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Factors Responsible For Loss To Follow Up In A Longitudinal StudyComparing Coronary Artery Bypass Surgery And PercutaneousCoronary Intervention

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FACTORS RESPONSIBLE FOR LOSS TO FOLLOW UP IN A LONGITUDINAL STUDY COMPAING CORONARY ARTERY BYPASS SURGERY AND PERCUTANEOUS CORONARY INTERVENTION

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CHAPTER I

INTRODUCTION

Subject loss to follow up that results in egregious clinical trial attrition has the potential to undermine the validity of research study data. Researchers assert that loss to follow up less than 5% is relatively innocuous, and should not adversely affect study validity. In contrast, loss to follow up exceeding 20% could potentially result in the introduction of study bias (6). From a statistical perspective, uncontrolled loss to follow up is capable of reducing a study's power and generalisability, and can introduce bias, ultimately affecting the integrity of the study data. Bias is regarded as any systemic error in a research study that incorrectly estimates the association between exposure and outcome (9). Factors indicative of bias include differing baseline characteristics between subjects seen and not seen during follow up, and unbalanced predictor variables between randomized groups at baseline and follow up (9).

The power of a study is determined by the ability of researchers to prove stated theorizations through the recruitment of an appropriate number of study subjects. Thus, a diminishing sample size resulting from loss to follow up will negatively affect study power. Researchers faced with seemingly insurmountable recruitment, retention, or loss to follow up issues may eventually resort to cancelling studies, although in many circumstances studies proceed despite having an insufficient sample size because of the pooling of data from similar studies through the use of standardized protocols (9). Generalisability is characterized by the

application of obtained study data to other study settings that differ from the study sample in which they have been tested (9). In many instances, the introduction of bias subsequently jeopardizes study generalisability by rendering data inaccurate and, thus, preventing its application to both the sample population and the general population. Generalisability issues can also occur in studies devoid of bias if study power is decreased, significantly, because the demographic of subjects enrolled in the research study may not be completely reflective of the general population (9).

[1]For this practicum project, lost to follow up analysis was conducted for the Coronary Artery Revascularization Study (C.A.R.E) at six and eighteen months. Subjects enrolled in the C.A.R.E study underwent coronary artery bypass graft surgery or a percutaneous coronary interventional procedure between February 1 and July 31, 2004 at [2]eight health institutions located in the Southern and Southeastern United States. Coronary artery bypass graft procedures were either on pump or off pump, and percutaneous coronary interventional procedures entailed the placement of either bare metal stents or drug eluting stents. Subject preoperative, intraoperative, and postoperative information was collected, and follow up was performed through direct subject contact or by physician contact. Institutional Review Board study approval was obtained at each individual center, and data was sent to coordinating study centers.

[1] 4208 subjects were enrolled in the C.A.R.E study; 4026 followed up and 182 (4.5%) were designated lost to follow up

[2] Centennial Hospital-Nashville, Tennessee; Central Florida Regional Hospital-Sanford, Florida; Denton Regional Hospital-Denton, Texas; Henrico Doctor's Hospital-Richmond, Virginia; JFK Medical Center-West Palm Beach, Florida; Medical City-Dallas, Texas; Medical Center Plano-Plano, Texas; Plaza Medical Center-Fort Worth, Texas

CHAPTER 2

LITERATURE REVIEW

Various clinical studies have illustrated that study subject loss to follow up and attrition are associated with certain patient characteristics. One study evaluated how serious, significant patient loss to follow up could potentially subvert clinical trial data, and it was found that subject apathy, stringent study rules and expectations, and logistical problems typically resulted in greater study attrition (3). Age was also a factor strongly correlated with loss to follow up. In this regard, younger subjects typically exhibited a greater pre-disposition for becoming lost to follow up (3).

In another study that examined the onset of attrition following cancer screening, investigators noted that uneducated minorities failed to schedule follow up appointments prior to study treatment randomization, and were, thus, lost to follow up (16). Subjects in this study diagnosed with depression were also notably lost to follow up (16). Investigators for a cardiovascular disease risk factor trial also determined that lost to follow up rates among enrolled Hispanic subjects were the most significant, in comparison to Caucasians. Researchers attributed this to language barriers, and the majority of Hispanic subjects lacking primary care physicians (7). Ultimately, the provision of bilingual research coordinators resulted in improved follow up rates for Hispanics (7).

Another study compared non-responders to responders with rotator cuff tears. Investigators administered a short form 36 quality of life questionnaire to study participants at the beginning to the study. Data indicated that non-responders had low scores for social and mental function, were less likely to have surgery, and drank alcohol sparingly (13). Researchers posit that declining health and shoulder function may have also contributed to subject loss to follow up among the non-responder demographic. Similarly, a 16 year follow up joint replacement study also concluded that subjects with declining health and worse joint replacement outcomes were likely to become lost to follow up (12). Other factors, such as birth outside the United States/Canada, homelessness, enrollment at a health department, and the use of financial incentives were determined to be associated with loss to follow up in a tuberculosis treatment trial (4).

Non-English speaking subjects are at risk of becoming lost to follow up because of language barriers that prevent them from communicating properly with research coordinators. This deters coordinators from emphasizing the importance of tuberculosis treatment (4). Homeless subjects are predisposed to becoming lost to follow up because of their inability to attend scheduled follow up appointments. This occurs as a result of research coordinators being unable to contact homeless subjects because they usually do not have permanent residences. The prevalence of alcoholism, substance abuse issues, and mental health problems among the homeless are also factors that pose a threat to study subject retention (4). Researchers postulate that subjects enrolled at health departments are prone to becoming lost to follow up because they consider health department sites geared toward providing health care to populations with elevated poverty and unemployment; researchers attribute the latter characteristics to loss to follow up rather than study subject enrollment at health departments (4). Researchers were

unable to determine why the provision of incentives during study treatment resulted in subjects becoming lost to follow up in this study. Conversely, in a study conducted with the intent to improve breast cancer screening follow up, researchers concluded that older subjects with onsite physician referrals, private insurance, or referrals from physicians for the evaluation of abnormal screening mammograms, were all predictive factors for timely, successful follow up (1). Notwithstanding, loss to follow up still remains a formidable issue for researchers who aspire to maintain the integrity of their study data. The identification of factors purported to be associated with loss to follow up, relative to subjects enrolled in clinical trials, could possibly be instrumental in assisting researchers to formulate specific approaches to identify subjects at risk of becoming lost to follow up. This would undeniably promote efforts to improve retention (8).

Several studies held distance from subject residences to study sites accountable for subjects becoming lost to follow up. One such study sought to determine whether travel distance, age, and sex were factors predictive of non-compliance. Subjects enrolled in this clinical trial underwent gastric bypass surgery, and were expected to attend follow up examinations at 3, 6, 9, and 12 months. Subjects were organized into cohorts according to the distance they lived from the hospital where they underwent surgery. Researchers concluded that subjects with residences greater than 100 miles from the hospital were lost to follow up with greater frequency (11). Other cited follow up deterrents included: change in residence, inability to travel as a result of inclement weather or illness, poor surgical results, displeasure with staff, and perceived unimportance of follow up by subjects (11).

A similar weight loss study also examined loss to follow up, albeit subjects underwent lap band surgery. Greater distances between subject residences and the study hospital was also associated with loss to follow up (15).

Researchers have used different techniques to reduce loss to follow up related attrition: these techniques ranged from improved communication and correspondence between study subjects and research coordinators, to the development of various programs to address loss to follow up: for example, the patient navigation program, which encompasses a wide range of advocacy and coordination activities, reduced loss to follow up among women from different racial backgrounds in a breast cancer screening clinical trial (1). Underlying the patient navigation intervention program are four key factors: case identification, identification of individual barriers to care, implementation of a care plan, and tracking following completion of the study (1). The inclusion of a lead in period in a randomized controlled pharmacological weight loss trial also reduced subject attrition by enabling researchers to evaluate potential study patients through their adherence to a placebo drug regimen. Patients that deviate from the prescribed drug regimen, or that exhibit a lack of enthusiasm, motivation, or commitment, could be excluded from further participation in the study prior to randomization (8). The caveat of lead-in period use is the potential for generalisability issues relating to the inability of researchers to apply prospective study data to less adherent subjects (8).

Extensive training and supervision of research coordinators were factors also shown to reduce loss to follow up and study attrition (8). Researchers in a cancer symptom management study trial implemented the use of a tracking system to reduce study attrition, and determined several other factors that contributed to overall subject retention. The use of a tracking system enabled researchers to record study withdrawals, identify possible reasons for subject drop out, and develop corrective techniques to prevent the same issues from recurring (2). Investigators have the option of individualizing data with respect to subjects that may potentially be non-compliant (5). However, this would entail deviating from follow up protocol, which could be

burdensome. Also, frequent contact between research coordinators and subjects, as well as the emphasis of a study's significance, are associated with improved follow up (5).

In another study, investigators collected standard subject information (phone numbers, home addresses, social security numbers, and drivers license numbers), in addition to numerous alternate contact information (phone numbers and addresses of relatives, friends, or neighbors), for the design of a methodical tracking system to contact study subjects during follow-up periods. With this tracking system, the follow-up process entails first calling the subjects repeatedly. If they are not responsive to phone calls, then coordinators will proceed to mail follow-up notices. If this approach also fails, then the alternate contacts they provided at the outset of the study will be contacted. Researchers observed that the collection of supplementary alternate contact information increases the likelihood that subjects are contacted for follow up (5). And lastly, in the instance that the latter proves ineffective, research coordinators will attempt to trace subjects through personal information they provided, such as social security numbers, school records, and drivers license numbers (5).

CHAPTER 3

STUDY OBJECTIVES

This study was designed with the intention of determining factors responsible for subject loss to follow up in the C.A.R.E study, and, to suggest potentially effective approaches to reducing loss to follow up attrition in clinical trials (14).

CHAPTER 4

SIGNIFICANCE

The inclusion of this knowledge into the criteria for prospective study subject selection could be instrumental for researchers in determining whether subjects might exhibit proclivities toward non-compliance. This would effectively improve and preserve study efficiency and resources by preventing subjects exhibiting factors strongly associated with attrition and loss to follow up from participating in clinical studies. However, preventing non-compliant subjects from enrolling in a study could potentially affect study generalisability relative to the greater public at large. Therefore, cognizance of these factors could also enable study investigators to formulate safeguards for retention of these subjects in longitudinal studies.

CHAPTER 5

MATERIALS AND METHODS

Subject health information was reported by hospitals participating in the C.A.R.E study. This, along with aggregate follow up data at six and eighteen months, was organized into Microsoft Excel® spreadsheets according to the follow up period and the procedure performed.

Each spreadsheet contained subject socio-demographic information (race, gender, and age), the hospitals where subjects underwent their procedures, factors related to subject life style (smoking and body mass index) and preoperative, intraoperative and postoperative health conditions (previous cardiovascular intervention, congestive heart failure, cerebrovascular accident, complications during surgery, hypertension, renal failure, chronic lung disease, myocardial infarction, peripheral vascular disease, hypercholesterolemia, cardiovascular disease, diabetes, angina, arrhythmia, cardiogenic shock, and resuscitation). Two additional spreadsheets were prepared containing median gross income and travel distance information for both bypass and catheterization subjects.

The majority of the reported data was de-identified, so reference to actual subject history files was necessary. Social security numbers were entered into Enformion-an online informational service tool- in order to determine subject zip codes and addresses (for the zip code median gross income, and distance analysis, respectively). Zip codes were entered into an online data quality tool, and recorded median gross income was reported for 2007. Addresses

were inputted into the yahoo maps application, and the distance (in miles) from subject residences to designated hospital sites was determined. Also, subjects were organized into cohorts relative to both distance and income.

Microsoft Excel® spreadsheets were exported to SAS version 9.2. Chi square analysis results indicated whether certain factors were individually, statistically significant relative to patient loss to follow up. Multivariate analysis determined whether several factors, in combination, were associated with loss to follow up. Odds ratio values indicated whether subject factors were predictive of loss to follow up attrition.

Research literature searches were conducted using the public medicine search engine to find existing retrospective analysis, lost to follow up studies. Keywords and phrases such as 'study attrition' and 'patient loss to follow up in clinical trials' were entered into the search box. Several articles were also found using the Google search engine.

CHAPTER 6

RESULTS

Subject socio-demographic and health factors were analyzed to determine the existence of a correlative relationship with loss to follow up.

