

IDENTIFYING RISK FACTORS FOR 30-DAY READMISSIONS IN PATIENTS WITH
CIRRHOSIS

INTERNSHIP PRACTICUM REPORT

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INTRODUCTION

Decreasing hospital readmission rates have been a priority of hospitals since the Affordable Care Act was passed in 2010. Before the Affordable Care Act was established, it was estimated that about 20% of Medicare patients were readmitted into the hospital within 30 days after discharge, and 12% of these readmissions are preventable. Through the Hospital Readmission Reduction Program under the Affordable Care Act, hospitals that have higher than standard readmission rates for acute myocardial infarction, pneumonia, and heart failure are penalized financially (McIlvennan et al., 2015). Even though cirrhosis is currently not a condition that is penalized under the HRRP, it is possible that one day it will be included as the number of conditions under the HRRP is growing yearly. Cirrhotic patients require frequent hospitalizations due to the many complications associated with the disease. Each hospitalization is expensive and costs the patient about \$20,000. A preventable hospitalization produces a financial strain on the patient and also a strain on the hospital due to the amount of attention required by hospital staff for each patient. By identifying factors that are associated with each readmission, it may be possible to prevent some of the readmissions.

This practicum is a retrospective study that examined patients who have been diagnosed with cirrhosis and were admitted and discharged from Baylor Scott and White All Saints Medical Center between September 2013 and September 2015. The purpose of this report is to identify significant factors that may lead to hospital readmission in cirrhotic patients, and the data can be used to implement change to prevent future readmissions in cirrhotic patients.

BACKGROUND

Before the Affordable Care Act was established, nearly 20% of patients were readmitted into the hospital within 30 days. Readmissions are a burden to the patient and the hospital. It was also estimated that 12% of the readmissions could have been prevented, and would have saved Medicare over 1 billion dollars (McIlvennan et al., 2015). Beginning in 2009, hospitals with high readmission rates for patients with pneumonia, acute myocardial infarction, or heart failure were identified on a website by the Centers for Medicare & Medicaid Services (CMS) (Axon et al., 2011). Even though the hospitals were named publically, hospitals still did not truly have an incentive to reduce readmissions until they were penalized financially under the Hospital Readmission Reduction Program (HRRP).

Before 2012, hospitals received payment through the inpatient prospective payment system (IPPS), which covered the cost of the patient's inpatient stay and any admission-related outpatient services on the date of admission or up to 3 days before the date of admission. The IPPS did not cover post-discharge services or care that may reduce readmissions. In 2013, the HRRP was established under the Affordable Care Act. Hospitals that had higher than expected readmissions received a maximum penalty of 1% of their total Medicare reimbursements, and in 2015 the penalty had risen to 3%. The conditions that were penalized under the HRRP by 2015 were acute myocardial infarction, heart failure, pneumonia, patients with acute exacerbation of chronic obstructive pulmonary disorder, and patients admitted for elective total hip and knee replacements (McIlvennan et al., 2015). Recently, data was released by the CMS that showed a total of 2,597 hospitals will receive a reduction of 3% of their total reimbursements due to high readmissions rates for the conditions listed above. The CMS will withhold a total of \$508 million

for fiscal year 2017, which is an increase of \$108 million from fiscal year 2016 (The 2,597 hospitals facing readmissions penalties this year, 2016). The HRRP will continue to expand its policies and include more conditions to the program. It is important to find ways to decrease early readmission rates for all conditions, especially for conditions like cirrhosis, which has high readmissions rates due to the life-threatening complications associated with the disease.

Cirrhosis is associated with high mortality and morbidity. It is also a disease that is associated with many complications. Patients who are first diagnosed with cirrhosis are asymptomatic, and are characterized by having increasing portal system pressure, and decreasing liver function. The disease is referred to compensated cirrhosis during the asymptomatic phase of the disease. The disease progresses into the decompensated stage when symptoms begin to occur, which include ascites, bleeding, jaundice, and encephalopathy (D'Amico, 2013).

Cirrhosis is the end-stage pathological result of chronic injury to the liver. Chronic injury to the liver leads to fibrosis, which is caused by abnormal wound healing, and the normal tissue is replaced by collagenous scar tissue. If there is continued injuries to the liver, fibrosis of the liver develops into cirrhosis, which is an advanced stage of fibrosis. There are many factors that cause chronic liver injuries and ultimately lead to cirrhosis. Factors include alcohol consumption, hepatitis, nonalcoholic steatohepatitis (NASH), age, obesity, and type 2 diabetes (Schuppan et al., 2012).

Prior to the decompensated phase of cirrhosis, patients are usually asymptomatic and many do not know they have cirrhosis. About 20% of patients with hepatitis C and 10% of patients with NASH will develop eventually cirrhosis (Schuppan et al., 2012). Patients with Hepatitis C or NASH frequently undergo liver biopsies for prevention purposes in order to treat the disease before it progresses. However, many patients are still presenting with an initial

diagnosis of cirrhosis. Once the complications appear, it may be life-threatening. Complications include variceal bleeding, ascites, spontaneous peritonitis and hepatic encephalopathy (Shuppan et al., 2012).

Physicians can use lab tests as a tool to diagnose patients with cirrhosis before symptoms manifest. Hyponatremia, decreased serum albumin and bilirubin concentrations, and decreased prothrombin time can be seen in lab tests for patients with cirrhosis (Ginès et al., 2008).

Hyponatremia is a common complication of cirrhosis caused by an increase in secretion of arginine vasopressin (anti-diuretic hormone) by the posterior pituitary, which decreases the ability of a patient to secrete water. The increase of water in the patient's serum decreases the serum sodium concentration and causes hypo-osmolality (Ginès et al., 2008). Hypoalbuminemia is caused by a decrease in production of albumin by the liver, and albumin can also be isolated to the interstitial fluid or in the peritoneal cavity due to ascites. Increased serum bilirubin levels are caused by cholestasis and a decrease in the excretory function of the liver. Prothrombin time is increased in patients with cirrhosis due to a decreased production of clotting factors V and VII by the liver. Even though there are laboratory signs of cirrhosis, a definitive diagnosis of cirrhosis will still need to be based on histology (Shuppan et al., 2012).

Another tool physicians use to determine the severity of cirrhosis in patients is the Model for End-Stage Liver Disease or MELD. MELD is a calculation used to determine the severity of a patient's chronic liver disease. MELD was originally developed to determine the 3-month mortality of a patient who has undergone a transjugular intrahepatic portosystemic shunt (TIPS) procedure, and uses three lab values which include serum bilirubin, serum creatinine, and international normalized ratio (INR). The formula for MELD is: $MELD = 3.78 \times$

$\ln(\text{serum bilirubin (mg/dL)}) + 11.2 \times \ln(\text{INR}) + 9.57 \times \ln(\text{serum creatinine} \left(\frac{\text{mg}}{\text{dL}}\right)) +$

6.43, and can be easily calculated with a calculator. A patient with a higher MELD score is more likely to die compared to a patient with a lower MELD score (Kamath et al., 2007, Weisner et al., 2003).

