IMPLICATIONS OF CLUSTERING ON SAMPLE SIZE CALCULATIONS IN RANDOMIZED CONTROLLED TRIALS

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CHAPTER I

INTRODUCTION

Primary care research is a growing field of study within clinical research. The majority of healthcare provided in this country is delivered by primary care physicians in the outpatient setting such as a clinic or the physician's office (1). Most of the research that has been conducted on advancements in the delivery of healthcare has focused on the hospital setting and has had little relevance to outpatient primary care delivery (1). There has also been a disconnect between clinician investigators and the basic science/public health investigators.

At the Primary Care Research Institute (PCRI), where my Internship Practicum was completed, the main goal is to merge the gap between clinician investigators and basic science/public health investigators. The sole purpose of the PCRI is to implement the knowledge gained from research to improve the lives of all people.

A research design that is greatly employed by primary care investigators is the cluster randomized controlled trial. During my internship practicum I worked with the NorTex Needs Assessment and the Cancer Screening Initiative Project, both of which are cluster randomized controlled trials. In learning about clustered trials, it has become apparent how much effort must go into the design of these trials. Clustering brings out a unique set of issues that the investigator must take into account before planning such a study. One of the most important issues is calculating an adequate sample size. An

inadequate sample size may result in an underpowered study, limiting the ability to draw conclusive results.

The main goal of this practicum report is to educate investigators about the intricate details related to the cluster randomized controlled trial design and the factors that need to be considered in the design and implementation of these trials. The report will specifically outline the effects of clustering on sample size calculations. It will touch on the important aspects of a clustered sample size calculation, such as the impact of the intracluster correlation coefficient, the design effect, and the effective sample size. The report will also display the growing demand for information on clustered trials as well as the need for investigator access to this information.

CHAPTER II

PART I- BACKGROUND AND LITERATURE REVIEW

Cluster Randomized Controlled Trials

The randomized controlled trial has existed as the gold standard of clinical trials for many years (2). When designed correctly, these trials have a low risk of bias and provide valid results (3). In traditional (or simple) randomized controlled trials, the individuals recruited to participate in the study are randomized to treatment groups. More recently, as the focus for clinical research shifts to the delivery of care in general practice, cluster randomized controlled trials are becoming increasingly valuable and common in the field of primary care research. In these trials, clusters or groups of individuals are randomized into a treatment assignment. The two main characteristics of cluster randomized controlled trials that set them apart from the simple randomized controlled trial are that (1) the units of assignment are identifiable groups and (2) the units of observation are members of those groups (4). Clusters can be hospitals, private practices, worksites or even communities (4). These unique characteristics allow for the testing of the best clinical practice or the best method for delivering healthcare. These trials are especially important when the goal of the research is to determine the effectiveness of a particular intervention that is geared towards the physician and delivery

of care due to the fact that the intervention is applied at the physician level and its effectiveness is assessed through observation of the patients (5).

Because most healthcare interventions are delivered at the hospital level, physicians' practices, or clinics, it is almost always necessary to adopt a clustered design. Each of these clinics or practices would represent a cluster of physicians and their respective patients would represent an additional level of clustering, thus, potentially creating multiple levels of clustering (3). The intervention is applied at the physician level while the outcomes are measured at the patient level (2). For most interventions based on the delivery of health care or health promotion, cluster randomized controlled trials are the only practical approach because it would be almost impossible to randomize individual patients to physicians who had received the intervention and to those that did not (6). While undeniably effective, this study design also creates a special set of considerations for sample size calculations and data analysis (2).

Figure 1 shows two different examples of clustering. The box labeled A shows a cluster with three different levels. The first level is represented by the clinic as a whole; which is seen as the large circle. Within the clinic, there are two physicians who would be considered the second level. Under each physician is a group of patients designated by the smaller circles and which represent the third level of the cluster. This type of multilevel clustering is called nesting (7). The box labeled B is an example of the simplest form of nesting that consists of two levels. This type of nesting is specifically referred to as clustering, although any form of grouping can also be called clustering (7).

The first level is that of the physician and the second level is comprised of the physician's patients.

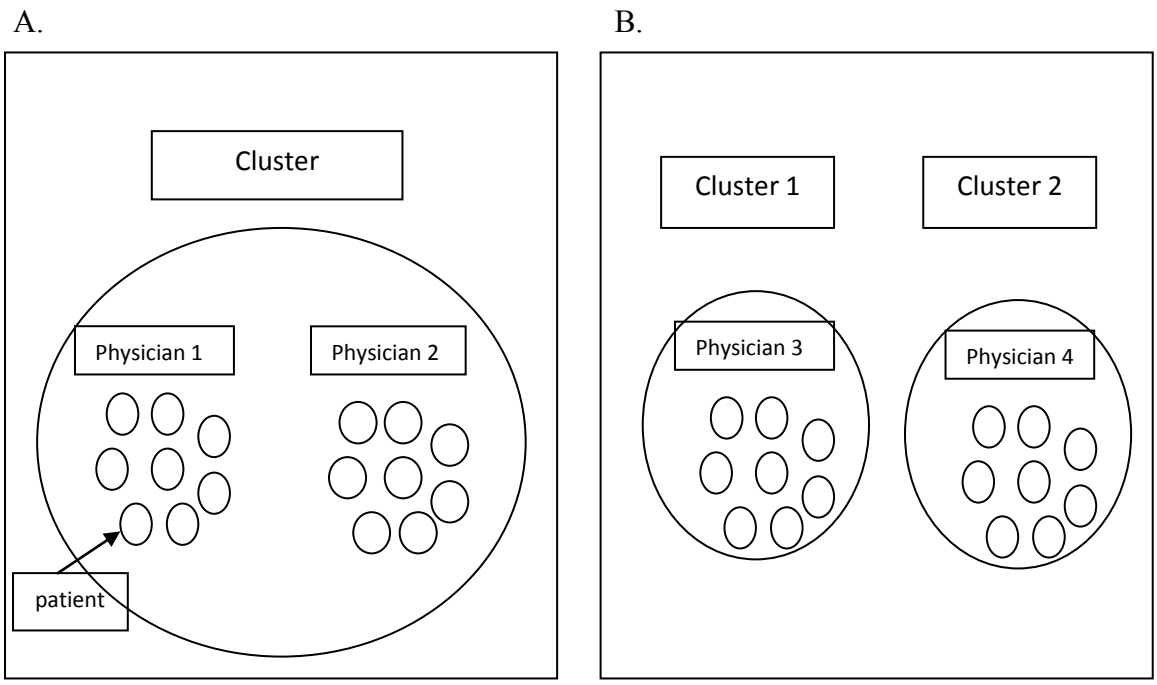


Figure 1. Diagram illustrating levels of clustering

While both of these examples will have some correlation among the members of the clusters, the example with three levels will have a larger correlation due to not only the similarities between patients but between the physicians who work together as well. This correlation will be discussed later in this section.

An example of a cluster randomized controlled trial that randomizes clusters at the clinic level is the Cancer Screening Initiative Project (CSIP). The aim of the CSIP was to test the effectiveness of a set of cancer screening guidelines provided as a Digital Video Disk (DVD) established to improve the physician's practice of cancer screening. In the CSIP, each clinic (which represents one or more physician) was randomized into the intervention group or the control group. The intervention group received the DVD and the control group did not. Randomizing by clinic as opposed to randomizing by each physician prevents physicians who share a practice from being randomized to different groups. This allows the investigator to reduce the risk of contamination across treatment groups (6). Contamination occurs when a physician in the intervention group leaks information about the intervention to a physician in the control group. Patient charts from each of the physicians will be prospectively reviewed to assess their cancer screening practices. The coordinator and any research personnel reviewing the charts were blinded as to which treatment group the clinics were randomized to. This reduced the risk of bias in the study. The value of this study design is that the cancer screening practices of physicians in both the control and treatment groups can be compared while taking the clustering effects into account. By introducing the DVD at the physician level, the investigator will be able to assess its impact on the patient level through an examination of their charts. The clustered design is the most practical way to assess this type of intervention. It would be almost impossible to randomize the individual patients to physicians who had received the DVD and to those who did not.

Advantages of Clustering

In addition to effectively examining healthcare interventions, cluster randomized controlled trials also allow the investigator to control for contamination between the intervention group and the control group (6). In the case of the CSIP, the physicians are randomized by clinic so that physicians in the same clinic will be in the same treatment group. This prevents one physician in the intervention group from intentionally or unintentionally leaking information about the intervention to a physician in the control group and, therefore, "contaminating" the results or unblinding other physicians. This would bias the analysis toward the null hypothesis of no intervention effect (4). Contamination of the results would ultimately decrease the validity of the study and is also referred to as a Type II error (6). The Type II error rate is the rate at which the intervention will be reported as ineffective when in actuality, it achieved the desired result (4). This becomes especially important when the physicians conduct their practice in the same clinic.

As stated earlier, it may not be feasible for some studies to be conducted by randomizing individual patients. Ethical issues may also arise if investigators were to ask physicians to withhold information obtained from an intervention from certain patients and give that valuable information to others.

Sample Size Considerations

Although most would agree that cluster randomized controlled trials are a very effective tool in primary care research, these trials are also very complex and provide an additional set of concerns for the investigator to consider when planning their proposed research. Both the design and analysis of cluster randomized trials requires a special set of considerations. One of the most important differences between cluster and individual randomized controlled trials is the sample size calculation. Investigators must determine the number of clusters and the number of patients to designate to each cluster (5).

In a clustered trial, there are factors at both the physician level and the participant level that must be taken into account in order to calculate an adequate sample size (6). These sample size considerations include the intracluster correlation coefficient (ICC), the design effect (DE) and the effective sample size (ESS). An inadequate sample size calculation can have detrimental effects on the power and validity of the study and can yield skewed results. In simple randomized controlled trials, there is an assumption that the outcomes of individuals are independent of each other (6), but when participants are clustered into groups this assumption is no longer valid. This is because the subjects within a cluster are more likely to have similar characteristics and potentially similar outcomes than subjects from another cluster (3). Patients generally get to choose their primary care physician. Patients who choose the same physician are more likely to have similar characteristics, such as socioeconomic status, and may interact with each other causing them to respond similarly (3). There are also covariates at the cluster-level that may effect all of the individuals within the cluster. Physicians have different levels and

methods of care that they deliver to patients, such as a particular focus on certain aspects of healthcare. These differences would be specific to the cluster and would differ from other clusters.

Intracluster Correlation Coefficient

The statistical term for the homogeneity within clusters is the intracluster correlation coefficient (ICC); sometimes referred to as the intraclass correlation coefficient. The ICC is often designated by the Greek letter ρ. As a measure of the relatedness of clustered data, it compares the variance within the clusters to the variance between the clusters (7). Standard values of ρ may range from 0 to 1 (7). A value of 0 would indicate that there is no correlation of the data within a cluster and a value of 1 would indicate that all of the data for one cluster were exactly the same. Very small values of ρ imply that the variance within clusters is much greater than the variance between clusters (7).

$$\text{Equation 1. } ICC = \sigma_b^2 / (\sigma_b^2 + \sigma_w^2) \qquad (8)$$

Equation 1 is the most frequently used equation used to describe the intracluster correlation coefficient. The variation between clusters is represented by σ_b^2 and the variation within clusters is represented as σ_w^2. This equation illustrates that the ICC is the proportion of the total variation in the outcome that can be attributed to differences between the clusters (8).

Calculation of the ICC is very important because even the smallest changes in this value may have a great impact on the power of the study (9). The power of a cluster randomized controlled trial is the power of a test in the analysis to detect the intervention effect (4). Calculation of the ICC requires pilot data from a study that was conducted on a similar population and measured a similar outcome as the study the investigator is looking to conduct. Once this value is obtained, the investigator would perform a sensitivity analysis on this value to explore the impact of various values of the ICC on the final sample size calculation and then use the value that provided the most conservative estimate (9). Unfortunately, these values may be difficult to obtain because very few authors report the ICC in their publications (10). When these values are published, many of them are from previous studies that only enrolled a small number of clusters. These estimates of the ICC most likely carry large standard error values and may not be very stable estimates (11). This is yet another issue that investigators must recognize when adopting a clustered design in their research.