The chi-square value for gender is listed in Table I. as 0.6389, which is considered statistically insignificant. Therefore, neither men nor women exhibited a greater pre-disposition for becoming lost to follow up.

In terms of ethnicity (as listed in Table I.), of the 4002 subjects that followed up, 266 were African American (6.65%), 3364 were Caucasian (84.06%), 189 were Hispanic (4.72%), and 183 patients were classified as belonging to Other (4.57%). The "Other" ethnicity was comprised of Asian Americans and Native Americans. Among the 182 patients lost to follow up, 11 were African American (6.04%), 130 were Caucasian (71.43%), 25 were Hispanic (13.74%), and 16 were Other (8.79%). According to the yielded data, Hispanics exhibited a greater proclivity toward becoming lost to follow up. A chi square value <.0001 attests to this.

According to Table I., zip code median gross income data was not statistically significant, while subject residence distance from hospitals, exceeding 100 miles, was statistically significant, and therefore strongly associated with loss to follow up. Of the 209 subjects that followed up, 175 lived less than 50 miles from the hospital they underwent either bypass surgery or cardiac catheterization (83.73%), 24 lived between 50 to 100 miles away from the hospital

(11.48%), and 10 lived greater than 100 miles away from the hospital (4.78%). Of the 108 subjects lost to follow up, 81 lived less than fifty miles from the hospital (75%), 14 lived between 50 to 100 miles from the hospital (12.96%), and 13 lived greater than 100 miles from the hospital (12.04%). The chi square value of 0.05 indicates that subjects who lived greater than 100 miles from their designated study sites were lost to follow up at a greater frequency.

Younger age was associated with loss to follow up. According to Table I., the mean age of subjects that followed up was 64.7 +/- 12.339 (N=4027), while the mean age of subjects that did not follow up was 62.8 +/- 12.9011 (N=182).

As listed in Table I., a mean body mass index value of 29.81 +/- 6.03 was associated with loss to follow up. While the mean body mass index value for subjects that followed up was 29.33 +/- 6.09.

Subjects that underwent a previous cardiovascular interventional procedure were more likely to follow up, whereas subjects that had not undergone a procedure were predisposed to becoming lost to follow up. According to Table I., of the 4022 subjects that followed up, 37.7% had undergone a previous cardiovascular interventional procedure. Of the 182 subjects that were lost to follow up, 29.67% (54) had undergone a previous interventional procedure. A chi square value of 0.072 indicates that subjects who had not undergone any previous cardiovascular procedures, prior to the study, were more likely to become lost to follow up.

Subjects diagnosed with congestive heart failure, hypertension, chronic lung disease, peripheral vascular disease, hypercholesterolemia, cardiovascular disease, and diabetes, prior to the study, were not likely to become lost to follow up. This was according to yielded chi-square results-listed in Table I. -which consisted of 0.2481, 0.8185, 0.1341, 0.3815, 0.6883, 0.3533, and 0.7215, respectively.

According to Table I., various intraoperative complications, cardiogenic shock, and resuscitation were factors determined to be statistically insignificant relative to loss to follow up, with chi square values of 0.4864, 0.2768, and 0.7102, respectively.

Postoperative renal failure was proven to be statistically significant for subjects lost to follow up, with a chi square value of 0.0527, which is listed in Table I. Conversely, postoperative arrhythmia was not correlated with loss to follow up. This was evidenced by a yielded chi square value of 0.1214, which is also listed in Table I. A total of 4025 subjects indicated whether they had postoperative renal failure-4.72% (190) had renal failure. Of the subjects that did not follow up, 1.65% (3) had renal failure.

According to Table I., a chi square value of 0.0384 indicates that angina is associated with loss to follow up. Out of 4003 subjects that followed up, 87.08% (3486) had angina. Of the 182 subjects that did not follow up, 92.31% (168) had angina.

Multivariate analysis was also conducted for several subject factors. The first set of maximum likelihood estimates analyzed the following combination of factors relative to loss to follow up: subject age (<.0001), African American ethnicity (0.031), Hispanic ethnicity (<.0001), Other ethnicity (0.0745), smoking (0.0033), arrhythmia (0.095), renal failure (0.504), myocardial infarction (0.0279), angina (0.035), and cardiovascular disease (0.0006). These values are listed in Table II. With the exception of the 'Other' ethnicity and arrhythmia, every other factor was designated statistically significant for subject loss to follow up based on chi square values.

Table III contains a combination of different patient factors. These included distance, income, age, African American ethnicity, Hispanic ethnicity, Other ethnicity, smoking, angina, cerebrovascular attack, and congestive heart failure. According to the chi-square values listed in

Table III, the only statistically significant factors were patient residences greater than 100 miles away from designated hospital sites (0.007), age (<.0001), and angina (0.0415).

While the univariate analysis results are merely observational, multivariate data and corresponding odds ratio values indicate whether certain factors are predictive of subject loss to follow up. Odds ratio results in Table II (a) that correspond to multivariate analysis data in Table II, suggest that younger age (0.972; 95% C.I: 0.963-0.981), Hispanic ethnicity (3.964; 95% C.I: 2.613-5.224), angina (1.899; 95% C.I: 1.234-2.921), and cardiovascular disease (1.647; 95% C.I: 1.238-2.192) are factors predictive of subject loss to follow up. Odds ratio data for myocardial infarction (0.740; 95% C.I.: 0.565-0.968) suggests improved follow up compliance. This is reinforced by a point estimate value of 0.740, which is less than 1. Odds ratio estimates for the second set of multivariate analysis data-in Table III (a)-indicate that younger age (0.965; 95% C.I: 0.948-0.981), Hispanic ethnicity (3.092; 95% C.I: 1.342-7.127), angina (2.070; 95% C.I: 1.028-4.166), and subject residences greater than 100 miles from designated study sites (3.234; 95% C.I: 1.453-7.196), were factors predictive of subject loss to follow up.

Table I: Univariate Analysis of Patient Factors and Chi Square Results

	6-18 Month LTFU Data		
Factors	**FU (N=4026)**	**LTFU (N-182)**	**P-Value**
Gender:			
Male	69.07% (2758/3993)	70.72% (128/181)	0.6389
Female	30.93% (1235/3993)	29.28% (53/181)	
Race:			
Black	6.65% (266/4002)	6.04% (11/182)	
Caucasian	84.06% (3364/4002)	71.43% (130/182)	
Hispanic	4.72% (189/4002)	13.74% (25/182)	<.0001*
Other	4.57% (183/4002)	8.79% (16/182)	
Distance:			
< 50 Miles	83.73% (175/209)	75% (81/108)	
50-100 Miles	11.48% (24/209)	12.96% (14/108)	
> 100 Miles	4.78% (10/209)	12.04% (13/108)	0.05*
Income:			
< 50 K	49.27% (101/205)	51.38% (56/109)	0.3588
50-100 K	42.93% (88/205)	36.70% (40/109)	
>100 K	7.80% (16/205)	11.93% (13/109)	
Age:	64.7 +/-12.339 (N=4027)	62.8 +/- 12.9011 (N=182)	62.8 +/- 12.9011 (N=182)
Body Mass Index:	29.33 +/- 6.09 (N=4027)	29.81 +/- 6.03 (N=182)	29.81 +/- 6.03 (N=182)
Cardiovascular Intervention (Previous):			
Yes	37.77% (1519/4022)	29.67% (54/182)	0.072*
Congestive Heart Failure:			
Yes	7.83% (314/4009)	5.49% (10/182)	0.2481
Cerebrovascular			

Attack:			
Yes	5.28% (212/4018)	5.49% (10/182)	0.8976
Smoking (Previous):			
Yes	48.30% (1944/4025)	48.62% (88/181)	0.8976
Peri-operative Complications:			
Yes	14.22% (566/3981)	12.36% (22/178)	0.4864
Hypertension:			
Yes	75.63% (3044/4025)	76.37% (139/182)	0.8185
Renal Failure (Previous):			
Yes	98.45% (190/4025)	1.65% (3/182)	0.0527*
Chronic Lung Disease:			
Yes	9.97% (401/4021)	6.59% (12/182)	0.1341
Myocardial Infarction:			
Yes	26.51% (1067/4025)	18.13% (33/182)	0.019*
Peripheral Vascular Disease:			
Yes	9.64% (388/4024)	7.69% (14/182)	0.3815
Hypercholesterolemia:			
Yes	63.93% (2573/4025)	65.38% (119/182)	0.6883
Cardiovascular Disease:			
Yes	15.57% (627/4026)	18.13% (33/182)	0.3533
Diabetes:			
Yes	33.34% (1342/4025)	34.62% (63/182)	0.7215
Angina:			
Yes	87.08% (3486/4003)	92.31% (168/182)	0.0384*
Arrhythmia:			
Yes	6.77% (271/4003)	3.85% (7/182)	0.1214
Cardiogenic Shock			

(intraoperative):			
Yes	0.87% (35/4006)	1.66% (3/181)	0.2768
Resuscitation (intraoperative):			
Yes	0.80% (32/4008)	0.55% (1/182)	0.7102

-Abbreviations: LTFU=Lost To Follow Up; FU= Followed Up; N=Number of Subjects
-Numbers in parentheses are reflective of subjects that either followed up or were lost to follow up, relative to the factors being analyzed.
-Values for Age and Body Mass Index are mean +/- standard deviation
*Indicates that values are significantly different

Table II: Multivariate Analysis of Factors and Chi Square Results

	Likelihood Estimates I	
Age	**Wald Chi Square**	**Pr>Chi Square**
Black	35.7169	<.0001*
Hispanic	4.6097	0.031*
Other	23.933	<.0001*
Previous Smoker	3.181	0.0745
Arrhythmia	8.6257	0.0033*
Renal Failure	2.7881	0.095
Myocardial Infarction	3.8278	0.504
Angina	4.8319	0.0279*
Cardiovascular Disease	8.5169	0.0035*

*Indicates that values are significantly different

Table II (a): Corresponding Multivariate Analysis Odds Ratios

Effect	Point Estimate	95% Wald C.I.	
Age	*0.972	0.963	0.981
Black Vs. Caucasian	1.272	0.822	1.970
Hispanic Vs. Caucasian	*3.694	2.613	5.224
Other Vs. Caucasian	*2.442	1.645	3.625
Previous Smoker-Yes Vs. No	*1.407	1.120	1.768
Arrhythmia-Yes Vs. No	0.612	0.343	1.089
Renal Failure-Yes Vs. No	0.462	0.213	1.001
Myocardial Infarction-Yes Vs. No	*0.740	0.565	0.968
Angina-Yes Vs. No	*1.899	1.234	2.921
Cardiovascular Disease-Yes Vs. No	*1.647	1.238	2.192

*Indicates that values are significantly different

Table III: Multivariate Analysis Of Factors And Chi Square Results

	Likelihood Estimates II	
	Wald Chi Square	**Pr>Chi Square**
50-100 Miles	1.9549	0.1621
>100 Miles	7.2697	*0.007
$50-100 K	1.7533	0.1855
>100 K	1.7706	0.1833
Age	17.0534	*<.0001
Black	0.1214	0.7275
Hispanic	2.7579	0.0968
Other	0.1515	0.6971
Previous Smoker	1.4602	0.2269
Angina	4.1557	*0.0415
Cerebrovascular Attack	2.0549	0.1517
Congestive Heart Failure	1.6499	0.199

*Indicates that values are significantly different

Table III (a): Corresponding Multivariate Analysis Odds Ratios

Effect	Point Estimate	95% Wald C.I	
50-100 Miles Vs. <50 Miles	1.076	0.563	2.057
>100 Miles Vs. <50 Miles	*3.234	1.453	7.196
50-100 K Vs. <50 K	0.887	0.566	1.389
>100 K Vs. <50 K	1.584	0.718	3.494
Age	*0.965	0.948	0.981
Black Vs. Caucasian	1.528	0.575	4.06
Hispanic Vs. Caucasian	*3.092	1.342	7.127
Other Vs. Caucasian	1.988	0.909	4.35
Previous Smoker-Yes Vs. No	1.311	0.845	2.034
Angina-Yes Vs. No	*2.07	1.028	4.166
Cerebrovascular Attack- Yes Vs. No	0.466	0.164	1.323
Congestive Heart Failure- Yes Vs. No	0.541	0.212	1.381

*Indicates that values are significantly different

CHAPTER 7

DISCUSSION

Retrospective analysis of follow up information from the C.A.R.E study provided insight into factors that could be held responsible for subjects becoming lost to follow up. Of the factors subject to analysis, several were significantly correlative with loss to follow up. Multivariate and odd ratio data illustrate that race was strongly associated with subject loss to follow up. This is attributable to Hispanic subjects. Researchers have attempted to elucidate reasons for minority study non-compliance; Edalman et al cites language barriers and the lack of a primary care physician as factors that preclude Hispanic subjects from appropriately following up with study investigators (7). The aforementioned study findings are not completely generalizable to the C.A.R.E study, though, with the exception of language barriers, because unlike the study conducted by Edalman et al., subjects were not required to follow up at hospitals. Instead, subjects were contacted by telephone and administered a health assessment, quality of life survey. Therefore, presumably, investigators and coordinators, alike, unable to speak Spanish, would invariably fail to follow up with Spanish speaking, Hispanics subjects. This could potentially jeopardize the veracity of study results. However, it can be argued that Hispanic subjects without primary care physicians are more likely to be uneducated and, therefore, exhibit non-compliant tendencies, suggesting they underestimate the significance of follow up as it pertains to their health (16). Nonetheless, during the initial stages of the C.A.R.E study, the

inability of coordinators to communicate properly with Spanish speaking subjects resulted in lost to follow up attrition. However, this was addressed after investigators employed bilingual study coordinators. This reinforces an assertion made by Edelman et al., that the recruitment of bilingual staff is integral to following up with Spanish speaking, Hispanic subjects.