The MELD score was adopted by United Network for Organ Sharing (UNOS) to prioritize the allocation of livers for patients requiring a liver transplant in 2002. Before MELD was used, a Child-Turcotte-Pugh (CTP) score was used. The CTP scoring system is flawed because it used both objective and subjective variables, such as the physician's opinion of the severity of ascites and encephalopathy, which allows more room for error in determining the severity of liver disease in patients. Many studies have been done since the implementation of using MELD scores to determine the patient's position while waiting for a liver. Studies have shown that the MELD score is a better estimator of mortality in patients with chronic liver disease. Currently liver allocation is based on severity of the liver disease determined by the patient's MELD score not the time spent on the transplant list, and initially saw a 15% decrease in mortality of patients who are on the transplant waiting list (Kamath et al., 2007).

Numerous studies have been performed examining the percentage of hospital readmissions that were possibly avoidable. Early readmissions have been associated with a higher mortality rate and poor patient outcomes. Hospital readmissions have been used to determine the quality of care provided to patients at the hospital. An early avoidable readmission is sometimes caused by a medical error or the patient receiving a lesser quality of care (Axon et al., 2011). In the case of cirrhosis, life-threatening complications, such as variceal bleeding, ascites, spontaneous peritonitis or hepatic encephalopathy, are often the cause for an admission in cirrhotic patients. If the complications are not well controlled after discharge, then the patient may require frequent hospital visits. Over 40,000 deaths per year in the United States can be

associated with a complication of cirrhosis. Cirrhosis leads to over 150,000 hospitalizations per year, and costs over 4 billion dollars per year (Volk et al., 2012). Annual admission rates for patients with cirrhosis have doubled within the past 10 years, and many cirrhotic patients require frequent hospitalizations (Sakkarin et al., 2016). Historically, cirrhosis has had a high 30-day readmission rate because of the numerous complications involved. According to various studies, 20% to 37% of cirrhotic patients are readmitted to the hospital within 30 days (Volk et al., 2012, Tapper et al., 2016). The estimated cost of each readmission is about \$20,000, and the costs are rising (Volk et al., 2012). Combined with increasing medical costs in cirrhotic patients and the possibility of reduced reimbursement by the CMS, the pressure of reducing readmission rates has been higher. By identifying the factors associated with early readmissions in cirrhotic patients, unnecessary readmissions may be prevented and decrease readmission rates.

SPECIFIC AIMS

The specific aims of this practicum project are:

1. To collect patient information including age, body mass index (BMI), ethnicity, serum sodium, model for end-stage liver disease score (MELD Score), number of medications prescribed to the patient at discharge, and whether or not the patient was readmitted within 30 days.
2. To assess whether there is a statistical significance between the values of age, BMI, ethnicity, serum sodium, MELD score, the number of medications prescribed to the patient at discharge, and if the patient is readmitted within 30 days after discharge.
3. To evaluate the significant factors that lead to a readmission within 30 days after discharge.

SIGNIFICANCE

Identifying the factors associated with 30-day readmissions may lead to reduced readmission in the hospital. Various strategies can be developed by the hospital that will help the patient have a better understanding of the disease, and also the hospital can take preventative measures to help the patient. In response to the HRRP, hospitals around the United States have implemented various strategies to help reduce the readmission rate of patients with congestive heart failure, a condition that is penalized under the HRRP. A factor that was identified was the miscommunication between the discharging hospital and the patients' primary care provider. The resulting strategy the hospital implemented was to send a discharge summary to the patient's primary care provider, and the result was a decrease in 30-day readmission (Bradley et al., 2013). The same principle can be applied to patients with cirrhosis. In order for this to be applied for patients with cirrhosis, the factors associated with higher readmissions need to first be identified. This practicum project is designed to identify any statistically significant factors that may contribute a patient being readmitted within 30 days after discharge.

METHODS

This practicum project was a retrospective study using data collected retrospectively from Baylor Scott and White's Allscripts electronic health records and databases. The MIDAS database was used to generate a list of patients who were admitted to Baylor Scott and White All Saints Medical Center between September 2013 and September 2015. The patient list was generated by the Baylor Scott and White finance department.

Potential subjects were initially identified by the principal diagnosis during the inpatient visit any of the following International Classifications of Diseases-9 (ICD-9) codes: alcoholic cirrhosis (571.2), cirrhosis not due to alcohol (571.5), biliary cirrhosis (571.6), hepatic encephalopathy (572.2), ascites (789.59), hepatorenal syndrome (572.4), spontaneous bacterial peritonitis (567.23), esophageal varices with bleeding (456.0, 456.2), portal hypertension (572.3), or paracentesis (54.91). The patient list contained the patients' age, medical record number, admission date and discharge data. The patients' medical record number was then used in Allscripts to obtain more data from the patients' admission to the hospital.

The data obtained from Allscripts was the patients' height, weight, serum sodium, serum albumin, serum bilirubin, serum creatinine, INR, the number of medications prescribed to the patient at discharge, and whether or not the patient was readmitted within 30 days. The data was collected and entered in an Excel spreadsheet. The patients' BMI was then calculated using the following formula:

$$BMI = \frac{(Weight\ in\ kilograms)}{(Height\ in\ meters)^2}$$

The MELD score was calculated using the following formula:

$$MELD = 3.78 \times \ln \left(\text{serum bilirubin} \left(\frac{mg}{dL} \right) \right) + 11.2 \times \ln(INR) + \\ 9.57 \times \ln \left(\text{serum creatinine} \left(\frac{mg}{dL} \right) \right) + 6.43$$

After collection of the data, a binary logistic regression statistical analysis was performed to determine if the variables contributed to a patient's readmission within 30 days of discharge. The independent variables are the patients' age, BMI, serum sodium, serum albumin, MELD score, and number of medications prescribed to the patient at discharge. The dependent variable is whether or not the patient was readmitted within 30 days after initial discharge. The program SPSS was used to perform the statistical analysis. The results will show which independent variable is significant in determining whether or not the patient was readmitted within 30 days. A receiver operating characteristic (ROC) curve was generated by SPSS, and the area under the curve was used to determine how good the model is at determining readmissions within 30 days.