When the ICC is greater than zero, as with the majority of cluster randomized controlled trials, the power of all tests performed in the analysis will be reduced compared to a simple randomized controlled trial with all other factors constant (4). Investigators must carefully plan the allocation of their subjects. As the number of clusters and the cluster size increases, the power of the study increases as well (4). However, the most important factor in increasing the power of a study is the number of

clusters. This increase in power is not without its limits in that the increase in power of a study becomes smaller with each additional group or member added to the design (4).

Design Effect

Due to the association of individuals within the clusters, cluster randomized controlled trials call for a significantly greater sample size than a simple randomized controlled trial. On average, cluster randomized controlled trials require 50 to 100% more subjects in order to achieve equal power as a simple randomized controlled trial (6). The ICC is used to calculate how much the standard sample size must be inflated to account for clustering effects. This inflation is called the design effect (2). It is also referred to in some texts as the variance inflation factor (VIF) (4). When the ICC is greater than zero, the design effect increases both as the ICC increases and the cluster size increases (4).

Equation 2. $DE = 1 + \rho (m-1)$ (7)

In this equation, DE= design effect, m= number of subjects in a cluster and ρ= ICC.

The design effect must be calculated during the planning of a cluster randomized controlled trial. In most studies, an investigator can use a standard sample size calculation then multiply that value by the design effect to estimate the sample size necessary for a clustered trial (12). Inflation of the sample size is necessary to avoid loss

of power in clustered trials. If the ICC is 0 then the design effect will be 1. In this case, the sample size would be unaffected. However, in human studies the value of the ICC, although very small, is most likely to be greater than zero and the design effect will magnify the total sample size needed (7). Even if the ICC is estimated to be very small, investigators should not take this value lightly because even a modest correlation can have a dramatic impact on the sample size (4).

To keep the design effect small, it is advisable to increase the number of clusters and decrease the number of subjects within each cluster (i.e., cluster size). Increasing the number of clusters while keeping the total sample size constant can also increase the power of a study (7). Decreasing the design effect increases the effective sample size of a study. The effective sample size is used to describe the number of subjects enrolled in the study that are statistically effective (7). The effective sample size is calculated by dividing the total sample size by the design effect (Equation 3). Another way to increase the power of a study is to increase the effective sample size while decreasing the design effect. Ignoring the design effect when calculating sample size can be vastly detrimental to the power of a study. In fact, the power will most likely not be adequate to detect the hypothesized effect of an intervention (12).

Equation 3. $ESS = mk/DE$ (7)

In this equation, ESS= effective sample size, m= number of subjects in a cluster, k= number of clusters, and DE= design effect.

When planning a study, the investigator can reverse the equations for design effect and effective sample size to calculate the total sample size needed in a cluster randomized controlled trial (7). For example, the total sample size needed for a clustered trial (m x k) can be found using Equation 3 given the effective sample size and the design effect.

Unequal Cluster Sizes

Variability in the cluster sizes of a study may create a need for a set of additional considerations (13). Imbalance in the cluster sizes can affect the power of the study if it is not taken into consideration. The most efficient design occurs when all cluster sizes are equal as the power of a study decreases as the cluster sizes become more unbalanced (13). This loss of power is due to a loss of precision in the smaller clusters. While the larger clusters show a gain in precision, it is not enough to overcome the loss of precision in the smaller clusters (13).

Many investigators ignore variability in cluster sizes because there has not been a practical or easily applied sample size formula to account for this variability as compared to the simple sample size formula used in studies with equal cluster sizes. When cluster sizes vary, the design effect formula requires knowledge of the actual cluster sizes in the study in addition to the ICC (13). This presents a problem for investigators because it is

very difficult to know the exact cluster sizes in the planning stages of a study. Participation in most studies is fluid as subjects are free to drop out at any point during the study.

In light of the fact that the power of a study may be decreased when the variability in cluster sizes is ignored, investigators must always be aware of this variability and account for it in their sample size calculations. Eldridge et al, advise investigators to be very cautious when imbalanced cluster sizes occur in their study especially if the ICC or the variation in cluster size is expected to be large due to potential detriments to the power of their study (13).

Analysis

Analysis of cluster randomized controlled trials is another issue that investigators will face when adopting this method of research. It is very important for investigators to understand and apply the concepts of the design effect, intracluster correlation coefficient and effective sample size. It has been found that investigators have quite often ignored the design effect when analyzing clustered data. Simpson et al found that fewer than 60% of reports from recent cluster randomized primary care trials actually took clustering into account when analyzing the data (14). Ignoring the design effect leads to an invalid P-value which in turn causes invalid judgments of statistical significance (12). The ICC in a clustered trial represents a violation of the assumption of independence that underlies most of the analyses used in randomized controlled trials therefore creating multiple costly errors when standard analyses are used (4). Many authors have noted that

ignoring clustering effects can cause extreme P-values, exceedingly narrow confidence intervals, and an increased chance of significant findings resulting in misleading conclusions (9).

There are two main options when analyzing clustered data. Investigators may analyze the data at the cluster level or at the patient level (5). When analyzing at the cluster level, the standard statistical tests may be used.

Reporting of Results

As mentioned earlier, it is not common practice for investigators to publish their ICC values. These values are essential to investigators trying to conduct similar clustered studies because estimating the ICC almost always requires some sort of pilot study. The ICC is one of the main things that helps investigators interpret the results of cluster randomized trials (15). Thus, reporting of this value would not only be beneficial in establishing the validity of the study, it would also be beneficial to the research community if the estimates were published (16).

In most cases investigators also fail to take between-cluster variation into account when calculating the sample size and almost never discuss issues of power loss (14). These are things that most of the experts on cluster randomized controlled trials agree to be very important when reporting results of cluster randomized controlled trials.

Given that clustering decreases the statistical efficiency of a study, it is also important that investigators state the reasons for randomizing clusters rather than

individuals (16). This information may help the reader determine whether this choice was justified given the clear statistical implications.

CHAPTER II

PART II- SPECIFIC AIMS

1. Review the importance of cluster randomized controlled trials in primary care research
2. Address the special issues that must be taken into account when calculating the sample size for cluster randomized controlled trials
3. Demonstrate the importance of taking clustering effects into account when calculating sample size
4. Demonstrate the importance of and the effects of changes of the intracluster correlation coefficient on sample size calculations
5. Demonstrate the effects of different cluster sizes on the power of the study

CHAPTER II

PART III-SIGNIFICANCE

This Internship Practicum Report will be of great significance to investigators who are designing and implementing cluster randomized controlled trials. It is very important for investigators to understand the intricacies of clustering effects in order for them to calculate an adequate sample size and produce a sufficiently-powered study. Sample size errors can lead to a decrease in the power of a study, decreasing the validity of its findings. Cluster randomized controlled trials are only recently gaining recognition as an important and crucial study design, and have therefore been afforded very little attention in literature (11). It is also doubtful that the implications of cluster effects are fully understood by many investigators. The demand for information concerning cluster randomized controlled trials is steadily increasing because of the increasing popularity of these trials, specifically in primary care research (3).

This report also has great significance to the PCRI and its practice-based research network NorTex. Research conducted by practice-based research networks almost always involves sampling patients from many physicians and clinics (17). This data usually has a hierarchical structure with patient outcomes clustered within physicians and many physicians clustered within the same practice (17). This inherent clustering requires the investigators to take into account the similarity within and between these

clusters. This report will inform them of the unique set of considerations they should apply to their studies.

CHAPTER II

PART IV- MATERIALS AND METHODS

The following methods were used to address the specific aims of this report.

1. **Review the importance of cluster randomized controlled trials in primary care research**

   A thorough review of the literature using PubMed and print resources from the UNTHSC library were used to find literature relating to this topic. Articles that were relevant to the topic were used and others found in the search that were not relevant were discarded or used by the writer to enhance general knowledge on the topic.

2. **Address the special issues that must be taken into account when calculating the sample size for cluster randomized controlled trials**

   These issues were explored through a literature search using PubMed and other UNTHSC library print holdings.

3. **Demonstrate the importance of taking clustering effects into account when calculating sample size**

Sampsize Software was used to calculate the standard sample size then the sample size was inflated by the design effect and the results were displayed in a spreadsheet.

4. **Demonstrate the importance of and the effects of incremental changes of the intracluster correlation coefficient on sample size calculations**

   The Sampsize Software displayed a range of ICC values and a range of cluster sizes based on specified power, significance level, standard deviation and minimum difference.

5. **Demonstrate the effects of different cluster sizes on the power of the study**

   The Sampsize Software allowed for adjustment of the number of clusters and cluster size while also displaying the value for power.

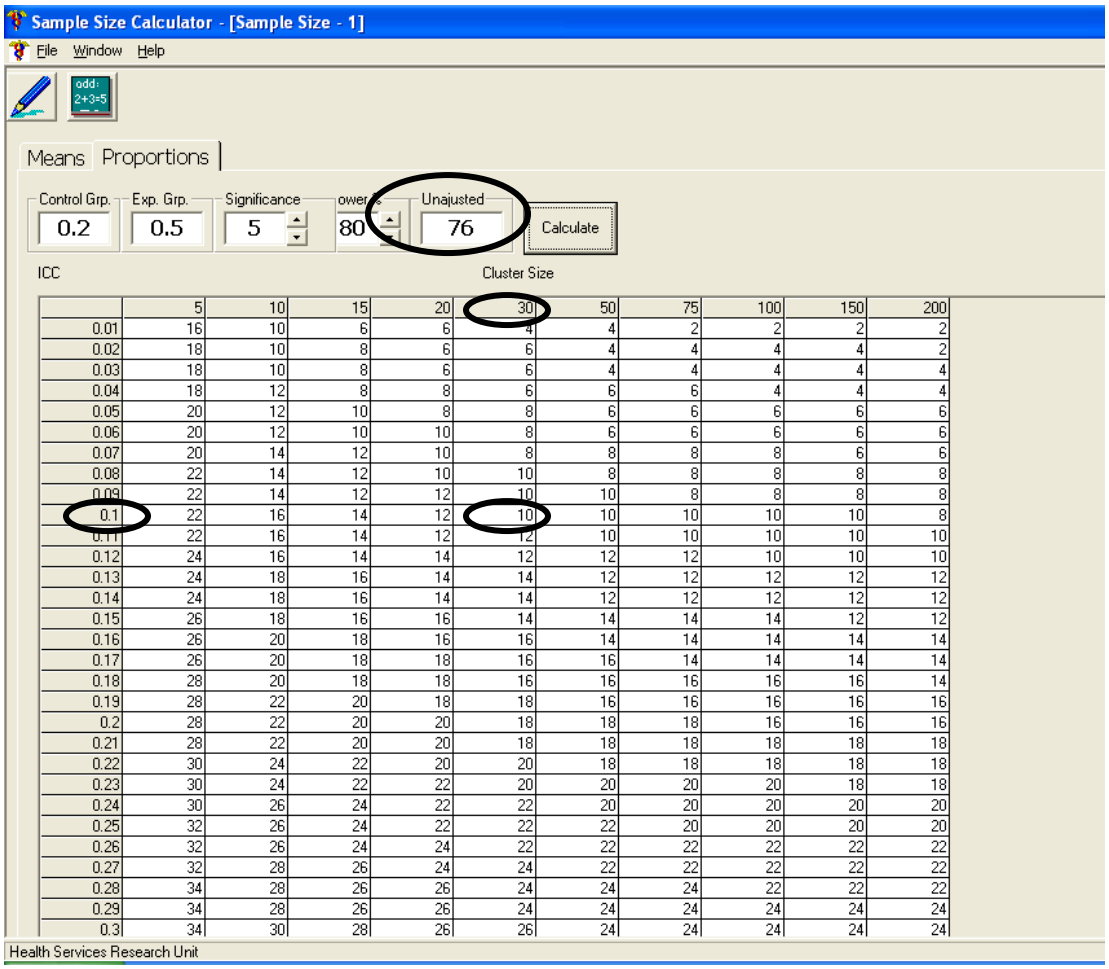
CHAPTER II

PART V- RESULTS AND DISCUSSION

The Sampsize software was used to demonstrate the importance of cluster effects on sample size, and tables were created from the data obtained using the software package as well as from the calculations using Equations 1 and 2 defined in background section. The numbers used for the calculations came from the Cancer Screening Initiative Project (CSIP). The intracluster correlation coefficient (ICC) for this study, as estimated by the Principal Investigator was 0.1. The power desired by the Principal Investigator was 80% with a significance level of 0.05. For feasibility purposes, the investigator chose to limit the number of clinics included in this study to 10 clinics with 30 patient charts being reviewed at each clinic. The study was designed to test the effectiveness of a Digital Video Disk (DVD) intervention on cancer screening practice by primary care physicians. Patient charts from each physician were reviewed to determine the level of cancer screening achieved. The investigator expected to find a 30% increase in the proportion of patient charts that show adequate screening from the control group to the experimental group.

