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The off-hours effect is a phenomenon where patients admitted during nights and weekends have poorer outcomes than those admitted during weekdays. This observation is often more pronounced in emergent conditions such as cardiogenic shock. Few studies have investigated the presence of an off-hour effect in patients with cardiogenic shock. In my thesis project, I explored the existence of an off-hour effect in 155 cardiogenic shock cases at a major urban hospital by evaluating patient outcomes. Patients admitted during off-hours had higher complication rates (OR=2.66, 95% CI, 1.29 to 5.49; $p=0.01$). I also found that patients admitted during on-hours waited longer to receive mechanical circulatory support devices after being admitted; however, this did not appear to negatively effect on-hour patient outcomes. While it appears that admission time does influence patient outcomes, the underlying cause for this effect is not yet understood.

SINGLE CENTER ANALYSIS OF THE OFF-HOUR EFFECT IN
CARDIOGENIC SHOCK OUTCOMES

INTERNSHIP PRACTICUM REPORT

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Caroline R. Harrison, B.S.

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CHAPTER I

INTRODUCTION

For decades, researchers have analyzed hospital data and noted in numerous instances that outcomes tend to be poorer when procedures or admissions occur during “off hours”, which are typically defined as holidays, weekends, and nights (MacFarlane, 1978; Bell, CM & Redelmeier D.A., 2001). This “weekend effect,” or “off-hours effect,” has been studied in various specialties with some finding a significant difference in patient outcomes (Bell, CM & Redelmeier D.A., 2001; Aylin et al., 2010; Leatherby, R.J., 2021) and some finding no differences (Becker et al., 2018; Dvorak et al., 2021; Grandhi et al., 2021). This effect is likely to be a more significant factor in the treatment of acute, deadly diseases where small deviations in timing could have a large impact on patient outcomes, such as cardiogenic shock (CS).

CS is a severe disease state where dysfunction of the heart leads to reduced cardiac output and tissue ischemia. This dysfunction can result from various heart diseases such as myocardial infarction, acute decompensated heart failure, arrhythmias, and valvular insufficiencies (Gaieski et al., 2022). Despite medical advances such as the use of acute mechanical circulatory support (AMCS) devices, pharmacological support, and revascularization procedures, CS still results in high hospital mortality, estimated between 27%–51% (van Diepen et al, 2017). While many studies evaluate weekend-effect and outcomes of myocardial infarction – a leading cause of CS – there are fewer studies evaluating all-cause CS. The few studies that do

address CS in this way do not find a consensus; some studies indicate a weekend effect is present (Harhash et al., 2021), while others do not (Sag et al., 2020).

To investigate the possible off-hours effect in CS treatment, I compared mortality, complications, and discharge destination among patients admitted to Baylor University Medical Center and diagnosed with CS during on- and off-hours. I predicted that if an off-hours effect exists in the treatment of CS, then mortality, complications, and unfavorable discharges would be higher for patients admitted during off-hours. I also investigated the possible causes of an off-hour effect. Due to staffing and resource limitations during off-hours, I predicted that these patients would wait longer to receive treatment, receive fewer advanced treatment options, experience longer hospitalizations, and spend longer periods of time on mechanical ventilation.

CHAPTER II.

BACKGROUND AND LITERATURE REVIEW

The characterization of weekend or off-hours effects has been an ongoing discussion, with studies presenting conflicting evidence as to the existence of a true effect. Several initial studies investigated the weekend effect primarily through analyses of mortality. In a retrospective study of 3,789,917 Ontario hospital admissions, patients with three acute conditions – abdominal aortic aneurysm, acute epiglottitis, and pulmonary embolism – experienced a higher mortality rate when admitted on the weekends. The researchers hypothesized that other diseases requiring non-elective emergent treatment could be affected by the time of admission (Bell & Redelmeier, 2001). In a later study of 4,317,866 emergency admissions to English hospitals, it was found that the in-hospital mortality rate was 10% higher for patients admitted on the weekends when analyzing the top 50 causes of death for this group (Aylin et al., 2010). Contemporary publications have begun narrowing this discussion by investigating specific conditions, such as a 2021 meta-analysis which found that unadjusted in-hospital, 30-day, and 90-day mortality were higher in patients admitted over the weekend for ruptured abdominal aortic aneurysms (Leatherby et al., 2021).

Other studies have been unable to detect a weekend effect. In a study of 22,451 non-elective trauma patients, the day of admission was found to have no effect on mortality or length of stay (Becker et al, 2018). As this discussion has developed, researchers have found that the weekend effect does not persist in certain scenarios. In a single-center study of deceased-donor

liver transplants, researchers noted that although the procedure does not occur on a predictable schedule and is urgent, no weekend effect was observed in one-year mortality and graft survival (Dvorak et al, 2021). A study of 6,052 acute ischemic stroke patients undergoing endovascular mechanical thrombectomy similarly found that admission on the weekend had no effect on in-hospital mortality or cost of service (Grandhi et al, 2021).

Researchers have begun to move beyond establishing the existence of a weekend effect and are now investigating the possible underlying causes. While studying a sample of hemorrhagic stroke patients, researchers found that the weekend effect was exacerbated when patients were admitted to a rural hospital, suggesting that the presence of experienced staff may play a role in the differing mortality rates (Mekonnen et al, 2020). Another study found that when they adjusted for the results of routine blood tests, the magnitude of the weekend effect on mortality was diminished, suggesting that the excess mortality can be explained by differences in the degree of sickness in weekend patients (Walker et al, 2017). Other studies have suggested the weekend effect is more common in elective surgeries, whereas staff associated with emergent procedures are often prepared and highly specialized, possibly explaining why the weekend effect is not observed in procedures such as liver transplants (Chen et al, 2019; Smith et al, 2018).

The body of literature addressing weekend effects in CS patients is not as comprehensive, however many studies investigate myocardial infarction, a major cause of CS (van Diepen et al., 2017). In a meta-analysis of 1,892,424 patients with acute myocardial infarction, it was found that off-hour admissions (at night or over the weekend) experienced a higher short-term mortality rate, a longer door-to-balloon time, and were less likely to receive percutaneous coronary intervention (Sorita et al, 2014). However, in a meta-analysis of patients with acute

myocardial infarction complicated by CS, no difference was found in 30-day mortality for patients admitted during off-hours (Sag et al, 2020). In a study that did investigate CS as the primary condition, 875,054 hospital admissions were analyzed and researchers determined that weekend CS admissions had higher in-hospital mortality (Harhash et al, 2021). Based on these findings, it is not yet clear if admission on weekends or at night impacts outcomes for patients diagnosed with CS. On one hand, this disease is emergent and requires immediate action to prevent poor outcomes; the differing levels of care during weekends or nights due to staffing and resource limitations may negatively impact patient outcomes. On the other hand, BUMC is well equipped to treat these patients due to the multidisciplinary shock team that remains available at all hours. This availability of expert care may eliminate deficits in patient care associated with admission time.

SPECIFIC AIMS

This study aimed to determine if admission time has an impact on outcomes for patients diagnosed with CS at Baylor University Medical Center (BUMC). This was determined by analyzing mortality, complication rates, and discharge destinations between patients admitted during on-hours and off-hours. After characterizing this effect, details of the hospitalizations were also compared to learn more about the possible source of deficit in patient care. I compared how long it took for patients to receive mechanical circulatory support devices and how long it took to receive vasopressor or inotrope support. I also investigated the duration of time patients spent in the hospital, the cumulative time patients spent on a ventilator, and the number of patients who receive advanced support between the admission time groups. These secondary analyses revealed specific areas of care that were affected by admission time and may guide future protocol changes to promote equitable care regardless of admission time.

SIGNIFICANCE

CS is a deadly condition and finding ways to improve treatment would benefit patients at risk for developing this disease. Currently, one of the leading methods to improve outcomes for patients with CS is the improvement of treatment protocols (Basir et al., 2019; van Diepen et al., 2017). The effects of admission time on CS have not yet been widely explored and represents a potential area where patient care can be improved. This project evaluated major endpoints such as mortality, complications, and discharge disposition which allowed us to understand if admission time had an influence on patient outcomes. The exploratory analyses allowed us to better understand this influence and relate it to how patients are treated during their stay. The results identified a possible area of weakness in the hospital's treatment protocols as well as several strengths, which has given some direction on how to mitigate these issues.

MATERIALS AND METHODS

Study Design and Inclusion Criteria

The present study is a retrospective analysis of patients diagnosed with CS during their stay at BUMC between July 2019 and July 2022. All patients had been discharged from the hospital or were deceased at the time of analysis. Patients were first identified as candidates for the Cardiogenic Shock Working Group (CSWG) Registry. This registry represents a multisite effort led by Tufts University to collect information about CS hospitalizations; however, the data used in this study was limited to patients seen at BUMC. All subjects included in my study had to fulfill the inclusion criteria of the CSWG Registry, outlined in Table 1. Patients inclusion was broken into two categories. The first category identifies hemodynamic values that may indicate a patient is in CS; patients must have experienced two or more of the listed hemodynamic values concurrently to qualify. If the hemodynamic values in Category 1 were not met but the patient required medication or mechanical support to maintain stable hemodynamics as described in

Table 1. Enrollment criteria for the Cardiogenic Shock Working Group Registry

Category 1	MAP < 60mmHg or a >30mmHg drop in MAP from baseline
	SBP < 90mmHg or a >30mmHg drop in SBP from baseline
	Pulse > 100
	CI < 2.2
	PAPI < 1.0
Category 2	CPO ≤ 0.6
	Requires the use of at least 1 vasopressor, inotrope, or AMCS device to maintain the above targets.

MAP, mean arterial pressure; SBP, systolic blood pressure; CI, cardiac index; PAPI, pulmonary artery pulsatility index; CPO, cardiac power output. Taken from CSWG Registry protocol (Kapur, 2021).

Category 2, they also qualified for enrollment. This study was approved by both the Baylor Scott and White Research Institute IRB and the North Texas Regional IRB.

Data Collection

Data were extracted from Baylor Scott and White electronic medical records. Patient demographic data included age, sex, race, ethnicity, body mass index, history of heart failure and history of chronic kidney disease. Outcome data included time of death or ongoing survival status, destination after discharge, and complications experienced during hospitalization. Ongoing survival status after hospitalization was evaluated based on follow-up phone calls, clinic visits, and physician notes indicating that the patient was still alive or was deceased.

Other values collected included time of admission, locations patient was admitted from, blood pressure at time of admission, time of discharge or death, time of CS diagnosis, time that first vasopressor or inotrope was given, time of AMCS device insertion, palliative care consultations, advanced heart failure therapies, number of days spent in the hospital, and cumulative time spent on mechanical ventilation.

Demographics, comorbidities, admission time, complications, medication times, time of AMCS device insertion, palliative care consultations, advanced heart failure therapies, and in-hospital time of death were recorded by multiple research coordinators as part of the CSWG Registry data entry process. Destination after discharge, locations patient were admitted from, and cumulative time spent on mechanical ventilation were all collected by me to supplement the available registry data. Diagnosis time for CS was partially collected by me and partially taken from the registry. 100 subjects in the original sample were enrolled in an earlier version of the CSWG Registry that did not record CS diagnosis time, while the remaining 67 subjects were

enrolled in the newer version that did record this value. For the 100 patients without a CS diagnosis, I recorded this information from the patient charts.

Definitions

Off-hour admissions were defined as occurring between the hours of 18:01 and 06:59 during weekdays and the hours occurring between 18:01 Friday and 06:59 Monday to account for the weekend. No admissions in this sample occurred on weekday holidays, so no patients were denoted as off-hour due to holidays. On-hour admissions were defined as occurring between 07:00 and 18:00 during weekdays.

Complications identified in this study include stroke, cardiac arrest, cardiac tamponade, valve injury, limb ischemia, acute kidney injury, vascular complications requiring intervention, bleeding requiring surgery or transfusions, pulmonary artery rupture, hemolysis, and hematomas greater than 3 cm. Pulmonary artery rupture was also investigated as a complication, but no subjects from this site were known to have experienced this complication. If a patient experienced any of the complications initially listed, they were counted as having a complication. Patients who had cardiac complications were defined as experiencing cardiac arrest, cardiac tamponade, or valve injury during their hospitalization. Vascular complications were defined as patients undergoing percutaneous coronary interventions (PCI), coronary artery bypass graft (CABG) surgeries, or having other vascular complications requiring surgery during their hospitalization. Additionally, bleeding complications were defined as incidences of bleeding requiring surgery, bleeding requiring transfusions, or hematomas greater than 3 cm.

Destination after hospital discharge was defined as being “favorable” or “unfavorable” with favorable discharges including patients sent home (excluding patients sent home on hospice care) or sent to inpatient rehabilitation services. Other discharge locations identified in this

sample and categorized as unfavorable included hospice care, long-term acute care facilities, skilled nursing facilities, and patient expiration.

To evaluate how quickly patients were given AMCS devices or medications, a “start-time” was recorded for each patient. Due to the severity of this disease, diagnosis and treatment of CS often occurs quickly after a physician suspects this diagnosis, which could occur in the emergency department (ED) or the outpatient clinic. As a result, the time that a patient is diagnosed or treated with CS often occurs prior to the official hospital admission time listed in a patient’s chart, making it difficult to determine the durations between diagnosis and treatments. To remedy this issue, a “start time” approximating the earliest time a patient might be identified as having CS was recorded. The start time was recorded as follows: ED arrival time for patients first seen in the ED, initial time of appointment for patients admitted from clinic, time in the procedure facility for patients admitted after elective right heart catheterizations or other scheduled procedures, and normal hospital admission time denoting when a transfer was completed for patients transferred from outside hospitals. This strategy allows for a complete picture of the early timeline associated with CS treatment to be evaluated.

Main Statistical Analyses

To analyze population characteristics, age was found to follow a normal distribution using the Shapiro-Wilks test and compared between groups using a t-test. All other characteristic variables were assessed using chi-squared tests, except in cases where the expected value for an observation was less than 5; then Fisher’s exact test was used.

Mortality events were recorded for up to a year after admission, including mortality occurring after initial hospitalization. I constructed a Kaplan-Meier plot of on- and off-hour mortality and compared them using a Log-rank test. I performed a Cox-regression to find a

hazard ratio, adjusting for age, sex, and comorbidities including obesity, systolic blood pressure less than 90 mm Hg upon admission, history of heart failure, and a history of chronic kidney disease. These variables are used in several scoring strategies to gauge shock severity and have been shown to be useful for predicting outcomes in patients with CS (Kalra et al, 2021). The proportional hazards assumption was evaluated using Schoenfeld residuals. For this analysis and later multivariable analyses, entries containing missing data were not included in the final analysis.

Complications were analyzed using chi-squared tests with Yates' corrections for continuity. This analysis was performed on incidences of all complications identified in this study excluding CABG and PCI procedures, cardiac complications, vascular complications, bleeding complications, and acute kidney injuries occurring during hospitalization. Odds ratios were calculated for each iteration of the analysis. Unfavorable discharge destinations were also analyzed using a chi-squared test with Yates' correction followed by the calculation of the odds ratio.

Multivariate logistic regression models were constructed to evaluate admission time as a predictor of all complications and unfavorable discharge locations. I evaluated the odds ratios of having a complication or having an unfavorable discharge location when adjusting for age, sex, and comorbidities as described previously for the Cox-regression.

Exploratory Statistical Analyses

Several durations associated with start-time, time of diagnosis, and treatment times were also compared. The duration between start-time and the insertion of the first AMCS device, the duration between start-time and the administration of the first vasopressor or inotrope, and the duration between start-time and diagnosis time were compared. Additionally, the duration

between diagnosis time and insertion of the first AMCS device as well as the duration between diagnosis time and administration of the first vasopressor or inotrope were compared. The number of cumulative hours a patient spent on mechanical ventilation and the number of days spent in the hospital were also evaluated. These durations were analyzed using non-parametric Wilcoxon rank sum tests after normality, evaluated using the Shapiro-Wilks test, was not met.

I also evaluated the advanced treatments patients received during their treatment course. I compared the proportion of individuals who received heart transplants, durable ventricular assist devices (VADs), or palliative care consultations during their hospitalization using chi-squared tests and odds ratios.

Analyses were performed using R 4.2.1 (R Core Team, 2022), as well as the survival (Therneau, 2022) and the epitools (Aragon, 2020) packages. For graphical visualization, the ggsurvfit (Sjoberg & Baillie, 2022) and ggplot2 (Wickham, 2016) packages were used. Statistical significance was assessed at a significance level of 0.05.

RESULTS AND DISCUSSION

Population

Of the 167 patients initially identified for this study, 12 were found to have been diagnosed with other types of shock and were excluded from statistical analysis. Of the remaining 155 patients, 83 were admitted during off-hours and 72 patients were admitted during on-hours. Demographic information, medical history of subjects, and admission details are summarized in Table 2. Included patients had a mean age of 61 and 75% were male.

