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ABSTRACT

Introduction: Patients with atrial fibrillation are at an increased risk of stroke. As part of stroke prevention, these patients are prescribed anticoagulants. The Emergency Medicine Department at the University of Texas Southwestern undertook a survey study to ascertain why some Emergency Department (ED) patients with atrial fibrillation are compliant with taking their anticoagulant therapy, whereas others are not. The objective was to assess whether or not patient health literacy/ numeracy played a significant impact on patient anticoagulant non-adherence.

Methods: The *Newest Vital Sign (NVS)* survey and *Modified Morisky Scale (MMS)* survey were administered to the subjects to measure their health literacy/ numeracy as well as level of motivation/ knowledge, respectively.

Results: Results showed that patient knowledge and motivation may have surpassed patient health literacy/ numeracy in impacting anticoagulant compliance among ED patients with a history of atrial fibrillation. Patient enrollment however did not meet threshold for power. As such, the results did not show statistical significance.

Conclusion: It is therefore recommended that future research continue in order to attain a large enough sample size to render statistically significant findings.

Keywords: Atrial Fibrillation, Anticoagulant, Stroke, Health Literacy/ Numeracy, Non-adherence, CHA₂DS₂-VASc, Vitamin K Antagonist (VKA), Novel Oral Anticoagulants (NOACs)

A SURVEY OF ANTICOAGULATION NON-ADHERENCE IN EMERGENCY
DEPARTMENT PATIENTS PRESENTING WITH ATRIAL FIBRILLATION

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INTERNSHIP PRACTICUM REPORT

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By

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TABLE OF CONTENTS

	Page
ACKNOWLEDGEMENTS.....	iv
LIST OF TABLES.....	vi
LIST OF FIGURES.....	vii
LIST OF APPENDICES.....	viii
CHAPTER I.....	1
Introduction.....	1
CHAPTER II.....	3
Background and Literature Review.....	3
Specific Aim.....	6
Significance.....	7
Materials and Methods.....	8
Results and Discussion.....	11
References Cited.....	32
CHAPTER III.....	36
Internship Experience and Journal Summary.....	36
APPENDICES.....	59
APPENDIX A: Supplemental Data.....	59
APPENDIX B: IRB Forms.....	69
APPENDIX C: Journal.....	98

LIST OF TABLES

Table 1: Demographic Information for Subjects.....	15
Table 2: Shark Tank.....	37 & 100
Table 3: Enrollment Trend at Four Weeks.....	56 & 136
Table 1A: Distribution of NVS Scores.....	59
Table 2A: Distribution of MMS Motivation Scores.....	60
Table 3A: Distribution of MMS Knowledge Scores.....	60
Table 4A: Distribution of NVS Scores by Motivation Scores.....	61
Table 5A: Statistics of NVS Score by Knowledge Score.....	62
Table 6A: Table of NVS Score by Knowledge Score.....	63
Table 7A: Statistics for Table of NVS Score by Motivation Score.....	64
Table 8A: Table of NVS Score by Motivation Score.....	64
Table 9A: Statistics of NVS Score by Motivation Score.....	65
Table 10A: Table of Education by NVS Score.....	66
Table 11A: Statistics for Education by NVS Score.....	67
Table 12A: New Power for Study.....	68

LIST OF FIGURES

Figure 1: Enrollment Numbers.....	12
Figure 2: Health Literacy/ Numeracy assessed by Newest Vital Sign (NVS).....	17
Figure 3: Patient Knowledge assessed by Modified Morisky Scale.....	18
Figure 4: Patient motivation assessed by Modified Morisky Scale.....	19
Figure 5: Comparison of Health Literacy and Patient Motivation.....	20
Figure 6: Health Literacy compared to Patient Knowledge.....	21
Figure 7: Comparison of Health Literacy and Patient Knowledge.....	22
Figure 8: Patient Education Level compared to NVS Score.....	23
Figure 1A: Distribution of NVS Scores.....	59
Figure 2A: Distribution of MMS Motivation Scores.....	60
Figure 3A: Distribution of MMS Knowledge Scores.....	61
Figure 4A: Distribution of NVS Score by Motivation Score.....	62
Figure 5A: Distribution of NVS Score by Knowledge Score.....	63
Figure 6A: Distribution of NVS Score by Motivation Score.....	65
Figure 7A: Distribution of Education by NVS Score.....	66

LIST OF APPENDICES

APPENDICES.....	59
APPENDIX A: Supplemental Data.....	59
APPENDIX B: IRB Forms.....	69
eIRB Modification for Study Participation.....	69
Informed Consent Form (English).....	72
Informed Consent Form (Spanish).....	77
HIPAA Authorization (English).....	82
HIPAA Authorization (Spanish).....	85
Atrial Fibrillation Enrollment Check List.....	88
Data Collection Sheet.....	89
Patient Demographic Information Sheet.....	90
Newest Vital Sign (English).....	93
Newest Vital Sign (Spanish).....	95
Modified Morisky Scale.....	97
APPENDIX C: Journal.....	98

CHAPTER I

INTRODUCTION

This practicum project sought to examine the association between health-literacy as it pertained to anticoagulation non-adherence in Emergency Department (ED) patients presenting with atrial fibrillation. Atrial Fibrillation is a serious medical condition that increases one's risk for stroke (Hicks, 2015). According to the American Heart Association in 2016, 2.7 million Americans were known to be diagnosed with atrial fibrillation (heart.org, 2017). The risk for atrial fibrillation increases as one ages, has a history of hypertension, has a past medical history of heart disease, a social history of excessive alcohol use, a genetic predisposition, and sleep apnea (heart.org, 2017). The risk for stroke increases with age, a history of congestive heart failure, hypertension, diabetes mellitus, previous stroke, vascular disease, and/ or atrial fibrillation (Melgaard, 2015; van Doorn, 2015). Prophylactic intervention for patients with confirmed atrial fibrillation and who are at an increased risk for stroke, includes managing the arrhythmia as well as prescribing a regimen of anti-thrombotic/ anti-coagulant medication. Though many patients are adherent to their physician's treatment plan, a certain percentage are non-compliant still. The aim of this study was to explore why certain patients who were diagnosed with atrial fibrillation were non-adherent with taking their prescribed medication and whether or not this shared an association with their level of health literacy. Is it because this subset of patients was more forgetful? Less concerned about their health/ condition? Or is it possible that perhaps these patients did not fully comprehend the extent and seriousness of their condition? In regard to these questions, ED patients presenting with atrial fibrillation were surveyed to gauge the level of their health literacy, motivation, and knowledge after it had been

confirmed by ED staff that the patient had been non-adherent in their medication regimen. The results of the survey were used to ascertain if a correlation existed between anticoagulant non-adherence and the health literacy of the patient. The ED at Parkland Memorial Hospital served as the site for the study, and Dr. Deborah Dierks served as the Principal Investigator.

CHAPTER II

BACKGROUND AND LITERATURE REVIEW

Atrial fibrillation is a serious medical condition which increases the risk of stroke in its patient population (Hicks, 2015). The CHADS2VAS metric for stroke risk, indicates the cumulative sum of risk factors, (i.e., congestive heart failure, hypertension, age >75 years, diabetes mellitus, previous stroke or embolism, vascular disease, age between 65-74 years, and female gender) all contribute to an increased risk of stroke (Melgaard, 2015; van Doorn, 2015). A designated treatment plan is implemented based on the patient's score, and will indicate whether or not the patient is prescribed a regimen of aspirin, warfarin, or heparin infusion in acute cases (StopAfib.org, 2009). Other treatment options for patients, besides administration of the vitamin K antagonist (VKA) warfarin, are the novel oral anticoagulants (NOACs): dabigatran, rivaroxaban, apixaban (bhf.org.uk, 2017). Though both VKAs and NOACs can be taken orally, the NOACs have been shown to be as effective, if not more so, than warfarin in preventing strokes (Hicks, 2015). Furthermore, NOACs do not require international normalized ratio (INR) monitoring and the subsequent medication adjustments as warfarin does. NOACs also have a more predictable pharmacology, less drug-drug interactions, and fewer dietary restrictions than the traditional route of warfarin (Heidbuchel, 2015). However, it should be noted that NOACS have been shown to decrease renal function as well as increase the risk for hemorrhage and myocardial infarction (Abdou, 2016). Furthermore, the dire effects of a VKA overdose can be reversed by the administration of vitamin K; whereas, NOACs have few antagonists which can quickly and efficiently reverse their anticoagulant properties in the event of trauma (Hicks, 2015).

The main goal of this study was to ascertain the association between a patient's health literacy and their adherence, or lack thereof, to prescribed anticoagulation medications. Patel (2013) reported that some patients and their families may not have fully comprehended the seriousness of atrial fibrillation and how imperative prophylactic drug treatment was to preventing stroke. A cursory review of the present literature indicated that patients were non-adherent for a variety of reasons. Some of these reasons had to do with the practicality of taking the medication itself. The international normalization ratio (INR) is a measure of a blood sample's Prothrombin Time (PT-a "measure of clotting time") to the PT of normal blood. The INR for a normal blood sample is a ratio of 1.0-1.5 (HealthEngine.com, 2017). Patients on warfarin are encouraged to submit to blood testing every 2-4 weeks to maintain their INR levels within a narrow therapeutic range with a ratio of 2.0-3.0 (Clark, 2013; Kew, 2014). This is impractical for some patients because they may find it inconvenient to obtain these frequent checkups. For others, transportation or the cost of the drugs themselves may have been a factor (Nerini, 2013). On the other hand, it has been shown that some patients skipped doses or intentionally under-dosed because they were under the impression they did not need their medication, or because they were afraid that they may present with unwanted side effects of the drug (bleeding and bruising). There are instances as well where patients missed a dose, and felt the need to take an extra dose to "even things out" (Di Minno, 2014). In both of these scenarios, the underlying problem was that the patient remained outside of the therapeutic range of their anticoagulant medication. If the patient under-dosed their medication, then their blood levels were subtherapeutic, and, thus, at an increased risk for stroke. Conversely, if the patient over-dosed, they were supratherapeutic, and, therefore, at an increased risk for bleeding and bruising.

It should be noted that adherence was typically higher when treating acute conditions than when treating a chronic, long-term ailment (Rodriguez, 2012).

It is important to consider how a patient's health literacy affected their compliance with taking medications and following their physician's instructions. It had been postulated that those patients with deficient health literacy would be at an increased risk for non-adherence (Seliverstov, 2011). According to ClinicalTrials.org, there were currently four studies in the various stages of recruiting/ enrolling subjects, exploring the relationship(s) between atrial fibrillation, anticoagulation adherence, health literacy, patient education, or some variety of the four as of June 2017 (ClinicalTrials.gov, 2017). The articles reviewed for this section seemed to indicate that there did appear to be a lack of understanding on the patient's part of how imperative it was that they adhere to their medication and that they obtain regular lab work to adjust their dosages (Clark, 2013). This, however, was a two-way street: Practitioners (doctors, cardiac specialists, nurses, and pharmacists) needed to collaborate more with each other and take the extra time, if needed, to properly educate their patients about their medical condition and treatment plan. This should have been conducted in such a way that the patient fully comprehended how their condition could affect them, and how they needed to take an active role in their own treatment (Heidbuchel, 2015).

Besides proposing improved communication between practitioner and patient, as well as better collaboration throughout the healthcare team as a whole, some initiatives proposed a better use of technology: cell phone text-messaging or calls, emails, calendar updates, electronic caps on prescription bottles (Nerini, 2013; Rodriguez, 2012). Other measures noted in the literature involved the patients filling out information/ score cards about their condition, the idea being that

the more well informed they were of their condition, the more adherent they would be in their treatment (Heidbuchel, 2015).

The prevalent theme throughout the literature was that patient education is imperative for a successful treatment plan. As such, the extent to which the patient comprehended their condition and the subsequent reasoning for the drug regimen, i.e., their level of health literacy, was to be further evaluated during this study. As the study progressed, further background exploration continued in order to expand upon the literature herein consulted in this section.

SPECIFIC AIM

Anti-thrombotic medication as an intervention for the prevention of stroke in patients with atrial fibrillation can be complex. There are many variables which can explain why one patient is adherent to their treatment plan while another patient is not. Though the underlying medical condition may be similar in both patients, why does one patient “stick with the program,” whereas the other takes their medication at levels which are sub-therapeutic, or even skips doses entirely? Possible causes include: i) discrepancy in the patient’s finances, ii) forgetfulness, iii) the patient does not like the medication, iv) the level of health literacy of the patient, or v) perhaps the patient lacks the proper motivation and/ or knowledge to appropriately manage their health/ condition based on their doctor’s instructions.

The underlying problem, and the main issue addressed in this study was to assess the association between health literacy and the level of anticoagulation non-adherence on the part of the patient.

Hypothesis: It was estimated that up to 40% of ED patients who presented to Parkland Memorial Hospital with atrial fibrillation were non-adherent with their anticoagulation

medication. It was anticipated that those patients who were non-adherent with their anticoagulation medications would be shown to have a low level of health literacy.

Aim: The aim of this study was to determine the prevalence of low health literacy in patients found to be non-adherent, defined as not taking their prescribed medication “on a regular basis under limited supervision” (Di Minno, 2014). For this practicum study, patients presenting to the ED with atrial fibrillation were deemed non-adherent by the treating physician based upon the patient’s physical exam, medical history, and INR score if available. *Prior to approaching each patient meeting the study’s inclusion criteria, the treating physicians were approached to ascertain if the patient, in the doctor’s professional opinion, had been compliant with their anticoagulant medication.*

Primary Outcome: The measure of health literacy among ED patients with atrial fibrillation was found using the *Newest Vital Sign Test*, which consisted of the subject answering to the best of their ability six questions based on a nutrition label. For each question the patient answered correctly, they received one point. The subject was deemed to have adequate health literacy if they scored four points or better. Conversely, they were deemed to have limited health literacy if they scored three points or less (Weiss, 2005).

SIGNIFICANCE

Although the subjects of this study garnered no direct personal benefit/ gain from this study, the data collected could potentially improve future protocol/ treatment plans for patients in the specified sub-population. The study was designed to offer a better understanding of anticoagulation non-adherence in patients presenting to the ED with atrial fibrillation. Furthermore, it was anticipated that the results of the study would offer a better understanding of

the impact health literacy has when discussing treatment plan options with patients diagnosed with this condition.

MATERIALS AND METHODS

This study was a prospective survey study with the collection of Protected Health Information (PHI). It was not anonymous (subjects were de-identified). Treating Emergency Department (ED) physicians were blinded to patient results.

a) Data Collection

A survey created by Pfizer known as the *Newest Vital Sign (NVS)* was administered to subjects who were pre-screened via Epic, an electronic medical records system utilized by Parkland Memorial Hospital, and the treating ED physician. This survey was a tool to measure the health literacy and numeracy of the test taker. Health literacy was defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decision” (Sileverstov, 2011). The *Newest Vital Sign (NVS)* measured three areas of health literacy: prose literacy (words), numeracy (numbers), and document literacy (forms) (Weiss, 2005).

The *NVS* was administered to subjects meeting the inclusion criteria (see below) who had been prescreened (Epic/ treating physician) and had given informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization. The test itself entailed the recruiter giving the subject a nutrition label and asking six questions pertaining to the information on the label. The *NVS*, which had previously been validated against the *Test of Functional Health Literacy in Adults (TOFHLA)*, was to take no more than three minutes to complete, and would give a valid representation of the level of health literacy possessed by the

subject (Weiss, 2005). The NVS was given in either English or Spanish, depending on the patient's preferred language.

b) Methods, Data Collection, and Sampling Techniques

Potential subjects meeting the inclusion criteria were recruited either by physician referral or by review of medical records via Epic. In order to have access to patient information for pre-screening, a HIPAA waiver via UT Southwestern Institutional Review Board (IRB) was granted. Data collection occurred from late August through early October 2017.

Eligible subjects who were pre-screened were approached in their ED examination room by research recruiters between physician and nurse examinations. The study and what is expected of the subject was explained to the patient. If they fully comprehended the nature of the study and expressed intent to participate, they were asked to give an informed consent as well as sign a HIPAA authorization form.

Upon completion of the informed consent form and HIPAA authorization, the *Newest Vital Sign* was administered to the patient concomitantly with a data collection form for recording the patient's demographic information. A battery of other surveys were administered as well for the benefit of the Emergency Medicine Research Department of UT Southwestern. These included the *Perception of AntiCoagulation Treatment Questionnaire (PACT-Q)* and the *Modified Morisky Scale (MMS)*. The treating physician was blinded to the questionnaire results of the study. The collected data was processed and interpreted by a bio-statistician as well as this co-investigator.

c) Population

The subject population for this study was drawn from patients admitted into the Emergency Department of Parkland Memorial Hospital.

Inclusion Criteria:

- 18 years of age or older
- Presents with atrial fibrillation
(Confirmed via ED 12-Lead EKG during patient workup)
- Past medical history of atrial fibrillation
- Currently prescribed anticoagulation medication
- Treating physician deems patient noncompliant with anticoagulation medications

Exclusion Criteria:

- Patient does not present with atrial fibrillation
- Patient's medical condition impedes or prevents their ability to participate in the study
- Less than 17 years of age
- Prisoners
- Patient is pregnant

d) Data Analysis

Scores from the *Newest Vital Sign (NVS)* (measuring health literacy/ numeracy) were classified as follows: Scores of four or more points were classified as having adequate health literacy; whereas subjects with scores of three points or less were classified as having low health literacy. Furthermore, scores of 0-1 were described as poor, scores of 2-3 were described as inadequate, and scores of 4-6 were deemed adequate. Scores from the *Modified Morisky Scale (MMS)* (measuring patient knowledge and motivation) were as follows: Scores of zero to one

were classified as having low knowledge or motivation; whereas subjects with scores of two or three points were classified as having high knowledge or motivation.

For the biostatistical considerations of the study, unpaired t tests were utilized to summarize continuous data, using means and standard deviation, or median and range. Data from the *NVS* and *MMS* were summarized and cross tabulated utilizing Fisher's exact test, using counts and percentages to express the data. Any differences were deemed statistically significant when $p < 0.05$.

To determine the association between perceived health literacy and anticoagulation non-adherence, multivariate regression was performed. For a stable multivariate model, the sample size was set at 250.

RESULTS AND DISCUSSION

a) Patient Demographics

During the six-week enrollment period between 21 August through 29 September 2017, 692 patients were pre-screened via Epic. Of those pre-screened, only 5% met the inclusion criteria. Forty-two percent of eligible patients were enrolled in the study. The following data represents the screening to enrollment breakdown of the subjects in the study (Figure 1).

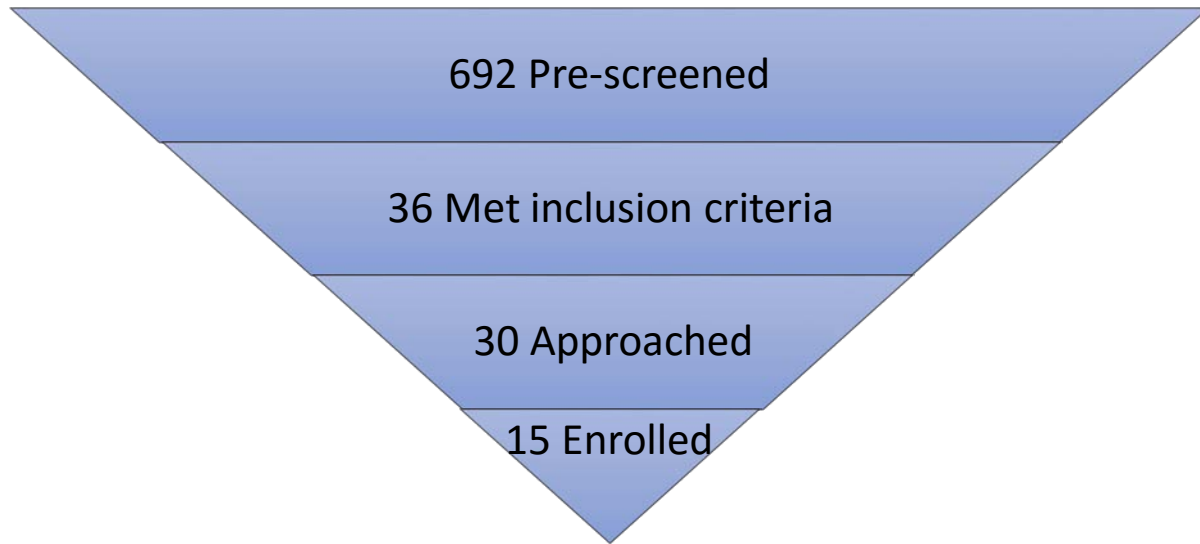


Figure 1: Enrollment Numbers

The mean age of the patients enrolled in the study was 61 years, with a standard deviation of 9.85. Their median age was 62 years, with the age range being 45 to 79 years. Forty percent (40%) of the subjects were female. In regard to race and ethnicity, about 27% were White, 53% were Black, and ~ 7% were Asian. Eighty-seven percent were of Non-Hispanic ethnicity. Thirteen percent (13%) of subjects spoke only Spanish and required the assistance of an interpreter.

The level of education of the subjects enrolled in the study was skewed to the right. In this regard, approximately 27% had completed grades 0-8, another 27% had completed some high school, 13% had a high school diploma or GED, 13% had completed 1-3 years of college, 13% had a college degree, and ~7% held a post graduate degree. Broadly speaking, approximately half of those enrolled (53.33%) had not complete high school (Table 1).

In regard to work status and household income, 73% of the subjects were unemployed. It should be noted, however, that 53% of patients were 60 years of age or older. Household income ranged from less than \$10,000 per year to up \$79,000 per year. Twenty-seven percent (27%) of

subjects had a household income of less than \$10,000 per year. Sixty-four percent (64%) of subjects had an income between \$10,000 and \$29,999 per year. Nine percent (9%) had an income between \$50,000 and \$79,000. Concerning the marital status of patients, ~47% were married at the time of the study, with only 7% of the subjects never having been married at all. Approximately 27% of the subjects were divorced or separated, and 7% were widowed (Table 1).

As for how the enrolled patients covered their healthcare costs, only 13% were uninsured, and another 20% had Parkland Plus, a locally owned health plan for uninsured patients. Twenty percent of subjects were on Medicaid, and 33% were on Medicare. Thirteen percent (13%) of subjects had private insurance. With this in mind, 50% of patients paid between 0-\$100 per month for their medications. Twenty-one percent (21%) paid zero dollars per month, and 14% paid between \$100-\$200 per month. Seven percent (7%) reported spending between \$200-\$300 per month, and another 7% reported spending between \$300-\$400 per month. It should be noted that these expenditures included the costs of *all* patient medications, not just their anticoagulants. To that end, 93% of subjects reported taking Coumadin (warfarin) as their primary anticoagulant medication. The other 7% reported Xarelto (rivaroxaban) (Table 1).

In regard to past medical history, 73% of the enrolled patients reported seeing a primary care physician regularly. The remaining 27% of subjects reported otherwise. As to their anticoagulant history, 73% of subjects were reportedly on anticoagulants for more than a year. Thirteen percent of subjects reported being prescribed anticoagulants for 6-12 months; the remaining 13% of subjects reported being prescribed anticoagulants for three months or less. Utilizing the CHAD (congestive heart failure, hypertension, age > 75 years of age, diabetes mellitus) scale for stroke risk, 53% of subjects reported a history of CHF, 87% reported a history

of HTN, 20% reported a history of stroke, and 53% reported a history of vascular disease (Melgaard, 2015; van Doorn, 2015) (Table 1).

Table 1: Demographic Information for Subjects

Variable	N	Mean	Std. Dev.	Median	Min	Max
Age (years)	15	61.2	9.9	62.0	45	79
NVS Score	15	2.5	2.4	2.0	0	6
Gender	Frequency	Percent		Race/Ethnicity	Frequency	Percent
Female	6	40.0		NH-White	4	26.7
Male	9	60.0		Black	8	53.3
				Hispanic	2	13.3
				Asian	1	6.7
Marital Status	Frequency	Percent		Primary Language	Frequency	Percent
Married	7	46.7		English	13	86.8
Never Married	1	6.7		Spanish	2	13.3
No Answer	2	13.3				
Separated/ Divorced	4	26.7				
Widowed	1	6.7				
Education	Frequency	Percent		Education	Frequency	Percent
Grades 0-8	4	26.7		No HS Diploma	8	53.3
Some High School	4	26.7		HS or College Diploma	7	46.7
HS Diploma/ GED	2	13.3				
1-3 years College	2	13.3				
College Degree	2	13.3				
Post Graduate Degree	1	6.7				
Income	Frequency	Percent		Employed	Frequency	Percent
<\$10,000/ yr	3	27.3		No	11	73.3
\$10-\$29,999/yr	7	63.6		Yes	4	26.7
\$30-\$49,999/yr	0	0				
\$50-\$79,999/yr	1	9.1		Insurance Status	Frequency	Percent

\$80- \$99,999/yr	0	0		Commercial/ Private	2	13.3
\$100- \$129,999/yr	0	0		Medicaid	3	20.0
≥\$130,000/yr	0	0		Medicare	5	33.3
				Parkland	3	20.0
				Uninsured	2	13.3
Regularly See PCP	Frequency	Percent		Monthly Medication Expenses	Frequency	Percent
No	4	26.7		\$0	3	21.4
Yes	11	73.3		\$0-\$100	7	50.0
				\$100-\$200	2	14.3
				\$200-\$300	1	7.1
				\$300-\$400	1	7.1
				Frequency Missing	1	7.1
Medication	Frequency	Percent		Medication Duration	Frequency	Percent
Rivaroxaban	1	6.7		< 3 Months	2	13.33
Warfarin	14	93.3		3-6 Months	0	0
				6-12 Months	2	13.33
				> 12 Months	11	73.33
Past Medical History	Positive History Frequency	Positive History Percent	Negative History Frequency	Negative History Percent		
Hx Of Congestive Heart Failure	8	53.3	7	46.7		
Hx of Hypertension	13	86.7	2	13.3		
Hx of Stroke	3	20.0	12	80.0		
Hx of Vascular Disease	8	53.3	7	46.7		

Frequency indicates number of Subjects; N = number of subjects

GED = General Education Diploma

HS = High School

Hx = History

NH = Non-Hispanic

NVS = Newest Vital Sign Survey

PCP = Primary Care Physician

NVS = Newest Vital Sign Survey

b) Results

Regarding the *NVS* scores, mean score was 2.53, indicating that at least half the subjects enrolled had inadequate health literacy (Table 1). The standard deviation was 2.39 (Table 1). Of the patients enrolled in the study, 33% exhibited adequate health literacy. Twenty-seven percent (27%) made a perfect score. Of those patients deemed to have inadequate health literacy utilizing the *NVS*, 20% had a score of zero, 27% patients had a score of one, and 20% had a score of two (Figure 2).