Distance was also a factor associated with loss to follow up; subjects that lived greater than 100 miles from the hospitals where they underwent either coronary artery bypass or catheterization procedures, became lost to follow up with greater frequency. This confounded investigators in the C.A.R.E study because, as previously stated, it was not required for subjects to travel and be administered physical follow up exams by physicians or other staff. Alternatively, subjects were contacted by phone. Therefore, after thoroughly reviewing subject health information, and data analysis results, it was concluded that subjects lost to follow up either moved or changed their telephone numbers. The latter is feasible, considering many people, presently, use cellular phones as opposed to landline telephones. And, by implication, this would not only affect the accuracy of C.A.R.E study data, but data from other numerous contact follow up studies, as well. In many instances subjects traveled distances that exceeded 100 miles with the intention of undergoing surgery. This especially held true for enrolled subjects at JFK Medical Center in West Palm Beach, Florida, after determining that an insubstantial amount of study subjects actually owned property in Florida. This, in combination with altered contact information, bears serious implications for investigators that aspire to achieve respectable follow up rates. Notwithstanding, even though the C.A.R.E study is designated a contact to follow up study, greater subject distances from follow up hospitals, alone, may be considered a factor predictive of loss to follow up. Both Lara et al. and Rhodes et al., investigators for similar longitudinal weight loss studies, concluded that subjects who lived

greater than 100 miles from designated study sites, where they underwent surgical weight loss procedures, were more likely to become lost to follow up (11, 15). The seemingly correlative relationship between contact loss to follow up and distance should be analyzed further in the future.

Mean body mass index and age values of 29.81 +/- 6.03 and 62.8 +/- 12.9011, respectively, were associated with loss to follow up. This data suggests that both younger subjects and subjects with increased body mass index values were predisposed to becoming lost to follow up. It can be posited that, generally, younger subjects have a tendency to be healthier than older subjects, which would render them less conscientious of their health and the importance of follow up in clinical trials. Also-not necessarily in the context of this study-younger subjects may have families and lead busier lives, which would hinder their ability to follow up with investigators, accordingly. In a study examining the burden of loss to follow up on clinical studies, Betz et al. states that subjects younger than 50 years old enrolled in clinical trials, are at significantly greater risk of becoming lost to follow up than older subjects (3). It is unlikely that subjects with elevated body mass index values are healthy, per se. Many of these subjects are probably beset with health issues that result from simply being overweight, or obese. According to an article published by Hoffman et al., elevated body mass index, characteristic of obesity, could potentially result in the following health complications: cardiovascular disease, high blood pressure, increased cholesterol and triglyceride levels, greater insulin resistance, and sleep apnea (10). Declining quality of life, associated with increased body mass index, may result in subjects failing to follow up. In addition, disillusionment with appearance, subsequently leading to depression and apathy, may also account for subjects becoming lost to follow up. Betz et al and Siddiqui et al., cite study apathy and depression as factors held accountable for

loss to follow up attrition (3, 16). Additionally, according to Norquist et al., subjects with declining health and shoulder function were prone to becoming lost to follow up (13).

According to multivariate analysis data and corresponding odds ratio results, previous smoking, angina, and cardiovascular disease were also factors predictive of loss to follow up. This could be attributed to declining health, even if these conditions were corrected through bypass or catheterization procedures. It can be argued that subjects who had experienced any one of the previously listed conditions-or smoked previously- are at greater risk of requiring additional revascularization procedures, eventually. Consider subjects diagnosed with cardiovascular disease, even though a surgical intervention may mitigate existing health issues, failure of numerous study participants to lead healthier lifestyles and periodically follow up with their cardiologists may result in progressive worsening of their condition. Subsequently, their quality of life would decline, rendering them less likely to follow up with C.A.R.E study investigators. The latter is reinforced by studies conducted by Murray et al. and Norquist et al., which both concluded that subjects with declining health were less likely to follow up (13, 12).

Subjects that had experienced myocardial infarction, or that underwent previous cardiovascular procedures were shown to follow up more frequently with study investigators, suggesting that they were probably more conscientious of follow up as it pertained to their health and the study's benefit. Thorough research literature searches for studies containing information about follow up compliance as it related to this demographic, proved fruitless. And therefore, the aforementioned postulation can neither be supported nor disputed by existing, published studies

Loss to follow up attrition was effectively controlled for the C.A.R.E study at 6 and 18 months, albeit subjects were still essentially lost to follow up. Various approaches to reducing

loss to follow up could be considered for the prospective 5-year contact follow up C.A.R.E. study.

Patient navigation systems are notable for reducing lost to follow up attrition through case identification, barrier identification, implementation of a care plan, and subject tracking following the completion of a clinical study (1). Case identification, barrier identification, and subject tracking are components of the patient navigation system that could be applied to contact follow up for the C.A.R.E. study. Through reference to the yielded statistical multivariate and odd ratio data, investigators could identify subjects predisposed to becoming lost to follow up, and use safeguards to promote subject retention and prevent study non-compliance. Any barriers to follow up, such as language comprehension issues, can also be identified and addressed by study investigators.

The design of a tracking system would also better ensure that subjects are not lost to follow up; tracking systems typically contain standard subject information (phone numbers, home addresses, social security numbers, and drivers license numbers) in addition to alternate contact information (phone numbers and addresses of relatives, friends, or neighbors). Davis et al. designed a tracking system proven to effectively reduce loss to follow up attrition (5). First, subjects were called repeatedly. In the instance they were not responsive to phone calls, coordinators proceeded to mail follow up notices. If this approach also failed, then the alternate contacts provided by subjects at the outset of the study were contacted. Researchers observed that the collection of supplementary, alternate contact information increased the likelihood that subjects would be contacted for follow up (5). If the latter was also ineffective, research coordinators then attempted to trace subjects through personal information they provided, such as social security numbers, school records, and drivers license numbers (5).

Lead in periods, or run in tests, have proven to be effective in predicting the compliance of potential study subjects. Even though this approach was not used to prevent lost to follow up attrition in the C.A.R.E study, hypothetically consider that if immediately following their surgical procedures, subjects were approached by investigators and instructed to contact coordinators after one month to report their progress. Ideally, subjects would be provided with a business card containing study site contact information, as well as a small, single page calendar, with an attached reminder, notifying them of the date they are expected to contact the study site. This test would enable investigators to gauge the study compliance of study participants. Subjects that failed to follow up would be called by coordinators and asked to report their health progress, also. Cognizance of this information by study investigators may prompt them to devise certain approaches that could possibly prevent these subjects from becoming lost to follow up; subjects could be contacted more frequently by coordinators, or investigators could call them, personally, and state the importance of follow up relative to their own personal health, and the study's results-emphasizing how their compliance and participation may benefit other people with similar cardiovascular issues (5). Investigators could also consider individualizing follow up requirements with respect to these subjects by excluding burdensome, critical data collection measures, or preparing a follow up schedule that does not conflict with their personal lives, thus increasing the likelihood they will follow up (5). Adjudication for the use of follow up individualization typically depends on whether investigators are willing to deviate from follow-up protocol for the sake of ensuring improved follow up rates from potentially non-compliant subjects.

CHAPTER 8

CONCLUSION

Statistical analysis of personal subject information resulted in the identification of factors predictive of loss to follow up. Multivariate data indicates that younger age, Hispanic ethnicity, previous smoking, myocardial infarction, angina, and cardiovascular disease are predictive of loss to follow up. Consideration of distance and income as factors yielded different multivariate results; subjects that lived greater than 100 miles from designated follow up sites, younger age, and angina were associated with loss to follow up. Corresponding odds ratio data for the first set of multivariate data suggest that younger age, Hispanic ethnicity, myocardial infarction, angina and cardiovascular disease are predictive of loss to follow up. Additional odds ratio results indicate that younger age, Hispanic ethnicity, angina, and subjects that lived greater than 100 miles from designated study sites, are predictive of loss to follow up.

Approaches presented to improve lost to follow up attrition included: the use of a patient navigation system, the development of a tracking system, the inclusion of a lead in period, the individualization of subject follow up, greater emphasis of follow up significance, and increased contact frequency with subjects. Each of these methods has proven to be highly effective in ameliorating lost to follow up attrition in other longitudinal, clinical studies.

C.A.R.E study follow up attrition at 6 and 18 months was not egregiously uncontrolled, and therefore, there was relatively little patient data available for analysis. Notwithstanding, several factors were still designated as predictive of loss to follow up, although the design and

statistical analysis would have potentially yielded more compelling results if there were more subjects lost to follow up. Subsequently, this may affect the generalisability of this study. Nevertheless, application of this study's design to the 5 year C.A.R.E follow up study would presumably be more appropriate.

CHAPTER 9

DESCRIPTION OF INTERNSHIP SITE AND ACTIVITIES

I shadowed the clinical research director at CRSTI, Tina Worley, and developed an improved understanding of study protocol design and approval. I also attended weekly research meetings and observed the process by which cardiovascular studies were accepted or rejected-for modifications or reasons of impracticality by clinical study investigators.

In addition, I also observed cardiac surgical procedures, attended presentations by physicians and CRSTI staff, and assisted research coordinators with study subject data entry and any clerical work.

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APPENDIX

June 2, 2010:

I started working at 8:30 AM; Michelle Bruns (MLA Director of Education) asked me to organize file folders alphabetically. After completing this task, I proceeded to research my tentative defense topic with Tina Worley (designated mentor at Cardiopulmonary Research Science and Technology Institute- RN, BSN, CCRC Director of Clinical Research). I explained to her, thoroughly, my interest in studying clinical research follow up attrition as it relates to study subject non-compliance, and the potential it has to completely undermine the integrity of recorded research data. She expressed great interest and support for my potential research topic. After our brief meeting, Tina presented information concerning appropriate clinical practices in human subject research. Her presentation lasted well over forty minutes, and was very informative. Later, Dr. Jeffrey Horsewell, an anesthesiologist, spoke about various cardiac surgical procedures and provided information pertaining to anesthesiology.

For approximately 2 hours, I conducted research online and came across several articles in reputable journals that I considered relevant to follow up challenges and study subject non-compliance. I reviewed these articles and discussed several other potential defense topics with Tina, which ranged from determining whether or not follow up issues are correlative with ethnicity, to the implementation of various social, behavioral factors in clinical research studies that would serve to reduce study subject follow up attrition and non-compliance, subsequently increasing the likelihood of long-term study subject correspondence with clinical research personnel. Once again, Tina was incredibly supportive and expressed her approval for my ideas. She also offered advice and explained how study subject use of cell phones, as opposed to landlines, potentially presents a

formidable challenge to clinical research personnel because of legal implications involving cellular phone number retrieval and accessibility. So, as a result, many former study subject participants can't be contacted for follow up assessment.

Also, before leaving, I assisted Tina with clerical tasks.

