Obstacles Associated with Physician Referral of Patients into Clinical Trials

Nick Torrez
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Understanding the safety and efficacy of potential new medications relies on evidence gained through the participation of subjects in clinical drug trials. Many clinical trial sites struggle with recruitment of suitable participants which can delay the progress of drug development. Physicians can play a significant role in influencing patients to enter into a clinical trial, however many physicians due not utilize their unique position to facilitate the recruitment of patients into clinical trials, which may help to advance medical science and improve future treatment options. The lack of participation by physicians in the referral of patients into clinical trials (Crosson et al. 2001; Daugherty C, 1995; Jenkins and Fallowfield, 2000; Lara et al., 2001) can potentially be explained by various obstacles. We propose that these obstacles may be issues such as time, lack of knowledge about clinical trials, lack of clinical trials suitable for patients, language barriers, conflict of interest, communication with local investigators, and trust in medical researchers.
OBSTACLES ASSOCIATED WITH PHYSICIAN REFERRAL OF PATIENTS INTO CLINICAL TRIALS

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OBSTACLES ASSOCIATED WITH PHYSICIAN REFERRAL OF PATIENTS INTO CLINICAL TRIALS

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of Biomedical Sciences University of North Texas Health Science Center at Fort Worth in Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Nick Torrez, B.S.

Fort Worth, Texas

April 2017
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Thank you to my major professor Dr. Hodge for providing me with direction, insight, and knowledge throughout my journey. I would also like to thank Dr. Maynard for helping me develop my project, and making me feel at home while learning at North Texas Clinical Trials (NTCT). It has also been a pleasure to have Dr. Mathew keep me on track and provide a new perspective during each of my committee meetings with him. I would also like to thank Dr. Jung for helping to further develop my presentation and critical thinking skills. The various tips and techniques I have learned from Jessica Anderson, CRC at NTCT, have helped me form a solid foundation for future work in the clinical trials industry, and I would like to thank her for the time she put into teaching me. My family has also been a great inspiration for continuing my education and I am blessed to have their support. I would also like to thank all of the doctors who took the time to participate in my survey.
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CHAPTER I

INTRODUCTION

The aim of this research project was to examine the various obstacles associated with physician referral of patients into clinical trials. The recruitment of patients is essential to the timely success of clinical trials when developing new therapeutics. Understanding the obstacles associated with patient recruitment into clinical trials by physician referral may help expedite the drug development process and thus reduce costs associated with development.

This study utilized a questionnaire to assess the barriers that physicians in Dallas County and Tarrant County may face when referring patients into clinical trials. The survey gathered both descriptive data as well as subjective data from local physicians in both Dallas and Tarrant County.
CHAPTER II
BACKGROUND AND LITERATURE REVIEW

Clinical research requires human subjects to volunteer for participation in studies investigating the safety and efficacy of drugs, tools for diagnosis, and techniques for treatment. Clinical research involves standardized processes to obtain evidence in support of the tested drug, tool, or technique (Koçkaya, 2015). Significant investment of resources is necessary for the continued progress in medical research and therefore, it is of great importance to healthcare consumers. The treatments developed help to ameliorate the various health conditions that people face worldwide (Campbell et al., 2001; Nathan and Wilson, 2003).

Clinical research is an important part of the United States economy. A Research America report noted that 136 billion dollars was spent in the United States for clinical research. The pharmaceutical industry spent the largest share on clinical research with an estimated amount of 38.5 billion dollars ("Sequestration: Health Research at the Breaking Point," 2013). This is unsurprising, due to the high cost of conducting a single clinical trial. The development of a new pharmaceutical product costs an average of 124 million dollars and usually takes more than 10 years to complete (Mowry, 2007).

The development process initially starts in a non-clinical phase that involves animal testing and may involve the refinement of the drug. After the pre-clinical phase an Investigational New Drug (IND) application is sent to the Food and Drug Administration (FDA) for approval. This approval allows the new drug to progress into phase I of clinical trials. The chances of the drug progressing from the pre-clinical phase, for approval by the FDA, is one out of a thousand (Birkenbach et al., 2014).
The developer then enters the drug into phase I of the clinical research process to uncover its properties and safety, using healthy individuals. Phase I of the drug development process usually takes 1 to 2 years to complete and costs approximately 3.8 million dollars (DiMasi et al., 2003). Phase I is important in finding the therapeutic dose range used in the subsequent phases.

Phase II of the drug development process, sometimes referred to as “proof of concept,” is conducted on the population with the ailment which the drug is intended to treat. Phase II of the drug development process costs 13.35 million dollars and takes close to 26 months (Birkenbach et al., 2014).

Phase III involves the recruitment of a large number of participants; however, this stage can also be very important in comparing the efficacy of the developed drug to that of the current treatment, so as to ensure that the new drug serves to benefit the population (Birkenbach et al., 2014). Phase III is an expensive phase of the drug development process and can cost 19.89 million dollars with administrative staff costing 2.3 million dollars. Phase III can last 2 ½ years (Birkenbach et al., 2014). The number of patients required for a phase III can be several thousands, depending on the nature of the disease and the design of the trial (Lipsky, 2001). Recruitment of patients into clinical trials has been cited as one of the biggest barriers to conducting clinical trials in the United States. Therefore, it can be hard to acquire the large number of participants needed for a clinical trial in phase III. An inability to recruit the necessary amount of patients can result in an extension or termination of the trial (Weisfeld et al., 2011).

It is necessary for the aforementioned phases to be completed so that the drug is approved by the FDA in the United States. The approval process is managed by the Center for Drug Evaluation and Research (CDER), a part of the FDA. Companies are responsible for having their products tested. The companies then send the results to CDER for further analysis.
before approval. CDER serves as an unbiased reviewer that determines if the benefits of taking the new drug outweigh the risks.

Phase IV involves post marketing surveillance to discover how the drug reacts in everyday life and helps to uncover any long term side effects of the drug. Phase IV may be required by the FDA if further testing is needed. Discoveries from phase IV can result in a drug being taken off the market or added restrictions to a drug. Phase IV can cost approximately 19.95 million dollars with staff costing around 3.3 million dollars (Birkenbach et al., 2014).

Sometimes the progress of the drug through the various steps can take longer than anticipated, which may result in a loss of patients or investigators. These losses can delay the drug approval by the FDA even further (Weisfeld et al., 2011). Delays in phases can also cause damage to the clinical trial sites involved with the sponsor. Some clinical research sites in the United States have shifted resources to more profitable enterprises or even ceased their clinical research activities altogether (Getz, 2010). The average clinical research site has a debt of around 400,000 dollars. This is unsurprising considering “many investigative sites need to borrow money to continue performing clinical trials” (Birkenbach et al., 2014). One reason this problem may exist is because, on average, 120 days are required for clinical trial sites to be reimbursed by sponsors and clinical research organizations for the work they have done; similarly, many sponsors attempt to defer payment of the clinical trial site until further along in the study. This deferment of payment is expected in situations where the sponsor must invest more money into lengthening a phase of the clinical trial. If these problems are not resolved it can be presumed that more clinical trial sites might stop participating in clinical research (Eustace et al., 2016).

Recent studies have cited the need for a more timely enrollment of patients to ensure the future success of U.S. Clinical Trials (Avins and Goldberg, 2007; "Sequestration: Health
Research at the Breaking Point," 2013; Sung et al., 2003). A lack of recruitment of patients can hinder the success of clinical research and cause “delayed study completion, trial failure, weakened results, introduction of bias, increased costs, slowing of scientific progress, and limiting the availability of beneficial therapies (Weng, 2012).” The issue of recruitment is also very important to the 10-20% of clinical trial sites which fail to recruit a single patient (Alvarenga and Martins, 2010). Sinackevich and Tassignon found that 86% of clinical trials experience a delay of 1-6 months during the patient recruitment phase, and 13% of clinical trials are delayed for more than 6 months (Sinackevich and Tassignon, 2004). Delays such as this can ultimately result in delayed treatment options for the target audience of the drug, device, or technique. These delays and a lack of suitable participants contribute to the overall cost of development and dissuade potential developers.

Physicians have a pivotal role in recruiting patients for clinical trials and enabling patient access to clinical trials (Howerton et al., 2007; Siminoff, 2008; Sullivan, 2004; Umutyan et al., 2008). Fifty-six percent of investigators cited recruitment of participants as a significant problem, according to a Applied Clinical Trials poll (Sullivan, 2004). Furthermore, the importance of physicians in the recruitment process is seen in various studies, where a commonly cited motive for patients taking part in clinical trials is the trust and advice of doctors (Daugherty C, 1995; Jenkins and Fallowfield, 2000). However, a number of physicians do not utilize their opportunity to help recruit patients for clinical trials to further the advancement of science and to possibly help their patients. For example, due to the decision of physicians not to offer clinical trials to their patients, some cancer patients eligible for clinical trials were not enrolled (Lara et al., 2001). Studies have found that only 10-20% of patients with cancer are told about clinical trials that they can participate in (Comis et al, 2003; Comis, 2005; Fenton, 2009). Additionally, a
survey by the National Cancer Institute discovered that 98% of primary care physicians did not discuss the option of clinical trials with their patient before referring their patients to a cancer specialist (Crosson et al., 2001). A large part of our knowledge about physicians’ opinions on barriers to recruitment for clinical research relies on oncologist views. To further increase the number of physicians involved in referring to clinical trials, it has been proposed that more physicians, including those outside of oncology, be surveyed (Avins and Goldberg, 2007; McKinney et al., 2006; Sherwood, 2004).

Specifically, time (Galvin et al., 2009; Ramirez et al., 2012), lack of knowledge about clinical trials, lack of clinical trials suitable for patients (Ramirez et al., 2012), language barriers (Nodora, 2010), conflict of interest (Hall et al., 2006), trust in medical researchers, (Hall et al., 2006) and lack of communication with local investigators (Galvin et al., 2009) have been suggested as barriers to physician referral of patients into clinical trials.

The “separation between clinical practice and clinical research” in the United States is one of the largest problems currently facing the clinical research industry. This separation is further emphasized by the finding that research discoveries tend not to be implemented in the regular practice of physicians (English et al., 2010). Research is not incorporated as a mission at most clinical practice sites and United States health systems. Furthermore, numerous health care professionals are not trained in research methods and may find it quite difficult to understand and implement results from research (Kramer et al., 2012). Some have suggested that it may also be hard for physicians to determine the benefit of their patient participating in a clinical trial versus undergoing standard treatment (Bonham et al., 2011). In addition, the system in the United States also appears to persuade physicians to focus on profitability, while deterring physicians from clinical research due to cost, risk, and time (Kramer et al., 2012). However, when doctors work
alongside pharmaceutical companies “there is a great deal of scrutiny”, for the doctor. This scrutiny is partly due to the publicized cases of conflict of interest concerning doctors and pharmaceutical companies. Furthermore, under the Patient Protection and Affordable Care Act corresponding to the Physician Payment Sunshine provision, the gifts that a doctor might accept from a drug company are required to be reported. Some states have extra rules concerning the relationship in “physician industry relations” (DiMasi et al., 2003). The barriers causing a lack of physician participation in the clinical trials process must be determined so that these barriers can be addressed by the clinical trial industry. Once a better understanding is gained about the factors responsible for the lack of participation by physicians in clinical research measures may be taken to reduce the cost of drug development by decreasing the amount of time spent recruiting patients.
SPECIFIC AIMS

The aim of this research project was to examine the various obstacles associated with physician referral of patients into clinical trials. We propose that these obstacles may be issues such as time, lack of knowledge about clinical trials, lack of clinical trials suitable for patients, language barriers, conflict of interest, communication with local investigators, and trust in medical researchers.

SIGNIFICANCE

The results from this study are significant because they will help bridge the gap between potential referring physicians and the medical research industry. This study has the potential to identify the problems associated with patient recruitment into clinical trials by physicians’ referrals. The data collected from this study may later guide future research to develop strategies that help raise recruitment levels in clinical trials. This could improve the quality and reduce costs of future drugs, devices, and treatment techniques in medical research.

MATERIALS AND METHODS

The current project sampled certified physicians, both Doctor of Medicine (M.D.) and Doctor of Osteopathic Medicine (D.O.), from Dallas County and Tarrant County. For the list of cities included in Dallas County see Appendix B and for the cities included in Tarrant County see Appendix C ("Cities in Dallas County," ; "Cities, Towns, Municipalities,"). IRB approval was obtained from the University of North Texas Health Science Center (UNTHSC) to conduct the survey (See Appendix D). A questionnaire (Appendix D) was delivered to physicians in each of the cities in Dallas and Tarrant County along with a cover letter (Appendix D) explaining the study. Delivery of the questionnaires began January 2, 2017. The questionnaires were delivered
during the hours of 8 A.M.- 6 P.M. Monday through Friday. The physicians chosen for the survey were those listed on google as doctors practicing in the city. The surveys were also delivered to doctors practicing in the medical offices attached to major hospitals in the Dallas Fort Worth area including Cooks Children’s Medical Center, Baylor Scott and White Medical Center Irving, Children’s Medical Center Dallas, Texas Health Harris Methodist, and Parkland Hospital Dallas. The survey was generated with physicians in mind and was designed to take less than ten minutes, as stated on the cover letter (Appendix D), to encourage participation by physicians. The questionnaire was delivered either to the doctors’ staff or to the doctor directly. The recipients were told that the questionnaire would be picked up in one week’s time. The recipient was also notified that the questionnaire needed to be filled out only once, whether online or on paper. If the questionnaire had not been filled out after one week, the staff or the physician was reminded that the online version could still be filled out until February 15, 2017. The online version of the questionnaire was administered through Survey Monkey.