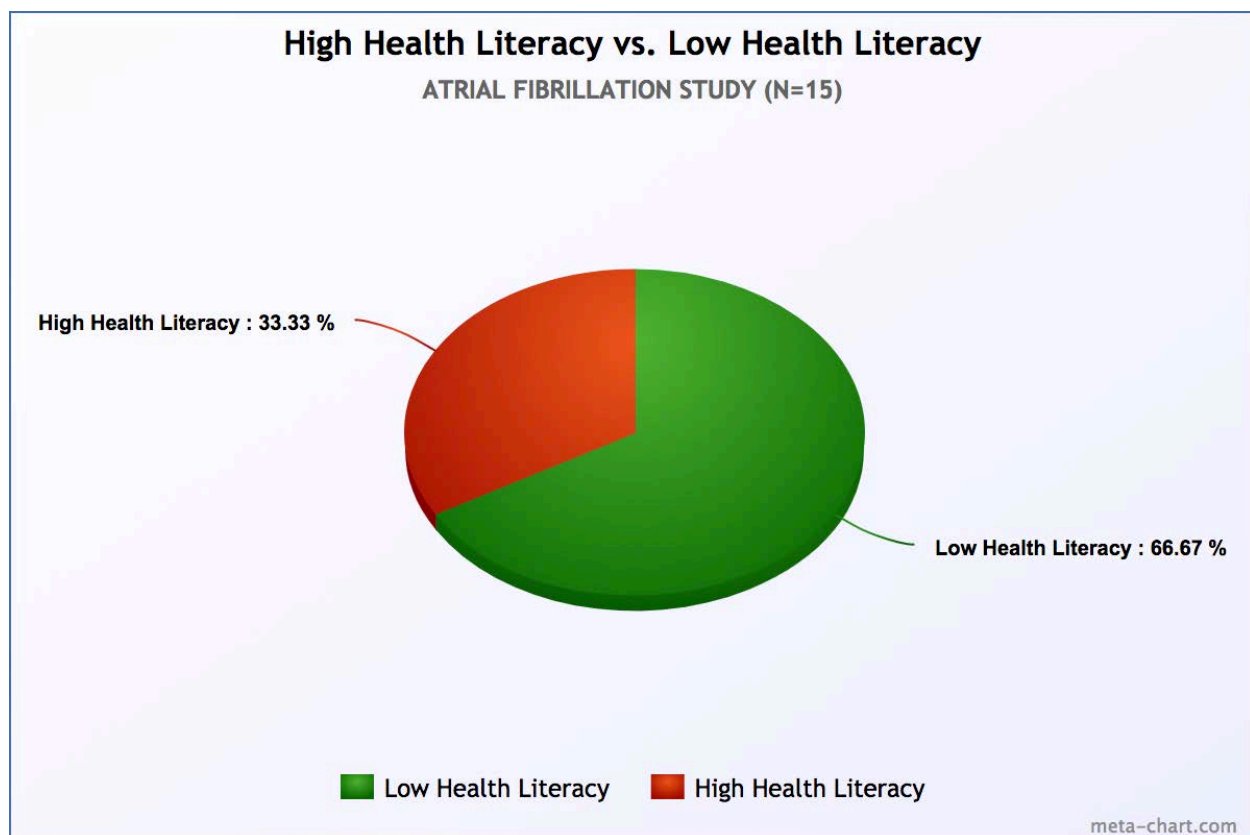


Figure 2: Health Literacy/ Numeracy assessed by Newest Vital Sign (NVS)

The *Modified Morisky Scale* survey served as the metric measuring patient risk for medication non-adherence. In this case it measured the patient's risk for not taking their anticoagulants as directed by their treating physician. The *MMS* was subdivided into two categories assessing the patient's knowledge, as well as their motivation. Patient knowledge was

the degree to which the patient understood the indications and benefits of taking their medication(s) as directed. Patient motivation was the degree to which the patient adhered to their medication regimen as directed.

In regard to Knowledge Scores, the distribution of results was as follows: 20% scored two points, whereas 80% scored three points. As such, and using the criteria given to establish non-adherence risk, all patients scored within the high knowledge range of the *MMS* (Figure 3).

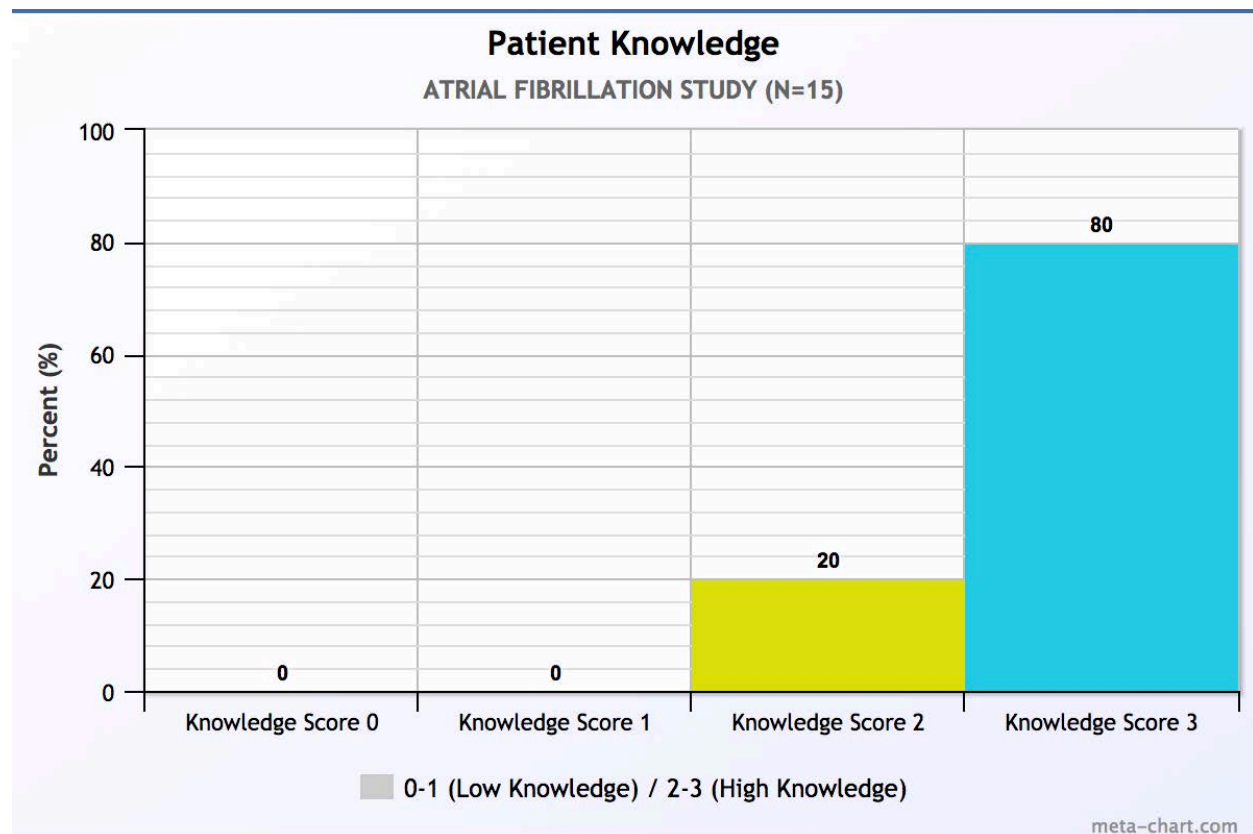


Figure 3: Patient Knowledge assessed by Modified Morisky Scale

Regarding patient motivation to adhere to their medication regimen, the distribution of scores indicated that 73% met the threshold for low-risk for non-adherence by scoring two or more points. The following range of scores represented the distribution of Motivation scores: 13% scored zero points indicating high risk for non-adherence; another 13% scored one point on

the Motivation scale. On the other end of the spectrum, 40% scored two points, whereas another 33% scored three points (Figure 4).

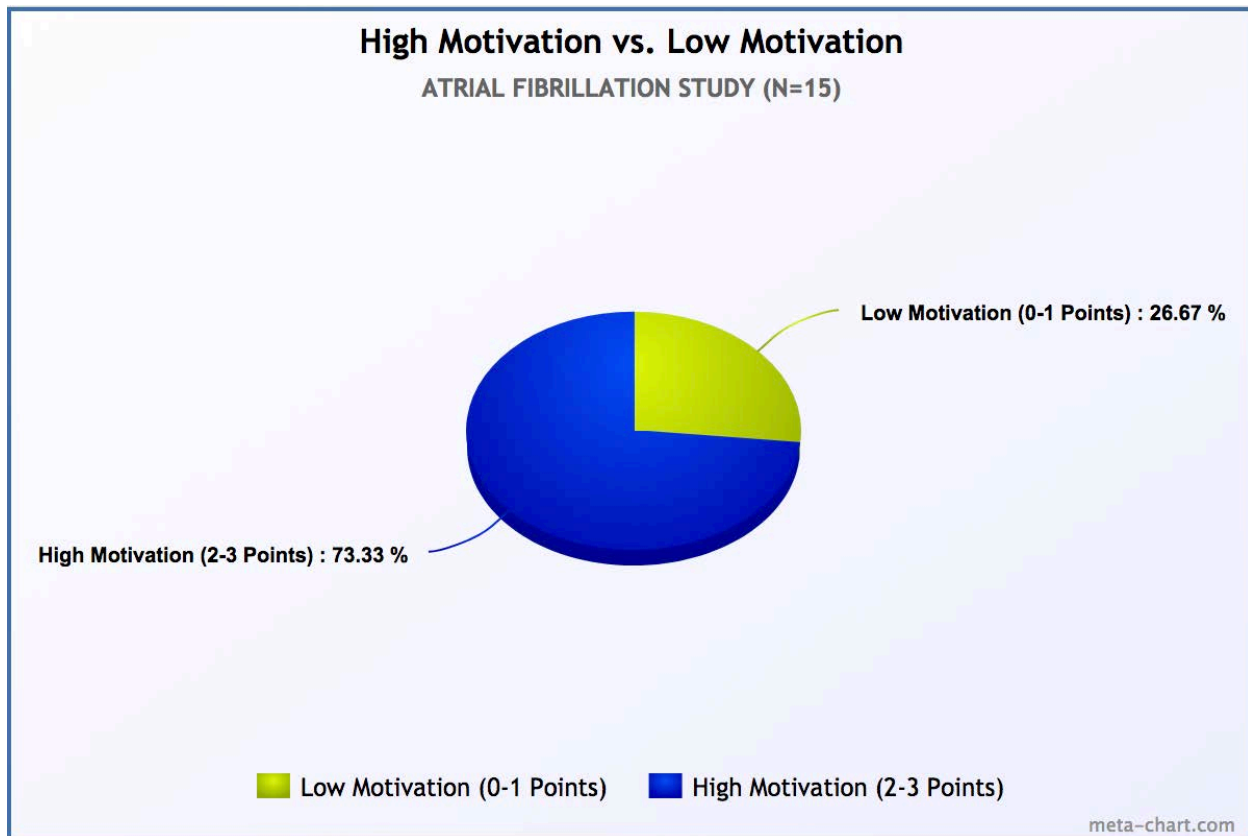


Figure 4: Patient motivation assessed by Modified Morisky Scale

A cross tabulation of *NVS* scores and *MMS* Motivation scores showed that ~68% of patients scored three or less points on the *NVS*, indicating less than adequate health literacy. The distribution for Motivation shows that ~47% had poor health literacy. Of these, ~29% had a motivation in the low range, and 71% had a motivation in the high range. Twenty percent demonstrated inadequate health literacy. Of these, 33% had a motivation in the low range, and 67% had a motivation in the high range. On the other end of the spectrum, 33% had adequate health literacy. Of these, 20% had a low score for motivation, and 80% had a high score for motivation.

There were ~27% of enrolled subjects who exhibited poor motivation (0-1) on the *MMS*. Of these, 50% demonstrated poor health literacy, 25% had inadequate health literacy, and one had adequate health literacy. Of the 73% patients who exhibited high motivation on the *MMS*, 45% showed poor health literacy, 18% exhibited inadequate health literacy, and 36% possessed adequate health literacy (Figure 5).

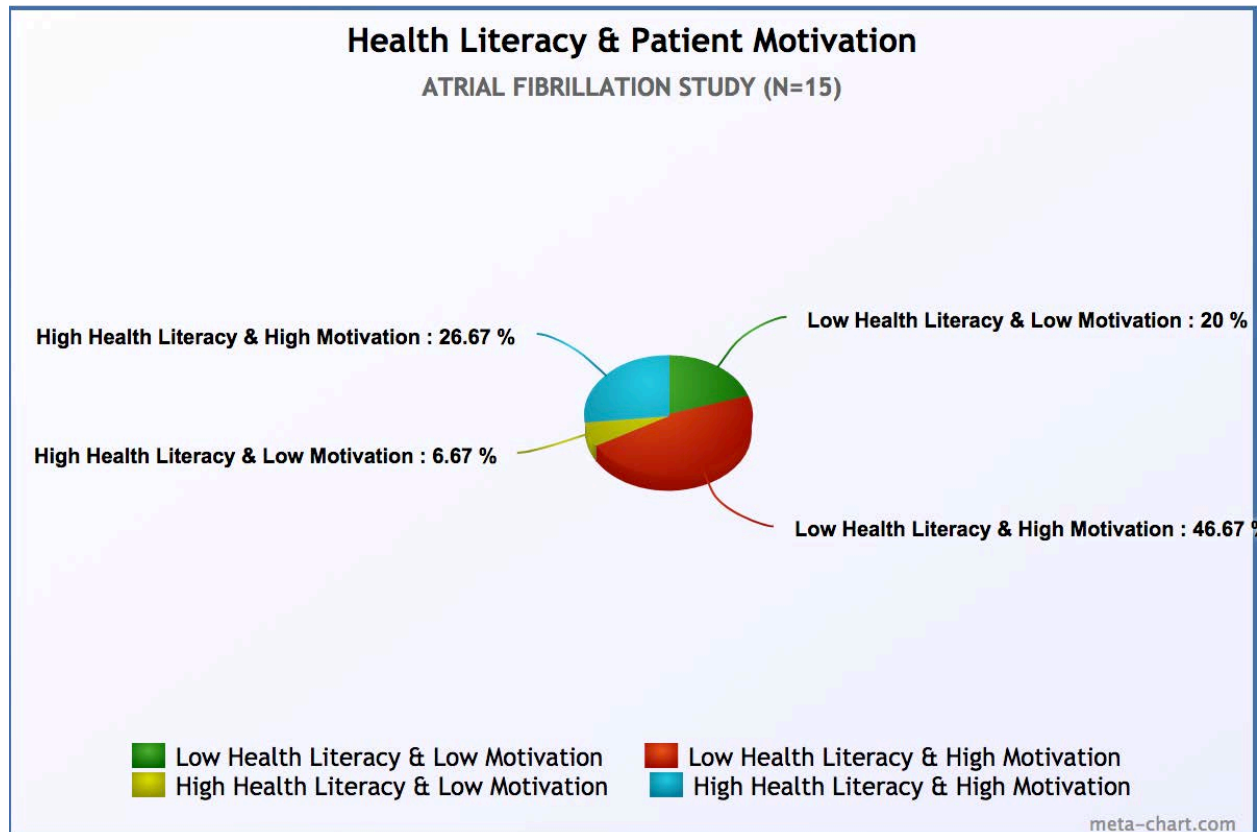


Figure 5: Comparison of Health Literacy and Patient Motivation

The cross tabulation of *NVS* scores and *MMS* knowledge scores showed similar findings: Approximately 67% of subjects scored in the poor to inadequate range for health literacy. Of particular note is that none of the subjects exhibited poor knowledge scores. The distribution for knowledge showed that ~47% of subjects had poor health literacy. Of these, 14% of subjects had a knowledge score of two, and ~86% had a knowledge score of three. Twenty percent (20%) of subjects exhibited inadequate health literacy. Of these, 33% of subjects had a knowledge score

of two, and ~67% of subjects had a knowledge score of three. On the other hand, there were 33% who possessed adequate health literacy. Of these patients, 20% had a knowledge score of two, and 80% of patients had a knowledge score of three (Figure 6). All subjects, regardless of exhibiting adequate or inadequate health literacy/ numeracy, scored within the high range for knowledge.

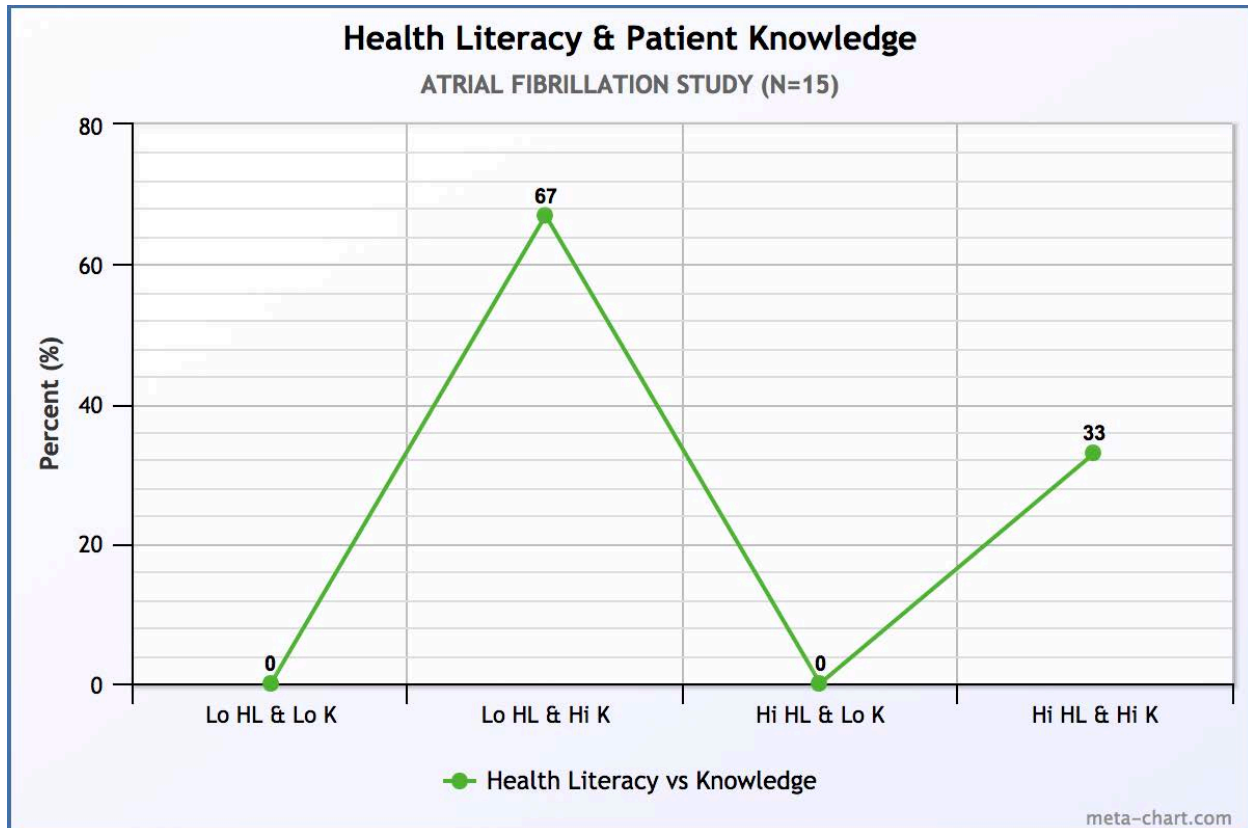


Figure 6: Health Literacy compared to Patient Knowledge

Recall while none of the patients exhibited poor Knowledge on the *MMS*, all subjects had high scores (2-3). Twenty percent (20%) of the study patients had a knowledge score of two. Of these, 33% had poor health literacy, another patient exhibited inadequate health literacy, and the third possessed adequate health literacy. The other 80% of patients had a knowledge score of three. Of these, 50% of subjects had poor health literacy, ~17% of subjects exhibited inadequate health literacy, and 33% of subjects possessed adequate health literacy (Figure 7).

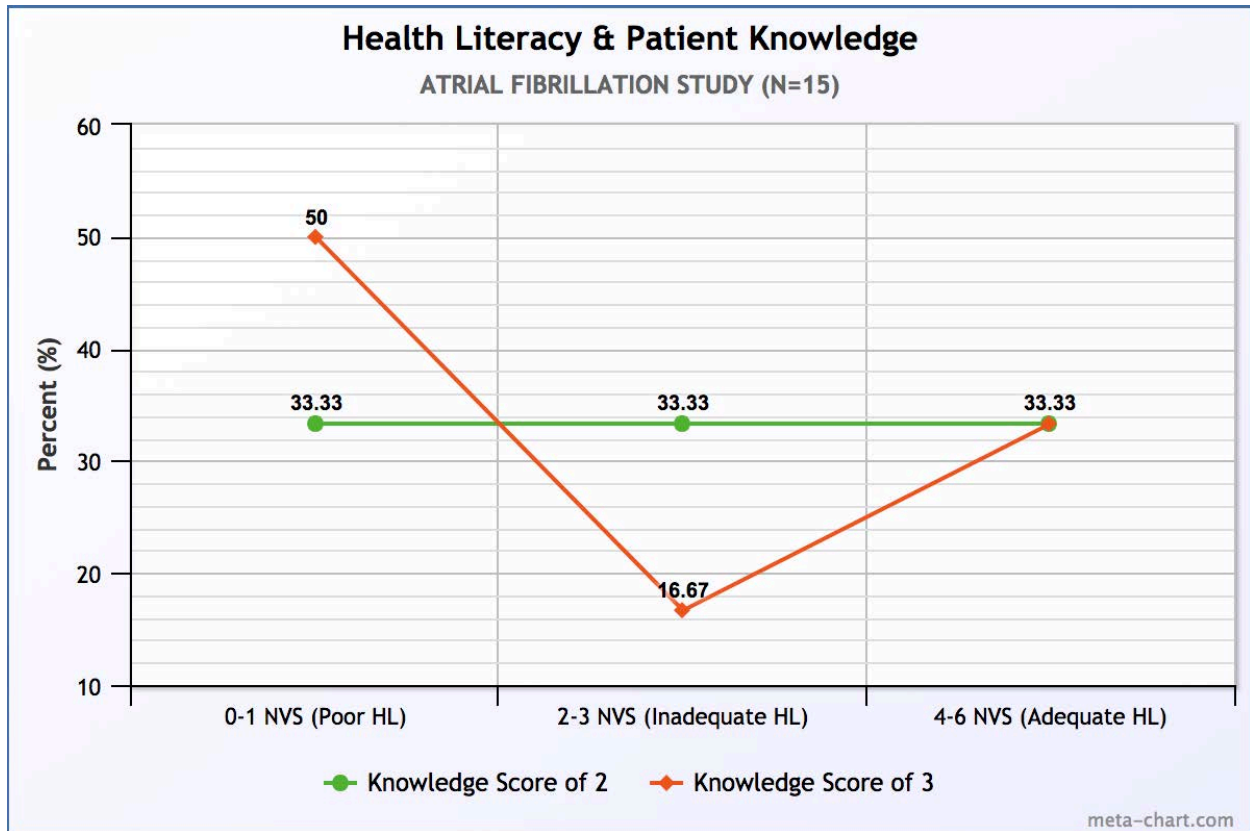


Figure 7: Comparison of Health Literacy and Patient Knowledge

It was found that an association did exist between the subject's level of education and their corresponding health literacy/ numeracy. A cross tabulation of NVS scores and the education levels showed that 33% of subjects who had at least graduated from high school, exhibited adequate health literacy/ numeracy. On the other hand, 53% of subjects who had not graduated high school possessed inadequate health literacy/ numeracy. Thirteen percent (13%) of subjects who had graduated high school were shown to possess inadequate health literacy as well (figure 8).