Significantly more patients of Hispanic descent were admitted in the off-hours, and significantly

Table 2. Characteristics of patients admitted during on- and off-hours

		On (N=72)	Off (N=83)	p-value
Age (years) ± 1 SD		60.5 ± 12.6	61.8 ± 12.8	0.52
Sex	Male	53 (73.6%)	63 (75.9%)	0.89
	Female	19 (26.4%)	20 (24.1%)	
Race	White	41 (56.9%)	51 (61.4%)	0.90 ^a
	Black	25 (34.7%)	27 (32.5%)	
	Asian	3 (4.2%)	2 (2.4%)	
	Other	3 (4.2%)	3 (3.6%)	
Ethnicity	Non-Hispanic	69 (95.8%)	67 (80.7%)	0.01^a
	Hispanic	3 (4.2%)	13 (15.7%)	
	Unknown		3 (3.6%)	
Comorbidities	Obesity	25 (34.7%)	33 (39.8%)	0.63
	History of HF	63 (87.5%)	61 (73.5%)	0.049
	History of CKD	29 (40.3%)	43 (51.8%)	0.20
Admission location	Transfer from OSH	18 (25%)	41 (49.4%)	<0.001^a
	ED	22 (30.6%)	32 (38.6%)	
	Right heart catheterization	14 (19.4%)	2 (2.4%)	
	Clinic	12 (16.7%)	1 (1.2%)	
	Other scheduled procedures	2 (2.8%)	3 (3.6%)	
	Other	4 (5.6%)	4 (4.8%)	

^a Fisher exact tests; OSH=outside hospital; ED=Emergency department; HF=Heart failure; CKD=Chronic kidney disease; significant values in bold.

fewer patients with a history of heart failure were admitted in the off hours. Additionally, the distribution of locations patients were admitted from differed between the two groups. More patients were admitted after elective right heart catheterization procedures or clinic visits during on-hours, while more transfers from other hospitals and ED admissions occurred in off-hours. Other characteristics were not significantly different between the two groups.

Survival, Complications and Discharge Location

Within 1 year of initial admission, 23 patients from the on-hour cohort were deceased and 36 from the off-hour cohort were deceased (Table 3). Though the Kaplan-Meier curve appears to show that off-hour admissions trend towards having a lower probability of surviving to one year (Figure 1), mortality was not significantly different between the two groups ($p=0.2$). When mortality was adjusted for age, sex, and comorbidities including obesity, systolic blood pressure

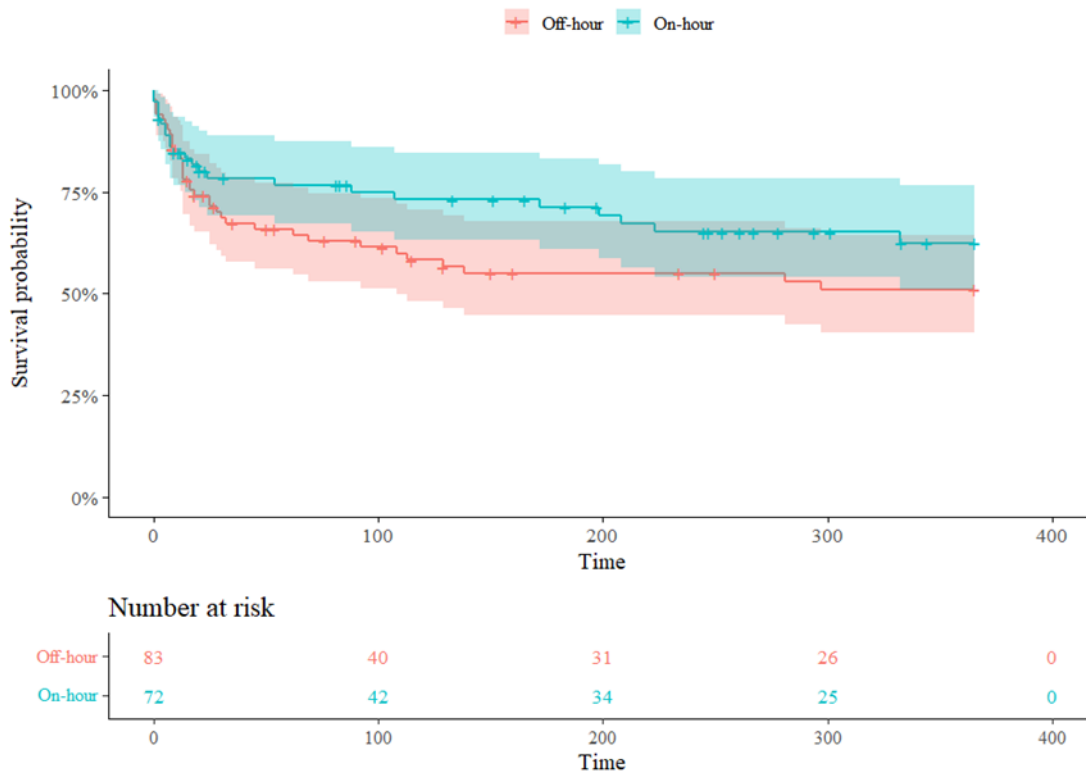


Figure 1. Kaplan-Meier curves comparing survival up to one year between on- and off-hour admissions.

less than 90 mm Hg upon admission, history of heart failure, and a history of chronic kidney disease, mortality was still not significantly affected. (HR=0.91; 95% CI, 0.51 to 1.61; $p=0.7$).

The complications encountered by this cohort are summarized in Table 3. Patients admitted during off-hours were 2.7 times more likely to experience a complication during their stay (OR=2.66, 95% CI, 1.29 to 5.49; $p=0.01$). The multivariable logistic regression adjusting for sex, age, and other comorbidities also suggests that admission during off-hours hours is associated with an increased risk of having a complication (OR=2.02, $p=0.08$). When analyzing specific complications, off-hour patients were more likely to have acute kidney injury (OR=2.19; 95% CI, 1.14 to 4.24; $p=0.03$). There was no significant difference in the risk cardiac complications, bleeding complications, or vascular complications requiring. Patients admitted during the off-hours trended towards having fewer favorable discharges (OR=0.48; 95% CI, 0.25 to 0.95; $p=0.0501$), though this was not statistically significant. The multivariable logistic regression analysis supported this, also showing that admission time did not significantly affect discharge location. (OR=1.57, $p=0.24$).

Table 3. Mortality, complications, and discharge locations in on- and off-hour admissions.

	On-hour admissions (N=72)	Off-hour admissions (N=83)	OR (95% CI)	<i>p</i>
One-year mortality	23 (31.9%)	36 (43.4%)	1.62 (0.84 – 3.18)	0.20
All complications	44 (61.1%)	67 (80.7)	2.66 (1.29 – 5.49)	0.01
AKI ^a	37 (51.4%)	58 (69.9%)	2.19 (1.14 – 4.24)	0.03
Cardiac complications ^b	16 (22.2%)	22 (26.5%)	1.26 (0.60 – 2.68)	0.67
Bleeding complications ^c	13 (18.1%)	18 (21.7%)	1.25 (0.56 – 2.84)	0.71
Vascular interventions	8 (11.1%)	11 (13.3%)	1.21 (0.46 – 3.36)	0.87
Favorable discharge location	51 (70.8%)	45 (54.2%)	0.49 (0.25 – 0.95)	0.0501

OR = Odds ratio; AKI = Acute kidney injury; CI=Confidence interval, significant p-values bolded. All complications include AKI^a, stroke, cardiac arrest^b, cardiac tamponade^b, valve injury^b, limb ischemia, vascular complications requiring intervention, bleeding requiring surgery or transfusions^c, pulmonary artery rupture, hemolysis, and hematomas greater than 3 cm^c. Vascular complications included percutaneous coronary interventions, coronary artery bypass surgeries, and other vascular complications requiring surgery. Favorable discharge locations included stable discharges home and inpatient rehabilitation centers.

Durations and Advanced Treatment

The comparisons of durations (i.e., time period between diagnosis time or start time and initiation of treatment modalities) are summarized in Table 4. The results of the Shapiro-Wilk tests showed that all of the analyzed durations followed non-normal distributions. The median duration between start-time and AMCS device insertion was significantly longer for patients admitted during on-hours than off-hour admissions (median= 308.2 vs 30.7 hours, $p<0.001$, figure 2a). The median duration between CS diagnosis time and AMCS device insertion was also significantly longer for on-hour admissions compared to off-hour admissions (median=98.8 vs 1.7 hours, $p=0.016$, figure 2b). The median durations between start-time and first vasopressor or inotrope medication, start-time and diagnosis time, diagnosis time and first vasopressor or inotrope medication, the duration spent on mechanical ventilation, and duration spent in the hospital were not significantly different between the groups.

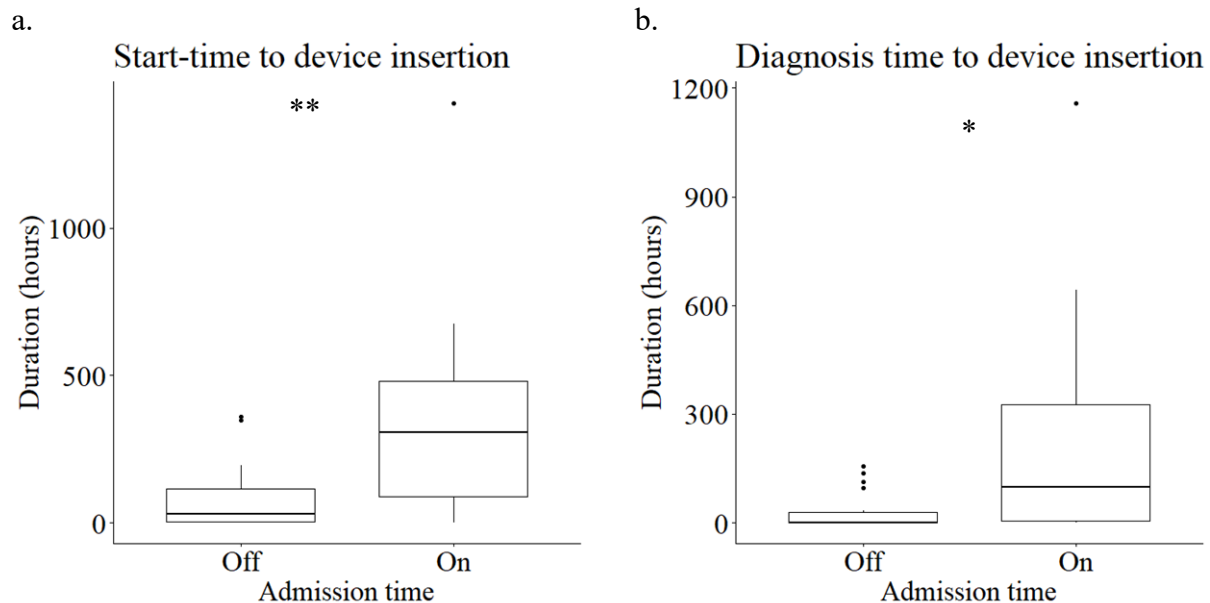


Figure 2. Comparisons of durations between on- and off- hour admission times; a) Comparison of duration between start-time and first device insertion; b) Comparison of durations between CS diagnosis time and device insertion; * $p<0.05$; ** $p<0.01$.

Table 4. Exploratory comparisons of durations between on- and off-hour admissions.

	On-hour admissions	Off-hour admissions	<i>N</i>	<i>p</i>
Start-time to device insertion (hours)	308.2 (88.3 – 481.4)	30.7 (2.3 – 114.2)	45	<0.001
Start-time to first medication (hours)	9.3 (3.9 – 38.0)	11.8 (3.1 – 86.1)	75	0.74
Start-time to diagnosis (hours)	8.1 (4.8 – 43.8)	17.4 (5.0 – 76.6)	128	0.21
Diagnosis-time to first device (hours)	98.8 (4.4 – 326.8)	1.7 (0.00 – 28.4)	36	0.016
Diagnosis-time to first medication (hours)	0.0 (0.0 – 3.2)	0.0 (0.0 – 2.8)	67	0.85
Duration spent in hospital (days)	15.0 (5.7 – 24.5)	15.0 (8.0 – 26.5)	155	0.59
Duration spent on mechanical ventilation (hours)	60.5 (39.5 – 127.8)	31.5 (19.0 – 126.5)	94	0.10

Data shown as median, (IQR); significant *p*-values bolded.

As shown in Table 5, there were not any significant differences between the number of heart transplant recipients, VAD recipients, or palliative care consults between on- and off-hour admissions.

Table 5. Comparison of advanced treatment options between admission hours.

	On-hour admissions (<i>N</i> =72)	Off-hour admissions (<i>N</i> =83)	OR (95% CI)	<i>p</i>
Heart transplants	12 (16.7%)	17 (20.5%)	1.29 (0.57 – 2.92)	0.69
VAD recipients	13 (18.1%)	12 (14.5%)	1.30 (0.55 – 3.07)	0.70
Palliative care consults	32 (44.4%)	29 (35.0%)	1.50 (0.78 – 2.85)	0.30

VAD=Ventricular assist device.

SUMMARY AND CONCLUSIONS

In this study, I found that patients admitted during off-hours had a higher chance of having a complication during their hospitalization, specifically a higher chance of having acute kidney injury. Additionally, discharge location appears to trend towards off-hour admissions having more unfavorable discharges, though not significantly so. However, admission time did not impact mortality.

Previous studies of admission time and CS did not find consensus on the impact that off-hour admission may have on mortality. A study from Harhash et al. (2021) found that weekend admission for CS did increase hospital mortality while a study from Sag et al. (2020) found no effect. The results of this study appear to support the results of the latter, however, the smaller sample size of this study compared to previous studies may have limited my ability to detect a small effect. Additionally, this study compared all-cause mortality at one-year and did not evaluate the causes of patient expiration, so it is possible some mortality events not related to the original CS diagnosis were included in the analysis. It appears more investigation is needed to elucidate if admission time truly influences mortality for patients with CS. Harhash et al. (2021) also reported a significant difference in the discharge destinations of their patients between groups; however, the locations identified in their study differ from those identified in this study, limiting direct comparison.

Harhash et al. (2021) also found that off-hour admission resulted in increased acute kidney injuries (OR=1.03; 95% CI, 1.02 – 1.04; $p<0.001$), which is in agreement with my findings, though I found a larger effect size within my sample. The study from Harhash et al.

(2021) only considered weekend patients in their off-hour group, which could be the source of the differing effect sizes. Acute kidney injury is a known common complication of CS, and mitigation is reliant on close observation of hemodynamic values and kidney function (Ghionzoli et al., 2021). It is possible that in off-hour admissions, this close observation is not achieved due to differences in hospital operations. Future studies could investigate whether hemodynamic and kidney function monitoring also vary by admission time in CS patients. If found to be true, protocols prioritizing hemodynamic and kidney function monitoring when CS is suspected could be implemented to reduce the disparity between on- and off-hour kidney injury. Several other results of my study do not align with previous studies; where Harhash et al. (2021) found that more transplants and VADs were placed in off-hour admissions, I found no effect of admission time.

The increased number of acute kidney injuries seen in the off-hours cohort may have been impacted by the larger number of Hispanic individuals also seen in this group. The risk of acute kidney injury seems to be higher in patients with diabetes (Patschan & Müller, 2016), and it is known that the prevalence of diabetes is higher in Hispanic populations (Aguayo-Mazzucato et al., 2019). Future studies of this sample may consider adjusting for Hispanic individuals or patients with a history of diabetes when analyzing the off-hours effect to determine if acute kidney injury probability is impacted by admission time. Additionally, studies focusing on cardiogenic shock in Hispanic populations could investigate a potentially disparate prevalence of acute kidney injury.

Differences between previous literature and this study may be a result of the uniqueness of the site where my sample was taken. The Center for Advanced Heart and Lung Disease at BUMC includes a heart failure clinic with cardiologists specialized in advanced heart failure and

heart transplant treatment. When compared to other locations, our site has a larger representation of CS cases caused by heart failure rather than acute myocardial infarction as seen in other studies. Patients with chronic heart disease experience symptoms differently from classic CS presentations and respond to treatments differently (Guerrero-Miranda & Hall, 2020), possibly accounting for differences in hospitalization courses. Additionally, many patients are referred to this site to receive heart transplants and VADs, which may account for the higher number of these treatments during on-hours compared to Harhash et al. (2021).

In addition to differing prevalence of heart failure patients at this location, BUMC is a very large urban hospital that also is involved with medical education. Consequently, the populations served by this hospital as well as the resources available differ from smaller rural hospitals and may have impacted the patient outcomes in this study. Though BUMC serves some patients from the rural areas surrounding the DFW metroplex, many patients live in the surrounding city and the differences in demographics between these two populations may impact replicability. Other studies have shown that the use of invasive hemodynamic monitoring during cardiogenic shock cases is higher in urban teaching hospitals than rural hospitals (Osman et al., 2021), and when comparing cases of cardiogenic shock caused by myocardial infarction, admission to large teaching hospitals is associated with lower mortality when compared to rural hospital admissions (Vallabhajosyula et al., 2019). Future studies might explore the off-hours effect in rural hospitals or adjust for the differences between institution size to better investigate the influence of this effect on cardiogenic shock cases.

The difference in complication rates between on- and off-hours may also be a result of on-hour patients receiving more routine care. The on-hours group consisted of many patients being seen in the clinic or for elective right heart catheterization. Regular follow up visits like

these are part of the standard of care for patients with heart disease seen at BUMC, so it is possible that more patients admitted in the on-hours were being seen regularly by a cardiologist to manage their heart disease. If more on-hour patients were receiving regular care for their heart disease, we could interpret the difference in complications as on-hour patients having fewer complications. Rather than off-hour patients experiencing deficits in care leading to more complications, we may be seeing a reduced number of complications in on-hour groups because of quality follow-up care. This could be further investigated by grouping hospital admissions for CS into patients seen routinely and patients not seen routinely, then evaluating their outcomes and predilection to be admitted in on- or off-hours. This could indicate the importance of regular follow-up appointments in reducing poor outcomes for patients at risk for CS.

My investigations of durations between admission and different treatments have not been performed in other studies of CS to my knowledge. Though I originally hypothesized that if an off-hours effect existed, it could be the result of a delay in treatment, my results showed that off-hour admissions received devices sooner than on-hour admissions. One factor influencing device insertion timing could be the availability of the facilities where these insertions are performed. During on-hours, scheduled procedures occur in the cardiac catheterization labs or operating rooms, reducing the number of rooms and staff available for unplanned emergent procedures. During off-hours, few procedures are scheduled which may allow emergent patients admitted during this time to quickly receive a device.