The data gathered were analyzed with binary logistic regression using the dichotomous dependent variable (i.e., yes or no) “during your career have you ever referred a patient to participate in clinical trial?”. During the binary logistic regression, the answer choice “no” was coded as 1 and “yes” was coded as a 0. With the regression model we looked for a model to best explain our dependent variables using the independent variables of attitudes and opinions. In other words, we sought to understand which variables helped to explain the probability of our outcome of whether or not a physician has referred a patient into clinical trials. We used the Omnibus and Hosmer Lemeshow test statistics to measures goodness-of-fit for the data. Univariate analysis was used to help identify important variables to put into the logistic regression equation. Any missing data was handled by means of multiple imputation using 5
imputations. The use of 5 imputations is considered adequate to correct missing data (Carpenter and Kenward, 2013; Rubin, 1987). During multiple imputation the data set is copied a certain amount of times, missing values are replaced in each imputed data set by using an imputation model, the analysis of interest is then carried out amongst all of the data sets. The resulting pooled estimate is then calculated by combining the estimates from each of the completed data sets (Hayati, 2015).

The questionnaire (Appendix D) was developed based on a review of the literature and surveys from other investigators (Avins and Goldberg, 2007; Galvin et al., 2009; Mainous et al., 2008; Nodora, 2010; Ramirez et al., 2012). A revised question from the Trust in Medical Researchers Scale, which has shown validity and reliability in previous research, is also included in the questionnaire (Hall et al., 2006). The questions concerning trust in medical researchers and communication with local investigators are both reverse coded in the questionnaire. The results from specialty, an open-ended question, were grouped. For example, those who answered Family Practice were included in the Family Medicine category and any those who answered with any type of “Surgery” specialty were included in the Surgery category. A similar method was employed for each of the specialty types. Descriptive statistics were gathered for each of the variables included in the model. The remaining questions assessed the opinions of physicians by utilizing a 5 point Likert scale; these questions will analyze how obstacles such as time, lack of knowledge about clinical trials, lack of clinical trials suitable for patients, language barriers, conflict of interest, communication with local investigators, and trust in medical researchers affect physician recruitment of patients into clinical trials. All analyses were performed using SPSS version 24.
Logistic regression is used when your dependent variable is dichotomous. The study design searched for variables which significantly influence the decision of a physician to refer a patient into clinical trials or not; therefore, the dichotomous variable is whether or not a physician has referred a patient into clinical trials. Upon a literature review of similar studies logistic regression has consistently been utilized to discover the odds of a physician referring patients into clinical trials based on a set of explanatory variables (Galvin et al., 2009; Mainous et al., 2008; Ramirez et al., 2012). Logistic regression also requires a considerable amount of respondents for analysis to discover if an explanatory variable is statistically significant. The Hosmer Lemeshow goodness-of-fit test statistic used also requires a fairly large sample size to detect small deviations (Bewick et al., 2005).

The various steps involved in the producing our results include the following: variable selection, model building, and goodness of fit testing. See Figure 1 below for the steps utilized to obtain our results. A table is also given in Appendix A of the variables included in the model and their corresponding questions.
Univariate analysis was utilized for variable selection. During univariate analysis, covariates are analyzed using a contingency table (if the covariate is categorical) and placed into a regression model one covariate at a time. The variables which will be selected to enter the logistic regression model are those whose significance value is less than $p<.25$ (Bendel and Afifi, 1977; Costanza & Afifi, 1979; Sperandei, 2014). For example, if we are building a logistic regression model with 10 covariates and 1 dependent variable and we wish to know which covariates to use as variables in our model we could use univariate analysis. During univariate analysis we would enter each of the covariates in a regression model, one at a time, and analyze the results for each variable. If the results for a variable show a significance of less than $p<.25$ then the variable will then be included as a variable in the logistic regression model. We would also analyze the contingency tables for each categorical variable, if necessary.
The classification table is used in binary logistic regression to display the percentage of the data correctly predicted by the model. This is done by comparing the percentage of data correctly predicted for each of the outcomes in the binary logistic regression model. The percentages correctly predicted are then averaged to give an overall percentage. For example, if a study contains a dichotomous dependent variable of “yes” or “no” and the fitted model correctly predicts 30% of the “yes” cases and 40% of the “no cases, then the overall percentage of data correctly predicted, according to the classification able, is 35%.

Pseudo R² calculation is used to measure the strength of association. This is similar to R² in linear regression. The pseudo R² value explains how much of the variability in the dependent variable can be explained by the fitted model. The Cox and Snell pseudo R² measure attempts to explain the variance on a scale which cannot reach a perfect value of 1. The Nagelkerke pseudo R² measure is an adjustment of the Cox and Snell measure and can reach a perfect value of 1. For example, if we conducted a study on mice to see whether or not they will develop dementia. The explanatory variables being diet, temperature, and activity. When the explanatory variables of diet, temperature, and activity are placed in the logistic regression it may then be called the fitted model. If the fitted model for development of dementia in mice is assessed using pseudo R² measures and a Cox and Snell value of .21 is reported as well as a Nagelkerke value of .31, both of these values can be interpreted to explain the variance in the dependent variables. The Cox and Snell value indicates that 21% of the variance in the dependent variable can be explained by the fitted model. The Nagelkerke value can be interpreted to mean 31% of the variance in the dependent variable can be explained by the fitted model. The Nagelkerke value is widely reported due to its ability to reach a maximum value of 1. Both the Cox and Snell measure and the Nagelkerke measure can be used in the model building state. There is also some debate
regarding whether or not the Pseudo $R^2$ values are measures of goodness-of-fit (Hosmer and Lemeshow, 2000). Therefore, it is included in the model building phase of our study on barriers to physician referral of patients into clinical trials.

The Omnibus test is a statistical test for goodness-of-fit. The Omnibus test compares the null model (without any explanatory variables) and the fitted model (the model containing the explanatory variables) to see which model reproduces the observed data better. For example, let's say data is gathered regarding a study on whether or not cats will like a new type of cat food. The explanatory variables are the taste, smell, and texture of the food. Therefore, the variables in the fitted model are taste, smell, and texture of the food. The null model does not contain any of the aforementioned explanatory variables. The Omnibus test is performed to see if the model with the variables fits the data better than the null model. This can be assessed using the significance value derived from the test. If the value is less than a set significance (usually .05) this indicates that the fitted model is significantly better at predicting the data than the null model. Therefore, if a significance of .03 is given for the cat food example the model is interpreted to fit the data well. This is one method to test the goodness-of-fit of a model. However, relying on one test to assess the capability of a model is discouraged (Menard, 2002).

The Hosmer Lemeshow test is also a statistical test used to assess goodness-of-fit. The Hosmer Lemeshow test analyzes the predicted values for each of the explanatory variables and compares these to the values from the gathered data. The null hypothesis for this test is that there is no difference between the values from the data gathered and those expected from the model (Menard, 2002). For example, let's say data is gathered regarding a study on whether or not dogs will like a new type of dog food. The explanatory variables in the model are smell, flavor, and color. During assessment of the model with the Hosmer Lemeshow test the data gathered from
the study is compared to the fitted model containing the explanatory variables of smell, flavor, and color. If the predicted values from the fitted model are very similar to the observed values, from the gathered data, we accept the null hypothesis that there is no difference between the observed values and predicted values. This can be assessed using a set significance value, usually .05. Therefore, if a significance of .05 is given for the dog food example the model correctly predicted values similar to those observed in the data gathered. The model generated is interpreted to fit the data well.

The Box Tidwell test is used to assess multicollinearity. Multicollinearity is when at least two variables in a model are highly correlated. When variables are shown to be highly correlated it may indicate that the variables are testing for the same thing. To utilize Logistic Regression there must be no multicollinearity between variables. The Box Tidwell test creates an interaction term between a variable and the natural log of that variable. The interaction term is then placed in the model. If the results indicate that an interaction term is significant (with a significance of less than .05) then there is multicollinearity between variables in the model (Vatcheva et al., 2016).

RESULTS AND DISCUSSION

The survey was coded with the dichotomous dependent variable, Yes or No, with a binary code of 0 or 1 respectively (Table 1). Two hundred and ninety-eight surveys in total had been delivered and 49 were received from physicians practicing within Dallas and Tarrant County. Therefore, the response rate for our questionnaire is 16.4%. Two of the surveys completed by respondents contained 2 or more answers and were therefore discarded from the study. Furthermore, the data collected contained 4 cases of missing values. The “triads not appropriate” question exhibited 1 missing value case and the “multilingual” question contained 3
missing value cases (see Table 2). We decided to address the missing data using multiple imputation, specifically using 5 multiple imputation models to maintain a sufficient sample size.

### Dependent Variable Encoding

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<th>Original Value</th>
<th>Internal Value</th>
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<td>Original data</td>
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<td>0</td>
</tr>
<tr>
<td></td>
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*Table 1: Variable Encoding*

### Imputation Models

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<th>Missing Values</th>
<th>Trials Not Appropriate</th>
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<td>3</td>
</tr>
</tbody>
</table>

*Table 2: Imputation Models*

The data was used to gather descriptive statistics including the mean and frequencies of the variables. The table below shows the mean for each of the variables. The mean is very close to the median for each of the variables (Table 3), including the binary question of the provider being multilingual. The pooled means from the imputed data are also given in the chart below, both charts contain very similar numbers for the means.
Table 3: Descriptive Statistics Table

The data for location, years of practice, race, and whether or not the doctor spoke one or more language (multilingual) were further analyzed using cross-tabulation bar charts. The chart for specialty (Figure 2) emphasizes the large amount of respondents from family medicine, surgery, and pediatrics. The chart for years of practice (Figure 3) indicates that most of the respondents to the dichotomous variable of ever referred where from physicians who have been practicing for over 15 years. Similarly, the bar chart for location of practice (Figure 4) demonstrates the majority of the respondents to the dichotomous variable of “ever referred”
where in private practice. The bar chart regarding race (Figure 5) indicates the physicians who responded where predominately Non-Latino White and of the few who identified as Latino physicians, all had referred a patient into clinical trials. The bar chart regarding the variable of the physician being multilingual (Figure 6) shows a larger amount of those who did not refer did not speak more than one language as compared to those who did refer and did not speak more than one language. Race, years of practice, and location (of practice), and specialty were not placed in the logistic regression model. Race, location (of practice), and specialty were primarily placed in the survey to assess bias in our sample. Using the variables in our logistic regression model would be quite challenging because of the large sample size needed to assess so many variables, one variable for each race, one variable for each of the locations (of practice), and one variable for each of the specialties. The charts below are from the original data and help to visually represent the makeup of our sample and those who did or did not refer a patient into clinical trials.
Figure 2: Specialty and Ever Referred Cross-Tabulation Bar Chart
Figure 3: Years of Practice and Ever Referred Cross-Tabulation Bar Chart: The numbers within the bars indicate the number of physicians who responded in each category.
Figure 4: Location and Ever Referred Cross-Tabulation Bar Chart: The numbers within the bars indicate the number of physicians who responded in each category.
Figure 5: Race and Ever Referred Cross-Tabulation Bar Chart. The numbers within the bars indicate the number of physicians who responded in each category.
Figure 6: Multilingual and Ever Referred Cross-Tabulation Bar Chart: The numbers within the bars indicate the number of physicians who responded in each category.

Variable Selection

From the imputed data, univariate analysis was conducted using each of the possible predictors to determine the independent variables to use in the binary logistic regression model. The predictors did not advance to the logistic regression model if their significance was above .25 after pooled univariate analysis (Bendel and Afifi, 1977; Costanza and Afifi, 1979; Sperandei, 2014). The categorical variable of Years of Practice was initially analyzed using the
four categories of Years of Practice listed in the survey (0-5 years, 5-10 years, 10-15 years, and >15 years). Separately analyzing Years of Practice by the categories listed in the survey resulted in significances greater than \( p > .25 \) (See Table 4). We then chose to divide the 4 Years of Practice categories into a dichotomous variable by dividing the categories into practicing greater than ten years or practicing less than ten years; as a result, the variable was then labeled Years of Practice (Binary). The resulting significance from the variable Years of Practice (Binary) is greater than \( p > .25 \) (\( p = .728 \), \( OR = 1.956 \), 95% C.I. = .486-7.867). The variables which were not used in the model included Years of Practice (Binary) (\( p = .345 \), \( OR = 1.956 \), 95 % C.I. = .486 – 7.867) Conflict of Interest (\( p = .548 \), \( OR = .833 \), 95% C.I. =.459-1.511) and Trust in Medical Researchers (\( p = .656 \), \( OR = 1.135 \), 95% C.I. = .650-1.983) (Bendel 1977;Costanza 1979;Sperandei 2014). In contrast, the variables included in the model were Multilingual, Unsure Where to Refer, Lack of Information, Trials Not Appropriate, Other Primary Language (Patient), and Informed by Investigators (see Table 5).