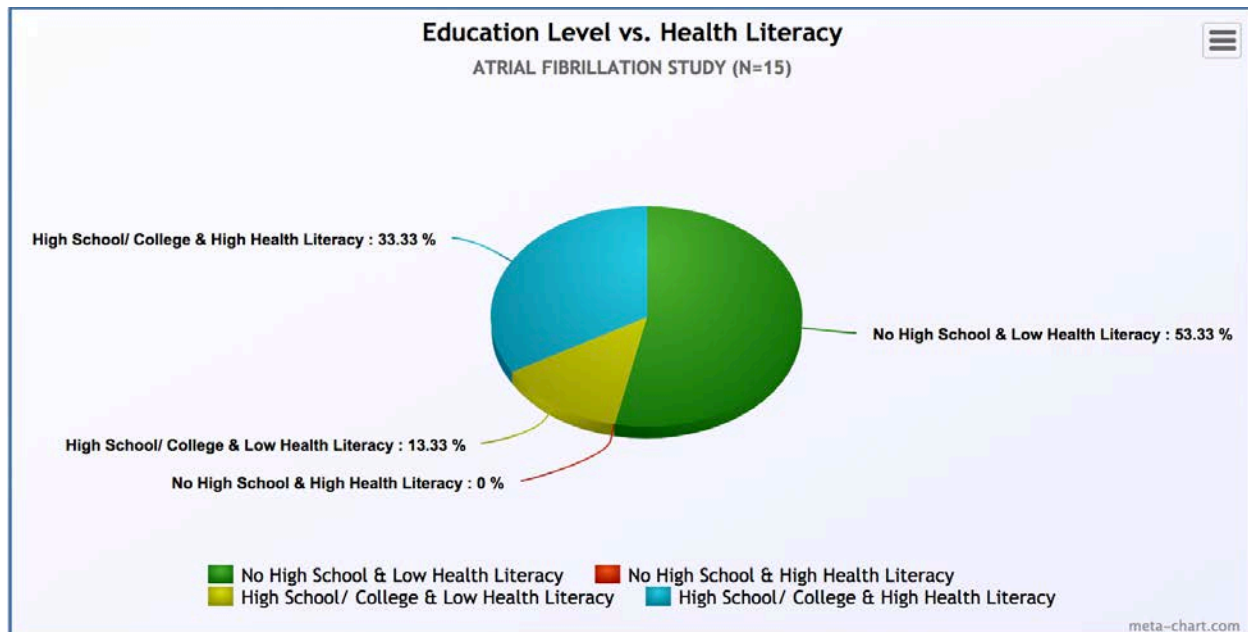


Figure 8: Patient Education Level compared to NVS Score

Though the data is sparse at this time, it should be noted that there was marginal significance detected between health literacy and patient motivation ($p = 0.08$ when alpha was set as 0.05). The relationship itself is inverse in nature. Furthermore, a significant association was found between subject education and the corresponding NVS score ($p = 0.007$ when alpha was set as 0.05). Recall that those patients who had at least a high school education tended to score higher health literacy/ numeracy on the NVS than their less educated counterparts. As noted above, when health literacy and motivation were compared, there was a marked difference between the two: As patient health literacy decreased, motivation increased. By comparing high and low motivation scores and high and low health literacy scores, a clearer picture of the discrepancy may be given. Regarding health literacy, 67% of patients exhibited inadequate health literacy, compared to 33% who possessed adequate health literacy. Regarding patient motivation, 73% exhibited high motivation, with the other 27% possessing low motivation. When compared to patient knowledge, 100% of the patients enrolled exhibited high knowledge.

c) Discussion

As noted by Hicks (2015), patients with atrial fibrillation are more predisposed to stroke as a result of allowing the condition to go untreated. As such, patients with atrial fibrillation are prescribed medications to treat the underlining arrhythmia, as well as anticoagulants as a preventative against clots and possible subsequent strokes. The purpose of this research study was to ascertain whether or not there was a relationship between anticoagulant non-adherence and patient health literacy in an ED patient population. It was anticipated that those patients with low health literacy were at a higher risk for anticoagulation noncompliance. Conversely, those patients with adequate health literacy were at a decreased risk for anticoagulation noncompliance. This was the working hypothesis for this study.

Over the course of the six-week enrollment period, other trends become apparent as more data was gathered and interpreted. As can be seen from the results sections of this thesis, the data indicated that though a patient had demonstrated low health literacy/ numeracy on the *Newest Vital Sign* survey, when the same patient was measured for knowledge and motivation on the *Modified Morisky Scale*, they scored more often than not as having high motivation and/ or knowledge. What does this mean for the study at hand? Though the data is scant at this early stage of the research, it points to the possibility that even though a patient may possess poor or inadequate health literacy, they may still possess enough knowledge and motivation to be compliant with their anticoagulant medications. Conversely, patients possessing adequate health literacy may exhibit low knowledge and motivation, thus demonstrating a propensity for non-adherence. Overall, the majority of patients (67%) in the study exhibited poor health literacy (Figure 2). As such, one would expect that the majority of those surveyed would be

noncompliant with their anticoagulation medications. As the data shows, this was not necessarily the case.

In the cross tabulation comparing patient *NVS* health literacy scores and *MMS* motivation scores, it was found that the ~47% of enrolled patients were found to have less than adequate health literacy, yet they scored high in motivation. On the other end of the spectrum, ~7% of the patients in this cross tabulation did exhibit high health literacy, but interestingly, they scored low motivation. Furthermore, recall that 20% exhibited low health literacy *and* low motivation, with the remaining ~27% showing high health literacy with high motivation. So, at face value, it may appear that patient motivation is a more significant factor than health literacy when it comes to medication compliance.

In the cross tabulation comparing patient *NVS* health literacy scores and *MMS* knowledge scores, it was found that the majority of enrolled patients (67%) were found to have less than adequate health literacy, and yet they scored high in knowledge. In this case, the rest of the enrollment population (33%) did exhibit high health literacy along with high knowledge scores. Again, as previously indicated in the results, none of the patients enrolled in the study scored low in knowledge. Using this last metric, health literacy/ numeracy may have less to do with patient knowledge than previously assumed.

When taken as a whole, the above interpretations could imply that possessing low health literacy/ numeracy has minimal effect on patient anticoagulant compliance. For that matter, possessing a high health literacy may not guarantee compliance as well. What then can be determined from the available data? Is it possible that patient knowledge and motivation play a more significant factor in medication adherence than their respective health literacy/ numeracy? As previously described in the results section, the sample size of the study was much too small to

allow any significant findings. That said, there did appear to be the makings of a relationship between health literacy and patient motivation. Though at present it appears as just a trend, the inverse relationship between patient motivation and health literacy is analogous to “a student with a low average IQ, but possessing a 4.0 GPA.” Put another way, patients exhibiting poor or inadequate health literacy may be more motivated to follow their doctor’s orders and be compliant with their medications.

In as much as patient demographic information is concerned, it was found that a significant relationship existed between a patient’s level of education and NVS score. The results of a two-sided Fisher’s Exact Test, yielded a p value of 0.007 (alpha set at 0.05). Recall from Table 1 that 53% of subjects did not possess a high school diploma or its equivalent. On the other hand, ~47% of subjects had graduated from high school and pursued higher education. When education level and NVS scores were cross tabulated, it was found that those subjects with a high school education or more tended to have higher NVS scores. Put another way, those subjects lacking a high school education, tended to score lower on the NVS, thus exhibiting lower health literacy/ numeracy than their counterparts. It should be noted as well, that though it was found to be a non-significant relationship, age was a possible confounder for level of education that should be controlled for in future research. As such, older patients tended to be less likely to have completed high school than their younger counterparts. If such a health disparity exists between these subpopulations, it should be explored further by garnering a larger sample size. Again, refer to Table 1 for patient demographic information.

d) Limitations

Several foreseeable limitations to this study were evident, for which some were controlled, and others were not. One such limitation which was controlled for to a certain degree was that of language barriers. The *Newest Vital Sign*, in its current form, was administered in both English and Spanish. Interpreters were present in the ED, but their availability was dependent upon the work-load of the staff.

A second limitation, and one that could not be totally controlled for, was the patient population from which the study sample was pulled. This study was dependent upon a convenience sampling of ED patients, Monday through Friday, 0800 to 1700. Parkland Memorial Hospital is no doubt a high volume medical center, but identifying and locating potential subjects proved to be a cumbersome task. Though inclusion criteria was relatively simple for this study, there were no absolutes, and it could not be guaranteed that enough patients would satisfy the inclusion criteria. Furthermore, once these patients were located and approached, 50% did not wish to participate in the study, or their present medical condition prevented them from participating in the survey. To help mitigate such limitations, Texas Emergency Medicine Research Associate Program (TEMRAP) interns were expected to be available to help locate and recruit prospective subjects. Due to an extended and cumbersome credentialing process, their contribution was far more limited than initially expected. As such, their contribution to gathering data was minimal.

A third limitation to this study was the possible disruption of clinical flow in the ED. Precautions were taken and standard operating procedures (SOPs) followed to limit this as much as possible, though it impacted the ability of researchers to recruit subjects. No matter the outcome of the practicum, patient care always came first and took priority over the study. The

occurrences were rare, but on two occasions, enrollment was paused to allow treating physicians and nursing staff to carry out their clinical duties or to facilitate patient transport to a different area.

In his study of numeracy and health literacy correlation, Griffey (2014) acknowledged other limitations which appeared relevant to the present study. As this study was conducted at a single site, generalizability may have been limited; furthermore, external validity of the study may have been limited as well due to some subsets of the possible sample population being excluded per exclusion criteria, such as the patient being a prisoner for example. Griffey (2014) also acknowledged that some patients were hesitant to participate in a study due to their self-perceived low health literacy, and would rather not run the possible risk of public shaming. As for the issue of convenience sampling, Griffey (2014) attempted to control for this by comparing the demographics of the sample to those of other comparable ED settings. A final observation was made in regard to the stress brought on by illness which may have affected the patient's ability to perform the cognitive tasks asked of them. Griffey (2014) attempted to control for such limitations by excluding those subjects too ill to participate in the study. To some extent, the exclusion/ inclusion criteria of the present study reflected similar initiatives to counter these limitations.

As for limitations actually encountered, several surfaced as the study progressed. Language barriers proved to be a more significant obstacle than initially expected. Even when utilizing a Spanish interpreter, the enrolling process could easily take up to an hour for this particular study, especially with all the subjective Likert style questions involved. Furthermore, the impression that Parkland language interpreters did not wish to participate in the process became apparent after several enrollments were completed. Because of the length of time and

attentiveness involved, this is surely understandable, especially with the more pressing clinical matters being evident in the ED requiring the services of language interpreters.

The biggest obstacle to the study turned out to be the lack of ED patients meeting the inclusion criteria. At the outset of the study, we *assumed* (incorrectly) that the patient population meeting the inclusion criteria would be large enough to generate a respectable sample size/ data pool. That unfortunately was not the case. At four weeks into the enrollment period, approximately 523 patients had been prescreened. Of those, 23 satisfied the inclusion criteria, and 21 were approached. Of those, 14 remained eligible after screening, and 13 were enrolled. Power was initially established at 250 patients. In the total period allotted for enrolling purposes, a scant 15 patients were enrolled. To actually meet power and lend the findings any significance, we would have needed to enroll for ~83 weeks at the same rate. It should be noted however that when a later power analysis was conducted for the more specific aim of evaluating patient health literacy/ numeracy, the new power was found to be 33 enrolled subjects with an $\alpha = 0.05$ (See Table 12A, Appendix A).

Continuing this, there was a human factor that could not be controlled. When working with human subjects, it must be accepted that even if a patient meets the initial inclusion criteria, they may not wish to participate. We found that with several patients, the timing was inconvenient for them, they were too tired, had vision problems, were too altered, or were too sick to complete the surveys. At the end of the study, it was noted that of the 30 patients who were approached for enrollment, 50% declined to participate in the study.

As can be seen by the above observations, the limited enrolling period and the subsequent small sample size greatly hindered the study's ability to reach power and thus find significant results. If feasible, and if this research is to continue, more researchers will be required along

with a greater enrollment period to reach the requisite number of study participants.

Furthermore, to increase the study's validity as well as generalizability to broader patient populations, more performance sites (other hospitals) should be incorporated into the study.

e) Summary/ Conclusion

As discussed above, there were several impediments present to the successful implementation of this study: smaller than anticipated population sample size, the fact that only one location was utilized for prescreening and enrollment, the need for more researchers, and an extended enrollment period (greater than six weeks). It is believed that taking these into consideration and taking the requisite steps to ameliorate them, future research will have a solid foundation from which to move forward.

Until more data is gathered, the present hypothesis that health literacy affects patient anticoagulant adherence cannot be adequately assessed. To that end, it may be fruitful to follow other avenues which may affect adherence as well, such as the patient's level of education, their income level, marital status, age, and race and ethnicity. Perhaps a patient's academic education, or lack thereof, makes them more perceptive to following medical instructions; perhaps it allows them to better understand the implications of their disease and how imperative it is to their health and standard of living that they take their medications as instructed. Income level may or may not be analogous to level of education, but perhaps it does influence whether or not a patient takes their medications as instructed. It may be as simple as whether or not they can afford their medications that week, or that month even.

It is perceivable that those patients who were still married at the time of their ED visit/ when the surveys were administered, may be more adherent than those patients who were not currently married. Perhaps having a partner or other family member who looks after the patient

may play a significant role in medication adherence. On the other hand, a patient's age may be indicative of whether or not they can adequately exercise independent care and judgement. Are older patients more apt to forget to take their warfarin than their younger counterparts? Is impaired memory a factor? With the demographic data collected for this study, these are more questions which can be asked and studied besides health literacy.

Expanding the study to other performance sites in the continental United States could allow for greater generalizability and validity by introducing data from much more diversified patient populations from different geographical regions of the country. Do East Coast patients exercise better compliance than their Midwestern neighbors? Are urban patients more compliant than rural patients, or vice versa? By expanding this study to other sites, these questions and more could be explored in further detail.

Besides giving a greater breadth to the research, it is possible that health disparities may emerge between different patient populations. As such, this would not only set a foundation for future research, but it could begin the process of addressing deficiencies in patient care between populations that have thus far gone undetected.

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CHAPTER III

INTERNSHIP EXPERIENCE AND JOURNAL SUMMARY

*****WEEK 1 (5/30-6/2)*****

As a week of “first,” Samita and I spent this week getting acquainted with the office staff of the UTSW Emergency Medicine Department as well as orienting ourselves to the UTSW campus as well as that of New Parkland Memorial Hospital. We attended our first department meetings concerning the various ongoing and closing research studies being headed by the department. Much like discussing after action reports and assessing the current status of ongoing studies as well as laying the foundations/ ground work for future studies.

It was also during this week that Samita and I read through various protocols of studies already IRB approved: 1) T2D & Health Literacy 2) A-fib & Anticoagulant Nonadherence 3) Pain Perception Across Providers 4) Chest-Pain Patient Preference for Follow- up Functional Testing 5) Double Paramedic Cost Evaluation. For myself, I found the A-fib and Anticoagulant Nonadherence study to be the most appealing. As such, I chose this study for my research practicum and began an initial literature review for relevant articles.

Samita and I attended the EM Residency Shark Tank Competition to hear about new research proposals from UT Southwestern EM Residents. The following are the proposed topics presented by their respective resident:

Table 2: Shark Tank

Resident	Faculty sponsor	Title of Study
Garrett Blumberg	Lynn Roppolo	Making the emergency department a safer place: managing the agitated patient
Robert Rash Mark Dresselhouse	Emily Gundert Jessica Hernandez	Evaluation of an Inexpensive Model for Transvenous Pacing Education
Daniel Jackson	Samuel McDonald Ellen O'Connell	A Patient Performed Medication Reconciliation in the Emergency Department
Luis Puchi	Gil Salazar	Better outcomes for Hispanic patients – Are they lost in translation?
Ken Wang	Kavita Joshi Jessica Hernandez	Procedure Associated loss of Situation Awareness
Lauren White	Jillian Horning	Palliative Care in the ED

The remainder of this week was spent looking through journal articles relevant to the A-fib Study as well as attending a training session on preparation for audit/ site-visits. I was fortunate enough to read a protocol as well as sit in on a conference call between the Principal Investigators for a new study being conducted at UTSW/ PMH concerning NSTEMI treatment protocols (survivability of patients sent to the ICU, or to the Cath Lab).

*****WEEK 2 (6/5-6/9)*****

Attended EM Research Dept. weekly meeting and was able to meet Dr. Idris, the Research Director, and other members of the department. Topics discussed ranged from open cases and whether or not they were reaching their recruitment quotas. Another topic broached was the use of social media to contact subjects/ family members in emergency situations. I learned that one aspect of GCP is that in any research study, the top two enrolling sites are usually the locations chosen for FDA audits. Protocol deviations/ violations were discussed as

well: AE are unexpected events with an adverse outcome that are in some way related to the study.

Began to do the work-up for my Friday research proposal Advisory Committee Meeting. Tentatively, the study I have chosen is entitled *Factors Associated with Anticoagulation Non-adherence in an Emergency Department Patient Population with Atrial Fibrillation*. The aims of the study were threefold: 1) Determine the prevalence of high risk for non-adherence with anticoagulation in an emergency department population with A-fib, 2) Determine prevalence of low [health] literacy in patients determined to be noncompliant, 3) Determine the association between adherence and patient preference. In the protocol, the proposed clinical impact would “provide further understanding of patient adherence with anticoagulation in those with atrial fibrillation. As many of these patients [would] present to the emergency department, understanding the impact of preference and literacy when discussing anticoagulant use is important.”

Samita and I attended a department staff meeting. The meeting covered the department employee report form from last year as well as a brain-storming session covering what is good, bad, and what can be improved within the department. In short, the meeting/ staff worked towards developing and implementing an Action Plan to be put in place over the next year.

At the end of the week, Samita and I presented our respective research proposals to our respective Advisory Committees. I presented to Dr. Mathew, Dr. Pierce, Dr. Gwartz, Dr. Ranjan, & Shannon McNabb. Dr. Rickords was in attendance as well. Not too terribly nerve racking. The feedback I was given is thus: A) Choose one (1) of the aims/ hypotheses to focus on. Gather the data for all three surveys, but doing all three would collect a lot of data, and working through the results may fall outside of the scope of what I will be accomplishing over the next

six months. B) I need to review/ rebuff my knowledge of biostatistics, as it will be imperative for not only my defense but understanding the data.

I am under the impression that one cannot have the *NVS* without the *MMS*. If that is indeed the case, then if abiding by the Committee's suggestion that I narrow my aims and hypothesis into one concerted aim/ hypothesis for my thesis, I believe that the *MMS* along with the *NVS* can be used to ascertain what association (if one exists) there is between health literacy and nonadherence.

*****WEEK 3 (6/12-6/16)*****

Spent a fair amount of time this week and a bit of the previous week working through the credentialing process. This included working through CITI-Training modules such as:

1. New Drug Development,
2. Overview of International Council for Harmonization – GCP,
3. Comparison of ICH E6 GCP & FDA Regulations,
4. Overview of US FDA Regulations for Medical Devices,
5. Informed Consent in Clinical Trials of Drugs, Biologics, and Devices,
6. Detecting and Evaluating Adverse Events,
7. Reporting Serious Adverse Events,
8. Audits and Inspections of Clinical Trials,
9. IRB Waiver of Authorization,
10. Limited Data Set,
11. UT Research Authorization,
12. How do Researchers Obtain, Create, Use, and/ or Disclose PHI,
13. Why the Privacy Rule Challenges for Clinical Researchers,

14. Data Use Agreements and Limited Data Sets-Recruitment for Participation in Research Studies,
15. Use of PHI for Research on Descendants,
16. Transition Provisions,
17. Research Accounting Statements,
18. Monitoring of Clinical Trials by Industry Sponsors,

Began creating an outline for research proposal. Operating under the impression that I am to choose one aim to focus on, I would be presumably working on Aim 2: “To determine the prevalence of low [health] literacy in patients determined to be non-compliant.” The primary outcome will be to “measure the prevalence of health literacy using the Newest Vital Sign” (NVS) survey. The hypothesis proposed that “those patients who [were] non-compliant [would] have low health literacy.” Throughout this week, I worked, and reworked each section of the research proposal: Introduction/ Summary, Problem/ Hypothesis, Significance, Background, Research Design/ Methodology, Limitations, Chapters, and References. By the end of this week I was able to submit a working draft to Dr. Pierce for review before submitting to Dr. Gwartz.

Rather than looking at the MMS and NVS, I was to look to the treating physician to find which patients may or may not have been compliant with their medications. As such, the NVS was to be the only survey I needed to administer in regard to the new/ narrowed scope of my research practicum (accessing health literacy in noncompliant a-fib patients). *As the study progressed, it was found that a combination of the NVS, the treating physician’s professional impression, the patient’s INR score, as well as the MMS all contributed to evaluating the patient’s compliance, or lack thereof, along with their level of health literacy.*

Was given the coverage analysis for my proposed study, which was subsequently approved. This phase of the research precedes the actual study itself. It was used by the medical center to evaluate the feasibility of actually conducting the study (fiscal costs).

Of particular note, Samita and I attended a lecture on *Current Topics in Research Administration*, given by Kim Moreland. Topics covered by Kim touched upon a) Procurement Updates, b) Federal Budget Implications, c) Indirect Costs, d) Single Audit and LOC Draws, e) R 35 Wards, f) Regulatory Reform Ideas.

*****WEEK 4 (6/19-6/23)*****

Spent this week filling out Parkland Memorial Hospital credentialing paperwork, as well as expanding my literature review. One article touched upon the use of the Newest Vital Sign as a quick screen for limited health literacy. The other compared traditional vitamin K antagonists (VKAs) and new oral anticoagulants (NOACs). The latter were found to be as effective, if not more so than preventing strokes, and with less of the untoward interactions and monitoring that accompany VKA prophylaxis.

Another touched upon a comparison of health literacy tests: validating Newest Vital Sign, REALM-R and METER, and SILS to the standard S-TOFHLA. It was found that the NVS had a good ability at detecting low health literacy when compared against the S-TOFHLA. As such, the NVS is a suitable tool for measuring health literacy in Emergency Department patients.

Yet more credentialing processes were completed: Institutional Conflict of Interest training/ acknowledgment for the UTSW IRB. I read the handbook sections for: Financial Conflicts of Interest in Research – Disclosure, Management and Reporting (RES-401), Conflicts of Interest, Conflicts of Commitment, and Outside Activities (ETH-104), and Outside Activities (Including Outside Employment or Board Service Policy (EMP-158).

It was during this week which I created the data collection sheet as well as developed the inclusion/ exclusion criteria for the study:

Inclusion criteria: 18 years of age or older, presenting with a-fib, past medical history of a-fib, currently prescribed anticoagulants, ED visit related to nonadherence of anticoagulant medications.

It is noted that as the enrolling portion of the study began, it was deemed that this inclusion criteria was too restrictive. As such, the inclusion criteria from the original protocol (history of A-fib and on anticoagulants) was implemented.

Exclusion criteria: medical condition precludes the patient's ability to participate in completing the study, patient is 17 years of age or younger, and/ or the patient is a prisoner.

Samita and I began practicing mock enrollments with each other. We found that Time is a big factor in the process, and both of us went over by 5-10 minutes each. Streamlining the process and being as efficient as possible were going to be key, not only to correctly get the information we needed, but to be cognizant and respectful of the patients' condition and emotional status. Samita and I planned to practice at least once a day until things actually got moving.

*****WEEK 5 (6/26-6/30)*****

Much of this week was spent practicing mock enrollment interviews with Samita, as well as working on edits to the research proposal received from Dr. Gwartz. During this time, I was successfully added to the protocol for the atrial fibrillation anticoagulation nonadherence study as a researcher by the University of Texas Southwestern Institution Review Board. This

information was forwarded to Dr. Mathew along with the requisite forms to be sent to the UNTHSC IRB: a) Protocol, b) evidence that I have been added to the UTSW protocol per the UTSW IRB, c) continuing renewal letter from UTSW IRB, stating that the study is current/active.

As to IRB mod approval, Samita and I were introduced to the process of submitting protocol modifications to the IRB (we both required Spanish versions of the Informed Consent Form as well as the HIPAA Authorization). When submitting a mod, two (2) versions of the mod need to be submitted: a tracked review of the documents showing the modifications made (dated), as well as a clean copy of the document (dated). After a mod has been made, it is submitted to the PI so that it may be submitted to the IRB. Only the PI may submit modified documents to the IRB.

The ever-present specter of a review of literature continued. I reviewed articles addressing long-term anticoagulant treatment with both VKAs and NOACs using the COM-B approach (capability, opportunity, motivation, and behavior). This approach works to better establish/ improve the patient's ability to take manage their own medications, improve patient adherence by lessening the complexity of their medication regimen if possible, and improve patient education about their condition and medications as well as address any concerns they may have about either.

Next was a review of compliance as it relates to Warfarin therapy in eligible patients. Successful patients have better communication with their doctors/ nurses about their condition, their treatment plan, and why it is important to be adherent. The point was made that those patients who adhere to a healthy lifestyle/ regimen, tend to be more adherent with diet and exercise, as well as their medications and appointments. Other research indicated that noted that

up to 1/3 of eligible patients meeting the criteria for VKAs were not prescribed them on discharge. This is significant because this particular study found that inpatients prescribed VKAs upon discharge had a higher rate of filling the prescription and staying compliant with the medication for up to one year, than did outpatients prescribed the medication after discharge who had a less high rate of filling the prescription or staying compliant for one year. Began an initial cursory review of the physiology of hemostasis.

*****WEEK 6 (7/3-7/6)*****

As with the previous week, as we were working through the credentialing process, Samita and I continued to practice mock enrollment interviews with each other. Received edits from Dr. Gwartz and continued to implement them into the draft of the research proposal. Submitted final draft of proposal.

Continued review of hemostasis and fibrinolysis. The plan is to review and get reacquainted with the physiology of blood clotting, atrial fibrillation, and how the separate drug interventions (VKAs, NOACs, heparin and its derivatives) are utilized to treat the condition.