June 3, 2010:

I read the articles I'd found yesterday while conducting research for 2 hours, and then listened to Dr. Michael Mack, a cardio thoracic surgeon, present information related to clinical research trials presently being conducted at Medical City hospital. Dr. Mack described one research trial in detail, the partner study, involving placement of artificial valves in study subjects. Following this discussion, I continued to research my defense topic, and came across several articles in the public medicine clinical journal. The first article, entitled "Determinants of Non-Compliance and Attrition in the Elderly" was a cohort study conducted in 1996 for the purpose of ascertaining factors that potentially pre-dispose elderly study subjects to becoming non-compliant relative to long-term follow up, resulting in possible "bias in estimation and loss of power in testing hypotheses." Researchers concluded that study subject non-compliance and attrition are chiefly associated with "older age, intervention group assignment, non-single family residence, no alcohol consumption" and to a lesser degree, depression.

''LOST to follow-up information in Trials (LOST-IT): a protocol on the potential impact" was another clinical study I reviewed involving follow up challenges related to randomized controlled trials. Researchers posit that loss to follow up should be defined as incomplete ascertainment of the primary outcome for controlled randomized trial participants. And, much like the researchers of the previously described study, elimination

of study subject health information-following study intervention-attributed to incomplete, or insufficient follow up- could potentially promote study bias and subsequent erroneous study results. Authors of this study also prepared a very thorough, detailed chart, categorically organizing different types of lost to follow up, which included: mistakenly randomized with inappropriate post-randomization exclusion; not received intervention with inappropriate post-randomization exclusion; withdrew consent; non-adherent; crossed over; loss contact.

Unlike the two previous clinical studies I read, the research article entitled "Reporting attrition in randomized controlled trials" wasn't actually a conventional study, in the sense that it was more informative and objective; researchers examined different factors normally held accountable for attrition and lost to follow up. Authors even elaborated on different types of attrition; attrition resulting from lost to follow up or missing data, which I consider unprecedented, presently, because I've yet to come across any article that has mentioned or presented a cause of research study attrition as missing or inaccurate study subject data. Researchers of this article also repeatedly emphasize, ad nauseam, the designation of randomized controlled trials as relatively balanced because of their reliance on baseline, study subject group characteristics. Also, to prevent data misrepresentation and better indicate the cause for clinical study attrition, researchers recommend that baseline characteristics for complete, accurate study subject data be analyzed separately from participants' lost to follow up data.

June 4, 2010:

Throughout the rest of the day, I mostly conducted online research and read several articles I'd encountered last week in the library. Also, since my designated research mentor at CRSTI, Tina Worley, was on vacation, Michelle Bruns reviewed the contents of my appendix for June 2 through June 3.

During the afternoon, I attended a presentation by Dr. James Edgerton, one of many cardiothoracic surgeons who perform surgical procedures for clinical trials conducted by CRSTI. He explained the anatomy and physiology of the heart, and discussed other concepts related to the cardiovascular system.

June 7, 2010:

My supervisor, Tina Worley, assigned me several tasks; the first entailed entering study subject data into a database for a comparative research trial involving the vasodilating agents Nitroglycerin and Cleviprex. Then, I was held responsible for including additional, supplemental information in the background section of a prospective, clinical trial protocol that examined the effectiveness of Trans-Cranial Doppler technology in achieving successful cardiac resynchronization therapy in patients with pacemakers.

I also attended a presentation by Dr. David Bowers, a cardiothoracic surgeon at Medical City Hospital. His presentation was relatively short and very interactive. He posed several questions to the class concerning the cardiovascular system. He also described various differences between veins and arteries, and explained how cardiac muscle functions.

June 8, 2010:

A meeting was conducted in the morning to discuss tentative trials at Medical City. The majority of the CRSTI research coordinators were present, in addition to several physicians. From what I recall, most of the meeting was spent deliberating whether or not a study comparing aortic insufficiency to aortic stenosis should be planned. Ultimately, it was decided, unequivocally, that comparison of the two listed conditions were considered highly unrelated. So, therefore, the study proposal was deemed futile and re-evaluation was recommended in an effort to design alternate study trials. Another study was presented to the board involving the alternate measurement of blood flow through the cranial artery by Cranial Doppler technology. This study piqued the interest of both the physicians and research coordinators

After the research meeting, both Tina Worley and Angela Riley (RT Executive Director of CRSTI Research) met to discuss what had occurred. They both decided that the cranial artery study was interesting and very likely to occur despite a lack of technicians at medical city trained to use cranial Doppler technology. They also agreed that several studies could potentially be developed from the aortic stenosis versus aortic insufficiency trial.

June 9, 2010:

I attended a meeting at 11:00 AM with Tina Worley and Angela Riley for a prospective research trial sponsored by The Medicines Company. The study was designated as retrospective and entailed measuring blood clotting in patients administered heparin, or heparin along with the test drug, CU2010, following C.A.B.G surgery with cardiopulmonary bypass. Also, the principal investigator, Dr. Horswell, and the sponsor, alike, required that TEG technology be used to measure blood clotting in the 6 patients

enrolled in the study. At the end of the meeting, the sponsor representative expressed her approval of the study, signifying that it will be conducted, eventually, as designed.

At 3:00 PM I accompanied Tina Worley to Syma Prince's office (RN, BSN, Director of Quality Outcomes) in order to begin writing a study protocol. Unfortunately, the principal investigator overseeing the research wasn't present, so the meeting to prepare the study protocol was deferred until June 11th.

Later, I was provided with an additional list of patient names and information in order to correct mistakes or simply complete data entry for the Cleviprex clinical trial. Once this was completed, I organized all of the paper files into a binder for storage.

In addition to completing data entry, I was also able to review an article I'd found earlier during the week that examines how attrition and loss to follow up undermine the integrity of research results in a clinical trial by jeopardizing study power, promoting bias, and threatening generalisability.

June 10, 2010:

I accompanied Tina Worley to the heart failure/transplant clinic in order to run several tests on a patient that received a left ventricle assist device, which promotes systemic blood flow in patients with heart failure. During the course of this procedure, Tina measured the patient's blood pressure and also recorded several readings listed on a heart monitor that connected to the LVAD. Tina then instructed the patient to walk for six minutes in the hallways surrounding the clinic in order to determine his cardiovascular endurance. After this, I observed Karen Roper (Senior Research Scientist, PhD) conduct a neuropsychological test on the patient, which mainly entailed asking the patient to recapitulate numbers and words in the sequences they were read to him. There was also a

portion of the exam where the patient was held accountable for interpreting several images, orally.

Later, I read several articles related to my tentative thesis. The journal article entitled "Factors associated with loss to follow up in a large tuberculosis treatment trial" identified several factors that could potentially be attributed to attrition/lost to follow up in clinical trials. These consisted of: birth outside the U.S, a history of homelessness, enrollment at a health department, and incentives during the treatment phase of a clinical trial. By implication, I understood why most of these factors contribute to attrition, but I wasn't sure about health departments and study incentives. According to this article, health departments are classified as "markers for sites serving populations with high rates of poverty and unemployment." So, it can be assumed that the health department sub-factors, poverty and unemployment, are attributed to attrition/lost to follow up. Unfortunately, the article's explanation for study incentives being designated as factors strongly associated with attrition is insufficient and ambiguous, so it might be in my best interest to study this further.

Researchers also listed several limitations of the study, which involved approaches to querying (sites were queried retrospectively once in a six year period) and study analysis (attrition factors based primarily on site level analysis as opposed to patient level analysis).

The next article I analyzed described an observational, cohort research study conducted for the purpose of determining factors that resulted in dropout and refusal amongst a group of patients being tested, neuropsychologically, for cognitive impairment. Ultimately, researchers concluded that cognitively impaired patients-versus non-

cognitively impaired patients- at the outset of the study will more than likely develop dementia and be non-compliant, resulting in eventual drop out. It was also determined that cognitively impaired patients were more likely to refuse neuropsychological tests during the screening portion of the study, also contributing to the total dropout. To digress, more than likely I'll refrain from using information from this study because it didn't actually present factors attributed to attrition/lost to follow up.

I considered another article I read interesting because it actually presented several approaches to research design proven to limit loss to follow up in an orthopedic surgery study. The article lists the following factors as integral to preventing loss to follow up from occurring; the exclusion of potential study subjects unlikely to complete follow up, administration of thorough and extensive informed consent (making sure to reiterate the challenges associated with being enrolled in a research study), obtaining contact information prior to randomization, development of a follow up schedule that best suits the patients, maintaining continuous contact with the study subjects and providing them with reminders for follow up, minimizing the length of follow up visits, and reduction in the demands imposed on foreign patients unable to speak English properly.

The last article I read was a research study entitled "Early Participant Attrition from Clinical Trials: Role of Trial Design and Logistics" that analyzed causes for early study attrition in a trial where cancer patients undergoing chemotherapy were recruited in order to determine whether or not a psychological intervention or a cognitive intervention would be more effective in assisting patients with cancer management and treatment related symptoms. The study was separated into two phases based on patient drop out; consent to first contact and screening to baseline (actual trial initiation). Through statistical analysis,

researchers were able to conclude that longer time intervals-relative to the two phases-relatively low patient education, and minority/race status (non-white) were all factors that pre-disposed patients to eventual dropout during both phases.

June 11, 2010:

Along with two other interns, I prepared a protocol for a retrospective study of a prospective collective database involving patients with an ejection fraction less than thirty percent, who had undergone aortic valve replacement surgery. We also downloaded and printed an SF 12 questionnaire-to be administered over the telephone during follow up-in order to assess the patients' quality of life, and whether or not they've experienced a cerebrovascular accident, or myocardial infarction.

Following preparation of the protocol, I resumed researching my tentative thesis and came across another journal article that examined attrition in various pharmacologic weight loss trials. According to researchers, loss to follow up/attrition was attributed to administration of a placebo or other specific weight loss medications, such as Rimonabant, for example. It was determined, statistically, that study subjects who received Rimonabant experienced a "5 percent greater adverse event related attrition and 5 percent lower non-adverse event related attrition than placebo groups."

Implementation of a lead in period, the intervention of skilled and knowledgeable clinical research coordinators and dieticians, and patient co-morbidity, associated with obesity, were factors shown to reduce attrition and loss to follow up. Lead in periods enable research investigators to gauge patient compliance, and typically entail assigning study subjects a drug regimen. Adherence to this regimen is indicative of potential patient

motivation and commitment to the study. Knowledgeable, skilled, and enthusiastic dieticians, as well as research coordinators, provided patients with sound, structured advice regarding different approaches to losing weight. Also, patients with severe obesity that pre-disposed them to death were more likely to remain in weight loss studies because of a greater, putative urgency to lose weight and improve their lifestyle.

June 14, 2010:

My group finalized the aortic valve replacement protocol and the SF 12 questionnaire for submission to the principal investigators for evaluation Then, I spent the remainder of the day conducting more research. I found several articles related to follow up and attrition. The first research study involved assessing different causative factors for attrition in minorities with cardiovascular disease. Ultimately, it was concluded that the follow up rate between white versus non-white participants, after 3 months, wasn't very different. Researchers attributed this to medical care access made readily available to minority patients by the research study staff. Conversely, reasons cited for loss to follow up amongst minorities were lack of health care insurance and a primary physician, while improved health deterred white study subjects from being compliant during follow up. Concerning minorities, researchers assert that providing low cost medical services and employing a bilingual staff are both factors that could potentially prevent loss to follow up from occurring.

In another study that evaluated patients lost to follow up with rotator cuff tears, responders were compared to non-responders, and it was determined that non-responders had achieved lower scores for social function and mental health on the SF 36, were less likely to have undergone any surgical procedures, and consumed relatively little alcohol.

Also, poor health and shoulder function were considered factors characteristic of non-responders lost to follow up. Researchers also noted a difference in study results yielded in response to the administration of the mail questionnaire and the telephone, quality of life interview. This suggests that the mode of administration may affect the patient's response.

June 15, 2010:

I attended a research meeting in the morning and presented my tentative thesis (factors held accountable in clinical trials for study subject attrition/loss to follow up, and potentially effective approaches to reducing loss to follow up and improving patient retention rate) as well as the aortic valve replacement protocol I helped prepare with two other interns. Investigators approved of my thesis topic, but suggested that the protocol be modified prior to official submission. For the remainder of the protocol meeting, the research coordinators presented trials for analysis by study investigators.