The values needed to calculate the sample size in the Sampsize software include a proportion for the control group, a proportion for the experimental group, significance

level, and power. As seen in the screen shot below (Figure 2), the control proportion entered was 0.2 and the experimental group proportion entered was 0.5. These proportions represent the amount of patient charts that show adequate screening. The significance level and power entered were 0.05 and 80% respectively.

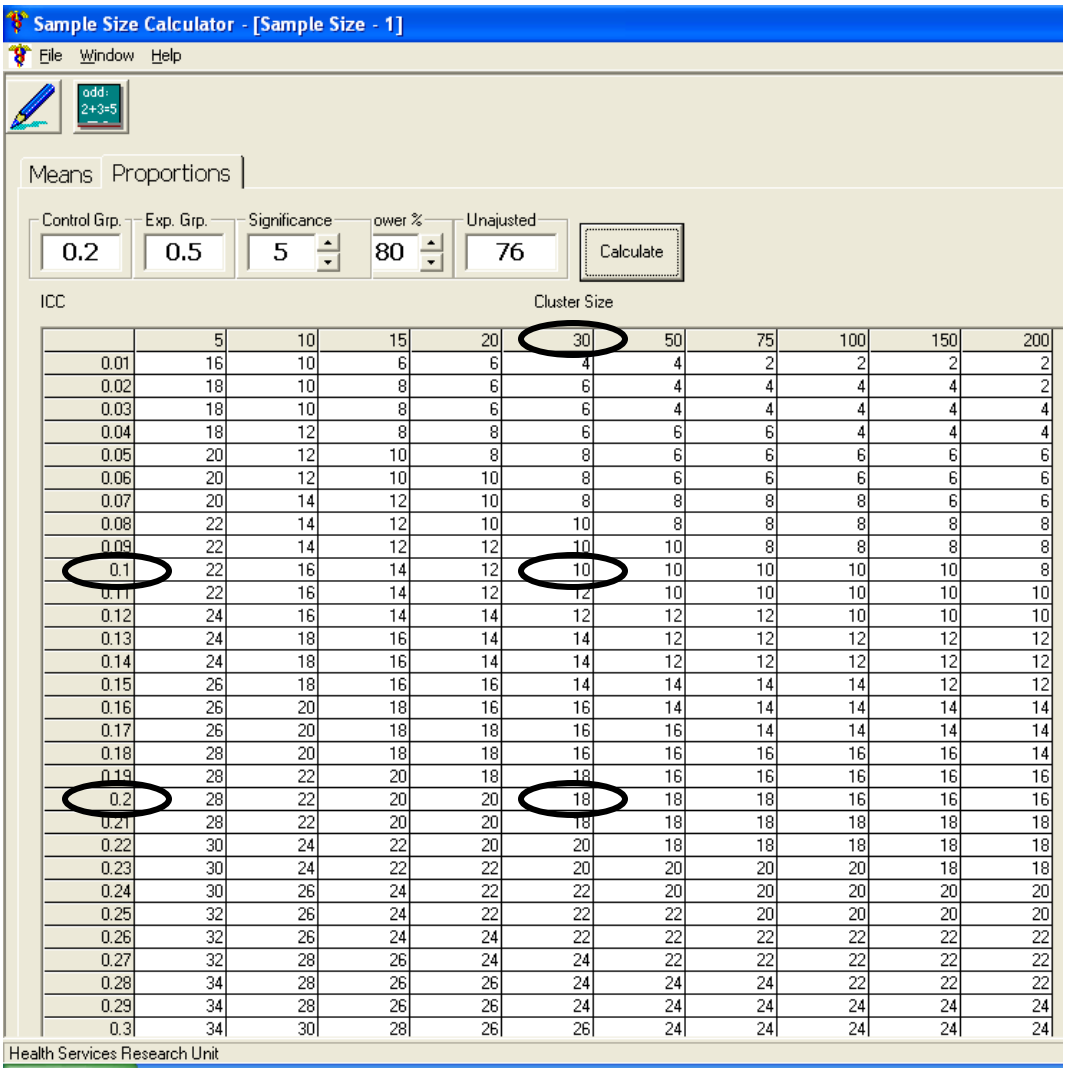


ICC	5	10	15	20	30	50	75	100	150	200
0.01	16	10	6	6	4	4	2	2	2	2
0.02	18	10	8	6	6	4	4	4	4	2
0.03	18	10	8	6	6	4	4	4	4	4
0.04	18	12	8	8	6	6	6	4	4	4
0.05	20	12	10	8	8	6	6	6	6	6
0.06	20	12	10	10	8	6	6	6	6	6
0.07	20	14	12	10	8	8	8	8	6	6
0.08	22	14	12	10	10	8	8	8	8	8
0.09	22	14	12	12	10	10	8	8	8	8
0.1	22	16	14	12	10	10	10	10	10	8
0.11	22	16	14	12	12	10	10	10	10	10
0.12	24	16	14	14	12	12	12	10	10	10
0.13	24	18	16	14	14	12	12	12	12	12
0.14	24	18	16	14	14	12	12	12	12	12
0.15	26	18	16	16	14	14	14	14	12	12
0.16	26	20	18	16	16	14	14	14	14	14
0.17	26	20	18	18	16	16	14	14	14	14
0.18	28	20	18	18	16	16	16	16	16	14
0.19	28	22	20	18	18	16	16	16	16	16
0.2	28	22	20	20	18	18	18	16	16	16
0.21	28	22	20	20	18	18	18	18	18	18
0.22	30	24	22	20	20	18	18	18	18	18
0.23	30	24	22	22	20	20	20	20	18	18
0.24	30	26	24	22	22	20	20	20	20	20
0.25	32	26	24	22	22	22	20	20	20	20
0.26	32	26	24	24	22	22	22	22	22	22
0.27	32	28	26	24	24	22	22	22	22	22
0.28	34	28	26	26	24	24	24	22	22	22
0.29	34	28	26	26	24	24	24	24	24	24
0.3	34	30	28	26	26	24	24	24	24	24

Figure 2. Output from SampSize Calculator for comparison of proportions displaying unadjusted and adjusted sample size calculations

The box labeled "unadjusted" indicates the standard sample size that was calculated without taking the clustering effect into account. If this study did not have a clustered design, the total sample size needed would be 76. In terms of the CSIP, there would need to be a total of 76 patient charts reviewed from all of the physicians to detect a 30% difference in cancer screening practice of the control group and the experimental group with a power of 80%. For an ICC value of 0.1 and a cluster size of 30 (i.e. 30 patient charts), the number of clusters needed is 10. If there are 10 clinics with 30 patient charts being reviewed at each clinic, the total sample size would equal 300 patient charts. This is almost 4 times as many patient charts as the unadjusted sample size. This extreme difference shows the impact of clustering on sample size calculations.

Changes in the ICC can also lead to drastic changes in the sample size of cluster randomized controlled trials. The bold circles in Figure 3 highlight the number of clusters required (each with a cluster size of 30) for an ICC value of 0.1 as well as an ICC value of 0.2. The number of clusters jumps from 10 to 18 with just a 0.1 increase in the ICC value. Increasing the ICC from 0.1 to 0.2 increases the total sample size from 300 to 540. This is almost a two fold increase in the total sample size. Table 1 shows how minute changes in the ICC can have a great impact on the adjusted sample size. It is very important for investigators to have the appropriate resources to adequately calculate the ICC for their study so that they may, in turn, calculate an adequate sample size and produce statistically valuable results.



	5	10	15	20	30	50	75	100	150	200
0.01	16	10	6	6	4	4	2	2	2	2
0.02	18	10	8	6	6	4	4	4	4	2
0.03	18	10	8	6	6	4	4	4	4	4
0.04	18	12	8	8	6	6	6	4	4	4
0.05	20	12	10	8	8	6	6	6	6	6
0.06	20	12	10	10	8	6	6	6	6	6
0.07	20	14	12	10	8	8	8	8	6	6
0.08	22	14	12	10	10	8	8	8	8	8
0.09	22	14	12	12	10	10	8	8	8	8
0.1	22	16	14	12	10	10	10	10	10	8
0.11	22	16	14	12	12	10	10	10	10	10
0.12	24	16	14	14	12	12	12	10	10	10
0.13	24	18	16	14	14	12	12	12	12	12
0.14	24	18	16	14	14	12	12	12	12	12
0.15	26	18	16	16	14	14	14	14	12	12
0.16	26	20	18	16	16	14	14	14	14	14
0.17	26	20	18	18	16	16	14	14	14	14
0.18	28	20	18	18	16	16	16	16	16	14
0.19	28	22	20	18	18	16	16	16	16	16
0.2	28	22	20	20	18	18	18	16	16	16
0.21	28	22	20	20	18	18	18	18	18	18
0.22	30	24	22	20	20	18	18	18	18	18
0.23	30	24	22	22	20	20	20	20	18	18
0.24	30	26	24	22	22	20	20	20	20	20
0.25	32	26	24	22	22	22	20	20	20	20
0.26	32	26	24	24	22	22	22	22	22	22
0.27	32	28	26	24	24	22	22	22	22	22
0.28	34	28	26	26	24	24	24	22	22	22
0.29	34	28	26	26	24	24	24	24	24	24
0.3	34	30	28	26	26	24	24	24	24	24

Figure 3. Output from Sampsize Calculator displaying sample size differences in two ICC values

Table 1 shows the unadjusted and adjusted sample sizes for several ICC values. When the ICC is small, i.e. 0.05-0.07, the adjusted sample size remains constant. When the ICC reaches 0.1, the adjusted sample size is inflated by 60 subjects; that constitutes a 25% increase in the adjusted sample size. As the ICC increases by only 0.05, from 0.1 to 0.15, the adjusted sample size increases by 120 subjects. That is an increase of 40%. From reviewing the data in the table, it is evident that the inflation of the adjusted sample size increases as the ICC increases. It is important for investigators who are conducting their research in environments with larger ICC's to take clustering into account in order to avoid insufficient sample sizes and limiting their ability to draw valid conclusions from the data.

Table 1: Sample Size Calculations for a Range of ICC Values

ICC	Unadjusted	Adjusted	DE 1+ρ (m-1)	ESS** mk/DE	Cluster Size (m)	Number of Clusters (k)
0.05	76	240	2.45	98	30	8
0.06	76	240	2.74	88	30	8
0.07	76	240	3.03	79	30	8
0.1	76	300	3.9	77	30	10
0.15	76	420	5.35	79	30	14

0.20	76	540	6.8	79	30	18
0.30	76	780	9.7	80	30	26
0.40	76	960	12.6	76	30	32

ρ= intracluster correlation coefficient (ICC), DE= design effect, ESS=effective sample size, m= cluster size, and k= number of clusters.

*Note- proportions, power, and significance are constant.