<table>
<thead>
<tr>
<th>Years of Practice Variable Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>B</strong></td>
</tr>
<tr>
<td>Pooled</td>
</tr>
<tr>
<td>5-10 years</td>
</tr>
<tr>
<td>10-15 years</td>
</tr>
<tr>
<td>&gt;15 years</td>
</tr>
</tbody>
</table>

Table 4: Years of Practice Variable Analysis
Table 5: Variable Analysis

The Box-Tidwell test was performed on the variables included in the model to assess multicollinearity. None of the variables were indicative of significant multicollinearity from the pooled output. Multicollinearity is when explanatory variables are substantially correlated in a
regression model which can cause unstable significance testing and biased standard errors (Vatcheva et al., 2016).

The frequency data for specialty displays the types of doctors who participated in the survey; however, the largest groups represented in this study are the specialties of family medicine, surgery, and pediatrics (Table 6) with percentages of 29.8%, 17.0% and 10.6%, respectively. In two cases the participants did not indicate their specialty and are labeled as not reported in Table 5. The variety of specialties can be easily seen using Figure 7. The small number of respondents from specialists is unsurprising seeing that Texas has “fewer specialists per capita than national averages.” Although, Texas does have higher than average per capita numbers for the specialties of transplant surgery as well as colon and rectal surgery (Singleton et al., 2015). This may explain why our questionnaire received a large percentage (17.0%) of surgery specialists. Although, a variety of medical specialties were sampled using the questionnaire a majority of the respondents practiced in a private practice setting (87.23%), as can be seen by Figure 8.
<table>
<thead>
<tr>
<th>Specialty</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>3</td>
<td>6.4</td>
</tr>
<tr>
<td>Dermatology</td>
<td>2</td>
<td>4.3</td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Family Medicine</td>
<td>14</td>
<td>29.8</td>
</tr>
<tr>
<td>Hypertension/ Lipidology</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>3</td>
<td>6.4</td>
</tr>
<tr>
<td>Not Reported</td>
<td>2</td>
<td>4.3</td>
</tr>
<tr>
<td>OB-GYN</td>
<td>2</td>
<td>4.3</td>
</tr>
<tr>
<td>Opthamology</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Otolarngology</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Pain Management</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>5</td>
<td>10.6</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Pulmonary Disease</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Surgery</td>
<td>8</td>
<td>17.0</td>
</tr>
<tr>
<td>Wound Care</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*Table 6: Specialty Table*
Figure 7: Specialty Pie Chart
The demographics of the physicians who responded (Table 7) revealed that the majority (59.6%) of the physicians identified as Non-Latino White and many physicians identified themselves in the other category (25.5%). The African American (6.4%) and Latino (6.4%) races were the least represented in our sample. This is unsurprising because underrepresentation of both Black and Hispanic physicians in Texas has been cited as an issue. This problem necessitates an addition of Black and Hispanic physicians to achieve greater diversity to reflect the diversity of the general population in Texas (Kazemier et al., 2015). In one case the respondent did not indicate their race and is therefore labeled as “Not Reported” in Table 7.

*Figure 8: Location Pie Chart*
Race

<table>
<thead>
<tr>
<th>Original data</th>
<th>Frequency</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>Latino</td>
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<td>6.4</td>
</tr>
<tr>
<td>Non-Latino White</td>
<td>28</td>
<td>59.6</td>
</tr>
<tr>
<td>Non-Latino African American</td>
<td>3</td>
<td>6.4</td>
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<tr>
<td>Not Reported</td>
<td>1</td>
<td>2.1</td>
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<tr>
<td>Other</td>
<td>12</td>
<td>25.5</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 7: Race Table

Model Building

Table 9 contains the results of the binary logistic regression model which found time and trials not appropriate to be statistically significant with a statistical significance of p=.023 (OR = .301, 95% CI = .107-.848) and p=.021 (OR = 3.395, 95% CI = 1.201-9.596), respectively. The odds ratios indicate that an increase of 1 point on the Likert scale question of “trials not being appropriate for the patients” is associated with a physician being three times less likely to refer a patient into clinical trials. The odds ratio for the time variable indicate that an increase of 1 point on the Likert scale under the question “I do not have the time necessary to refer patients to clinical trials” is associated with a decreased likelihood of not referring a patient into clinical trials. In 2009 Galvin et al. also found time as significant variable of physician referral of patients into clinical trials in “Predictors of physician referral for patient recruitment to Alzheimer disease clinical trials.” His research determined time to be a barrier to physician referral of patients into clinical trials.

Taking a closer look at the answer from our data on whether or not a physician referred a patient and the question of whether or not the physician believes they “do not have the time to refer patients to clinical trials,” further justifies the results of the logistic regression (Figure 9). From our data more physicians who referred a patient into clinical trials decided to “mildly agree” or “strongly agree” with the statement that “they do not have the time to refer patients
into clinical trials” as compared to those who have never referred patients into clinical trials. Although seemingly counterintuitive, this may be due to the fact that physicians who have previously referred a patient into clinical trials are aware of how much time is needed to refer a patient into clinical trials and therefore in their current state they do not have time to refer patients into clinical trials, or the physicians make time to refer the patients even though they do not have the time.

Figure 9: Time and Ever Referred Cross-Tabulation Bar Chart: The numbers within the bars indicate the number of physicians who responded in each category.
The data from cross tabulation (Table 8) further exhibits the reason time is considered clinically significant. Of the respondent who answered yes to having referred a patient into clinical trials 43.4% (30.4% + 13.0%) mildly or strongly agreed with the statement “I do not have time to refer patients into clinical trials”, compared to only 25% (20.8%+4.2%) of those who have never referred a patient into clinical trials. This demonstrates that a large percentage (43.4%) of physicians who have referred patients into clinical trials in our survey, believe that they do not have time to refer patients into clinical trials.

<table>
<thead>
<tr>
<th>Ever Referred and Time Cross-Tabulation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Original data</td>
</tr>
<tr>
<td>yes</td>
</tr>
<tr>
<td>% within Ever Referred</td>
</tr>
<tr>
<td>% of Total</td>
</tr>
<tr>
<td>no</td>
</tr>
<tr>
<td>% within Ever Referred</td>
</tr>
<tr>
<td>% of Total</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>% within Ever Referred</td>
</tr>
<tr>
<td>% of Total</td>
</tr>
</tbody>
</table>

Table 8: Ever Referred and Time Cross-Tabulation Table

These data suggest the belief that “trials are not appropriate for patients” is associated with a physician being 3 times less likely to refer a patient into clinical trials as they move up one unit of the Likert scale (OR=3.395, 95%, p=.021, CI=.430, 13.414) The significance of the respondents’ belief that the trials are not appropriate for the patient is reasonable (See Table 9). The lack of engagement by physicians in clinical research and the disjunction between scientific
research and clinical care have been suggested as a reason why physicians might not be able to determine whether participating in a trial or undergoing standard treatment is a better option for their patient. Furthermore, the aforementioned effects could be detrimental to the developer and those involved in the approval process of the drug. The narrow inclusion criteria associated with some trials may exclude many patients who have the ailment for which the drug is intended (English et al., 2010). Excluding such patients allows for an experiment devoid of potential confounders such as a comorbidity or concurrent medications the patient may be taking (Kramer et al., 2012). Ultimately, these restrictions to enrollment help to “simplify the trial itself” at the cost of increasing the difficulty of recruiting patients for participation into the trial (Birkenbach et al., 2014). In earlier phases of clinical trials these restrictions are particularly necessary to facilitate the ease of determining efficacy and therapeutic dose. However, when stringent criteria are employed in the advanced phases of trials it becomes harder to gain the necessary number of participants and can result in a lengthening of the recruitment process (Kramer et al., 2012). The problem of recruitment is further evidenced in some protocol amendments. Nine percent of protocol amendments are due to obstacles of recruiting patients for participation in clinical trials (Birkenbach et al., 2014). There is also a chance that the referring physician may not be informed about the inclusion criteria and this can dissuade him from referral into clinical trials.
The model correctly predicted 72.1% of the cases in the original data with a sensitivity of 71.4% and a specificity of 72.7%. The model correctly predicted over 70% of cases in each of the imputed models as well (See Table 9). Pseudo $R^2$ values for the model were also calculated with the Cox and Snell $R^2$ value displaying that the model explains 34.1% of the variance in referral of patients and the Nagelkerke $R^2$ stating that model explains 45.4% of the variance in the original data. The imputed data displayed a Cox & Snell $R^2$ value of greater than 32% for each of the imputations and a Nagelke $R^2$ value of greater than 42.8% in each of the imputations (See Table 11).

### Table 9: Variables in the Equation Table

<table>
<thead>
<tr>
<th>Variables in the Equation$^a$</th>
<th>B</th>
<th>S.E.</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>95% C.I.for EXP(B)</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
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<tr>
<td>Pooled</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>.318</td>
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<td>.430</td>
<td>13.414</td>
<td></td>
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<tr>
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<td>.649</td>
<td>1.311</td>
<td>.408</td>
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<td>.803</td>
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<td>Time</td>
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<td>.528</td>
<td>.023</td>
<td>.301</td>
<td>.107</td>
<td>.848</td>
<td></td>
</tr>
<tr>
<td>Trials Not Appropriate</td>
<td>1.222</td>
<td>.528</td>
<td>.021</td>
<td>3.395</td>
<td>1.201</td>
<td>9.596</td>
<td></td>
</tr>
<tr>
<td>Other Primary Language (Patient)</td>
<td>-.525</td>
<td>.418</td>
<td>.209</td>
<td>.592</td>
<td>.261</td>
<td>1.341</td>
<td></td>
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<tr>
<td>Informed by investigators</td>
<td>.291</td>
<td>.325</td>
<td>.371</td>
<td>1.338</td>
<td>.707</td>
<td>2.532</td>
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</tr>
<tr>
<td>Constant</td>
<td>-3.404</td>
<td>2.596</td>
<td>.190</td>
<td>.033</td>
<td>.000</td>
<td>5.396</td>
<td></td>
</tr>
</tbody>
</table>

$a$. Variable(s) entered on step 1: Multilingual, Lack Information, Unsure Where, Time, Trials Not Appropriate, Other Primary Language Patient, Informed by Investigators.
<table>
<thead>
<tr>
<th>Imputation Number</th>
<th>Observed</th>
<th>Predicted</th>
<th>Percentage Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Ever Referred</td>
<td>yes</td>
</tr>
<tr>
<td>Original data</td>
<td>Ever Referred</td>
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<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
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<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Ever Referred</td>
<td>yes</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Ever Referred</td>
<td>yes</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Ever Referred</td>
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<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Ever Referred</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Ever Referred</td>
<td>yes</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Overall Percentage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Table 10: Classification Table*
Goodness-of-fit testing

The Omnibus test indicates that the addition of the variables increases the ability to predict the decision of whether or not a physician refers a patient into clinical trials with a statistically significant value of .012 (Chi-square = 17.908, df = 7) for the original data and a significance of less than .05 in each of the imputations as well (see Table 12). This indicates that the variables included in the model do help to explain the variance in the outcome variable of whether or not a physician will refer a patient into clinical trials. Similarly, the Hosmer and Lemeshow goodness-of-fit test demonstrates that there is no significant difference between the observed frequencies and the predicted frequencies. The result of the Hosmer Lemeshow test exhibited a Chi-square value of 10.355 (p>.24, df = 8) according to the original data, each of the imputations maintained a significance of p>.05. We may, thus, reject the null hypothesis that there is a significant difference between the observed and predicted frequencies in the original data and each of the imputations with a significance of p >.05 in the model and each of the imputations.
Omnibus Tests of Model Coefficients

<table>
<thead>
<tr>
<th>Imputation Number</th>
<th>Chi-square</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Data: Model</td>
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<td>7</td>
<td>.012</td>
</tr>
<tr>
<td>Imputation 1: Model</td>
<td>18.228</td>
<td>7</td>
<td>.011</td>
</tr>
<tr>
<td>Imputation 2: Model</td>
<td>18.940</td>
<td>7</td>
<td>.008</td>
</tr>
<tr>
<td>Imputation 3: Model</td>
<td>21.490</td>
<td>7</td>
<td>.003</td>
</tr>
<tr>
<td>Imputation 4: Model</td>
<td>18.228</td>
<td>7</td>
<td>.011</td>
</tr>
<tr>
<td>Imputation 5: Model</td>
<td>21.200</td>
<td>7</td>
<td>.003</td>
</tr>
</tbody>
</table>

*Table 12: Omnibus Test of Coefficients*

**SUMMARY AND CONCLUSION**

A logistic regression was performed to determine the effects of time, lack of information, being multilingual, unsure where to refer patients, inappropriate trials, and the patient having another primary language on the likelihood that a physician will not refer a patient into clinical trials. Forty-seven surveys were analyzed with 23 physicians having referred a patient into clinical trials and 24 physicians who have never referred a patient into clinical trials. According to the Omnibus Test of Model Coefficients the logistic regression model was significant with Chi-squared value of 17.908 (p=.012, df=7) for the original data. Each of the multiple imputations displayed a Chi-squared value of greater than 18 (p<.012, df=7). The model was also significant according to the Hosmer Lemeshow goodness-of-fit test with a Chi-square value of 10.355 (p>.24, df = 8) according to the original data, each of the imputations maintained a significance of p>.05. The majority of the data in the sample came from the specialties of family medicine, surgery, and pediatrics which comprised 29.8%, 17% and 10.6% of our sample, respectively. Our sample population also consisted predominately of Non-Latino White physicians (59.6%) and physicians who were in private practices (87.23%). Although lack of knowledge about clinical trials, language barriers, conflict of interest, communication with local
investigators, and trust in medical researchers were not significant variables in determining whether or not a physician referred a patient into clinical trials, the model built suggests that time and trials not appropriate for patients are significant variables, when trying to explain the likelihood of referral.