After the meeting, I met with my research group to amend the protocol for re-submission to the study investigators. Once this was completed, I searched through journal databases online for information related to my study topic. I was in the process of reading an article I'd come across, when I was presented with the opportunity to attend another meeting for a valve replacement trial. At the meeting, several nurses and research coordinators mainly discussed the health conditions of patients set to undergo valve replacement surgery. They also reviewed the surgery schedule with the surgeon set to perform the actual operations.

Following the meeting, I resumed reading an article entitled "Improving Follow-Up to Abnormal Breast Cancer Screening in an Urban Population," which detailed a study that employed the use of patient navigation (a type of care management that covers a wide

range of advocacy and coordination activities) to promote faster, more efficient diagnostic follow up for patients with detected breast abnormalities during screening. The navigation program was designed to address "patient, provider, cultural, and system level factors" that prevented the accessibility of "cancer diagnostic and treatment services" to patients in a fair, equitable, and timely fashion. There are four key components that underlie the patient navigation program, which include identifying barriers to follow up for each individual case, formulating a plan to address barriers, developing a tracking system, and preparing a mechanism for case identification. Implementation of patient navigation improved rates of follow up by approximately 15 percent among "a racially diverse group of urban women." Ultimately, researchers concluded that the navigation program is highly beneficial to patients because it effectively addressed issues associated with follow up procedures after cancer screening for the detection of breast abnormalities.

June 16, 2010:

Tina Worley, my research mentor at CRSTI, sent me the aortic valve replacement protocol that I'd previously submitted for evaluation by study investigators in order to modify several sections for IRB review. Alteration of the protocol entailed formulating a chart for recording follow-up information, including the sponsors' names on the title page, and correcting the description of MACCE (major adverse cardiovascular or cerebral events) events in the study objectives section. Tina also instructed me to meet with Morley Herbert PhD, a Biostatistician, to discuss statistical and data analysis related to the study.

After modifying the protocol, I read an article that presented different approaches to improving patient retention in a randomized clinical trial involving cancer treatment. Following retrospective data analysis, it was proven that consistent communication

between research coordinators and study subjects was effective in signifying the importance of the trial, and ultimately promoted patient willingness and adherence to treatment regimens. Treatment fidelity was also another factor held accountable for patient retention in the study. Patients administered treatment correctly, in a timely and efficient manner, felt more reassured and weren't likely to complain about complicated, different, or unconventional forms of treatment. Also, extensive training of research coordinators was shown to reduce attrition; not only were the staff trained to administer different forms of cancer treatment therapy, but they were also taught how to help support patients, psychologically, throughout the course of their treatment intervention. Reliance on the use of a tracking system was also attributed to greater study retention because it identified possible reasons for patient withdrawal, and recommended various techniques to rectify potential study related issues. Patient compensation in the form of transportation stipends and shared decision making amongst both research coordinators and study subjects also effectively contributed to reduced study attrition.

June 17, 2010:

I searched through several databases for more articles and really didn't come across very many. However, I did find an orthopedic implant study that made a concerted effort to determine whether implants in patients lost to follow up, or patients that died, had the same outcome as subjects that continued to be assessed. It was determined that study subjects loss to follow-up typically had more declining health issues than patients that remained in the study and participated in follow up procedures, accordingly.

Researchers also studied the implications of loss to follow up, and how it could potentially undermine the integrity of yielded data. They maintain that failed orthopedic

implants in patients lost to follow up could result in inaccurate, overly optimistic results if loss to follow up is significant. So, researchers emphasize the importance of "minimizing and accurately quantifying" patients loss to follow up in order to increase the likelihood of achieving sound, accurate results. Additionally, to prevent loss to follow up from adversely impacting study data, egregiously, it was recommended that it be quantified by an overall rate instead of a cumulative rate; this serves to effectively "disguise loss to follow up."

June 18, 2009

I arrived at work and began preparing my research proposal. Sometime after lunch, I attended a congenital heart defect presentation by Dr. Eric Mendeloff, who's a pediatric cardiac surgeon. His presentation lasted about 1 hour. Then, I resumed working on my research proposal, and later, added a Seattle Angina questionnaire to the appendix of the aortic valve replacement protocol.

June 21, 2010:

I attended a meeting with Syma Prince to inquire about any previous follow up studies conducted in order to research my tentative thesis topic. She suggested that I review follow up information collected from a coronary artery revascularization registry study. Even though I wasn't able to access patient information and follow up history (at the time), she provided me with two published articles that detailed follow up, outcome studies that CRSTI conducted. After reviewing both articles, I worked on my research proposal and then modified the aortic valve replacement protocol according to instructions sent via email by Tina Worley.

June 22, 2010:

I arrived at the hospital early for the weekly research team meeting. My group presented the aortic valve replacement protocol we'd prepared, and the investigators present suggested that we modify certain sections and include the angina heart failure questionnaire. After the meeting, I worked on my proposal and managed to finish discussing factors held accountable for loss to follow up. Toward the end of the day, I attended a presentation by Dr, Judson Hunt, a nephrologist, who discussed renal issues associated with cardiac transplantation. He prepared a power point presentation that detailed kidney function and their filtration rates prior to and following cardiac transplantation surgery.

June 23, 2010:

I attended a presentation by Dr. Kenneth Cooper at the Cooper Clinic in Dallas, Texas. He discussed his personal background and offered tips to leading a healthier lifestyle. Following the presentation, I worked on my research proposal for a while, and then accompanied Michelle Bruns around parts of the hospital as she offered the interns a brief tour of several Doctors' practices.

June 24, 2010:

I worked on my research proposal throughout the morning and submitted it sometime during the afternoon. I also read an article about an observational study comparing conventional coronary artery bypass graft surgery and off pump coronary artery bypass surgery. Researchers determined that the mortality rate of both procedures was equal. I also attended a presentation by Dr. Morley Herbert, a Biostatistician, who discussed information related to data organization and analysis.

June 25, 2010:

I reviewed another observational study sponsored by CRSTI that evaluated both conventional coronary artery bypass surgery and percutaneous coronary intervention (drug eluting stents). After reviewing the collected patient follow up data, it was determined that the rate of revascularization was greater for percutaneous interventions, but the mortality and myocardial infarction rates were the same for both procedures. I also searched through other clinical trial databases for articles that presented various approaches to reducing loss to follow up from occurring.

In the afternoon, Dr. James Edgerton, a Cardiothoracic Surgeon, presented surgical procedures commonly used to correct coronary artery disease.

June 28, 2010:

I searched for more articles in the medical city library and assisted Michelle Bruns in preparing file folders for physicians. I read several published articles but ultimately decided against including them in this entry because they weren't very pertinent to my project.

June 29, 2010:

I received my reviewed proposal via email from Dr. Gwirtz. So, I spent most of the day correcting it. I also watched several videos with the interns about different cardiac surgical procedures and the founding of CRSTI.

July 2, 2010:

My research mentor at CRSTI, Tina Worley, assigned me and another intern the task of conducting a social security death index search on the website ancestry.com. During the afternoon, following the search, I attended a presentation by Dr. Deepika Sopal, a cardiologist, who discussed different radiological techniques used to determine whether or not patients have

cardiovascular disease. Some of these techniques include echocardiogram and nuclear stress testing. After the presentation, I worked on modifying my proposal for resubmission.

July 7, 2010:

I spent time working on my proposal, searching for more articles related to my project, and analyzing an article I came across that examined recruitment and retention in a preventative weight gain study. In the study, researchers postulated that certain factors could be predictive of study dropout. These included: poor eating behaviors, decreased physical activity, greater stress, emotional instability, depression, and non-white ethnicity.

July 8, 2010:

I arrived at work and continued to modify my proposal. At this point, it's essentially complete; I just need to alter the study design section. I met with Syma Prince to discuss accessing patient data for my project. And, she decided it would be best if I speak with the biostatistician for CRSTI, Dr. Morley Herbert. However, she did inform me that patient history and follow up information from the care study was only available at six and eighteen months. I considered this somewhat disconcerting because initially I'd hoped to analyze patient follow up information at five years. In spite of this, she assured me that CRSTI needed to contact roughly eight hundred more CARE subjects to complete their five year follow up study.

After meeting with Syma, I went to the library and collected several articles that I'd asked the librarian to retrieve for me last week. I read and analyzed some of these articles prior to leaving for the day.

One of the articles I read examined inadequate follow up in patients that had abnormal mammogram results. In this study, researchers attempted to identify factors held responsible for

subjects lost to follow up after abnormal mammography screenings. Race/ethnicity was strongly considered when assessing follow up outcome.

After women were notified of their abnormal mammogram results, physicians recommended that they follow up after 3-6 months, or immediately, depending on the seriousness of their condition. It was determined that women instructed to follow up after 3-6 months are more likely to be lost to the study. Researchers attribute their behavior to misinterpretation of their condition and a lack of urgency. Whereas women instructed to follow up immediately following their mammograms are typically more compliant out of fear at the prospect of being diagnosed with breast cancer.

Other factors held accountable for loss to follow up included: race/ethnicity, continuity of care, and pain experienced during the mammogram procedure. In this study, African American women, in comparison to white women, were shown to be lost to follow up at a greater rate. Presently, researchers are unable to offer any explanation regarding this disparity. However, they do postulate that health illiteracy, health care system trust issues, and underestimation of follow up importance are factors that might be responsible for their incompliance. In terms of continuity of care, women without health insurance providers were more prone to be lost to follow up. And lastly, women that experienced pain during the mammogram procedure were more likely to avoid follow up. Researchers argue that this can be corrected if clinic/hospital staff develops alternate approaches to minimizing pain during the procedure.

July 9, 2010:

I spent the majority of the day reading articles. My research mentor at CRSTI, Tina, notified me that she contacted Dr. Morley Herbert and scheduled a meeting with him on Tuesday to discuss my project.

July 12, 2010:

I spoke with Karen Roper and Michelle Bruns concerning my project. Karen informed me that she'd included me on the agenda for the research meeting tomorrow, meaning that I would be asked to explain the progress of my research. I also read and analyzed an article about patients lost to follow up in a Pap smear study. This study was conducted at a cancer-screening center in South Texas. Researchers evaluated potential causes for patient loss to follow up in a group of low income, middle-aged Hispanic women that had abnormal pap-smear results. According to researchers, the majority of abnormal pap-smear findings aren't typically indicative of cervical cancer, or carcinogenic cell growth; instead, mild abnormal hormonal fluctuations, or changes in the cell composition lining the cervix, are commonly implicated as causative factors for abnormal pap-smear screening results. Nonetheless, it's still customary for patients to undergo additional pap-smear screening at either 3 or 6 months.

In determining the factors responsible for patient loss to follow up, researchers interviewed both the staff and patients. This unconventional approach to analysis precluded any remote possibility that data obtained from this study could be accurately generalized to the greater population. Notwithstanding, the aforementioned factors included: Pap smear follow-up at alternate sites, poor communication, and inordinate follow up requirements. There were several instances where patients visited alternate screening sites for Pap smear follow up examinations under the impression that clinics shared patient records. Thus, some patients were inadvertently designated as lost to follow up by research staff even though they'd completed procedural follow up requirements, appropriately, at another site. In terms of communication issues, patients expressed dissatisfaction toward clinic staff that scheduled follow up appointments without their consent. Also, post cards sent by clinic staff reminding patients of

their follow up appointments were only written in English. This presented an issue to patients that were only literate in Spanish. In regard to inordinate follow up procedures, staff was required to contact patients assiduously even if the Pap smear results were abnormal, albeit innocuous. And upon contacting the patients, paradoxically, they'd downplay the seriousness of the abnormal results. As a result, patients perceived their prospective Pap smear follow up appointments as unimportant and were more predisposed to intentionally miss them.

July 13, 2010:

I presented my thesis statement and tentative research design scheme at the morning meeting. Afterwards, I met with Dr. Morley Herbert to discuss retrieving and analyzing patient follow up data from the CARE study at eighteen months. Dr. Herbert offered great advice and suggested I examine several factors that could be attributed to patients becoming lost to follow up. These included: patient residence proximity to the clinic where they underwent either the CABG or PCI procedures, health status, ethnicity, patient education, onset of MAACE events, and the necessitation of prolonged ventilation during surgery. To commence analyzing patient data at eighteen months, Dr. Herbert referred me to Janet Williams, the IT at CRSTI. Janet agreed to assist me and said she'd prepare an exported, detailed chart of patients that were loss to follow up, along with other pre-operative information.

