern at Baylor Research Institute.

ICE CREAM for Research

The Nursing Research department conducted a study titled "ICE-CREAM for Research: Increasing staff nurses understanding about research." This study was designed to motivate staff about the research process. In order to do this, all staff was invited to participate in a study in which they filled out a survey asking what their preferred flavor of ice cream was and how comfortable they were with research. After completion of the

survey, the participant was given an individual sized portion of their chosen ice cream flavor. Participants were given informed consent and taught about inclusion and exclusion criteria before they were given the surveys. A pilot study was performed on the administrative leadership of the institution prior to the actual study being conducted. The pilot study included 20 participants and showed that the procedure was feasible with a few minor adjustments. The larger portion of the study was broken down into four sessions, with an overall total of 286 participants.

I was very involved in every step of this study from study start-up to data analysis. I was given the protocol that had been written for the main study by the Nursing Research department and had to create a pilot study protocol from this document. A consent form also had to be created for the pilot study as well. After creating these documents, I completed the IRB submissions for both the pilot study and the main study. This was my introduction to the process of submitting an application to the IRB. The ICE CREAM study was eligible for exempt status and, therefore, did not have to go to full board review. Despite this classification, it still required several of the elements of a full IRB submission and was a practical way to learn the IRB submission process.

The pilot study was conducted in order to evaluate the protocol for its feasibility. I prepared all the consents and surveys that were to be handed out during this study. During the study pilot there were a couple of protocol deviations in which certain steps of the written protocol were completed out of order. It was also discovered that in order to make the study run more efficiently, these steps probably needed to be rearranged within the protocol. I created a second IRB submission to the IRB in which I reported the

protocol deviations and applied to amend the order of steps in the protocol. These amendments were approved and the protocol deviations were acknowledged and ruled to not affect the safety of the participant. The main study was then conducted.

The main study had been divided into four sessions: the day shift at Baylor All Saints Medical Center, the night shift at Baylor All Saints Medical Center, the day shift at Baylor Southwest Medical Center and the night shift at Baylor Southwest Medical Center. I participated in the main study by explaining to the participants the importance of the consent process and having them read and sign their own consent documents. I also answered any questions the participants had about the purpose of the study and the purpose of clinical trials in general. The day shift at Baylor All Saints produced 162 participants and the study staff and I started to mass consent small groups of individuals due to the sheer volume of people wishing to participate. At the conclusion of each session the consent forms and the surveys were counted to ensure that everyone that completed a survey was consented.

During each of the four sessions of the main study there were instances in which certain participants did not initial all of their consent pages and this deviation had to be reported to the IRB. In order to report the matter efficiently, I counted the number of deviations after the last session and reported them as one large deviation. This deviation was ruled to not affect patient safety and was acknowledged by the IRB.

After the main study was concluded, I collected all of the surveys and entered the participant data into a spreadsheet for data analysis. The surveys included information about favorite ice cream flavor, discipline of the participant, previous participation in

research studies and the participant's comfort with the research process before and after the study. I completed all of the data analysis produced for this study. Certain information such as the whether or not the participants had ever participated in research and their flavor preference were analyzed by percentile and depicted as pie charts. The two questions pertaining to the participant's comfort before and after the research study were scored on a 0 to 5 Likert scale. This data was depicted as a pie chart as well as being further broken down by descriptive statistics. The t-test was performed to determine whether or not there was any change in the participants comfort levels before and after completing the study. Pivot charts and tables were created to show correlations between two different data fields. For example, flavor preference and gender were depicted together to evaluate how many female participants chose chocolate as their favorite flavor.

The last element of this study was an educational presentation to the nursing staff about the process of research that utilized the ICE CREAM study as an example for the different steps of creating and conducting a clinical research study. I created some of the supplemental information given to the attendees. This supplemental information included a research study flowchart that gave a pictorial outline of individual steps of creating a research study as well as a written document that supplements the flow chart. The written document contained a short description of the steps on the flow chart as well as the reasoning behind completing each step. I also wrote an abstract about the study that is to be incorporated into a poster. The Nursing Research council wishes to display this poster at a nursing research convention that is occurring at the beginning of next year.

New Research Coordinator Handbook

The internship site wanted to design a handbook that could be given to a new inexperienced research coordinator that would act as a set of guidelines to the different aspects of coordinating a study and I was given the responsibility of drafting it. The handbook incorporates Baylor Research Institute policies with FDA regulations and GCP/ICH guidelines to produce a set of steps that can be followed from site evaluations to site closeout.

The first chapter of the handbook is a background and information chapter. The first section of this chapter contains information about the Food and Drug Administration along with the different centers within the FDA that regulate clinical trails. The following section continues by explaining the developmental schema for bringing a new drug to market. This includes a detailed description of each phase of drug development and what studies in those phases often entail. The drug development section is followed by a device development section in which the developmental plan for a new device and how these devices are classified is explained. The different device applications, the 510k and the PMA, are also described. This pathway varies widely from the drug developmental pathway. The next section of the handbook contains a short description of biologics and their path to market followed by a section pertaining to combination products. The section pertaining to combination products begins by defining what one is. This section continues by describing the process for deciding what the product's primary mode of action is and thus what regulatory controls to which the device will be subjected.

This introductory chapter of the handbooks is designed to give a coordinator perspective into which development pathway his or her study falls into. Each developmental pathway and each phase along the developmental pathway has certain aspects that are unique to that point in its clinical trials. This knowledge will allow the coordinator to anticipate the general elements of a study by knowing in what phase of development it is.

The next chapter is devoted to the ethics of research and the Institutional Review Board. This chapter opens with a short history of the evolution of ethics in research, covering everything from the Nuremberg Trials to the Belmont Report to the modern regulations. The underlying cause of each event is described as well as the effects the event had on the research community. This section is designed to give the background necessary for understanding why processes such as informed consent and entities such as the IRB are essential elements in research involving human subjects.

The next section is the ethics chapter which explains the process of informed consent. This section delineates each element that is required or recommended by the FDA. It also discusses elements of informed consent that are recommended by the ICH. The Baylor Research Institute polices regarding the informed consent document are integrated into the explanation of this document. This section not only explains the physical informed consent document but it also talks about consenting a patient. FDA, GCP/ICH and Baylor Research Institute policies about the process of consenting a patient are integrated together to give an outline of how to conduct oneself when consenting a potential study subject.

The next section is a guidance document for submitting a study for IRB review. Each of the Baylor Research Institute IRB forms is explained and a timeline is given for their ideal submission times. Guidelines for completing a study budget are also included. The first part of this section is devoted to submitting new studies to the IRB. This includes studies that will require full board review, those which can be expedited and those studies that can apply for exempt status. The qualifications for each of these classifications are explained along with what to expect when a study is classified as either exempt, expedited are requiring full board approval. The section includes timeframes for submitting studies, information concerning who composes the IRB and what are typical examples of an exempt study, an expedited study and a study requiring full board review.

Besides new study submissions, this section discusses the continuing review process, study protocol deviation and amendment processes, and the study close out process. The reasoning behind having these submissions is explained and the appropriated forms that are needed are reviewed. This section describing the IRB should allow the new coordinator to have a comfortable understanding of all the elements required for producing a successful IRB submission.