The logistic regression model explains 45.4% (Nagelkere R²) of the variance in the decision of a physician to not refer a patient into clinical trials and correctly classified 76.7% of the cases in the original data. An increase in the belief that the trials are not appropriate was associated with a physician being 3 times less likely to refer a patient into clinical trials with a statistical significance of p=.021 (OR = 3.395, 95% CI =1.201-9.596). An increase in the belief that the physician does not have time to refer a patient into clinical trials is associated with a 69.9% decrease in the chance not referring a patient into clinical trials with a statistical significance of p=.023 (OR = .301, 95% CI = .107-.848).

**LIMITATIONS**

Limitations to the study may include bias due to sampling and sample size. With a larger sample size there may have been more variation in answers which could lead to the determination of more variables to be put into the model. An increase in the diversity of the samples location of practice, race, and specialty may have influenced the data as well. The sample obtained for this survey was a convenience sample which did not utilize any randomizing techniques. There are many physicians in both Dallas and Tarrant county and this survey may not accurately represent the opinions of physicians in both counties.

The question regarding race in the questionnaire includes Non-Latino African American, Non-Latino White, Latino, and Other / Not Reported; the Other / Not Reported category has the potential to miss further races such as Asian and Native American.
The question regarding the years of practice has the possibility of being unclear because of lack of specificity. Rephrasing the question to state the following may have been beneficial: how long have you been practicing in your current specialty after graduating from medical school? This would help to make sure that the respondents had an answer which could be standardized by graduation from medical school, thus yielding more quantitative data.

While gathering the data some physicians commented that they did not believe the questionnaire was addressed to them and thought it was addressed to the principal investigator. This problem may have been due to the survey stating the name of the principal investigator at the beginning of the survey (Appendix D). Therefore, I believe restructuring the layout of the cover letter so that it starts with a note to the doctor and ends with the name of the principal investigator and student investigator may have been helpful in increasing the participation of physicians.

The cover letter delivered with the survey also contains a typographical error stating that those in “Dallas county and the city of Fort Worth” were chosen to participate; however, the survey was intended for physicians practicing throughout Tarrant County and not just in the City of Fort Worth. Although completed surveys were picked up from within Tarrant County and outside of Fort Worth, some physicians may have not participated due to this error.

The question regarding time may also be misinterpreted due to the double negative in the question. The question states “I do not have the time to refer patients into clinical trials” with the answer choice on a 1-5 Likert scale starting with the number one representing completely disagree and the number five representing completely agree. It is also possible that the doctor who have referred patients into clinical trials have an idea of how time consuming referral of a
patient into clinical trials may be and therefore are more likely to consider time a “reason for not referring patients into clinical trials”.

If the analysis was to be performed again it would be beneficial to address the aforementioned problems including the question about race, the question regarding time, and the layout of the survey. It would also be wise to maybe encourage further physician participation with incentives and to change the question regarding year in practice to a continuous rather than categorical response.

FUTURE RESEARCH

Future research on the barriers associated with referral of patients into clinical trials may be helpful in increasing the enrollment of patients into clinical trials. Specifically, further research into the various reasons doctors may consider the available clinical trials to be inappropriate for their patients. Although, some have suggested that it might be hard for physicians to determine the benefit of their patient participating in a clinical trial or undergoing standard treatment. This may in part be due to the divide between scientific research and clinical care of patients. This divide is amplified due to the lack of training in research methods among many healthcare professionals (Bonham et al., 2011). It is also possible that doctors may not consider their patient to be appropriate for the clinical trials available due to the exclusion criteria. Similarly, the narrow inclusion criteria associated with some trials may prohibit many patients who have the ailment which the drug is intended (English et al., 2010). Ultimately, these restrictions to enrollment help to “simplify the trial itself” at the cost of increasing the difficulty of recruiting patients for participation into the trial (Birkenbach et al., 2014). However, if some physicians consider the inclusion criteria too stringent, and therefore inappropriate for their patients, future research may help to find ways to increase recruitment of patients into clinical
trials by physicians despite stringent inclusion criteria. For example, the use of technology in the screening and recruitment to increase the efficiency of clinical trials is an area for improvement (Kramer et al., 2012). Further use of technology in recruitment for clinical trials may be used to help keep doctors informed about clinical trials and help to make it easier for doctors to determine if the clinical trial is more beneficial for their patient as compared to the standard treatment available. This may lead to an increase in the amount physicians considering the available clinical trials to be appropriate for their patients.

Our data suggests that drug developers could focus on how to improve the process of referral into a trial, with respect to the amount of time it takes for referring physicians. Further research concerning physician lack of time as a facilitator of referral into clinical trials may also be helpful in determining why doctors who have referred patients into clinical trials might consider time to be a significant barrier, as compared to those who have never referred patients into clinical trials. Similarly, it may also be of interest to discover whether or not physicians who have recruited patients into clinical trials consider the process to be a pleasant experience or if they consider it to be too time consuming. Our outcome concerning the time variable was very unexpected due to previous research by Ramirez et al. (2012) and Galvin et al. (2009) which found time to be a significant barrier to referral of patients into clinical trials. Therefore, further research into why physicians who have referred patients into clinical trials might not believe they have the time to refer a patient into clinical trials could help to identify a problem associated with the experience doctors may have when engaged in clinical trials.
CHAPTER III
INTERNSHIP SITE

My research internship practicum was completed at North Texas Clinical Trials in Ft. Worth, Texas under the site director Dr. Brian Maynard, PhD. Jessica Anderson, CRC, was in charge of data management, investigational drug, regulatory matters, and lab testing. The clinical research site was focused on primarily neurological and psychiatric trials during my time working alongside the staff.

North Texas Clinical Trials was established near Fort Worth’s medical district in 2012. The facility primarily focuses on clinical trials related to Central Nervous System disorders. The principal investigator is Dr. Sandra Davis, MD, a psychiatrist with much experience in both addiction and pediatrics. The staff has a collective experience of over a decade in performing pharmaceutical trials in the Dallas-Fort Worth area.
JOURNAL SUMMARY

During my internship at North Texas Clinical Trials I have been able to see some of the difficulties associated with executing clinical trials. I also conversed with the various staff members, who have been in the clinical trial industry for an extensive amount of time, and discovered some of the major difficulties currently associated with clinical trials. Patient recruitment was one of the hindrances that was regularly noted as a difficult part of performing clinical trials. I soon discovered the problem concerning lack of referral of patients into clinical trials by physicians, both through research and experience with this problem first hand at North Texas Clinical Trials. This knowledge helped me to form my research project and the questions that would be asked in my survey.

While at North Texas Clinical Trials I sat in on various important staff meetings and conference calls. I was also able to analyze the agreements and other major documents concerning site participation in clinical trials. These experiences have allowed me to gain insight into management of clinical research sites and the steps which must be taken to start a clinical research trial at a facility. I also had the advantage of getting to have one on one conversations with Dr. Maynard, site owner, about the benefits and struggles of clinical research management.

At North Texas Clinical Trials I had the pleasure of working with a great staff who helped me develop skills for employment in the clinical trials industry. In reference to regulatory work, I helped to file important documents, write note to files, keep track of informed consents, get patient packets ready, create lab kits, and break down lab kits. I was also able to help prepare data from previously closed studies for long term storage. I was also able to assist in drug storage and accountability as well. I was also able to help enter data into the electronic data resource, mark things that necessitated signatures, interact with the monitors, perform some of the patient
tests, as well as help with some of the lab processing. A large part of my stay at North Texas Clinical Trials was spent contacting current patients, scheduling current patients, and recruiting future patients for clinical trials.
Appendix A
VARIABLE AND QUESTION TABLE
<table>
<thead>
<tr>
<th>Variables</th>
<th>Questions</th>
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<tbody>
<tr>
<td>Years of Practice</td>
<td>How many years have you been in your practice?</td>
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<tr>
<td>Multilingual</td>
<td>Do you speak more than one language?</td>
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<tr>
<td>Ever Referred</td>
<td>Have you ever referred patients for participation in clinical trials?</td>
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<tr>
<td>Lack Information</td>
<td>I lack access to information about clinical trials</td>
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<tr>
<td>Unsure Where to Refer</td>
<td>I am unsure where to refer patients to clinical trials</td>
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<tr>
<td>Time</td>
<td>I do not have the time necessary to refer patients to clinical trials</td>
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<tr>
<td>Trials Not Appropriate</td>
<td>The trials available are not appropriate for my patients</td>
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<tr>
<td>Conflict of Interest</td>
<td>I fear being perceived as having a conflict of interest by patient when referring them to clinical trials</td>
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<tr>
<td>Trust in Medical Researchers</td>
<td>I completely trust medical researchers</td>
</tr>
<tr>
<td>Other Primary Language (Patient)</td>
<td>I believe my patients who have a primary language other than English may find the clinical trial difficult to participate in</td>
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<td>Informed by Investigators</td>
<td>Investigators near me have kept me informed about their studies</td>
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Appendix B
CITIES IN DALLAS COUNTY
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Appendix C
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APPENDIX D

COVER LETTER AND SURVEY
Title: Obstacles Associated with Physician Referral of patients into Clinical Trials
Institution: University of North Texas Health Science Center
Principal Investigator: Dr. Lisa Hodge, Ph.D., Associate Professor
Student Investigator: Nick Torrez

Introduction:
A study is being conducted to ascertain obstacles associated with referring patients for enrollment in clinical trials. Identifying these obstacles may help to develop strategies that can help to improve medical research and increase the number of patients enrolled in clinical trials to ensure the reliability of new therapeutic techniques.

You have been selected to partake in this study because you are a physician in Dallas County or in the city of Fort Worth. The questionnaire attached will gather your ideas on clinical research. The survey should take no more than 10 minutes and your participation is appreciated.

Risk: There is not an apparent foreseeable risk associated with participating in this study.

Benefit: There is no precise benefit associated with participating in the study; however, the study allows an opportunity for physicians to express their concerns associated with referring patients to clinical trials. These concerns may then be identified so that future research may address the concerns to benefit both the physician and the patient when recruiting patients for future trials.

Agreement to participate: Participation by physicians in the study is voluntary. If you wish to participate in the study, please fill out the survey and it will be picked up once completed. You may also complete the survey online at the following website:
The survey should be completed by February 15th of 2017.

Confidentiality: The survey will not ask for any identifiable information.

Leaving the study: Once the study has been completed and sent in the mail there is no way to withdraw from the study due to the lack of identifiable information.

Questions and Concerns: If you have any questions in regards to the research you may contact the following:

Student Investigator: Nick Torrez, Email: Nick.Torrez@my.unthsc.edu, Phone: 817-718-4509.

If you may have questions about your rights as a research subject, please contact the University of North Texas Health Science Center Institutional Review Board at 817-735-0409.

Thank you for your participation in this study.
1. How many years have you been in your practice?
   a. 0-5
   b. 5-10
   c. 10-15
   d. >15

2. What is your Race/ Ethnicity?
   a. Non-Latino White
   b. Non-Latino African American
   c. Latino
   d. Other/ not reported

3. Do you speak more than one language?
   a. Yes
   b. No

4. What is your specialty?

5. Location of your practice?
   a. Academic/ Teaching hospital
   b. Private Practice
   c. Community hospital
   d. Other

6. Have you ever referred patients for participation in clinical trials?
   a. Yes
   b. No

For each statement below, please circle the number that best characterizes how you feel about the statement, on a scale of 1-5 with 1 = Strongly Disagree, and 5 = Strongly Agree.

7. I lack access to information about clinical trials
   \[\text{Strongly Disagree} \quad \text{Mildly Disagree} \quad \text{Neutral} \quad \text{Mildly Agree} \quad \text{Strongly Agree}\]
   \[1 \quad 2 \quad 3 \quad 4 \quad 5\]

8. I am unsure where to refer patients to clinical trials
   \[\text{Strongly Disagree} \quad \text{Mildly Disagree} \quad \text{Neutral} \quad \text{Mildly Agree} \quad \text{Strongly Agree}\]
   \[1 \quad 2 \quad 3 \quad 4 \quad 5\]

9. I do not have the time necessary to refer patients to clinical trials
   \[\text{Strongly Disagree} \quad \text{Mildly Disagree} \quad \text{Neutral} \quad \text{Mildly Agree} \quad \text{Strongly Agree}\]
   \[1 \quad 2 \quad 3 \quad 4 \quad 5\]

10. The trials available are not appropriate for my patients
11. I fear being perceived as having a conflict of interest by patients when referring them to clinical trials

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Mildly Disagree</th>
<th>Neutral</th>
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<th>Strongly Agree</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</table>

12. I completely trust medical researchers

<table>
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<tr>
<td>1</td>
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<td>3</td>
<td>4</td>
<td>5</td>
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</table>

13. I believe my patients who have a primary language other than English may find the clinical trial difficult to participate in

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Mildly Disagree</th>
<th>Neutral</th>
<th>Mildly Agree</th>
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<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</table>

14. Investigators near me have kept me informed about their studies

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<th>Strongly Disagree</th>
<th>Mildly Disagree</th>
<th>Neutral</th>
<th>Mildly Agree</th>
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<td>1</td>
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<td>4</td>
<td>5</td>
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</tbody>
</table>
APPENDIX E

INTERNSHIP JOURNAL
Monday, August 15, 2016

This visit primarily focused on getting acquainted with the layout of the site and where everything is stored. I was introduced to the members of the site that were there. I was also able to see the various databases used for entering information into the system for patients. I was able to help search through some of the protocol books to find necessary forms and make copies of them. This helped me to realize the wide array of forms used in clinical research. The forms are also fairly detailed. I was also instructed on the fact that anytime anything is marked through the person who made the strikethrough must sign and date next to it as confirmation of who administered the strikethrough. I also reviewed some of the protocol.