I worked on my proposal and the present appendix entry for the remainder of the day.

July 14, 2010:

I attended a presentation by Dr. Karen Roper on ethics in research. She discussed her academic background and events in history that contributed to the development of human research regulations. She also administered a personality assessment quiz and

provided interns with documents that described the Belmont report and the informed consent process.

Janet Williams, the designated computer specialist at CRSTI, is still in the process of exporting subject data-to compact data discs- from the study I'll be analyzing.

July 16, 2010:

I assisted Tina Worley with data entry for a seventeen-year heart transplant study. Patient creatinine levels (to determine the glomerular filtration rate), plasma rejection rates, and re-hospitalization rates were recorded up to four years following the surgery- this was dependent on when the heart transplantation procedure was performed. Whether subjects had undergone dialysis treatment following surgery, or expired, was also noted in the excel spreadsheet. After recording this data, Tina and I analyzed it and prepared a thorough summary for review by the study investigator.

For the rest of the day, I worked on my proposal and completed it. However, I've been instructed by staff at CRSTI to withhold submitting my proposal for a month until subject data from the C.A.R.E. 6-year follow up study is completed.

July 19, 2010:

I arrived at work and accompanied Tina to the C.A.T.H (cardiac catheterization lab) lab in order to obtain blood samples from a patient that underwent a heart transplant procedure six months earlier as part of a CRSTI research study. The patient's blood would be sent to a lab for analysis of human leukocyte antigen levels; elevated levels are indicative of immunological rejection. It's highly recommended by research coordinators and physicians, alike, that heart transplant patients attend follow up appointments, periodically, throughout the year. To digress, during the follow up appointment, blood is

withdrawn for testing, and cardiac tissue biopsies are conducted to determine heart function and integrity. When we'd arrived, the patient wasn't prepared to undergo the aforementioned procedures, so Tina decided it would be best to return sometime during the afternoon.

In the interim, Tina and I headed to a private wing of the hospital where I observed her administer informed consent to a kidney transplant patient for participation in an immunological, kidney rejection research study, in which both white blood cells and human leukocyte antigens would be measured in urine to determine the onset of acute kidney rejection. After reading through the informed consent document, the patient voluntarily agreed to be in the study.

Eventually, Tina and I returned to C.A.T.H lab and collected the heart transplant patient's blood sample. Blood was withdrawn during the cardiac visualization procedure and biopsy; the instrument used to scrape and collect the cardiac tissue for microscopic analysis was inserted through the femoral artery.

I also read an article that examined retention in clinical trials. In this study (**Maximizing Retention in Community-based Clinical Trials)**, researchers present a variety of different retention strategies for use in community based clinical trials. I considered the following approaches most applicable to my research project: conducting a run in test, maintenance of between-assessment with contacts, and use of a participant tracking system.

Researchers commonly conduct run in tests to gauge prospective study subject compliance. In many instances, potential subjects will be assigned a strict drug regimen, or they may be asked to follow up with research coordinators prior to commencement of the

study. Deviation from the regimen, or failure to follow up, indicates to investigators that the subject in question may potentially be non-compliant when they're in the study. So, run in tests are valuable to researchers because they promote study efficiency and the conservation of resources-this prevents investigators from investing fruitless time and effort in recruiting potentially unreliable, non-compliant subjects. Conversely, a caveat to the use of run in tests involves generalisability and bias: since certain subjects may be excluded from a study as a result of their potential non-compliance-as measured by the run in test-this could affect the study power, and subsequently, generalisability as well, because of reduced study subject heterogeneity. Thus, there's a greater probability that data yielded from this study wouldn't be generalizable to the greater population. And, study bias usually occurs because investigators would only select study subjects that demonstrate compliance, discipline, and cooperativeness during the run in period.

Maintenance of contact between research coordinators and study subjects has shown to reduce study attrition associated with loss to follow up. Therefore, it's integral that research staff aspire to maintain contact with subjects during periods between follow up. This could be achieved through the provision of holiday and birthday cards, newsletters, or telephone numbers to speak with research staff.

The development and use of a tracking system may also reduce loss to follow up. Researchers in this study collected standard patient data (phone numbers, home address) in addition to alternate contacts. Investigators also devised a methodical system for contacting patients during follow up, which I considered ingenious: first, subjects would be called repeatedly. If they weren't responsive to phone calls, then coordinators would proceed to mail follow up notices. If this approach also failed, then the alternate contacts

they provided would be contacted. And lastly, in the instance that the latter proves ineffective, research coordinators would attempt to trace subjects through personal information they provided, such as social security numbers, school records, and drivers license numbers.

July 20, 2010:

I arrived at work earlier than usual to attend the weekly research meeting. Potential studies and studies currently in progress were discussed. Following the meeting, I observed an aortic valve replacement surgical procedure performed by Dr. Todd Dewey, a cardiothoracic surgeon on the board of CRSTI study investigators. I didn't stay in the operating room for the entire procedure; I left after the insertion of the biosynthetic valve.

Upon arriving back at the office, I sent Janet Williams, the computer technician at CRSTI, an email asking if she'd completed exporting the C.A.R.E study data to compact discs for my research project. She responded to my message, promptly, and informed me that she was still in the process of exporting the data, albeit more than likely, she'd be finished sometime during the week.

July 22, 2010:

I observed a coronary artery bypass graft procedure (off-pump) performed by Dr. Todd Dewey. The blood vessel grafted was the femoral vein, and since the surgery was off-pump, a heart-lung machine wasn't used. I also spoke to the anesthesiologist on call, Dr. Luis Michaelson, who provided me with a thorough description of his professional responsibilities in the operating room.

Later, I attended a presentation by Dr. Mitchell Magee, a cardiothoracic surgeon/oncologic surgeon, who described various forms of esophageal and lung cancer, and different surgical approaches commonly employed by surgeons to extricate tumors, or

simply treat cancer. Dr. Magee also presented statistical information related to cancer mortality rates. Sometime during the presentation, Janet Williams, the computer technician for CRSTI, delivered the exported C.A.R.E study data to my office.

I also revised my proposal and submitted it to my committee for review.

July 23, 2010:

I attended a stem cell research presentation at the University of Texas Southwestern Graduate School; two scientists described the work they've conducted and provided the interns with a tour of the research laboratories. They also prepared mouse neural stem cell slides, and cardiac cell slides, for visualization with a light microscope. Another researcher explained the use of a device that simulates homeostatic, in vivo conditions (in mice) in order to observe and measure heart function.

Upon arriving back at CRSTI, I proceeded to organize C.A.R.E patient data using Microsoft Excel.

July 26, 2010:

I arrived at work and began organizing patient data from the C.A.R.E study. First, I prepared a spreadsheet combining pre-operative and follow-up information from patients that underwent either coronary artery bypass surgery, or percutaneous coronary interventions. This proved to be incredibly tedious-taking well over five hours to complete. Once everything was retrieved and organized into two separate databases-according to the procedure performed-I then analyzed the different factors (recorded as column headings) relative to each patient. This entailed arriving at patient totals for each factor and postulating, inconclusively, whether it could potentially be associated with loss to follow up attrition. Later, I altered certain components of my research proposal.

July 27, 2010:

I attended the weekly research meeting and presented the study design of my project. I also explained how I've organized all the C.A.R.E patient data in an excel database. After the meeting, I met with Morley and discussed conducting several statistical tests to illustrate whether certain factors significantly influenced the loss to follow up rate. We also deliberated over the secondary objective of my research project, which involved preparing a tracking system and an alternate consent form, designed with the intention to reduce patient loss to follow up attrition. Ultimately, he approved of my study design, although apprehensively, because he was skeptical as to whether I'd have sufficient time to prepare an elaborate, viable tracking system. He also recommended that I design an accessible, user friendly loss to follow up website-to supplement the tracking system and loss to follow up consent form-in order for patients to effortlessly follow up with study investigators on their computers. Ultimately, we both concurred that his idea was ingenious, so I agreed to also include it in my project objectives.

Eventually I left Morley's office and decided to speak with the IT, Janet Williams, to discuss the design of my tentative tracking system. Janet was incredibly supportive of my idea and overall concept for the tracking system. However, she strongly suggested that I prepare a comprehensive form as a template for the database that she'd program into Microsoft Access. Following my brief meeting with Janet, I proceeded to continue organizing loss to follow up patient information at eighteen months, for both catheterization patients and bypass patients. While I was working, Michelle Bruns notified me that Syma Prince, in quality, wanted to meet with me to discuss something important. So, I met with Syma and was confounded when she asserted it was imperative that I

procure IRB approval for my research project, because I'd never intended to contact patients or use patient information inappropriately (in violation of patient privacy federal regulations). Notwithstanding, she still strongly suggested that I acquire IRB approval. I then conferred with Tina, who personally spoke with Syma, and reassured her that I wasn't doing anything inappropriate or complicit with the patient information since I was essentially conducting a case study, which had previously been sanctioned by Tina herself, Morley, and other members of the CRSTI staff. Once she'd convinced Syma that I didn't require IRB approval, we discussed my project, extensively, and she argued that the secondary objective of my research project was futile, and potentially onerous and time consuming, considering the difficultly that constitutes designing a tracking system database. So, she recommended that I forgo the design process, entirely, and simply describe the tracking database and other approaches that could potentially reduce loss to follow up attrition. Taking her constructive, shrewd criticism into consideration, I altered the design of my project; instead of designing an actual tracking system, follow up consent document, and website, I'd just describe the latter and suggest approaches that could potentially address lost to follow up rates in longitudinal clinical studies.

July 28, 2010:

I literally spent the majority of the day calculating BMI for every patient lost to follow up in the CARE study at eighteen months. Then, I started to analyze coronary bypass patient data. I also worked on my appendix.

July 29, 2010:

I was scheduled to observe several cardiac interventional procedures in the CATH lab during the morning. However, there weren't any in progress. So, after speaking with

Jennifer Ledbetter-a nurse in the CATH lab that moderates the procedure schedule-she recommended that I return sometime during the afternoon.

In the interim, I updated my appendix and organized more of the CARE study data in excel. Prior to returning to the CATH lab, the interns and I met with Syma Prince in her office to discuss abstracts. She conducted an exercise that entailed assigning each student an abstract to read and critique. I accidentally misunderstood her directions and failed to assess the trivial shortcomings of the abstract (confusing title, incomplete sentences, etc). In spite of this, I still learned a great deal regarding abstract preparation and submission.

After the meeting I headed straight to the CATH lab. Jennifer introduced me to Ginger, a cardiovascular technician, who was relegated the task of directing me to rooms where procedures were scheduled to occur. The first procedure I observed was a lower extremity angiogram. The patient undergoing the procedure was an older female that was administered a series of anesthetics rendering her consciously sedated. The presiding Cardiologist, Dr. Bruce Bowers, performed the procedure with the intention of visualizing peripheral blood vessels to determine whether her occlusion warranted conducting percutaneous intervention. After observing live radiological feed and images, Dr Bowers decided that it would be in the patient's best interest for him to perform an interventional procedure that would correct the atherosclerotic, occluded blood vessels. Typically, it can be argued that the standard course of action for addressing blood vessel occlusion would be through stent placement. However, Dr. Bowers intended to use an alternative product provided to him by a cardiac device representative-more specifically, a cutting edge balloon that functions by correcting occlusion through blood vessel expansion (this representative was also present during the procedure). Unfortunately, though, upon insertion of the

balloon into the blood vessel, retraction occurred, repeatedly, so it was extricated from the patient and given back to the representative, who informed me that the company he represented would test the device to determine why it was ineffective. So, immediately following the removal of the balloon device, Dr. Bowers proceeded to place stents in both of the patient's legs. Then, the blood vessels were visualized and the patient's peripheral blood flow had improved, significantly. This attests to the procedures effectiveness in decisively correcting the patient's occluded, peripheral blood vessels.

Dr. Bowers also performed the second procedure I observed, a Balloon Aortic Valvotomy (BAV), on an elderly male patient with a stenotic aortic valve. This patient was also consciously sedated during his procedure. Initially, Dr. Bowers wasn't certain if this patient necessitated this procedure since his aortic valve didn't appear to be sufficiently narrow enough. However, after visualization, and the approximate determination of the inter-arterial area, the patient was designated a viable candidate for BAV. I considered the most interesting part of the procedure observing the balloon inflation, and the subsequent, immediate improvement in blood flow illustrated visually.