I believe that these observations may be a result of the different patterns of admission location that occurred between the two groups. The on-hour patients were often admitted after clinic visits and elective right heart catheterization procedures, which are a part of routine heart failure treatment and may occur with stable patients. It is possible that these patients were

diagnosed and admitted in the earlier stages of shock and thus did not immediately require an AMCS device, leading to a longer duration. More patients admitted in off-hours came from the ED or were transfers from outside hospitals. These patients may have been in more advanced stages of shock which led them to seek emergency treatment or be transferred for higher levels of care in the off-hours. When our site received these patients, they may have been more critical and required AMCS devices more quickly to be stabilized.

To better understand these differences, future studies should record the severity of each patient's disease using the SCAI SHOCK stage classification (Naidu et al., 2022). This scoring system uses a combination of hemodynamic values, lab values, and supportive requirements to assess the severity of cardiogenic shock cases. This measurement would allow us to determine if differences in treatment are a result of more critically ill patients arriving during-off hours or differences in the care patients receive.

Though this study suggests there is an interaction between patient outcomes and admission time, there may be a more complex relationship at play. While there may be differences in staffing and other hospital operations between on- and off-hours, there may also be differences in the patients that are seeking care. The kinds of admissions that occur in off-hours differ from on-hours, representing more ED admissions and transfers from other institutions for higher levels of care. These admission patterns may also be affected by BUMC's role as a central hospital with advanced resources not found at other hospitals. It is possible that the off-hour effect could be more pronounced in rural hospitals with fewer designated staff for CS treatment. Additionally, characterizing patients by admission time only may not reveal the entire picture; further analysis based on diagnosis time occurring in the on- or off-hours may better reveal

deficits in patient care at different times. Further studies will be needed to find consensus on the role that admission time plays in CS outcomes and to elucidate the source of this effect.

REFERENCES

- Aguayo-Mazzucato, C., Diaque, P., Hernandez, S., Rosas, S., Kostic, A., & Caballero, A. E. (2019). Understanding the growing epidemic of type 2 diabetes in the Hispanic population living in the United States. *Diabetes/Metabolism Research and Reviews*, 35(2), e3097. <https://doi.org/10.1002/dmrr.3097>
- Aragon, T. J. (2020). *epitools: Epidemiology tools* (R package version 0.5-10.1). The Comprehensive R Archive Network. <https://CRAN.R-project.org/package=epitools>
- Aylin, P., Yunus, A., Bottle, A., Majeed, A., & Bell, D. (2010). Weekend mortality for emergency admissions. A large, multicentre study. *BMJ Quality & Safety*, 19(3), 213–217. <https://doi.org/10.1136/qshc.2008.028639>
- Becker, F., Vogel, T., Voß, T., Mehdorn, A.-S., Schütte-Nütgen, K., Reuter, S., Mohr, A., Kabar, I., Bormann, E., Vowinkel, T., Palmes, D., Senninger, N., Bahde, R., & Keschull, L. (2018). The weekend effect in liver transplantation. *PloS One*, 13(5), e0198035. <https://doi.org/10.1371/journal.pone.0198035>
- Bell, C. M., & Redelmeier, D. A. (2001). Mortality among Patients Admitted to Hospitals on Weekends as Compared with Weekdays. *New England Journal of Medicine*, 345(9), 663–668. <https://doi.org/10.1056/NEJMsa003376>
- Ghionzoli, N., Sciacaluga, C., Mandoli, G., Vergaro, G., Gentile, F., D'Ascenzi, F., Mondillo, S., Emdin, M., Valente, S., & Cameli, M. (2021). Cardiogenic shock and acute kidney

injury: the rule rather than the exception. *Heart Failure Reviews*, 26(3), 487–496.

<https://doi.org/10.1007/s10741-020-10034-0>

Guerrero-Miranda, C. Y., & Hall, S. A. (2020). Cardiogenic Shock in Patients with Advanced Chronic Heart Failure. *Methodist DeBakey Cardiovascular Journal*, 16(1), 22–26.

<https://doi.org/10.14797/mdcj-16-1-22>

Chen, Y.-F., Armoiry, X., Higenbottam, C., Cowley, N., Basra, R., Watson, S. I., Tarrant, C., Boyal, A., Sutton, E., Wu, C.-W., Aldridge, C. P., Gosling, A., Lilford, R., & Bion, J. (2019). Magnitude and modifiers of the weekend effect in hospital admissions: A systematic review and meta-analysis. *British Medical Journal: Open*, 9(6), e025764.

<https://doi.org/10.1136/bmjopen-2018-025764>

Dvorak, J. E., Lester, E. L. W., Maluso, P. J., Tatebe, L. C., & Bokhari, F. (2021). There Is No Weekend Effect in the Trauma Patient. *Journal of Surgical Research*, 258, 195–199.

<https://doi.org/10.1016/j.jss.2020.08.065>

Gaieski, D. F., & Mikkelsen, M. E. (2022, March 22). Definition, classification, etiology, and pathophysiology of shock in adults. *UpToDate*. <https://www.uptodate.com>

Grandhi, R., Ravindra, V. M., Ney, J. P., Zaidat, O., Taussky, P., & de Havenon, A. (2021).

Investigating the “Weekend Effect” on Outcomes of Patients Undergoing Endovascular Mechanical Thrombectomy for Ischemic Stroke. *Journal of Stroke and Cerebrovascular Diseases. The Official Journal of National Stroke Association*, 30(10), 106013.

<https://doi.org/10.1016/j.jstrokecerebrovasdis.2021.106013>

Harhash, A. A., Kennedy, K. F., Fendler, T. J., Khumri, T. M., Nassif, M. E., Magalski, A., & Sperry, B. W. (2021). Comparison of Outcomes Among Patients With Cardiogenic

- Shock Admitted on Weekends Versus Weekdays. *The American Journal of Cardiology*, 144, 20–25. <https://doi.org/10.1016/j.amjcard.2020.12.061>
- Kalra, S., Ranard, L. S., Memon, S., Rao, P., Garan, A. R., Masoumi, A., O’neill, W., Kapur, N. K., Karpaliotis, D., Fried, J. A., & Burkhoff, D. (2021). Risk Prediction in Cardiogenic Shock: Current State of Knowledge, Challenges and Opportunities. *Journal of Cardiac Failure*, 27(10), 1099–1110. <https://doi.org/10.1016/j.cardfail.2021.08.003>
- Kapur, Navin K. (2021). Cardiogenic Shock Working Group Registry. Shock 1000 Registry. IRB 018-699.
- Leatherby, R. J., Shan, M. R., & Antoniou, G. A. (2021). Editor’s Choice - Systematic Review and Meta-Analysis of the Effect of Weekend Admission on Outcomes for Ruptured Abdominal Aortic Aneurysms: A Call for an Equitable Seven Day Vascular Service. *European Journal of Vascular and Endovascular Surgery: The Official Journal of the European Society for Vascular Surgery*, 61(5), 767–778. <https://doi.org/10.1016/j.ejvs.2020.12.022>
- MacFarlane, A. (1978). Variations in number of births and perinatal mortality by day of week in England and Wales. *British Medical Journal*, 2(6153), 1670–1673. <https://doi.org/10.1136/bmj.2.6153.1670>
- Mekonnen, B., Wang, G., Rajbhandari-Thapa, J., Shi, L., Thapa, K., Zhang, Z., & Zhang, D. (2020). Weekend Effect on in-Hospital Mortality for Ischemic and Hemorrhagic Stroke in US Rural and Urban Hospitals. *Journal of Stroke and Cerebrovascular Diseases. The Official Journal of National Stroke Association*, 29(10), 105106. <https://doi.org/10.1016/j.jstrokecerebrovasdis.2020.105106>

- Naidu, S. S., Baran, D. A., Jentzer, J. C., Hollenberg, S. M., van Diepen, S., Basir, M. B., Grines, C. L., Diercks, D. B., Hall, S., Kapur, N. K., Kent, W., Rao, S. V., Samsky, M. D., Thiele, H., Truesdell, A. G., & Henry, T. D. (2022). SCAI SHOCK Stage Classification Expert Consensus Update: A Review and Incorporation of Validation Studies. *Journal of the Society for Cardiovascular Angiography & Interventions*, 1(1), 100008.
<https://doi.org/10.1016/j.jscai.2021.100008>
- Osman, M., Balla, S., Patibandla, S., Kheiri, B., Caccamo, M., Bianco, C., & Sokos, G. (2021). Regional Variation in the Adoption of Invasive Hemodynamic Monitoring for Cardiogenic Shock in the United States. *The American Journal of Cardiology*, 148, 174–175. <https://doi.org/10.1016/j.amjcard.2021.02.028>
- Patschan, D., & Müller, G. A. (2016). Acute Kidney Injury in Diabetes Mellitus. *International Journal of Nephrology*, 2016, 6232909. <https://doi.org/10.1155/2016/6232909>
- R Core Team (2022). *R: A language and environment for statistical computing* (version 4.2.1). R Foundation for Statistical Computing, Vienna, Austria. <https://www.R-project.org/>
- Sag, C. M., Zeymer, U., Ouarrak, T., Schneider, S., Montalescot, G., Huber, K., Fuernau, G., Freund, A., Feistritz, H.-J., Desch, S., Thiele, H., & Maier, L. S. (2020). Effects of ON-Hours Versus OFF-Hours Admission on Outcome in Patients With Myocardial Infarction and Cardiogenic Shock: Results From the CULPRIT-SHOCK Trial. *Circulation: Cardiovascular Interventions*, 13(9), e009562.
<https://doi.org/10.1161/CIRCINTERVENTIONS.120.009562>
- Sjoberg, D. D., & Baillie, M. (2022). *ggsurvfit: Easy and flexible time-to-event figures* (R package version 0.1.0). The Comprehensive R Archive Network. <https://CRAN.R-project.org/package=ggsurvfit>

- Smith, S. A., Yamamoto, J. M., Roberts, D. J., Tang, K. L., Ronksley, P. E., Dixon, E., Buie, W. D., & James, M. T. (2018). Weekend Surgical Care and Postoperative Mortality: A Systematic Review and Meta-Analysis of Cohort Studies. *Medical Care*, 56(2), 121–129. <https://doi.org/10.1097/MLR.0000000000000860>
- Sorita, A., Ahmed, A., Starr, S. R., Thompson, K. M., Reed, D. A., Prokop, L., Shah, N. D., Murad, M. H., & Ting, H. H. (2014). Off-hour presentation and outcomes in patients with acute myocardial infarction: Systematic review and meta-analysis. *British Medical Journal*, 348, f7393. <https://doi.org/10.1136/bmj.f7393>
- Therneau, T. M. (2022). *survival: A Package for Survival Analysis in R* (R package version 3.4-0). The Comprehensive R Archive Network. <https://CRAN.R-project.org/package=survival>
- Vallabhajosyula, S., Dunlay, S. M., Barsness, G. W., Rihal, C. S., Holmes, D. R., & Prasad, A. (2019). Hospital-Level Disparities in the Outcomes of Acute Myocardial Infarction With Cardiogenic Shock. *The American Journal of Cardiology*, 124(4), 491–498. <https://doi.org/10.1016/j.amjcard.2019.05.038>
- Walker, A. S., Mason, A., Quan, T. P., Fawcett, N. J., Watkinson, P., Llewelyn, M., Stoesser, N., Finney, J., Davies, J., Wyllie, D. H., Crook, D. W., & Peto, T. E. A. (2017). Mortality risks associated with emergency admissions during weekends and public holidays: An analysis of electronic health records. *The Lancet*, 390(10089), 62–72. [https://doi.org/10.1016/S0140-6736\(17\)30782-1](https://doi.org/10.1016/S0140-6736(17)30782-1)
- Wickham, H. (2016). *ggplot2: Elegant graphics for data analysis*. The Comprehensive R Archive Network. <https://ggplot2.tidyverse.org>

CHAPTER III.

INTERNSHIP SITE

My internship was completed at the Heart and Lung Transplant and Pulmonary Research Center, a department within the Baylor Scott and White Research Institute (BSWRI) and located at the Baylor University Medical Center (BUMC) in Dallas, Texas. This department functions to develop and carry out studies sponsored by outside groups and initiated by investigators at BUMC.

Within this department, I worked with the Heart-pod, a group of staff who work primarily with cardiologists and other researchers to complete studies relating to advanced heart failure, heart transplants, medical devices, and any other areas relating to patient treatment. BUMC is a nationally recognized transplant center performing a large volume of transplants yearly. This was the first hospital to perform a heart transplant in Texas and their physicians have continued to lead transplant research. While caring for a large population of patients experiencing heart disease and requiring advanced treatment, this site has supported many studies investigating the treatment of heart disease.

One such study is the Cardiogenic Shock Working Group (CSWG) Registry, a multisite study with the goal of collecting data from patients hospitalized for CS. As a participating site in this registry, BUMC has access to the data collected at their own site. The sample of patients identified for this registry became the basis for my own study.

JOURNAL SUMMARY

As an intern in the Heart-pod, I took on many of the roles associated with a research enrollment analyst. I participated as key personnel on clinical research studies such as the CSWG Registry, the Rare Genetic Diseases (RGD) Registry, and a study titled RNA Sequencing in Subjects with Sarcoidosis (RNASeq).

For the CSWG Registry, I assisted in data entry for the previous round of enrollment. Additionally, I have worked to assess the queries later released by our sponsor to improve the dataset. In the process of learning data entry skills, I have discovered how to use Epic, a common electronic medical record (EMR). This includes the ability to efficiently read a patient's chart and extract key details about their hospitalization in an efficient manner. I have also gained experience working with the REDCap electronic data capture (EDC) platform. This software is used in this study and many others to collaboratively collect data for clinical research studies. I have learned how to enter data, communicate with data managers through this software, and generate data reports to use in my own project and for regulatory purposes.

In addition to my data entry responsibilities, I was also trained to screen individuals for inclusion in the study. This involved reading through hospital communications to identify potential candidates, then evaluating their charts for the specific criteria required by the study. After finding evidence that I believed qualified a patient for a study, I contacted the physicians and advanced practice providers to confirm the diagnosis.

After this process was completed, candidates could be approached to gain informed consent. Initially, I shadowed other research staff as they obtained informed consent from patients to observe how they completed this process. I later attended a meeting with the research education staff to learn about BSWRI's policies surrounding informed consent. Learning how to properly obtain informed consent has allowed me to interact with patients and learn how best to approach patients about research. I have gained experience communicating complicated scientific ideas in a way that is understandable to patients with varying degrees of health literacy.

After working with the department for a few weeks, I was able to join other research staff on different studies in a supportive role. The RGD Registry was initially handled by a different department, so I assisted in the process of moving all of the paper documentation and logistics over to our department. I have also worked to create a list of patients who have agreed to be reconsented for the registry as the principal investigator (PI) has now changed since moving the study. This has involved reviewing notes from past coordinators to determine who has been contacted by phone and who has not been responsive. Unlike the CSWG Registry, informed consent for this registry can be obtained through mail, so we have prepared to send these consent documents to patients who have verbally agreed to receive them during past phone conversations. I also worked to draft a letter to send to unresponsive patients that will allow us to discern if they are truly lost to follow up or willing to be reconsented.

The RNASeq study was initially written by a PI that has since left the institution and thus enrollment was postponed. I joined the study in a supportive role with another staff member and worked to screen patients. In the process of screening, I helped to identify and resolve some issues with the protocol. I communicated with the principal investigator to clarify which medications might exclude someone from the study and to clarify the inclusion criteria surrounding pregnant

women. Additionally, I communicated with the staff medical writer to update the diagnosis requirements for sarcoidosis, the disease under study. I have assisted in identifying the first few patients to be enrolled in this study by evaluating their past radiological reports and determining if their diagnosis fits the inclusion criteria of the study. I have aided in the consent process, ensuring that the necessary blood samples are drawn in the clinic and delivering them to the Genomics Core staff for processing and analysis.

In addition to working on these research studies, I have also engaged with several educational opportunities while interning at BUMC. I have attended the weekly Heart Selection Committee meetings where multidisciplinary physicians and staff meet to discuss candidates for transplant. By listening to these discussions, I have learned about the multitude of patient characteristics that are evaluated to be considered for heart transplant. Social, financial, behavioral, and medical issues are all heavily considered before all committee members vote on whether to list a patient.

In addition to these meetings, I have attended lectures for staff and physicians on varying topics. I have learned about different medical devices in the field of cardiology such as left ventricular assist devices and extracorporeal membrane oxygenation, as well as diseases such as pulmonary hypertension and sarcoidosis. These opportunities to expand my own knowledge have allowed me to apply my previous medical knowledge in new, clinically focused ways and at times informed my understanding of the clinical studies I was working on.

My internship experience has left me with invaluable skills that I will be able to use in any future areas of medicine I may find myself in. I have gained a deeper appreciation for clinical research and the individuals that help to ensure it is done correctly. I hope to continue working in clinical research with the skill and expertise I have learned here.

APPENDIX A

DAILY JOURNAL

Daily Activities Journal

Caroline Harrison

Clinical Research Management Internship

Baylor University Medical Center

Heart and Lung Transplant and Pulmonary Research Center

Week 1

6 June 2022

Internship Activities

- Completed the set-up for my Baylor-Scott and White accounts.
- Read through the Shock 1000 study protocol, learned about how the study is run and about the REDCap database that is used. Watched the training video for REDCap to learn about how data is input. Also worked with the leading coordinator to learn about how the data entry process goes for this study and what steps I need to take next.
 - Attended a meeting where a study representative explained what steps need to be taken before the data lock at the end of June. I will try to get access to REDCap and EPIC soon so that I can participate in data entry.
- Set up access to iRIS, the website used to track studies and IRB communications.
- Requested an ID badge and building access.