The last section in this chapter covers the specific policies and procedures for reporting adverse events. This includes local and non-local adverse events and serious adverse events and unanticipated events that pose risk to subjects and others. This section defines each of these classifications and details the appropriate timing and process for submitting the events for IRB approval. The FDA, ICH and Baylor Research Institute regulations and policies are incorporated into the explanations of adverse event

submissions. This section is designed to eliminate confusion over reporting different categories of adverse events.

The third chapter covers all the oversight entities that are involved in research. This chapter explains that research involving human subjects requires oversight from various different parties in order to ensure that the safety of the human subjects is not jeopardized when moving a novel product through the developmental process. This chapter is designed to familiarize the research coordinator with the different representatives he or she will be working with throughout the clinical trial and what they should and should not be reviewing.

The first section in this chapter defines what a sponsor company is and what its particular responsibilities are during a research study. This includes what the sponsor should be reporting to the FDA as well as what type of agreements and documentation needs to be shared between the study site and the sponsor company such as confidentiality agreements. These explanations are followed by a section detailing the how a specific study site is evaluated and selected by the sponsor. A list of minimum criteria for a site to be considered for most studies is included in this explanation. This section also describes what the study coordinator should expect when completing a site evaluation form for a sponsor.

The next two sections describe different entities hired by the sponsor to help maintain the oversight of a clinical trial. These entities are contract research organizations and data safety and monitoring boards. These sections briefly define these entities, but focus on the interaction these representatives from these oversight organizations will

have with a study coordinator. This information includes guidance on how to answer queries and tips for creating and maintaining a strong relationship with a clinical research associate. These sections are followed by a description of monitoring visits. A checklist of documents that are commonly inspected on a monitoring visit is provided to facilitate an efficient monitoring visit. Also provided is a brief description the general procedures for a monitoring visit and a list of suggestions on how to ensure a productive monitoring visit.

The last section explains the audit process that may be conducted by the FDA, the sponsor or Baylor Research Institute. This section provides practical advice for preparing for an audit, such as what documentation should be easily accessible and how a typical audit is generally conducted. This section includes a checklist of material to have on hand for the auditors and this section also includes what possible rulings may be decided by each of these entities after an inspection is completed. This section is designed to ease some anxiety often felt by a coordinator before an audit by supplying the coordinator with information and tools to help prepare for one.

The final chapter in the handbook is devoted to study management. This chapter provides outlines of various aspects of coordinating a study including; recruitment, budget making and billing compliance, record keeping responsibilities, time management and drug storage and accountability. The section concerning recruitment includes practical advice for different types of recruitment strategies ranging from small meetings with the PI to main stream advertisements such as radio announcements and billboards. This section also details the coordinator's responsibilities for gaining IRB approval on

different types of advertisements. This responsibility to submit to the IRB will depend on the type of advertisement the coordinator wishes to employ.

The section pertaining to budgets and billing compliance contain common study procedures and who to contact to obtain an estimate on their cost. This section will provide a guideline for allocating study funds for PI and coordinator time and other common study elements such as shipping and laboratory fees. It contains information regarding common budgetary debates that will be encountered when negotiating with the sponsor. The section reiterates the difference between standard of care and research procedures and who gets billed for each classification. The Baylor Research Institute policies are integrated into this section and include information regarding the where the budgets should be submitted and what the normal turnaround time is for a new study budget. This will give a new coordinator an idea of when to submit a budget to initiate negotiations with the sponsor.

The subsequent section regards information on the record keeping responsibilities of the study coordinator and details the local policy on record retention. It also includes guidelines for completing electronic and paper case report forms as well as tips on remote data capture. This section is followed by a related section containing suggestions on time management. The time management section is a collection of tools that can be utilized to help organize study information and records for easy access and includes examples of previous timelines for studies as a supplement to these tools. This will allow a study coordinator to estimate how much time needs to be allocated specific steps in a study.

The last section in this chapter pertains to drug storage and accountability. Information included in this section pertains to Baylor Research Institute and FDA regulations regarding the storage of novel drugs. This will include information on keeping temperature logs, the specifications for controlled access depending on the type of medication, and how drug is received at this location. It includes information about the research contact in the hospital pharmacy and general information pertaining to keeping the drug in the hospital pharmacy as opposed storing it in the research department. This section concludes with common forms of medication compliance checks employed by study sponsors.

The handbook concludes with an appendix that contains several tools for the new clinical researcher. These tools include: help websites containing information of clinical trails, flow charts depicting different product developmental pathways, quick IRB form reference charts, a sample budget, sample completed IRB forms, sample consent forms, monitoring and audit checklists and a recruitment plan the coordinator can customize to their particular study. These are supplemental materials to facilitate study management. I created some of these tools and compiledthe rest from different sources. Everything is referenced with a sources page listed at the back of the handbook.

IRB Experience

Throughout my internship experience, I submitted various applications to the IRB. These included full board and exempt applications. This required that I become adept at completing the Baylor Research Institute IRB forms as well as become aware of what goes into an IRB submission. The rule of thumb that was given to me was that

anything the patient sees has to be reviewed by the IRB. I learned how to create consent forms that were written at an eighth grade level for studies that involved various fields of study. The IRB also requires a list of study staff and their contact information, the principal investigator's current CV, financial disclosures from every member of the study staff, a statement of scientific validity and copies of the protocol and investigator brochure.

I have been responsible for drafting four full board review applications, two have of which have gone before the IRB and have been approved. The last one is still in the process of being completed. Each submission has raised its own issues and presented a unique learning experience.

The first study was a study on the effects of a selective estrogen receptor modulator or SERM on vaginal and vulvar atrophy in post menopausal women. It was the first study I had ever submitted to the IRB and became a model for all future submissions. It was during this study submission that I learned the difference between a local and central IRB and who gets jurisdiction over a study. The local IRB always has jurisdiction over studies done at sites affiliated with them. This was a point of contention with the sponsor, but both parties soon came to this conclusion.

The second study I submitted to the IRB was for a venous thromboembolism (VTE) study. It wasexamining the effects of the long term use of a novel medication in preventing recurrence of a VTE in patients with a history of pulmonary embolism or deep vein thrombosis (DVT). This study's protocol included three unincorporated amendments. Due to this circumstance, several study management tools had to be created

and implemented to ensure that patient safety was not compromised by following an outdated protocol. These tools included referencing, in bold red lettering across the parts in the protocol that had been updated, the current amendment procedures; creating cheat sheets that contained all the current inclusion/exclusion criteria; creating a reference sheet that defined which concurrent medications were acceptable and which were not; and a flow chart that was color-coded to reflect which person on the study staff was responsible for fulfilling that duty.

The third study's protocol examined the efficacy of a type I device in measuring the cervical length of pregnant women. This device had been approved by the FDA because it was substantially equivalent to products already on the market. The company wanted to gather more information about this product to help convince healthcare providers that this device is an inexpensive and efficacious alternative to a trans-vaginal ultrasound. What made this study a great learning experience is that it included pregnant women and minors as study subjects. This entailed special applications to the IRB to include these two vulnerable populations in order to ensure that these populations were not unduly tested. The principal investigator also wanted to apply to waive the requirement for parent permission due to the fact that pregnant women in Texas, no matter their age, are allowed to consent to medical treatment regarding their pregnancy. This study was also unique in the fact that a certified nurse midwife was the principal investigator. This study will be reviewed in the upcoming months.