RESULTS

Data was collected on a total of 262 patients with cirrhosis who were admitted to Baylor Scott and White All Saints Medical Center between September 1, 2013 and September 30, 2015. The association between the independent variables and whether or not a patient is readmitted is shown in Table 1. By setting the significance value (alpha) to 0.05, only the MELD score ($p=0.025$) and the number of medications that were prescribed to the patient at discharge ($p=0.018$) showed a statistically significant association with readmissions within 30 days after discharge. The Odds Ratio indicate that patients with a higher MELD score are 1.052 times more likely to be readmitted within 30 days, and patients who are taking more medications are 1.070 times more likely to be readmitted within 30 days. The other factors, age ($p=0.927$), sex ($p=0.157$), BMI ($p=0.639$), serum sodium ($p=.729$), serum albumin ($p=0.454$), and duration of admission ($p=0.829$) had p -values greater than 0.05, so they were not statistically significant and, thus, do not have an effect on readmissions.

The Hosmer and Lameshow test was used to test if the model is a good fit for the data. Since number of readmissions observed is not significantly different than the predicted number of readmissions, this model indicates a good fit. Table 2 shows the ability of the model to correctly predict readmissions in patients. This model is able to correctly predict 94.9% of patients who are not readmitted within 30 days, but only able to predict 12.9% of patients who are readmitted within 30 days. Overall, the model can predict whether or not a patient will be readmitted within 30 days correctly 68.3% of the time.

Table 1: Association of Factors with Odds Ratios of Readmission in Patients with Cirrhosis

Factor	Sig (p<0.05)	Odds Ratio	95% CI
Age	0.927	1.001	0.976-1.027
Sex	0.157	0.655	0.364-1.177
BMI	0.639	1.008	0.974-1.044
Serum Na	0.729	0.988	0.923-1058
Serum Albumin	0.454	1.058	0.913-1.225
MELD	0.025	1.052	1.006-1.099
Length of Stay	0.829	0.994	0.944-1.047
Number of Medications at Discharge	0.018	1.070	1.011-1.132

CI, Confidence Interval; Sig, Significance value (p<0.05); BMI, Body-Mass Index;

MELD, Model for End-Stage Liver Disease

Table 2: Ability to Predict Readmissions

Observed		Predicted		
		Readmission		Percentage Correct
		No	Yes	
Readmission	No	168	9	94.9
	Yes	74	11	12.9
Overall Percentage				68.3

DISCUSSION

Between September 2013 and September 2015, 85 of 262 cirrhotic patients were readmitted to Baylor Scott and White All Saints Medical Center within 30 days of discharge. This is a readmission rate of 32.44%, which is in the upper range compared to previous studies that were conducted. Previous studies showed a range of 20% to 37% of cirrhotic patients were readmitted to the hospital within 30 days (Volk et al., 2012, Tapper et al., 2016).

In previous literature, increased BMI, MELD score, and number of medications were shown to be significantly associated with readmissions within 30 days (Volk et al., 2012, Tapper et al., 2016, Agrawal et al., 2015). However, in the population at Baylor Scott and White All Saints Medical Center, only MELD score ($p=0.025$) and the number of medications ($p=0.018$) showed statistical significance. The odds ratio for MELD score was 1.052, which means for every one-unit increase in MELD score, the patient will be 1.052 times more likely to be readmitted within 30 days compared to another patient with a lower MELD score. In a previous study, the three-month mortality rate for patients with a MELD score between 20 and 29 was 19.6%. For patients with a MELD score of 30 and 39, the three-month mortality rate was 52.6%, and for patients with a MELD score greater than 40, the three-month mortality rate was 71.3% (Wiesner et al., 2003). Patients with a higher MELD score had a higher three-month mortality rate. A higher MELD score means that the patient's liver disease is more severe, and leads to more life-threatening complications, which may require more hospital visits.

The number of medications a patient is taking also showed statistical significance in predicting early readmissions. A patient that is taking more medication usually has more complications compared to a patient that is taking less. A missed dose or a misunderstanding of

how to take the medication can lead to life-threatening complications, especially in patients with cirrhosis. For example, patients with cirrhosis are prescribed lactulose to prevent hepatic encephalopathy, and need to titrate their dosage as specified by their physician to have a specified number of bowel movements per day. Patients who do not properly take lactulose can become confused and develop hepatic encephalopathy, which can be life-threatening and lead to admission into the hospital (Sharma et al., 2009).

The limitations to this practicum study is that the study is a single center retrospective study. There was a system wide switch at Baylor Scott and White from ICD-9 codes to ICD-10 codes on October 1, 2015. In order to stay consistent with the patients' principal diagnosis, only data from before the switch was used, and is not the most current data available. Because of this, the current readmissions rate may not reflect the 32.44% readmission rate of cirrhotic patients present in this data. Another issue with this study is that it is a retrospective study and also only uses data from a single hospital, which decreases the generalizability of this study to other parts of Texas or the United States. Since the data is only from Baylor Scott and White All Saints Medical Center, it is also possible that a patient who was discharged from Baylor Scott and White All Saints Medical Center was readmitted to a different hospital within 30 days. A multicenter study, including data from all of the hospitals in the area, will need to be performed apply the results to populations in different areas. Factors such as patient education and communication will also need to be assessed. Another limitation to this practicum study is the ability for the model to correctly predict whether or not a patient will be readmitted within 30 days. According to table 2, the overall percentage of the model correctly predicting a readmission is only 68.3%. This means the model is not a poor model but it is not a very good model either, so it may not be a very good tool for hospitals to use. Further studies can be

performed using a larger sample size, and different independent variables in order to derive a better model.

There have been prospective studies performed that implemented different strategies that include using a checklist in the electronic provider order entry system for patients with cirrhosis. The results show that by using an electronic checklist reduced 30-day readmissions in patients with cirrhosis (Tapper et al., 2016). Other strategies to reduce the readmissions rate for heart failure have also been studied and can be applied to patients with cirrhosis. Studies that aimed to reduce readmission rates in patients with heart failure used a multidisciplinary approach. Patients who received interventions from the multidisciplinary team which included a nurse specialist, pharmacist, dietician, and social worker. The results of this study were that patients who received multidisciplinary interventions had a reduction in admissions to the hospital (Holland et al., 2005). These strategies can be applied to the patient population at Baylor Scott and White All Saints Medical Center in the future in order to decrease readmission rates.

In conclusion, this practicum project collected information on 262 patients, which included age, BMI, sex, serum sodium, serum albumin, MELD score, length of stay during the admission, and also the number of medications prescribed to the patient at discharge. The factors that were statistically significant were MELD score and the number of medications prescribed to the patient at discharge. Patients with higher MELD scores and more medications are 1.052 and 1.070 times more like to be readmitted to the hospital within 30 days. Even though the findings are the same as previous studies conducted in other parts of the United States, this study further emphasizes the type of patient who is more at risk to be readmitted within 30 days.

INTERNSHIP SITE

My internship site was the Baylor Research Institute (BRI) at Baylor Scott and White All Saints Medical Center in Fort Worth, TX. My on-site mentor was Theresa Cheyne. She is currently the Clinical Research Manager at the site and manages both the Transplant Research Department and the Clinical Trials Office in addition to Theresa, there are three research nurses, a clinical research coordinator, a research nurse supervisor, and a regulatory specialist.