Research Project Activities

- Looked through several UpToDate articles, which I will be organizing in my Zotero account.
- Some questions that may be worth looking into:
 - Does IABP improve patient outcomes? Some studies suggest it may not
 - When should an IABP be placed? Some evidence shows outcomes are improved if placed before PCI
 - Does ECMO improve outcome when used with other devices? ECMO is used because you would think it could improve organ perfusion and outcomes, but evidence shows it may not.
 - Comparison of Impella devices, when are certain versions used and why?
 - Does the cause of the cardiogenic shock impact how well a device works?
- In the future, another search term to use when researching is “centrifugal-flow devices.

- Will meet with cardiologists next week after they return from a conference. Then I should be able to generate a better research question and begin work on my project proposal presentation.

Action Items

- Obtain ID Badge
- Complete BSW training
- Get access to EPIC and REDCap

7 June 2022

Internship Activities

- Completed the BSW conflict of interest form and submitted.
- Read through a document on EPIC access and how to use EPIC for research activities. Learned how to request EPIC training which will allow me to access EPIC for data entry activities.
- Gained access to EPIC Playground, a mocked-up version of EPIC where I can practice using an EMR in preparation for data entry.
- Gained access to REDCap database, but I am not assigned to a project, so I will need to check back in on getting access to the SHOCK 1000 database.
- I should be able to go with some of the other coordinators later in the week to begin learning how informed consent is given to patients.

Action Items

- Obtain ID badge
- Get access to EPIC training

8 June 2022

Internship Activities

- Gained access to EPIC training and completed the training. The EPIC security team will be notified that I have completed training overnight so I will hopefully gain access to EPIC in the next few days.
- I now have access to the V3 Shock 1000 registry on the REDCap database, so I was able to look at the data that has already been inputted and learn about some of the analytic tools available via REDCap. Currently, most of the data has not been inputted so hopefully I can help to build this dataset soon.
- Observed two patient consents today for the Shock 1000 study.
 - There is an informed consent document that the coordinator reviews with the patient in terms they can understand. Work through the main points such as risks and payment, check that they understand what they are being asked to do.
 - The Shock 1000 study is a registry study so the consent process is simpler than studies that may involve samples being taken from a patient or a patient having to return for multiple visits.
- Obtained an ID so I can now enter doors

- There is a training process so that you can be allowed to do informed consents, so I will look into doing that soon so I can participate in consenting patients for studies. Additionally, the cardiologists will be back in town soon so I can begin working on developing my research project.

Research Project Activities

- Looked at some of the variables being recorded for the Shock 1000 trial. Because demographic information is taken, it would be possible to look at this data-set from a health-disparity perspective. Literature shows that there does appear to be a disparity in women, but maybe we could differentiate between cause of CS.

Action Items

- Get access to EPIC and be trained on data entry
- Training for informed consents

9 June 2022

Internship Activities

- Summarized the variables present in the Shock 1000 registry to make it simpler to know what data points are being collected. I also created a timeline example to try and better picture what time points have data collection associated with them.
- Observed a clinical coordinator communicating with nurses to try and have blood drawn for a study. Because the blood draws are not present in EPIC, it is a bit more challenging for staff to remember to do them as it is an extra step in their already busy day. I am curious why the blood-draws cannot be added to patient orders in epic so the phlebotomy team can see them.
- I also went to the OR floor with another coordinator and observed the signature of an informed consent. I would like to have access to more of the protocols so I can understand more of the studies being run in this department.
- Still do not have access to EPIC, possible that email with login info will come tomorrow. If the info has not arrived by Monday, will have to follow up.
- I was sent the link for a staff lecture next week that I will likely attend. Additionally, I need to find out when the transplant candidate meetings are so I can attend.

Research Project Activities

- I read a little more into ECMO and IABP devices, and have communicated with two of the cardiologists that work heavily with the research department via email. Dr. Hall has suggested that we look into outcomes based on different timepoints.
 - A possible hypothesis is that physicians and staff are more fatigued at night or on weekends, you could analyze to see if outcomes are significantly worse on the times of concern.

Action Items

- Do a literature search on hospital outcomes based on day/night or weekend/weekday.
- Gain access to EPIC
- Begin proposal planning

10 June 2022

Internship Activities

- I shadowed 2 coordinators to consent a patient for 3 different studies. Ade explained to me that they have better enrollment numbers when doctors are willing to speak with patients before the coordinators. This helps the patient feel more at ease, as they see the research as also connected to a physician they trust rather than just being introduced by a stranger from the research division they have no rapport with. The patient was willing to enroll in both studies, but it is always made clear that they can unenroll at any time.
- Hira showed me how the samples for one of her studies are packaged and shipped, explaining that deidentified studies require that the patient info not be included in the bag.
- I still have not received account information for EPIC, so I may have to follow up with the EPIC security team on Monday. I would like to be able to start data-entry on Monday or Tuesday, so this is critical.

Research Project Activities

- I have looked further into patient outcomes during “off-hours” I.e., weekend or night. Joost also wants to speak with Dr. Alam to see if there are any other ideas for analysis, but for now I will continue performing a literature search on this topic.
 - Off-hours outcomes have been studied in many other diseases, though not heavily in cardiogenic shock. Additionally, the registry data available may allow me to look at some more unique variables such as duration between events.

Week 2

13 June 2022

Internship Activities

- Today I gained access to EPIC and have been familiarizing myself with the EMR. I have been reviewing data that has already been input and then finding it in the patient chart. Finding some of the data is proving difficult and/or time consuming, but I am able to follow what data I’m looking for conceptually. I have been able to ask Ade when I really cannot find a piece of data, which has been helpful. This is what I spent most of the day doing.
- I went with Hira, a coordinator, to get a consent from a patient for a study. However, when we arrived the patient was still in pain after a procedure so we opted to leave the documents with their spouse and get the consent later, so as to preserve an ethical informed consent.
- Attended Webex meeting where medical providers discussed whether or not a patient was a good candidate for a DT VAD (destination-therapy ventricular assist device). Listened as they created a plan to mitigate risks for the patient. This conversation involved members of multiple specialties. Finances and behavior health had an input.
- I will meet with Lisa tomorrow to learn more about finding and inputting the Shock 1000 data points.

Research Project Activities

- Joost has scheduled a meeting with Dr. Hall for Thursday, where hopefully I can nail down a few more aspects of my project.
- The committee meeting has been moved back due to conflicts, so I will now have an extra day or so to work on my proposal.
- There are plans to meet with Joost on Thursday and really hammer out the details of this project.

Action Items

- Begin data entry for the Shock Study
- Complete presentation for project proposal
- Review some relevant statistical concepts

14 June 2022

Internship Activities

- I trained with Lesia on data entry this morning and began data entry. It took several hours but I completed data entry on one patient and began entry on another. It looks like for now I will be able to complete about 1 patient a day, and will hopefully continue becoming more familiar with EPIC. This is where most of my time was spent today.
- I have been invited to several other meetings this week, to discuss progress on various research projects.

Research Project Activities

- I confirmed with Joost that we will move our meeting to talk about my project details to this Friday.

Action Items

- Continue data entry

15 June 2022

Internship Activities

- I spent the entire day entering data for the Shock 1000 registry. I discussed with the other coordinators on data entry and we identified a few data points that we have never been able to find in the charts, suggesting it is either outdated or there is another way it is listed that we are not aware of. This included values such as LVEDD, it seems that LVIDD is the more commonly taken measurement. I also learned about the differences between acute mechanical circulatory devices and dischargeable devices. Neville also had a suggestion for me to check in order to find the removal times for various devices in an easier way.

Action Items

- Continue data entry

16 June 2022

Internship Activities

- I spent a majority of the day on data entry for the Shock 1000 study. I learned the difference between trans thoracic echoes and trans-esophageal echoes. I also had a question about data entry for PTT and INR. My coworkers have suggested that PTT stands for Prothrombin time however I thought it stood for Partial Thromboplastin time. I think they are likely correct, but it is confusing with similar acronyms.

Research Project Activities

- I met with Dr. Hall about my project and she had some valuable ideas. She is the PI for this study for our site, and I appreciate her more clinical perspective. I can contextualize my projects by discussing protocol development as protocols are very important for the treatment of cardiogenic shock. She also suggested I try and evaluate the discharge location of patients because discharging to a long care facility is more indicative of people with poorer outcomes.

Action Items

- Continue data entry
- Begin preparing proposal draft

17 June 2022

Internship Activities

- I spent much of the day again on data entry, I am getting a little faster. We also had a lunch with the office so I was able to get to know a few more of my coworkers.

Research Project Activities

- I met with Joost to discuss some of the specifics of my project. This weekend I will try and pin down some more of the specifics as far as statistical analyses go. He has also loaned me a biostatistics book for clinical research, it has a section on the Kaplan-Meier curve I will need to review. Currently, I will perform several analyses that are commonly performed in the literature and a few tests that are exploratory because I will likely not find anything significant.

Action Items

- Plan out methods for proposal
- Continue data entry.

Week 3

June 20 2022

Internship Activities

- Today I have been working on data entry again. We had a meeting last Friday where we checked in on the progress of the Shock data entry efforts, and my goal is to finish entering data on one patient every day. Currently I finish one patient and start another most days, so hopefully I can catch up and start and finish a chart every day. I am at a point where I am familiar with where to find most of the data points, but it is still a

time-consuming process. It also really depends on the complexity of the chart; some are rather fast visits and others have much more data associated and take longer to complete.

- There was a morning huddle meeting, they covered some tips for coordinators using translators. It is not recommended that coordinators themselves act as translators unless they have been officially trained as a translator. Apparently, this process is also time consuming, but luckily a coordinator can request translator services if needed.

Research Project Activities

- I have worked on my report a small amount today, in preparation for the project proposal meeting on Thursday. I currently have an outline that needs to be fleshed out further, which I plan to work on during the return train ride. The draft is due on July 1, so I still have some time to complete these ideas and incorporate notes given during the Thursday meeting.

Action Items

- Data entry
- Proposal draft

21 June 2022

Internship Activities

- I have been working through data entry for the Shock Registry. We found out today that my name is not on all of the documentation it needs to be, especially if I would like to be involved in consenting patients. I spoke with Ade about getting my name on the “Delegation of Authority” form, but this issue is complicated by the fact that the documentation has not yet been altered to show Dr. Hall as the PI. This cannot get fixed until the sponsor organization gets back Ade with a different form. This very much reminds me of Franz Kafka’s *The Castle*. With luck, I should be able to get my name on the paperwork and maybe consent one or two patients. Neville thinks I have observed enough consents to do it myself, and I think I fully understand the process.

Research Project Activities

- I have drafted the methods for my proposal and also begun communicating with the UNTHSC library about a literature search relating to my project. I have never used this service before, but I am interested to see if they could help me. My initial project proposal meeting is on Thursday, so I think I’d like to finish making some slides today, practice them today or tomorrow, then be ready by Thursday. I have spoken with Joost about having a slide for the study site, to give Dr. Berg and Dr. Ortega some context surrounding this project.

Action Items

- Shock data entry
- Slides for project proposal meeting

22 June 2022

Internship Activities

- I completed further data entry on the Shock 1000 registry. We are working towards finishing the data entry on this study, and we learned that there will actually be an extension on the data lock for this study. This has alleviated some of the pressure, but I will continue entering data in the time being. I also attended a staff elcture about lung transplants and the types of rejection that can occur. I learned that most lung transplants are really only expected to last a finite amount of time, maybe 10 years or so. I am interested in knowing why donor tissue would not live to the life expectancy of the individual, perhaps it has to do with the period of time if was not in a body.

Research Project Activities

- I finalized the slide deck for my proposal presentation tomorrow. I will rehearse this presentation a bit tonight and make sure I can answer.

Action Items

- Prepare presentation for tomorrow

23 June 2022

Internship Activities

- In the morning, I was able to virtually attend the heart transplant committee meeting. In this session, one patient was actually not placed on the list, on the basis of several observations. The patient was not compliant with medications in the past, and committee members felt the patient would not do well with the daily medicine requirements of heart transplant. Additionally, the patient did not have sufficient social support, and the committee members did not feel confident the patient would have the help necessary after a transplant. I am curious if Medicare will pay for home-health support, and if having this would sway the committee. Additionally, if a person had enough money to hire a home-health nurse, would that influence their place on the heart-transplant list? If the ability to hire help is a significant indicator for transplant, this could leave a possible opportunity for inequity, which would be interesting to look into. Found an article from Park et al, 2022 describing organ transplant in the United States.
- I continued data entry for Shock 1000, but this entry is proving complicated because the patient was placed on several devices. Each device requires additional data entry, and I am learning that these data points are located in different places in the EMR.

Research Project Activities

- The research project proposal meeting went really well. I need to develop some analyses to try and address possible confounds, which should be fairly straightforward to incorporate. Overall, the committee was receptive to the general idea of the project and just had questions to further improve the project design and better answer this question. I will continue to work on the report draft and incorporate these improvements.

Action Items

- Complete project proposal draft by July 1

- Shock data entry

24 June 2022

Internship Activities

- I have confirmed that I am on the proper documentation to give informed consents to patients, and I gave one to a patient for the Shock study today. It went well, but I felt a little unprepared and may want to rehearse a little before next time. Neville observed to make sure I hit everything. Unfortunately, I had 2 copies of the consent, one in black-and-white, the other in color, and I swapped one of the pages out. Ultimately, this has no real impact on the content of the consent; the information on the pages was verified to be identical and I documented this error, but in future I will be more careful not to make mistakes. After giving a consent, a consent processing note must be made and there is also a binder where a different researcher has to verify that you filed the paperwork correctly. I am not able to access media on EPIC, so Neville will have to upload the documents. I also was able to find my way around the hospital myself today, which also felt like an accomplishment.
- I completed another entry for the Shock 1000 registry. The patient stay I entered data for was really complex and involved placement of several devices, so this took me longer than I'd hoped, but I completed it today.

Research Project Activities

- I have begun expanding my collection of relevant literature, but I need to come up with a way to decide which papers should be included. There are too many studies to reference them all, so I will likely need to look at the systematic reviews and the journals I pulled them from.

Action Items

- Review informed consent process
- Work on research proposal draft

Week 4

27 June 2022

Internship Activities

- Visited aphaeresis lab with Tyler, some of the nurses showed me the apheresis machine and how it works, mentioned a UV active drug that plays a role in rejection therapy, will need to follow up on this topic. We also needed some signatures from an individual getting an antibody infusion to treat lung fibrosis. I don't know as much about lung fibrosis causes, but would be interesting to get into more lung topics as my project settles down.
- Went back to cath lab with Hira to drop off blood tubes. Samples are meant to be taken during biopsy.
- Continued data entry, We are down to 12 missing data entries now, and 2 cannot be entered until a patient is discharged, so we are on track. I finished another entry today and started another.

Research Project Activities

- This morning I worked some on the background portion of my report, I need to parse out some of these ideas into a deeper discussion. I think that I could look at some of the possible confounds that have been studied as one direction. I would also like to look at the type of analyses that have been run, would be relevant for the project. I also need to find more literature relating to protocols as a way to improve shock treatment.

Action Items

- Shock data entry
- Project proposal draft

28 June 2022

Internship Activities

- This morning, I attended the research updates meeting from home as it began at 7am. At this meeting, updates from various research projects were discussed and updates given. I learned a little more about the financial side of clinical research; Dr. Hall requested enrollment not be expanded on certain studies as it would no longer be financially reasonable for the department. I was also recognized at the meeting as new research staff. A physical therapist gave her proposal for a research project investigating the benefits of PT in the ICU for patients with cardiogenic shock, which seems like a really novel topic based on the literature I have read. The physicians present gave some feedback to develop the protocol for her proposal.
- I worked through more data entry for the Shock 1000 Registry. I've been able to complete about 1 chart a day, so the backlog is nearly finished. I am optimistic that by the end of next week I will at least have backlogged data complete, and then can move to the recently enrolled patients.

Research Project Activities

- Most of the sections of my draft are going well, but I am struggling to sort through the literature available to write a background section. I am having no issues finding articles, but I feel that I have not been extremely purposeful in selecting articles and may need to step back to reorganize my ideas. The other sections have not given me as much trouble.

Action Items

- Research proposal draft
- Shock data entry

29 June 2022

Internship Activities

- I completed one chart for Shock 1000 data entry today, but will spend the rest of my time on my proposal draft today.

Research Project Activities

- In order to have a complete draft ready for viewing tomorrow, I need to clean up the background section of my draft and also update the summary section. To refine the ideas in my background, I ordered the most relevant literature based on journal quality and type of analysis, giving precedence to literature published in the last three years in high impact journals, especially focusing on systematic reviews and meta-analyses. I think this has greatly improved this section and the evidence for each section is of a much higher quality. I will be able to send in a draft of this proposal tomorrow morning for the cardiologists to look at, before sending in an updated draft on Friday to the committee.

Action Items

- Shock data entry
- Finish up proposal draft

30 June 2022

Internship Activities

- Attended an informed-consent with Tyler. The patient was interested in the study and was willing to sign, but because of limb weakness did not want to finish the document by writing the date. It was still possible to get a legitimate consent, the patient was being seen the next day to get some further information about the study so the date will be obtained then.
- CAH2686 Continued work on Shock data entry, I was able to complete 2 charts today. However, I realized I had been using lab values for pro-BNP as a BNP value in the data entry, so I had to go back into all of the charts I've already finished to make sure this mistake was not present in the past data I had entered. I found the mistake in a few different charts but have since corrected this issue.