The fourth protocol to be submitted the IRB is an open-label extension study to the first study I submitted. This protocol was intriguing because it had no end date on the

study. The subjects for the first study are given the option of continuing on the study medication after the double-blind portion at their last study visit. If they agree, then they undergo the informed consent process for this study and are given a six month supply of the study medication. The subject returns to the clinic every six months to be evaluated. If the sponsor and the principal investigator deemed it appropriate, the subject could stay on the study medication for six more months and the cycle repeats itself. This presents a new challenge when trying to draft the consent and the application and the wording used had to be carefully thought through.

I have also submitted two studies that fell under exempt status to the IRB. I learned what criteria a study had to meet to fall under this classification. Exempt studies are convenient because they do not have to be submitted at a specific time and the review time is often shorter than a study that must go to full board review. The studies that fit these criteria were the ICE CREAM study and my thesis, as both of these clinical studies were educational in nature.

The IRB also requires that each member of the study staff has to have completed Baylor Research Institute's online IRB training. I have helped principal investigators and other study staff, that are less computer savvy, navigate through these lessons. These lessons have to be updated every two years and this is sometimes a point of contention with busy principal investigators. I have learned that the study coordinator has to be cautious when approaching a principal investigator about finishing past due lessons.

Informed Consent

Informed consent is probably one of the most important aspects of conducting a clinical study. I learned how to draft and present informed consent to patients during my internship. The Baylor Research Institute has a template that contains some standard language that has to be incorporated in a clinical study consent document. It is up to the study coordinator to make sure that the consent contains all the FDA required elements. This information must be written in language that is understandable on an eighth grade level. This is difficult when trying to explain technical medical procedures in a consent document. It is also hard to revert back to non-technical writing after being required to do so for so many other aspects of the job. I learned the importance of breaking down sentences and using more colloquial terminology when trying to get a consent document down to the appropriate grade level.

One of the helpful tips I learned was to include an informed consent document in a potential study patient's chart. This reminds the principal investigator to approach the patient about the study and give them the consent documents during their next visit. In addition, the patient has time to read through the document and write down questions he or she has before the study coordinator has a screening visit with them. During my internship, I observed consent being given and gave informed consent to the subjects on my thesis project as well as the participants of the ICE CREAM study. It was interesting during the ICE CREAM study to see what questions were asked about research. The participants wanted to know about the research process and asked very insightful questions about informed consent and the research study process in general.

Study Visit Observations

This internship site offered a wide variety of studies in which to participate and observe. I was able to observe drug and device studies, clinic visits and surgeries. Each study visit is approached differently, depending on what the subject is expected to do and how the subject reacts. The longest study visits usually were the screening visits. It was during these visits that informed consent was given and the study was explained to the subject. The shortest and often the most laid back studies were just simple compliance and subject check-ups.

I observed two different device studies, one was an adhesion barrier device that was applied during a laparoscopy and the other was a cardiac stent registry study. I was able to observe surgeries for both of these studies. The barrier device study was a blinded study in which the subject either received the device or the best practice surgical technique. The subject returned a month later for a second look laparoscopy to evaluate the efficacy of the product and clear out any adhesions that were forming. I was able to see one of each surgery. The coordinator was responsible for taking down data during the procedure when the principal investigator would announce the site and type of adhesions.

The registry stent study was held in the catheterization lab. I became certified in conducting the NIH stroke scale to help evaluate patients before and after their operation. The study coordinator was responsible for recording the type of stent employed, the quantity and the deployment of the stents. I was able to observe a few of these surgeries. One of the subjects has a bovine type two classification of their heart and carotid stent anatomy. This anatomy led to a very complicated deployment of multiple stents.

During clinic visits, I would take the lab samples the other coordinators had drawn and process them for shipping. This entailed centrifuging and transferring samples into appropriate containers and properly packaging them to be shipped. I took an IATA/DOT shipping certification class for biological materials in order to correctly package these materials. I also assisted in pill counts for compliance and recording concurrent medications. I was taught how to enter data into a remote data capture program and complete case report forms.

Site Initiation Visits and Monitor Visits

I was able to observe three site initiation visits, two of which were for the sublingual medication studies that my thesis was conducted in conjunction with and the SERM site initiation visit. These are all day events which start in the research department and then move to visit the principal investigator's clinic and the pharmacy. During these visits the study coordinator meets the monitor for their study. The monitor goes over the main points of the study and inspects different areas to ensure that they site is equipped to conduct the research and reiterates what the sponsor expects of the study site. This includes items such as documentation, enrollment deadline and confidentiality. During this time I was able to ask questions regarding the protocol for clarification.

The monitor was then taken on a tour of the facilities and is shown the drug storage room in the research department that is for drugs that are not stored by the hospital pharmacy, the records room where the regulatory binders are stored, and the offices. Everything is examined from temperature logs to the security of the drug room. If the study medication is classified as a controlled medication or if it is used for an

inpatient trial, it is stored in the hospital pharmacy. When this was the case, the monitor was shown where the drug is kept and met the research pharmacist. The pharmacy binder is explained at this time as well. The monitor is then taken to the clinic rooms where the patient will be seen. At this time the monitor, the coordinator and the principal investigator then meet to go over the principal investigator's responsibilities during the trial.

During these visits, I learned the importance of being mindful of the principal investigators time. This means preparing for these visits by having the study binders together, forms filled out and questions already written out. This way anything the monitor needs to point out can be easily accessed. This is important because the principal investigators have their own practices they have to tend to and often do not have more than an hour of time to spare for these meetings.

I also observed periodic monitoring visits for an ongoing study. This is a time where the monitor is able to review queries with the coordinator and resolve any issues that need to be addressed. The monitor will also compare the case report forms to the original documentation in the medical record to confirm accurate data collection. These visits also allow the monitors to collect any other information they need to resolve conflicting data. It is important to maintain a good working relationship with monitors, not only because they are the ones reviewing your data, but they also report back to the sponsor. If the sponsor receives outstanding reports about a site, then the company may wish to give the site other clinical trials as well.

Continuing Education Opportunities

This internship has offered several additional classes and seminars to augment my knowledge of the clinical research field. I have attended an IATA/DOT Packaging and Shipping of Hazardous Material class and am now certified to ship biological materials from the site to a central laboratory. This class taught the proper packaging of laboratory samples and how to properly identify the packaged materials to the shipping company. I became certified in performing the NIH stroke scale via a web based training module. This module taught the tests to give to the patients and how to score their responses on the stroke scale. The department attended a billing compliance class where the proper way to record and bill research related procedures was taught. The distinction between what is to be billed to the patient's insurance and what is to be billed to the Baylor Research Institute was made during this session. I also attended two webinars produced by the ACRP (Association of Clinical Research Professionals). The first webinar pertained to GINA, the Genetic Information Nondiscrimination Act. It describes what the act entailed and how this act will affect the way research is conducted and subjects are consented. The second webinar was on working with a Principal Investigator and getting the most out of that relationship. It offered tips on maintaining good communication and time management. I also attended two classes given by MedTrials. The first instructed on the how to maintain good documentation practices. The second was on study management. This class covers the gamut of issues that are confronted when coordinating a study.