*****WEEK 7 (7/10-7/14)*****

Attended introduction to IRB training class. It was a good review of good clinical practice (GCP) as well as a review of the Tuskegee Experiment, Nazi experiments, the Nuremburg Code, the Thalidomide Tragedy and the subsequent Kefauver-Harris Amendments, the Declaration of Helsinki, the National Research Act, and the Belmont Report. Furthermore, we revisited what IRBs are and what they do: “Ensure the protection of the rights and welfare of human subjects through the review of all research protocols involving human subjects, scientific validity, and ethical review.” Reviewed the Common Rule, “Exempt” and “Expedited” criteria, as well as the 111 criteria for IRB approval.

Went over IRB continuing reviews, study modifications, and reportable events (AEs/ SAEs, UPIRSOs) and their timelines for reporting, protocol violations and deviations.

Looked at what it takes for new study IRB submission: eIRB Study SmartForm, the study protocol, as well as the ICF, HIPAA authorization form, Investigator's Brochure, and the recruitment materials.

Reviewed the *process* of giving/ receiving informed consent (disclosing information so that the patient may make an informed decision, facilitating understanding, promoting the voluntariness of the decision to enroll or decline participation) per 45 CFR 46.116.

Later in the week, Samita and I attended an Emergency Department Research meeting about DISC test results for the department staff. DISC stands for: Dominance, Influence, Steadiness, Conscientious. The idea was to discover how our personalities affect our behavior, and how are behavior affects those around us. The concept is that once we learn what our strong character traits are, as well as those of our co-workers, we can adapt to accommodate those around us. I received and completed my own DISC survey. Not surprisingly, I'm a CS/ CS (Conscientious and Steadiness). I found it very interesting to see how by adapting my behavior to others, we may be more compatible when working together.

Samita and I began working on a Quality Improvement Project for Shannon concerning how to address the ways to prevent/ reduce the number of patients who walk out of the ED without being seen/ treated. It was proposed that this number could potentially be reduced by allowing TEMRAP students/ interns to go into the waiting area of the ED and talk with patients who were waiting to be treated. It is believed that by doing so, the number of patients who left without being treated would decrease, and that there would be a concomitant increase in patient satisfaction.

In my background review of the topic for writing the QIP protocol, I found that prior research had shown that patients who leave without being seen (LWBS) tended to be male, younger, of minority race, uninsured or on Medicaid, and non-English speaking. Furthermore, patients who LWBS had probably walked out previously without being seen/ treated. Another article from Sweden noted that when compared to nurse-led triage physician-led triage teams seemed to show improved efficiency as well as quality.

*****WEEK 8 (7/17-7/21)*****

Continued to read pulled articles for the Quality Improvement Project concerned with addressing the incidences of patients leaving the PMH ED without being treated:

The first article addressed reducing waiting time (length of stay) by implementing a new triage style known as Medical Team Evaluation (MET), which involves having a treating physician on the front-end of the patient's care. Implementing such practice was found to decrease waiting time for patients, especially those with an Emergency Severity Index (ESI) of 4 and 5, as well as a 2 and 3. Patients with an acuity of 1 require rapid intervention and are usually a priority.

Another article put forth the query of how long patients were willing to wait to be seen. Utilizing surveys, it was found at specific facility, patients were usually willing to wait up to two hours, before leaving the ED.

Yet another expounded upon using an Early quick Acuity Score (EQAS) in triage to facilitate a faster through time for patients, as opposed to the Traditional Acuity Score (TAS). The premise discussed proposes that when LWBS patients leave and have no ESI score, the data is lacking about the demographic make-up of these patients. And since there is no data to look

into, addressing the issue of why patients leave before they are seen/ treated is more difficult to address/ ascertain.

The fourth article (and one pertinent to the TEMRAP students getting involved) addressed decreasing ED wait times by streamlining patient intake/ triage and reducing redundancies in the clinical flow the patient receives, and utilizing “patient partners” on the front-end of the patient in-take. The article proposed that it is possible to improve a facility without implementing high costs. Not only did the ED efficiency improve, but so did patient satisfaction.

The next article described the effectiveness of using Resident Physicians as Triage Liaison Providers on the front end of ED patient treatment. This model when compared to a similar design utilizing Attending Physicians in the same capacity was found to be effective in reducing Door to Provider time (DTP), increasing patient satisfaction, reducing LWBS percentages, and proved to be more cost effective with a greater return on investment (ROI).

And finally, the remaining article sought to reduce LOS stay by introducing a “Flexible Care Area” (FCA) into their existing ED. It is a front-end strategy, similar to the fast-track model of treating low acuity patients (ESI 3-5). The patients are “kept vertical” in the FCA, while sicker patients (ESI 1-2) are treated in ED beds. LOS is reduced, as less ill patients which require fewer resources are treated, and “fast-tracked;” whereas ESI more resources are able to be utilized on the 1s and 2s. The authors noted that LWBS was reduced as well with this model.

After submitting the QIP protocol, I was given an opportunity for another side project for Shannon regarding the VAS Pain Scale Study which pertained to how ED nurses and physicians subjectively interpreted a patient’s level of pain when compared to the patient’s own interpretation of pain level. The study sought to find and address any inherent biases ED staff

may have had towards any subpopulations that come into the ED with a chief complaint of pain. My role in this was to take the demographic data and VAS scores from the patient and the corresponding ED staff who treated them and put the data in a coded format into a database/spreadsheet format so as to facilitate ease of access for when the biostatistician interpreted the data.

*****WEEK 9 (7/24-7/28)*****

Turned in the requisite forms (Research Proposal forms as well as Intent to Graduate form) to the Graduate School of Biomedical Sciences office. Found out as well that our studies have been approved by the UNTHSC IRB. Completed imputing coded data for the VAS study. Began working on the Parkland Pathways modules as part of the credentialing process to gain access to the Parkland ED.

Spent the day going over hemostasis, with special attention paid to the different factors of the Intrinsic and Extrinsic as well as common pathways. Addressed how these three pathways are essential for the creation of Thrombin, and the subsequent role the latter plays in the creation of Fibrin as well as the roles of platelets and Ca^{2+} in the clotting process.

Reviewed the role of Plasmin in dissolving clots (Fibrin Degradation), as well as the role of anticoagulants both natural and prophylactic. Addressed several morbidities including a) Thrombocytopenia b) Hepatic Failure c) Disseminated Intravascular Coagulation (DIC) d) Hemophilia (A and B). Went over the various coagulation tests that may be performed to ascertain if a patient's specific Clotting times are within normal/ acceptable ranges:

1. Prothrombin Time (PT) – evaluates extrinsic pathway
2. International Normalized Ratio (INR) – used in monitoring warfarin therapy
3. Activated Partial Thromboplastin Time Test (aPTT) – evaluates intrinsic pathway
4. Thrombin Time (TT) – used in monitoring Heparin therapy

5. Whole Blood Clotting Time – reflects the time of thrombin generation.

Any deviation from normal bleeding times may be indicative of defects in the vasculature, platelet function and count, as well as due to drugs such as dextran, indomethacin, and salicylates.

Was introduced to the electronic patient information center (Epic) system. I was trained on how to screen patients in the ED by Khushbakht Bakhshi, a research coordinator in the Emergency Medicine Research Department. When screening, it is paramount to take good notes of all the patients screened, as it is against practice to just randomly select patient charts. One is to only review/ screen those charts where the patient seems to initially meet the inclusion criteria. Proper documentation is imperative in the event of audits, so that documentation and practices may be satisfactorily reviewed.

Later in the week, I followed Khushbakht down to the ED to observe how prescreened patients are to be properly approached and enrolled, should they meet study inclusion criteria. It is imperative to confirm each of the inclusion criteria as well as any of the exclusion criteria. Document everything, even when just screening Epic for potential subjects.

*****WEEK 10 (7/31-8/4)*****

Completed the Parkland training modules pertaining to HIPAA, patient abuse reporting, personal protective equipment (PPE), “Code Green”, reporting agencies such as the DOJ, TXDHHS, and OCR, the Emergency Medical Treatment and Labor ACT (EMTALA), patient rights, fraud, as well as the Anti-Kickback Statute and Stark Law. Submitted completion certificates and proof of study participation to Research Credentialing.

At this week's Emergency Department meeting, the proper procedures for exceptions from informed consent were discussed: it is an emergency situation, treatment is needed immediately, the patient cannot consent, and there must be the prospect of benefit. Current studies which fell into this category were the ESETT study and the ACCESS study. We also discussed modifications for carrying out Community Consultation Plan (CCP) as well as opt-out mechanisms for patients in the study population wish to opt out. A recent "Watchdog" article painted the Emergency Medicine Research Department in a negative light. Basically, the article made much to do about nothing, but was written with such a slant as to indicate that the research being conducted here does not give one iota for the rights, safety, and welfare of patients.

Began a review of atrial fibrillation and treatment. Topics addressed included an increase in stroke risk with an increase in age. Associated risk factors include mitral valve stenosis, prosthetic heart valves, PMH of previous stroke or TIA [highest risk for subsequent stroke], age > 75 y/o (or between the ages of 65-75), HTN, DM, CHF, decreased liver function, CAD, female gender, thyrotoxicosis. Several of these can be used to interpret the risk of stroke utilizing the patient's CHADS₂ score. Low risk is 0-1; moderate to high risk is ≥ 2 . Polypharmacy was noted as being a strong predictor for anticoagulant non-adherence in patients with atrial fibrillation.

The pros and cons of warfarin therapy were addressed:

- Cons: have a delayed onset/ offset, an unpredictable dose response, a narrow therapeutic range, drug-drug and drug-food interactions, problematic monitoring, high bleeding rates, slow reversibility, excessive dosing predisposes patient to hemorrhage, inadequate dosing predisposes patient to stroke/ pulmonary embolism, proper dosing is usually found by trial and error, INR monitored at least monthly (every 2-4 weeks)

- Pros: INR assesses anticoagulant level (optimal therapeutic range is between 2.0-3.0), ability to maintain INR is improving, multiple antidotes are available (Vitamin K), omitting one or two doses is not clinically problematic, no liver toxicity, it has been around since 1954, inexpensive, no anticoagulant has demonstrated superior efficacy or safety.

It should be noted however that the novel oral anticoagulants (NOACs) have been rather well received as an alternative to the traditional route of warfarin. The NOACs include Dabigatran, Rivaroxaban, Edoxaban, and Apixaban. They do not require INR monitoring, have a more dependable pharmacology, and have been found to be just as effective as Warfarin as a prophylaxis for stroke, and are better tolerated in elderly patients. On the other hand, NOACs have fewer effective antidotes in the event of trauma.

The Intrinsic and Extrinsic pathways are dependent upon Vitamin K1 and K2.

The Intrinsic Pathway involves all clotting factors *within* the blood vessel, has a slower clotting time, and utilizes the activated partial thromboplastin test (aPTT).

The Extrinsic Pathway involves the initiating factor (tissue factor) outside of the blood vessel, has a faster clotting time, and utilizes the Prothrombin test (PT).

Heparin works on the activated factors of the intrinsic pathway (XIIa, XIa, IXa, Xa, Thrombin).

VKA work on factors within both the extrinsic and intrinsic pathways (VII, IX, X, II [Prothrombin], as well as Proteins C, S, and Z).

WEEK 11 (8/7-8/11)

Began the week with a review of the effects of heparin on hemostasis. Heparin has a high affinity for activated Factor X (Xa), but less so of an effect on thrombin. To have its effect on Xa, heparin must interact with ATIII (Antithrombin III); heparin potentiates the actions of ATIII. To have an effect on thrombin, heparin must bind with ATIII as well as an enzyme. The

heparin/ ATIII complex neutralizes the actions of Factors II (thrombin), IX, X, XI, XII, XIII. “Thrombin-induced activation of Factors Va and VIIIa is inhibited by the heparin/ ATIII complex.” Low concentrations (“mini-doses”) of heparin are sufficient to carry out anticoagulant functions. Platelet Factor IV (from endothelial cells) is a protein which can neutralize heparin. Anticoagulant effects of heparin disappear within hours of cessation of infusion. Adverse effects of heparin may include thrombocytopenia and/ or thrombosis as well as potential osteoporosis. On the other hand, heparin may be indicated in pregnant mothers, as it does not cross the placenta, and has no untoward effects on the fetus.

Weekly Emergency Medicine Department meeting discussed the TXA study as well as the ESETT study. We reviewed exceptions from informed consent as well as community consultation protocols, especially in light of the recent “Watchdog” article, which actually turned out to be a blessing: given its wide circulation and distribution (paper and internet), the article actually informed *more* people about the study and how to opt out of it if they wanted to (non-consent bracelet and necklace). Basically, it was free advertising.

Had an introduction and data abstractor training session for the study *The Influence of Time-to-Diagnosis on Time-to-Treatment for STEMI Patients*. The study is a retrospective cohort study. The PI for the study is Dr. Maya Yiadom of the Emergency Medicine Department at Vanderbilt University. The study is looking at data from seven different medical facilities across the country for the years 2014-2016 (review of electronic health records for STEMI ED patients). The aim of the study is to determine the effect the time-to-diagnosis has on time-to-treatment for STEMI patients as it relates to patient survival up to one year post STEMI. The study “will quantify the differences in the diagnosis-to-treatment interval,” in the two patient populations.

Samita and I practiced working through a patient's chart to extract information for the STEMI study. Practicing looking through EPIC required a good bit of detective work and intuition. There were 9 instruments used to gather patient data: i) Hospitalization ii) Demographics iii) Emergency Department iv) Electrocardiograms v) Past Medical History vi) Initial Laboratory Results vii) STEMI Intervention viii) Ejection Fractions ix) Follow-up. Of particular importance, were the EKG diagnosis times and the time to the CATH-Lab (times and notes). After gathering the information into packets, we practiced putting the respective information into RedCap. It took much practice to get efficient at locating the requisite information in Epic. Furthermore, printing source documents was imperative as well.

*****WEEK 12 (8/14-8/18)*****

Began a review of anticoagulants, antiplatelets, and thrombolytics. This pertained to the heparins and hirudin (leeches), warfarin, aspirin, and streptokinase. Essentially, the mechanism of action, structure, metabolism, $T_{1/2}$, dosing, as well as the requisite antidote in the event of bleeding were discussed.

Samita and I continued to practice data extraction from Epic for the STEMI study (pertaining to the time from diagnosis to time of treatment and the respective link to patient outcome), and inputting the data into RedCap. We also helped out with the orientation for the Fall TEMRAP students' orientation. This included them getting their UTSW access badges, how they were to conduct themselves while in the ED, HIPAA, the role they would play in the upcoming quality improvement project (reducing the number of patients who leave the ED without being treated), and getting credentialed.

Began screening patients for the atrial fibrillation study in Epic. It was at this early point that I began to suspect that enrollment numbers would be more difficult to obtain than I had

initially expected. Of the patients I was screening as potential enrollees based on their signs and symptoms an concomitant chief complaint, very few were meeting inclusion criteria. Screened 57 patients this week, with zero meeting inclusion criteria.

*****WEEK 13 (8/21-8/25)*****

Discussed with Khushbakht the proper procedure for enrolling patients: Locate the POD in which the patient was located and approach the treating physician to find out whether or not the patient met inclusion criteria as well as whether or not it was permissible to approach the patient (altered mental status, too sick, etc.), confirm the patient's identity, explain the study to them and their role in it, and ask if they would like to participate, thoroughly go through/ explained the IFC and HIPAA authorization forms and sign, patient demographics, and finally, complete the study surveys.

This was the first week where I spent a good amount of time actively screening potential patients for the atrial fibrillation study. I checked for an INR score between 2.0-3.0, an ECG of atrial fibrillation/ flutter, the patient's past medical history, as well as current and past medications. Given how some signs and symptoms could be ambiguous and indicative of a myriad of ailments, I began to lean more towards screening patients 40 years and older, as atrial fibrillation (along with other stroke risk factors) appears more in older patient populations. If nothing changed and recruitment remained low, we (Shannon and I) discussed modifying the protocol via the IRB to screen for patients who had been admitted via the ED.

This week I prescreened 137 potential patients, zero met inclusion criteria. Because we were looking for non-compliant patients, we excluded those patients who were compliant, in line with the inclusion criteria developed for *my* study. We have since adopted the original inclusion

criteria of the University of Texas Southwestern protocols: the patient has a history of atrial fibrillation and *is on* anticoagulants.

Samita and I helped out with the orientation for the second batch of TEMRAP students. Same procedures as before.

*****WEEK 14 (8/28-8/31)*****

Spent much of this week actively screening for potential patients. I prescreened 95 patients and enrolled five. Entered those already recruited into Velos (links patients enrolled in studies by UT Southwestern to their Parkland medical records number).

*****WEEK 15 (9/5-9/8)*****

Spent much of this week actively screening for potential patients utilizing original UTSW protocol inclusion criteria. One day in particular proved to be rather frustrating: I went down to the ED to recruit. Had difficulty locating patients, as a mass casualty incident moved them around the ED to different pods/ rooms. The one patient I was able to locate was not currently on anticoagulants; therefore, they did not meet the less-restrictive inclusion criteria. On another occasion, the patient I was able to locate had impaired vision and could not complete the NVS portion of the surveys as they could not read/ see the nutrition label utilized for that particular study.

I was able to enroll two Spanish speaking patients with the assistance of a Parkland interpreter. This turns the enrolling process from a 15-20 minute long procedure into one that can last up to one hour, given the length and subjectivity of some of the surveys, particularly the Perception of Anticoagulation Treatment Questionnaire (PACT-Q).

Continued data extraction for the STEMI study from Vanderbilt.

I prescreened 108 patients this week, and enrolled a total of three.

*****WEEK 16 (9/11-9/15)*****

Enrollment number for this week were as follows: Prescreened 116 for eligibility, approached 10 meeting inclusion criteria, and was able to successfully enroll four.

Emailed Dr. Gwartz regarding enrollment numbers and my concern that the study will not reach power. The following numbers were sent in the email:

Table 3: Enrollment Trend at Four Weeks

Sean's study											
Start Date: Aug 17, 2017	#	%	per day	per week							
Business Days	21										
Weeks	4										
Patients Pre-Screened	523		25	131							
Patients Meeting Inclusion Criteria	23	4%	1	5	eligibility rate						
Patients Approached	21	91%	1	5	approach rate (of those eligible)						
Patients who remained eligible after screening	14	67%			eligibility rate						
Patients Enrolled	13	93%	1	4	enrollment rate (of those approached)						
Patients refused	1	7%			refusal rate (of those approached who remained eligible after screening)						
Rate	2.49%										
Patients Enrolled per Week	3.25										
Expected Enrollment in the Six Week Period	19.5 (+/-)										

Based on these numbers, I had pre-screened on average 25 patients per day, 131 per week. Of those patients pre-screened, 23 (4%) met the inclusion criteria. Of those, 21 (91%) had been approached, with 14 (67%) remaining eligible. Of those remaining eligible after screening, 13 (93%) had been enrolled; one patient (7%) refused participation.

The enrollment rate was above the 90th percentile for those meeting the inclusion criteria. The issue at hand was that the number of those meeting the inclusion criteria was much lower than expected. Another unforeseen barrier was the one week suspension of enrollment near the end of the enrollment period.

Worked on the Vanderbilt STEMI study and continued data abstraction. Attended meeting for the TEMRAP trainers and filled them in on the recruiting procedures for the A-Fib Study.

*****WEEK 17 (9/18-9/23)*****

Worked on the Vanderbilt STEMI study and continued data abstraction for the majority of this week. I was able to complete the case forms for 12 out of 50 STEMI patients for 2014. Site approval was granted that Friday. Enrolling was therefore able to continue.

Came in with Mario and Samita to help Shannon out with the STEMI study that Saturday. Printed off the source documents for the MRNs already completed. I completed 18 cases, and printed the source documents for nine.

*****WEEK 18 (9/25-9/29)*****

Enrollment number for this week were as follows: Prescreened 151 for eligibility, approached 6 meeting inclusion criteria, and was able to successfully enroll one.

Completed more Parkland Pathways training: Emergency Operations for 2017 and Abuse & Neglect.

Assembled recruitment packet pdf for the TEMRAP students and assembled two folders with the study materials to be available down in the ED for TEMRAP students should they be able to locate and enroll potential patients. Went to the Parkland to drop folders off in the ED for the TEMRAP students as well as went by Language Services to service the Alvin Unit (mobile translating device).

*****WEEK 19 (10/2-10/6)*****

Prescreened a total of 28 for eligibility, approached three meeting inclusion criteria, and was able to successfully enroll one. This was the last week of patient enrollment. For the remainder of the week, Samita and I along with Shannon met with the biostatistician and turned over our compiled data. We began working on the body of our respective theses as well as beginning our Power Point presentations. It was also during this time than Samita and I came up with a road map setting a timeline for the completion of our research and presentations.

*****WEEK 20-22 (10/9-10/27)*****

The last three weeks were spent summarizing the daily journal, making figures, working on the PowerPoint presentation, and working on the body of the thesis prior to submittal.

APPENDICES:

APPENDIX A: SUPPLEMENTAL DATA

Table 1A: Distribution of NVS Scores

NVS_Score	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	3	20.00	3	20.00
1	4	26.67	7	46.67
2	3	20.00	10	66.67
4	1	6.67	11	73.33
6	4	26.67	15	100.00

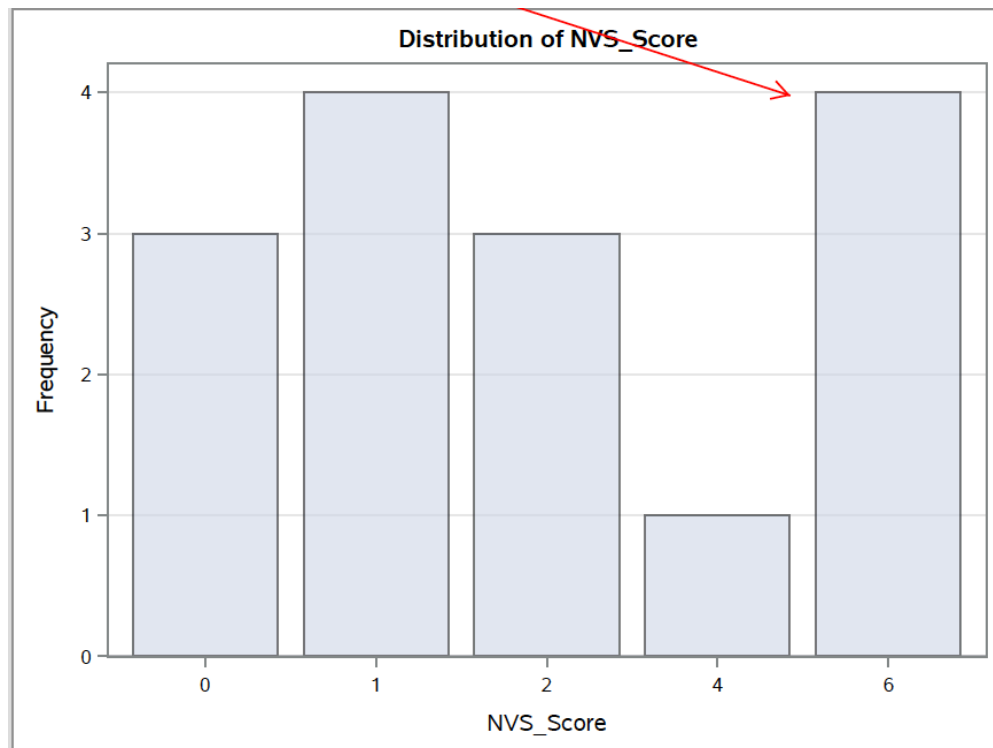


Figure 1A: Distribution of NVS Scores

Table 2A: Distribution of MMS Motivation Scores

Motivation_Score	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	2	13.33	2	13.33
1	2	13.33	4	26.67
2	6	40.00	10	66.67
3	5	33.33	15	100.00



Figure 2A: Distribution of MMS Motivation Scores

Table 3A: Distribution of MMS Knowledge Scores

Knowledge_Score	Frequency	Percent	Cumulative Frequency	Cumulative Percent
2	3	20.00	3	20.00
3	12	80.00	15	100.00