There are currently over 20 studies being conducted at the site. The studies include clinical trials in transplant, cardiology, women's health, diabetes, hepatology and nephrology. The studies are divided up amongst the staff, and each study has a lead coordinator and also a back-up to help the lead coordinator whenever she needs help. The regulatory specialist is in charge of the regulatory affairs for each study.

INTERNSHIP EXPERIENCE

During the first week of my internship, I did not have access to Baylor Scott and White computers or network, so my time was spent reviewing protocols of ongoing studies, and gathering documents from source binders for the different study coordinators. After gaining access to computers and Baylor Scott and White's Electronic Health Records, I was able to help study coordinators screen for patients, and gather data from the patients' charts that were required for the source documents. I was also assigned the task of creating source documents for the new studies that were about to begin in July. Ava, a research nurse, and Sandra, the nurse supervisor, were both very helpful and answered any questions I had about the study protocols, medical terminology, procedures, and also general questions about research.

Throughout the internship, I was able to shadow study coordinators while they obtained informed consent from patients, perform study visits, and I also observed Dr. Ruiz perform a kidney transplant. I was also given the opportunity to help recruit and consent patients for a study Dr. Manjushree Gautam started in 2012. The aim of this study was to provide a patient with more education and consults from other health professionals, such as a pharmacist or physical therapist, and compare the readmission rates of these patients with patients who received standard of care to see if there is a decrease in readmission rates. Because of my involvement with this study, I attended monthly meetings with a team led by April Jones, a nurse supervisor in the transplant unit. The main goal of the team was to reduce the 30-day readmissions rate of cirrhotic patients at the hospital. Members of the team included Dr. Gautam, pharmacists, physical therapists, social workers, dieticians, chaplains, and nurses. It was very

interesting to see how passionate everyone was in trying to improve patient care and ultimately reduce readmission rates.

On most mornings, I log into AllScripts EHR to screen for a potential patient who may be for the cirrhosis readmissions study, and also login to Centricity to screen for potential patients for a thrombocytopenia study. Most of my time was spent working with Ava on a study that required a lot of data entry and updating data in the EDC. The study was a Phase 3 clinical trial that examined a drug used to treat cancer and the effects it has on preventing rejection of a kidney transplant. In addition to working on this study, I was assigned various tasks by Theresa that helped the coordinators and principal investigators keep track of the different studies at the site, and helped the study coordinators with anything they needed help with. I was also able to observe the role of the PIs in the various studies. I saw how important communication is between all of the study staff, the monitors, and the sponsors for each study. Weekly meetings were planned between the study staff and the PIs of the studies. During the meetings, the study coordinators update the PIs on the progress of the patients and studies, provide the PIs with any significant changes or adverse events relating to a study, and for the coordinators to obtain signatures on lab reports and study documents.

I had an opportunity to attend an IRB meeting at BUMC in Dallas. I learned about the IRB and their involvement with the studies. Before any study can be conducted at the site, it must be approved by the IRB, and any changes to the protocol or informed consent must also be approved by the IRB before it is used. The IRB reviews the study protocol, informed consent forms, and all study documents to ensure that the language in these documents do not sway or coerce the patient into participating in a study. The IRB also reviews the studies for safety and well being of the patient. During the meeting, two studies that I was familiar with was up for

review, and it was interesting to see them discuss a study. It also made me realize how I missed a couple of things when I wrote the informed consent form by placing the sponsor informed consent form into Baylor's template for informed consent forms.

Overall, I had a great experience and really enjoyed learning from and working with the research staff at Baylor Scott and White All Saints Medical Center.

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APPENDIX A: Daily Journal

Week 1: June 1, 2016 to June 3, 2016

01 June 2016

Today was my first day. In the morning Theresa introduced me to the staff. I met with Claudia and signed a confidentiality agreement. I also read and signed the Baylor Scott and White Privacy and Security Handbook. In the afternoon I was able to go through a protocol and informed consent forms for Dr. Gautam's cirrhosis study. This is a study I will work on, and hopefully will be able to do my practicum project on it. I also researched articles on cirrhosis, and different intervention techniques to lower readmission rates for certain diseases.

02 June 2016

I did not have computer access, so I did more research for my practicum project. Later I sat in on a conference call with Theresa about the new BSW clinical research website. I also put lab manuals in binders, so they don't get lost in the lab.

03 June 2016

Today, I went to the application workshop and admissions panel at UNTHSC. I met with Dr. Barbara Miller from Baylor College of Dentistry. I did not go to the internship site today.

Week 2: June 6th to June 10th, 2016

06 June 2016

I still did not have computer access. In the morning, I helped Shawnta label boxes of case report files and binders on studies that have been closed that were storage. I wrote IRB numbers and the name of the study on the front of the box. I also sat in on a meeting where each of the study coordinators updated Theresa on where they are with each study.

07 June 2016

I finally received computer and e-mail access. I set up the account, and started to do the modules required for clinical research in the Baylor Learning Network. I created a spreadsheet for one of Ava's studies and the number of visits each subject had.

In the afternoon, I reviewed a protocol on a Nonalcoholic Steatohepatitis (NASH) study. I researched a little more on the disease and found out that there are currently no treatments for it. The only medications are to treat underlying conditions like diabetes and obesity.

08 June 2016

In the morning, I shadowed Susan while she obtained informed consent from a patient for the NASH study. After the patient consented to participate in the study, Susan completed the initial screening process and scheduled her for a liver biopsy to confirm she met the criteria for the study. The final part of the screening process was a physical examination. I went with Susan and the patient to the clinic for a physical examination with Dr. Modi. Later in the day, I went to a meeting with Theresa, Ava, and Sandra to update Dr. Fischbach about the studies he is the PI for.

09 June 2016

I received the protocol for a study about Antibody Mediated Rejection (AMR) of kidney transplants. I read over the protocol, and began to create source documents for the study. I received source documents from other studies and used them as a template. In the afternoon, I began CITI training.

10 June 2016

I finished my CITI training in the morning, and continued to create the source documents for the kidney AMR study. In the afternoon, I met with Dr. Gautam and the nurses who are working on the cirrhosis readmissions study. We went over my role in the study, and set future meeting dates. The study is still under continuing review from IRB and the Spanish translation of the informed consent form also needs approval from the IRB. We need IRB approval before we can do anything with the study.

Week 3: June 13 to June 17, 2016

13 June 2016

I continued to work on creating the source documents for the kidney AMR study. During lunch, we had a lunch and learn where everybody discussed different ideas to present throughout the year at each lunch and learn. After lunch, I went over the source documents I created with Leah and Theresa. They gave me suggestions on where to put everything and different changes to make.