July 30, 2010:

I attended a transplant meeting in the heart failure clinic. Physicians, nurses, and other coordinators met to discuss heart transplant patients, as well as 3 prospective candidates for heart transplant surgery. I also completed a lost to follow up chart for coronary artery bypass patients in the C.A.R.E study.

August 2, 2010:

I finished preparing an 18 month lost to follow up chart in excel for patients that underwent cardiac catheterization procedures in the C.A.R.E study. And I submitted excel

tables illustrating various trends and differences-relative to certain factors, such as age, ethnicity, etc-in data among cardiac catheterization and coronary artery bypass patients lost to follow up.

I also came across two research articles that examined whether travel distance was associated with loss to follow up in clinical trials.

The first study was conducted in England; both male and female subjects were enrolled and underwent lap band procedures. Patients were expected to follow up with consultant radiologists at 6 weeks for band adjustments. And thereafter, each subject was held accountable for scheduling follow up appointments; this usually depended upon their desire for band readjustment. Subjects that followed up more frequently exhibited greater weight loss, which was determined through calculation of the percent excess weight loss. Whereas patients that progressively scheduled and attended less follow up appointments were noted as having decreased percent excess weight loss. Researchers postulated that this was attributed to longer travel distances between patient residences and follow up clinics.

A chart was prepared that listed travel distance intervals between patient residences and the hospital (0-10 miles; 10-20 miles; 20-30 miles; >30 miles). And, after thorough analysis, it was concluded, definitively, that a correlation existed between longer travel distance and follow up: patients that lived farther from the facility that administered the lap band readjustment procedure were less likely to schedule and attend follow appointments after 6 weeks.

The other research article I read was also a weight loss trial; although instead of lap band, subjects underwent Roux-en-Y gastric bypass surgery. Participants enrolled were

both male and female, and the surgery was performed at a hospital. Post-operative follow up appointments were scheduled at 3 weeks, 3 months, 6 months, 9 months, and 12 months.

Researchers were confounded by the number of subjects lost to follow up throughout the course of the study, which led them to theorize that analysis of subject travel distance, age, and sex were factors that could potentially elucidate lost to follow up related attrition.

Patients were divided into three groups according to the distance between their residences and the follow up clinic (<50 miles, 50-100 miles, and >100 miles). And, like the aforementioned lap band study, it was determined that study subjects were compliant and attended the first post-operative follow up appointment at 3 weeks. At nine months, follow up compliance markedly decreased for each cohort. At twelve months, follow up compliance declined for subjects that lived less than 50 miles from the clinic, and improved among patients in the 50-100 mile and >100 mile cohorts. Researchers cited transportation issues, inclement weather, poor surgical outcome, and displeasure with research coordinators as probable reasons for patient non-compliance.

Also, age and sex were analyzed as predictors of follow up compliance at 12 months through the use of the chi-squared test. P values less than .05 were considered statistically significant. Researchers determined that male patients were more compliant than female subjects (91.3% versus 69.3%; P=0.40).

August 3, 2010:

I attended the weekly research meeting. Due to time constraints, I wasn't called upon to explain the progress of my research project.

During the afternoon, I spoke with Liane Hayes, from Quality, about accessing patient social security information from two hospital sites in the C.A.R.E study. She managed to retrieve this information, which I entered into my CATH lost to follow up excel spreadsheet.

August 4, 2010:

Using social security numbers, I conducted a thorough address search for patients that underwent cardiac catheterization procedures at the Plano Medical Center in Plano, Texas. Once I finished finding the patient addresses, I measured the distance between the patients' residences and the medical center. I then proceeded to find addresses for patients that participated in the C.A.R.E study at Henrico Doctor's Hospital in Richmond, Virginia.

August 5, 2010:

I searched for addresses and started calculating the distance between patient residences and the Henrico Doctor's Hospital. Since there were more patients lost to follow up at this site than at the Plano Medical Center, it took the entire day for me to finish. I also attended presentations given by the two summer interns at CRSTI.

August 9, 2010:

The addresses of C.A.R.E patients that underwent C.A.B.G surgery were retrieved using the information services website, Enformion. Proprietary patient information, such as social security numbers and names, were input into search boxes to determine the latter. As I've mentioned in previous entries, patient addresses were used to determine the distance between patient residences and hospitals where follow up procedures were administered.

Later, I spoke with my advisor, Dr. Patricia Gwirtz, concerning the submission of my research proposal to the institutional review board at the University of North Texas Health Science Center. She recommended that I fill out and submit the appropriate exemption form, promptly. I downloaded the form, filled it out, and asked Syma Prince, from Quality, to prepare a letter certifying that I was granted permission to use classified patient information from the C.A.R.E study for my project.

August 10, 2010:

I attended the weekly research meeting; the interns presented new information on their projects to C.R.S.T.I members and other research projects were discussed.

Following the meeting, I spent most of the day determining C.A.R.E study patient income through the use of their zip codes, on a website called Melissa's Data.

I also completed preparing an abridged version of my research proposal for submission to the I.R.B.

August 11, 2010:

I assisted Liane Hayes, from Quality, with the preparation of forms for the C.A.R.E study (C.A.B.G patients). This entailed recording the following proprietary patient information: social security number, date of birth, patient initials, etc. It's important to note that over one hundred forms were prepared.

August 12, 2010:

I prepared forms and conducted a social security death index search to ascertain whether patients from the C.A.R.E study were deceased.

August 13, 2010:

I resumed conducting a social security death index search for both CATH and CABG patients in the CARE study. Additionally, the face sheets of patients determined to be alive were reviewed, and their phone numbers were written on their follow up form.

August 16, 2010:

I made copies of my research proposal and other data tables I'd prepared to present them at the weekly research meeting. Then, I finished patient zip code median gross income and distance tables, and discussed them with my on-site mentor, Tina Worley.

August 17, 2010:

I presented my research proposal and other data related to my project at the weekly research meeting. Then, for the rest of the day, I assisted a research coordinator with clerical work, and organized patient data into an excel spreadsheet for my project.

August 18, 2010:

I assisted the aforementioned research coordinator with clerical work, again, which entailed copying data CD's and filling out forms

Later, I accompanied my onsite mentor, Tina Worley, to the hospital IRB meeting. She presented research proposals for two studies: a cardiovascular imaging study, and a trans-cranial Doppler pacemaker optimization study.

I spent the rest of day working on my project.

August 19, 2010:

I met with Tina to discuss my project, and she suggested that I alter my patient data tables slightly to make them more easily understandable. This entailed adding the total number of patients lost to follow up for each hospital site. It's important to note that

patients were organized into cohorts according to their zip code median gross income, and the distance, in mileage, their primary residence was from the hospital they underwent their procedure.

Later, I met with Syma and Janet from Quality to ask if they'd be willing to provide me with patient loss to follow up information at 12 months for the CARE study. Janet said she'd organize the patient data according to specifications I'd provided for the 6 and 18 month lost to follow up patient information, and notify me when she was finished.

August 20, 2010:

I attended the transplant meeting. Board members deliberated over whether three patients were acceptable candidates for heart transplantation. Following the meeting, I observed an aortic valve replacement surgery with the CRSTI research scientist, Karen Roper. After three hours (immediately following the insertion of the valve), I left the operating room to continue working on my project.

August 23, 2010:

I briefly met with Tina to discuss the information I'd present at the upcoming research meeting. She suggested that I alter several patient data tables to make them more easily understandable. After I completed preparing the data tables, I made several copies, and then asked Tina if I could leave early to meet with my mentor/principal investigator at school, Dr. Gwirtz, so she could sign my expedited IRB form.

Once Dr. Gwirtz signed the form, I submitted it, along with an abridged version of my research proposal. The coordinator that reviewed my proposal, Heather Kline, said it was incomplete, and instructed me to download and fill out a HIPAA authorization form, and a retrospective chart review form.

August 24, 2010:

Unfortunately, I wasn't able to present the data tables I'd prepared because of time constraints, although it was tacitly understood, amongst the investigators, that I would present at next weeks research meeting

Following the research meeting, I started working on completing the HIPAA authorization form, which took longer than I'd anticipated because of its comprehensiveness.

While I was in the process of completing the authorization form, Kevin Korngut, an IT at CRSTI, asked if I'd be willing to assist him by editing patron addresses in an excel database. Ultimately, I ended up assisting him, and finished after approximately 2 -3 hours. I spent the rest of the day working on the authorization form.

August 25, 2010:

I completed the HIPAA authorization form and started filling out the retrospective chart review form. I encountered several issues pertaining to risk assessment while completing the latter; I wasn't sure if the approach CRSTI used to store patient data posed a formidable type of informational risk. And, initially, I struggled identifying different factors-beneficial to patients-that would justify conducting my lost to follow up case study. It's important to note that I spent the entire day working on the retrospective chart review form.

*I didn't attend work on August the 26th, or August the 27th, because of health reasons.

August 30, 2010:

I completed both the retrospective chart review form and the HIPAA waiver application form, and sent them to my advisor/research study principal investigator, Dr.

Patricia Gwirtz. Dr. Gwirtz agreed to sign the forms and send them to me electronically, ensuring the prompt review of my research protocol by the University of North Texas HSC Institutional Review Board.

Also, I re-organized patient distance cohort information for the research meeting with the intention of making it more easily understandable.

August 31, 2010:

I presented the cohort information I prepared at the meeting, and Dr. Mack suggested that I include a patient denominator (total number of patients that weren't lost to follow up) to allow for statistical analysis of the patient data.

For the rest of the day, I assisted Amy Kenady with filing duties and the preparation of compact discs containing patient health information.

September 1, 2010:

I prepared more compact discs, and also assisted Amy with additional filing responsibilities. I was also relegated the task of creating labels for file cabinets containing patient medical records. Before leaving work, I emailed Janet Williams, in Quality, asking if she'd completed preparing the 12-month lost to follow up compact disc I'd requested.

September 2, 2010:

I continued assisting Amy Kenady with filing duties and prepared forms for patients in a clinical research study. Also, I received the signed forms from Dr. Gwirtz, electronically, and submitted them to the institutional review board at the University of North Texas HSC for review.

September 3, 2010:

Janet Williams provided me with the compact disc containing patient follow up information at 12 months. Patients lost to follow up were entered into an excel database spreadsheet, along with their accompanying proprietary information.

After entering almost half of the CA.B.G and C.A.T.H patient follow up information, I left work a little early so I'd have sufficient time to board my flight.

September 8, 2010:

Last Friday I'd submitted my research protocol to the IRB-at the UNTHSC-for review. Today I received an email from an Office of Human Research Protection employee, stating that I needed to complete additional forms in order for my research protocol to be considered reviewable by the chair; these included: a conflict of interest form and an expedited review form. She also recommended that I extensively redact the HIPAA and retrospective forms (according to a comprehensive outline she provided) I previously submitted, as well as email a scanned copy of the original IRB approval letter for the C.A.R.E study. So, throughout the day I put fourth a concerted effort to complete the aforementioned forms and revise previously submitted forms. In addition to the latter, I also spent a couple of hours entering 12-month follow up data for CABG patients in the C.A.R.E study.

September 9, 2010:

I spoke with Tina regarding the status of my project, and indicated that I required a copy of the IRB approval letter for the CARE study. Tina mentioned that she had a saved, recent copy of the letter, and eventually sent it to me via email.

I spent the rest of the day working on cardiac catheterization C.A.R.E patient data entry and my retrospective protocol review form.

September 10, 2010:

I arrived at work early to attend the weekly transplant meeting with my onsite mentor, Tina Worley, and the executive director of CRSTI, Angie Riley. The meeting lasted approximately one hour.

Following the meeting, I worked on both the HIPAA and retrospective protocol forms until they were complete. Then, I emailed my advisor and principal investigator, Dr. Gwirtz, concerning the status of the conflict of interest form I'd asked her to fill out. Apparently, her secretary had forgotten to send it yesterday, but notwithstanding, I received it promptly and saved it to my computer. After thoroughly reviewing the documents I completed, I proceeded to email my research protocol packet to the OHRP-IRB at UNTHSC.

September 13, 2010:

I spent the majority of the day working on my project, which entailed organizing the 12-month lost to follow up data I'd received last week from Janet Williams. I also calculated body mass index values for patients with recorded height and weight.

Also, I briefly assisted Amy Kenady with clerical tasks.

September 14, 2010:

I attended the weekly research meeting, and helped Amy Kenady update patient files for an ongoing clinical trial.