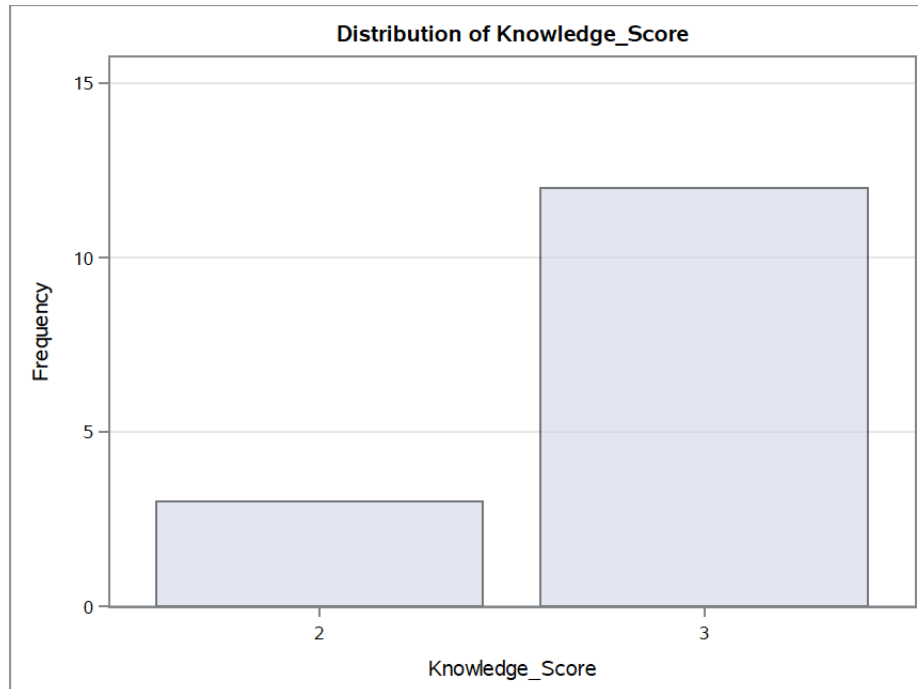


Figure 3A: Distribution of MMS Knowledge Scores

Table 4A: Distribution of NVS Scores by Motivation Scores

Frequency Percent Row Pct Col Pct	Table of NVS_Score by Motivation_Score					
	NVS_Score	Motivation_Score				Total
		0	1	2	3	
	0	0 0.00 0.00 0.00	1 6.67 33.33 50.00	2 13.33 66.67 33.33	0 0.00 0.00 0.00	3 20.00
	1	0 0.00 0.00 0.00	1 6.67 25.00 50.00	0 0.00 0.00 0.00	3 20.00 75.00 60.00	4 26.67
	2	1 6.67 33.33 50.00	0 0.00 0.00 0.00	2 13.33 66.67 33.33	0 0.00 0.00 0.00	3 20.00
	4	1 6.67 100.00 50.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	1 6.67
	6	0 0.00 0.00 0.00	0 0.00 0.00 0.00	2 13.33 50.00 33.33	2 13.33 50.00 40.00	4 26.67
	Total	2 13.33	2 13.33	6 40.00	5 33.33	15 100.00

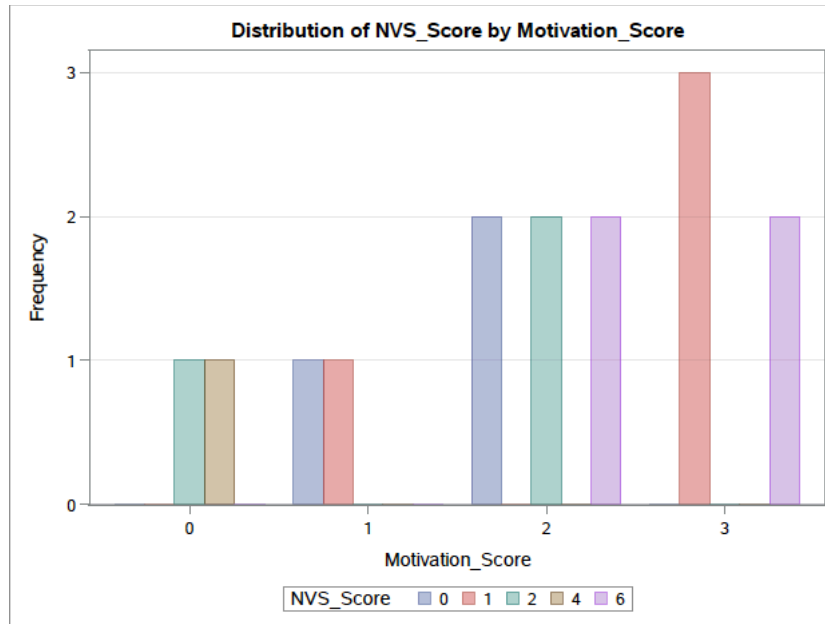


Figure 4A: Distribution of NVS Score by Motivation Score

Table 5A: Statistics of NVS Score by Knowledge Score

Statistics for Table of NVS_Score by Knowledge_Score			
Statistic	DF	Value	Prob
Chi-Square	2	0.4762	0.7881
Likelihood Ratio Chi-Square	2	0.4473	0.7996
Mantel-Haenszel Chi-Square	1	0.0795	0.7779
Phi Coefficient		0.1782	
Contingency Coefficient		0.1754	
Cramer's V		0.1782	
WARNING: 83% of the cells have expected counts less than 5. Chi-Square may not be a valid test.			
Fisher's Exact Test			
Table Probability (P)		0.2308	
Pr <= P		1.0000	
Sample Size = 15			

Table 6A: Table of NVS Score by Knowledge Score

Frequency Percent Row Pct Col Pct	Table of NVS_Score by Knowledge_Score			
	NVS_Score	Knowledge_Score		
		2	3	Total
	0-1	1 6.67 14.29 33.33	6 40.00 85.71 50.00	7 46.67
	2-3	1 6.67 33.33 33.33	2 13.33 66.67 16.67	3 20.00
	4-6	1 6.67 20.00 33.33	4 26.67 80.00 33.33	5 33.33
	Total	3 20.00	12 80.00	15 100.00

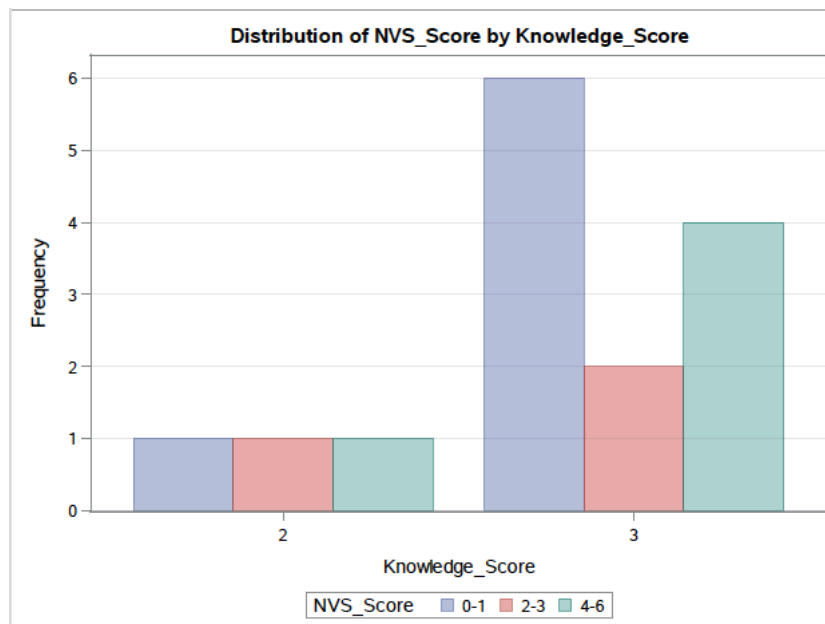


Figure 5A: Distribution of NVS Score by Knowledge Score

Table 7A: Statistics for Table of NVS Score by Motivation Score

Statistics for Table of NVS_Score by Motivation_Score

Statistic	DF	Value	Prob
Chi-Square	2	0.1948	0.9072
Likelihood Ratio Chi-Square	2	0.1986	0.9055
Mantel-Haenszel Chi-Square	1	0.0886	0.7660
Phi Coefficient		0.1140	
Contingency Coefficient		0.1132	
Cramer's V		0.1140	
WARNING: 83% of the cells have expected counts less than 5. Chi-Square may not be a valid test.			

Fisher's Exact Test	
Table Probability (P)	0.2308
Pr <= P	1.0000

Sample Size = 15

Table 8A: Table of NVS Score by Motivation Score

Frequency Percent Row Pct Col Pct	Table of NVS_Score by Motivation_Score			
	NVS_Score	Motivation_Score		
		0-1	2-3	Total
	0-1	2 13.33 28.57 50.00	5 33.33 71.43 45.45	7 46.67
	2-3	1 6.67 33.33 25.00	2 13.33 66.67 18.18	3 20.00
	4-6	1 6.67 20.00 25.00	4 26.67 80.00 36.36	5 33.33
	Total	4 26.67	11 73.33	15 100.00

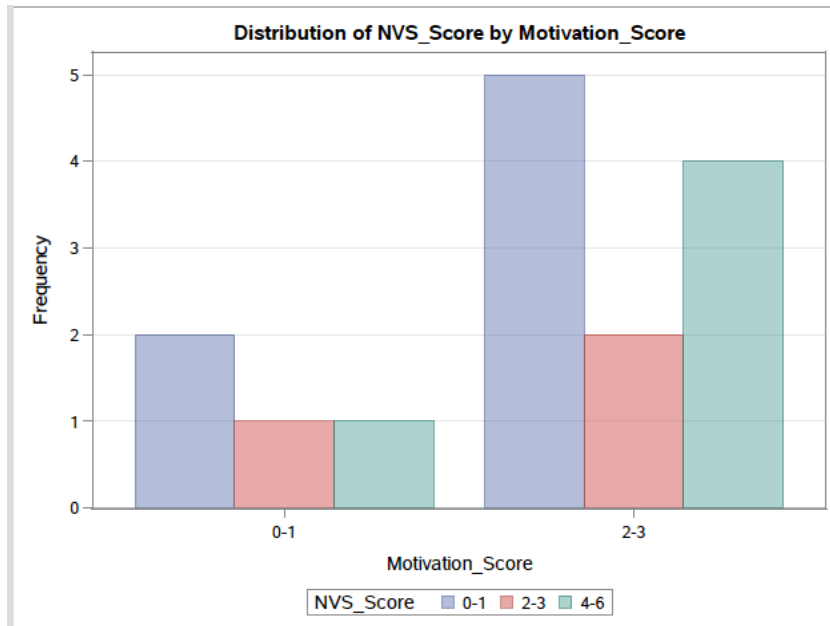


Figure: 6A: Distribution of NVS Score by Motivation Score

Table 9A: Statistics of NVS Score by Motivation Score

Statistics for Table of NVS_Score by Motivation_Score

Statistic	DF	Value	Prob
Chi-Square	12	18.2917	0.1071
Likelihood Ratio Chi-Square	12	20.4188	0.0596
Mantel-Haenszel Chi-Square	1	0.2416	0.6230
Phi Coefficient		1.1043	
Contingency Coefficient		0.7412	
Cramer's V		0.6376	
WARNING: 100% of the cells have expected counts less than 5. Chi-Square may not be a valid test.			

Fisher's Exact Test	
Table Probability (P)	<.0001
Pr <= P	0.0871

Sample Size = 15

Table 10A: Table of Education by NVS Score

Frequency Percent Row Pct Col Pct	Table of Education_Code by NVS_Score		
	Education_Code	NVS_Score	
		0-3	4-6
	no HS degree	8 53.33 100.00 80.00	0 0.00 0.00 0.00
	HS or College	2 13.33 28.57 20.00	5 33.33 71.43 100.00
	Total	10 66.67	5 33.33
			15 100.00

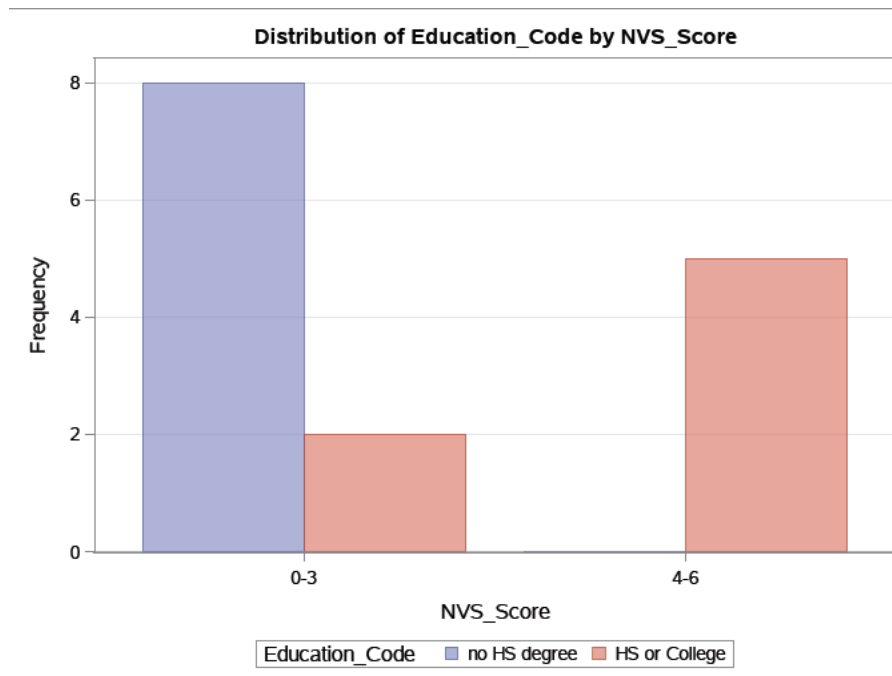


Figure 7A: Distribution of Education by NVS Score

Table 11A: Statistics for Education by NVS Score
Statistics for Table of Education_Code by NVS_Score

Statistic	DF	Value	Prob
Chi-Square	1	8.5714	0.0034
Likelihood Ratio Chi-Square	1	10.7197	0.0011
Continuity Adj. Chi-Square	1	5.6585	0.0174
Mantel-Haenszel Chi-Square	1	8.0000	0.0047
Phi Coefficient		0.7559	
Contingency Coefficient		0.6030	
Cramer's V		0.7559	
WARNING: 75% of the cells have expected counts less than 5. Chi-Square may not be a valid test.			

Fisher's Exact Test	
Cell (1,1) Frequency (F)	8
Left-sided Pr \leq F	1.0000
Right-sided Pr \geq F	0.0070
Table Probability (P)	0.0070
Two-sided Pr \leq P	0.0070

Sample Size = 15

Table 12A: New Power for Study

Spearman correlation power.						
Numeric Results for Testing Correlation Hypotheses: H0: $\rho_s = 0$; H1: $\rho_s \neq 0$						
					Detectable correlation	
	Sample			H0	H1	
	Size	Target	Actual	Corr	Corr	Target
	N	Power	Power	ρ_0	ρ_1	Alpha
	374	0.8	0.821	0	0.15	0.05
	181	0.8	0.798	0	0.2	0.05
	130	0.8	0.802	0	0.25	0.05
	87	0.8	0.822	0	0.3	0.05
	51	0.8	0.81	0	0.4	0.05
	33	0.8	0.801	0	0.5	0.05
	21	0.8	0.81	0	0.6	0.05

APPENDIX B: IRB FORMS

6/27/2017

<https://eresearch.swmed.edu/eIRB/Doc/0/JQL48N8LH4I4DBN24PKS70TDA0/fromString.html>

UT Southwestern
Medical Center

eIRB System

From: [Waley Hua](#)
Institutional Review Board
IRB - 8843

To: [Deborah Diercks](#) , [Shannon McNabb](#)

Date: Tuesday, June 27, 2017

Re: Modification Approval

IRB Number: STU [042017-076](#)

Modification Number: Mod1_STU [042017-076](#)

Title: Factors Associated with Anticoagulation Non-adherence in an Emergency Department Patient Population with Atrial Fibrillation

A modification to the above referenced study regarding changes to study personnel is has been approved by the UT Southwestern Institutional Review Board (IRB) via an expedited review procedure on Tuesday, June 27, 2017 in accordance with 45 CFR 46.110(a)-(b)(2). The approval period for the modified research study will begin on Tuesday, June 27, 2017 and lasts until Friday, May 04, 2018.

If you have any questions related to this approval letter or about IRB policies and procedures, please telephone the IRB Office at [214-648-3060](tel:214-648-3060).

Warning: This is a private message for authorized UT Southwestern employees only. If the reader of this message is not the intended recipient you are hereby notified that any dissemination, distribution or copying of this information is STRICTLY PROHIBITED.



University of Texas Southwestern Medical Center
Institutional Review Board

5323 Harry Hines Boulevard
Dallas, Texas 75390-8843
phone: [214-648-3060](tel:214-648-3060)
fax: [214-648-2171](tel:214-648-2171)

<https://eresearch.swmed.edu/eIRB/Doc/0/JQL48N8LH4I4DBN24PKS70TDA0/fromString.html>

1/2

6/27/2017

Print: Mod1_STU 042017-076 - Modification 1 for IRB Study #STU 042017-076

UT Southwestern Medical Center

eResearch eIRB/eCOI/eOAE

Date: Tuesday, June 27, 2017 4:36:03 PM

View: 1.0 Modification Type

Print Close

[Help](#)

1.0 Modification Type

* 1.0 What type of change is being made?

Administrative Change - For example: change in Study personnel (not including PI/CO-I), minor administrative/grammatical changes to study materials (ICD, Protocol, advertisements, etc.) which don't change meaning, etc.

* 1.1 Check all that apply:

☒ Study Personnel

☐ Principal Investigator☐ Co-Investigator☐ Protocol☐ Investigator Brochure☐ Consent Form☐ HIPAA Authorization☐ HIPAA Waiver of Authorization☐ Target Enrollment☐ Recruitment Materials☐ Other

1.2 If this modification corresponds with a modification requested by the study sponsor, please provide the modification name/number, protocol version or other identifier(s):
Adding Sean Harla to the study

View: 11.0 Study Personnel

11.0 Study Personnel

Current Research Coordinator:

Shannon McNabb

11.1 Primary Research Coordinator:

Shannon McNabb

Current Primary Administrative Contact:

Shannon McNabb

11.2 Primary Administrative Contact:

Shannon McNabb

Current Other Study Personnel:

Last Name	First Name	HIPAA	GCP	HSP
Bakhshi	Khushbakht	10/22/2015	10/21/2015	10/22/2015
Harla	Sean			
Jiang	Janice	11/28/2016	11/28/2016	11/28/2016
McNabb	Shannon	4/26/2016	4/28/2016	5/4/2016
Puente	Mario	3/11/2016	3/11/2016	3/11/2016

11.3 Other Study Personnel:

Last Name	First Name	HIPAA	GCP	HSP
Bakhshi	Khushbakht	10/22/2015	10/21/2015	10/22/2015
Harla	Sean			
Jiang	Janice	11/28/2016	11/28/2016	11/28/2016
McNabb	Shannon	4/26/2016	4/28/2016	5/4/2016
Puente	Mario	3/11/2016	3/11/2016	3/11/2016

Current Non-UTSW Study Personnel

Last Name	First Name	Middle Name	Institution
There are no items to display			

11.4 Non-affiliated Study Personnel:

Last Name	First Name	Middle Name	Institution
There are no items to display			

<https://eresearch.swmed.edu/eIRB/ResourceAdministration/Project/PrintSmartForms?Project=com.webbridge.entity.Entity%5B0ID%5BEAAD2E0C6D7...> 1/2

6/27/2017

Print: Mod1_STU 042017-076 - Modification 1 for IRB Study #STU 042017-076

11.5 Do the study personnel changes affect the consent form?

Yes ☐ No ☒

View: 14.0 Summary of Changes and Next Steps

14.0 Summary of Changes and Next Steps

14.1 You Indicated this modification is changing/updating the following items:
Study Personnel

Note: If administrative or other changes are indicated, please ensure that all applicable sections have been revised/updated.

14.2 Please follow the link to edit the study:

[MS1_STU 042017-076](#)

14.3 Comments:

Added Sean Harla

The University of Texas Southwestern Medical Center
Parkland Health & Hospital System

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: Factors Associated with Anticoagulation Non-adherence
in an Emergency Department Patient Population with
Atrial Fibrillation

Funding Agency/Sponsor: UT Southwestern Medical Center

Study Doctor: Dr. Deborah Diercks

You may call the study doctor or research personnel during regular office hours at 214-648-7207. At other times, you may call them at 214-648-7207.

Instructions:

Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?

This study is being done to determine in patients presenting to the ED with Atrial Fibrillation, if there are factors that impact adherence with anticoagulation. By looking at patient preferences through the Perception AntiCoagulant Treatment Questionnaire (PACT-Q), literacy, and risk factors we hope to add to the body of evidence on this topic.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you have Atrial Fibrillation.

Do I have to take part in this research study?"

No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.



If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?

About 250 people will take part in this study at UT Southwestern and Parkland Health & Hospital System.

What is involved in the study?

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

Screening Procedures

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

Procedures and Evaluations during the Research

Once the patient has given informed consent, the following questionnaires will be verbally administered:

- a. Data Collection Form
- b. Perception AntiCoagulant Treatment Questionnaire
- c. Newest Vital Sign Questionnaire
- d. Modified Morisky Scale

The treating physician will then be asked to complete their portion of the data collection form.

How long can I expect to be in this study?

It should take less than 15 minutes to complete these surveys. You and your doctor will not be given the results of these surveys. This is all you are required to do for this research study.

You can choose to stop participating for any reason at any time.

What are the risks of the study?

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be



guaranteed. This risk will be minimized by coding of patients' data and protection of private health information. This study will abide by all federal, state, and institutional regulations in place governing the protection of human subjects and protected health information, to the extent allowed by law.

What are the possible benefits of this study?

If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with Atrial Fibrillation in the future. Information gained from this research could lead to better management protocols for these patients.

What options are available if I decide not to take part in this research study?

This is not a treatment study. You do not have to be part of it to get treatment for your condition.

Will I be paid if I take part in this research study?

No. You will not be paid to take part in this research study. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?

No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?

It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Parkland Health & Hospital System.

You retain your legal rights during your participation in this research



Can I stop taking part in this research study?

Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

Will my information be kept confidential?

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Research Administrators and Auditors from this hospital
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Whom do I call if I have questions or problems?

For questions about the study, contact Dr. Diercks at 214-648-7207 during regular business hours and at 214-648-7207 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.



SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

Name of Participant (Printed)

Signature of Participant

Date

Time

AM / PM

Name of Person Obtaining Consent (Printed)

Signature of Person Obtaining Consent

Date

Time

AM / PM



The University of Texas Southwestern Medical Center
Parkland Health & Hospital System

**CONSENTIMIENTO PARA PARTICIPAR EN UNA
INVESTIGACIÓN**

Título de la investigación: Factores asociados con el incumplimiento del
tratamiento anticoagulante en una población de
pacientes con fibrilación auricular en el
Departamento de Emergencias

Organismo de financiamiento/patrocinador: UT Southwestern Medical Center

Médico del estudio: Dra. Deborah Diercks

Puede usted comunicarse con la médica del estudio o con el personal de
investigación, durante horas hábiles al 214-648-7207. Fuera de ese horario, se puede
comunicar con ella al 214-648-7207.

Instrucciones:

Lea detenidamente este formulario de consentimiento y tómese el tiempo para decidir si
desea o no participar. A medida que los investigadores hablen con usted sobre este
consentimiento, pídale que le expliquen cualquier palabra o información que no entienda
claramente. A continuación se indican el propósito del estudio, los riesgos,
inconvenientes, molestias y otra información importante acerca del estudio. Si decide
usted participar, se le entregará una copia de este formulario para que la conserve.

¿Por qué se realiza este estudio?

Estamos realizando este estudio para determinar si existen factores que afecten el
cumplimiento de tratamiento anticoagulante en pacientes que acuden al Departamento
de Emergencias (ED, por sus siglas en inglés) con fibrilación auricular. Al observar las
preferencias de los pacientes mediante el Cuestionario de Percepción de Tratamiento
Anticoagulante (PACT-Q, por sus siglas en inglés), el nivel de lectura y escritura y los
factores de riesgo, esperamos añadir pruebas a este tema.

¿Por qué se me pide participar en este estudio de investigación?

Se le ha pedido que participe en este estudio porque tiene usted fibrilación auricular.

¿Tengo que participar en este estudio de investigación?

No. Usted tiene el derecho a elegir si desea o no participar en este estudio de
investigación. Si decide participar y luego cambia de opinión, tiene plena libertad de
dejar de participar en cualquier momento.



Su decisión de no participar en este estudio de investigación no cambiará sus derechos legales ni la calidad de la atención médica que reciba en este centro.

¿Cuántas personas participarán en este estudio?

Aproximadamente 250 personas participarán en este estudio en UT Southwestern y Parkland Health & Hospital System.

¿Qué implica este estudio?

Si usted acepta voluntariamente participar en este estudio de investigación, se le pedirá que firme este formulario de consentimiento y se le realizarán las siguientes pruebas y procedimientos. Algunos procedimientos pueden ser parte de su atención médica estándar, pero otros se hacen únicamente para los fines de este estudio.

Procedimientos de selección

Para determinar si usted cumple con los requisitos para estar en este estudio, los investigadores le harán preguntas sobre su salud, incluidos los medicamentos que esté tomando y cualquier procedimiento quirúrgico al que se haya usted sometido.

Procedimientos y evaluaciones durante la investigación

Una vez que el paciente haya otorgado el consentimiento informado, se realizarán verbalmente los siguientes cuestionarios:

- a. Formulario de recopilación de datos
- b. Cuestionario de Percepción del Tratamiento Anticoagulante
- c. Cuestionario de los signos vitales más recientes
- d. Escala modificada de Morisky

Luego se le pedirá al médico responsable que complete su parte del formulario de recopilación de datos.

¿Cuánto durará mi participación en este estudio?

Completar las encuestas le tomará menos de 15 minutos. No se les darán los resultados de las encuestas ni a usted ni a su médica. Eso es lo único que se le pide para este estudio de investigación.

Usted puede elegir dejar de participar por cualquier motivo y en cualquier momento.

¿Cuáles son los riesgos del estudio?

Estrés psicológico

Algunas de las preguntas que le haremos como parte de este estudio podrían parecerle incómodas. Usted puede negarse a responder cualquier pregunta, tomar un descanso o interrumpir su participación en este estudio en cualquier momento.

Pérdida de confidencialidad

Siempre que se recopila información, existe el riesgo potencial de la pérdida de confidencialidad. Se hará todo lo posible por mantener la confidencialidad de su información; sin embargo, no puede garantizarse. Este riesgo se minimizará al



codificar la información del paciente y proteger la información médica privada. Este estudio cumplirá con todas las reglamentaciones federales, estatales e institucionales vigentes, que regulan la protección de sujetos humanos y la información médica protegida, en la medida en la que lo permita la ley.