Research Project Activities

- I sent my draft out to Dr. Alam and Dr. Hall, who both responded with some suggestions for additional tests that could be performed on the data. Dr. Hall thinks it would be prudent to also look at durations from admission, though I am wondering if this comparison will give us useful information about shock treatment if some patients came in without shocks cardiogenic shock and developed it while being treated. I also need to add in some definitions for
- I will need to update the placeholder definitions of on- and off-hours when I hear back from Dr. Hall and Dr. Alam about what times would be best for BUMC.

Action Items

- Incorporate edits
- Shock 1000 data entry

1 July 2022

Internship Activities

- I had a difficult time entering data on one of the charts today as the patient had been transferred in from an outside facility. Luckily, Neville was able to show me how to access the pdf of information sent with the patient when they were admitted, so I was

able to get more information about when they were diagnosed with cardiogenic shock. Otherwise, I would have listed this data as missing, so this was a great new tool to learn about.

Research Project Activities

- I spent the morning working on incorporating new edits into my research proposal draft. I updated with the new analyses being added to my project based on Dr. Hall and Dr. Alam's suggestions, as well altering my background to be a bit more concise. I am also adding IRB information per Joost's suggestions and double checking my references to make sure they are correct. I sent the draft to the committee this afternoon. Timeline-wise, I need to file the proposal with the graduate department by the 18th, so hopefully I can hear back about edits late next week or early the following week, giving me enough time to edit the document.

Action Items

- Shock 1000 data entry

Week 5

5 July 2022

Internship Activities

- Attended a VAD meeting which was scheduled suddenly as two patients seemed to emergently require a device. Though behavioral health was not as confident in one of the patients, the committee elected to still approve for VAD in hopes that the patient will still succeed. It is nice that despite weighing all of the cons of this patient, the physicians are still willing to give a patient a chance, though one hopes that the patient will be able to keep up with the device.
- I was able to complete the second to last backlogged chart for the Shock 1000 registry and begin the final backlogged chart. At the end of the day, I also went through and checked on the discharge dates for the more recently consented patients and verified which patients we can begin data entry for.

Research Project Activities

- I am waiting to hear back from the members of my thesis committee about the draft I sent last week, but will continue to review myself for the time being.

Action Items

- Shock data entry
- Research proposal editing

6 July 2022

Internship Activities

- Attended a meeting where upcoming and current research projects were discussed with Dr. Hall. Enrollment is one of the main ways an ongoing project is evaluated, and the question of enlarging enrollment goals came up again. It seems some studies allow the organization to make some money, however, one of the projects is grant-

funded which means the available funds should be spent. Any grant funds not used would be sent back.

- I completed the last chart for shock that was backlogged from previous months, so now I have moved to inputting data from patients enrolled in the last month. There are currently only 5 charts left,

Research Project Activities

- I am working to obtain the necessary documentation for IRB approval at the UNTHSC. I have emailed Dr. Mathews and will hopefully hear back soon.

Action Items

- Shock data entry
- Editing proposal

7 July 2022

Internship Activities

- Attended heart transplant committee meeting. There was a patient who mostly seemed like a good candidate for transplant but had a recent nicotine test that showed a low level of nicotine in his system. It was not clear if the test results suggested he was actually still smoking or just exposed to second-hand smoke. Interestingly, this patient also has a pet raccoon, which was shared with the committee as it was a possibility that the raccoon could carry some diseases that would jeopardize the implant. It was decided that because the animal had seen a vet and was an indoor pet, it was not likely that it posed any risks to the patient's future health.
- Attended lecture about medications given after heart transplant. I've seen some of these medications in charts while entering data, so it was interesting to hear more about them. These medications are immunosuppressive and function by modifying T-cell function or inflammation cascades. Dr. Patel also noted that not all hospitals use the same treatment regimens, so I am curious how a medical center decides what standard regimens they will adapt. Additionally, lecturer noted that there is a serious interaction between Paxlovid (recent COVID treatment) and transplant drugs, leading to nephrotoxic symptoms.
- I continued working on Shock data entry, completing part of a recently consented patient. This chart is taking longer than others as the patient's stay was very complex.
- Visited processing lab with Tyler and observed how he centrifuges and divides out aliquots of serum before mailing off to the research lab. Not all studies require this kind of processing for blood samples; for example, Neville's study only requires blood sent at ambient temperatures. Processing will depend on what exactly the study is hoping to analyze in the sample; ex. DNA is more stable than other molecules.

Research Project Activities

- I have heard back from Dr. Mathews about the required IRB documentation, so I will need to begin collecting IRB letters. It is also not clear if documentation will be required for both the CSWGR and the Umbrella Heart protocols. I believe I will need IRB approval from the UNTHSC for both as I am using my status as a key personnel member on both to complete my project.

Action Items

- Collect IRB documentation
- Shock data entry

8 July 2022

Internship Activities

- Today I did another informed consent, which went a little smoother than last time. The patient was attentive, but did not recall speaking with a doctor about any research studies. Despite this, the patient was still open to hearing about the study and I was able to go through the entire informed consent document. The patient did not have any questions and was open to signing. I made sure that my paperwork was not mixed up this time, and also learned how to scan all of these documents. I still do not have uploading capabilities in EPIC, but I am now able to send the informed consent documents to Neville who can upload them.
- We had a meeting about the progress of Shock which went well. We are totally caught up on the backlog and are just finishing data entry for recent patents. The data lock is occurring on the 18th so there is about a week left to complete this.
- I finished one chart for Shock data entry and began another, but this hospital stay was also fairly complex. I should be able to have everything finished by the deadline, and I also want to check over the entries I finished to be sure I have values entered for everything and don't have missing data points on my early entries that I now know how to find.

Research Project Activities

- I confirmed that Dr. Berg received my draft, but did not hear back from Dr. Ortega. I have not heard back from Dr. Mathews about further IRB topics. I have emailed Eva Patel to obtain IRB documentation.

Action Items

- Shock data entry
- Collect IRB documentation

Week 6

11 July 2022

Internship Activities

- We had a huddle meeting in the morning where we discussed enrollment in the department's various projects and other logistic information.
- I finished my last chart for data entry and began the process of rechecking the data I have already entered. I was able to fill in a few gaps on the first few charts I completed, using the new skills I have acquired during this project. I created a spreadsheet to track my progress and confirm I had checked that all data was input for my designated charts. By the end of the day, I had a few charts left to confirm as finished.

Research Project Activities

- I received edits from Dr. Berg, but will likely address them tomorrow in favor of completing the shock data entry.

Action Items

- Finish data entry
- Edit project proposal

12 July 2022

Internship Activities

- I completed checking over my section of shock data entry, confirming that all data was entered and no blanks were accidentally left.

Research Project Activities

- I was able to download the data from the V3 database and look more closely at the V2 and V3 datasets. I performed a preliminary sorting of the subjects into on and off hours, finding that there is a decently even spread of data. I also worked with R to relearn how to download packages, finding a package for power analyses. I performed a power analysis based on the new information I had gathered about my sample and began adding this to my proposal draft.

Action Items

- Complete proposal draft

13 July 2022

Internship Activities

- Today Ade noted that when viewing a data report for RedCap, it still shows that some data was not entered, despite all pages being marked as “unverified,” the designation for a completed record. In order to locate the incomplete records, I clicked through every form in the RedCap database, flagging the records that were missing data on our main spreadsheet. I found that some entries were only missing one or two small data points while a few were missing all of the individual time-point data. The time-point data can be time consuming to enter, so I am a little concerned about meeting the data-lock which is on Monday. Neville has agreed to try and complete a few charts tomorrow to help meet the deadline
- I attended a staff lecture about ECMO. The presenter described the different ways ECMO can be utilized and the improvements that are being made in the field. Currently it is still being investigated whether or not the reduced breathing rate patients on ECMO experience is deleterious for lung tissue. I am also curious if VA ECMO (which must be used when patients have heart problems) can be used in patients with healthy functional hearts.

Research Project Activities

- I made some final edits on my draft this morning and sent it to Dr. Alam and Dr. Hall again, to see if they have any final comments. I also received a few comments from Dr. Ortega. I also sent a copy to Johanna, the biostatistician for BUMC.

Action Items

- Complete data entry for Shock

14 July 2022

Internship Activities

- I attended the heart transplant committee meeting in person this morning. Though there were concerns it might be crowded, I was able to sit along the wall and take a few notes on the meeting for one of the research nurses. Compared to calling in virtually, it was much easier to keep track of which patient was being discussed as they projected the patient charts during the meeting. There were concerns for one patient as they seemed to have difficulties learning about how to take medication regimens and how to handle the medical equipment. However, Dr. Hall felt that if they could meet the patient at their level, they would be able to accurately communicate with the patient about how to maintain their care.
- I continued entering data for shock. We found today that the time-point portion of the form does not get activated until earlier timepoints for other events are recorded. With this in mind, it turns out that records I thought had only a few missing pieces of data were also missing the time-point data. There is now even more data missing than I realized, so Neville and I made a large effort to complete a large amount of data entry. We should be able to complete all data entry by the end of day Friday.
- I attended a lecture given by one of the cardiologists aimed at informing fellows and other physicians on systolic heart failure and the pathophysiology of this disease. I was able to answer some of the multiple-choice questions about cardiophysiology posed during this presentation.

Research Project Activities

- I heard back from Johanna, but will address her notes after the data entry is complete.

Action Items

- Complete Shock entry

15 July 2022

Internship Activities

- This morning we received another email extending the data lock deadline for Shock. It now does not have to be completed until August 1. I spent the day checking the entire database for missing data again, with plans to complete the missing entries next week. There are still 4 records missing data, but there is now more than enough time to finish entry.

Research Project Activities

- I will work on my proposal draft over the weekend and send out an updated copy on Monday. It will need to be filed by Friday.

Action Items

- Finish draft

- Finish shock entry

Week 7

18 July 2022

Internship Activities

- Completed data entry for the last two flagged Shock records, so as far as I know, Shock entry is officially finished. Ade will verify that all data has been entered soon, but the data lock is not until August 1st so it is not as pressing.

Research Project Activities

- I sent another draft of my project proposal to my committee for some final notes. This will need to be filed by the end of the week, meaning I will be finished with the proposal portion soon.

Action Items

- Finish proposal draft
- Begin organizing shock data

18 July 2022

Internship Activities

- I attended a VAD meeting where physicians discussed a novel procedure they hoped to perform. The procedure has been done at other hospitals but not at BUMC. The patient already had a VAD in place, however they wanted to perform a percutaneous coronary procedure. The patient seemed stable enough that they all agreed to perform the procedure.
- I spoke with Joost about starting a new study at the office and he recommended I get my data collection organized and we may speak with Shelby next week about a new project.

Research Project Activities

- I am working with Johanna, one of the BUMC biostatisticians, to check that my plans for setting up a data collection excel document is sound. I will take today to organize data, identify what variables I need to pull from the V2 and V3 subjects, then send her my document.

Action Items

- Organize shock data sheets

20 July 2022

Internship Activities

- Attended a lecture given by physicians at BSW Plano. They outlined some of the new technology being developed in addition to a new strategy for approving new devices. They are able to use devices while working directly with the design team so that small changes can be made after each initial test run.

Research Project Activities

- I spent the day identifying the columns of data I need from the larger data sheet available to me. I have made sure that when moving columns and combining data, the order of subjects is the same and data is not getting mixed among subjects. I occasionally do random checks along my subjects to ensure data has been moved properly. I have one large sheet containing data from both V2 and V3, and I've created a separate data entry table for V2 and V3 as I'll need to pull slightly different variables from each one.

Action Items

- Data entry for thesis

21 July 2022

Internship Activities

- The heart transplant committee meeting was cancelled for today
- I attended a lecture about VAD alarms and maintenance. They explained how to check a VAD when visiting a patient, how different VAD devices will impact blood pressure, and what values are used to evaluate VAD function.
- I attended a meeting for the heart pod where we made sure we were prepared for next week's research meeting. We reviewed which studies are active and what topics needed to be discussed at the meeting.

Research Project Activities

- I finished setting up my data collection spreadsheet and also learned how to use the data entry functions on Excel. This allows each row to be displayed as a single form, to prevent me from entering data on the wrong row. I have my subject information in a separate sheet so as to maintain data security.
- The paperwork for my proposal was officially filed, so now I need to file an intent to graduate. I also scheduled my thesis presentation for November 3.

Action Items

- Thesis project data entry

22 July 2022

Research Project Activities

- I worked on entering data for my project. I am finding that locating the referring physician is a difficult task, and I will need to decide if I will include patients in the analyses that were transferred in from outside hospitals. If a patient was diagnosed at an outside hospital and arrives to BUMC for further treatment, then this could falsely decrease the amount of time between diagnosis and advanced treatment at BUMC, versus patients who were diagnosed with cardiogenic shock at BUMC. It may be worth running the analysis on the entire data set and then also analyzing only non-transferred patients.
- I am making note of any rules I am making for data entry, such as blood pressure measurements occurring within 3 hours of the 24-hour timepoint.

- I am struggling to enter data for patients admitted prior to September 1, 2019, as this is the date when the EPIC EMR was implemented. For these patients, data is straddled between EPIC and a historical data viewer. The historical data viewer is less organized

Action Items

- Thesis project data entry

Week 8

25 July 2022

Internship Activities

- We received information about the CSWGR and the next iteration of the database. They will open up a placeholder for the V4 database in the first week of August. I will attend a training course on August 1st so that I can get access to the placeholder database.
- I received a patient list from Ade that I screened for the registry. I verified that they fit the study criteria and also confirmed that they were diagnosed with cardiogenic shock by emailing the cardiology team members. One of the patients has already been discharged but will be in the clinic on Friday, so I will reach out the NP scheduled to see him and plan to consent him after he speaks with a doctor on Friday.
- I am also working to complete the prospective data entries for V2 and V3. For the patients that were consented for follow up, I am accessing their charts to find any 30 day and 1 year follow up information, then recording this in the database.

Research Project Activities

- I am continuing to collect data for my thesis project. I have heard back from Johanna and will make some changes to my data collection excel as recommended, specifically combining the V2 and V3 data collection columns. If I want to complete data entry by the end of August, I need to complete entries for at least 6 patients a day. This is a reasonable amount, some days I have been able to complete more than this amount already.

Action Items

- Look for emails where doctors have approached screened patients
- Data collection for thesis

26 July 2022

Internship Activities

- This morning was the Heart Research Committee meeting. We heard about what studies are ongoing and several new studies were presented. There is another Shock registry that the department may join, as well as some investigator-initiated trials from some of the cardiologists.
- I went with Neville to consent one of the screened patients after receiving an email from Dr. Gong stating they were amenable. The patient and family members asked several questions about the study and we had a conversation about what this research

is about and what kind of data is collected. We also went and spoke to another patient Dr. Gong recommended and we covered the informed consent document with him. He preferred to sit with the information for another day so we agreed to return tomorrow.

- We also went and spoke to a patient that Dr. Gong had consulted on, but was not being seen by any cardiologists anymore. The patient had not heard about the study from any doctors so it was more difficult to begin the conversation. Ultimately this patient was not amenable to joining the study so we left the consent document and a phone number to call in the event the patient changed their mind.
- I scheduled a meeting with Michelle Acker, a member of the education office who will meet with me on Thursday to allow me to do a mock consent. Completing this training will allow me to consent patients independently.

Research Project Activities

- I was only able to complete 4 entries today but will hopefully be able to complete more later in the week.

Action Items

- Thesis data entry
- Shock prospective data entry

27 July 2022

Internship Activities

- Today I needed to leave early for an appointment, so I completed some more of the prospective data entries for Shock in the morning and completed 6 thesis data entries before leaving.

Research Project Activities

- I completed 6 entries today, so I met the goal.

Action Items

- Thesis data entry
- Shock prospective data entry

28 July 2022

Internship Activities

- I attended the Heart Transplant Committee meeting in the morning. Members of the kidney transplant team attended for the first patient, who would need a kidney transplant prior to receiving a heart transplant. Consequently, the patient was not listed for transplant. The physicians updated patients who had previously been listed, discussing if they were still compliant and doing well. One patient was discussed for a non-transplant procedure a physician wanted input on, however another doctor then wanted to initiate the process of transplant screening despite the initial doctor not wanting to. The committee decided to vote on whether the process would be initiated at all, which was not an event I had seen before.

- I completed my mock interview and have been checked off by education to complete informed consents on my own.
- I went to see one of the patients I previously visited and spoke with about the study. Though he was amenable when we last spoke, he expressed today that he no longer wanted to participate. I confirmed that he still had the proper contact information if he changes his mind.
- I attended a lecture given by Dr Hall about cardiogenic shock and how to identify it. She explained that lactate levels tend to correlate with shock severity so I may consider incorporating this into my project.

Research Project Activities

- I completed 10 entries today, which has me caught up for a daily average of 6. According to the tracker I have on the sheet, I am a quarter through data entry, but will also need to do some work to clean my “destination after discharge column”. I need to email Dr. Alam and Dr. Hall again to ask about how the destinations should be sorted.

Action Items

- Thesis data entry
- Shock prospective data entry

29 July 2022

Internship Activities

- Ade has asked that I complete the follow up phone call for a patient in the V3 registry. She did not respond today so I will call on Monday to try and obtain the follow up data.
- I met with a patient in clinic and consented them for the registry. Rosemary came with me to see the consent process. It was a really positive experience and I also gained experience using an LAR as the patient was physically unable to sign. I also met Dr. Guererro who spoke with the patient about the study.

Research Project Activities

- I completed 7 data entries today, so I reached my goal.
- I met with Joost to discuss my data entry sheet and spreadsheets I am using. We also discussed some ideas I’ve had about excluding some groups from certain analyses. Patients transferred from outside hospitals who were already diagnosed with shock will likely not be included in many of the exploratory analyses.