**Values were rounded to nearest whole number

One of the main reasons that an increasing ICC also increases the total sample size required for a study is that increasing the ICC decreases the effective sample size (ESS). The ESS is the number of subjects in the sample size that are statistically effective (7). This trend is shown in Table 1. The ESS steadily decreases from 98 subjects to 77 subjects from an ICC of 0.05 to an ICC of 0.10. It shows an unexpected increase to 79 subjects when the ICC is 0.15 and 0.20. It also increases again to 80 subjects when the ICC reaches 0.30. However, it decreases again to 76 subjects when the ICC is 0.40. These deviations from the trend could possibly be due to the values of the cluster sizes and number of clusters and will be discussed later in this section. When patients within groups are very similar to each other (as indicated by a larger ICC value), there is less statistically valuable information obtained from the data than there would be from the same number of patients in a simple random sample due to a decrease in variability (17). Because of this effect, more subjects are required to produce an

adequately powered study. It is important that investigators remain mindful of this trend when they are estimating their sample size.

Another significant trend seen in Table 1 is the increase in the design effect (DE) observed with an increasing ICC. The design effect was calculated to be 2.45 at the smallest ICC (0.05) and increases up to 12.6 as the ICC reaches its largest value on the table of 0.40. From the design effect equation (Equation 2), one would expect this increase to occur. The design effect calculates how much the standard sample size must be inflated to take clustering effects into account. This value is extremely important and has great implications for not only the sample size calculation but for the analysis as well. Table 2 shows the design effect and effective sample size for different m and k values. The smallest design effect is seen when the number of clusters (k) is 22 and the cluster size (m) is 5. While these specific numbers may not be feasible in an actual study, it is important for investigators to recognize that they should try to keep the number of clusters as large as possible and the cluster sizes as small as possible. This will keep the design effect small while keeping the study adequately powered.

Unlike the ICC, the effective sample size is generally greater when the design effect is small. A small design effect signifies the minimal effect of the clustering on the data. However, as seen in Table 2, this is not always the case. Some of the m and k pairs show an increase in the effective sample size when the design effect increases. Cluster sizes 10, 15, 20, 50 and 75, for example, all demonstrate an increasing design effect and

effective sample size. The increase in total sample size is one possible method for overcoming the design effects.

Table 2: Design Effect and Effective Sample Size Calculations for a Range of m and k Values

Cluster Size (m)	Number of clusters (k)	DE 1+ ρ(m-1)	ESS (mk/DE)
5	22	1.4	79
10	16	1.9	84
15	14	2.4	88
20	12	2.9	83
30	10	3.9	77
50	10	5.9	85
75	10	8.4	89

ρ= intracluster correlation coefficient (ICC), DE= design effect, ESS=effective sample size, m= cluster size, and k= number of clusters.

* ICC=0.1, Power= 80.

**DE=Design Effect and ESS=Effective Sample Size.

Changing the cluster size and the number of clusters can also change the power of a study. To increase the power of a study, it has been shown to be most effective to keep the cluster size the same and increase the number of clusters (4). This helps to offset some of the loss of statistical efficiency due to clustering. Figure 4 shows the sample size required to produce a study with a power of 80% and the sample size required to produce a study with a power of 85%. An increase in power requires an increase in the total sample size for both clustered and simple randomized trials. The unadjusted sample size increased from 76 to 88 (an almost 16% increase). If the cluster size is constant (30 subjects), the number of clusters increased from 10 clusters to 12 clusters. The total adjusted sample size increased from 300 to 360 (20% increase). If the number of clusters is constant (10 clusters), the cluster size increased from 30 subjects to 75 subjects. The total adjusted sample size would have increased from 300 to 750 (150% increase). It is much more feasible for investigators to increase their total sample size 60 subjects instead of 450 subjects to increase the power of their study. This observation illuminates the considerable increase in the power of a study as a result of a slight increase in the number of clusters. The implication for investigators from this data is to distribute their subjects into multiple clusters with relatively low cluster sizes for greater study power.

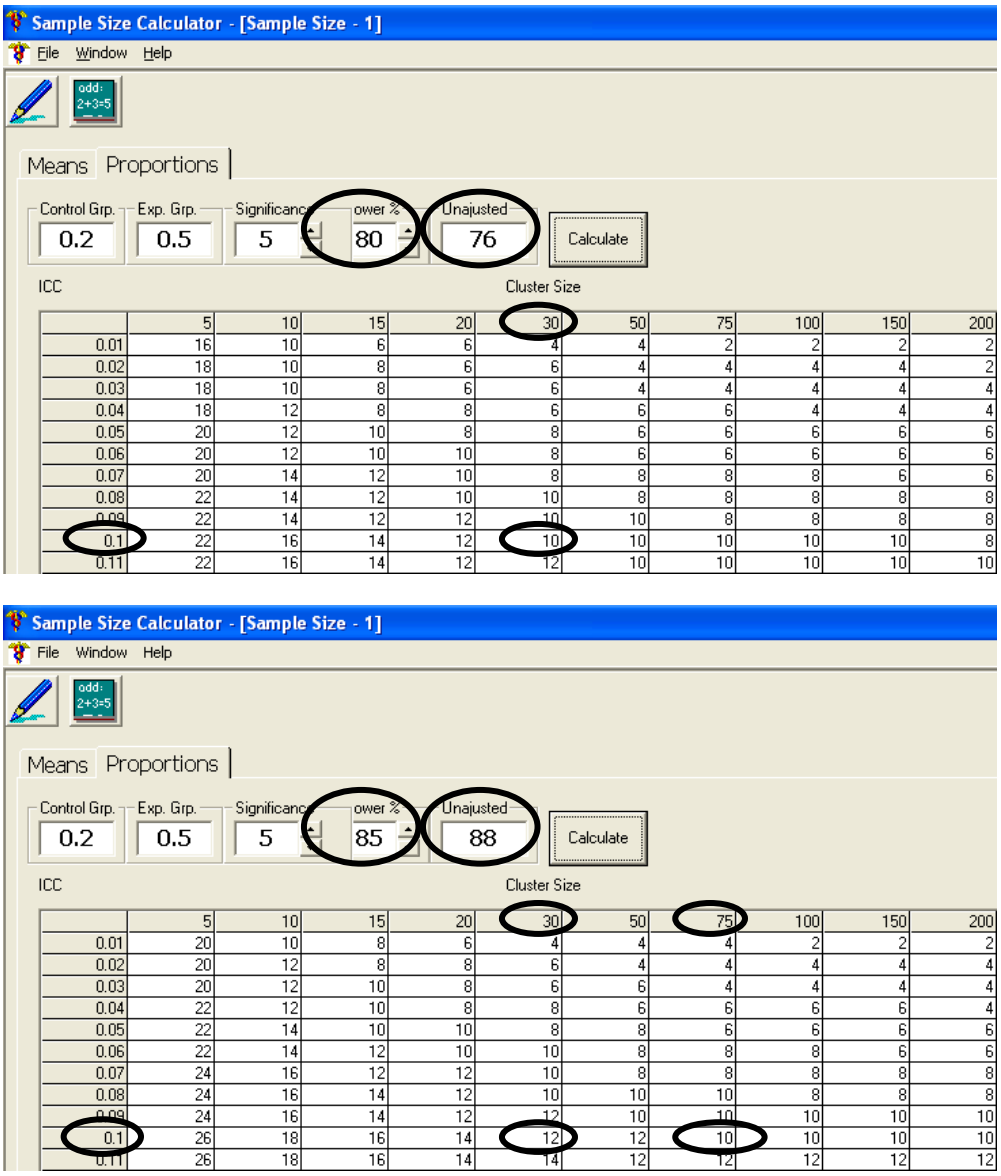


Figure 4. Output from SampSize Calculator displaying sample size calculations for an increase in power

CHAPTER II

PART VI- SUMMARY AND CONCLUSIONS

As demonstrated in the previous section of this report, clustering creates some very important implications on the sample size calculation of a randomized controlled trial. Some of the factors that are important for the investigator to consider and estimate properly are the intracluster correlation coefficient (ICC), the design effect (DE), and the effective sample size (ESS). All of these things must be taken into account when planning a cluster randomized controlled trial.

One can expect the clustered sample size of a study to be significantly larger than the standard sample size of a simple randomized controlled trial. This is due to the fact that clustering causes some of the statistical efficiency of a randomized controlled trial to be lost. Standard sample size calculations are based on the assumption that outcomes between individuals are uncorrelated (6). When subjects are randomized by clusters instead of by individuals, especially within a physician's practice, there is more likely to be a correlation in the responses. This correlation is described the ICC. A larger ICC indicates greater dependence and similarity in the clusters as well as the outcomes from those clusters. This creates a need for more subjects as there is less statistically valuable information obtained from clusters with larger ICC's. When the ICC is very small, changes in the value of the ICC have very little effect on the sample size. However, when the ICC value reaches a certain point or threshold, small changes in the ICC can

cause great changes in the sample size. As seen in the results, a 0.1 increase in the ICC can lead to an almost 4 fold increase in the total sample size.

In order for a cluster randomized design to achieve the equivalent power of a simple randomized trial, the standard sample size estimate must be inflated by the design effect (9). Thus the design effect must be calculated during the planning stages of a clustered trial. The design effect is calculated using the ICC as well as the cluster size and may be multiplied by the standard sample size estimate to calculate the clustered sample size. As stated in the results of this report, the design effect increases when the ICC increases. Investigators should try to keep the design effect as small as possible. In order to accomplish this, it is advisable for investigators to increase the number of clusters (k) and decrease the number of subjects within each cluster (m). This will not only keep the design effect low, but it will also create a more adequately powered study.

The design effect also has a great effect on the effective sample size of a cluster randomized controlled trial. The effective sample size is the number of subjects enrolled in a study that are statistically effective (7). The value of the effective sample size is generally less than the total sample size due to the lack of variability in the data. The effective sample size is calculated by dividing the total sample size by the design effect. The effective sample size is large when the design effect is small (7). The ICC also has an effect on the effective sample size of a study. As the ICC increases, the effective sample size decreases. Due to this effect, more subjects are needed to achieve a highly powered study.

The power of a study is not only affected by the design effect and the effective sample size, but by the cluster size and number of clusters as well. Increasing the number of clusters while keeping the cluster size the same has been shown to be the most effective method of increasing the power of a study. Investigators must be mindful of this as well as the other implications outlined in this section and throughout this report. Without this knowledge, studies will be conducted whose results have no true value to the investigator or to the medical community who may rely on the results for information as to how they should conduct the practice of healthcare.

This practicum report has some limitations. First, one limitation of this project is that it does not present any new information to the topic of clustered randomized controlled trials. It relates facts about these trials that are already documented and enlightens the reader as to the nature of these trials. Also, due to the limited knowledge of the researcher, the project only goes into limited depth of the biostatistics involved in cluster randomized controlled trials. However, those who are unfamiliar with this type of research will be sufficiently informed on the topic and will take away valuable information about how clustering effects the sample size of a study and how to overcome these effects.

There is no question that the unique design and analysis of cluster randomized controlled trials are not fully understood by the research community (14). Less than 60% of reported cluster randomized primary care trials took clustering into account in the analysis of their data (14). This means that over 40% of the trials that were reviewed

were subject to finding a low p-value that was too small and reporting significant findings that may not have necessarily been significant. There are many ways this need for information can be addressed. One of them being reports such as this report that seek to inform investigators of the problems they may encounter in designing and implementing a cluster randomized trial and the things they must consider when calculating the sample size of the study. Simpson et al suggest that all reports featuring cluster randomized controlled trials should include descriptions of the sample size calculations showing where clustering effects were taken into account (14). Of the 21 articles they examined, only 4 of them included sample size calculations or discussions of power that allowed for clustering (14). Published descriptions of sample size calculations would be a very valuable tool to investigators attempting to conduct a cluster randomized controlled trial.

The ICC, one of the key pieces of information used to interpret a cluster randomized study, is almost never reported by investigators in their published findings (15). This information is invaluable to investigators who are planning a study within a similar setting. The ICC is estimated mostly from previously published studies. This informational need may be satisfied by a published set of guidelines for investigators to follow when reporting findings of cluster randomized trials. It is imperative that investigators have available to them the adequate resources needed to conduct a valid and meaningful clustered trial. Despite the statistical implications surrounding cluster randomized controlled trials, they remain one of the most valuable tools in primary care research and therefore should be afforded the attention they require and deserve.