¿Cuáles son los posibles beneficios de este estudio?

Si usted acepta participar en este estudio, podría no haber beneficios directos para usted. Los investigadores no pueden garantizar que usted se beneficie de la participación en esta investigación.

Esperamos que lo aprendido en este estudio beneficie en el futuro a otras personas con fibrilación auricular. La información obtenida en esta investigación podría conducir a mejores protocolos de control para estos pacientes.

¿De qué opciones dispongo si decido no participar en este estudio de investigación? Este no es un estudio de tratamiento. No tiene que participar en este estudio para recibir tratamiento por su afección.

¿Me pagarán si participo en este estudio de investigación?

No. Usted no recibirá ninguna remuneración por participar en este estudio de investigación. No hay fondos disponibles para cubrir gastos de estacionamiento, transporte de ida y vuelta al centro de investigación, horas de trabajo u otras actividades perdidas, ni salarios no recibidos o gastos de guardería infantil.

¿Le cobrarán a mi compañía de seguros o a mí parte de este estudio de investigación?

No, no se le cobrará a su compañía de seguros ni a usted lo que se realiza en el estudio de investigación (es decir, procedimientos de selección, procedimientos experimentales o procedimientos de supervisión / seguimiento descritos anteriormente).

Sin embargo, la atención médica estándar para su afección (atención que hubiese recibido aunque no hubiera participado en este estudio) es responsabilidad de usted (o de su compañía de seguros o programa gubernamental). A usted se le cobrará, de manera regular, todo procedimiento para su atención médica estándar.

¿Qué sucede si me lesiono como consecuencia de mi participación en este estudio?

Es importante informar inmediatamente de cualquier enfermedad o lesión al equipo de investigación cuyo nombre aparece al inicio de este formulario.

No habrá indemnización disponible por lesiones sufridas durante su participación en esta investigación por parte de University of Texas Southwestern Medical Center en Dallas ni de Parkland Health & Hospital System.

Usted conserva sus derechos legales durante su participación en esta investigación.



¿Puedo dejar de participar en este estudio de investigación?

Sí. Si decide participar y luego cambia de opinión, tiene plena libertad de dejar de participar en este estudio de investigación en cualquier momento.

Su decisión de dejar de participar en este estudio de investigación no afectará su relación con el personal ni con los médicos de UT Southwestern. Su decisión de participar o no en el estudio no afectará de manera alguna sus derechos legales ni la calidad de la atención médica que reciba.

¿Se mantendrá la confidencialidad de mi información?

La información médica obtenida durante este estudio y los resultados de cualquier prueba o procedimiento que pudiera afectar su atención médica podrían incluirse en su expediente médico. La información incluida en su expediente médico estará disponible para proveedores de atención médica y personas autorizadas, incluida su compañía de seguros.

Usted debe saber que ciertas organizaciones que pueden ver y/o copiar su expediente médico para investigación, control de calidad y análisis de datos, incluyen las siguientes:

- Administradores y auditores de investigación de este hospital
- Representantes de organismos gubernamentales, como Food and Drug Administration (Oficina de Alimentos y Fármacos, o FDA, por sus siglas en inglés) de Estados Unidos, encargados de mantener la seguridad de la investigación para las personas
- UT Southwestern Institutional Review Board (Consejo de Revisión Institucional de UT Southwestern)

Además de este formulario de consentimiento, se le pedirá que firme una "Autorización para el uso y la divulgación de información médica protegida". Esta autorización proporcionará más detalles sobre cómo se utilizará su información para este estudio de investigación, y quién puede ver y/u obtener copias de su información.

¿A quién llamo si tengo preguntas o problemas?

Si tiene preguntas sobre el estudio, comuníquese con la Dra. Diercks al 214-648-7207 en el horario regular de atención, y al 214-648-7207 fuera de ese horario, los fines de semana y los días festivos.

Si tiene preguntas sobre sus derechos como participante en una investigación, comuníquese con la oficina de Institutional Review Board (Consejo de Revisión Institucional, o IRB, por sus siglas en inglés) de UT Southwestern al 214-648-3060.



FIRMAS:

**USTED RECIBIRÁ UNA COPIA DE ESTE FORMULARIO
DE CONSENTIMIENTO PARA QUE LA CONSERVE.**

Su firma a continuación certifica lo siguiente:

- Ha leído (o le han leído) la información proporcionada arriba.
- Ha recibido respuestas a todas sus preguntas y se le ha indicado a quién llamar si tiene más preguntas.
- Ha decidido voluntariamente participar en esta investigación.
- Entiende que no renuncia a ninguno de sus derechos legales.

Nombre del participante (en letra de imprenta)

Firma del participante

Fecha

Hora

a.m./p.m.

Nombre de la persona que obtiene el consentimiento (en letra de imprenta)

Firma de la persona que obtiene el consentimiento

Firma

Hora

a.m./p.m.



**The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas**

**Authorization for Use and Disclosure of
Health Information for Research Purposes**

NAME OF RESEARCH PARTICIPANT: _____

What is the purpose of this form?

This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: Factors Associated with Anticoagulation Non-adherence in an Emergency Department Patient Population with Atrial Fibrillation. This is a study that is trying to determine in Atrial Fibrillation patients presenting to the ED, if there are factors that impact adherence with anticoagulation treatment. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and other others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?

Parkland Health and Hospital System and UT Southwestern Medical Center may use or share your health information with Deborah Diercks, MD and her staff at UT Southwestern Medical Center ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers?

Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- The UT Southwestern Institutional Review Board (IRB). This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at UT Southwestern may review the records of your participation in this research. A representative of the IRB may contact you for information about your experience with this research. If you do not want to answer their questions, you may refuse to do so.

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

How will my health information be protected?

Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT Southwestern on this research project. There is a risk that the Recipients could share your

information with others without your permission. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact being used?

Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?

The Researchers will collect information about the medications you take, your past medical history, and any tests/procedures ordered in the ED.

Will my health information be used in a research report?

Yes, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will not include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care and a tracking code. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?

Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?

No, this authorization is voluntary. Your health care providers will continue to provide you with health care services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?

This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: Dr. Diercks at 5323 Harry Hines Boulevard, Dallas, TX. 75390. Phone number 214-648-7207.

Will I receive a copy of this authorization?

Yes, a copy of this authorization will be provided to you.

Signatures:

By signing this document you are permitting UT Southwestern Medical Center to use and disclose health information about you for research purposes as described above.

Signature of Research Participant

Date

Time: AM/PM

For Legal Representatives of Research Participants (if applicable):

Printed Name of Legal Representative: _____

Relationship to Research Participant: _____

I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above. The basis for this legal authority is:

_____.

(e.g. parent, legal guardian, person with legal power of attorney, etc.)

Signature of Legal Representative

Date

Time: AM/PM

**The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas**

**Autorización para el uso y divulgación de
información médica con fines de
investigación**

NOMBRE DEL PARTICIPANTE EN LA INVESTIGACIÓN: _____

¿Cuál es el propósito de este formulario?

Esta autorización describe de qué manera el/los investigador(es) utilizará(n) y compartirá(n) la información sobre usted y su salud, cuando participe en el estudio de investigación: Factores asociados con el incumplimiento del tratamiento anticoagulante en una población de pacientes con fibrilación auricular en el Departamento de Emergencias. Estamos realizando este estudio para determinar si existen factores que afecten el cumplimiento de tratamiento anticoagulante en pacientes que acuden al Departamento de Emergencias (ED, por sus siglas en inglés) con fibrilación auricular. La información médica se considera "información médica protegida" cuando con ella es posible identificarlo a usted individualmente. Al firmar este formulario, usted autoriza que los investigadores y otras personas (descritas en detalle a continuación) tengan acceso a y compartan esta información. Si tiene preguntas, consulte con un miembro del equipo de investigación.

¿Quiénes podrán utilizar o compartir mi información médica?

Parkland Health and Hospital System y UT Southwestern Medical Center pueden utilizar o compartir su información médica con la Dra. Deborah Diercks y su personal en UT Southwestern Medical Center ("Investigadores") para los fines de este estudio de investigación.

¿Mi información médica protegida se compartirá con alguien, además de los Investigadores? Sí, los Investigadores pueden compartir su información médica con otras personas o entidades que trabajen con ellos en el Proyecto de investigación ("Receptores") con fines directamente relacionados con la realización de este estudio de investigación o como lo estipule la ley. Esas otras personas o entidades incluyen:

- UT Southwestern Institutional Review Board (Consejo de Revisión Institucional, o IRB, por sus siglas en inglés) de UT Southwestern. Es un grupo de personas responsables de garantizar que se respeten los derechos de los participantes en investigación. Los miembros y el personal del IRB de UT Southwestern pueden revisar los registros de su participación en esta investigación. Un representante del IRB podría comunicarse con usted para obtener información sobre su experiencia en esta investigación. Usted puede negarse a responder a sus preguntas si así lo desea.

La información médica recopilada durante este estudio y los resultados de cualquier prueba o procedimiento que pudieran afectar su atención médica pueden incluirse en su expediente médico.

Página 1 de 3

Revisado en enero de

Id. del estudio: STU 042017-076 Fecha de aprobación: 5/5/2017 Fecha de



La información incluida en su expediente médico estará a disposición de proveedores de atención médica y personas autorizadas, incluida su compañía de seguros.

¿Cómo se protegerá mi información médica?

Siempre que sea posible, su información médica se mantendrá confidencial, según lo estipula la ley. Las leyes federales de privacidad podrían no aplicarse a otras instituciones, empresas u organismos que colaboren con UT Southwestern en este Proyecto de investigación. Existe el riesgo de que los Receptores compartan la información sobre usted con terceros sin su permiso. UT Southwestern no puede garantizar la confidencialidad de la información médica de usted después de haberla compartido con los Receptores.

¿Por qué se utiliza mi información personal de contacto?

La información personal necesaria para comunicarse con usted es importante para que el equipo de investigación de UT Southwestern Medical Center se comunique con usted durante el estudio. Sin embargo, su información personal de contacto no se divulgará sin su autorización.

¿Qué información médica se recopilará, usará y compartirá (se divulgará)?

Los Investigadores recopilarán información sobre los medicamentos que usted toma, su historia médica y cualquier prueba o procedimiento ordenado en el Departamento de Emergencias (ED).

¿Se utilizará mi información médica en un informe de investigación?

Sí, el equipo de investigación podría elaborar un informe de investigación (a veces se le llama "informe del caso").

El informe de investigación no incluirá su nombre, dirección, número de teléfono ni número de seguro social. El informe de investigación podría incluir su fecha de nacimiento, sus iniciales, las fechas en las que recibió atención médica y un código de seguimiento. El informe de investigación también incluirá la información que recopile el equipo de investigación para el estudio.

¿Se utilizará mi información médica con otros fines?

Sí, los Investigadores y los Receptores podrían utilizar su información médica para crear datos de investigación con los que usted no pueda ser identificado. Los Investigadores y los Receptores pueden utilizar y compartir información de la investigación que no revele su identidad en una publicación sobre los resultados del Proyecto de investigación, o con otros fines de investigación no relacionados con este Proyecto de investigación.

¿Debo firmar esta autorización?

No, esta autorización es voluntaria. Sus proveedores de atención médica continuarán proporcionándole servicios de atención médica aunque usted decida no firmar esta autorización. Sin embargo, si decide no firmar esta autorización, no podrá participar en este Proyecto de investigación.

¿Cuánto tiempo durará mi autorización?

Esta autorización no tiene fecha de vencimiento. Usted puede cancelarla en cualquier momento. Si decide cancelar esta autorización, ya no podrá participar en el Proyecto de investigación. Los Investigadores podrían utilizar y compartir su información médica recopilada antes de que usted cancelara la autorización. Para cancelar esta autorización, debe enviar la solicitud de cancelación por escrito a: Dra. Diercks, 5323 Harry Hines Boulevard, Dallas, TX. 75390. Número de teléfono 214-648-7207.



¿Recibiré una copia de esta autorización?

Sí, se le proporcionará una copia de esta autorización.

Firmas:

Al firmar este documento, usted autoriza a UT Southwestern Medical Center a utilizar y divulgar información médica de usted con fines de investigación, como se describe arriba.

Firma del participante en la investigación

Fecha

Hora: a.m./p.m.

Página 3 de 3

Revisado en enero de

Id. del estudio: STU 042017-076 Fecha de aprobación: 5/5/2017 Fecha de



ATRIAL FIBRILLATION ENROLLMENT CHECKLIST

INCLUSION CRITERIA

• 18 years of age or older	Y	N
• Presents with Atrial Fibrillation	Y	N
• Currently prescribed anticoagulants	Y	N
• Past medical history of Atrial Fibrillation	Y	N
• ED visit related to nonadherence to anticoagulant medication	Y	N

EXCLUSION CRITERIA

• Medical condition precludes ability to participate in completing survey	Y	N
• Less than 17 years of age	Y	N
• Prisoner	Y	N
• Pregnant	Y	N

DATA COLLECTION SHEET

Subject Number: _____

Name: _____

MRN: _____

DOB: _____

Date of ED Visit: _____

Chief Complaint: _____

EKG: _____

Diagnosis: _____

NVS Score: _____

Poor(<3)

Adequate(≥ 4)

Subject ID _____

Date _____

Patient Demographics

Gender: ☐ Male ☐ Female

Age: _____

What is the patient's race?

- | | | | |
|---|-----------------------------------|--|---|
| <input type="checkbox"/> White | <input type="checkbox"/> Chinese | <input type="checkbox"/> Vietnamese | <input type="checkbox"/> Other Pacific Islander |
| <input type="checkbox"/> Black or African American | <input type="checkbox"/> Filipino | <input type="checkbox"/> Other Asian | <input type="checkbox"/> Native Hawaiian |
| <input type="checkbox"/> American Indian or Alaska Native | <input type="checkbox"/> Japanese | <input type="checkbox"/> Guamanian or Chamorro | <input type="checkbox"/> Other |
| <input type="checkbox"/> Asian Indian | <input type="checkbox"/> Korean | <input type="checkbox"/> Samoan | <input type="checkbox"/> No Answer |

What is the patient's ethnicity?

- | | |
|---|--|
| <input type="checkbox"/> Not of Hispanic, Latino/a, or Spanish origin | <input type="checkbox"/> Hispanic Puerto Rican |
| <input type="checkbox"/> Hispanic Mexican, Mexican American, or Chicano/a | <input type="checkbox"/> Other Hispanic, Latino, or Spanish origin |
| <input type="checkbox"/> Hispanic Cuban | <input type="checkbox"/> No Answer |

What is the patient's religious affiliation?

- | | | |
|---|--|--------------------------------------|
| <input type="checkbox"/> Protestant Christian | <input type="checkbox"/> Evangelical Christian | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Jewish | <input type="checkbox"/> Muslim | <input type="checkbox"/> No Answer |
| <input type="checkbox"/> Buddhist | <input type="checkbox"/> Roman Catholic | |
| <input type="checkbox"/> Hindu | | |

What is the patient's education? (Please check the box that corresponds to the highest level completed.)

- | | | |
|---|---|------------------------------------|
| <input type="checkbox"/> Grades 0-8 | <input type="checkbox"/> 1-3 years college | <input type="checkbox"/> No Answer |
| <input type="checkbox"/> Some High School | <input type="checkbox"/> College Degree | |
| <input type="checkbox"/> HS Diploma /GED | <input type="checkbox"/> Post Graduate Degree | |

Is the patient currently employed? ☐ Yes ☐ No

What is the patient's marital status?

- | | | |
|---|----------------------------------|------------------------------------|
| <input type="checkbox"/> Never Married | <input type="checkbox"/> Widowed | <input type="checkbox"/> No Answer |
| <input type="checkbox"/> Separated/Divorced | <input type="checkbox"/> Married | |

What is the patient's approximate household income?

- | | | |
|--|---|--|
| <input type="checkbox"/> Less than 10,000/year | <input type="checkbox"/> 50,000-79,000/year | <input type="checkbox"/> 130,000/year or above |
| <input type="checkbox"/> 10,000-29,999/year | <input type="checkbox"/> 80,000-99,999/year | <input type="checkbox"/> no answer |
| <input type="checkbox"/> 30,000-49,999/year | <input type="checkbox"/> 100,000-129,999/year | |

Insurance Status:

- | | | | | |
|-----------------------------------|-----------------------------------|----------------------------------|--|---|
| <input type="checkbox"/> Medicaid | <input type="checkbox"/> Medicare | <input type="checkbox"/> Veteran | <input type="checkbox"/> Commercial (Private Ins.)/Obamacare | <input type="checkbox"/> Uninsured (Self-Pay) |
|-----------------------------------|-----------------------------------|----------------------------------|--|---|

PICO: In patients presenting to the ED with Afib, there are factors that impact compliance with anticoagulation

Survey:

Basics:

1. Age
2. Sex
3. Zip code
4. Primary language spoken at home
5. Highest level of education (circle one):
 - a. **Completed Graduate School Completed College (Bachelor's) Some College
Graduated High School Some High School Less than High School**
6. Do you see a PCP regularly?
7. Do you have health insurance?
8. If yes to number 5, are you on (circle one):
 - a. **Medicaid Medicare Private Insurance**

Medication/Medical History:

1. Which of the following medications are taking (you can circle more than one)?
 - a. **Warfarin Dabigatran Apixaban Edoxaban Rivaroxaban Aspirin**
2. How often do you take the medication(s) in number 1 (e.g. once a day, twice a day, once in the morning and once at night, etc.)?
3. How long have you been taking the medication(s) in number 1 (circle one)?
 - a. <3 months
 - b. 3-6 months
 - c. 6-12 months
 - d. >12 months
4. Are you taking any other medications?
5. If yes to number 4, how many other medications are you taking?
6. How much money do you spend on medication per month (circle one)?
 - a. **\$0 \$0-100 \$100-200 \$200-300 \$300-400 \$400-500 \$500-600
\$600-700 \$700-800 \$800-900 \$900-1000 >\$1000**
7. Do you have a history of heart failure?
8. Have you ever been diagnosed with Diabetes Mellitus?
9. Have you ever been told you have high blood pressure?
10. Are you taking any blood pressure medications?
11. Have you ever had a stroke?
12. Have you ever had an experience where you had temporary weakness, vision problems, or slurred speech on one or both sides of the body?
13. Have you ever had a heart attack?
14. Have you ever had an experience where you felt pain, numbness, or weakness in one of your arms or legs?

Health Literacy:

1. PACT-Q (attached)
2. Newest Vital Sign (attached)

Stroke Risk Perception:

1. What do you think your risk for developing a blood clot in the brain is (1 is highly unlikely, 2 is unlikely, 3 is intermediate risk, 4 is likely, 5 is highly likely)?
a. 1 2 3 4 5
2. What do you think your risk for developing a bleeding in the brain is (1 is highly unlikely, 2 is unlikely, 3 is intermediate risk, 4 is likely, 5 is highly likely)?
a. 1 2 3 4 5
3. On a scale of 1-5 (1 being not at all concerned and 5 being extremely afraid), how afraid are you of developing the following outcomes after having a stroke?
 - a. Altered vision
 - b. Blindness
 - c. Trouble moving facial muscles
 - d. Trouble moving arms
 - e. Trouble moving legs
 - f. Altered sense of touch
 - g. Altered sense of smell
 - h. Paralysis
 - i. Balance problems
 - j. Difficulty swallowing
 - k. Difficulty talking
 - l. Memory loss
 - m. Difficulty controlling emotions
 - n. Depression
 - o. Pain
 - p. Changes in behavior
 - q. Death

CHAD2VAS:

1. History of CHF – **1 point**
2. History of hypertension (resting BP 140/90 mmHg on at least 2 occasions or on current antihypertensive medication) – **1 point**
3. Age >75 – **2 points**
4. Diabetes mellitus (fasting glucose >125 mg/dL or treatment with oral hypoglycemic agent and/or insulin) – **1 point**
5. History of stroke, TIA (transient ischemia attack), or TE (thromboembolism) – **2 points**
6. History of Vascular Disease (MI, peripheral arterial disease, or aortic plaque) – **1 point**
7. Age 65-74 – **1 point**
8. Female – **1 point**



Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT:

This information is on the back of a container of a pint of ice cream.

1. If you eat the entire container, how many calories will you eat?
Answer: 1,000 is the only correct answer
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much icecream could you have?
Answer: Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving office cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
Answer: 33 is the only correct answer
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
Answer: 10% is the only correct answer

READ TO SUBJECT:

Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?
Answer: No
6. Ask only if the patient responds "no" to question 5): Why not?
Answer: Because it has peanut oil.

ANSWER CORRECT?

Yes	No

Number of correct answers:

Interpretation

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.



Nutrition Facts

Serving Size ½ cup

Servings per container 4

Amount per serving

Calories 250 Fat Cal 120

%DV

Total Fat 13g 20%

Sat Fat 9g 40%

Cholesterol 28mg 12%**Sodium** 55mg 2%**Total Carbohydrate** 30g 12%

Dietary Fiber 2g

Sugars 23g

Protein 4g 8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.





Hoja de Resultados para el Nuevo Signo Vital Preguntas y Respuestas

LEA AL SUJETO DEL ESTUDIO:

Esta información aparece al reverso de un envase de helado.

1. Si consume todo el helado en el envase, ¿cuántas calorías habrá consumido?

Respuesta: 1,000 es la única respuesta correcta

2. Si le permiten consumir 60 gramos de carbohidratos como refrigerio, ¿cuánto helado puede consumir?

Respuesta: Cualquiera de las siguientes es correcta: 1 taza (o cualquier cantidad hasta 1 taza), la mitad del envase". Nota: si el sujeto del estudio responde "dos porciones", pregunte "¿Cuánto helado sería si lo midiera para ponerlo en un tazón?"

3. Su médico le aconseja reducir la cantidad de grasa saturada en su dieta. Usted normalmente consume 42 gramos de grasa saturada al día, que incluyen una porción de helado. Si deja de consumir helado, ¿cuántos gramos de grasa saturada consumiría cada día?

Respuesta: 33 gramos es la única respuesta correcta

4. Si normalmente consume 2,500 calorías al día, ¿qué porcentaje de su valor diario de calorías habrá consumido si consume una porción?

Respuesta: 10% es la única respuesta correcta

LEA AL SUJETO DEL ESTUDIO:

Imagínese que es alérgico/a a las siguientes sustancias: penicilina, cacahuete (maní), guantes de látex y picaduras de abeja.

5. ¿Es seguro consumir este helado?

Respuesta: No

6. (Pregunte sólo si responde "no" a pregunta 5): ¿Por qué no?

Respuesta: Porque tiene aceite de cacahuete (maní)

¿RESPUESTA CORRECTA?

sí	no

Número de respuestas correctas:

Interpretación

Resultado de 0-1 sugiere alta probabilidad (50% o más) de alfabetización limitada.

Resultado de 2-3 indica la posibilidad de alfabetización limitada.

Resultado de 4-6 casi siempre indica alfabetización adecuada.



Datos nutricionales

Tamaño de la porción 1/2 taza
Porciones por envase 4

Cantidad en cada porción
Calorías 250 Calorías de grasa 120

% del valor diario (VD)*

Grasa total 13 g 20%

Grasas saturadas 9 g 40%

Grasas trans 0 g

Colesterol 28 mg 12%

Sodio 55 mg 2%

Total de carbohidratos 30 g 12%

Fibra dietética 2 g

Azúcares 23 g

Proteína 4 g 8%

*El porcentaje de valores diarios (VD) se basa en una dieta de 2,000 calorías. Sus valores diarios pueden ser mayores o menores dependiendo de las calorías que necesite.

Ingredientes: Crema, leche descremada, azúcar líquida, agua, yemas de huevo, azúcar morena, grasa de leche, aceite de cacahuete (maní), azúcar, sal, carragenano, extracto de vainilla.

Modified Morisky Scale (MMS)

Instructions: Ask the patient each question and circle the corresponding “yes” or “no” response. Circle the answer to each question and sum the score for the motivation column and sum the score for the knowledge column. Report the results on the CMAG-1 Patient Summary Assessment form.

Question	Motivation	Knowledge
1. Do you ever forget to take your medicine?	Yes(0) No(1)	
2. Are you careless at times about taking your medicine?	Yes(0) No(1)	
3. When you feel better do you sometimes stop taking your medicine?		Yes(0) No(1)
4. Sometimes if you feel worse when you take your medicine, do you stop taking it?		Yes(0) No(1)
5. Do you know the long-term benefit of taking your medicine as told to you by your doctor or pharmacist?		Yes(1) No(0)
6. Sometimes do you forget to refill your prescription medicine on time?	Yes(0) No(1)	
Total score	_____ 0–1 = Low motivation 2–3 = High motivation	_____ 0–1 = Low knowledge 2–3 = High knowledge

APPENDIX C: JOURNAL

WEEK 1

Day 1: Tuesday 5/30/17

•AM: Arrived at the UT Southwestern Medical Center campus along with Samita. Met with Shannon McNabb, and had a very short/ concise tour of the campus. Had an initial introduction to the office/ research department itself. Had an introductory meeting with Shannon and Samita about concerning a little bit about us, and what we hope to achieve during the internship as well as in the future.

During the meeting, Shannon spoke to the differences to conducting human subject research in an ED, especially as to the difficulties of obtaining pt. informed consent as it relates to prior consent from the physician seeing the pt. This is a big handicap, as it potentially disrupts the clinical flow/ care of the pt. We, as researchers, obtain a HIPPA waiver in regard to pt. medical history (why they are in the ED that day), and approaching them about whether they wish to participate in a research study. According to PMH policy (as mandated by the Department of Research Administration), researchers may only approach a pt *after* asking the treating physician to do so. This has the potential to disrupt clinical flow.