14 June 2016

I continued to work on the source documents. They were not completely finished because we were waiting for the sponsor to send us eCRF guidelines for the study. I will be able to finish the source when I find out what data the sponsor wants us to record. Later in the day, I read protocols for a different kidney study that compared two different immunosuppressant drugs and to find the best concentration of the drug in order to have sufficient immunosuppression to prevent rejection and at the same time avoid nephrotoxicity.

15 June 2016

I attended a pre-site visit. The monitor went through the protocol for the study, checked to make sure we have all of the equipment needed for the study, and that they have been serviced.

16 June 2016

In the morning, I went with Susan to day surgery to see Dr. Wortley perform liver biopsies on two patients, who were being screened for the NASH study. At 11:30, I went to a meeting with Dr. Gautam and others who are on the Resource study. We discussed the protocol of the study, and talked about my role in the study, which is to obtain consent from the patients and then let the nurses know who agreed to consent and who is in the treatment group, so they can follow up with the patients. In the afternoon, I sat in on a conference call with Sandra and Jack about contracts and budgets on a couple of studies.

17 June 2016

In the morning, I watched another liver biopsy to screen the patient for the NASH study. Later, I shadowed Ava administer study drug to a kidney transplant patient. The patient received the study drug instead of Prograf, which is an immunosuppressant that prevents organ rejection. In the afternoon, I went to UNTHSC to meet with Dr. Chakraborty, who is a member on my committee. I also sat in a telephone conference with Sandra and Ava about a kidney transplant study that looked at Cytomegalovirus (CMV).

Week 4: June 20, 2016 to June 24, 2016

20 June 2016

In the morning, I organized a binder for a study. I went with Susan to observe explain the inform consent to two patients for the Cystatin C study. I worked on the proposal for my practicum project. The sponsor for a kidney Antibody Mediated Rejection study e-mailed the eCRF completion guidelines to us, and I was able to work on the source documents for the study more.

21 June 2016

I observed Meagan enter data into the EDC for a uterine fibroids study. The EDC system was different than others I have seen, so the way data is entered is different. Afterwards, I went with Theresa and Leah to meet with Dr. Fischbach. During the meeting, Theresa and Leah updated Dr. Fischbach on his patients who are on studies, and Dr. Fischbach authorized changes in medication doses to follow the study protocol.

22 June 2016

Sandra is preparing for a remote monitoring visit, and asked me to scan and redact source material for the monitor. Documents containing patient information cannot leave the premises. I gathered all of the required documents, redacted them using a program, and sent the documents to the monitor. In the afternoon, Jack showed me how to create an informed consent form for a new study. The sponsor had sent their version of the informed consent form, but it needed to be put into Baylor's format and language. When I was finished, I sent the ICF to Theresa so she can edit it.

23 June 2016

Theresa sent back the ICF for a new study with comments after she proofread it. The ICF needed to be at an 8th grade reading level, so I needed to change the larger words. I e-mailed the form back to Theresa, so she can review it and submit it to the IRB. Later in the day, I helped Ava pre-screen patients for a study that looks at an investigational immunosuppressive drug. Observe Susan screen a patient for the NASH study

24 June 2016

In the morning, I went through the partner ICF for the new study and formatted and edit it. I also helped Meagan with copying informed consent forms from a study that will be scanned into patient files. In the afternoon I worked on my proposal for my practicum project to submit to the IRB next week.

Week 5 June 27 to July 1, 2016

27 June 2016

Today a monitor from Intercept came for a site monitoring visit. I sat in with the monitor and Susan to go over queries. In the afternoon, I finally got access to Baylor's EMR. Ava showed me how to use AllScripts. She taught me how to look for a specific patient, and also see which patients are currently in the hospital. After learning how to navigate AllScripts, I helped Ava look for patients that may qualify for an antibody mediated rejection (AMR) drug study.

28 June 2016

In the morning, I observed Susan enter data into the eCRF for a NASH study. Then I spent the rest of the day pre-screening patients that may qualify for study Ava is working on.

29 June 2016

In the morning, I went with Susan to Interventional Radiology to observe a biopsy performed on a patient. The biopsy is to identify if the patient qualifies for the NASH study. The physician performing the procedure explained how he uses the ultrasound machine to guide the biopsy needle, so he doesn't hit the portal vein and hepatic artery. In the afternoon, Susan went over the protocol and inclusion/exclusion criteria for a thrombocytopenia study. For the rest of the day I went through the schedules of the hepatologists to find patients that may qualify for this study.

30 June 2016

I continued to prescreen patients for the thrombocytopenia study and the AMR study. Susan also showed me how to create a list of patients that may qualify for Dr. Gautam's study. I started to pre-screen for patients that might qualify for that study.

1 July 2016

Throughout the day I organized binders from studies that have closed more than six months ago. The files are stored in boxes at a storage facility, and will be destroyed in 20 years.

Week 6: July 4, 2016 to July 8, 2016

4 July 2016

The office was closed today for Independence Day.

5 July 2016

I continued to put old study files in boxes that will be shipped off to storage. A monitor from the thrombocytopenia study came for a visit. I accompanied the monitor and Susan to speak with Dr. Modi and the pharmacy department. The monitor was discussing goals for the study, and talked about key points to the study. In the afternoon, I helped Ava and Susan pre-screen patients for their studies.

6 July 2016

In the morning, I finished boxing up files from closed studies. I also sat in a Site initiation visit for a thrombocytopenia study in subjects with liver disease. The monitor went over the key inclusion/exclusion criteria, and the study protocol. Afterwards, I observed Susan enter source data into the eCRF, and also observed her answer queries. Dr. Modi also sent Susan names of a couple of his patients to see if they qualify for the thrombocytopenia study. I went over their medical records to find out if they qualify.

7 July 2016

In the morning, I screened for patients that may qualify for a different liver study for Susan. Later in the day, I put files for another closed study in boxes, so they can be shipped off to storage.

8 July 2016

The hospital had a blood drive in the morning, so I donated blood with the other people in the department. Afterwards I went through the lab kits in the storage room, and disposed the ones that were expired or from closed studies.

Week 7 July 11, 2016 to July 15, 2016

11 July 2016

I continued to help Susan screen for patients for her studies. In the afternoon, I attended a meeting with Dr. Gautam and the people who are working on the project that aims to reduce readmission rates in patients with cirrhosis. During the meeting, they went through different issues that may lead to a patient's readmission within 30 days. They also came up with different solutions and ways to implement the solutions for the issues. Dr. Gautam also wanted to change the protocol for her study to include consultations from a pharmacist and a physical therapist.