Towards the end of the day I learned about the various procedures involved in closing the site for the day and the what must be locked. I also learned what procedures usually take place during each day of the week and the schedule I will have with the site.

Tuesday, August 16, 2016

I tried to assess why the protocol was set up in such a way. It seems that many of the procedures present help to assure the validity of the results and of diagnosis. This was very informative because the subject matter of the research is a difficult topic but has the ability to help influence many lives. The use of a third party to assure that the diagnosis is correct is an example of a precautionary step that I believe is unique to this type of study. The timeline of screening, starting the medication, and then going through a washout phase is something I did expect. However, some of the research trials allow for an open trial be offered after the subject has finished the initial trial. This seems very efficient because it allows both benefit to the patient if they have been responding well to the drug and gives long term data to the company from a familiar patient.

Wednesday, August 17, 2016

This day focused on helping make copies and getting to learn where things are placed in patient binders. The patients each have a binder with various forms that have been signed including the most up to date informed consent available. We were also able to get any of the necessary forms ready for subjects who would be coming in soon. This stack of forms we got ready included scales to assess the patient and other protocol forms like informed consent. The scales we needed were determined by a small chart in the back of the protocol book which was very handy.

I was also able to sit in on a teleconference between Dr. Maynard and a company. The teleconference was very informative because it showed the initial steps of requesting the startup of a trial with a company. This process involved the company representative asking many questions including: What are the qualifications of the employees? How many clinical trials do they have going on? What is the setup of the site? If the site was familiar with the procedures?
The company representative also gave a basic summary of current information about the trial. I really appreciated this opportunity to get to sit in on the trial start up process.

Thursday, August 18, 2016

I realized the many scales used in the trial are a way to also assess whether the subject is mentally safe to stay in the study as well as assess if the drug has any adverse side effects. I was also able to understand the concept that companies must sell themselves and their faculty to trials to be considered as a site. The call from the previous day also asked for documentation of the qualifications of the employees which seems to be a basic procedural rule, however I realize that this is a very important step in determining whether a site will receive a clinical trial or not.

Friday, August 19, 2016

The day started with the doctor looking at and signing off on patient documents. The patients which we saw seemed very normal initially, which I believe is a testament to how the medication is able to help the subjects. I was able to see the scales used to assess the patient and the general physical exam which was performed. There were also some scales which involved assessing the patients handwriting. I believe this scale to be very beneficial because it can help determine the functional effect that a drug will have in reducing the stresses associated with the condition in what to many seems like a very simple task. The doctor also showed me what cog wheeling was and how to identify it. I was also able to see the parkinsonian symptom present while a patient was trying to perform a certain focused intent task.

I was also shown the many trainings that staff must participate in online to assure that they are qualified to do certain tasks. I was also shown how to set up the recording device for patients before they are interviewed. The recording task is done through a third party hired by the trial company, not the site, and seems efficient in keeping track of the recordings and transmitting them to another person who confirms that the patient has the condition necessary for qualification in the study.

Monday, August 22, 2016

I was able to review some of the different scales for each of the studies to see how they differ in relation to the scope of the study they are assigned to. It seems that the Abnormal Involuntary Movement Scale (AIMS) is very popular across the various studies on Dyskinesia. This is very reassuring because it allows the results to be compared within the study and with the results from other similar research. Some of the protocols also call for analysis by a third party to assure that certain criteria are met for patient inclusion and progress; this method seems to be a good way to assure that a patient is diagnosed correctly and is doing well.

I was also able to help with the assembly of binders for patients and learning where certain data belongs in the binder. During the end of the day I got to help get things ready for a patient which would be coming in to have labs drawn.
Tuesday, August 23, 2016

Understanding some of the scales was a major part of this day. Including learning the acronyms such as the Y-BOCS and CSSRS. Some of the scales also require video recording so that a patients’ improvement may be assessed. However, it is necessary to review the protocol for the various scales given to patients. It seems that the majority of the scales are given during the baseline visit. I believe this approach allows for patient improvement to be adequately assessed using the method most suitable for the scope of clinical research on dyskinesia, while taking into account cost effectiveness.

Wednesday, August 24, 2016

This day focused on helping to assemble binders with the necessary scales and paperwork for patients which would be visiting. A new study added had a significant difference in scales. I also learned that to administer the scales you must be trained, usually each scale involves a new training. The scales involved in the newest study are very straightforward but also seem to test the motor movement of the patients in a very different way, using handwriting; therefore, I believe this scale has the chance to improve patient assessment greatly by testing a basic functional movement which the patient probably uses daily and an improvement in this action will likely have a significant impact on quality of life.

A speaker also came to visit who had Tourette’s Syndrome. Her speech consisted of a brief description of Tourette’s, what it is like for a child with Tourette’s, a Tourette’s activity, and a question and answer session. The activity was really effective in helping me relate to the patients in the clinic during the preceding days.

Thursday, August 25, 2016

The Tourette’s Syndrome speech given the day before allowed me to reflect on the various methods used in assessing a patient. This helped me realize the various symptoms of Tourette’s which she described in the context of assessments used. The statements which she made also made apparent the fact that currently there are not any great treatments for Tourette’s Syndrome; consequently, my appreciation for the impact that the research performed in the clinic may have in the lives of various people who are struggling with the syndrome is humbling.

Through my observations, I was also able to see the many different which Tourette’s Syndrome impacts the lives of those suffering from the syndrome. Many of the patients have little evidence of the syndrome to the untrained eye and I was unable to notice any tics at first; however, there are also some patients who have tics which are more apparent. The impact that these tics have on the lives of the different patients is varied. This makes me wonder if there is a correlation between dosage and severity of tics in the clinical trials? I believe this will likely be solved during phase III studies.

Friday, August 26, 2016

This day began with the observation of 4 patients. This included helping set up the rooms and the ECG machines. I also helped to prepare kits necessary for each patient which included
various test and vials to be run. I was informed that there are stickers, patient numbers, and visit
dates which are placed on the majority of the data collected from the patients.

I also helped to mark outpatient sensitive information from medical records during an
early termination. I was informed of the various processes which must take place during an early
termination. It seems that an early termination visit is very similar to the regular last visit in
regards to the various procedures as well as assessment scales used.

Monday, August 29, 2016

I was instructed on some parts of EDC and how information is entered electronically. I
was also able to see some of the process that goes into dealing with a Serious Adverse Event
(SAE). I was able to help organize the various scales used and was able to see how some of the
scales could potentially diagnose mental health conditions.

Before helping out at the site I wondered how a correct diagnosis would be obtained for a
psychiatric condition and how the accuracy of the diagnosis would be assessed. Now that I have
seen parts of the process, I realize that during clinical research on psychiatric illness there is
great emphasis on scales for assessment of patients. The research part of the process comes into
play when a second unidentifiable diagnose is used to affirm a diagnosis using a recording.

Tuesday, August 30, 2016

After understanding some of the various scales. I realized how difficult it us be to have
accurate information in psychiatry. This may ultimately affect the passage of psychiatric drugs
through the phases of drug development and ultimately delay the approval of a drug. Therefore,
it seems that development of drug for psychiatric disorders is an important process, especially
considering the population in need.

Wednesday, August 31, 2016

There were many patients in the office today. I was able to set up binders for many of the
patients and learn how certain headings must be filled out and how the informed consent process
works. The various patients were very pleasant and many of them displayed signs of need. The
idea of people with a psychiatric illness who are so in need of a remedy that they will try a new
drug which they know little about is humbling. I believe this demonstrates true courage to fight
to regain control of your life. I am inspired by the strength displayed by many of the patients.

Thursday, September 1, 2016

This day was insightful because it allowed me to reflect on the need of the population
addressed by the drugs utilized in the clinical trials on site. Currently there is no standard
prescription for many of the conditions which the drugs plan to market toward and it is nice to
see the development of a groundbreaking drug that has the potential to change lives for the
better. I am also amazed at how each of these participants have different interest in mind when
joining the study but will ultimately be a part of the development of a medication that will help to treat others with their same condition; consequently, children who have the condition may have the opportunity for a symptomless life.

Friday, September 2, 2016

This day was very hectic and fun. The binders which were put together were utilized in the patients’ rooms to take notes and fill out paperwork. Many of the documents require someone to double check them and a large part of the end of the day was spent on making sure everything was in order and that we had everything filled out. The patients were very kind and seemed to be doing well.

Monday, September 5, 2016

Labor day

Tuesday, September 6, 2016

This day was focused on addressing my topic and understanding how I might incorporate some of my experience with the site in developing my topic. I believe the large influx of referrals from a recent ad placed on the radio by the drug company sponsor can help me when trying to understand the logistics of acquiring patients for studies.

Wednesday, September 7, 2016

Today involved seeing many patients and making sure that all of the source documents and scales were signed and proper protocol was followed. I was also able to help call some of the referrals and schedule them in for a screening visit. The referrals were then organized and placed in a database to see who we have called and who has passed the phone screening. Many of the patients were very knowledgeable about their condition; however, some were seeking a diagnosis because psychiatrists are very expensive.

Thursday, September 8, 2016

Calling referrals was a main part of my duties this day. However, I was also able to check the source documents to make sure that everything was filled out. I enjoyed speaking with many of the patients over the phone, although the first time I did it I was very nervous. The patients are very kind and honest about their condition. The conversation I had on Wednesday also helped me to realize how beneficial clinical trials can be to those who are undiagnosed. This offers an opportunity for a diagnosis which can be life changing and otherwise unaffordable. I am very happy to be helping at a site that does so much for a population which can be overlooked at sometimes.
Friday, September 9, 2016

This day had the most patients scheduled since I have been at the site. Everything was very smooth and all of the patients were ultimately pleased with their experience. Many of the patients were new screens; therefore, I was able to see how much went into screening a patient for the clinical trial. Some of the patients failed screening and this was disappointing to many of the staff members due to the work put in and the fact that some of them were diagnosed but unable to participate due to other circumstances. After the patient visit we thoroughly checked many of the documents and prepared the documents for EDC entry. I am still a little confused about the specifics of EDC entry and the any purposes it serves. It also seems like it would be a good idea for an EDC system to be invented which automatically updates the staff on what the next patients visit looks like and the various documents that they must have processed at this visit and the labs that must be undergone.

Monday, September 12, 2016

I was able to help order some of the things necessary for the office and for some of the upcoming trials. I was showed how there is usually a set list of things necessary for the site to have before starting trials for some companies. To start the trials as quick as possible it is best to have all of the things that are on the list. This allows for a quick and efficient start to performing the clinical trials. I believe there are many ways of ordering supplies, one of them being a third party organization. The fact that a third party can be used helps to show ways in which the clinical trials community is influential in the purchase of medical supplies. The current trials at the site are very interesting.

Tuesday, September 13, 2016

I spent part of the day helping to label some of the newly delivered kits and place them in the correct area. There labels on the kit are very specific and give an expiration date. It is very important to look at the expiration date and the type of kit when getting it ready for the patient. I am still learning how to correctly file things. Each page has a specific place and it is nice to know that clinical trial sites must be so organized. The monitors are very important in maintaining the organization at sites. This is also very beneficial for future inspections by sponsors. However, I really believe that an easier format for organization should be developed for clinical trials. The advancements in technology must be utilized by sponsors to help clinical trial sites move efficiently at an effective pace without missing any specific details. I also realize that possibility for information to get lost when using technology may be frightening to both sponsors and clinical trial investigators.

Wednesday, September 14, 2016

Today the staff and I were able to see patients. The contact that occurs with the patients has become my favorite part of conducting clinical trials. The patients are very open and comfortable with the staff and some have been in studies which are very longlasting. The
connection that some of the patients have with the staff is very trusting and inspiring to see. The new patients who are being screened also seems to be very comfortable with some of the staff. The role of a clinical trial coordinator seems to include much more than dealing with data and organization of the office; specifically, the job requires good communication skills with patients and I believe that being close to the staff at North Texas Clinical Trials has helped me to develop better communication skills. I am grateful for this because I consider it a lasting skill that is useful in many situations and across all careers.

Thursday, September 15, 2016

Today was spent helping the staff organize for tomorrow’s patients. It is also necessary to go over the data we received from patients and enter it into the electronic resource provided through a third party hired by the sponsor. The site requires a training which is necessary to make sure that those entering data are aware of what they are doing and exactly how to do it. The data can also be viewed by the sponsors. This seems like a great way for the sponsors to maintain a watchful eye on various sites and help them to maintain a good standing. The data entry process is very time consuming; however, I really appreciate the process which allows for a quick check to make sure everything is working efficiently. I also realize how important it is to have encrypted data in some cases and the need to make sure that everything is password secure so that patient information is kept private.