CHAPTER III

INTERNSHIP EXPERIENCE

The Internship Practicum was completed with Dr. Cardarelli and the staff at the Primary Care Research Institute (PCRI). The PCRI aims to improve the health of North Texas residents by combining public health research and primary care practice (11). The studies that I worked on were both being conducted through the North Texas Primary Care Practice-Based Research Network (NorTex), which is part of the PCRI. NorTex was created to provide a common ground for physicians in the fields of family practice, internal medicine, obstetrics/gynecology, geriatrics and pediatrics to participate in primary care research aimed at improving the quality of life of their patients (10).

One study I was involved with during my time at the PCRI was the Cancer Screening Initiative Project (CSIP). This study was designed to test the effectiveness of a DVD of cancer screening guidelines on cancer screening beliefs and practices of primary care physicians. My role in the CSIP was to assist the research coordinator in the daily activities of the study including recruitment of subjects, informed consent, data entry and management. My duties included:

1. Recruitment
    a. Created a list of physicians to contact for the study from a published directory of physicians in the Dallas/Fort Worth metroplex

b. Made phone calls to physician's offices and clinics to acquire study interest

c. Provided interested clinics/physicians with study materials via fax or mail for further consideration of the study

d. As result of my role in recruitment specifically, two physicians were engaged in study enrollment.

2. Follow up

a. Made follow up calls to physicians or clinics that had already been contacted for the study.

b. Sent faxes to physicians to follow up on the study information they had received.

c. Visited some clinics with the coordinator to follow up with more information on the study.

3. Meetings

a. Attended any meetings the Research Coordinator had with clinics/clinicians participating or interested in participating in the study, such as recruitment visits and when consent was obtained

b. Attended meetings with the sponsor, Moncrief Cancer Resources, to present and get updates on the progress of the study.

4. Intervention

a. Participated in randomization of clinics

b. Delivered the intervention to the clinics assigned to the treatment group to ensure the research coordinator remains blinded.
c. Tracked the progress and deadlines of participants who received the intervention

5. Study Instruments
    a. Assisted in proofreading the survey for any errors prior to submission to the IRB.
    b. Assisted with writing the methods section that will be part of a manuscript for this study.
    c. Delivered a post-test survey to all participants and tracked progress and deadlines

The other study that I worked very closely with was the Needs Assessment Project. I worked with the coordinator for this study from the beginning of its development. This project was developed to assess the current delivery of care in North Texas in the areas of pediatric care, cardiovascular disease, cancer screening, and immunizations. A few of my duties in assisting with this project were:

1. IRB paperwork
    a. Filled out the IRB form for the expedited review of the study. The study is being conducted at John Peter Smith (JPS), Parkland and Cooks Children's Hospitals in addition to the University of North Texas Health

Science Center (UNTHSC). Each of these sites requires their own IRB approval of the study.

b. Filled out the HIPAA waiver for the chart review that will be conducted by the physicians in the study.

2. Study Instruments
    a. Entered report aliases to the online questionnaire to be utilized during statistical analyses
    b. Administered the paper survey to a participant
3. Recruitment
    a. Created a contact log to keep track of the physicians who had been contacted for the study.
    b. Contacted several NorTex members and sent them information on the Needs Assessment via fax, mail or email
    c. Followed up with each physician after the information was sent
    d. Attended recruitment/ consent meetings with physicians and the coordinator

I also assisted the Senior Project Coordinator of the PCRI on an ongoing study being conducted. This study is called the North Texas Healthy Heart II Study. My responsibilities for this study were to complete the Serious Adverse Events forms for both the UNTHSC IRB and the JPS IRB. I also observed patient visits that are a part of

the Healthy Heart Study. During these patient visits, I observed the informed consent process, the subject questionnaire and some of the patient processing.

Outside of my duties for both studies, I also assisted in recruiting members for NorTex. I sent packets with a welcome letter, an enrollment form and a NorTex brochure to physicians in the Dallas/Fort Worth Metroplex. Several of the physicians to whom I sent letters decided to join the research network. I also assisted the Senior Project Coordinator with the NorTex Registry Project which collects information on patients who are interested in participating in research in order to create a database of potential subjects for future studies. I helped in expanding this project to private clinics that are members of NorTex in that I presented the project to a physician currently participating in the Needs Assessment study and he agreed to participate.

Both the Needs Assessment and the Cancer Screening Initiative Project are cluster randomized controlled trials involving physicians as the participants. Upon completion of my Internship Practicum in the Primary Care Research Institute, I have learned about the unique design and implications of cluster randomized controlled trials as well as the complex duties of a clinical research coordinator.

APPENDIX

DAILY JOURNALS

Week 1

Monday June 2, 2008

Today was the first day of my internship. I learned that I would be working on two studies during my time at the Primary Care Research Institute. I was given copies of the protocols for both studies as well as other research materials such as the surveys involved. I spent some time going over the protocols to familiarize myself with the overall aims and procedures of the studies. I also attended the weekly staff meeting that occurs every Monday. During this meeting the team members discuss the status of the various projects they are involved with. It was very good that this occurred on my first day as it gave me some insight into the types of research being conducted at the PCRI. I learned about the North Texas Primary Care Practice-Based Research Network that was founded by Dr. Cardarelli. NorTex is a network of primary care clinics that serve under-represented populations of the DFW area. I was given a survey to proofread that is to be used in the Cancer Screening Initiative Project. Some of my duties as I take part in the research will be to contact some of the physicians involved in the study, delivering the intervention to the sites so that the coordinator can remain blind, accompany the coordinator as she goes to recruit new sites and to look up possible new physicians to recruit into the study. I also discussed a potential idea for my project proposal which is the effects of clustering on sample sizes.

Tuesday June 3, 2008

Today I worked on the clinic recruitment list for the Cancer Screening Initiative Project. There was a recently published directory of physicians in the Dallas/Fort Worth metroplex that I looked in to find possible new clinics and physicians in Tarrant County to recruit into the study. I started to create a list of these possible clinicians and checked them against the existing list to determine if they had already been contacted. I was also given an IRB form to fill out for the other study I am working on. This study is going to be conducted at other sites than just UNTHSC so IRB approval at the other sites is necessary. The IRB form was for the JPS Health system. I used the protocol as well as the previously approved UNTHSC IRB form to fill out the form for JPS.

Wednesday June 4, 2008

I obtained the IRB form for UT Southwestern hospital system and began filling it out using the same information I used to fill out the form for JPS. This form was for Parkland hospital. Filling out these forms gave me a better understanding of the study protocol. I also filled out the appropriate HIPAA waiver for UTSW for the Needs Assessment study. For the CSIP I drafted the participant selection section of the methods that will be used in the final report of the study. I also worked on the study procedures section. I used the methods section of another study as a model.

Thursday June 5, 2008

I went over the IRB forms I completed with the study coordinator. The forms were very detailed and certain information I as unsure of so it was helpful to go over them and discuss what I was missing. I found that the more I worked with the protocol and the IRB forms, the more familiar I became with the study. I also worked on the clinic recruitment list and got closer to finishing that task. I discussed my project topic some more with Dr. Cardarelli. He gave me an article to start on that talked about clustering effects. I think this is going to be a very interesting article but I am going to need to do a lot more research because my knowledge on the topic is very little. I think it will be a unique topic. I am starting to see how much I am going to learn from this experience and I am very excited. This is very interesting research and I know that I will take a lot from this experience.

Friday June 6, 2008

Today I had my first committee meeting with all of my committee members. I was excited to share what I had done so far at my site and to hear what was in store for me in the future. We discussed the topic of my project and I everyone on my committee thought that it would be a good avenue to explore. It will require a lot of research and some help from the staff but I am very excited about it and everyone here is so willing to help. So now I am moving forward and doing some research. I also want to look at some examples of proposals done in the past so that I can have a general understanding of what

they are all about. One thing that I was surprised about was that Dr. Cardarelli believes that my project could possibly be publishable so that is very exciting. I hadn't even thought of that as a possibility. Today I also finished the clinic recruitment list for the CSIP. Next week I am going to sit on some calls with Nicole and start making some calls on my own to potential clinics. I am excited to get more and more involved in the study and take on more responsibilities.

Week 2

Monday June 9, 2008

As with all Mondays, today was the task meeting. It was very interesting to hear Dr. Cardarelli talk about the future progress of the Primary Care Research Institute. I got to hear about the progress of the Healthy Heart Study as well as some other ongoing projects. I met the new coordinator for the Needs Assessment Project. I'm very glad that I came at the time that I did because I get to see what its like to start a study from the ground up. I got to see firsthand the monster that is IRB paperwork. So I am excited to work with her and learn together in how to put a research study together. I looked through the list of eligible clinics that had been contacted to participate in the CSIP and noted which ones showed signs of still being interested in the study. I noticed that it can take a few phone calls just to get in contact with the person that can help you get in touch with the physician. It takes a lot of work to keep reminding clinics of the study and to make sure the doctor has received the study information. I knew that it was difficult to recruit participants for studies but I have found that it's increasingly more difficult when

the subjects are physicians with a very busy schedule and not so friendly office staff. It requires a lot of time and patience and dedication to getting your study off the ground. Today I also got to fill out some clinic eligibility forms for the cancer screening study. These are filled out for each clinic that has agreed to participate in the study and they are kept on record.

Tuesday June 10, 2008

Today I got to put together some folders that we will bring to clinics to possibly recruit them into the study. These folders have a membership form for NorTex, a list of projects, a letter from Dr. Cardarelli describing NorTex, and also a brochure about NorTex and a brochure for the CSIP. Making these folders was helpful because I learned some more about NorTex and what a membership entails. I also looked through the survey for the CSIP one more time for errors before it is resubmitted to the IRB. I also worked on entering new potential clinics into the database for the CSIP clinic list. These clinics are eligible for the CSIP but they have to be contacted and given information about the study. Sometime later this week I will actually be placing calls to them and sending them information about the study.

Wednesday June 11, 2008

This morning I started with putting together some letters to send to clinics that describe the CSIP. These letters included a letter from the research coordinator and a brochure with information on the study. I also listened in on calls that Nicole, the research coordinator, made to clinics explaining a little bit about the study and inviting them to participate. After I listened in on a few calls I started to make phone calls of my own. It was a little nervous at first but I found that most people weren't too difficult and most just requested that information be faxed to the doctor so that the physicians or the office manager could look over it. Once I made a few calls and got a few fax requests I filled out all of the cover sheets and printed the letters on letter head. I even got to replace Nicole's name with mine since I was the one who contacted the office. That was pretty exciting. So I'm becoming more and more involved in the process of recruiting and I'm really enjoying learning about everything.

Thursday June 12, 2008

Today I made more recruitment phone calls to clinics and physicians offices inviting them to take part in the CSIP. I found that most clinics were receptive as to receiving the information but I don't know exactly how helpful they will be in making sure that the doctor actually gets to read over the information and make a decision as to participate or not. I sent out many faxes and letters to clinics including the CSIP brochure.

Friday June 13, 2008

It was a very productive day for my phone calls. I had my first physician call back and say that he was interested in participating! I had just sent him a fax earlier in the day and he had his nurse call back right away and say that he was interested. It was very exciting. The next step after a physician says that they are interested is to send them the NorTex membership form. We also draft a thank you letter to send with that as well. They must complete the NorTex membership form because they must be members to participate in the CSIP. It is just a very short one page form. Once that form is complete they send it back and then we send them a membership folder. This folder has a letter from Dr. Cardarelli thanking them for joining and giving them some more information about the network. It is rare to have a doctor reply so quickly and it is nice to have someone as excited about the research as you are.