12 July 2016

In the morning, I worked on changing the protocol and informed consent forms for Dr. Gautam's study. Theresa showed me how to submit the revised protocol and informed consent forms to the IRB for approval. In the afternoon, I helped Ava and Susan screening a patient for a study which looks at the benefits of an immunosuppression drug in patients with kidney transplants.

13 July 2016

Throughout the day I helped Ava with verifying and entering data into the EDC for one of her studies. I also helped Susan screen patients for one of her studies.

14 July 2016

I helped Ava verify the source for adverse events on one of her studies matched the data entered in the EDC. I also helped her enter the data into the EDC.

15 July 2016

I spent the day pre-screening for patients that may qualify for Susan's study and Ava's study.

Week 8 July 18, 2016 to July 22, 2016

18 July 2016

In the morning, I screened for patients for Dr. Gautam's cirrhosis study, but did not find any candidates. I also made a table highlighting the similarities and differences between the three NASH studies our site is conducting.

19 July 2016

I helped Susan look for potential patients for her NASH and thrombocytopenia studies. In the afternoon, I prepared new binders and source documents for one of the on-call kidney transplant studies.

20 July 2016

A study is having a remote monitoring visit. Sandra asked me to gather and redact the source material the monitor requested. I went through the subject binders to find the necessary supporting documents and physician notes.

21 July 2016

I continued to gather and redact the source documents for the remote monitoring visit. The monitor also requested copies of the new informed consent forms for the patients who have been re-consented under the new consents.

22 July 2016

The monitor requested more documents for the remote monitoring visit. I also began creating source documents for a study that is open for enrollment. I prepared the binders and checklists for each visit, so all of the documents are ready when a patient enrolls in the study.

Week 9: July 25, 2016 to July 29, 2016

25 July 2016

Throughout the day I helped Ava go through patient binders to verify that the data in the binders matched the data in the eCRF. I also helped her enter more data in the eCRF. Later in the day, I started the online training for certification to be able to start entering data in the eCRF.

26 July 2016

In the morning, I finished the online training for the EDC and also signed the delegation of authority log that will allow me to enter data into the EDC. In the afternoon, I attended a meeting about reducing cirrhosis readmissions rates at the hospital. I also spoke with Dr. Gautam about her study, and how to approach patients and consent them for her study.

27 July 2016

I spent the day entering data from one of Ava's studies into the EDC. I also started the process of getting my project approved by Baylor's IRB.

28 July 2016

I finished up the forms required and submitted my proposal to the IRB for approval in the morning. Theresa sent me informed consent forms from a sponsor that needed to be converted into BRI's informed consent format. I also went through the informed consent and made sure the language was at an 8th grade reading level.

29 July 2016

In the morning, I screened for patients that may qualify for the different studies we have. Theresa also sent me informed consent forms for a new study that is about to open. The ICFs are from the sponsor, so they needed to be converted to BRI's format.

Week 10: August 1, 2016 to August 5, 2016

1 August 2016

I began screening for patients that may qualify for Dr. Gautam's cirrhosis readmissions study. In the afternoon, I went with Theresa to consent a patient for the cirrhosis study.

2 August 2016

The monitor from a study e-mailed Ava a list of queries that needed to be answered. I helped Ava go through the patient binders and answer the queries. In the afternoon, I went with Theresa to consent a patient for the cirrhosis readmissions study.

3 August 2016

I began creating source documents and preparing the patient binders for a new Type 1 hepatorenal syndrome study.

4 August 2016

In the morning, I pre-screened patients for a thrombocytopenia study for Trista. Later in the day, I continued to edit the source templates for the new HRS study.

5 August 2016

The IRB sent back the submission for my practicum project and needed corrections. I corrected the forms, and submit them back to the IRB for approval.

Week 11: August 8, 2016 to August 12, 2016

8 August 2016

A patient is getting a kidney transplant at the hospital. I helped Sandra check to see if the patient qualified for a study. I went with Sandra to talk to the patient about to study and to get his consent to participate in the study. The patient agreed to participate in the study. Afterwards we met with Dr. Fischbach to evaluate inclusion and exclusion criteria and to make sure he was eligible to participate in the study. I went to gather all of the lab kits for the required blood draws per the protocol.

9 August 2016

In the morning, I went with Sandra to talk to a patient about a study for patients with thrombocytopenia. She declined to participate in the study because she lives far away. Afterwards I continued to work on answering the queries for Ava's study. In the afternoon, I went to the bi-weekly meeting about reducing cirrhosis readmissions at the hospital.

10 August 2016

In the morning, I screened for patients that would qualify for the cirrhosis readmission study. I spent the rest of the day verifying the source documents and the data entered in the EDC for one of Ava's studies. In the afternoon, I observed Sandra consent a patient who qualifies for a hepatorenal syndrome study.

11 August 2016

Sandra needed another binder created for one of her studies so it will be ready patient enrolls in the study. I went with Theresa to see the patients on our studies to collect vital signs and dispense drugs.

12 August 2016

I went with Theresa and Sandra to talk to Dr. Gonzalez about the patient participating in one of his studies. They discussed the plan of action for the patient, and whether or not to

Week 12: August 15, 2016 to August 19, 2016

15 August 2016

I continued to enter data into the EDC for one of Dr. Fischbach's studies. I reviewed the patient's chart in Allscripts and printed out lab reports to file with the source documents. The lab reports need to be reviewed by Dr. Fischbach, so I got them ready for him to sign.

16 August 2016

In the morning, I pre-screened patients for Dr. Gautam's study. Then, I continued to help Ava enter data for her study. In the afternoon, Sandra asked me to create source documents for a new study that is about to be active.

17 August 2016

I continued to enter data for Dr. Fischbach's antirejection study. I also reviewed queries that needed clarification on the medication dosage of the concomitant medications. A monitor from a hepatology study was here for a monitoring visit. I sat in for part of the visit and observed Trista answer the monitor's questions about the EDC.

18 August 2016

I went with Sandra and Theresa to talk to Dr. Gonzalez about a potential type 1 hepatorenal syndrome patient who may qualify for a study. Theresa also updated Dr. Gonzalez about the other hepatology studies that were enrolling at the hospital. I had a question about entering data for a study, and he explained how he wanted it to be entered in spreadsheet.

19 August 2016

In the morning, a patient came to receive a kidney transplant, and she qualified for a research study. I went with Sandra to talk to the patient and tell her about the study. She was very interested, and decided to participate in the study. In the afternoon, I was able to observe Dr. Ruiz perform on a kidney transplant on the research patient.

Week 13: August 22, 2016 to August 26, 2016

22 August 2016

I gathered the necessary blood collection tubes for the patient who recently received a kidney transplant, and brought the tubes down to the transplant clinic, so they can draw the patient's blood for the research visit. In the afternoon, attended a meeting with Theresa and the staff about each person's goals and the issues that are present with each study. After the meeting, I went with Sandra to talk to a research patient about how he is feeling after the kidney transplant surgery, and Sandra documented the visit in the progress notes.