Friday, September 16, 2016

Today we were able to see patients. Some of the patients are so well accustomed that they already know what the next steps are during the process. I really have an appreciation for these patients who are both helping themselves and helping to test the drug for others. Everyone is in a really good mood because it is a Friday. Since we have almost everything prepared for the patients visit, it makes the visit very easy and fast. The data gathered will then be read over to make sure nothing is missing and the staff signatures needed are usually gathered during the visit process. There are many steps in the clinical trial process and the amount of effort that goes into each step is astounding. The amount of people and collaboration it takes during the drug testing phase is remarkable.

Monday, September 19, 2016

Today was primarily focused on entering data into our electronic resource and making sure that we have the kits necessary for the week. Entering the data does take quite a while; however, I was told that it is much like other things in life and gets easier over time. It is also necessary to call patients as a reminder to make sure that their upcoming visit dates are confirmed. Some of the patients may have to sign an updated informed consent and we try to let them know that ahead of time if possible so that they may plan accordingly. This is beneficial for the patient because the informed consent process is lengthy and justifiably so because the patient must be fully informed about any changes made and the risks associated with participating in the clinical trial. I believe it may also help to establish a trust between the patient and the medical research staff to let them know that we are here to protect their rights and to be honest when it
comes to clinical trials. This is necessary because patients must be informed about the pros and cons of participating in clinical trials; furthermore, the lack of trust after trials such as the Tuskegee Syphilis experiment have caused a major divide between medical researchers and certain populations which can only be remedied by honesty and the development of trust.

Tuesday, September 20, 2016

There was a lot of unpacking to do today with some of our supplies. We also receive some patient retention items which needed to be sorted through. The patient retention items are very awesome and I applaud the sponsors for putting so much effort into making this a very pleasant experience for the patients. We also moved around some of the furniture in the office to open up some space. The staff seems to like it and I hope the patients do as well. I do wonder how much different a long term study is from one which can be done in a couple of days? It seems as if a study which occurs very quickly may have a lot of participants because of little time commitment; however, I would imagine it would be very stressful for the staff and the patient researcher-patient connection may not be as apparent. I have a respect for the long term trials and the trust that they are building in the clinical research community by maintaining a connection with patients.

Wednesday, September 21, 2016

The day went by pretty fast with a considerable amount of patients. I was able to explain some of the necessary forms to the patients and inform them that their safety is a concern for all of those involved in clinical research; therefore, it is necessary that we know about any changes in medications or events. The medications are important because if the patient begins taking a certain medication it could harm their health if the medication is a contraindication and it even has the possibility to affect the data collected which could cause a larger scale effect on the development process of a drug and its effectiveness. The researcher-patient trust dynamic must therefore be strong for the patient divulge intimate health details. The social aspect of this job is very surprising and continues to push me out of my comfort zone and provide me with a great experience.

Thursday, September 22, 2016

Today was focused on getting the necessary paperwork together for the coming patients. We also attempted to get some of the data entered into the electronic resource. The different studies that we have at the site require separate sets of test and it is necessary to check the resources available from the sponsor to make sure that no change has been made and the correct tests are given. The different resources utilized to assess a patient are usually provided by the sponsor and are usually either delivered or in print. Some of the test may also have a copyright so it would be necessary for the sponsor to provide them instead of allowing them to be printed on site. The longer I am working with the clinical trials industry the more I realize the impact it makes in the American economy and how many different parts there are in the clinical trial process. I appreciate that all of these parts work in unison toward the ultimate goal of improving society through the development of new medications. However, I also believe that with so many
working parts there is also a large chance of miscommunication and error. Constant communication is necessary for the process to be efficient and generate the best results.

Friday, September 23, 2016

The patients seen today were very nice and in a pleasant mood. I am starting to get to know the patients and it has been nice to make a connection with them. This Friday was fairly short. Therefore, we were able to see patients and enter their data into the electronic resource. I also helped to copy stuff and add paperwork to binders. There are various sections in the patient binders; however, for the most part they are self-explanatory and easy to use. Such ease of use is especially important when assembling binders so that the task which follow are done properly and without hesitation. The patients continue to be my favorite part of interning at this clinical trial site.

Monday, September 26, 2016

Today was a simple day of filing paperwork. However, I was also able to get certifications for some of the courses required for upcoming studies. The certification required for each study can be different and the staff must then do an online training, in most occasions. This method seems very efficient and justifiable. Furthermore, in some cases it seems that only a certain amount of people staff members needed to have certain specific training and this makes it easier for the staff as well. Some of the trainings did take a daunting amount of time. However, I believe they may be useful in future applications and especially for the future studies. I realize that this job, like many others, is about constantly learning new information and adapting. I like that it keeps you on your toes and involves constantly managing a large influx of information. The demands of this job never cease to amaze me and the staff is truly inspiring.

Tuesday, September 27, 2016

Getting ready for tomorrow's patients was the primary objective of today. This involved making sure that all of the test kits had a label and the necessary paperwork was arranged. The binders must be in order and the supplies must be checked to make sure that everything is in perfect shape for the arrival of the patients. We must also have the patient retention items ready and sorted for their delivery to the patients. The binders are also rechecked and a coversheet is made to assure that everything that is necessary is placed in the binders. The lab must also be in good condition and anything necessary to collect samples should be ready and in place for staff administration. These steps help assure a visit which is very efficient and quick so that the patients can continue with their day.

Wednesday, September 28, 2016

The patient day went as expected. Everyone was able to complete the required paperwork and to complete all of the tests necessary. The patients seemed very content and I learned exactly what distinguishes an adverse event from a severe adverse event. The patients were also very happy to receive their retention items. After all of the patients were seen the rooms were then
cleaned and the tests were processed and sent off. The lab area was then cleaned and anything which needed to be entered into the electronic resource was entered. Today was very easy and it made me think that I am getting the hang of this job. I appreciate the staff telling me about how they entered into this field and how long it took them to feel comfortable doing what they do. For me it seems the stressful part is how many opportunities there are to mess up. I believe that that is why there are so many steps in the clinical trials process, so as to minimize any effects that mistakes can have and to keep facilities running well. The many steps in the process require much communication and it seems that clinical trials run heavily on the use of electronic resources for communication, data management, and oversight. It makes me wonder about the steps of the process before such efficient electronics? However, I do also believe that there is a lot of room for misinterpretation in emails and electronic documents; I wonder if this has caused any upsets in the clinical trial community.

Thursday, September 29, 2016

Today is spent getting ready for patients and making patients binders for their upcoming visit. It is necessary to have the necessary patient tests, paperwork, and information in the binder. We also try and flag any important pages so that there is nothing overlooked. I have also been taught how to do drug accountability. The process of doing drug accountability is not that hard and it is interesting to note how the process fits into the larger scheme of having blinded or unblended studies. There can also just be patient blinded studies. However, I have been told that the double blinded studies are the best and assure that there is no bias when gathering data. However, I do think that there may be circumstances where it might be absolutely necessary for the investigator to know and not the patients.

Friday, September 30, 2016

The patients seen today have been very fun to talk to. I appreciate how happy many of them are about the drug and how interested they are in their health. To think that some of our trials are actually making a difference in the lives of patients is amazing and fulfilling. All necessary information was gathered and signatures obtained. It is a Friday so everyone in the office is in a very cheerful mood as well. I am happy that this day has gone by so pleasantly. Towards the end of the day we filed away anything that needed to be put back into the patients charts and we also entered the data into the electronic resource. I was also able to look at the protocol for the upcoming study and take some time to try and understand why some of the things were done in certain ways. It is interesting to see the methods that some of the sponsors use when generating a study. I know it is probably very difficult to deal with so many different layers which are involved in the clinical trial industry. I also understand that the use of third parties for resources can also cause further difficulties. However, this further emphasizes the point that in the clinical trials industry communication seems to be a key to the success of drug approval, the success of larger pharmaceutical corporations, and the success of the small businesses attached. There must be a steady stream of communication between all of the players for the overall success. Those affected by the disease which the approved drug alleviates are also benefited.
Monday, October 3, 2016

Today was spent taking inventory and making sure that we have enough inventory for the rest of the week. It is nice to know that the sponsor pays for many of the supply expenses when it comes to doing tests for the studies. However, this further emphasizes the massive undertaking of developing a drug. The amount of money which is required to cover these expenses is astounding. I have been thinking that if the NIH (or another government foundation) invested money into the development of drugs if there would be a difference in the price. I think that sponsors hope to benefit from the prices set on drugs after they are put on the market. Although these prices help to keep the sponsors developing new drugs, I also believe that they may deter some patients who actually need the drug. Therefore, I believe this is the intersection where the new insurance plans set in place must benefit everyone and help Americans receive the medications necessary for their conditions, as well as promote healthy lifestyle choices for Americans.

Tuesday, October 4, 2016

Today I was able to help get the required paperwork necessary for tomorrow’s patients and make binders. I also helped to organize and file various papers and ask some questions about in what areas there could be improvement in the clinical trial process. I believe, since working here, that there could be much improvement if the protocol was written with more emphasis on the clinical trial site point of view. I think that making the protocol as easy as possible for the clinical trial site is absolutely necessary for proper collection of data. However, I was also reminded that the sponsors have an investigator meeting before the start of a new trial in which the staff gets a ticket to a certain location and spends a few days learning about the upcoming trials, asking questions, and meeting who they will be working with. I appreciate that the sponsors spend the necessary time and money to allow a thorough explanation to clinical trial staff and to answer any questions which may come up.

Wednesday, October 5, 2016

Today is a patient day and everything was already prepared a day in advance for efficient patient visits. All of the necessary documents were signed and filled out. The patients medication was dispensed and entered into the electronic resource. I was able to help take the patients vitals and guide them through the process necessary for their specific clinical trial. I was also able to do video tests on some of the patients. I have been able to see what I think is an improvement in some of the returning patients and I am delighted to see them in such good shape. The clinical trial industry is allowed to see such groundbreaking achievements in the pharmaceutical industry it is astounding. It makes me wonder how many great improvements the staff must have seen in some medications, because I have only been here a couple of months and the improvements I have seen in some patients is amazing. At the end of the day we put in some of the patient data into the electronic resource and filed anything which necessitated filing. We also cleaned up the rooms and the lab area before going home.
Thursday, October 6, 2016

Today was spent putting the rest of the patient data into the electronic resource and organizing. I was able to learn more about the conditions we were studying and how they occur. Some of the current treatments were explained to me and what makes the sponsors treatment novel was also explained. After learning this I realize the immense benefit that some of these drugs may have for patients who have little options for treatment (even though many of the other treatments seem to have more risk than benefit). It makes me further realize the difficulty that parents who put their children into clinical trials must have. I appreciate that parents are brave enough to both attempt to help their children and help to build better drugs for those affected with diseases similar to that of their child’s. I believe having resources for the parents of children in clinical trials may serve to benefit the trust that people have in clinical trials and to help the parents of patients create a good home for their children and their specific needs.

Friday, October 7, 2016

Today many of the patients had quick visits that were fairly simple. The medication logs have also been filled out and all of today’s documents have been completed. Any necessary filing was done however there are some things I do not know where to file so I must ask about that as soon as possible. I realize how so many of the different forms can get confusing. However, I am lucky to have a staff which is helpful and eager to teach me. I also think that some of the clinical trial lingo took me a while to get used to. The job is definitely getting a little easier as time goes by and I appreciate how much I am learning every day. I think that my time management skill are still not up to par with the rest of the staff though and I hope to improve my skills in the upcoming months. I realize that this job necessitates good time management skills to properly perform all tasks necessary in a given period of time.

Monday, October 10, 2016

Columbus Day

Tuesday, October 11, 2016

Today was spent gathering the necessary items for the next patient day and doing inventory. I believe we were short on a couple of items so I was able to call and request more. I was also able to learn how to fill out some of the forms that are required in case there is an SAE or an AE and how to contact places to gather medical records if necessary. I was told that it was easier to get medical records from some offices than others. I can see how this would be possible. For instance, I understand that large hospitals have a high influx of patient and the staff may be on a time crunch; therefore, it might be harder to gather the medical records from in a timely manner as compared to a smaller clinical with less people and ample staff. Every staff member I spoke to while requesting medical records was very nice and made the experience a good one.
Wednesday, October 12, 2016

The patients which came in today had very fast visits. One of the studies today required a lot less paperwork due to the visit that the patient was on and at first I was caught off guard to see how little was required. I was then able to see why upon looking at the larger timeline and the attached schedule. It was a very uneventful day which made for a great Wednesday. The staff members informed me of what the monitor sends back after her visit and the necessary things that must be addressed, if the monitor found any. I see how this part of the process keeps the clinical trial site running effectively. Once the problems are addressed the monitor will see that they have been properly managed during their next planned visit. I really appreciate the staff telling me how this works and the importance of this part of the process.

Thursday, October 13, 2016

Today was focused on getting things ready for the patient visits tomorrow. I learned where to keep the various sheets that come with the patient retention items. I was also introduced to exactly where we keep the data associated with older studies which have already been closed. It is required that we keep the data from closed studies on site. I now realize that the data kept from closed studies can take up large amounts of room. Having this information is a good measure to make sure that the data can be recovered in case of an accident. However, I would think it might be helpful for new methods to be developed because keeping so much data on site has the possibility of hindering the amount of space which can be used for future studies.