Journal Summary

Each page in the journal represents a week at my internship site. It chronicles my day to day activities. This includes everything from the mundane copying and preparation of documents to my experiences observing surgeries and shadowing doctors. It is a detailed recollection of my time as an intern and shows the progression of my responsibilities at the Baylor Research Institute. The journal may be found in the Appendix B.

APPENDIX A

STUDY TOOLS

Sublingual (suhb-**ling**-g*wuhl*) Sprays

A short explanation of how this thing works

What Does Sublingual Mean?

- Sublingual simply means under the tongue.

- A sublingual drug is a drug that is meant to be taken up through the blood vessels under your tongue and in the floor of your mouth.

- This is compared to a oral (swallowed) medicine, which is meant to be taken up into the blood vessels of your stomach and intestines.

Why Would Someone Take a Sublingual Medicine instead of Oral Medicine?

- You do not have to swallow this drug. This allows you to take this medicine even if you have difficulty swallowing or are very nauseated from your cancer treatment.

- This medicine works faster than an oral medicine.

Why Would Someone Take a Sublingual Medicine instead of Oral Medicine?

- When a drug is taken orally (swallowed) you have to wait for the drug to be digested.

- The drug travels to your stomach. There it is broken down and goes into your blood vessels.

Why Would Someone Take a Sublingual Medicine instead of Oral Medicine?

- When the drug is broken down, some of the drug will no longer work. This means that not all of the drug you took is getting into your blood.

- The drug can only work if it gets into your blood. The drug uses the blood to get to the brain. This is like using the highway to get to another city.

Why Would Someone Take a Sublingual Medicine instead of Oral Medicine?

- The brain is where the drug works to take your pain away.

- Getting an oral drug to the brain takes time because the drug has to go to many different parts of the body before it gets to the brain.

Why Would Someone Take a Sublingual Medicine instead of Oral Medicine?

- A sublingual drug goes directly into the blood through the blood vessels under your tongue and in the floor of the mouth. This lets it get to the brain quicker.

- This is like starting off a trip to another city on the highway instead of having to drive through town to get to the highway.

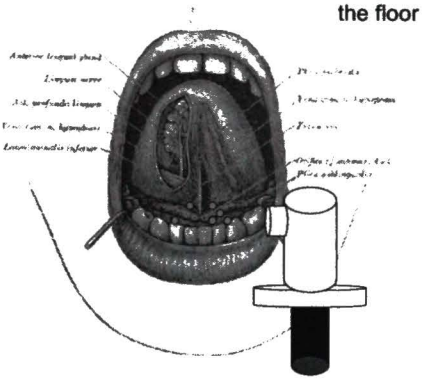
Why Would Someone Take a Sublingual Medicine instead of Injected Medicine?

- This drug is not injected. This means you don't have to be stuck with a needle.

How this Drug Works

You spray the drug underneath your tongue.

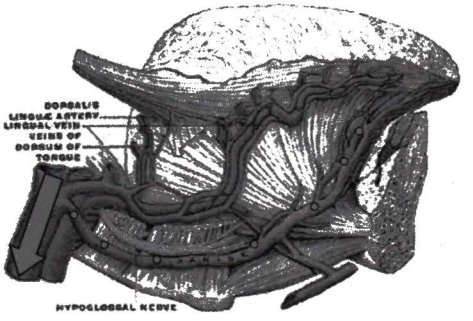
It is taken up by the skin under your tongue and the floor of you mouth



Once it is taken up the drug will enter into the blood vessels and go into the blood stream.

Illustration 1 Copyright 2008 by bartelby.com. Used with permission.
Anatomy of the Human Body. Gray, Henry. Fig 1013.

How this Drug Works



Once the drug enters the veins in mouth and tongue, it travels to the veins in your neck.

Illustration 2 Copyright 2008 by bartelby.com. Used with permission
Anatomy of the Human Body. Gray, Henry. Fig 559.

How this Drug Works

Once the drug enters the veins in your neck, it travels in the blood to the a vein that empties into your heart.

This vein will carry the blood into your heart.

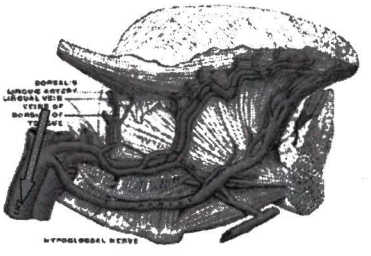


Illustration 3 Copyright 2008 by bartelby.com. Used with permission.
Anatomy of the Human Body. Gray, Henry. Fig 559.

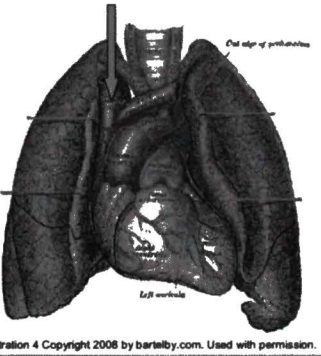


Illustration 4 Copyright 2008 by bartelby.com. Used with permission.
Anatomy of the Human Body. Gray, Henry. Fig 490.

How this Drug Works

The drug is pumped in the blood out of the heart through the aorta.
The blood then travels to the brain where the drug can take action.

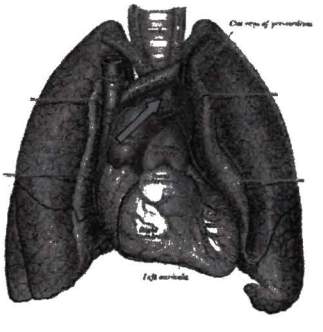


Illustration 5 Copyright 2008 by bartelby.com. Used with permission
Anatomy of the Human Body. Gray, Henry. Fig 490.

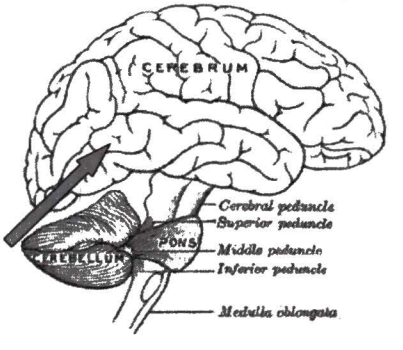


Illustration 6 Copyright 2008 by bartelby.com. Used with permission
Anatomy of the Human Body. Gray, Henry. Fig 677.

Why Is It Important To Take This medicine Exactly The Way I Was Told?

- It is very important to take this medicine exactly as told in order for the drug to work.

- If you swallow the drug, then it will go into the stomach and be broken down into pieces that cannot work on the brain.

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- If you do not hold the drug under your tongue for 30-60 seconds the drug will not be have time to diffuse (move across the skin) into the blood stream.

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- Diffusion works because there is a more drug on one side of a barrier than another. In this case we have two barriers:
  - The floor of the mouth and the skin of the tongue
  - The blood vessel wall

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

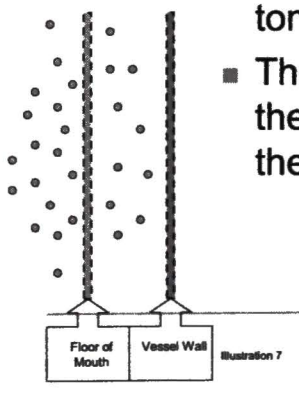


Illustration 7

- You spray the drug under your tongue.
- There is more drug on the outside of the floor of your mouth, so some of the drug moves across it.