23 August 2016

In the morning, I began creating notecards for the different nephrology and hepatology studies for the PIs and study coordinators. These contain the basic information about the study and main inclusion and exclusion criteria for each study, and can be used as a quick reference. I also attended a conference call with Sandra and Dr. Fischbach for a site selection visit for a new study that Dr. Fischbach will be PI for. In the afternoon, I continued to work on the study notecards, and I went with Sandra to talk to a patient who is on one of her studies.

24 August 2016

In the morning, I went on Allscripts to screen for patients who may qualify for Dr. Gautam's study. I attended a meeting with Ava and a clinical trials educator from a thrombocytopenia study. She talked about the number of subjects that are enrolled in the study, and she also discussed different strategies other sites used to screen for patients. This study is enrolling slower than expected due to the inclusion and exclusion criteria. The patient is on a kidney transplant study. I also continued to work on the study notecards, and I went with Sandra to visit a patient who was on a kidney transplant study.

25 August 2016

When I arrived, I pre-screened patients to see if they qualify for Dr. Gautam's study. I helped Ava answer queries. Many of the queries that were generated by the data management because the generic name for a medication was not entered. In the afternoon, I worked on the study notecards. Then I gather the required blood collection tube for a patient's visit tomorrow, and I brought it downstairs to the transplant clinic.

26 August 2016

In the morning, I went down to the transplant clinic with Ava to see a patient and give him his stipend for the research visit. I observed Ava process the blood that was drawn for the research visit. A couple of queries were generated for Ava's study, so I observed her answer the queries.

Week 14: August 29, 2016 to September 2, 2016

29 August 2016

I finished creating the study notecards, laminated, and distributed them to the coordinators. Sandra asked me to edit the source documents for a study to reflect what is being asked in the EDC. I also began creating study cards for women's health studies that are being conducted at the site.

30 August 2016

I emailed Nick Carpino from the finance department to obtain a list of patients for my project. The list will include every patient that was admitted to Baylor Scott and White All Saints Medical Center from September 2013 to September 2015. Unfortunately, I received an automated response that he was on vacation until next week, so I have to wait before I can get the list. After lunch, I went with Sandra and Ava to meet with Dr. Fischbach. They updated him on the status of his patients and his studies. After the meeting, I observed Sandra enter data into the EDC for one of her studies.

31 August 2016

In the morning, I attended a meeting with Theresa. During the meeting, everybody gave updates of their studies, and discussed issues they might be having. A couple of coordinators needed some help to get caught up, so the other coordinators offered to help. In the afternoon, I went to talk to a patient to give her more information about Dr. Gautam's research study. She was interested, but did not want to consent to the study.

1 September 2016

I pre-screened patients for Dr. Gautam's study in the morning. I also created patient binders for the on-call studies so it will be ready when a patient enrolls. For the rest of the day, I verified and entered data into the EDC for Dr. Fischbach's kidney rejection study.

2 September 2016

Theresa asked me to create a table comparing the similarities and differences between the NASH studies. I went through the protocol and inclusion/exclusion criteria for the studies, and highlighted the differences in the table. This table was then sent to the hepatologists, so they can decide which study is best for a patient. For the rest of the day, I continued to verify the data in the EDC for Dr. Fischbach's study.

Week 15: September 5, 2016 to September 9, 2016

5 September 2016

The office was closed today in observance of Labor Day.

6 September 2016

I pre-screened for patients that may qualify for Dr. Gautam's cirrhosis readmissions study. I approached one patient and talked to her about the study. I went over what was involved, and how it may benefit patients in the future. She declined and did not want to participate in the study. Afterwards, I went to a meeting with the team involved in preventing readmissions in patients with cirrhosis. Some data was presented, and it was interesting to see how many patients were readmitted within 30 days.

7 September 2016

I pre-screened patients for Dr. Gautam's cirrhosis readmissions study, and then met her at a patient's room. She explained the study and how it can benefit patients and the hospital in the future. I went through the informed consent form with her, and answered a couple of questions she had about the study.

8 September 2016

I attended a FDA Readiness class at BUMC. The class was presented by Lynn van Dermark from Medtrials. She went through the process of a FDA investigation and what to expect during an inspection. She also gave tips on how always be prepared for an investigation.

9 September 2016

Michelle, the Nurse Practitioner from Dallas Nephrology Associates, sent me a patient who is getting a biopsy because he is showing signs of rejection. I screened him to see if he qualifies for an antibody mediated rejection study.

Week 16: September 12, 2016 to September 16, 2016

12 September 2016

I began collecting data for my project. Nick from the finance department sent me an excel spreadsheet with a list of every patient who were admitted into the hospital between September 2013 and September 2015 with cirrhosis. I used the patient's medical record number to look up the patient's chart in AllScripts, then I looked at the lab tests performed from the visit and entered the values in the excel spreadsheet.

13 September 2016

I continued to collect data for my practicum project throughout the day. I also met with a pharmacist from the sponsor of a study. She discussed the enrollment data for the study, and new data regarding the investigational drug. After meeting with her, I went to the weekly meeting with Dr. Fischbach.

14 September 2016

Throughout the day I collected data for my practicum project. In the afternoon, I went to talk to a patient who was eligible for Dr. Gautam's cirrhosis readmissions study. She was very interested in the study. I went over the informed consent form with her and emphasized that participation in the study was completely voluntary. She agreed to participate in the study, and was randomized to the control group. She will continue to receive all of her treatments according to the hospital's standard of care.

15 September 2016

In the morning, I continue gathering information from AllScripts and entering it into a spreadsheet for my project. In the afternoon, I helped Ava enter data for one of her studies into the EDC.

16 September 2016

I pre-screened for patients in AllScripts that may qualify for Dr. Gautam's study. Dr. Gonzales e-mailed Sandra a potential patient for a type 1 hepatorenal syndrome study. I observed Sandra screen this patient and go over the inclusion and exclusion criteria. The patient's serum creatinine level was not high enough, so she did not qualify for the study.

Week 17: September 19, 2016 to September 23, 2016

19 September 2016

I spent the day gathering and entering into the spreadsheet for my project.

20 September 2016

I sat in on a teleconference with Ava and Sandra about a study. They talked about how many subjects were enrolled since the previous teleconference a couple of months ago. They also gave us an overview about the changes that were made in the study. In the afternoon, I reviewed subject binders and compared that data in the source to the data in the EDC to make sure everything was entered. The sponsor is having a data lock in October and they will be doing interim data analysis.

21 September 2016

I continued to review the data that was entered in the EDC for Ava's study. I also entered new data from blood tests for subjects that recently had a visit in the transplant clinic. In the afternoon, Theresa held a meeting with the staff. In the meeting we discussed what we learned from the FDA readiness class, and things the staff needs to do to be prepared for a FDA audit.