Action Items

- Complete thesis data entry
- Shock prospective data entry
- Follow up call

Week 9

1 August 2022

Internship Activities

- We had a huddle meeting in the morning where we discussed new enrollments and updates in the office.
- I screened patients from the Heart Checkout email list for shock, searching for potential subjects diagnosed with shock. I sent a list of patients to be screened to the physicians and made note of who was confirmed to have shock.
- I completed all of the V2 prospective data entry, so that database is now complete.
- I called a patient from the V3 database for the one year follow up, but they did not answer.

Research Project Activities

- I emailed Dr. Hall and Dr. Alam to get more feedback on my project ideas, and Dr. Alam came by my desk to further discuss the “physician specialty” data point. It seems that depending on where a patient is first seen, they may be admitted from the cath lab or from the clinic, though I am still not sure what noting the specialty of the provider will tell us. The column is almost entirely cardiology so far, so it doesn’t appear that there would be changes between off and on hours.
- I continued data collection for my project.

Action Items

- Data entry
- Shock screening

2 August 2022

Internship Activities

- I attended a training call today about the new shock registry which I will have access to later this week. This isn’t a complete database, however, it will allow us to enter some preliminary data about patients we have already consented.
- I need to talk to Ade when she returns next week to check if I should begin entering subjects in the new database. We are up to 7 subjects right now, and I will continue to screen.
- I went and consented a new patient for Shock. It was a good conversation and the patient seemed engaged in the discussion. I answered some questions about what cardiogenic shock is and the patient was very willing to sign. I also stopped by an ICU patient to try and consent, but they were in the middle of being moved so I opted to return the next day.
- Shelby contacted me requesting a meeting for Monday where I will learn about a new study the department is taking on. Kiersten will also be on this project as well as a new coordinator. The project is related to rare genetic diseases, which will be a new subject and probably exciting.
- The follow up patient from Monday called me back and I was able to record one month data. It was a very pleasant conversation and I gained experience gauging NYHA levels.

Research Project Activities

- I continued with data entry for my project, I am ahead of schedule and will definitely finish before the end of August. I may need to make a second pass if any of my data points are adjusted, however, so this is probably for the best.

Action Items

- Thesis data entry
- Shock Screening

3 August 2022

Internship Activities

- I returned to one of the patients today and gained experience using the translation device because the subject was Spanish speaking only. The conversation progressed a little slower than it normally would as I communicated sentence by sentence, but they were able to reply with questions. I left the informed consent document in English and Spanish as they had an English-speaking son who would arrive later on, and I told them I would return the next day.
- I attended a staff lecture on chronic cough that covered some interesting alternative treatments for chronic cough when the underlying lung disease has already been treated. Similar to chronic pain, it seems that the reflexive nerves associated with coughing can become over-sensitized during a long-lasting lung illness, causing a person to continue coughing after the disease is gone. There are some speech therapy and physical therapy options that allow patients to finally end this cycle.

Research Project Activities

- I continued data entry for my project, I think I will be 50% done by the end of the week. Data entry will likely get smoother as I progress. Once I reach the V3 patients, I won't have to locate the shock diagnosis time anymore which will save me time.
- I am noticing that some subject charts have no diagnosis or mention of cardiogenic shock anywhere in their charts. I have spoken with Shelby and will give a list of patients to Ade when she returns. It seems that they probably should not have been included in the study at all, and I will exclude them from my data. I am wondering if I can fill in any subjects I lose with V4 subjects, but I will first see how large of an issue this is.

Action Items

- Thesis data entry
- Shock screening

4 August 2022

Internship Activities

- I visited the same patient again today to finish the consent if they were amenable. However, when I arrived, they had already filled out the paperwork while I was gone on an English copy. I knew this would not work as the copy is in English and the subject only speaks Spanish, so I tried to explain to the patient that I appreciate them talking about the paperwork with their son and signing, but it would not be a viable

consent unless I was there. I tried to see if the patient would sign, but his wife did not want him to as she felt he was too ill. There was also some confusion with the translator, it seemed that the patient was briefly willing to sign, but again his spouse did not want him to be bothered. As the wife seemed frustrated with the situation, I opted to leave my phone number and requested she call if he was feeling strong later on.

Research Project Activities

- I completed further data entry for my project. I found another subject with no cardiogenic shock diagnosis.

Action Items

- Thesis data entry
- Shock screening and consent

5 August 2022

Internship Activities

- I changed the status of all V2 patients in IRIS to “complete” as they have finished the study, however, I need to check with Ade to find out if I need to also check if each patient is deceased as I did not note this when I completed the prospective entries.
- I confirmed that my VPN functions in the event I need to complete data entry from home.

Research Project Activities

- I completed a large number of data entries today and I am officially halfway done with this pass on the data. I need to remember to use the admission times recorded on this excel document as I have altered a few admission times. Whoever recorded data sometimes excluded admission to BHVH, but when I completed data entry with Ade and Lesia we included BHVH admissions. This way the data will be as consistent as possible.

Action Items

- Shock data entry
- Shock screening

Week 10

8 August 2022

Internship Activities

- I met with Kiersten and Shelby this morning to discuss a new project our department is taking on. It is a rare genetic disease registry that has been running since 2009, but has recently changed primary investigators. We met with the previous coordinator and research nurse to learn how the study has been organized in the past and visited their office to see how many binders will need to be moved. There is an upcoming monitoring visit where we can learn more about the electronic case report forms where data is collected. In the meantime, I will need to update the spreadsheets being

used to track patients and likely create a better tracking document that explains when data can be taken.

Research Project Activities

- I continued with data entry today. As I near the end of the V2 registry data, I am finding more patients with no mention of a shock diagnosis in their charts. I am hoping there will be fewer than 10 lost data points and may have to consider collecting data from V4 patients if I lose too many more.

Action Items

- Project data entry
- Shock enrollment
- RGD registry organization

9 August 2022

Internship Activities

- I worked on identifying the patients who have already been contacted recently for the RGDR. Some patients have been contacted five times with no response, so we may not contact these patients again. The primary investigator does want us to attempt to contact again, so we may try emailing instead. Will reach out to regulatory to see if this would be acceptable.
- I screened for shock patients from the physician emails again. I identified a few new patients to potentially consent for the shock study and will reach out to confirm the diagnosis with the physicians.

Research Project Activities

- I continued to enter data for my project, noted a few more patients I will have to exclude due to not having a shock diagnosis. I also found an entry where the MRN was swapped at some point. The patient listed in iRIS under this subject number does not match the MRN number I was given. The data listed in the RedCap matches the MRN number, but not the iRIS patient. Also, the patient who had data collected was not eligible for the study in the first place and was not consented to prospective follow-up. However, follow-up data was taken, so I showed Ade what I had found and she may email the sponsor.

Action Items

- Data entry for thesis project
- Organize subjects for RGDR
- Shock enrollment

10 August 2022

Internship Activities

- I went through a few more patients for the RGDR. I am organizing patients based on whether they have recently been contacted and agreed to re-consent for the study.

- One of the patients I was screening for enrollment in the cardiogenic shock study passed away, so I will list as retrospective. This had surprised me as the patient seemed to be improving based on emails from physicians, but shock is very dangerous and hard to recover completely from.

Research Project Activities

- I met with Joost today to discuss several points about my project. I will email Dr. Alam to revisit the data point he suggested about recording the specialty of the referring physician, possibly switching to address whether an admission was planned or unplanned. I will also contact Dr Hall again to further discuss how patients are discharged and what different locations suggest about patient stability.
- I worked on more data entry for my project, I am over 60% finished now.

Action Items

- Shock enrollment
- RDGR subject organization

11 August 2022

Internship Activities

- I attended the Heart selection committee meeting virtually. They did not mention any patients I thought would be good for potential shock enrollment, but they did go over a few interesting cases. One patient was delisted for a brief alcohol use relapse, but the doctors planned to revisit for possible relisting in 2 months. It seems that they want to keep them off the list during a period where the transplant would be more harmful to this patient, that way they could not match and wouldn't have to decide between accepting a transplant and re-stabilizing their life. The physicians also seem extremely willing to work with the patient to relist them, and there were many providers advocating for this patient.
- I attended the next Shock lecture given by Dr. Hall. She gave an overview of the various Impella devices and other devices used to treat shock. She also further discussed treatment plans for shock and how hospitals should organize to treat these patients. I now understand when the CVICU is used and why so many patients are transplanted to this center. Dr. Hall also emphasized the necessity of having an exit strategy for patients, explaining that we should not initiate treatment for patients that are not likely to recover.
- I spoke with Shelby about joining a new study to help with patient screening. I will need to meet with the pulmonologists on Monday to discuss what kind of patients we are looking for because we will need 8 pulmonary patients and 8 cardiology patients to study this disease. There are also some issues in the protocol that

Research Project Activities

- I continued entering data, I was able to completely finish the V2 data and move on to V3. Of the V3 patients I've seen so far, there are far fewer problems with the data.
- I heard back from Dr. Alam about one of my questions, but not the other, may follow up next week.

Action Items

- Thesis project data entry
- RGDR subject organization
- Read RNAseq protocol

12 August 2022

Internship Activities

- We had a false alarm fire evacuation.
- I went with Shelby to begin moving documents from the rare genetic disease registry to our office. We located the original informed consents which will be useful to create a master list of patients involved in these studies.
- I spoke with Shelby about the RNAseq protocol as I had a few questions.
- I met with a patient to get informed consent for the Shock registry. The patient was very pleasant and willing to join the study. Now there are 10 enrollees for the shock registry, and I may be able to get another next week.

Research Project Activities

- I worked with the IT department to download R-studio and R. I created a fake data set to begin practicing how to use R again, and I was able to run a few statistical tests. My next step will be to create another fake data set that looks more like the data I will actually analyze, that way I can practice how to create graphics in R and construct the Kaplan-Meier curve, which will be new to me.
- I completed further data entry for my project, I am now 75% finished with data entry.

Action Items

- Complete data entry
- RGDR organization
- RNAseq presentation prep

Week 11

15 August 2022

Internship Activities

- Today I presented the RNASeq project to the pulmonologists in order to communicate about the enrollment criteria of the study. Dr. Mallard sent me a possible candidate after the presentation; however, this raised more questions about enrollment for this study. The patient had not been treated for sarcoidosis but was diagnosed 20 years ago. The record of her diagnosis was not available electronically, but the physician explained that he had called the patient and confirmed she had had a bronchoscopy in the past. I noted these points down to raise with Hira the next day.
- Spoke with Ade about the shock study, and she explained that I should hold a list of retrospective candidates rather than give them subject numbers. I have now adjusted the tracking sheet to include a retrospective candidate list I will update separately from the consented list.

- I identified a patient for the Shock study who I will continue to monitor. They are currently too critically ill to consent.
- I received an email about addressing queries in the Shock registry. I need to view a video to complete training and be permitted to address queries.

Research Project Activities

- I worked on data entry for my project, I am scheduled to finish the first pass over the data by the end of the week.

Action Items

- Data entry for thesis project
- Shock enrollment
- Shock query training

16 August 2022

Internship Activities

- I spoke with Hira about the RNASeq project as well as Dr. Bindra. Dr. Bindra suggested we consider enrolling patients without obtaining records for the histopathological report, but after meeting with Joost it seems this will likely be necessary. There was also some confusion as to what kind of drug regimens exclude patients from enrollment and whether those criteria should be used. I sent an email to Dr. Bindra as the PI, as well as Dr. Gottlieb and Dr. Mathai as sub-Is, to communicate with the RNA genome core manager. Hopefully, we can gain enough clarity to move forward with enrollment soon.
- Kiersten and I went and moved more of the RGDR files, preparing for the monitoring visit scheduled next week. We will need to move the shelf sometime this week so that the binders can be better organized.
- I identified a few patients that are potential candidates for shock but many are still too ill to go and consent. I will wait until they are closer to discharge to ask the physicians to confirm their diagnosis.

Research Project Activities

- I met Dr. Alam briefly in the hall while moving files and we spoke about the specialist data point in my project. I explained that mostly cardiologists identify and admit shock patients, and that we could instead look at how emergent a case is to find some variability. We agreed that if I did not have enough time, I would not record this data point so that my project can be completed on time.
- I met with Joost to discuss my research project and we discussed some deadlines for my project. I plan to have all data collection and cleaning efforts complete by 8/31. In the meantime, I will define what tests I want to run in a list format to discuss with Joost next week.

Action Items

- Get shelf for RGDR binders
- Data entry for thesis project
- Shock enrollments

- Shock query training

17 August 2022

Internship Activities

- Today I attended RGDR training to gain access to the eCRF. We learned how data entry for this project will work and how to set up the online account. I think I can make a spreadsheet that would allow future coordinators to easily track when data was last entered and when the next data point can be entered again.
- Kiersten and I moved the shelf used by the department that used to have the Rare genetic disease study. The shelf is now in our department in preparation for the future monitoring visit.
- I continued monitoring individuals I screened for shock. All are still too ill or unable to consent for some reason.

Research Project Activities

- I continued with data entry for my project, entry is still progressing on schedule.

Action Items

- Data entry for thesis project
- Shock enrollments
- Shock query training

18 August 2022

Internship Activities

- I attended the heart selection committee meeting this morning, they addressed a few patients that I have now screened for cardiogenic shock. I will need to confirm the diagnosis of these patients before seeking enrollment, and several may be admitted for a while given they have been approved for transplant or LVAD.
- I attended a lecture given by Dr. Guererro about the use of right heart catheters in shock patients. He reminds clinicians that the PAC is a diagnostic tool only and will not treat the patient. He explained way the hemodynamic values taken by a PAC can be used to evaluate a patient in shock.
- In the heart pod huddle meeting we discussed a few points about everyone's studies in preparation for the large research committee meeting next week.
- I screened individuals from the heart checkout emails and identified 3 patients today that could be enrolled in the shock registry. I will monitor patients for stability to find an appropriate time to consent them.

Research Project Activities

- I continued with data entry, tomorrow I only need to complete 4 more charts for the first pass of data entry.
- I learned that you can create drop down menus for data entry in excel. I will likely use this feature to clean data for discharge location.

Action Items

- Data entry for thesis project
- Shock enrollments
- Shock query training
- RGDR eCRF account

19 August 2022

Internship Activities

- I moved all of the binders for the RGDR onto the shelf we moved yesterday. I filed away some loose regulatory documents into the correct binders.
- I emailed the physicians and APPs about some patients to consent for shock but did not hear back. I will need to check back in on Monday.

Research Project Activities

- I completed the first pass of data entry for my thesis project and will now begin the second pass. This will be much faster as I am just confirming a few admission times for about 40 entries. I anticipate completing this pass early next week.

Action Items

- Data entry for thesis project
- Shock enrollments
- Shock query training
- RGDR eCRF account

Week 12

22 August 2022

Internship Activities

- I checked the heart checkout emails to find any weekend events or new patients for Shock screening. I found 5 potential patients, but only one was a good candidate. I will likely email about this patient in the next few days as they are still critical at this time. I also checked on the other patients that passed the screen to see if any of them have stabilized over the weekend.
- Ade explained that she was notified that we need to mark which patients had one-year follow ups on iRIS for shock. This will involve changing the details on our subjects to include the follow-up appointment.

Research Project Activities

- I began the second pass on data entry. This will involve making sure that I have recorded all times of death available to me, checking I have recorded a “start time” marked by the first chart I can identify where a doctor examined the patient. I am also checking that I have notes on how the patient was admitted (RHC, clinic visit, ED, etc).
- I also began working on an outline document to summarize what statistical analyses I need to complete for this project. I will need to have this completed for my Wednesday research check-in meeting

Action Items

- Finish shock data check
- Shock screening

23 August 2022

Internship Activities

- The heart research committee meeting was this morning, and we discussed the RNASeq study with the physicians on the call. We went over the other studies currently in progress, reviewed upcoming research, and addressed other research-related issues.
- We had a monitoring visit from the RGDR monitor. She looked through our regulatory documentation and said all seemed in order. She also answered a few questions we had about the study which will help us prepare to re-consent patients in the coming weeks.
- I worked on the RDGR spreadsheet to track data entry and believe it is almost complete. I will have to check how useful it is when we can finally begin data entry.

Research Project Activities

- I continued working on the second pass over my data, I am over halfway finished now and should be able to complete it tomorrow.
- I completed the statistics outline document for the check-in meeting tomorrow.

Action Items

- Shock project data check
- Shock screening

24 August 2022

Internship Activities

- I looked over my screening list and updated discharge dates for a few shock patients. I also began working on updating iRIS with follow up appointments for the prospective follow ups.

Research Project Activities

- I went over the outline of my proposed statistics with Joost and confirmed which data points I still need to complete.
- I was able to complete the second pass on my data, so now I will just need to work on cleaning some of the columns. I will hopefully have this done by the end of next week, if not earlier.

Action Items

- Data cleaning for shock
- Shock screening

**Sick with COVID 8/25 and 8/26

**Received emails about shock consents that forwarded to Neville who consented patients.

Week 13

29 August 2022

Internship Activities

- I completed the RGDR spreadsheet I had been working on previously and can hopefully get access to the database this week. I spoke with Kiersten and we will be able to begin the process of reconsenting subjects in the next week or so. We will need to finalize the list of patients who have been contacted already and who have agreed to be reconsented.
- I checked over my existing patient list for Shock, updating discharge information and times for upcoming appointments when data can be taken.

Research Project Activities

- I cleaned columns for cumulative time spent on vent and MAP. There were both calculated columns and I was having issues with some equations resulting in an error. There were cells with erroneous dashes that were interrupting the calculations. I was able to remove these and move the data columns into my main data sheet.
- I have pulled data for lactate levels at admission to use as a possible additional variable for the multivariate analysis, however it only exists for a fraction of my subjects. I'm not sure if the analysis will be able to be performed with missing data.