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- Some of that drug diffuses (moves) across the blood vessel wall.
- The drug will keep moving across the blood vessel wall until there is the same amount of drug on both sides

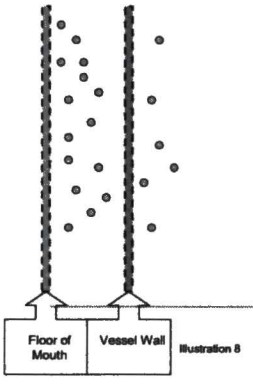


Illustration 8

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- Blood in the blood vessels is flowing and takes the drug with it.
- This is like putting a toy boat on a stream. The stream takes the boat with it.

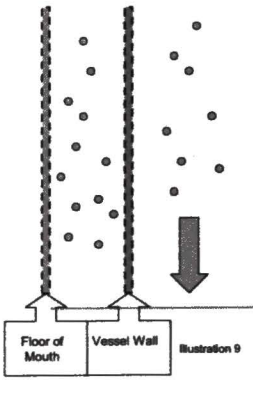


Illustration 9

Why Is It Important To Take This medicine Exactly The Way I Was Told?

- When the blood takes the drug away, more drug is pulled into the blood.
- This is like being in line at a rollercoaster. Some of the people in line are taken away by the first rollercoaster car. More people can then move up and get into the next car.

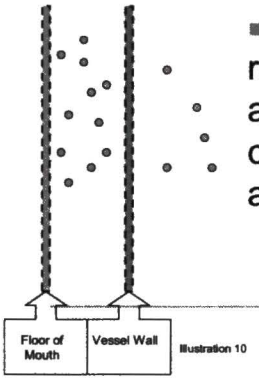


Illustration 10

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- This movement across two different barriers takes time. This is because of a couple of issues:
  - The openings the drug passes through are very small.
  - The drug has to pass through each barrier one at a time. It can not just rush past both.

Why Is It Important To Take This Medicine Exactly The Way I Was Told?

- The process of the drug moving across the barriers is why you have to hold the drug under your tongue for 30-60 seconds!

Bibliography (Where Can I Find More Information)

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Re: Illustration Usage

bartlebycom@aol.com
To: Bittenbinder, Emelia

Please consider this email permission to use the materials listed in the manner described.

Sincerely,

Steven van Leeuwen
President, Bartleby.com, inc.

-----Original Message-----
From: Bittenbinder, Emelia <millie.bittenbinder@baylorhealth.edu>
To: 'bartlebycom@aol.com' <bartlebycom@aol.com>
Sent: Tue, 23 Sep 2008 10:53 am
Subject: Illustration Usage

I am a graduate student at UNT Health Science Center and am conducting a thesis project. I wanted to use some of the illustrations posted on your site in a PowerPoint presentation for patient education. My thesis is on the importance of patient education and part of it entails giving a small population (6 subjects maximum) an educational presentation on their medication. I wish to use certain illustrations from Gray's anatomy. How do I receive permission to do so?

Emelia Bittenbinder
254-931-0162
Millie.Bittenbinder@baylorhealth.edu

Sublingual Administration Questionnaire

1. Have you ever taken a medicine by placing it under your tongue?

Yes No

2. Did you find this information helpful?

Yes No

3. Do you like getting information about your treatments from your doctor and other staff?

Yes No

Please circle the number that shows how familiar you were with this medicine **before** viewing the presentation.

1 2 3 4 5

Not at all Very Familiar

5. Please circle the number that shows how familiar you are with your medicine **after** viewing the presentation.

1 2 3 4 5

Not at all Very Familiar

6. Was this information easy to understand?

Yes No

7. Do you feel more comfortable about taking this type of medicine?

Yes No

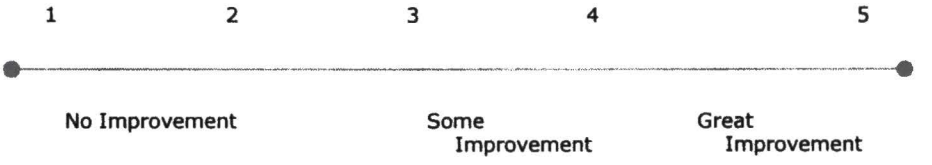
8. Will you be more careful about how you take your medicine after learning this information?

Yes No

9. Would you ever want to get more information like this in the future?

Sublingual Administration Questionnaire for Study Coordinator

In your opinion, how well did this patient improve his or her administration of the sublingual medication?



APPENDIX B
DAILY JOURNAL

June 2, 2008

I completed the IRB training and was shown around the office and hospital. Today was a welcome and taking care of logistics day.

June 3, 2008

I was given a few protocols to read over and find questions to ask. I found out that not all protocols have been proofed as carefully as one would expect. Jennifer took me along with her as she consented a patient for a cardiac stent study. I was oriented to Baylor Research Institute polices and where I could go to find resources on them as well as other general Clinical Research references.

June 4, 2008

I sat in on a study visit for one of the Women's Health study with Theresa. I was showed how to enter things into an electronic chart. I read a few more protocols for various studies that are coming up or are in progress. I went over a new protocol with Tracy. The sponsor is coming on Monday to do a site initiation visit and we came up with questions that needed to be asked during that meeting

June 5, 2008

I was taught how Baylor Research Institute's local IRB wants local and non-local SAE's and adverse events to be documented and in what time period the IRB needs to be notified of these occurrences. We went over the differences between SAE's and unexpected events.

I was asked to create an informed consent document quiz to be used to test competency. I drafted a made up consent document with different elements missing and submitted that to be read over.

I attended a shipping class on how to properly ship biological materials. I learned the difference between a Category A and B materials and the different ways they need to be handled. The proper way to label a package and how to appropriately dispose of dry ice was also covered in this class

June 6, 2008

I had a meeting with my site coordinator to sign off on my journal and talk about my thesis. There was an employee appreciation picnic today as well.

June 9, 2008

Emailed my major professor about my proposal and started researching information on education and patient compliance. Attend a site evaluation meeting for a possible new study. Learned what information the sponsor look for and was allowed to ask questions about different aspects of the potential protocol and observed the site evaluator and Principle Investigator interaction.

June 10, 2008

Two monitors visited today and I observed monitor, coordinator interaction. I learned how to communicate and what they to bring the monitors when they visit. One of the monitors was closing out a study. The other was present for a routine monitoring visit. It was decided that a community calendar needs to be created to coordinate monitor visits, as the site becomes busier and busier. I was given the new QuatRX protocol from the evaluation visit and was told to do the IRB submission and adapt their informed consent into the Baylor Format.

June 11, 2008

We had staff meeting today and learned that Baylor All Saints is doing an educational study to get nurses excited about research. I am doing the exempt IRB submission, adapted the main study protocol and informed consent to a pilot study format, and am responsible for getting everything signed and submitted ASAP. I probably will be helping with some of the poster presentations as well.

June 12, 2008

I continued with the full IRB submission and collecting data for the exempt educational study. I contacted Lori Batchelor to find out financial information to help form a budget. I completed a site evaluation for GlaxoSmithKline on one of our PI for a vaccine study and submitted it. I ran a consent to a patient for one of the other research nurses.