22 September 2016

In the morning, I pre-screened for patients who may qualify for Dr. Gautam's cirrhosis readmissions study. For the rest of the day I helped Ava enter and review data for her study.

23 September 2016

I spent the day finishing up gathering and entering data for my project. I also helped Sandra create a pre-screening log for a study to send to Dr. Yango.

Week 18: September 26, 2016 to September 30, 2016

26 September 2016 to 30 September 2016

My grandmother passed away, and I was in Houston for her funeral.

Week 19: October 3, 2016 to October 7, 2016

3 October 2016

In the morning, I screened patients who are currently admitted in the hospital for Dr. Gautam's study. I also helped Ava by screening for patients that may qualify for thrombocytopenia studies. In the afternoon, I continued to help Ava enter data for her kidney transplant study.

4 October 2016

In the morning, I screened for patients for the cirrhosis readmissions and thrombocytopenia studies. I also attended the monthly meeting for reducing cirrhosis readmissions in the hospital. In the meeting, I gave an update on the status of the cirrhosis readmissions research study. Dr. Gautam gave me some advice on how to recruit more patients for this study. Other members provided updates on how their assigned items were progressing. They are currently in the process of putting together a patient education booklet for all cirrhosis patients to take home when they are discharged.

5 October 2016

In the morning, I went with Sandra to meet a patient in the transplant clinic who is there for routine clinic visit. I observed her collect the information she needed for the research study. Afterwards, I observed her process labs and I took the labs down to be shipped out.

6 October 2016

I screened for new potential patients that may qualify for the cirrhosis readmissions study in the morning. I also answered a couple of queries for Ava's kidney transplant study. In the afternoon, I attended an IRB meeting at BUMC. This was the first IRB meeting I have ever been to and it was an interesting experience. The IRB discussed the studies that were undergoing continuing review, revisions, and new studies. Each member was assigned a study, and then presented their opinions of the study at the meeting. Principal investigators of some new studies were present also, and the IRB asked them any questions they had regarding the study. Once all of the questions were answered, the investigative team members left the room and the IRB discussed their opinions and then voted on whether or not the study will be approved.

7 October 2016

I pre-screened patients for Dr. Gautam's study and the thrombocytopenia studies. I worked on creating tables for my project, and researched more background information.

Week 20: October 10, 2016 to October 14, 2016

10 October 2016

The monitor from Dr. Fischbach's study sent Ava and me a list of medications that were classified under the wrong category in the EDC, so I spent the day updating the EDC and changing the medications to the correct category. I also worked on my thesis during the day.

11 October 2016

A monitor came for a monitoring visit. I brought him down to meet Theresa in pharmacy. I observed him perform his monitoring visit, and take inventory of the drug that was not dispensed to ensure it matched up with records. In the afternoon, I went with Ava and Sandra to meet with Dr. Fischbach for our weekly meeting. I also attended a staff meeting where the coordinators provided updates for each study.

12 October 2016

I began updating a spreadsheet that contained the status of all of the studies that were conducted at BAS. This spreadsheet contained the name of the study, number of subjects enrolled, the target number of subjects, and the status of the study. This spreadsheet is for Theresa, and she will use it when she meets with the director of BRI and the vice president of Baylor Scott and White All Saints.

13 October 2016

I went through the lab kits in the kit room and separated the expired kits out. I sorted the contents of the kits so they can be donated. I also finished the spreadsheet for Theresa. There were also a couple of queries that were generated for one of Dr. Fischbach's studies, so I went through the patient's chart and answered the queries. Later in the day, I observed Maria and Sandra work on the continuing review for a study.

14 October 2016

I spent the day working on my thesis. I finished creating tables, and the discussion section. Earlier in the day, I pre-screened potential patients for Dr. Gautam's study. I went to talk to a patient, but he was not interested in the study.

Week 21 October 17, 2016 to October 21, 2017

17 October 2016

In the morning, I shadowed Ava during a study visit with a patient who has had a kidney transplant. I watched Ava draw labs and obtain information from the patient such as medication changes and adverse events. I also attended a conference call with different coordinators in a thrombocytopenia study. During the call, the sponsor discussed different ways to enroll more patients, the number of patients enrolled in the study world wide, and the remaining timeline of the study.

18 October 2016

In the morning, I screened patients for Dr. Gautam's cirrhosis readmission study. Dr. Fischbach presented during a lunch and learn about the different types of rejection in patients with kidney transplants. He discussed the clinical symptoms and treatments for each type of rejection. For the rest of the day, I worked on my practicum project presentation.

19 October 2016

I assisted Sandra with a remote monitoring visit. I gathered the source documents he needed, scanned, and redacted the source documents to send to him. I also helped Ava enter data for her kidney transplant study. In the afternoon, I helped screen for patients for a thrombocytopenia study.

20 October 2016

I shadowed Ava and Theresa while they consented a patient for a MRI study. Theresa discussed the risks and benefits of the study, and also reiterated that the study is completely voluntary. She decided to participate in the study, so I was able to observe the whole consenting process.

21 October 2016

I worked on my final draft and presentation. A couple of queries were generated for Ava's study appeared in the EDC. I went through the patient's binder and answered the queries. In the afternoon, I went to talk to a patient about Dr. Gautam's cirrhosis readmissions study. The patient decided to not participate in the study.

Week 22 October 24, 2016 to October 28, 2016

24 October 2016

Throughout the day, I continued to work on my presentation. I also attended a conference call with Ava about the thrombocytopenia study. The medical monitor discussed enrollment statistics, and gave us tips on recruiting.

25 October 2016

I attended a class about liver transplants offered by Baylor. In the morning, the pre-transplant coordinator talked about what a patient does when they are being evaluated to receive a liver. A surgical technician talked about the surgical procedure during a kidney transplant. An ICU nurse also came and talked about what to expect after a patient is finished with surgery. Dr. Gonzalez gave a presentation on the progression of liver disease to liver failure, and the clinical complications associated with liver failure.

26 October 2016

In the morning, I went to practice my presentation with Dr. Gwartz. In the afternoon, I went with Ava to meet with Dr. Fischbach. We discussed his patients who were on research studies, and he addressed the severity of the adverse events that occurred for the patients.

27 October 2016

In the morning, I screened for patients for the cirrhosis readmissions study and a thrombocytopenia study. I went to talk to a patient about the cirrhosis readmission study, and gave him information about the study. In the afternoon, I attended a presentation for a new study during the site initiation visit. The monitor presented explained the study protocol and gave us tips on recruiting for patients.

28 October 2016

In the morning, I went to watch a defense presentation at school. In the afternoon, I went to a kidney and pancreas transplant class offered by Baylor. The class presented information about patient care, pre and post surgery care, and common medications for transplant patients.