Action Items

- Clean data for shock
- Screening for shock
- RGDR organization

30 August 2022

Internship Activities

- I verified on iRIS that all of the statuses for V3 patients have been accurately updated. Now all V3 subjects show that they have completed the 1-month follow-up.

Research Project Activities

- I worked with my survival data today and found that I'm not sure when to censor individuals. I did not take specific data on when I last had a status for patients, so I may need to go back in and take this data.

Action Items

- Learn about censoring for survival curves
- Shock screening
- RGDR organization

31 August 2022

Internship Activities

- Today while checking on some shock data for my individual project, I found that queries had been released for our site. I was able to download a report of all our queries and organize them to show which queries had been posted the longest. We did not receive emails about these queries which seemed odd, but I will begin working through queries based on how recent they are, tackling the oldest queries first.
- Most of the queries are repetitive. There are discrepancies between admission time and lab value times because some labs were drawn while patients were still in the ED. Additionally, there are around a dozen queries resulting from confusion between PT and PTT lab values. It would be best if we could contact research coordinators or associates at Tufts, but for now we will try to note these repetitive issues in our query responses.

Research Project Activities

- I met with Joost today and discussed some of the questions I've been having while cleaning data. He recommends contacting Johanna, the biostatistician, so I will email her later today explaining some of my questions. I primarily need to establish how my data needs to be set up for the survival curve and whether missing pieces of data will impact a multivariate analysis.
- I also need to email the physicians about complication data for my project. There may be some more interesting ways to look at the data that I am not aware of.

Action Items

- Email Johanna
- Shock data cleaning

- Shock queries

1 September 2022

Internship Activities

- Today I finally gained access to the eCRF for the RGDR. It turns out I needed to complete electronic signatures for the training I completed. I can now view data that was previously entered. The monitor Sam has been updating Kiersten and I about updates that need to occur in the binders and about the status of two consents that seemed ambiguous at first.
- I worked through some more of the queries for shock, finding that there are a few more confused lab values for lactic acid and lactic acid dehydrogenase values. I also wrote the monitor some notes about Troponin labs, as there are two different types of Troponin labs and it is unclear which value Tufts would like.
- I attended the grand rounds lecture given today by Dr. Hall and the head of hepatology transplantation. They gave a presentation about dual organ transplant and the protocols that currently surround this procedure. Organ allocation and listing is complicated when individuals require both organs and protocols are still evolving.

Research Project Activities

- I heard back from Dr. Alam and Dr. Hall with some other pairings of complication data that I can use. I have gone back to recalculate the columns with these new pairings.

Action Items

- Shock data cleaning
- Shock queries

2 September 2022

Internship Activities

- I finished most of the remaining shock queries today, and will be able to complete them on Monday. I have continued to note information about our site's practices in the query responses. I will also need to check again on Monday to see if any new queries have been added. So far queries have occurred only in the "Causes of Shock" and "Admission" pages, so I predict we will see more in the coming weeks.

Research Project Activities

- I heard back from Johanna who confirmed I will need a date for each patient and whether or not they were alive or deceased at that check. I did not have to check every patient as I had times of death recorded for around 60 of my subjects. I finished the check for the remaining 100 patients today and now have all the necessary data for the survival curves.

Action Items

- Shock data cleaning
- Shock data analysis

- Shock queries

Week 14

5 September 2022

-Labor day

6 September 2022

Internship Activities

- I screened a patient for the RNASeq study, but found that the patient did not meet the protocol's requirements.
- Attended a huddle meeting where we discussed the current studies and any issues we might need to bring to Dr. Hall at the research meeting. We discussed the challenges we have been having with RNASeq and how we might bring those to Dr. Hall's attention.
- I worked through some more queries for the shock study. They are progressively being added every day, and I am not currently sure as to when they will finish looking over the data and when these queries are due, but so far I've been able to address everything in under a week.

Research Project Activities

- I was able to use my survival data to make a Kaplan-Meier curve and perform a Logrank test to compare patient survival. Though the results were not significant, this is still an interesting result of the study so far. I also finished setting up the tables for the fisher exact tests for complication and discharge location data.

Action Items

- Shock report data analysis
- Shock data queries

7 September 2022

Internship Activities

- I summarized the data taken by the Shock registry for devices so that it can be compared to another study the research department is considering taking on. I went through the codebook on REDCap and listed which values are recorded for different devices, as the values needed for ECMO differ from Impella.
- We had our research meeting with Dr. Hall and brought up issues discussed on Tuesday. The new registry being considered for Impella devices was also discussed and determined to be too similar to the Shock registry.
- I also worked on a few more shock queries. One repetitive issue is that PT test values were entered in the place of PTT test values. The proteins tested by this lab are different and the ranges are not the same, so all of them have been flagged. Our site does not run PTT tests at all, rather they use a more modern version called the aPTT test, so I have notified the data manager that we have aPTT values if they would like them in future.

Research Project Activities

- I was able to complete Fisher exact tests for complications and destination after discharge, and have begun drafting the final report. I am emailing Dr. Berg about how my final report should be informed by my project proposal, as some topics are not likely to change very much. I also need to email Johanna some questions about the Cox regression and other multivariate analyses I am wanting to perform.

Action Items

- Shock report data analysis
- Shock queries

8 September 2022

Internship Activities

- I attended the heart transplant committee meeting virtually this morning and learned of a few more patients that could be candidates for shock I will check later.
- I attended the heart pod huddle where we finalized a few issues with various studies. During this meeting I spoke with Dr. Alam who came by the office to chat about some research issues.
- I responded to more queries for the shock registry, focusing on the oldest queries. There are a few queries that have been difficult to fix but I have managed to repair any issues highlighted by the data manager.

Research Project Activities

- I spoke with Dr. Alam who has several goals for the coming months in regards to my research. He wants me to submit an abstract for ACC which is coming up on the 21st for the deadline. There are also some other conferences he thinks my research could be received at and encouraged me to present at a Thursday lecture in October. I will work on producing an abstract for ACC in the coming week so that it can be edited in time.
- Dr. Alam also mentioned extending my role after the internship as a “research volunteer” so I can work towards a potentially new project for a spring conference.

Action Items

- Shock project data analysis
- Shock queries

9 September 2022

Internship Activities

- I completed some more shock queries, I may need to check in with Neville and Ade about assistance completing the rest of the queries next week.

Research Project Activities

- I emailed Johanna some questions about my analyses and I will need to make some alterations to what I have so far. I need to run Chi-squared tests rather than Fisher exact

tests. Additionally, I need to make sure that I am picking a mortality follow-up date that allows a good amount of my individuals to have a complete follow-up time period.

- I met with Joost to discuss my project and some of the recommendations made about submitting abstracts from Dr. Alam. The deadline is coming up very soon so if I am able to submit, I will need to finish it very soon. There may be an issue with a research embargo from UNTHSC, so I will need to communicate more with Dr. Mathew to see if submitting abstracts would be acceptable.

Action Items

- Thesis project report
- Shock queries

Week 15

12 September 2022

Internship Activities

- Today I screened 2 patients for the shock project, ensuring they met the standards set by the CSWGR protocol and contacting the providers to confirm their diagnosis.
- There was a patient I was hoping to consent for shock today, however the patient was discharged before any providers could speak with him. This patient may return to the hospital in the next month so I will check their appointments until the one month follow up window closes.
- I worked to complete more shock queries. There is a meeting tomorrow to address any questions that have come up so I will generate a few questions as I work today.

Research Project Activities

- I worked on completing more of my analyses for my thesis project and to report in the abstract. I found a discrepancy between some of the p-values for chi-squared tests I ran earlier so I worked on figuring out what the issue was. I found that the formula I had used to calculate an odds ratio did not make use of the Yates' correction, which I will need to use to avoid overestimating significance.

Action Items

- Shock queries
- Thesis project

13 September 2022

Internship Activities

- This morning I participated in the blood drive occurring at our building.
- I also attended a drop-in meeting to ask a few questions about the shock queries. I asked about how we should address some of the queries we have been receiving. The data manager has said it's ok to alter more than the queried entry; ex. If a systolic blood pressure was queried, I can also alter the diastolic or other values that must be taken at the same time.

- Some of the queries I addressed today were very time-consuming; some of the time points that were entered were not correct, which requires all of the data associated with that time to be reentered.
- I sent an email to one of the cardiologists about a patient they will see tomorrow in the clinic. They agreed to speak with the patient about research so that I can consent them at the end of the appointment.

Research Project Activities

- I worked on finalizing the chart I want to include with the abstract. I am reporting the statistics the way I have seen previously but I will have to verify if this is accurate.

Action Items

- Shock queries
- Shock abstract
- Thesis draft

14 September 2022

Internship Activities

- I completed two informed consents today for shock. The first occurred in the clinic after the cardiologist spoke with the patient. Later on, another patient became available for a consent before having a heart transplant.
- There was a staff lecture about sarcoidosis that was given for staff today. The pulmonologist spoke about common diagnosis strategies and treatment strategies. Interestingly, some patients are not immediately treated for sarcoidosis if it doesn't seem like it would be useful.
- Joost meeting

Research Project Activities

- I completed the table and text for the shock abstract I'm planning to send to ACC. I sent the first draft of my abstract today to Dr. Alam. I am hoping to send this to Dr. Hall and many others once I receive some initial thoughts.

Action Items

- Shock abstract
- Shock queries
- Shock project

15 September 2022

Internship Activities

- I attended the heart selection committee meeting this morning, several patients were approved for transplant and I was able to screen an additional candidate for the shock study.
- We heard back from the shock data manager today stating that we would be able to use aPTT and LVIDD values. This will require us to go back into the charts and find these lab values. Complicating matters, some PTT values were queried because PT

values were entered, but PTT values that were entered as missing are not queried so we will need to manually go through and check charts again for aPTT and LVIDD values.

- A lecture was given today about group two pulmonary hypertension by one of the cardiologists. This lecture was a little hard to follow as it was very focused on treatment options and protocols for physicians. Interesting information was shared about how to determine a diagnosis for this disease compared to other types of pulmonary hypertension.
- I was only able to get through 10 queries today. I found several entries that indicated that there was no data to enter, but when I checked the chart there are multiple values that can be entered. After checking with Ade, I entered the missing data in the EDC.

Research Project Activities

- I worked on the materials and methods section for the final thesis report. I am hoping to complete the writing for my main analyses soon, then move to the preliminary analyses.

Action Items

- Shock abstract
- Shock queries
- Shock project

16 September 2022

Internship Activities

- I worked on more queries for the shock registry in order to hopefully make the deadline of the 30th. I was able to respond to 38 more queries today, and I am hoping they will be fully resolved next week.
- Dr. Alam emailed about a potential shock candidate, however the patient's case is still developing. I will continue to monitor this patient to see if they later qualify for shock.

Research Project Activities

- I received edits on my ACC abstract from Dr. Alam. My sections were, for the most part, too long and Dr. Alam was able to make them much more concise. I worked through these edits and altered information that was requested.

Action Items

- Shock abstract
- Shock queries
- Thesis draft

Week 16

19 September 2022

Internship Activities

- This morning there was meant to be a meeting of the key personnel for the sarcoidosis project. However, there was a problem with the meeting scheduling and the two co-investigators were not invited and could not come on short notice. In the meeting, we discussed a questionnaire to determine if a patient has an active infection. Additionally, I was able to confirm what kind of medications I should be wary of when screening patients for this study.
- I also screened 3 patients for the shock registry today. I was able to email the physicians about a few of the shock candidates.
- Ade came and asked for some numbers relating to how many patients we followed up with for CSWGR V3. The sponsor is suggesting we only completed 3 entries, however it appears we completed at least 40 of them.

Research Project Activities

- There were further edits sent about my ACC abstract. I have continued to alter the abstract per the many suggestions I am receiving. Dr. Alam came and spoke to me about the table associated with my abstract and we brainstormed some possible figures to make that would be more eye-catching.
- I also started an email chain with Johanna, the biostatistician, to make sure my statistics have been reported correctly. I am not going to report chi-squared statistic values anymore. I will just focus on the odds ratios, confidence intervals, and p-values.
- Yesterday, Dr. Alam messaged me about a shock journal where my research could potentially be published in a manuscript.

Action Items

- ACC abstract figure
- Shock queries
- Thesis draft

20 September 2022

Internship Activities

- I created a report for the impella device data on the V3 database in order to help Rama. She is another coordinator working on a project requiring some of this data, so this will hopefully get her ahead.
- I worked on completing more shock queries.

Research Project Activities

- I received some more comments from Johanna about the abstract statistics, I had not properly added one of the columns. I was able to fix this error and add it into the figure.

- I incorporated more comments into my abstract and checked the submission guidelines again. I made a few more alterations to my figure per recommendations from others.
- I worked on the materials and methods section for my thesis draft as well as reporting the statistics of these initial tests. I need to complete the multivariate logistic regressions I had planned for these main analyses and that section of analysis will be mostly complete.
- I spoke with Dr. Alam about future directions this research needs to take. He suggests cutting the dataset down so that patients with extended periods of time between their admission and diagnosis would not be included. Another direction would be to group subjects by time of diagnosis rather than admission, exploring whether the time that physicians identified the disease plays a more significant role. Finally, I will need to get the SCAI score for all the members of my dataset before I can present at ACC or work on a manuscript.

Action Items

- ACC abstract
- Shock thesis draft
- Shock queries

21 September 2022

Internship Activities

- I worked on more shock queries, we are scheduled to finish early, giving us enough time to deal with any further questions from the data manager.

Research Project Activities

- Dr. Hall sent a few more edits this evening to incorporate into the abstract. They have been uploaded to the version on the ACC portal now.
- I pulled some numbers for my data set to show Dr. Alam, specifically how many patients I would still have if we excluded everyone who did not have a shock diagnosis within 48 hours of admission. It looks like there would still be enough individuals, though I wonder if I could screen the V4 candidates and add some new subjects that had a diagnosis within 24 hours of admission.
- I met with Joost to look at some of my progress and discuss the direction of my research. For my upcoming thesis, I will likely stick closer to my original plans and consider further changes to the data set for future work. I will also need to come up with a system for SCAI scoring on retrospective patients, but this additional variable will also likely not be on my main thesis and will be used in future work.

Action Items

- Shock thesis draft
- Shock queries

22 September 2022

Internship Activities

- This morning I attended the heart selection committee meeting. Several patients were approved for listing and one was deferred for test results. None of the patients presented today seemed good shock candidates but I will note them in case they are rehospitalized. Some of the other individuals I have been monitoring were mentioned and several seem to have become more critical so I will wait to approach.
- Sent messages about one shock candidate, they are now stable, but none of the providers have spoken with him yet. Per instructions from Ade, I will request again that a provider speak with the patient first.
- Neville and I were able to complete the queries for shock save 4. These last 4 belong to a chart we discovered had no cardiogenic shock diagnosis. Neville has contacted the data manager to ask if we should delete this form or if she would want to so she can keep better track of everything.

Research Project Activities

- The deadline for the ACC abstract was supposed to be today, but it has now been extended to next Tuesday. I have checked with Dr. Alam and we agreed that no further changes to the abstract are necessary.

Action Items

- Shock thesis draft

23 September 2022

Internship Activities

- There was a last second VAD meeting discussing a patient this afternoon. The patient seems to be a VAD candidate but is declining so the physicians needed a decision to be made quickly. The VAD will be implanted next week if possible, but emergency placement may occur over the weekend.
- I checked through the screened patients who have had shock diagnoses confirmed by the physicians. Most are still too critical to contact, but one seems like they could be contacted next week. They may be discharged to BIR soon so I will need to keep checking.

Research Project Activities

- I completed the multivariate analyses for my project and have prepared the datasets for my exploratory analyses. I will hopefully be able to progress further on this over the weekend.

Action Items

- Shock thesis draft

Week 17

26 September 2022

Internship Activities

- I completed an informed consent for the shock registry. I spoke to the patients in their hospital room and answered their questions about the study. I completed the consent paperwork as well as the process note, and filed these papers in the proper binders. I also checked on the other patients that have already been consented to see if they have been discharged from the hospital yet, this way we can begin tracking for follow-up.

Research Project Activities

- I completed the final defense paperwork required by the UNTHSC biomedical science department.
- I worked on completing the last of the exploratory analyses and reviewed the work I completed over the weekend. I have finished reporting many of my statistics and formatting the tables. I have partially drafted my discussion section but may need to produce more of a literature review of cardiogenic shock treatment.

Action Items

- Shock project draft
- Shock consenting

27 September 2022

Internship Activities

- I checked on the Shock queries and found that no new queries had been listed.

Research Project Activities

- I am working on developing my interpretation and discussion of my results. I am also having issues customizing my graphs in R, and one of my box-plots will not graph properly. For some reason all of my “NA” values are not being dropped from the graph, leading to an incorrect figure.
- I found one data point I had to verify in the chart despite earlier data cleaning. I confirmed that the individual received a medication in 2021 rather than 2012. I am also working to analyze the durations in my study without outliers.

Action Items

- Shock project discussion

28 September 2022

Internship Activities

- I emailed Dr. Guererro about a patient he will be seeing in the clinic tomorrow. Dr. Guererro agreed to speak with the patient about the shock registry so that they can possibly be consented.

Research Project Activities

- Today I found a serious issue with my data set that will have to be resolved before I can report any of my results. I noticed that the column with the on/off sorting variable seemed incorrect and when I went to verify it, I found it was in the wrong order. I wasn't sure when this error occurred but I was concerned that all of the statistics I had run and reported had not been comparing the correct groups and were just artifacts.
- To fix the data set, I decided to change the way I had organized the sheet. Rather than keep calculations on separate tabs of the same sheet, I now have all calculated values on the same sheet and I recopied values from the registry data set again. After this process, I feel confident in the quality of the data set.