Week 3

Monday June 16, 2008

Today was our weekly task meeting. I got to share with everyone about the recruitment calls that I was making and the letters and faxes that I was sending to possible participants in the CSIP. I even had one physician call back and express interest the same day that I had faxed him the information. So I faxed him the NorTex membership form which he filled out and faxed back to me. Now the next step is to send him the folder with all of the NorTex information. It also has an additional survey that

the physicians are asked to complete. Our recruitment for the CSIP is up and Dr. Cardarelli was very pleased to hear that. It sounded like the Healthy Heart Study is coming along very well. I also talked with Dr.Fulda who is the Assistant Director of the PCRI. She knows a lot about the statistics side of things as well as the research coordination aspect. We talked about things that I may want to see and accomplish in my time here. She suggested that I make a checklist of things I would like to be involved in and experience while at the PCRI. Some things that I can think of are sitting in on an IRB meeting here at the UNTHSC and possibly sitting in on an informed consent process that involves actual patients instead of physicians so that I could see the difference. I also set up a meeting with her to talk about the statistics involved in my practicum report and the overall timeline I have to finish the project. I also finished calling doctors on my list and sent faxes and letters with information on the CSIP.

Tuesday June 17, 2008

I am very excited for today because today I get to attend a meeting with Moncrief Cancer Resources. They are the sponsors for the Cancer Screening Initiative Project that I have been working on with Nicole the RC. I was very interested to observe the interaction between the sponsor and the PI and RC. Some things on the meeting agenda were to discuss funding, updates on the research protocol, the filming schedule and distribution plan for the DVD intervention, and the timing of the deliverables. They have actually run into problems in putting the DVD together and production is about 2 months behind. So of course there is a need for additional funding from the sponsor to cover the

additional costs incurred due to this delay. It was interesting to see how that works as well. The sponsor was actually very receptive and just agreed that since it was their fault that the DVD was not ready that they would willingly cover any additional costs. Overall I would say that it was a great experience and I learned a lot about the relationship between the PI and the sponsor. I learned that it is important to create positive collaborative relationships because this makes it easier for everyone involved and creates a good atmosphere for the study to evolve. For the rest of the day I put together recruitment letters for Nortex. Each physician gets one as a separate invitation from the study recruitment letter.

Wednesday June 18, 2008

Today was a very productive day. I had a meeting with Dr. Fulda this morning to talk about my project and the statistics involved. She does the sample size calculations and such before the study starts so she knows a lot about my topic. She was very helpful in narrowing down my focus to just a few specific aims and she had some very useful articles and books for me to get some information from. I feel a lot better about the direction my project is going in. I felt a little bit lost at first just because I didn't know how to narrow my focus and to provide some new insight onto the topic. I am very excited because I think that my project will be very unique and I know that I will learn a lot. I also finished making some phone calls to the clinics that had yet to be contacted on the CSIP.

Thursday June 19, 2008

The focus today was a little different than the focus for the phone calls that I made yesterday. Today I was calling clinics that have already been contacted on the CSIP and needed some follow up on whether or not the doctor had even received the information. I know that a lot of things come across physician's desks each day so it helps to kind of remind them to look over the materials. Also many of them who are not interested in the study probably just set the information aside so it is necessary to call back and get their decision on whether or not they are interested in participating. This is yet another barrier I have found in the recruitment process. In multi-physician practices it can be very hard to find out if each doctor received/looked at the information because you pretty much have to speak to each nurse. Many times we will leave messages and never hear back from them. So we just make a phone call once a week or so and if they are still unresponsive we just mark them as not interested. This helps keep our focus on contacting those clinics who may actually be interested.

Friday June 20, 2008

Things are coming along well with the CSIP recruitment. We now have a total of 14 clinics, some one physician and some two physician clinics. We also have four physicians who are interested in the study but have not yet been enrolled. We have two meetings next week with two of the interested physicians just to formally present the study. A lot of physicians prefer to hear about the study in person and I think that is understandable. I also feel that they would be more likely to participate or at least consider participating if they are actually presented the information in person. I know

that I would be more likely to participate if someone physically came to my office. So I am very excited for those meetings. It will be interesting to see how they go and to see the physicians' response to the information as it is presented. We also bring a folder with the NorTex membership form and letter. Today I made files for the 14 interested clinics. In each file I put the directions to and from the clinic to UNTHSC and also the clinic eligibility forms.

Week 4

Monday June 23, 2008

Today I learned about serious adverse event reporting (SAE). In the Healthy Heart II Study anytime a patient is hospitalized there must be a SAE form sent to both the UNTHSC IRB and the JPS IRB. One thing that surprised me was that all of these events must be reported even if they are not at all related to the study. Patients that undergo an elective procedure and are hospitalized during the course of the study must report these procedures to the study personnel and the study personnel must then report these events to the IRB within 7 days of notification. Today I learned that it will be my responsibility to fill out these forms while the Senior Coordinator is out of the office. We also had the task meeting today. It is very exciting to hear how much the PCRI is growing and all of the great opportunities for collaboration with other institutions. The UNTHSC is

currently trying to recruit more clinician researchers to the campus which is really promising to the future of clinical research at the HSC.

Tuesday June 24, 2008

The NorTex Needs Assessment study was the focus of today. I assisted the coordinator of this study in going through the survey and assigning report aliases to the questions and the answers of the questions. This is needed so that when the statistical analyses are performed the headings for the questions are shorter and easier to work with. I also proofed the study for any errors and corrected those errors. Any changes made to the wording of the study will eventually be submitted to the IRB. I also filled out another SAE form for a patient in the Healthy Heart II Study.

Wednesday June 25, 2008

Today my focus was on contacting the CSIP participating clinics/clinicians and reminding them about the NorTex agreement of cooperation and the NorTex survey. The physicians had all received the welcome folder containing these documents but they had yet to return them to the PCRI. I just made sure that the physicians had received them and asked a few of the nurses to remind the doctor to send them back to us.

Thursday June 26, 2008

Since we have a pretty good idea that one of the multi-physician clinics who had previously said they would participate in the CSIP was probably not going to participate,

I spent most of the day calling multi-physician clinics. These clinics had previously been contacted but we had not heard from them in quite some time. I faxed information on the CSIP to them again and most of the nurses said that they would make sure the physicians received the information. I left a few messages with some office managers and was able to cross a few off the list who told me that they were not interested in participating at this time.

Friday June 27, 2008

Today I made some follow up calls to doctors who had shown interest in the CSIP. I called the office of the physician who I had previously called and recruited for the CSIP to make an appointment so that we could go and present the doctor with the NorTex welcome folder as well as the study timeline. The coordinator and I were thinking that the doctor might be timelier in returning the documents for NorTex if we explained the documents in person and let the doctor know what the information would be used for. I set that meeting up for next week.

Week 5

Monday June 30, 2008

Today I completed the SAE forms for a patient in the Healthy Heart II Study. This patient had a cholecystectomy last year while still enrolled in the study. The date and nature of the procedure was revealed in their follow up visit. We also had our weekly

meeting today. I learned about an exciting research proposal that Dr. Cardarelli is submitting about breast cancer screening in African American women. It is well known that there is a large disparity in health outcomes of white and black women diagnosed with breast cancer and it is very exciting that there is being research conducted that could bridge the gap and improve the healthcare of black women.

Tuesday July 1, 2008

To keep track of all of the clinics that we contacted for the CSIP, each one needs a clinic eligibility form. The clinic eligibility form determines which clinics are eligible to participate in the study. In order to be eligible, the clinic must be in Tarrant County, have at least one eligible physician, have at least one physician willing to participate in the study and they must allow us to have access to charts. The clinics that said they were not interested in participating in the study were marked ineligible since they did not meet the last two criteria. As for the clinics that have not responded to any of our attempts at contacting them, they will be marked ineligible if they have not responded before the consent process begins.

Wednesday July 2, 2008

Today we focused on getting things ready for the consenting process of the CSIP. The DVD should be completed by the end of this month so we are hoping to start consenting the physicians the last week of this month into the first week of August. Today I filled out clinician eligibility forms for each of the physicians that are participating in the study.

I also made folders for each physician that included the consent form, study timeline, and the clinician eligibility form. Each physician will get a copy of the signed consent form to keep for themselves. The clinician eligibility form will be completed at the time of consent.

Thursday July 3, 2008

Today I made a list of the participating physicians and the status of their recruitment documents. The clinics or clinicians who were not already a part of NorTex needed to fill out the enrollment form in order to participate in the study. They were also asked to complete an agreement of cooperation as well as a survey for NorTex. Many of the physicians have been slow to complete these forms. I can see how it can be difficult for the research coordinator to urge the physicians to complete the forms without making it seem like nagging. These forms need to be completed before the study begins. For many of the doctors we will bring the forms with us when we meet with them to go over the consent forms and hopefully they will fill them out while we are there. I prepared the necessary documents for these meetings.

Week 6

Monday July 7, 2008

Since it has taken so long for the sponsors of the CSIP to create the intervention, we have been a little worried that some of the doctors may not be as interested in

participating in the study as they once were. Some of them take a long time have been out of contact for quite a while as they are very hard to get in contact with. So today I contacted some clinics that may be used as backups in case we have some physicians back out and decide not to participate in the study. Some of the clinics I contacted requested information to be faxed or mailed and I got that information out to them as requested.

Tuesday July 8, 2008

Today I went with the coordinator of the CSIP to meet with an interested physician. This physician was one that I had contacted previously and had gotten back to us immediately expressing his interest. We had already received his enrollment form for NorTex but we wanted to meet with -him to discuss the details of the project and to see if he would fill out the other required forms while we were there at his office. We updated him on the study timeline and he was very receptive to the project and very eager to help in anyway he could. His assistant was also in the meeting with us and she was very helpful in setting up the next meeting which will be for the informed consent process. He even filled out the forms for us while we waited. This was a big plus for us since it has usually been taking quite a bit of time for the physicians to find enough time to complete the survey and cooperation of agreement with NorTex. It is always exciting to work with a physician who is very interested in our research and has an office staff that is so willing to help.

Wednesday July 9, 2008

Today I was involved with the Needs Assessment project. I went with the coordinator to drop off IRB amendments. There were some changes to the survey as well as some changes to the type of compensation that was being offered to the physician participants. The type of CME credit that was being offered was changed by the UNTHSC PACE office. These changes had to be approved by the IRR here as well as at JPS. It was interesting to see that the JPS IRB academic offices were right in the hospital. It was a much different setting than the UNTHSC IRB.

Thursday July 10, 2008

I was surprised this morning when I got into work and checked my email to see a message from a physician that I had contacted quite a few weeks ago. She expressed interest about the study based on the CSIP documents that she had received. What is even more interesting about this case was that when I had originally spoken to her office staff, one of her office reps had told me that she was not interested in doing the study. Since this person was not a direct representative of the physician such as her nurse or clinic manager, I decided to go ahead and just send her the brochure materials in the mail so that they would go directly to the doctor herself.

Friday July 11, 2008

Today I helped prepare some documents to be sent to JPS for the Needs Assessment and the NorTex Registry Project. Both of these projects are in the process of

being approved by the IRB. This is their preliminary approval for each host location. I made sure each one got mailed out to the appropriate IRB.

Week 7

Monday July 14, 2008

Today I helped with contacting the participating clinics to schedule meetings for the physician's informed consent. I sent faxes to some of the harder to reach physician's offices. It seems that most of the time they are more receptive to having something in writing than if they receive a phone call.

Tuesday July 15, 2008

Today we had a brainstorming session to talk about a research opportunity that Dr. Cardarelli had been presented with. He wants to use the best practice research methodology to come up with a sustainable tool that can be used by physicians to improve cancer screening. I felt that it was an invaluable experience for me to have because I got to be a part of the process of planning a study and was able to observe the thought process behind creating a plan to produce a study with valuable output.

Wednesday July 16, 2008

Today we contacted some more physicians and followed up on previous attempts to reschedule informed consent for the CSIP. We were very happy that no one dropped from the study. All of the meetings have now been rescheduled.

Thursday July 17, 2008

I turned my project proposal into the Graduate School today. I was very excited to finally get it turned in since it had been completed for quite some time. I got all of the signatures that I needed and I was very happy with the final outcome of the proposal. I am excited to begin working on my final project now.

Friday July 18, 2008

Today was a team building day at Chuck E Cheese. We took the last half of the day off and everyone in the PCRI went to eat pizza and play games as Chuck E Cheese. It was a good break from the work week and it was good to have a little fun together.