Friday, October 14, 2016

Today we are able to see patients. I was able to do EKG’s on all of the patients today. I was also able to fill out the various information regarding vital signs for each of the patients. It is necessary to be very precise in regards to the times that each phase of obtaining vital signs begins and ends. Therefore, the vital signs take quite a while to complete. I understand the need to continually analyze vital signs in the study to avoid any liabilities; furthermore, it is also very important to maintain patient safety and obtaining vital signs can help to signify any negative trends or identify any symptoms in the patient early on. Continually analyzing the vital signs of patients’ is also very necessary for the patient to tell us any information they may have regarding how they have been feeling while on the medication. If the patient reports anything they asked be asked as much information as necessary to find out if they know what the cause was and if they had to go to the hospital. This helps to separate an adverse event from a severe adverse event in the study.

Monday, October 17, 2016

We started to put in the rest of the patient data into EDC today. We had a couple of inquiries which we had to address. Today I realized how hard it is to really keep track of all of the passwords necessary for each of the programs utilized by the various clinical trials. The EDC has become simpler since I have been around the program. There are also questions about
informed consent on the EDC which is helpful in reminding everyone that the Informed consent is a very important document and must be filled out diligently. The way that the monitor can see the answers to our inquiries in real time is amazing and allows for efficiency when addressing issues that could turn into larger problems. Much of it is done online. However, this may also allow for misunderstanding in some cases. With an increase of millennials in the job market, I believe the movement toward incorporating more technology into the workplace is justified.

Tuesday, October 18, 2016

This Tuesday we did not have too many patients. We began by checking vitals on the patients we did have and running labs. I was able to conduct some of the video tests necessary for one of the studies. The video tests must also be uploaded and saved into a drive that is saved on the site. I believe including recordings in long term studies is a good idea for the safety of the patients and may help to visually assess the benefits the patient has experience; however, this only applies for diseases with characteristic physical symptoms that can be visualized. I have learned about some of the various standardized scales used in research for the purpose of assessment of patients. These surveys are how data is collected on subjects to track their changes. The changes are then analyzed on a large scale to determine whether or not the drug is statistically significant in helping the patient and their condition.

Wednesday, October 19, 2016

Wednesday was spent organizing some of the papers received. The various signatures needed for many documents is very assuring. Gathering these signatures allows for security for both the clinical research site and the patients’ rights. These documents are then filed away in accordance with the patients’ data. For instance, it is important that any time an update is made to the protocol the patient must be notified and must also sign the new informed consent saying that they understood the changes and their rights. Accommodations can be made for those who are impaired. Toward the end of the day we went through the various offices to organize and clean up. We also has to make sure that the biohazard container would be picked up soon because it was getting fairly full.

Thursday, October 20, 2016

This was spent completing the cleanup from yesterday. Any of the necessary data which needed to be entered or saved and labeled was done according to the protocol. Drug accountability was done in both the patient charts as well as the master log. This is very important in keeping with both the sponsor and FDA standards to make sure that the patient is getting the correct medication and the correct dose. Additionally, this is important for the correct determination of the medication being significant as compared to other drugs presently available on the market. I have also been able to see what a couple of the phases of drug trials looks like. I am very surprised that they place such restrictions on inclusion and exclusion criteria. I realize that both of that inclusion and exclusion criteria help to eliminate covariates so as to make it easier to determine the efficacy of the medication; however, exclusion of patients due to such
strict criteria does not seem the natural variation which is present in the real world to be tested during clinical trials. The stringent criteria also makes it more difficult for patients to be successfully referred into clinical trials.

Friday, October 21, 2016

I was able to sit in on some of the tests done by the physician today. The insight I gained from sitting in was immeasurable. A large part of the physicians’ job is interpreting how the patient is handling the medications and running any of the tests necessary. Many of the decisions about patients’ safety and medication use is determined by the physician after meeting with the patient. This physician must learn the protocol and how to administer each of the scales so as to administer them correctly for further analysis by statistics. The physician must also keep track of the various Severe Adverse Events reported and any symptoms that the patients may have. Our physician in the office does a great job of connecting with the patients and determining if a symptom could mean something more severe. I appreciate the opportunity to see this part of the clinical trial process.

Monday, October 24, 2016

Today was spent getting things in order and filing anything necessary. I was also able to learn more about the patient recruitment process. I primarily learned how to find patients for clinical trials and how to contact them. I find it very disappointing that we do not have too many physicians who refer their patients into our clinical trials. Our current research has the ability to help so many people and to think that some people might have a life changing experience on the medication but do not know about the trial is sad. I believe both physicians and researchers must step up to benefit those patients who are suffering from illnesses that can significantly affect the patients’ life. I believe referring into clinical trials is one way to help those suffering from some illnesses and can benefit the future outlook for those diagnosed with the illness.

Tuesday, October 25, 2016

Today was spent calling patients for entrance into our upcoming clinical trials. I learned more about the questions that must be asked while on the phone with the patients for the upcoming clinical trials. The questions are usually in accordance with the protocol and serve as a pre-screening. If the patient passes the pre-screening then a date is scheduled for a screening with our physician. We attempt to schedule the screenings on the days that are most convenient for the physician and the patient. Exclusion and inclusion criteria correspond closely with the questions for pre-screening.

Wednesday, October 26, 2016

We saw patients today. I was able to record some of the videos and save them. I was also able to help send off the videos. When packing the lab tests it is important to use dry ice so as to keep them fresh for the main lab. Once the lab has received them it takes a couple of days before
we receive the results and file them according to the patient. The doctor must see the lab results to make sure everything is okay with the patient and that their body is responding well to the medication. If the labs show anything out of the ordinary it is important for the doctor to see this and make sure that it is not something which necessitates having the patient drop out of the study for the protection of the patients’ health. The results must then be addressed in the electronic data resource to make sure that the physician has seen the results and that everything is okay.

Thursday, October 27, 2016

I went through one of the shipments from a third party to make sure that we have the supplies for another upcoming study. We were missing a couple of things so it was important to call them and make sure that we received them soon. We also had incorrect items in our shipment which needed to addressed so as to return the items received and have the other items delivered. We also went through each of the items necessary for the study, as stated by a list from the sponsor. We were then able to file anything necessary and put anything necessary into the electronic data resource and address any queries that were posted. We also had to get all of the paperwork ready for the next day and make sure that there was no revision to the informed consent since the patient’s last visit. We then placed the informed consent in front to make sure that it was filled out first.

Friday, October 28, 2016

Today was spent seeing the patients. All of the patients were really great many of them know the routines we go through so the process goes by really fast. I was able to record any of the necessary test and send them off if needed. I was also able to help centrifuge tests and send them off. After the patients had left we needed to make sure that everything was filled out okay and all of the required signatures had been obtained. We also reviewed the cover pages of each patients chart to fill out any of the necessary questions as record of the test performed and the obtained signatures. This also serves as a method to double check that none of the kits gathered were expired.

Monday, October 31, 2016

We received the tests back from the patients’ labs which were mailed to the lab the week before. We then looked at the queries for each of the patients charts to make sure that they correlated. The patients’ labs were then delivered to the physician so that she may make sure that everything seems okay and that the patients are not in danger in any way. We then retrieved the physicians signature on the document to make sure that the patients safety is not in danger. The document is then filed in the patients chart for reference during the next visit. The queries were then fixed in the electronic resource. I appreciate this part of the electronic resource. I believe that it helps to maintain the safety of the patient and reminds the staff that patient safety is always the first and foremost goal in performing clinical research.
Tuesday, November 1, 2016

Today was used to go over patients’ charts and make sure that all signatures and necessary had been filled out for each of the patients’ visits. The day was primarily focused on getting ready for a monitor visit soon. The monitors must come frequently so as to make sure that all rules are being followed. The monitors help to make sure that if there is a Food and Drug Administration audit. All of the necessary paperwork and precautions take would be up to the Food and Drug Administration standards so that the drug would not have any problem getting approved. If there are any mistakes a protocol deviation must be filed and depending on the severity it may need to be sent to various authorities for oversight. We also got any paperwork and lab kits ready for the patient which will be coming tomorrow.

Wednesday, November 2, 2016

Today we had patients. I was able to help conduct patient vital signs and to record any videos necessary for the patient tests. I also helped to pack labs for shipment. I was able to send the videos off for the patients who needed it. After a recent protocol change it is necessary to send the patient videos off on a different schedule than was required initially. I was also able to talk to Dr. Maynard about my project and what we may find. All of the paperwork filled out today was reviewed to make sure that everyone signed everything correctly and everything was filled out according to protocol. The patient data was then entered into the electronic resource.

Thursday, November 3, 2016

I was able to learn more about entering data into the electronic resource today. The resource specifically requires you to enter data from patients tests and any paperwork filled out by the patients. The monitor is able to see this and can make a query. Once a query is made you must address the problem, which sometimes arises from a typo. The monitor may then look at this and make sure that the problem was sufficiently resolved. Any email interactions between the monitor and yourself must be filed for future reference. I appreciate the detail that goes into addressing the queries and the amount of time put into making sure the data obtained is pristine. We also were able to go through our kits and make sure that we had all of the resources necessary for the next visits. I was able to order more kits for the upcoming visits and anything else which was needed during the patients visit.

Friday, November 4, 2016

Today I was able to take vitals on patients and help to centrifuge the labs. Once the lab protocol had been followed we packaged the labs and shipped the off. I was also able to help perform the video tests and send off any of the tests necessary. I also was able to screen some more patients for the upcoming trials. Many of the patients screened today did not seem to qualify; however, this really made me see how some studies are looking for a very specific type of person affected by an illness. This method of patient selection helps to make sure that the patients in the study do not introduce too many covariates and that the phase is completed.
efficiently, without a huge cost. However, this comes at the expense of introducing real world problems that the general public might have when on the drug.

Monday, November 7, 2016

Today was spent making sure that all of the data gathered from last week is filed in the correct place and that all queries have been addressed. The various queries were primarily simple of answer and only took a couple of minutes. I also called to confirm the shipment that we are to receive from the third party company hired through the sponsor. The shipments usually arrive in 3 days; however, there is an option to have an overnight delivery if necessary. I was able to help fill out some of the drug logs as well.

Tuesday, November 8, 2016

The shipment from last week was received around noon. I went through the shipment to make sure that all that we had ordered was delivered. A paper usually comes with the delivery to make sure that we received it and this paper must then be faxed back and kept on file as well. I then spent time placing each of the items where it needed to go and labeling the kits. Once the kits are labeled they are placed in a specific area as well so that we know where to go and get the kits on patient days. We also spent time getting the patient packets ready for tomorrow and making sure that there wasn’t any other paperwork necessary for the patient to fill out. Some of the patient packets necessary for tomorrow are very lengthy for some of the upcoming screenings.

Wednesday, November 9, 2016

Today we saw a couple of patients. We used some of the materials we received yesterday and I was happy that all of the visits went by swimmingly. I helped to take vitals and process the labs before packaging. I also recorded any videos for those patients which necessitated them and sent off some according to protocol. I also helped to go over the paperwork completed. I was then given a run through of what a typical screening visit looks like. The screening visits take a large amount of time to complete for all of the parties involved and for the upcoming studies it can vary. It is important that we know this kind of information so that the doctor who works with our site can schedule appointments appropriately based on the length of time that a visit may take.

Thursday, November 10, 2016

We received the shipment from our third party company today. I went through the shipment to make sure that all of the materials which were necessary for the future studies were included in the shipment. All of the materials were then reviewed to make sure that everything necessary was here. Most of the materials were primarily there for safety reasons in case of any accidents which may happen when the patient is on site. I think that the sponsor had good foresight to include a lot of things on the required list. I believe that everything was very
appropriate and well planned. However, for some reason it was hard to get ahold of one of the company reps that we were assigned and it was necessary for us to continue calling her and leaving her messages.

Friday, November 11, 2016

All of the kits and paperwork that we had prepared for today’s visit were utilized and it was nice to see how quickly everything went. I was able to take vitals, help centrifuge labs, and to do any video recording necessary. We were also able to continue calling patients to try and screen them for the upcoming studies. The patient retention materials were also delivered to the current patients. I was also taught about some of the new measures which were implemented to make sure things continue to go smoothly. I think all of the measures we take help to ensure patient safety and are justified accordingly. We also addressed any queries toward the end of the day.

Monday, November 14, 2016

Today I was able to go through inventory to make sure nothing was needed. I was also able to help address some of the queries which had arisen. Upon getting ready for the upcoming studies. I was able to see some of the paperwork required during the beginning of the studies and help to deliver them so that they could be filled out. The upcoming studies are very exciting and have the potential to help many people. It was also fun to see this because Dr. Maynard had invited me to listen in on one of his conference calls when he was getting ready for this study. We have all of the resources for the study and I think the whole office is very happy. The patients we have been screening seem very nice and I am happy we can provide them with a possible treatment for what they are struggling with.

Tuesday, November 15, 2016

Today we spent most of our time screening patients and scheduling them for upcoming visits. We also called the patients who will be coming in on Wednesday as a reminder that their visit is tomorrow. I am getting better at the screening process. Initially I was very nervous, but now that I have screened a few people it is not bad at all. I also made sure that we had all of the tests back from the third party company so that we could have them signed by our physician in the morning and then place them in the appropriate file for each patient. All of the kits and necessary paperwork were gathered for tomorrow’s patients. We also made sure to clean the various offices and rooms.