June 13, 2008

I obtained signatures and completed the exempt IRB form for the educational study and sent it for review. If finished the QuatRX submission as best I can until I receive the consent template from the sponsor.

June 16, 2008

I spent the day researching Pub Med for relevant article for my thesis proposal.

June 17, 2008

I went through training to be able to administer the NIH Stroke Scale to patients. I continued to research articles for my thesis proposal.

June 18, 2008

I obtained signatures for a departmental research support form. I attended a webinar on GINA, Genetic Information Nondiscrimination Act and learned about what consequences this new legislature has on research and on normal day to day living.I also continued to research articles for my thesis proposal.

June 19, 2008

I started writing my thesis proposal and continued to look up additional information.

June 20, 2008

I attended a staff meeting for the Research Department, continued writing and researching my thesis proposal.

June 23, 2008

I had the stomach flu and did not come in to work

June 24, 2008

I worked on my proposal. I finished my background section and started working on the practicum design section.

June 25, 2008

I worked on my proposal. I had to resubmit one of the educational studies consents to the IRB to change a grammatical error. We received the regulatory documents for a the Women's Health study and I began filling out the paperwork for that. I contacted the Radiation Safety Committee to learn how to get a study approved through them. I am learning what all goes into a full IRB submission and am filling out a lot of the forms.

June 26, 2008

We held the pilot for the educational study today. It gave us an opportunity to see what type of traffic control was needed to get the study done appropriately. Once surveys were collected I made a table to summarize the data to bring to the PI. I continued working on documents for the IRB submission and started working on the consent document. The one the sponsor sends and the template for BRI IRB are different from each other. We are aiming to submit to the IRB pre-review on July 14th. I finished my rough draft of my research proposal.

June 27, 2008

I am continuing to work on the IRB submission. I attended a webinar on working with a PI. It talked about useful and innovative strategies for getting the best cooperation between your PI and the study staff.

June 30, 2008

I observed a second look endoscopy for one of the ongoing studies at this site. The informed consent document was revised and sent to the sponsor for approval. I started working on a data analysis for the educational study and am relearning how to do data analysis in Excel.

July 1, 2008

I continued to work on the data analysis of the educational study for research awareness.

July 2, 2008
I finished working on the data analysis for the educational study and submitted it to the PI. I started to revised my thesis proposal with the changes that my Major Professor suggested as well as for grammatical errors I could find. I instructed a new sub-investigator on how to use the IRB training modules.

July 3, 2008
I emailed my revised proposal to my committee members. I helped draft a revised informed consent for the sublingual pain medication study that reflected the newest amendment as well as the changes the local IRB wanted.

July 7, 2008
I have started to work on the power point I need to create for my thesis. I did some more revisions on my thesis proposal per my site coordinators advice.

July 8, 2008
The PI for the nursing education study requested that I edit the data analysis and make it in to a form that could be presented at the next Nursing Administration meeting. I took all the data and put together a power point presentation so the charts could be printed out as handouts. I revised some of the graphs to make them easier to read and added instructions on how to read a pivot chart graph on the first graph in the handouts to expedite understanding. I attached the written data analysis and made handouts for the meeting members. I also went and made copies of the informed consents and flyers for the main educational study that will be held in a couple of weeks. The coordinators who are working on the Women's Health Study and I met to discuss how things were going with getting that study to the IRB. There has been some confusion between the Sponsor and the site as to IRB jurisdiction. The Sponsor wants us to submit to the local and central IRB. We only submit to the local IRB because they are the ones with jurisdiction. We are consulting our IRB to see what they say and are talking to the sponsor to straighten the situation out.

July 9, 2008
The PI for the nursing education study wanted advertisements for the study to post in the different hospital units and for electronic distribution. I created a flyer for posting and a flyer for email distribution. I also edited the protocol to reflect the changes that needed to be made after holding the pilot study and seeing how things worked. Most of the changes had to do with logistical issues. I also changed the survey to lessen confusion at the study. The subjects were having difficulty figuring out which side of the survey to fill out first. I added a 'Please fill out this side first to the top and bottom of the survey'. All of these changes had to be submitted to the IRB for approval with a Form 7 that is signed by the PI. I completed these tasks, got the PI signature and submitted to the IRB and am waiting to hear back from the IRB.

July 10, 2008
We had the site initiation visit for the sublingual Fentanyl study. We received training on how to use the medication and how to educate the patients to use the ediaries. We met with the PI to discuss the protocol and any questions we had with it. We showed the monitor the pharmacy, our offices and storage areas and the patient exam rooms. We hope to start enrolling patient in a couple of weeks for the study. We had our weekly staff meeting to discuss upcoming business and training. I received more advice from my committee members and revised my proposal one more time.

July 11, 2008
I worked on my power point presentation for my thesis and went to get signatures and do some research in the library.

July 14, 2008
Today I continued to work on my presentation and questionnaire for my thesis.

July 15, 2008
I finished a rough draft of the power point presentation and the questionnaire and started on the protocol. I requested the approval timeline for the Nursing education study, because we needed to post flyers.

July 16, 2008
I continued to work on my protocol. I went with one of the research nurses while she consented a patient for a device study. The patient will be going to surgery on Monday. They flyers received approval for the educational study so I started to make copies and post the flyers in hospital.

July 17, 2008
I finished posteing all the flyers for the upcoming study in the hospital. At lunch time we had a booth for Research Awareness. This was to let employees and patients know that there is research at Baylor All Saints. They fill out a form indicating which areas of research they or a family member may be interested in participating and that information goes in to a database. They are contacted if a study in that area comes our way. It gives us idea of what this community is interested in. A new physician wants to start a Hepatitis study at All Saints. I am starting the Form 1 and Informed Consent Document.

July 18, 2008
I continued to work on the Form 1 and Informed Consent Document.

July 21, 2008
Today I went and shadowed Dr. Johns, who is the medical director of the research department and a gynecologist. The morning started in surgery for one of the current device studies. Regrettable the subject screen failed. The rest of the day was spent in his office watching various procedures, including a procedure that only Dr. Johns and a

physician in Connecticut perform. We had a study subject come in for a follow-up visit. She was evaluated and a second-look surgery was scheduled.

July 22, 2008
I finished working on the Form 1 for the new study and sent it to be reviewed. I started to convert the sponsor's consent document into the Baylor format. I attended a training on billing compliance with all the research nurses. There is a new system that is being instituted at Baylor and we all had to be through a training.

July 23, 2008
I completed the ICF and sent it to be proofed. We performed the first two large sessions of the educational study. We had 162 subjects in the afternoon and 78 subjects during the night. I consented subjects during these sessions and collected all the surveys and consents after for analysis.

July 24, 2008
I spent today entering in all of the survey data into an excel program after doing a final count of the consents and surveys. I produced preliminary data and sent this to the PI. I also made sure we had everything that was needed for next weeks study sessions.

July 25, 2008
I am continuing to work on the chapters for a training handbook today.

July 28, 2008
I worked on correcting my Powerpoint presentation for my thesis. I also worked on my protocol and the handbook.

July 29, 2008
I continued working on bringing down the reading level of the Powerpoint. I received advice from the study coordinator on the study and am trying to make it a bit less general. I did some research on how the FDA performs audits for the handbook.