In order for Parkland Hospital to maintain its LEVEL I Trauma Center status, they must conduct research.

PROS: Parkland has high pt. traffic as well as a very diverse pt. population. Clements Hospital on the other hand has no real research branch, but is very open to research nonetheless. Furthermore, Clements tends to have a less diverse pt. population

CONS: Parkland's Research Department policy has placed is more restrictive than federal regulations. Therefore, obstacles are present when getting pt. informed consent, for as it currently stands, the possibility for disrupting clinical flow is apparent.

Shannon also outlined what our activities may include over the next several months of the internship: learning the basics of Clinical Research Management, office work and paper work for example. We were asked if we would like to be assigned projects to help pick up the slack, or shadow Shannon in her daily activities around the office. A possible idea was web design/ web content for an Emergency Medicine Research Department webpage, as currently, none exist.

•PM: Sat in on a meeting between Shannon and Dr. Blomkalns, discussing possible new research projects for the future. We were given a more thorough tour of the campus, as well as the “new” Parkland Hospital by Mario Puente, lead study coordinator for Emergency Medicine Research within PMH’s ED.

Day 2: Wednesday 5/31/17

•AM: Sat in on a weekly meeting for the Surgery Research Department along with office staff from the Emergency Medicine Research Department. Discussed were various research studies currently being conducted as well as how to better facilitate cooperation and collaboration between both departments. Similar to giving after action reports, an analysis was given to closed and ongoing studies to identify what is/ was working, identify barriers/ obstacles, and to create “cheat sheets” to streamline future discussions and to hit and address major points for respective research projects.

For the remainder of the morning, I read various protocols for proposed research studies which had not yet been launched.

•PM: Attended/ sat in on a huddle for industry sponsored studies being conducted by the EM Research Dept. Of the sponsored studies discussed, one was a prospective observational study concerned with PEs and DVT, another concerned sepsis, and another addressing psychotically agitated patients in the ED.

Was given an invite to attend the “Shark-Tank” competition which serves as a forum for UTSW residents to present and compete for funds for their proposed research.

Continued to read protocols for proposed studies:

1) T2D & Health Literacy 2) A-fib & Anticoagulant Nonadherence 3) Pain Perception Across Providers 4) Chest-Pain Patient Preference for Follow- up Functional Testing 5) Double Paramedic Cost Evaluation

Subsequently, we had a huddle (Samita, Shannon, & myself) to discuss which of the studies we found most interesting and thought we would like to pursue. To give us a better feel of the process of patient recruitment, Shannon ran us through a mock recruitment as well as an overview of the documentation for informed consent (IFC).

My personal preference out of the protocols is the one addressing anticoagulant nonadherence in an emergency department patient population with a-fib.

For the rest of the afternoon, I then proceeded to search the UNTHSC Library's website for journals and articles relevant to the protocol literature.

Day 3: Thursday 6/1/17

•AM: Upon my arrival, I was sat in on the 2017 Shark Tank Competition, to hear about new research proposals from UT Southwestern EM Residents. Some pretty interesting ideas were presented to the forum, such as a new approach to trans-venous pacing training to improve residence confidence and competency in the procedure, and an electronic format for patient medication reconciliation that has the intended effect of providing the clinical team with an accurate list of patient medications. Another posited an increase number of Spanish speaking providers would reduce misdiagnoses as well as improve the clinical outcomes for ESOL patients. Another presentation proposed team based training (**Situational Awareness Global Assessment Tool**) to improve team competencies and patient outcomes in resuscitations. Another proposed ED palliative care for ESRD patients. And lastly, a group presented a project for managing agitated ED patients, and thus making for a safer environment in the ED.

Table 2: Shark Tank

Resident	Faculty sponsor	Title of Study
Garrett Blumberg	Lynn Roppolo	Making the emergency department a safer place: managing the agitated patient
Robert Rash Mark Dresselhouse	Emily Gundert Jessica Hernandez	Evaluation of an Inexpensive Model for Transvenous Pacing Education
Daniel Jackson	Samuel McDonald Ellen O'Connell	A Patient Performed Medication Reconciliation in the Emergency Department
Luis Puchi	Gil Salazar	Better outcomes for Hispanic patients – Are they lost in translation?
Ken Wang	Kavita Joshi Jessica Hernandez	Procedure Associated loss of Situation Awareness
Lauren White	Jillian Horning	Palliative Care in the ED

The last presenter (faculty) before we broke for yet another meeting on CRM training gave a very interesting presentation regarding research into changing SOPs for CPR in the field prior to transport. The proposed new

protocol, which calls for 100-120 compression/ min, elevation of the patient's head AND chest, and mechanical compression devices indicated a marked improvement in patient outcome/ survivability, especially in regard to neurological outcomes. Further research is indicated in this study; nonetheless, the findings presented were very interesting and looked promising.

Right before lunch, Samita, Shannon, and I caught the tail end of a training session on how to prepare for an FDA audit/ site-visit.

- PM: Continued to compile journal articles for my literature for my research practicum proposal regarding atrial fibrillation and medication nonadherence in regard to patient health literacy and numeracy. Signed confidentiality agreement for PHI & intellectual property.

Day 4: Friday 6/2/17

- AM: Spent most of the morning reading through the ACCESS Trial protocol.

- PM: Conference call meeting for the ACCESS Trial PIs. It was interesting to see how a research study is initially discussed between sites and PIs in a forum format.

Discussed initial literature review with Shannon, as the relevance of my key search words (*atrial fibrillation* AND *nonadherence*), and possible suggestions for next week.

*****WEEK 2*****

Day 5: Monday 6/5/17

- AM: Began CITI-Training modules for conflict of interest, good clinical practice, human subject protection, and research HIPPA.

- PM: Spent the remainder of the afternoon completing/ working on CITI-training modules. Over the course of the day, I was able to complete the Conflict of Interest modules, and began chipping away at the Good Clinical Practice modules. The former reinforced what we had learned about Financial Conflicts of Interest as well as Significant Conflicts of Interest. Conflicts of Commitment, Consciences and Institutional Conflicts of Interest were covered as well.

For the latter, the modules covered had to do with Humanitarian Use Devices, Phase I Human Subject Trials, and The Belmont Report. Respect for persons, Beneficence, and Justice are the main cornerstones of the latter, and the pillars for which it is known.

Day 6: Tuesday 6/6/17

•AM: Completed journal entry for yesterday, and subsequently began working on more CITI-Training modules: New Drug Development, Overview of International Council for Harmonization – GCP, and the comparison of ICH E6 GCP & FDA Regulations.

Attended EM Research Dept. weekly meeting and was able to meet Dr. Idris, the Research Director, and other members of the department. Topics discussed ranged from open cases and whether or not they were reaching their recruitment quotas. Another topic broached was the use of social media to contact subjects/ family members in emergency situations. I learned that one aspect of GCP is that in any research study, the top two enrolling sites are usually the locations chosen for FDA audits. Protocol deviations/ violations were discussed as well: AE are unexpected events with an adverse outcome that are in some way related to the study. Other points of interest were that JPS operates under its own IRB, whereas, Methodist operates under the IRB of UT Southwestern. There was some discussion on the collecting of demographic information on people surveyed during community consultations (EFIC requirement). It was decided that a cross-sectional demographic from the DFW at large would suffice for this information, as gathering such personal details from people at a festival in public could be impractical.

ACCESS Trial was discussed: prepare for IRB approval.

HOBIT Trial for SIRENS was discussed: Searching for possible study sites in the state of Texas. Sites have to meet specific criteria: Hyperbaric Chamber in close proximity of ICU.

•PM: In the afternoon, began to do the work-up for my Friday research proposal Advisory Committee Meeting. Tentatively, the study I have chosen is entitled *Factors Associated with Anticoagulation Non-adherence in an Emergency Department Patient Population with Atrial Fibrillation*. The aims of the study are threefold: 1) Determine the prevalence of high risk for non-adherence with anticoagulation in an emergency department population with A-fib, 2) Determine prevalence of low [health] literacy in patients determined to be noncompliant, 3) Determine the association between adherence and patient preference. In the protocol, the proposed clinical impact “will provide further understanding of patient adherence with anticoagulation in those with atrial fibrillation. As many of these patients will present to the emergency department, understanding the impact of preference and literacy when discussing anticoagulant use is important.”

To help us get started on our research proposals for Friday, Shannon had a huddle with Samita and me, addressing our proposed studies, how to create a project summary, and how to format our handout sheets for the attending advisory committee members.

Day 7: Wednesday 6/7/17

•AM: Finished diary entry from yesterday. Began working on research proposal for Friday, consulting my notes from the meeting we (Samita and I) had with Shannon yesterday. Filled out Project Summary sheet for Advisory Committee Meeting hand-out.

•PM: Shannon sent back my first draft of the hand-out for said meeting. Began work on a power point presentation to accompany the presentation. Samita and I attended a department staff meeting. The meeting covered the department employee report form from last year as well as a brain-storming session covering what is good, bad, and what can be improved within the department. In short, the meeting/ staff worked towards developing and implementing an Action Plan to be put in place over the next year. Notes from the meeting are thus:

Things we do well: Team work, showing up, communication, resourcefulness, flexibility, being able to prioritize, team-building, dedication, making people feel welcome.

Things we can improve: Keeping people in the loop, being concise, being timely, being cognizant of what is appropriate for the place and time/ speaking with the appropriate context/ through the proper channels, accountability/ buddy system, giving and receiving feedback, call-in procedures, active listening, being open to new ideas, “after action reports” (what worked and what did not), professional communication expectations, assume positive intent in all situations/ clear the air if something is bugging you,

Policies/ procedures to create for the department: Dress code, call-in procedure, promotions/ professional development, step-by-step instructions (job descriptions)/ desk manual, PTO/ leave policy.

Day 8: Thursday 6/8/17

•AM: Finished diary entry from yesterday. Edited draft of project summary sheet for Advisory Committee Meeting tomorrow (Friday 6/9/17). Began working on power point presentation to accompany hand-out, and was able to complete the task before going to lunch.

•PM: Samita and I each went through a trial run-through research proposal for our respective research studies with Dr. Pierce and Shannon present. Received feedback as well as critiques on where we could improve. I liked how Samita gave a pretty thorough background of T2D in her presentation.

Food for thought I may consider for my presentation: more background information on A-fib (patient population, etc.) as well as what medications are prescribed besides just Warfarin. I know that there are New Oral Anticoagulation drugs as well which are not vitamin K antagonists (Warfarin) becoming more popular. I need to be more familiar as well with CHAD2SVAS as well.

Day 9: Friday 6/9/17

•AM: Finished my presentation folders for the Advisory Committee Meeting today, which is at 13:00. Going over my presentation until it is time to present. Had lunch with the whole Advisory Committee thanks to Dr. Pierce.

•PM: Gave my research proposal to the Advisory Committee: Dr. Mathew, Dr. Pierce, Dr. Gwartz, Dr. Ranjan, & Shannon McNabb. Dr. Rickords was in attendance as well. Not too terribly nerve racking. Feedback from the ACM: A) Choose one (1) of the aims/ hypotheses to focus on. Gather the data for all three surveys, but doing all three would collect a lot of data, and working through the results may fall outside of the scope of what I will be accomplishing over the next six months. B) I need to review/ rebuffer my knowledge of biostatistics, as it will be imperative for not only my defense but understanding the data.

For the former, I am under the impression that the MMS is the backbone of the study as it is the measure of nonadherence, the NVS measures health literacy, and the PACT-Q measures the pt's perception of their own treatment. Therefore, I am under the impression that, that one cannot have the PACT-Q without the MMS; neither can one have the NVS without the MMS. If that is indeed the case, then if abiding by the Committee's suggestion that I narrow my aims and hypothesis into one concerted aim/ hypothesis for my thesis, I believe that the MMS along with the NVS can be used to ascertain what association (if one exists) there is between health literacy and nonadherence.

Shannon provided clarification for Samita and myself of the difference between a HIPAA Waiver, and HIPAA Authorization: the former is granted by the IRB for the purpose of prescreening pts in the ED. The latter, signed along with an IFC, is an authorization from the pt to utilize their PHI in a research capacity.

*****WEEK 3*****

Day 10: Monday 6/12/17

•AM: Began the morning by editing last week's journal entries. Completed CITI-Training modules:

- Overview of US FDA Regulations for Medical Devices
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events
- Audits and Inspections of Clinical Trials

•PM: Continued CITI-Training modules from the morning:

- Monitoring of Clinical Trials by Industry Sponsors

Began working on/ creating an outline for research proposal due Friday. Initial draft of The Summery (I.) completed. Samita and I had a huddle with Shannon to discuss points we should focus on for our respective proposals. Operating under the impression that we are to choose one (1) Aim to focus on, I will be presumably be working on Aim 2: "To determine the prevalence of low [health] literacy in patients determined to be non-compliant." The primary outcome will be to "measure the prevalence of health literacy using the Newest Vital Sign" (NVS) survey. The hypothesis proposes that "those patients who are non-compliant will have low health literacy."

I will make an effort over the next few days to understand more precisely what I will be seeking to determine with a narrowed focus, as well as morphing the existing IRB approved protocol into a proposal draft with the new narrowed aim/ scope in mind.

Rather than looking at the MMS and NVS, I can look to the treating physician to find which patients have/ have not been compliant with their medications. As such, the NVS will now be the only survey I need to administer in regard to the new/ narrowed scope of my research practicum (accessing health literacy in noncompliant a-fib patients).

Day 11: Tuesday 6/13/17

•AM: Completed more CITI-Training modules:

- IRB Waiver of Authorization -Limited Data Set -UT Research Authorization

-How do Researchers Obtain, Create, Use, and/ or Disclose PHI

-Why the Privacy Rule Challenges for Clinical Researchers

-Data Use Agreements and Limited Data Sets -Recruitment for Participation in Research Studies

-Use of PHI for Research on Descendants -Transition Provisions -Research Accounting Statements

Began working again on outline and draft of research proposal. Yesterday I was able to put down a working summary. Today the plan is to start the Problem/ Hypothesis section, the Significance section, Background, Research Design/ Methodology section, Limitations section, and the Chapters section.

Was given the coverage analysis for my proposed study pertaining to a-fib and nonadherence. This phase of the research precedes the actual study itself. It is used by the medical center to evaluate the feasibility of actually conducting the study (fiscal costs).

As far as I can tell by reading the document, the analysis covers:

-FDA status in regard to investigational items (drug/ device).

-Whether or not “routine costs will be covered based on a) whether or not the item falls within a benefit category? b) the study has a therapeutic intent? or c) do the study patients have a diagnosed disease? (all three must be met in order for routine costs to be covered in clinical trials)

-To be covered by routine costs, the trial must also satisfy seven desirable characteristics: 1) “funded by NIH, CDC, AHRQ, CMS, DOD, or VA;” 2) “supported by centers or cooperative groups that are funded by the above agencies;” 3) “conducted under an IND reviewed by the FDA;” 4) “drug trial is IND exempt according to UTSW’s IRB determination (21 CFR 312. 2(b)(1).”

-Whether or not the study is a Qualifying Device Trial Analysis and its FDA status.

-Qualifying criteria for device trial coverage for Investigation Devices, PMA Trials, 510k Approval Trials, Post-market Approval Trials, and 510k Post-Approval Extension Trials.

-Medicare Administrative Contractor Approval.

•PM: The Coverage Analysis has been approved. Next up will be site approval.

Continued to work on research proposal for Friday.

Day 12: Wednesday 6/14/17

•AM: Resumed work on research proposal from yesterday. Primary focus today will be the background section, as well as the works cited section. The Chapters section will be included at the end of the day after I am satisfied with the majority of the document. Endgame for today is have completed an initial first rough draft. For the morning, literature review will be my main concern.

•PM: Finished background section of the proposal. Reviewed articles for works cited section.

Day 13: Thursday 6/15/17

•AM: Main goal for this morning is to insert citations, complete works cited section, rework limitations sections, and do a good edit of the draft.

•PM: Continued to rework research proposal: Works cited, limitations section, made corrections per Shannon's first edit.

Day 14: Friday 6/16/17

•AM: Attended a lecture on *Current Topics in Research Administration*, given by Kim Moreland. Topics covered by Kim touched upon a) Procurement Updates, b) Federal Budget Implications, c) Indirect Costs, d) Single Audit and LOC Draws, e) R 35 Wards, f) Regulatory Reform Ideas.

There was discussion as to the baseline/ threshold of what constitutes a micro-purchase (<\$3,500), which do not require competitive quotes. Some institutions have \$10,000 baselines, and others have \$25,000.

Discussed the grace period for FY 2017, for the implementation of the procurement standards in 2 CFR 200.317–200.326.

Discussed to a degree the National Defense Authorization Act (NDAA) – micro provision makes permanent changes in the US Code. Provides authorization of funding for DOD.

Discussed budget/ funding cuts to research proposed in the newly proposed presidential budget or FY 2018.

Eliminates funding for nearly 20 smaller independent agencies. For obvious reasons, many oppose this, including some Republican law makers in Washington! In a nutshell, the new budget cuts non-defense R&D by 22%, and increases Defense R&D by 10%. The budget includes an indirect cost rate for NIH grants that will be capped at 10% of total research.

Discussed full-year Continuing Resolutions (CR), a series of short-term CRs, and Omnibus bill (FY 2017).

Federal shut-down?

Discussed F&A → Indirect Costs (costs incurred for a common of joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved) → Overhead Costs. So, F&A = Indirect Costs = Overhead.

$$\text{F\&A Rate} = \frac{\text{Total indirect costs taht support organized research}}{\text{Total direct costs of organized research}}$$

F&A = Administrative Costs, which are capped at 26%; Facilities Costs (new buildings and capital improvements – depreciation, operations and maintenance, Library).

Foundations pay less for F&A costs than the federal government.

Gates Foundation policy on Indirect costs: “Whenever possible, specifically allocable costs of an applicant organization’s project should be requested and justified in the proposal as direct costs.... Once included in direct costs, the 10% F&A rate can be applied to the Total Direct Costs.”

Hypothetical exercise: How would a \$50-\$60 million/ year budget cut affect UTSW?

A discussion of what is “research effort?” It is not clearly defined.

Continued working on research proposal.

•PM: Continued working on research proposal. Sent initial draft to Dr. Pierce for review before submitting it to Dr. Gwartz.

*****WEEK 4*****

Day 15: Monday 6/ 19/17

•AM: Finished last week’s journal entries and began to do more lit review. One article touched upon the use of the Newest Vital Sign as a quick screen for limited health literacy. The other compared traditional vitamin K antagonists (VKAs) and new oral anticoagulants (NOACs). The latter were found to be as effective, if not more so than preventing strokes, and with less of the untoward interactions and monitoring that accompany VKA prophylaxis.

•PM: Worked on filling in Parkland Memorial Hospital credentialing paper work.

Day 16: Tuesday 6/20/17

•AM: Answered emails for IRB Training scheduled for 11 July. Got an office computer, so now I will have printer access. Still waiting to have access to the Conflicts of Interest page so that I may proceed with the credentialing process.

Continued with more literature review. Comparison of health literacy tests: validating Newest Vital Sign, REALM-R and METER, and SILS to the standard S-TOFHLA.

•PM: Continued literature review. In the article measuring various health literacy tools against the S-TOFHLA, it was found that the NVS had a good ability at detecting low health literacy when compared against the S-TOFHLA. As such, the NVS is a suitable tool for measuring health literacy in Emergency Department patients.

Day 17: Wednesday 6/21/17

•AM: Still am not able to access the UTSW Conflict of Interest and Outside Activities Module to continue on with the credentialing process. Continued to do more literature review.

•PM: Continued with literature review. In the afternoon, Samita, Shannon, myself, and a TEMRAP intern went through a mock recruitment for the various research projects we will be conducting over the next few months. What I found is that practice will make the overall flow of the survey taking go a lot more smoothly. Also, it is imperative to know the ICF and HIPAA waivers forwards and backwards. For my own part, I will need to construct some sort of sheet with the answer choices on it for the PACT-Q portion of the surveys to facilitate a smoother recruitment process.

In a nutshell, I need to rehearse the delivery of the recruitment and become more efficient and thorough in its delivery.

Day 18: Thursday 6/22/17

•AM: Finished yesterday's journal. Completed Institutional Conflict of Interest training/ acknowledgment for the UTSW IRB. I read the handbook sections for: Financial Conflicts of Interest in Research – Disclosure, Management and Reporting (RES-401), Conflicts of Interest, Conflicts of Commitment, and Outside Activities (ETH-104), and Outside Activities (Including Outside Employment or Board Service Policy (EMP-158).

•PM: Finished readings from the morning. Typed up data collection sheet and inclusion/ exclusion criteria sheet for my study. Data collection will have the following information: Subject number, name, medical records number, date of birth, ED visit date, patient's chief complaint, EKG, Diagnosis, and NVS score as well as whether or not it is "poor" or "adequate" based on whether or not is less than or greater than or equal to 4. Inclusion criteria: 18 years of age or older, presenting with a-fib, past medical history of a-fib, currently prescribed anticoagulants, ED visit related to nonadherence of anticoagulant medications. Exclusion criteria: medical condition precludes the patient's ability to participate in completing the study, patient is 17 years of age or younger, and/ or the patient is a prisoner.

Day 19: Friday 6/23/17

•AM: Received research proposal draft back from Dr. Gwartz this morning with edits. Began revisions for new draft.

•PM: I was able to implement the edits from Dr. Gwartz into the new draft and submitted it to Shannon for approval before leaving for the day.

Samita and I sat down to practice mock recruitments on each other. Time is a big factor in the process, and both of us went over by 5-10 minutes each. Streamlining the process and being as efficient as possible are going to be key, not only to correctly get the information we need, but to be cognizant and respectful of the patients' condition and emotional status. If they are going to be gracious enough to allow us to inconvenience them during a stressful time, we need to repay that trust and respect by doing our jobs quickly and effectively. Samita and I plan to practice at least once a day until things actually get moving.

*****WEEK 5*****

Day 20: Monday 6/26/17

•AM: Finished last Friday's journal entry. Did more literature review concerning the topic of long-term anticoagulant treatment with both VKAs and NOACs using the COM-B approach (capability, opportunity, motivation, and behavior). This approach works to better establish/ improve the patient's ability to take manage their own medications, improve patient adherence by lessening the complexity of their medication regimen if possible, and improve patient education about their condition and medications as well as address any concerns they may have about either.

- PM: Made revisions on research proposal based on critiques from Shannon on the latest edited draft.

Resubmitted new draft proposal to Dr. Gwartz in preparation for resubmission to the whole Advisory Committee this Friday.

Day 21: Tuesday 6/27/17

- AM: Printed off a stack of recruitment packets. Samita and I ran each other through our respective mock recruitments. We are better than the other day. Our times were significantly improved: I only went 20 minutes, she went about 16-17 minutes. Still too slow for the estimated 15 minutes we have been given to complete each recruitment. We plan on doing more throughout the week and into the future until we are credentialed and actually start doing it for real in the ED.

- PM: Made an edit to the inclusion/ exclusion criteria sheet in the recruitment packet (added pregnancy to exclusion criteria).

Continued literature review: Discussion of who exhibit adequate compliance with their warfarin regimen.

Successful patients have better communication with their doctors/ nurses about their condition, their treatment plan, and why it is important to be adherent. The point was made that those patients who adhere to a healthy lifestyle/ regimen, tend to be more adherent with diet and exercise, as well as their medications and appointments. According to the Journal of Clinical Nursing article, it really is imperative that patients AND doctors are on the same page regarding the treatment plan.

Another article from the Journal of Cardiac Failure, noted that up to 1/3 of eligible patients meeting the criteria for VKAs, were not prescribed them on discharge. The article goes on to point out that inpatients prescribed VKAs upon discharge had a higher rate of filling the prescription and staying compliant with the medication for up to one year, than did outpatients prescribed the medication after discharge who had a less high rate of filling the prescription or staying compliant for one year.

Day 22: Wednesday 6/28/17

- AM: Per Shannon, I have been successfully added to the protocol for the atrial fibrillation anticoagulation nonadherence study as a researcher by the UTSW IRB. This information was forwarded to Dr. Mathew.

Hopefully now I will soon be approved by the UNTHSC IRB subsequent to submitting the requisite forms/

documents to Dr. Mathew: a) Protocol, b) evidence that I have been added to the UTSW protocol per the UTSW IRB, c) continuing renewal letter from UTSW IRB, stating that the study is current/ active.

Samita and I did another practice mock recruitment. After conferring with Shannon yesterday, we realized that we had been rushing through the ICF and HIPAA Authorization under the misunderstanding that the whole recruitment process is to take 15 minutes or less. After some clarification as well as remembering that informed consent is a process not constrained by time (it can take as much time is need for subject to fully comprehend the nature of the study/ research).

As such, Samita and I gave a more thorough run through of the ICF and HIPAA Authorization before proceeding with the surveys themselves. This also allows for a more thoughtful survey process as well. My time today was just over 15 minutes for the four surveys. Samita completed her three surveys in just under 10 minutes.

- PM: Shannon, Samita, and myself went into the conference room to learn how to submit mods to the IRB. When submitting a mod, two (2) versions of the mod need to be submitted: a tracked review of the documents showing the modifications made (dated), as well as a clean copy of the document (dated). After a mod has been made, it is submitted to the PI so that it may be submitted to the IRB. Only the PI may submit modified documents to the IRB.

Shannon submitted the atrial fibrillation study protocol, as well as the approved modification of adding me to the protocol to Dr. Mathew.