Action Items

- Shock project statistics verification

29 September 2022

Internship Activities

- I attended the heart transplant committee meeting in the morning. During the meeting, they discussed a waitlisted patient diagnosed with cardiac sarcoidosis. Dr. Hall noted they could be a good fit for the RNASeq project, so I noted down the patient.
- We identified the patient for the RNAseq study and after screening, they fulfilled all of the study requirements. I spoke with Hira about preparing to consent the patient as we will need to organize a blood draw. The patient is scheduled to be seen in the clinic next week.
- The patient I had meant to consent today never arrived for their appointment, so we were unable to complete the consent.

Research Project Activities

- I repeated all of my statistical tests and re-reported my results in my project draft. So far, the results have not changed, suggesting that I must have made the error with my sorting variable after I initially ran my statistics. The process of improving my dataset has been beneficial for my confidence in my work, however, and the new organization will better guarantee the quality of my study.

Action Items

- RNASeq consent
- Thesis draft

30 September 2022

-Out for medical school interview

Week 18

3 October 2022

Internship Activities

- I checked the CSWGR database for further queries and found none we hadn't responded to. Neville had messaged me earlier about a few queries but had taken care

of them as they were just issues with the unit on drug dosages, not as time consuming to fix.

Research Project Activities

- I finished the first draft of my proposal today. I was able to make good progress on the discussion section over the weekend and today I wrapped up a few ideas and read over the document again for cohesiveness. Some portions were taken from the proposal and I wanted to make sure they had been changed appropriately.
- I am wondering if the literature review would benefit from an overview of shock treatment and the different strategies used. Might explain why I am looking at certain durations and events in my analysis.
- I sent the draft out to my committee, but caught an issue I'd like to resolve before sending it to the cardiologists. I reported several of my durations in minutes, but the numbers are so large they do not conceptually mean a lot. I will convert everything to hours before sending it to the physicians and Johanna the biostatistician.

Action Items

- Edits for shock report draft

4 October 2022

Internship Activities

- We consented the first patient for the RNASeq study. The process was complicated slightly by the fact we offer a gift card. This introduces more paperwork to the process, for example we have to get tax information from the patient. Then, the gift card has to be collected from upstairs and brought downstairs to the clinic. I am not sure if we have to get the informed consent before we can request the gift card, but if there is any way we could have the gift card ready in future that would likely streamline the process.
- I looked back at some of our other candidates considered for RNASeq now that we have the consenting process finalized. There is a patient who appears to be a good candidate, but I cannot access her original pathology report from 2001 in the EMR. I emailed her pulmonologist Dr. Mallard hoping he might have a copy of the record, but he recommended we contact the pulmonologist. Dr. Bindra sent a message to the pulmonologist asking about this patient and for other patients diagnosed with sarcoidosis in the pathology report. This was towards the end of the day so I am sure we will hear back tomorrow.

Research Project Activities

- I have confirmed that my room for my defense is booked with my university, and the paperwork for my defense has been signed by all appropriate individuals.
- I emailed Dr. Mathews and found that my last day in the office will be Nov. 25. I was confused before and thought that my internship ended after the thesis, but this is the date on the original emails sent about the internship. This will allow me more time to complete the abstract and manuscript draft I am hoping to wrap up towards the end of my internship.

Action Items

- Editing shock report draft

5 October 2022

Internship Activities

- The pathologist got back to us with the patient's histology report, it turns out her original bronchoscopy samples were not indicative of sarcoidosis. She was later diagnosed on the basis of imaging and symptoms, and Dr. Mallard confirms he feels confident in the diagnosis. Dr. Bindra stated we will likely change the protocol to include imaging in the diagnosis standards for pulmonary sarcoidosis; as it stands, only a histopathological report can confirm pulmonary sarcoidosis.
- I sent out an email about potential shock candidates to consent, but many are critically ill and I won't be able to consent until next week. Hopefully I can confirm some of the diagnoses this week so next week can run smoother.

Research Project Activities

- I met with Joost today about my project which he feels is in good shape. I will work through his edits today as well as finish converting all of my minutes to hours.
- As I was working on this, I ran into the same box-plot issue as before, but have figured out how to resolve it. R was previously reading the column as a character variable, but I have now converted it into a numeric variable.
- I tried to find a way to collapse all of my box-plots into one figure with R as they all have the same units now, but this is proving difficult. I keep getting syntax errors on a relatively simple function, and I am not sure what is going wrong. I will continue to consult R forums; it likely has to do with how my data is uploaded to R.

Action Items

- Shock report draft
- RNASeq screening

6 October 2022

Internship Activities

- I finished going through the last coordinator's notes for the RDGR and transferring the important information to a spreadsheet. We can now see which patients have been contacted multiple times with no response, we can see who wanted to re-consent, and who are research subjects in other studies. Hopefully next week we can finalize the addresses and prepare to actually mail study materials out.
- The pathologist sent a list of potential sarcoidosis patients to check towards the end of the day. I will begin tackling these tomorrow.

Research Project Activities

- I sent out copies of my report draft to Dr. Alam, Dr. Hall and Johanna. I will probably wait until I get edits back from a few more individuals before I send out another draft to everyone, I am thinking I will only need another iteration or two which I should be able to finish by the end of October.

Action Items

- Shock report draft
- RNASeq screening

7 October 2022

Internship Activities

- I worked through a screening list of potential sarcoidosis patients sent by the pathologist. The diagnosis is sometimes a little hard to follow in the chart because the pathology report alone does not confirm the diagnosis. The patient's physician also needs to rule out infections and correlate with other symptoms. From the main list, I identified the most promising patients and sent notes about those patients to the PI Dr. Bindra. None of the pulmonary sarcoidosis patients are seen regularly at BHVH but many have appointments on the BUMC campus, so I am working with Shelby to see if we can call each patient and see if they are interested in coming to the Sammons building for this study, given that we will cover valet parking and offer gift cards.
- I drafted a letter to send to individuals we have not been able to contact about the RGDR. It is possible that we just have an incorrect phone number but the address is correct. The letter asks patients to check that they would no longer like to be in the study or if they would like to be reconsented. This way we can figure out who is truly lost to follow-up. We also may be able to catch a few more individuals who actually do want to be involved in the registry.

Research Project Activities

- I received edits from Dr. Berg towards the end of the day. His email was very positive, stating the draft is very good, I will work through these edits on Monday.

Action Items

- Shock report draft

Week 19

10 October 2022

Internship Activities

- I worked with Hira to plan how future consents for the RNASeq study will be performed. She will reach out to regulatory staff to see if the department can reach out to patients, or if we should contact their primary care physicians to then contact patients. I also heard from Ahmad with an updated protocol for RNASeq, allowing us to consent pulmonary sarcoidosis patients with chest CTs as diagnostic imaging.

Research Project Activities

- I worked through the edits I received from Dr. Berg which were focused on wording. I have incorporated these into my main thesis document.
- I am working to get a data collection sheet set up to begin collecting SCAI scores. I have read the most recently updated article for SCAI scoring to try and learn how it is gauged for patients. Also, after reviewing the literature, scoring is typically done at arrival, then the highest score reached by a patient during their stay is also recorded. I will reach out to Dr. Alam and Dr. Hall to make sure my understanding of the scoring is correct to ensure accuracy of my data.

Action Items

- SCAI scoring
- Project finalizing

11 October 2022

Internship Activities

- Today I attended the training session for the V4 shock database launch. This meeting included a lecture about the devices we will be taking data on in the hopes data entry will be easier with the extra information. They also introduced some new standards for sites to maintain such as making progress on data entry throughout the study and enrolling enough individuals. This meeting also mentioned that in order to publish material using registry data, researchers would need to first request permission from the steering committee of the CSWGR. I had not heard of this previously, so permission was not requested before submitting the ACC abstract. I will consult with Joost tomorrow about the possible impact on my own project and future abstracts.

Research Project Activities

- Dr. Hall and Dr. Alam emailed today about SCAI scoring, confirming some of my ideas and sharing some other factors they look for when scoring patients. Patients on ECMO are usually considered “E”, and patients who are already on home milrinone will be automatically bumped to “C” if their hemodynamics are found to be poor. Looking for the number of pressors and inotropes used in the physician's notes will probably be most useful for determining what stage a patient was at when arriving. We have also decided to record SCAI score at diagnosis to possibly account for patients with a delayed shock diagnosis.

- I have worked to begin scoring patients in the excel sheet I have built. This sheet will not include the patients I previously identified as not having shock. This way, the collected data can be quickly moved to my main sheet for analysis.

Action Items

- SCAI scoring
- Project finalizing

12 October 2022

Internship Activities

- Today we consented another patient for the RNASeq study. We did not know this patient was coming ahead of time, but Hira and I were able to quickly get the paperwork set up and met the patient in clinic. To streamline the process in the future, it would be great if we could consent patients before they have labs drawn as currently, patients are having to be stuck twice by phlebotomy as one of our upcoming patients is elderly, this could be particularly helpful. Hira and I will see if this is possible.
- I screened three more potential patients for the CSWGR. Dr. Guererro confirmed one of them, reported that the last two did not have shock, but sent me two more shock patients to approach.
- I went to BHVH to try and obtain informed consent from the three confirmed patients, but none of the patients were available to speak with. None of them will be discharged extremely soon, so I will try and get the consent tomorrow.

Research Project Activities

- I spoke with Joost today about my current efforts to finalize my thesis document, which are well underway and going well. We also discussed SCAI scoring data collection and Joost instructed to complete scoring for all CSWGR subjects and to work with Neville so that this dataset can be used in the future.
- We also discussed the CSWG steering committee and notifying them about the projects I am working on with their datasets. Joost plans to consult with Dr. Hall first to see what actions we will need to take.

Action Items

- SCAI scoring
- Project finalizing

13 October 2022

Internship Activities

- I attended the heart selection committee meeting this morning and identified some possible patients for the registry. In this meeting, one of the cardiologists presented a patient somewhat suddenly, so I was able to observe how the physicians consider a patient in real time. Though the presenting cardiologist felt sure the patient needed mechanical support, it was determined a right heart cath would still be necessary to make the decision.

- I gained informed consent from one of the patients for shock, but the other two patients were once again unavailable. I will coordinate with Neville to see if he can approach tomorrow as I have a meeting in Fort Worth tomorrow and plan to work from home.
- I screened two more patients for the CSWGR and will try to get the diagnosis confirmed in the coming days.
- I attended a lecture on pulmonary hypertension due to left heart disease, which covered some diagnostic strategies and treatment strategies.
- Dr. Bindra extended an invite to the research department for a talk about a new drug on Monday evening. I may attend as I have never been to an event like this.

Research Project Activities

- I may need to contact Dr. Ortega again in regards to notes on my final project, I have not yet heard back from him.
- I am working through the formatting manual made available by UNTHSC to begin formatting my paper per the university standards.

Action Items

- SCAI scoring
- Project finalizing

14 October 2022

Internship Activities

- I began entering patients into the V4 database today so that hopefully we can begin data entry earlier to maintain good standing as a site. I am just getting the baseline information in as a scaffold so that it will be faster to begin the data collection process later on. One of the upcoming prospective data collections will need to be done via phone call, and collecting data in the registry would be safer than keeping the information on an excel sheet.

Research Project Activities

- I incorporated some of the ideas brought by Dr. Alam into my conclusions section. He thinks the delay in device insertion seen for on-hour patients may be a product of scheduling availability in these facilities. If other patients are already scheduled for procedures during the day, newly diagnosed patients may have a difficult time getting into the cath lab or operating room.

Action Items

- SCAI scoring
- Shock project finalizing

Week 20

17 October 2022

Internship Activities

- I added more of the newly consented patients for CSWG into the V4 database. There is a new data point for what insurance a patient has that I believe can be located in the

RCO link under encounter information, but I will check with Ade that I am recording this value correctly.

- No new queries for the V3 shock database were added, though a number of queries are yet to be resolved on Tuft's end.

Research Project Activities

- I went and met with Dr. Berg to discuss my upcoming final presentation. I will need to send him the slides for my presentation as well as my CV so he can introduce me at the presentation. I will likely aim for a 30-minute presentation that just covers the content of my paper, and I need to make sure I include acknowledgments.
- I worked on my thesis report and downloaded the university thesis handbook. This document has all the details I will need to

Action Items

- Thesis presentation
- Thesis final draft

18 October 2022

Internship Activities

- None of the shock patients on my screening list are stable enough to be consented, so I will not ask to meet with them yet.
- I spoke with Kiersten about the Rare Genetic Disease Registry, I need to have a list of addresses for individuals who did not respond ready by around Friday.

Research Project Activities

- Today Johanna Van Zyl, the biostatistician, sent back edits of my thesis paper. The largest change is that she explained the method for removing outliers is not scientifically legitimate as there was not a reason for their removal and the rank-sum test I used does not require that outliers be removed to achieve normality. After removing outliers, I found a significant value for the patients on mechanical ventilation, so I will need to remove this result from the final version.
- Johanna also suggested some changes be made to my figures. I need to add a risk table to the Kaplan-Meier curves and change the y-axis to percentages.
- I wrote the Acknowledgement portion for my report today, ensuring to thank individuals from the HCS and Baylor.

Action Items

- Thesis project draft finalizing

19 October 2022

Internship Activities

- There were no updates on the shock patients I am currently screening.
- Checked with Hira about RNASeq patients, we may have Dr. Bindra contact patient's physicians. We will need to hear back from regulatory before knowing if we can consent patients in the clinic building where many of these patients are seen.

Research Project Activities

- I met with Joost to discuss the project which is coming along nicely. He said he will send further edits later today; I mostly would like help with my abstract to make sure it is appropriate.
- After speaking with Joost, I emailed Dr. Hall about the CSWG steering committee. She states she will ask how I can communicate with them to get them drafts of my work.
- I worked further on the draft, updating formatting and doublechecking that all formatting settings match the university requirements.

Action Items

- Thesis report final draft

20 October 2022

Internship Activities

- I worked on the patient address list for the RGD Registry. I finished going through the last coordinator's notes and identified which patients were non-responders and need a letter.

Research Project Activities

- I finalized my thesis report today. I read over it several more times and changed a few statements for clarity. I verified that all of the citations were done correctly and were appropriately referenced in the text. I sent the final version to my committee and Dr. Mathew.

Action Items

- RGDR addresses

21 October 2022

Internship Activities

- I finished the address list for the RGD Registry and sent it along to Kiersten. We spoke with Tony and Shelby about mailing requirements and how to get the correct type of envelopes.
- I also screened a few more patients for Shock and listed them in my enrollment notes for future emails to the physicians.

Research Project Activities

- I heard from Dr. Hall about how to communicate with the CSWG steering committee. She also let me know that the Temple hospital has more Shock data that may be useful for a future manuscript for this project.

Action Items

- Thesis presentation slides

Week 21

24 October 2022

Internship Activities

- Today I completed some more entries for the cardiogenic shock working group registry. I am just inputting a few basic characteristics for shock so that the patients have entries to work with for data collection.
- I obtained an informed consent form from a patient for the shock registry today. I spoke with the patient at length about the trial and they were very interested in hearing more. I completed paperwork filing and the associated process note for the consent. Neville completed the quality assurance entry for the consent and I added the patient to iRIS.

Research Project Activities

- I worked to complete SCAI scoring for the registry patients. There are some patients I am having trouble scoring, but I have marked these patients and will ask Dr. Alam and Dr. Hall later on.

Action Items

- SCAI scoring

25 October 2022

Internship Activities

- I presented the major findings of my project to the cardiologists during the monthly research committee meeting. There were some brief comments for feedback and then I needed to leave for my interview.

*out rest of day for medical school interview

26 October 2022

Internship Activities

- I screened more patients from the heart checkout email for shock and sent an email to the physicians to confirm the diagnosis.
- I verified this morning that a patient on my screening list did not have shock. 3 different providers including Dr. Hall confirmed the patient did not have shock so I have since noted this on our screening sheet.
- I spoke with Kiersten and it seems that the letter we want to send to patients to confirm their enrollment may need regulatory approval. We will work with Shelby to figure out exactly what we need to do to safely send these letters out to patients.
- I completed the invoice paperwork for my ACC abstract submission, so that the department can compensate the entry fee.

Research Project Activities

- I worked further on the presentation slides for the defense, they should be completed tomorrow.

Action Items

- SCAI scoring

27 October 2022

Internship Activities

- Kiersten and I worked to assemble the mailing for reconsenting RGDR patients. There is a form that is meant to give us outside access to medical records, but the form does not precisely match the cover letter that has been IRB approved. It is not clear what patients should write in some banks and I think it will be ambiguous when they receive it. We need to see if some of the information can be pre-filled prior to mailing for ease of completion.
- I attended the heart transplant committee meeting and found some more patients to screen for shock. I will send communications about these individuals later on.
- I screened a patient for the sarcoid study, but they were not eligible due to previous treatment.

Research Project Activities

- I sent the final version of my slides to Dr. Berg for brief review. I have also begun prepping the presentation, luckily after presenting to the cardiologists I already have some idea of how the presentation will go.

Action Items

- SCAI scoring

28 October 2022

Internship Activities

- Today I spent a large amount of time on SCAI scoring. This data entry process is a bit slower than anticipated and I feel I am a little behind. After my defense, I will likely dedicate more of my daily activities to entering scores so that I can complete it before the end of the internship.
- Hira and I heard back from regulatory staff, we will be able to consent patients for RNASeq at the clinic building where they are scheduled rather than asking them to come to Sammons. This will make the process far more convenient for patients.

Research Project Activities

- I reviewed my presentation slides again to prepare for next week's presentation.

Action Items

- SCAI scoring