July 30, 2008
I made final preparations for the educational study. I made sure that people had directions on how to get there. We had the third session of it at Baylor Southwest in the afternoon. It was not as large as the sessions at All Saints but it was a good opportunity to teach people about the research study process.

August 6, 2008
I entered in all the data from the Southwest educational studies and then combined everything for an overall analysis. I sent the initial data to the PI and did some very basic statistical analysis.

August 7, 2008
I went to an IRB meeting in which All Saints had two studies under review. This was held at BUMC in Dallas. It was a good opportunity to see how the review process works. I also divided an ICF into three separate ones because the study had three distinguishable parts. I started writing up protocol deviations for the educational study.

August 8, 2008
I finished writing up the deviations for the educational study and am waiting for the PI to sign them so I can send them to the IRB. I am working on my Powerpoint presentation again. I have a meeting to discuss a new project that I will be helping to write the protocol and ICF.

August 11-15
This week I met with the PI of the educational study. We discussed how the study went and what changes we could make to improve the design. We talked about some of the results that I had already analyzed and how we may want to change the wording of some of the questions because of possible misinterpretation by the participants. We discussed what data she needed to be analyzed and what she wanted in the data analysis write up. I am also to write up an abstract for the project. We discussed how and when we were going to present the results. We are going to make a poster for the project. We also are going to make a introduction to research presentation that will be shown during the presentation of results. This presentation will incorporate the results and design of the of the study to personalize the information the participants are receiving.

After knowing what data needs to be analyzed I have been working to get that done. The study has a good turnout, with 286 participants overall. This was over 10% of the population that was eligible to participate.

I found out that I have to send my thesis project to both the Baylor and the UNTHSC IRB for approval. This has to do with school and site regulations. I have been getting a submission ready for both of these respective review boards. I am the principal investigator for Baylor study and my major professor is the principal investigator for the UNTHSC study. Both sites have their own unique forms and way they wish for things to be submitted so it has been a real learning process to get both submissions together.

I also have been looking up what is involved in FDA audits to finish a chapter for a coordinator handbook.

August 18, 2008
Today I had a phone conference with the sponsor of the cancer breakthrough pain study. I also finished doing the data analysis for the educational study. There were several more division of data to be made and analyzed.

August 19, 2008
I started to write up the data analysis for the educational study. I completed an audit chapter for the SOP clinical research handbook that is being made. This chapter included information on federal, local and sponsor audits as well as help suggestions on what to

have prepared for an audit. I made some minor changes to my IRB submissions to Baylor and UNTHSC.

August 20, 2008
I continued to write up the data analysis and choose what information needed to be presented. I start working on an abstract for this data. Also I filled out a financial form for my IRB submission to Baylor.

August 21, 2008
I had a medical school interview in El Paso

August 22, 2008
I burned a dvd for one of the studies and continued to work on the data analysis and abstract for the educational study. I submitted my IRB submissions to both school. I witness a stent surgery for a registry study. I had a meeting with a nurse who is trying to do novel research for her department. I am helping to instruct her on how to write a protocol and start a research project.

August 25- August 29
This week was mostly spent sorting out how to get two IRB to approve a study. One of the key issues was the informed consent. What I had to do was get Baylor to approve the consent. UNTHSC then will have to stamp the same consent so the consent will have two stamps on it. There has to be a letter sent from one IRB to another that states that the reason for having two IRB stamp a single consent was to avoid showing the subject duplicate consents. Now I have to take the one that Baylor approved back to UNTHSC because of the changes they made to it.

I went with one of the research coordinators to retrieve information from different patient medical records. I learned how to look up the information and where to find the paper charts.

I helped organize the supply room. We rearrange how the lab kits were stored and labeled everything for convenience. This way if someone new comes in they know whose lab kits are whose. We set up a freezer and an EKG as well.

I ran back and forth between UNTHSC and Baylor almost everyday trying to get the IRB situation sorted out. I sent my Major Professor the method of obtaining two IRB approvals for one study so in the future there is not as much back and forth.

September 2
I had an medical school interview at TCOM.

September 3
I started working on two more data analysis for the ICE CREAM study. The results presentation will be the 16th. The PI wanted two other analysis done to complete the results. I set up two databases for the staff here as well. One is the for the budget so the manager can keep track real time of how much money is available. The other was a

database for potential study subjects. This database keeps all their contact information and areas of interest as well as totals all the people in a particular area of interest

September 4
I finished the data analysis for the ICE CREAM study. I started to create a reference handout for the people who attend the results party. The results will be given at a Focus on Nursing Research meeting along with a research 101 presentation. I created flow charts and guides to the process of creating and conducting a research study.

September 5
Today I met with the PI of the ICE CREAM study and we talked about my handouts and what she wants to do for a presentation. I made some adjustments to my presentations. I also have been given the draft of the Coordinator handbook and am to format that. The reg packet for the new PE study also came and we are starting to put together the IRB submission.

September 8
Today I worked on the Form 1 for the new PE study. I consolidated the protocol, the IB and the amendments onto the form for IRB submission. I also emailed the radiation committee to see what needed to be done about diagnostic tests that will require radiation.

September 9
Today I finished up a draft of the form 1 and entered in the advice from the radiation committee. I started to work on the Informed Consent. This protocol had more issues than anticipated, but we are trying to work them out with the sponsor.

September 10
I sent a draft of the ICF to the study coordinator and started to work on the new coordinator handbook again. I have received many resources that will help make this a good reference for new coordinators. Everyone is being helpful with this project. Some of the coordinators have given me more resources and some have helped write some to the handbook.

September 11
I continued to work on the handbook in the morning. In the afternoon I corrected the form 1 with some additional data we received. I also took a draft of the consent over to the coordinator and we went through it piece by piece deciding what needed to be changed. There are still some issues that are not resolved but we are having a meeting next week with the PI to discuss some of them and we are also in contact with the sponsor on others.

September 12

I have been working on the handbook and will continue to do so. I received an email from my major professor to start working on my thesis paper. I have started looking up some more information for the background. I also have been looking at the format of the thesis and hope to turn in an outline early next week for Dr. Gwirtz to look over.

September 15-September 19

We are working on a new PE study that has proven to be quite complicated. This week the study coordinator and I have been trying to get an informed consent ready for pre-review. Normally this would be a very straight-forward process, but in this case there have been several delays. There were several amendments to the study and these were not always reflecting in the sample consent the sponsor sent. This has caused some questions with certain sections of the informed consent document. The sponsor also mandated we keep a lot of their language, there was much negotiation going on to try to get the sponsor language and the BRI IRB language in the same consent for. The study coordinator and I met with the PI and the study coordinator that works in his office, so we could all be on the same page about this study, especially since his coordinator is new to research and the protocol is very complicated. The study coordinator and I are creating tools to assist in simplifying the protocol. These will include flow charts with the specific duties or the coordinator and the PI for each visit. The form 1 is also taking a while to create, because of issues with the protocol. There were some questions on how to reflect certain radiations risks in diagnostic tests that are standard of care. The sponsor mandated that the risks of these procedure be kept in the consent, so the radiation committee has to approve the language used in the consent and all of these tests have to be reflected on the form 1. I spent a lot of time back and forth with the radiation committee contact to ensure that we were documenting everything appropriately.