Week 8

Monday July 21, 2008

Today I worked on the Needs Assessment study. It got approved by the UNTHSC IRB on Friday. So today we started the recruitment process. We were contacting the clinics in the UNT Health system. My focus was on the physicians that are here in the PCC. This included the Family Medicine physicians, Pediatrics and

Internal Medicine physicians. I sent emails to all of the Family Medicine Physicians outlining the study and their responsibilities should they want to participate. Since we were unsure exactly which physicians were actually still practicing in the other two departments, we decided to contact their clinic managers so that we could ask them about the best way to get in contact with their physicians. I left messages with those two clinic managers.

Tuesday July 22, 2008

Today was much like yesterday. I just helped to contact physicians for the Needs Assessment and tried to figure out the best way to contact some of the physicians.

Wednesday July 23, 2008

Since the CSIP has had another delay, the coordinator has been working on a new grant for the Komen foundation. So today, I helped her search for some articles on mammograms and their efficacy and effects on mortality.

Thursday July 24, 2008

Switching back the Needs Assessment project, I created a database in Microsoft Access so that the recruitment process could be better organized. The database will hold all the names of the physicians we contacted to participate, their response, what type of compensation they will receive, their contact info, and also a checklist for completion of the survey and chart reviews.

Friday July 25, 2008

Today we recruited our first physician for the Needs Assessment. She was very interested in doing the study so we scheduled a meeting with her today to do the informed consent so that she could get started. Once she signed the informed consent it is a really easy process. We email her the link for the survey and once she completes the survey she is given the numbers for five charts for her to do the chart reviews on. And once we find out that she has completed the chart reviews, we complete the paperwork for her to get her compensation.

Week 9

Monday July 28, 2008

Today we had our weekly task meeting to discuss the status of everyone's everyday activities. We talked about the status of each project that is going on. We also went over the job descriptions of everyone in the PCRI including the research assistants so that all of the new people knew exactly what everyone's assigned responsibilities were. I also started on a project where I will be entering data from the Healthy Heart Study's follow up calls to all patients enrolled in the study. I am entering them onto an excel spreadsheet so that the information is all in one place and is easily accessible for anyone who wants to know the information.

Tuesday July 29, 2008

Today I sat in on a meeting with Billy Moore from Parkland along with the research coordinator for the Needs Assessment and the senior coordinator of the PCRI. This meeting was to discuss the IRB procedures of Parkland. It had been a learning experience for the PCRI because this is our first time working with Parkland. At one time we assumed that they would have the same procedures as UTSW and that we could go through the UTSW IRB to get the study approved but that is not the case. Parkland likes to do things a little differently than UTSW. So we had to reformat some documents such as the informed consent and the research summary to fit their format. As a result of the changes that had to be made, they are the last ones to get IRB approval. But it has been a good learning experience for everyone involved and now a more structured format for turning things into the Parkland IRB has been created for future submissions.

Wednesday July 30, 2008

I observed another meeting to recruit a physician to possibly participate in the Needs Assessment. I went with the senior coordinator to recruit a pediatrician located at the Albert Galvan clinic. This physician is one who has not had a lot of experience with participating in research. We brought the informed consent as well as a copy of the survey so that she could see the length of the survey and approximately how long it would take for her to complete it. She was reluctant to commit to participating but we left the information there for her to look over a bit more closely.

Thursday July 31, 2008

It seems like recruitment for the Needs Assessment is going to be more difficult than I thought. One clinic that I was very hopeful about participating in the study has had some concerns about the amount of time it would take to complete the chart reviews. They also don't want to put any more work on their office staff by asking them to complete the chart reviews. I asked to set up a meeting to meet with them but it looks like they are just going to not participate.

Friday August 1, 2008

Today I contacted some of the NorTex private clinics by e-mail to introduce them to the study. I will give it a few days to see if they answer my e-mail and if they don't then I will give them a call. I also finished entering the data from the Healthy Heart Follow up phone calls into the excel spreadsheet.

Week 10

Monday August 4, 2008

Today I caught up with the coordinator of the CSIP just to get an update on how Moncrief was doing with the development of the DVD. It seems that they are on target with their August 25th deadline for getting the DVD to us. All of the physicians except for 3 have been scheduled for consent. I got the dates and times of the consent meetings from her so that I could put them on my calendar and I would be prepared. Those meetings will start two weeks from today. I am excited to finally get that study started. I

enjoy going out to the meetings with the physicians as it gives me a chance to meet the physicians we are going to be working with. I will be assisting with the consenting process as much as I can.

Tuesday August 5, 2008

Today we had our weekly task meeting. I got an assignment from Dr. Cardarelli for the Komen grant. I am to prepare the public abstract for the proposed research study that they are requesting as part of the grant application. I also contacted several JPS clinics who have physicians who work for UNT Health but see patients at the JPS clinics. I contacted these clinics to get an updated list of their providers. These clinics will then be randomized as to what compensation they are getting for the Needs Assessment. I also made some follow up phone calls to some physicians that I had contacted last week. These physicians are already members of NorTex so I was just presenting the new study to them and hoping to set up a meeting so that we could give them more details about the study.

Wednesday August 6, 2008

I did some more follow up work today. There were a few physicians whose phone numbers were old and no longer in use so I mailed these physicians a letter I had drafted that gave a little detail about the study and how they would be compensated for their participation. I also began contacting physicians who are not already members of NorTex today. Most of these physicians had already been contacted for the Cancer

Screening study but they did not express outright interest in participating and we already had the needed amount of clinics participating. I also read over the proposal for the Komen grant so that I could get a better idea of what the study entailed.

Thursday August 7, 2008

I resumed contacting physicians from my list of physicians. I sent faxes and letters. So far I have contacted about 30 physicians from the list. I also worked on the public abstract for the Komen grant.

Friday August 8, 2008

I finished the abstract today and sent it to have one of the coordinators review it before I send it to Dr. Cardarelli. I also contacted more physicians for the Needs Assessment. Next week I will begin to make follow up calls to the physicians that I had faxed or mailed to make sure that they had received the information and to possibly set up a meeting with them and the coordinator to go over more details.

Week 11

Monday August 11, 2008

Today I updated the NorTex Recruitment database for the physicians who I have been re-contacting for NorTex and the Needs Assessment. I added a column to the

database for these notes. I also sent more faxes and letters about NorTex and the Needs Assessment.

Tuesday August 12, 2008

Dr. Cardarelli reviewed the public abstract that I had been working on and gave me some suggestions of corrections to make. It was still a little too scientific so I had to reword some things and format it a little differently. I didn't realize how hard it can be to write non-scientifically when you are so used to writing things to a scientific audience. We also had the task meeting today. I also had one doctor whom I had re-contacted for NorTex last week return his enrollment form today. I sent him the welcome folder and the other NorTex documents he would need to return.

Wednesday August 13, 2008

I made the very last revisions to the public abstract. I had one more physician return his enrollment form today so I sent him his welcome folder. I also made follow up calls to 25 of the physicians I had sent information to last week. Most of them requested the info to be resent and some of the office staff said that the information was on the physician's desk and that they were in the process of reviewing it. I also sent more faxes and letters to physicians on the recruitment list.

Thursday August 14, 2008

Today I worked on creating a new NorTex Member List. This database will have all the names of the clinics and physicians that are a part of NorTex. It will make it easier for anyone who wants to know information about any of the members to find the information. I also made follow up calls to some members of NorTex that I had contacted previously about the Needs Assessment. I sent faxes and letters as the clinics requested. I also received yet another enrollment form from a physician I had contacted last week.

Friday August 15, 2008

Today we had an impromptu research planning meeting for a R01 grant that Dr. Cardarelli would like to apply for. This study would be based off of the Healthy Heart study data. I really like these meetings because it is always interesting to be involved in the process of coming up with an idea for a study. I also sent more faxes and letters about NorTex to physici ans on our recruitment list.

Week 12

Monday August 18, 2008

Today I finished sending NorTex letters to the physicians in the NorTex recruitment list. We also had our first consent meetings for the CSIP. We are now able to start consenting the physicians because the DVD is going to be ready by next Monday. Today we had a lunch meeting with our first physician. We of course had to go through

the informed consent form and we also went over the study timeline again and made sure we had all of the NorTex documents we needed. We also began randomizing each of the clinics.

Tuesday August 19, 2008

Today we had the task meeting as well as three meetings with physicians who are participants in the CSIP. The consent meetings have been very productive and it is looking like we have a great set of participants. Everyone seems very eager and willing to help and most of them are very interested in how the project will turn out.

Wednesday August 20, 2008

Today I worked on the NorTex member list. I am in the process of transferring the member information from an excel spreadsheet to an access database where it will be easier to view the information. We also had more consent meetings for the CSIP. I am thoroughly enjoying getting to meet the physicians and I am excited that this project is finally starting.

Thursday August 21, 2008

Today I finished the NorTex list by adding all of the outside affiliates and private clinics. I looked through the enrollment forms we had received to make sure that they were on the list and their information was correct. We also had two more consent meetings for the CSIP.

Friday August 22, 2008

I tagged along with the coordinator working on the Needs Assessment today. We went to a very interesting clinic here in Fort Worth to recruit a physician. His practice was started in the fifties by his father and he now runs it. It was very good to meet him and he was also very interested in participating in the study. Our last consent meeting of the week for the CSIP is today in Colleyville. Our meetings have been very successful and I am also very excited about the physicians who have been randomized to the intervention group. They are very easy to work with and will have no problem completing watching the DVD in time.

Week 13

Monday August 25, 2008

Today we had two consent meetings for the CSIP. Overall, these meetings have been going very well. It has been a very good learning experience for me to be involved with the physician participants. It will be very good experience to have in the future as I am sure to have to work with many physicians. The pre-test survey was also sent out to the physicians who had been consented. The physicians were given the option of completing the survey on paper or online. Most of them opted to take the survey online however, there were a few physicians who would rather not do it on the computer and opted to take the paper version. The physicians were given a timeline of 72 hours to complete the survey.

Tuesday August 26, 2008

Today we had the weekly task meeting. There weren't any pressing updates on anything. I came up with the idea of adding more physicians to the NorTex recruitment database from the directory that I used to find physicians to recruit for the CSIP. I only added physicians who were in Tarrant County before because that was one eligibility requirement for the CSIP. So now I will go through the DFW directory of physicans and add those physicians who are outside of Tarrant County.

Wednesday August 27, 2008

Today's consent meeting was with one of the UNTHSC physicians right in the Primary Care Center. Now we only have two more physicians to consent. Several physicians have also completed their pre-test surveys and the majority of the clinics have been randomized. I also continued working on the NorTex recruitment list.

Thursday August 28, 2008

To take a break from entering physicians to the NorTex list, I sent out some letters to physicians who had yet to be contacted a second time for NorTex. I thought it best to make sure that everyone on the old list had been contacted again before I started to send letters to the new physicians.

Friday August 29, 2008

Today I had an informal meeting with Dr. Cardarelli, Anna and Dr. Fulda. We talked about the next steps to completing my final report for the Internship Practicum. I was given the links to the software I will be using as well as the users manual for it. I will be looking over that this weekend so that I can become familiar with it before I start using it. We talked about the timeline for my project and everyone agreed that I had plenty of time to accomplish my specific aims. It was suggested that I focus a lot on the theory of cluster randomized controlled trials so I have some work to do to add some of that to my background/literature review. In the coming month I will also be increasing my knowledge on the subject so that when it comes time for me to defend I will be very well prepared.

Week 14

Monday September 1, 2008

Labor Day Holiday!

Tuesday September 2, 2008

Today we had our weekly task meeting. I worked with the NorTex recruitment list as well as going over the materials Dr. Fulda and Dr. Cardarelli gave me to help with my final project. I learned how to use the software and went through the instruction manual. I also went over the notes that Dr. Cardarelli made when coming up with the sample size calculation for the CSIP.

Wednesday September 3, 2008

Today we had our last consent meeting for the CSIP. All of the physicians have now been consented and all of the pretest surveys have been delivered. I also continued working on the NorTex Recruitment list.