Sometime during the day, I received an email from a UNTHSC OHRP employee stating that my research protocol was considered fraudulent because I hadn't sought recent signatures from Dr. Gwirtz on several revised forms. Instead, I had scanned, copied, and emailed documents she'd originally signed for my initial submission, under the impression

that this would suffice for expedited, IRB review. To ensure the prompt review of my protocol, I contacted Dr. Gwirtz and scheduled an appointment to meet on Thursday at 7:45 A.M.

September 15, 2010:

I met with Liane Hayes and discussed accessing patient data for my research project, and she recommended that I consult Janet Williams. I met with Janet, and she agreed to prepare an additional compact disc with updated 12-month follow up patient data.

For the rest of the day, I determined the distance between patient residences and C.A.R.E Hospitals, as well as median zip code gross income for patients lost to follow up at 12 months.

September 16, 2010:

I met with Dr. Gwirtz and she signed several of my IRB review forms. Then, I submitted my research protocol packet to an OHRP employee at UNTHSC.

September 17, 2010:

I attended the transplant meeting and spent the entire day determining the ages of care patients with listed birthdates. At the time, I wasn't aware that a formula existed which enabled the calculation of patient ages more efficiently. So, I'd been calculating patient ages manually, which proved to be incredibly tedious.

September 20, 2010:

The scheduled research meeting was canceled because CRSTI research coordinators were obligated to attend a conference. So, I arrived at work later than usual for a Tuesday, and proceeded to work on my project.

I continued calculating patient ages and updated my lost to follow up spreadsheets to account for newly arrived patient information from two hospitals. I also assisted Amy Kenady (research assistant) with clerical work.

September 21, 2010:

I began removing patient information from my lost to follow up spreadsheets that would not be subject to analysis. This included inconsequential patient information and other perioperative and postoperative data.

I also met briefly with Tina to discuss on-going projects I could work on. And, she mentioned that she needed assistance updating a heart failure database in the transplant medical offices.

September 22 + 23, 2010:

For the next two days I continued updating patient data. This entailed adding new patients to my lost to follow up spreadsheet. I also started preparing an outline for my master's thesis.

September 24, 2010:

I attended the transplant meeting with Tina Worley (on-site mentor). Afterwards, I worked on my project and left work early for personal reasons. It's worth mentioning that earlier in the week I'd agreed to assist Karen Roper (research scientist) with her clinic rotation, but because of the aforementioned prior personal commitments I'd made, I was unable to.

At work, I completed determining the distance/income values for CATH patients lost to follow up at 12 months, and I was also notified that my research project had been approved by the IRB.

September 27, 2010:

Patient body mass index values and ages were determined. Tina Worley (on-site mentor) entered a formula into my spreadsheet, which allowed for the calculation of patient ages at the onset of the CARE study (patient birth date subtracted from the procedure date, divided by 365.5). Patient ages were calculated at twelve and eighteen months.

I also organized files with Amy Kenady (research assistant).

September 28, 2010:

I attended the research meeting, which was longer than usual, presumably because last weeks meeting had been canceled. Later, I assisted Amy Kenady with document preparation responsibilities and entered data into lost to follow up spreadsheets for my project.

September 29, 2010:

I spent the entire day re-organizing CATH and CABG patient data tables to reflect new updated information I'd been provided with by Janet Williams (IT from the Quality Department).

September 30, 2010:

I met with Morley Herbert (statistician at CRSTI) and presented the lost to follow up information I'd prepared for my project. After reviewing the data, he suggested that I include the total number of patients for each follow up phase (6, 12, and 18 month).

Additionally, he recommended that I focus on determining the zip code gross income and patient distance information for CATH and CABG patients lost to follow up at eighteen months, only.

October 1, 2010:

I attended the transplant meeting and spoke to Tina Worley about it afterwards. She'd asked if there was quorum and I'm almost certain I mentioned yes at the time; however, there wasn't. So, as a result, nurses, research coordinators, and physicians present weren't able to determine which patients would receive heart transplants.

After speaking to Tina, I updated the lost to follow up patient information according to Morley Herbert's specifications.

October 4, 2010:

I completed updating the lost to follow up patient data and submitted it to Morley Herbert (contracted CRSTI statistician). Morley said he'd contact me after he reviewed the data, which now included the total number of cardiac catheterization patients and coronary artery bypass patients in the CARE study, along with a newly created column indicating whether they followed up, or were lost to follow up. Also, zip code income and distance analysis was restricted to patients lost to follow up at 18 months. Thus, sheets containing the aforementioned data were deleted for the 6 and 12 month follow up periods.

October 5, 2010:

After the weekly research meeting, Morley notified me that he'd completed reviewing the data. His only reservation concerned the format of the zip code income, distance analysis spread sheet: he instructed me to remove certain headings and columns that deterred him from properly analyzing the data.

So, following our meeting, I returned to my office and proceeded to re-format the spreadsheet according to Morley's specifications. I also updated my appendix and began outlining my tentative CARE study essay.

October 6, 2010:

I spent the majority of the day assisting Amy Kenady retrieve echocardiogram results for patients participating in a cardiovascular research trial. Afterwards, I completed altering the CARE data for re-submission.

October 7, 2010:

I resubmitted the CARE data to Morley for analysis. He contacted me during the afternoon, asking about two column headings that each listed myocardial infarction-he presumed that I'd accidentally duplicated the pre-operative myocardial infarction column. I explained to him that the other column indicated whether patients experienced myocardial infarction post-operatively.

I also printed out the "Declaration of Intent to Defend" form, and solicited Tina for her signature.

Before leaving work, I scheduled a meeting with Syma Prince to discuss the CARE study, and updated my appendix entries for this week.

October 8, 2010:

During the transplant meeting I received an email from my advisor, Dr. Patricia Gwirtz, stating that I'd filled out the "Declaration of Intent to Defend" form incorrectly. She instructed me to type my responses, acquire Tina's signature, and scan/email the form, promptly, so she'd be able to submit it to the graduate school office.

After sending the form, I met with Syma Prince to discuss the CARE study. She answered several questions I had, namely, whether the study was randomized and if patients were eligible for participation even if they'd undergone any previous revascularization procedures. Syma also provided follow up rates at 6, 12, and 18 months, and she recommended that I include information about the ongoing 6-year follow up study.

October 11, 2010:

Dr. Karen Roper-Research Scientist-approached me and asked if I was interested in assisting her retrieve the recorded diameters of intubation tubes used on patients that underwent valve replacement surgery for a clinical trial. She explained that this information would be included in an ongoing dysphagia study. I was relegated the task of collecting patient anesthesia reports and copying them. This entailed sifting, exhaustively, through patient health records.

October 12, 2010:

I attended the weekly research meeting and resumed searching for patient anesthesia reports. After I'd conducted a thorough search of patient records in the CRSTI offices, I met with Karen to discuss numerous patient anesthesia reports I was unable to retrieve. In every instance, either the anesthesia report wasn't included as part of the patient health history documentation, or the health history folder was missing, altogether. Karen didn't attribute this to anything, really. She suggested that I search for the missing reports in the hospital's medical records department.

Karen accompanied me to the medical records department and provided me with a thorough explanation describing how to properly, and efficiently, search for medical records by date and patient account number (through reference to a patient information

sheet). Initially, Karen assisted me; she'd find the designated patient files, and I'd sift through them, looking for the anesthesia reports. Eventually, though, she left to attend a meeting, so I continued searching for the patient files alone.

I assiduously searched through the archived patient files for hours, anticipating that I'd retrieve every single missing patient's anesthesia report. However, I didn't.

I returned to the CRSTI offices with the intention of discussing the aforementioned predicament with Karen. Unfortunately, though, she wasn't present. So, I spoke with Tina and asked her to simply inform Karen that I was still unable to find several required patient anesthesia reports.

October 13, 2010:

In a final attempt to retrieve missing patient anesthesia reports, Arti and I resolved to search through electronically stored patient files in the Medical Records Department. This process entailed navigating through the Medical City Hospital patient database, which required the assistance of an attendant.

Ultimately, we weren't able to find reports for three patients that underwent valve replacement surgery in 2007. The attendant explained that patient medical files hadn't been electronically uploaded, procedurally, to the hospital database until recently. This accounted for the missing electronic files.

I also assisted Amy Kenady prepare compact discs containing patient echocardiogram information.

October 14, 2010:

I spent the entire day revising my appendix entries and re-reading several articles I'd printed as potential source material for my research project.

October 15, 2010:

I attended the transplant meeting and re-read several articles that I'd included in my research proposal. I also emailed Dr. Herbert to see if he'd completed his analysis of my data. He assured me that he'd be done by next week.

October 18, 2010:

Shortly after arriving to work, I met with Dr. Herbert to discuss the progress of my project. He mentioned that he'd reviewed the data I'd submitted, and explained several statistical tests he conducted, which included the following: chi-square, the T-test, and the Fischer test. He also mentioned that he'd email me the results of his analysis when he finished.

For the rest of the day, I read articles and prepared data packets for Amy Kenady.

October 19, 2010:

I received the analyzed data from Dr. Herbert via email. I reviewed the data and met with him during the afternoon. He briefly explained the results and described the different types of statistical analysis he conducted. I also asked if he'd be available sometime during the week to discuss the data at length, and he agreed to meet with me tomorrow.

October 20, 2010:

Dr. Herbert arrived, unannounced, to my office and asked if I had time to review the statistical data yielded from his analysis. We reviewed the data together, and periodically, throughout his explanation of the data, I interrupted him and asked questions because I'd forgotten a great deal of statistical concepts. He explained everything incredibly well and even provided me with several suggestions for data tables and graphs that would serve to illustrate factors statistically significant for loss to follow up.

October 21, 2010:

I read more articles and started to design data tables for the research meeting next week. Unfortunately, I had issues interpreting the results, so I sought assistance from Dr. Karen Roper. Karen methodically explained the results and suggested that I present a different percentage better representative of the patients loss to follow up. After discussing the data with Karen, I left work early for personal reasons.

October 22, 2010:

I didn't attend work because of prior personal commitments.

October 25, 2010:

Dr. Karen Roper edited the information I was set to present at the research meeting. She suggested that I change the order of patient factors and include the multivariate analysis data in my discussion.

After meeting with Karen, I worked on the methods and materials portion of my essay. I also considered emailing Dr. Herbert to ask him whether he'd corrected certain values that were input incorrectly into SAS. However, I remembered that he was on vacation and wouldn't be back until Wednesday.

October 26, 2010:

I presented the univariate and multivariate statistical analysis results to the CRSTI committee members. During my presentation, I realized that I had unintentionally forgotten to provide necessary background information. And, as a result, after I finished, most of the committee members were confused. One member had trouble interpreting the frequency percentage results for distance analysis. I explained that patients who lived more than 100 miles away from the hospital they underwent their procedure, were more

likely to become lost to follow up. Another member seemed disillusioned by the miniscule number of patients lost to follow up over the course of 6 and 18 months. I explained to him that the lost to follow up attrition of the CARE study was controlled for, effectively, at 90%, and that I'd intended to use the five year follow up data for my project prior to being told that it was incomplete. A physician then asked why I had not taken his unsolicited advice-ascertaining whether patients had insurance HMOS-into consideration. I told him that insurance information wasn't provided on many patient face sheets.

Following the research meeting, I completed the methods and materials for my study, and began interpreting and writing my results.

October 27, 2010:

I met with Morley to discuss certain data interpretation issues I'd been having. I also asked if he'd corrected the body mass index results. He assured me that he'd send me the results sometime at the end of this week, or early next week.

After meeting with Dr. Herbert, I worked on the results section of my thesis.

October 28, 2010:

I worked on my literature review at the library. I'd asked Tina earlier during the week if I could take off work.

October 29, 2010:

For personal health reasons, I opted not to attend the transplant meeting on Friday. However, I still went to work-around 9-and finished the results section of my thesis, as well as the literature review.

November 1-5, 2010:

I spent the entire week working on my thesis. On Tuesday I left work early for health reasons, and I was subsequently absent on both Wednesday and Thursday.

November 8-12, 2010:

I worked on my thesis and submitted it to my committee on the 10th. For the rest of the week, I worked on my presentation.

November 15-16, 2010:

I finished my presentation on the 16th. I'm scheduled to present to my advisor, Dr. Gwirtz, on November 22nd. I've also agreed to present to the C.R.S.T.I. staff on the November 23rd.