We met with the PI for the Fentanyl study and talked about enrolling and recruitment strategies. The study coordinator for that study has set up a specific day she will be in the office for this study as well as head and neck cancer registry study. This will be a time I could identify patients for my study as well. After this get together the PI has 10 potential registry patients and 8 potential Fentanyl patients. If any of these potential Fentanyl patients enroll, I will approach them for my study. This is up from zero potential patients and is really exciting. It attest the power of having a sit down meeting to make sure everyone is on the same page.

I also have been working on the handbook this week. It is coming along and I think in the next four or five weeks it will be completed. It will have four main sections (Introductory information, oversight entities, ethical and patient protection policies, and study management.) Everyone has been very helpful in supplying me with information for this handbook.

The ICE CREAM study presentation will be next Wednesday. I have been helping that PI get information together as well as create some tools for her to handout as well. I have been editing her presentation also.

September 22- September 26

This week I consented my first patient to put on my thesis. We went over what my thesis entailed when the study coordinator gave him the consent for the Fentanyl study to look over. He will be eligible to start the Fentanyl study next week, which is when I will have him complete the procedures for my thesis. I also handed out another consent document to a potential subject.

This was also the week we finished the ICE CREAM study. The Sundae Results party was Wednesday. We held two sessions, one in the morning an one in the afternoon. During these sessions the PI presented a Powerpoint presentation about research 101 and how to conduct a project as a nurse. The presentation covered the complete process, starting with and idea and literature search and ending with data analysis. This is important because the nursing population at Baylor All Saints is relatively research naive. There is also a very specific path potential nurse investigators have to follow. This includes submitting their idea to the nursing research council and getting paired with a 'research expert.' The presentation also has an interactive aspect. The attendees were asked questions in which they answered electronically with remotes. These questions were asked before that specific topic was covered and after the topic was explained to increase the presentation impact.

I only spent a few days at work this week as I had medical school interviews Monday and Thursday.

September 29-October 3

We finished completing the IRB submission for the new PE study. This was an interesting submission due to the fact that there are three unincorporated amendments that update the protocol. The IRB sent us a letter back from pre-review stating that they did not like this at all and if we could get the sponsor to incorporate the amendments that would be best. They sponsor said that was against their policy. This meant we had to make mechanism to ensure patient safety. All the amendments have bold red lettering stating what page in the protocol they affect. The protocol has bold red lettering over the parts that needed to be changed that reference the amendment. What the lettering did not cover was crossed out. This makes it impossible to follow the outdated parts. We also have a full inclusion/ exclusion cheat sheet, a concomitant medication cheat sheet and an updated flow chart that is color coded to show who does what during a specific visit. All this was submitted to the IRB with a cover letter explaining the steps taken to ensure patient safety.

I enrolled a patient onto my thesis on Tuesday. He did not seem to have a problem with the Powerpoint presentation and stated that the information was very understandable. This was wonderful news. We also have a couple of other patients that may potentially be eligible for the Fentanyl study. The other patient I gave the consent form to last week ceased treatment and therefore ceased having the breakthrough pain necessary for enrollment. After I completed my study, I helped with the screening visit and took down all of the patient's concomitant medications. We had difficulty with the electronic diaries but sorted that out. Blood was taken and a urine sample was collected.

Once the visit was completed we finished spinning down the blood and preparing the samples for shipment.

I also missed Thursday and Friday of this week for medical school interviews.

October 6 – October 10

This week I worked on the training handbook. I finished the first section and have moved into the ethics are IRB section, which should be done by next week. I went with the study coordinator for the Fentanyl study and we retrieved more drug from the pharmacy so our patient could increase his dosing. We are hoping he titrates soon, but he states that this drug is really working. We also returned his opened cartridges back to the pharmacy.

We have a new potential study that another coordinator and I will work on together. This one is with a class I device. The device is approved, but they company wants to gather more data on it for marketing purposes. We are trying to learn if a certified nurse midwife would be acceptable as a principal investigator for the study as long as there is a physician as a sub-investigator. The coordinator on this study and I completed a draft of the Form 1 and the consent form and submitted it to our manager for review. This will be an interesting study because it will include pregnant women, ages 13 and above. Thus the study will encompass two vulnerable populations that will be scrutinized by the IRB. Another issue that will have to be addressed is whether or not the minors in this study will have to receive parental permission. Under Texas law, all pregnant women, regardless of age, may seek medical treatment for their pregnancy with parental permission. The local IRB acknowledges this in their policies but states they will review the issue on a case by case basis.

We will have a Site Initiation Visit for the Fentanyl rollover study. The monitor will initiate this study as well as review the first subject we put on the double-blind study. This visit should go well, since the monitor is already aware of our facilities an the pharmacy due to the initiation of the double blind study. There have been a few changes on timelines, and we will have to submit a new consent form to the IRB to reflect these changes. This is a good visit to reassure the monitor that we have been conducting the double blind portion correctly.

October 13 – October 17

I spent the first part of the week working on my thesis draft. I completed the first section of the draft and sent it to my committee members for review and revisions. On Tuesday I processed laboratory samples for shipping on the patient on the cancer breakthrough pain study and my thesis. On Wednesday I accompanied another coordinator to a patient visit for a VVA study. I was to take the patient's laboratory sample for processing, but the patient was undecided about her participation in the research study and went home to think about her decision more. On Thursday we teleconferenced in for the IRB meeting that was reviewing the pulmonary embolism study that had been causing so many issues since it had three non-incorporated amendments. The meeting went surprisingly well and the study passed with very minor revisions. We are just waiting on the budget now. Then I attended a web based eCRF

training with the study coordinator for the breakthrough cancer pain study. This training showed us how to enter data into their eCRF format. Friday, I added previous human clinical trial information into the form 1 for the new cervix measurement study. This study will be interesting to go to IRB review because it has a certified nursing midwife as the PI. I also started the forms to get approval to enroll pregnant women and minors. This study will be a learning experience in respect to these two special populations, as I have not worked on a study that included them.

October 20 -October 24

The VVA study has an open-label study that is a rollover from the initial study. Another coordinator and I are working on creating an IRB submission for this rollover study. The problem that became apparent with this protocol is that it has not end date. Patients will come to the clinic and be evaluated and if the patient, the investigator and the sponsor agree the patient will participate in the study for six more months. This is to be repeated until there is cause to terminate the patient from the study. Completing an IRB submission and a consent form has proven to be difficult due to these reasons. The wording has to be chosen carefully to ensure the patient understands the protocol is set up in this fashion.

I also have been working on my thesis. I completed a draft minus the results and discussion and summary and conclusions sections. I am going to wait another week to complete these in hopes of enrolling another patient in my thesis project. I sent the draft of my thesis to my major professor and committee members to revise and hope to hear from them next week. My mentor is returning to Texas next week so we can discuss my thesis.

Friday I attended a MedTrials class on good documentation practices or GDP. This class was located in Dallas and ran from 8-3:30. This class defined good documentation practice and associated terms, described the procedures and tools used during data collections to ensure protocol compliance, described the steps involved in query resolution and best practices for prevention, and explained the impact of EHR on clinical research and actions needed to ensure compliance with regulatory requirements. This was a very informative class and I will certainly utilize this information in my future career. The class content was excellent, but the opportunity to sit in a classroom with other coordinators from different sites and backgrounds and learn what works for them was priceless.

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