Thursday September 4, 2008

Today I continued with the list. I have now added around 300 physicians within a 30-40 mile radius from Fort Worth. I also reviewed some additional articles for my final project.

Friday September 5, 2008

Today I continued with the list as well as prepared the NorTex recruitment materials for mailing. I also read a few more articles and found some very useful information to add to the background section of my thesis.

Week 15

Monday September 8, 2008

Today I was given a short list of physicians to contact for the Needs Assessment. I will be responsible for following up with them and will be their main contact person for the study. They had all been contacted previously but those attempts were not successful.

So I tried a different means of communication than had been previously used. Some of them I tried email and some of them I sent faxes or mailed letters with Needs Assessment info. I also worked on sending out some NorTex recruitment letters.

Tuesday September 9, 2008

I wanted to give the physicians time to receive the Needs Assessment information and possibly look over it before I tried to contact them again so I did not make any phone calls today. Instead I worked on putting together the NorTex brochures, recruitment letters, enrollment forms and project lists to be sent to physicians.

Wednesday September 10, 2008

I continued with the letters and the list.

Thursday September 11, 2008

Today I followed up with the physicians I contacted for the Needs Assessment. Most had received the information but the physician was still looking over it.

Friday September 12, 2008

Today I mailed about 90 letters to physicians in the DFW area to be recruited for NorTex. I also had one enrollment form returned to us from a batch of letters I had sent out two weeks ago. It was from a clinic in Dallas. So I mailed them a welcome folder

and added them to our list of NorTex members. I dropped off one DVD today for the CSIP.

Week 16

Monday September 15, 2008

Today I visited a physician's office and dropped off a paper survey for the Needs Assessment. He was having trouble finding time to complete the survey online because it has to be done in one sitting. I also brought the NorTex contract for him to sign. I left him with my email address so that he could contact me when he has completed the survey and I can come pick it up. I also contacted my other Needs Assessment contacts and there was one that declined to participate. Some of them requested the info to be resent and so I sent faxes to them. I also dropped off one DVD today to a physician that I could not reach on Friday.

Tuesday September 16, 2008

I sent another group of NorTex recruitment letters today to some clinics in the Dallas area. We also had a meeting to discuss the recruitment of an NIH funded clinical researcher to the health science center. We discussed several ideas of approaches to recruit these researchers and I came up with the idea of possibly creating a DVD visual on the health science center and the city of Fort Worth. I thought that would be effective in giving them a better idea of what the city is like and what the school is like as well. I think it is very exciting to have someone of such caliber possibly coming to the health

science center and I am very glad to be a part of it. We also had a task meeting this afternoon as well.

Wednesday September 17, 2008

I dropped off two DVD's today which means that all of the physicians who have completed the pre-test and had been randomized to the intervention group have received the DVD. One clinic is still pending. I also began the search for the new clinical researcher position. We have a list of about 60 possible candidates and we are doing searches on them to find more information.

Thursday September 18, 2008

Today I received NorTex enrollment forms from two physicians I had sent letters to last week. So far it seems as if the recruitment is going well. We get a few enrollment forms in every week. I think that there would be a lot of physicians who would be interested in joining NorTex but they have just not been introduced to it. I also continued with the search.

Friday September 19, 2008

Today I dropped off a Needs Assessment folder to a physician's nurse up in internal medicine. I explained to her the study and the forms that were in the folder. She said that she would make sure the doctor received the information. I also sent another group of 30 NorTex recruitment letters.

Week 17

Monday September 22, 2008

Today I put together folders for the candidates that were most qualified for the new researcher position. I went through them a little more carefully to make sure that they had the adequate history of NIH funding and PI experience.

Tuesday September 23, 2008

Today we had another meeting about the clinical researcher recruitment with representatives from the Health Institutes of Texas. We got some good ideas on who to look for and how to get them interested in coming to UNTHSC. We also had the weekly task meeting today. I continued the search and continued making files for the qualified candidates.

Wednesday September 24, 2008

I made a contact log today of the physicians I have been made responsible for contacting. I created a table with each of the physician's names and the dates of all contacts as well as the mode of contact. At one office I am never able to reach the office manager so I just asked if I could drop off a folder with the information and if they would make sure that the physician got the information. I dropped off that folder in the afternoon. I also continued the search.

Thursday September 25, 2008

Today I received another NorTex enrollment form from a doctor in Frisco who is interested in joining. I sent him a welcome folder today with the appropriate documents. I also emailed some of my Need s Assessment contacts just to follow up with them. I also went with the CSIP coordinator to meet with a physician who expressed interest in the study. We would like to add one more to the study because we had a clinic drop out last week. The physician was very interested in the study and agreed to participate.

Friday September 26, 2008

Division of Research Retreat. We talked about the goals and the mission for the division. We talked a bit about the growth of the PCRI and NorTex and the educational programs that they are working on implementing. We went through the structure of the PCRI as well as its main purpose and goals. Overall, I thought that it was very interesting and exciting to hear about the growth of the Division of Research. I was very impressed with the potential it shows.

Week 18

Monday September 29, 2008

Today I created a memo to send to the physicians in the CSIP study who were randomized to the intervention group. It is a reminder that they have two weeks to complete watching the DVD. I sent this to two physicians today. We also had a meeting

about the Needs Assessment recruitment. I gave to status of all of my contacts. I sent a physician some information about the Needs Assessment because I found out that she had moved clinics from the previous address we had for her. I also started creating a list of talking points for Dr. Cardarelli when he is calling potential researchers to recruit them for the Health Institutes of Texas/PCRI clinical researcher position.

Tuesday September 30, 2008

Today I spoke with the office manager of one physician that I have been trying to recruit for the Needs Assessment. I explained the study to him and reminded him that I had dropped off a folder for the physician with all of the information in it. We had the task meeting today as well. I continued the search for the HIT recruitment as well as working on the talking points/checklist.

Wednesday October 1, 2008

I faxed another two week reminder for the CSIP DVD. I also created a memo to send to the physicians who had already completed the DVD just to thank them for their promptness and to remind them that they would be receiving the post-test in a few weeks. I also updated the randomization database so that I could keep track of when the post-tests are supposed to be delivered. I created a calendar for myself as well so that I can keep track of all of the physician's 6 week mark when the post-test should be delivered.

Thursday October 2, 2008

Today I completed the talking points/checklist and compared it to the script that was created for the phone calls. Today I also started to search for a clinician investigator in Texas that could possibly be recruited for the Family Medicine position. We are hoping to find a DO researcher in the department of family medicine that is at an institution close to UNTHSC.

Friday October 3, 2008

Today I continued with the physician search. I completed my list of public health schools and the top medical schools for primary care. I also delivered the last DVD.

Week 19

Monday October 6, 2008

Today I delivered a CSIP post-test survey to a physician who requested it in paper form. I also stopped by another participant's office to make sure they were not having any further problems with the DVD. While I was out, I also dropped off a folder with Needs Assessment information to a physician in Burleson who is part of the research network. Later in the afternoon I received a call from the physician's office that I had dropped off the paper survey saying that the survey was complete.

Tuesday October 7, 2008

I followed up with some of my Needs Assessment contacts today. I was told that one physician hadn't had a chance to look over the information and one physician was not in their office. I also picked up the survey that had been completed yesterday.

Wednesday October 8, 2008

I had two physicians to call today for the CSIP. It was time for their two week reminder for the DVD. These two physicians now have two weeks until their deadline to watch the DVD. I also emailed two other physicians the survey link for the post-test.

Thursday October 9, 2008

For the Needs Assessment, I visited a physician who has not completed his survey and was unable to see him so I left a note. I also emailed a 48 hour notice to the two physicians I emailed the post test survey link to yesterday. They now have 48 hours to complete the survey per the study protocol. I also received an enrollment form from a physician that I had sent NorTex information to. I began preparing NorTex letters to be sent to the rural physicians that are affiliated with TCOM.

Friday October 10, 2008

I worked on my practicum report today. I also worked on the NorTex letters to the rural physicians and I also added them to the recruitment database so that their progress can be tracked.

Week 20

Monday October 13, 2008

Today I finished the NorTex letters and sent them to the rural physicians. I also finished entering them into the database. I also dropped off a CSIP post test survey to a physician who requested the paper form. I emailed and faxed some thank you memos to the physicians who had completed the post test survey already. I also faxed some follow up memos to physicians I have contacted for the Need Assessment. I also left a voicemail for one physician who is a part of UNTHealth.

Tuesday October 14, 2008

Practicum report

Wednesday October 15, 2008

Practicum report

Thursday October 16, 2008

Practicum report

Friday October 17, 2008

I picked up the paper survey that I had dropped off on Monday to a physician participating in the CSIP. I faxed a reminder to one physician who has reached their two

week mark for watching the DVD. I also reminded the other two physicians who have yet to watch the DVD through email and fax. I also emailed a reminder to a physician that I emailed the post test survey link to on Monday.

Week 21

Monday October 20, 2008

Today I dropped off a survey to a CSIP participant. I faxed a thank you memo to a physician who completed the survey last week. I also called and emailed participants for the Needs Assessment.

Tuesday October 21, 2008

I tried to visit with a physician who has still not completed the survey for the Needs Assessment. I worked on my practicum report today. I also followed up with two other physicians I am trying to recruit for the Needs Assessment.

Wednesday October 22, 2008

Today I worked on printing out the PCRI Journal for the rural physicians. I also made some phone calls to try to set up meetings for the Needs Assessment.

Thursday October 23, 2008

I mailed out the PCRI Journal to the rural physicians as part of NorTex recruitment. We also had a brainstorming meeting this morning about the possibility of submitting a grant for the Dept. of Defense. One of the CSIP physician's office called to ask about the UTSW paperwork which means that he has completed watching the DVD. Now there are only two intervention physicians left to complete the DVD.

Friday October 24, 2008

Practicum Report

Week 22

Monday October 27, 2008

Today I faxed reminders for the CSIP DVD's and post-tests. Two physicians completed their post-test surveys today. I picked one post test up from the physician's clinic and I also ran an errand to the Tarrant County Public Health building. We also received an enrollment form from one of the rural physicians that I had sent NorTex information to. I also worked on my practicum report.

Tuesday October 28, 2008

I updated the member list, the recruitment list and the CSIP log. I also sent a welcome folder to the rural physician. I emailed the post-test link to one of the CSIP participants and called his office to let him know it had been sent. He completed the

survey a few hours later. I also set up a meeting with one of the physicians who has yet to finish watching the DVD to make sure that he was aware of the deadline.

Wednesday October 29, 2008

I spent most of the day catching up with my Needs Assessment contacts. I sent the physicians faxes and some emails as well as a few phone calls to try and get a response about their interest in participating in the study.

Thursday October 30, 2008

Practicum Report

Friday October 31, 2008

I updated my Needs Assessment contact log. I've made a table for each physician that outlines every contact I have made with them, the method of contact and the result of the contact. I also made calendars for each of the CSIP participants so that we have a physical log of the post-test and DVD correspondence and completion dates. I also worked on my practicum report until I left to attend the meeting I set up with one of the CSIP intervention participants to remind him of the DVD.

Week 23

Monday November 3, 2008

Today I sent thank you memos to two physicians who completed their post-test and/or the DVD last week. I updated the databases with these notes as well as a phone call we received late on Friday from one physician's office who completed the DVD that day. I also worked on my practicum report.

Tuesday November 4, 2008

I sent the CSIP post test survey to one physician today and worked on my practicum report.

Wednesday November 5, 2008

Today I emailed a DVD reminder to our last remaining physician. I also made some edits to my internship experiences section of my thesis as well as the results section.

Thursday November 6, 2008

Practicum report

Friday November 7, 2008

Practicum report

Week 24

Monday November 10, 2008

Practicum Report

Tuesday November 11, 2008

Today I received notice that the last physician has completed the DVD for the CSIP. I was very excited to close that chapter in the study and to focus on the delivery and tracking of the post-tests. I also worked on my seminar presentation.

Wednesday November 12, 2008

Seminar Presentation

Thursday November 13, 2008

Seminar Presentation

Friday November 14, 2008

Seminar Presentation

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