Wednesday, November 16, 2016

Today, as always, our patients were very compliant and good. Any problems which the patient noted were documented and signatures obtained. I helped to do the recording tests of the patient and take vitals. I believe this is a part of the normal schedule for the various clinical research coordinators. The labs were taken, if necessary, for each patient and sent off according
to protocol standards as well as the video recordings. If there were any informed consents they were checked to make sure that everything was filled out appropriately and then filed in the right place. It was also necessary to make sure that all of the staff had their paperwork signed for the upcoming studies.

Thursday, November 17, 2016

The various screenings which needed to be scheduled were scheduled today. We received some of the lab results back so they were put in the appropriate place so that our physician may read over them and assure that everything is going well. I was also told that if there were any problems seen in the patient a medical director from the study would call and inform us as well. I think this is just an added precautionary measure just in case a physician does not see something. I appreciate that this is a step taken by studies to make sure patient safety is maintained. The various queries were also resolved. Any paperwork which needed filing was also filed accordingly. We also got any lab kits needed ready for tomorrow and labeled for each of the patients. All of the paperwork which we might need for tomorrow was also gathered.

Friday, November 18, 2016

Today we were able to see a lot of patients. The patients seem to be enjoying their day and most of them have plans for thanksgiving so we must make sure that their schedules, and those of other patients in the study, can fit in a day that is fitting for both the protocol, the physician, and the patient. I was able to take the vitals of the patients and centrifuge the labs. I also helped to ship the labs and do any video recording necessary. We also were able to address some of the drug that had recently been shipped in. I learned the process of checking drug in, recording it in the log, and where to file the necessary paperwork. The drug must be kept very secure in a locked and temperature controlled room. This helps to assure that the drug is preserved well and that no one has access to the drug besides those designated access. Once drug is received from the patient it is also saved in the room and this is also checked by the monitor.

Monday, November 21, 2016

I learned further information about the drug process. During each visit we must collect the patients previous drug and make sure that they took the required amount, as stated in the protocol. In some instances, more drug is given to the patient in case they cannot come in for their visit until a couple of days afterward. In drug trials, it is important in many cases, that the drug be taken everyday. This helps to ensure that the tests taken reflect the drugs efficacy and reduces the confounding variables in the data. Although I do understand why this part of the process is necessary, I addressing the confounding variables present help to make the drug further ready for introduction into the market for the general population. If a patient does not take a drug for long enough they may be kicked out of the study due to non-compliance.
Tuesday, November 22, 2016

Today we made sure that everything was in order before we left for thanksgiving. This involved making sure that we had enough supplies for the upcoming patient visit days, making sure all inquiries were answered, and making sure all paperwork was filled out correctly. Anything which needed to be filed was done so accordingly. We also tried to make sure that all of the drug logs were up to date and any patients that needed to be called were contacted. We were also able to screen some patients towards the end of the day as well. We also made sure that the patients that we had scheduled were appropriate according to the protocol. Any of the paperwork which needed to be filled out and sent for the upcoming clinical trials was completed. We also made sure that we did not need to send off anything and that all of the labs had been collected for the current patients.

Wednesday, November 23 -25, 2016

Thanksgiving vacation

Monday, November 28, 2016

Today we called patients to screen them for the upcoming trials. We were also able to fill out some of the other necessary paperwork for the trials and fax it back to the necessary company. Along with starting a new trial, the staff must get certified in a few extra procedures. It is important that the staff becomes certified through an online training as to assure that they can properly perform the various tasks. It seems that although some of the tasks are very similar in between clinical trials, it is still important to so the online training and file the certificates for each of the staff members. The trainings may include things like how to use the online resource and proper techniques when performing certain procedures.

Tuesday, November 29, 2016

Today we were able to check in the drug shipment and to also make sure that the drug logs were up to date. It is important that it is documented which drugs are used when and by which patients. This should then correspond with the drug log in the patients chart as well. The drug Is also checked by the monitor to make sure that all of the information from the online resource, the patient drug log, and the larger drug log correspond with each other. We were also able to get the patient packets and the kits ready for the patients that we see tomorrow.

Wednesday, November 30, 2016

Today is a patient day and I was able to help centrifuge lab tests and pack the shipments. I was also able to record the appropriate patients for their tests and shipped the recorded tests which necessitated shipping. Today we also tried to enter as much of the data from the patients into the electronic resource as possible. We also made sure that everything was filled out and all
signatures were obtained. Any patients who needed an updated consent form were given one and the consent was reviewed with them. I was also able to talk to staff members about how the upcoming trial will be different from the current trials that we are doing. The procedures seem to be very different and this further emphasizes the need for flexibility of the staff members who help to administer clinical trials. The field requires a lot of learning for each trial.

Thursday, December 1, 2016

I further learned what the trials are like for the new studies. They have very different procedures and have a very different timeline than the current studies. Some of the things which both of the studies have include taking vital signs. I believe this is a procedure that is likely to be included in most clinical trial studies due to patient safety. I was also able to learn about the drug for the trials. The drug has a different temperature that it needs to be stored at and the way it is administered is a bit different. We have some experienced staff who will be administering the drug. I think the new trials seem to be a little more technical, However, it is very fun to see the differences between the trials we are currently doing and the ones we will be doing.

Friday, December 2, 2016

Today is a patient day and we used the packets we made yesterday as well as all of the kits we gathered and labeled yesterday. Many of our patients in the clinical trial have moved into an advance phase of the clinical trial which requires a longer time span between each visit. Therefore, we see the patients less often and provide them with a certain amount of drug as deemed appropriate by the sponsor. This phase is not blinded so all patients are actually on the drug and all of those involved in the clinical trials know this as well. It is nice to see that during this phase they are able to continue taking the drug, hopefully it can be out on the market soon for those affected.

Monday, December 5, 2016

Today was primarily spent filing various forms and addressing any queries. Any further equipment that was sent for the clinical trials was unpacked. I was also able to help with the new EKG machine not long ago. The EKG machine usually carries a set of instructions for setup and also for how to send an EKG. We also continued to get the binders ready for the upcoming trials. This includes the regulatory binder, which had most of what was needed inside of it. We were also able to go through each room and clean it thoroughly. We also sent in an order for office supplies, specifically more paper and sticky notes.

Tuesday, December 6, 2016

Today was spent getting ready for the tomorrows patients by getting their patient packets ready as well as their lab kits labeled and set. We checked to see if there was a new informed consent. I also got to discuss the future process of how visit will go according to the protocol of the new trials. I also got to see what goes into early terminating a patient due to non-compliance.
The process requires much paperwork and evidence that the patient has not been compliant. I am told that the monitors also take great care in seeing why a patient was early terminated and making sure that the paperwork is filled out correctly. It is especially important to retrieve the drug from patients who did not comply, as well as explaining to them why they are being terminated early.

Wednesday, December 7, 2016

Today is a patient day that went by very quickly. I was able to take vitals, package lab tests, ship lab tests, and record patient tests. We were also able to answer any inquiries necessary. For some of the patient who were entering into the newer phase they must complete a new informed consent and a doctor was there to discuss with them any concerns they may have. I was also able to talk to Dr. Maynard about my project for a little while. I think the project is headed in the right direction and I am eager to see the results. I realize that sample size might be an issue because of the lack of time that many doctors have. I was also able to help move some of the office furniture around to provide some spacious areas in the workplace.

Thursday, December 8, 2016

Today was spent entering patient data into the electronic resource. I also went through the inventory to see if there were any more kits which needed to be ordered for the next patient visits. The process of placing an order is quite fast, however on our last order the third party said that they did not receive it. The third party stated that this was a problem they had been having for a while and where trying to fix. From this experience I realized how crucial communication is throughout each of the parts involved in clinical trials. Any kits necessary for tomorrow’s patients were gathered, kits were labeled, and patient packets were made. The process of labeling kits used to take me a lot longer; however, with the right pen and a line of kits I can get it done in no time.

Friday, December 9, 2016

Patients were seen today. The day went by very quickly. I was able to help send off labs, take vitals, and do video recording tests. I sent off any of the tests which needed to be sent. I was also able to sit in on a conversation with the monitor to discuss various information the site must know. This call was very similar to the over the phone training we had done previously. The call contained a lot of information that was useful and it gave insight into the trial. I think the most important part was hearing what communication is like with a representative of the company that might be the new monitor for our trial. We then cleaned up the office before leaving for the weekend.

Monday, December 12, 2016

The day was spent unpacking the various items we received from the third party company. I also filed the paperwork attached to the package in the necessary place and faxed the
confirmation forms as well. These steps are taken to make sure that the site has enough supplies and keep track of how they are used. I was also able to ask some of the staff members if the startup process for the upcoming trial was like that of other trials they had been involved in. It seems that the startup process is very long and involves a lot of agreements; however, each of the agreements is necessary and there is also a required site initiation visit. Our site ignition visit was very good. It involved a person coming and going through the supplies we needed, the documents needed, the on-site drug, the patient forms needed, and showing us a slideshow about the trial. Afterwards any questions were answered.

Tuesday, December 13, 2016

Today we got ready for tomorrow’s patients by putting patient packets together labeling lab kits. The day was quite interesting because we also got to call patient for the new study. I continue to realize how difficult recruitment is, especially concerning the inclusion and exclusion criteria of the protocol. I believe that the future of the industry might be in finding better ways to inform doctors about clinical trials or inform the general public about clinical trials. I think the clinical trials which are receiving a lot of money currently are those related to cancer research. I have also read that doctor referral is common in cancer research.

Wednesday, December 14, 2016

Today went by quickly without too many patients. We were able to enter the patient data into the electronic resource. I was also able to see some of the new techniques used in processing the labs for the newer studies. I think these techniques are very interesting; furthermore, I asked some of the staff members why the techniques use might be a required part of the protocol. Upon hearing the explanation about blood cells and the drug it makes sense to me now. We also filed away any of the necessary paperwork and answer any queries which had come to our attention.

Thursday, December 15, 2016

Today we got ready for the upcoming patients tomorrow. The packets and labs kits were prepared and we made calls to remind the patient about their visits. We checked to make sure that there were no new changes to the informed consent or protocol. I was then able to make sure and file anything necessary. The lab results that we received were also placed in the appropriate box for signatures and any previous inquiries were handled. We also made sure to communicate with the new trial monitor to make sure that everything was okay and on track.

Friday, December 16, 2016

Today I was able to centrifuge lab tests, pack tests, ship tests, do video recording tests, ship video recordings, and help take vitals. I really enjoyed talking with our patients they have become even more comfortable with me and I think they have developed a trust with me and I will be sad to not see them after my internship. We also had to fix a computer problem early this morning because our physician was not able to sign into one of the programs so we had to call
them and get everything back in order. The process did not take too long once we found the right person to help us. I think this was a lesson on thinking quick and finding ways to fix problems as quick as possible.

Monday, December 19, 2016

Today was spent entering data from the previous visits and addressing any queries. We also received some lab results so it was necessary to place those in the appropriate place so that they may be looked over and signed. We were also able to further discuss what the patient visits are like for the new studies. The patient visits seem rather confusing to me right now, although I’m sure I will get it. The patients we have scheduled seem very eager to try a drug which may help them and it is nice to know that they can also help other in the process. Any regulatory filing was done and queries were answered.

Tuesday, December 20, 2016

We were able to clean all of the rooms today and organize. I was also able to file some of the documents. Some calls were made to see if we could schedule anyone for a screening for trials. I also was able to discuss with staff about how long the screening process happens and exactly what can happen during the process. I was informed that you can contract with a company for a certain number of patients and if you reach that amount of patients you can then negotiate a contract for more patients. In some clinical trials it is very hard to find the appropriate patients and therefore this stage can last even longer than the time allotted due to revisions. In many cases I believe the sites are just left to get patients in whatever way possible. One of our trials has been very awesome and provided us with flyers and information for prospective patients during the screening process.

Wednesday, December 21, 2016

Today I was able to call and set up appointments for the upcoming weeks. I was also able to help screen some of the patients for trials. We have all of the queries answered and we are going through some of our trial documents again to make sure that everything is filled out correctly. We also made sure to update the drug log. We will get a while off for Christmas break and I think everyone realizes that it is much needed. I have realized how much I know today because filing was a breeze and helping to schedule patients was a lot easier as well.

Thursday, December 22-30, 2016

Christmas vacation
Monday, January 2, 2016

Today was my last day interning at North Texas Clinical Trials. It was very fun and there wasn’t too much work to do today. We did continue to file anything necessary and put in patient information into the electronic resource if it was necessary. We were also able to screen some patients by phone for the upcoming studies. The patient which were screened were very compliant and easy to schedule. If there were any queries these were addressed promptly. We also made sure to make sure that all of the paperwork that was filled out while I was gone had the correct signatures and that everything was filled out correctly. It was also very important to go over the informed consents and to make sure that everything was filled out on the patients’ part and the part of the staff. I am very happy I was able to do my internship with such an awesome and welcoming place.

January 2-February 15, 2017

Will be dropping off and picking up surveys throughout the cities in Dallas and Tarrant County. My project has chosen to keep the identity and location of the survey respondents anonymous so as to increase participation in the survey. My project utilizes google maps to find various physicians within each of the cities to deliver surveys to. The surveys were then picked up in one week’s time. Surveys where dropped off from Monday- Friday.


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