Day 23: Thursday 6/29/17

- AM: Gathered information on Hemostasis as well as atrial fibrillation. The more I know about the physiology of blood clotting and the arrhythmia itself, the better I may be able to interpret the overall picture the treatment plans these patients receive. Next up will be to gather more general information about the drug protocols for treating atrial fibrillation.

Received edited draft of research proposal from Dr. Gwartz and began revisions in order to submit to the Advisory Committee by the June 30th deadline.

- PM: Continued working on edits for the revised research proposal. Put in data analysis section for how the data would be interpreted.

Shannon made the request to have my ICF and HIPAA authorization forms translated into Spanish.

Day 24: Friday 6/30/17

•AM: Finished final edits to draft research proposal and submitted to Advisory Committee: Drs. Gwartz, Pierce, Ranjan, Mathew, as well as Shannon.

Samita and I went through another mock recruitment. Our times are getting better, but it still needs a bit of work. Even though consent is an ongoing process, I think we need to be a little more confident in our execution of the informed consent (i.e., I still think we can be more thorough and still be concise).

•PM: Reviewed hemostasis: the mechanism of blood clots as they naturally occur in the body secondary to trauma.

*****WEEK 6*****

Day 25: Monday 7/3/17

•AM: Continued review of hemostasis and fibrinolysis. The plan is to review and get reacquainted with the physiology of blood clotting, atrial fibrillation, and how the separate drug interventions (VKAs, NOACs, heparin and its derivatives) are utilized to treat the condition.

Samita and I went through another mock recruitment. Our times are getting more efficient. As of yet though, I believe we still need to be more confident when going over the ICF and HIPAA authorization form.

Day 26: Wednesday 7/5/17

•AM: Finished up the diary entry from Monday. Continued to read PowerPoints concerning hemostasis as well as drug interventions/ anticoagulants.

➔ Submitted the revised draft of my research proposal last Friday (06/30/2017). Have yet to receive any feedback. Res-submitted draft this morning in an email marked as “high priority”.

Received edits from Dr. Gwartz, and promptly began on them.

•PM: Completed the edits before lunch. Resumed going over hemostasis and anticoagulants.

Completed power point: *Blood Coagulation and Fibrinolysis* by Prof. Asim K. Duttaroy, of the University of Oslo.

Day 27: Thursday 7/6/17

•AM: Yesterday, I was informed that the IRB approved mods to the ICF (removed research personnel from the form). Went over revisions before submitting proposal.

WEEK 7

Day 28: Monday 7/10/17

•AM: Prepared recruitment packet for TEMRAP interns to start gathering data. Made sure the packet contained both English and Spanish versions of the NVS, as well as had 2 copies each of the ICF and the HIPAA authorization. Filled out Master of Science Evaluation of Research Proposal with Scoring Rubric so that I may begin collecting signatures.

•PM: Worked more on understanding Hemostasis.

Naturally occurring coagulation inhibitors include anti-thrombin III, which binds to factors IXa, Xa, XIa, XIIa. Anticoagulant action of ATIII is accelerated by heparin, but heparin will have no anticoagulant action without ATIII.

The TM-PC-PS system (destruction of protein factors) degrades cofactors V and VIII:C which inhibits prothrombinase and tenase complexes.

Day 29: Tuesday 7/11/17

•AM: Attended introduction to IRB training class. It was a good review of good clinical practice (GCP) as well as a review of the Tuskegee Experiment, Nazi experiments, the Nuremburg Code, the Thalidomide Tragedy and the subsequent Kefauver-Harris Amendments, the Declaration of Helsinki, the National Research Act, and the Belmont Report.

Furthermore, we revisited what IRBs are and what they do: “Ensure the protection of the rights and welfare of human subjects through the review of all research protocols involving human subjects, scientific validity, and ethical review.” Reviewed the Common Rule, “Exempt” and “Expedited” criteria, as well as the 111 criteria. Went over IRB continuing reviews, study modifications, and reportable events (AEs/ SAEs, UPIRSOs) and their timelines for reporting, protocol violations and deviations.

Looked at what it takes for new study IRB submission: eIRB Study SmartForm, the study protocol, as well as the ICF, HIPAA authorization form, Investigator’s Brochure, and the recruitment materials.

Reviewed the *process* of giving/ receiving informed consent (disclosing information so that the patient may make an informed decision, facilitating understanding, promoting the voluntariness of the decision to enroll or decline participation) per 45 CFR 46.116.

•PM: Came back from the IRB training to catch the tail end of the weekly EM Department meeting. Caught the tail end of the discussion of AED and defibrillator companies working towards technology to measure the effectiveness of rescuer compressions by measuring the depth of compression.

Day 30: Wednesday 7/12/17

•AM: Put together recruitment packet pdf document for TEMRAP students for *Factors Associated with Compliance with Outpatient Follow-up in Chest Pain Patients Discharged from the Emergency Department*.

Observed Khushbakt create an IRB application for a new research study being sponsored by the EM Department about a new way of training EM residents on Trans-Venous Pacing (TVP).

Got new articles to read for a background section for a study being conducted at PMH regarding how/ why pts leave the ED without being seen/ treated.

•PM: Attended a EM Research Dept. meeting about DISC test results for the department staff. DISC stands for: Dominance, Influence, Steadiness, Conscientious. The idea is to discover how our personalities affect our behavior, and how are behavior affects those around us. The concept is that once we learn what our strong character traits are, as well as those of our co-workers, we can adapt to accommodate those around us. Meeting each other half way to create a more harmonious/ productive work environment.

Day 31: Thursday 7/13/17

•AM: Received and completed my own DISC survey this morning. Not surprisingly, I'm a CS/ CS (Conscientious and Steadiness). Will review more later, as I find it very interesting to see how by adapting my behavior to other peoples' style, we may be more compatible when working together.

Began reading through pulled articles for literature review regarding why patients walk out of EDs before being seen/ treated.

The first article measured how assigning acuity scores to patients earlier in triage affected whether or not they walked out before being seen. Prior research has shown that patients who leave without being seen (LWBS) tend to be male, younger, of minority race, uninsured or on Medicaid, and non-English speaking. Furthermore,

patients who LWBS have probably walked out previously of an ED without being seen/treated. [*Early Quick Acuity Score Provides More Complete Data on Emergency Department Walkouts – Paris B. Lovett, et al.*]

•PM: Typed up a rough draft of a Quality Improvement Project protocol for an upcoming GIS study looking to see if there are ways to reduce the number of patients in the PMH ED who leave before they are treated by ED staff. It is proposed that this number can potentially be reduced by allowing TEMRAP students/ interns to go into the waiting area of the ED and talk with patients who are waiting to be treated. It is believed that by doing so, the number of patients who leave without being treated will decrease, and that there will be a concomitant increase in patient satisfaction.

Day 32: Friday 7/14/17

•AM: Spent the morning getting my TB skin test checked. As expected, it was negative. Drove to the UNTHSC and was able to collect the signatures of Drs. Gwirtz and Ranjan. Submitted TB skin test results to Kathryn Kocureck for credentialing purposes.

•PM: Continued working on Quality Improvement Project protocol for PMH ED patients who leave without being treated. Submitted rough draft to Shannon for review/ consult.

Continued literature review for Quality Improvement Project. An article from Sweden proposes that physician-led team triage improves efficiency and quality in EDs as compared to a nurse-led team triage. Efficiency outcome variables included: i) time to physician, time from physician to discharge, and LOS; ii) four-hour turnover rate; iii) LWBS; iv) unscheduled returns; v) mortality after 7 and 30 days. [*Improved Quality and Efficiency After the Introduction of Physician-led Team Triage in an Emergency Department – Lena Burstrom, et al.*]

*****WEEK 8*****

Day 33: Monday 7/17/17

Continued to read pulled articles for the Quality Improvement Project concerned with addressing the incidences of patients leaving the PMH ED without being treated.

The first article addressed reducing waiting time (length of stay) by implementing a new triage style known as Medical Team Evaluation (MET), which involves having a treating physician on the front-end of the patient's care. Implementing such practice was found to decrease waiting time for patients, especially those with an

Emergency Severity Index (ESI) of 4 and 5, as well as a 2 and 3. Patients with an acuity of 1 require rapid intervention and are usually a priority. This study did note that having a physician involved in triage had a positive effect on radiological imaging, perhaps for the benefit of the downstream MDs treating the patient in the ED. [*Medical Team Evaluation: Effect on Emergency Department Waiting and Length of Stay – Julian Lauks, et al.*]

Another article put forth the query of how long patients were willing to wait to be seen. Utilizing surveys, it was found that at this specific facility, patients were usually willing to wait up to two hours, before leaving the ED. The demographic data gathered indicated that patients older than 25 y/o were more willing to wait the two or more hours to be treated. [*How Long are Patients Willing to Wait in the Emergency Departments Before leaving Without Being Seen? – Sanorar B. Shaikh, MD, et al.*]

The third article expounded upon using an Early quick Acuity Score (EQAS) in triage to facilitate a faster through time for patients, as opposed to the Traditional Acuity Score (TAS). The premise discussed therein proposes that when LWBS patients leave and have no ESI score, the data is lacking about the demographic make-up of these patients. And since there is no data to look into, addressing the issue of why patients leave before they are seen/ treated is more difficult to address/ ascertain. The idea is that by having more data on the LWBS patients, they can better be compared to non-LWBS patients. [*Early Quick Acuity Score Provides More Complete Data on Emergency Department Walkouts – Paris B. Lovett, et al.*]

The fourth article addressed decreasing ED wait times by streamlining patient intake/ triage and reducing redundancies in the clinical flow the patient receives, and utilizing “patient partners” on the front-end of the patient in-take. The article proposed that it is possible to improve a facility without implementing high costs. Not only did the ED efficiency improve, but so did patient satisfaction. [*Minimizing ED Waiting Times and Improving Patient Flow and Experience of Care – Assaad Sayah, et al.*]

Day 34: Tuesday 7/18/17

Continued Literature Review for the Quality Improvement Project addressing ED patients that leave without being treated/ seen (LWBS).

The first article described the effectiveness of using Resident Physicians as Triage Liaison Providers on the front end of ED patient treatment. This model when compared to a similar design utilizing Attending

Physicians in the same capacity was found to be effective in reducing Door to Provider time (DTP), increasing patient satisfaction, reducing LWBS percentages, and proved to be more cost effective with a greater return on investment (ROI). [*Effectiveness of Resident Physicians as Triage Liaison Providers in an Academic Emergency Department – Victoria Weston, MD, et al.*]

The next article identified cutoff times patients are willing to wait, before the chances of them walk-out begin to increase. It was found that a 20-35 minute wait is optimal; after that time frame, the chances of a patient walking out begin to increase. In this study, the authors noted as well that an LWBS numbers decreased when the time interval between Door to Provider decreased as well. [*Identifying Patient Door-to-Room Goals to Minimize Left-Without-Being Seen Rates – Shea Pielsticker, BS, et al.*]

The final article sought to reduce LOS stay by introducing a “Flexible Care Area” (FCA) into their existing ED. It is a front-end strategy, similar to the fast-track model of treating low acuity patients (ESI 3-5). The patients are “kept vertical” in the FCA, while sicker patients (ESI 1-2) are treated in ED beds. LOS is reduced, as less ill patients which require fewer resources are treated, and “fast-tracked;” whereas ESI more resources are able to be utilized on the 1s and 2s. The authors noted that LWBS was reduced as well with this model. [*The Impact of a Flexible Care Area on Throughput Measures in an Academic Emergency Department – Jayne McGrath, RN, MS, CEN, CCRN, CNS-BC, et al.*]

Day 35: Wednesday 7/19/20

Looked over more power point materials regarding the physiology of hemostasis to better understand on which factors of the intrinsic/ extrinsic pathways certain anticoagulants work on.

Took a side project for Shannon regarding the VAS Pain Scale Study which pertains to how ED nurses and physicians subjectively interpret a patient’s level of pain when compared to the patient’s own interpretation of pain level. The study seeks to find and address any inherent biases ED staff may have towards any subpopulations that come into the ED with a cc of pain. My role in this is to take the demographic data and VAS scores from the patient and the corresponding ED staff who treated them and put the data in a coded format into a database/ spreadsheet format so as to facilitate ease of access for when the biostatistician interprets the data.

Day 36: Thursday 7/20/17

Continued putting VAS Pain Scale Study into a database/ spreadsheet format.

Day 37: Friday 7/21/17

Continued putting VAS Pain Scale Study into a database/ spreadsheet format.

*****WEEK 9*****

Day 38: Monday 7/24/17

•AM: Drove to the UNTHSC to turn in Research Proposal forms as well as Intent to Graduate forms to the GSBS office. Found out as well that our studies have been approved by the UNTHSC IRB.

•PM: Continued putting VAS Pain Scale Study into a database/ spreadsheet format. Completed coding the VAS data up to the last date of data (7/17/17).

Day 39: Tuesday 7/25/17

Spent the day going over hemostasis, with special attention paid to the different Factors of the Intrinsic and Extrinsic as well as common pathways. Addressed how these three pathways are essential for the creation of Thrombin, and the subsequent role the latter plays in the creation of Fibrin as well as the role of platelets in the clotting process. The PowerPoint discussed as well the integral role Ca^{++} plays in the activation/ conversion of certain clotting factors

Discussed the role of Plasmin in dissolving clots (Fibrin Degradation). Discussed the role of anticoagulants as well, both natural and prophylactic.

Addressed several morbidities including a) Thrombocytopenia b) Hepatic Failure c) Disseminated Intravascular Coagulation (DIC) d) Hemophilia (A and B).

Went over the various coagulation tests that may be performed to ascertain if a patient's specific Clotting times are within normal/ acceptable ranges:

- **Prothrombin Time (PT)** – evaluates the extrinsic pathway. Normal range is 11-15 seconds. A prolonged PT may be indicative of Vitamin K deficiency.
- **International Normalized Ratio (INR)** – result of PT expressed as a ratio where the patient's clotting time of PT plasma is divided by the clotting time of a normal/ control plasma. Therapeutic interval is considered to be 2.0-4.5. Used in the monitoring of Warfarin therapy.

- **Activated Partial Thromboplastin Time Test (aPTT)** – Evaluates intrinsic pathway. Normal range is 25-35 seconds.

Prolonged PT and aPTT may be indicative of a deficiency of Factors X, V, II, or I (rare)

- **Thrombin Time (TT)** – normal time is 14-15 seconds. A prolonged TT may be due to Heparin or Hypofibrinogenemia.
- **Whole Blood Clotting Time** – 4-10 minutes. “Time taken for blood to clot mainly reflects the time required for the generation of Thrombin.

Abnormal bleeding time may be indicative of a) vascular defect b) platelet function defect c) platelet count abnormality d) drugs – dextran, indomethacin, salicylates (aspirin).

Day 40: Wednesday 7/26/17

Spent the day reviewing Hemostasis PowerPoint from the previous day.

Day 41: Thursday 7/27/17

Spent the majority of the day getting acquainted with the electronic patient information center (Epic) system with Khushbakht Bakhshi, a research coordinator in the Emergency Medicine Research Department. As a cursory introduction, she showed me how to screen for potential subjects/ recruits via the ED board and individual patient charts.

When screening, it is paramount to take good notes of all the patients screened, as it is against practice to just randomly select patient charts. One is to only review/ screen those charts where the patient seems to initially meet the inclusion criteria. In the case of the atrial fibrillation medication non-adherence study, we are initially screening for patients with one of the following chief complaints: a) chest pain b) shortness of breath c) dizziness/ fatigue e) leg pain/ swelling f) fatigue g) confusion h) abdominal pain i) palpitations/ tachycardia j) atrial fibrillation.

Khushbakt showed me how she makes her own list of screened patients for possible recruitment. The patient is chronologically numbered, the time of admission is recorded as is the patient's name, medical record number, age and sex, their location in the ED, and their chief complaint. If for any reason, the patient does not meet inclusion criteria, or even meets one (1) of the exclusion criteria, they are deemed DNQ (does not

qualify), and they are crossed off the list. All of this is recorded in the case audits are conducted, so that documentation/ records and practices may be satisfactorily reviewed.

In total, screened 37 patients. None met inclusion criteria.

Day 42: Friday 7/28/17

Followed Khushbakt in the ED in the AM hours. Observed how a research coordinator would go about screening and recruiting patients in the ED. Approach the specific “Pod” of the Parkland ED, confer with the treating physician that it is acceptable to approach the patient for the intent of research recruitment. Confirm that the patient in the room is indeed the patient you are looking for. Introduce yourself and your intent, briefly explain the study and what is required of the subject. It is imperative to confirm each of the inclusion criteria as well as any of the exclusion criteria (I am starting to find that actually finding a patient who meets all inclusion criteria and is free of exclusion criteria is easier said than done). Document everything, even when just screening Epic for potential subjects!

Spent the rest of the afternoon trying to establish/ confirm possible dates in November for the my thesis defense, as well as gather the requisite information to access and complete the Parkland Pathways modules so that I may gain access to the Parkland ED and begin subject recruitment.

*****WEEK 10*****

Day 43: Monday 7/31/17

Worked all day on Parkland training modules which covered topics from HIPAA to patient abuse reporting, to personal protective equipment (PPE), Code Greens, reporting agencies such as the DOJ, TXDHHS, and OCR, to name a few. Discussed Emergency Medical Treatment and Labor Act (EMTALA), patient rights, as well as fraud, Anti-Kickback Statute and Stark Law.

Day 44: Tuesday 8/1/17

Completed Parkland training modules and submitted completion certificates and proof of study participation to Research Credentialing.

The latter modules covered more extensively personal, as well as patient safety at Parkland. Great emphasis was given to hospital acquired infections awareness/ prevention as well as preventing/ reporting patient abuse,

blood borne pathogens as well as airborne pathogens, PPE, emergency operation planning, MRI safety, proper lifting, patient restraint, patient rights, informed consent, advanced directives.

Day 45: Wednesday 8/2/17

Reviewed PowerPoint addressing atrial fibrillation and treatment (*The New Frontiers in Atrial Fibrillation*).

Current management of atrial fibrillation includes antiarrhythmic drug therapy and catheter ablation or Maze procedure if the pathology is unresponsive to the antiarrhythmic therapy, and anticoagulant therapy as a measure for stroke prevention. Topics addressed included an increase in stroke risk with an increase in age. Associated risk factors include mitral valve stenosis, prosthetic heart valves, PMH of previous stroke or TIA [highest risk for subsequent stroke], age > 75 y/o (or between the ages of 65-75), HTN, DM, CHF, decreased liver function, CAD, female gender, thyrotoxicosis. Several of these can be used to interpret the risk of stroke utilizing the patient's CHADS₂ score. Low risk is 0-1; moderate to high risk is ≥ 2 .

The initial start of warfarin therapy carries with it an initial/ inherent risk of hemorrhage. Furthermore, it appears that patients over the age of 80 tend to experience more/ greater hemorrhage events than do those less than 80 years old. After this initial "onboarding," this risk decreases as one continues the drug therapy. The authors noted as well that those patients of 80 years of age or older were more apt to become nonadherent within the first year of therapy compared to their younger counterparts. The pros and cons of Warfarin therapy:

- Cons: delayed onset/ offset, unpredictable dose response, narrow therapeutic range, drug-drug and drug-food interactions, problematic monitoring, high bleeding rates, slow reversibility, excessive dosing predisposes patient to hemorrhage, inadequate dosing predisposes patient to stroke/ pulmonary embolism, proper dosing is usually found by trial and error, INR monitored at least monthly
- Pros: INR assesses anticoagulant level (optimal therapeutic range is between 2.0-3.0), ability to maintain INR is improving, multiple antidotes are available, omitting one or two doses is not clinically problematic, no liver toxicity, it has been around since 1954, inexpensive, no anticoagulant has demonstrated superior efficacy or safety [it should be noted however that NOACs have been rather well received as an alternative to the traditional route of Warfarin – does not require INR monitoring, more

dependable pharmacology, and has been found to be just as effective as Warfarin as a prophylaxis for stroke, better tolerated in elderly patients]

It is projected that the incidence of atrial fibrillation will increase over the coming decades, especially as the population ages. Furthermore, the PowerPoint authors allege that almost $\frac{3}{4}$ of ischemic strokes in patients with atrial fibrillation are due to either under-dosing their anticoagulation medication or a complete discontinuation of drug therapy.

Intracerebral hemorrhage can increase (>10%) on antithrombic therapy, and up to 40% on aspirin therapy. It goes without saying that ICH on anticoagulant therapy can be catastrophic.

Direct oral alternatives to warfarin include Dabigatran (thrombin inhibitor), as well as the Xa inhibitors Rivaroxaban, Apixaban, and Edoxaban [the last three are NOACs].

According to the authors of the PowerPoint (*The New Frontiers in Atrial Fibrillation*), the strongest predictor for non-adherence is polypharmacy. As such, patients modify how they take their meds based on how many other medications they are taking, to make their lives more convenient, to reduce untoward effects, and to reduce costs.

Day 46: Thursday 8/3/17

*Continued reviewing PowerPoint (*The New Frontiers in Atrial Fibrillation*), starting with an introduction to NOACs.

Begins with a review of the limitations of Warfarin:

- Slow onset of action → overlap of parental anticoagulant
- Genetic variation in metabolism → variable dose requirements
- Multiple food and drug interactions → frequent coagulation monitoring
- Narrow therapeutic index → frequent coagulation monitoring

Elderly patients are at a higher risk of stroke and hemorrhage. It is thought that NOACs will better serve this patient population, as the former has a wider therapeutic index, shorter half-life, no dietary interference, do not require monitoring, and have fewer drug-drug interactions, as opposed to Warfarin. Unfortunately, NOACs (which target Xa and Thrombin) have no antidote in the event of trauma.

Dabigatran targets and inhibits Thrombin (IIa) with a consistent and predictable pharmacology. Lower doses for elderly patients, those with decreased renal function, and CHADS₂ of 1 or less; higher doses for those with a CHADS₂ of 2 or more. Contraindicated in those patients who are stable on Warfarin therapy, have impaired renal function, liver disease, or who have poor compliance. 150 mg bid if low risk of bleeding; 110 mg bid if patients has measurable risk or at least one clinically relevant non-major risk.

Patients at low to moderate risk (score of 0-1) may be advised to take aspirin, 81-325 mg qd, possibly with an OAC if their CHADS₂ score is 1. Aspirin may also be taken concomitantly with clopidogrel for patients at moderate to high risk, if the traditional route of Warfarin is contraindicated.

Rivaroxaban and Apixaban both target Xa.

“Cytochrom P450 2C9 genotyping may identify mutations associated with the impaired metabolism of Warfarin. Furthermore, Vitamin K receptor Polymorphism testing can identify whether patients required low, intermediate, or high doses of Warfarin.” However, it should be noted that the “routine” testing of CYP2C9 and VKORC1 to genotype patients before beginning Warfarin therapy was not supported based on current evidence at the time of this PowerPoint (2008).

*Began reviewing next PowerPoint (*Preventing Atrial Fibrillation Related Strokes with Anticoagulant, September 2012 – June 2013*). The authors of this PowerPoint concluded that 25% of men and women over the age of 40 will develop atrial fibrillation, and that the “lifetime risks of atrial fibrillation are 1 in 6, even in the absence of prior CHF or MI.”

CHADS₂ is very widely used as a recognized scale for thrombosis and stroke risk. Factors included are CHF, HTN, age (≥ 75 y/o), DM, Stroke/ TIA/ TE.

CHA₂DS₂ – VAS_C: added categories for vascular disease, age 65-74 y/o, and sex category (female gender).

Other acronyms/ metrics for measuring stroke risk: ATRIA, *HAS-BLED and HEMORR₂HAGES. *Only one of the three to demonstrate significant predictive performance for ICH.

Attended monthly EM Department meeting. Discussed status of proposed as well as open studies. In the initial stages of being proposed are several studies which seek to investigate substance abuse patterns across different age ranges.

The proper procedures for exceptions from informed consent were discussed: it is an emergency situation, treatment is needed immediately, the patient cannot consent, there must be a prospect of benefit. Current studies which fall into this category are the ESETT study (seeks to measure the effectiveness of Fosphenytoin, Valproic Acid, and Levetiracetam in ED patients with Benzo-refractory status epilepticus, and the ACCESS study which seeks to determine whether late or early Cath-Lab access would be beneficial to Non-STEMI V-fib cardiac arrest patients.

Discussed modifications for carrying out Community Consultation Plan (CCP). The CCP is submitted to the IRB for approval, then the study is presented to the community. The feedback the study team receives from the community is then taken back to the IRB for review. A revised study protocol is then approved by the IRB based on the community feedback. Finally, the community is notified before the final version of the study is launched.

Opt-out option mechanisms were discussed (necklaces and bracelets), as well as surveys and demographic information collection. It was proposed that at most, gathering the zip-codes of survey takers would be satisfactory as a valid indicator for demographics.

Day 47: Friday 8/4/17

Reviewed PowerPoint (*Acute Management of A-Fib*). The PowerPoint leads the reader through an ED scenario where an elderly female presents who is hemodynamically unstable (tachycardic, hypotensive, RR 24, altered mental status). EKG indicative of new-onset atrial fibrillation with RVR [rapid ventricular response] and ischemia. The text suggests that the indicated treatment is immediate cardioversion to restore hemodynamic stability, and that restoring a regular sinus rhythm supersedes protection from thromboembolic risk. At this point, the PowerPoint is a proponent of rate control over rhythm control.

The next PowerPoint to be reviewed (*Evidence Based Management of Anticoagulant Therapy*), centered upon VKA drug therapy. Initially, patients should begin with a loading dose of 10 mg qd for the first two days, after which, their subsequent dosing will be based upon INR. The authors suggest that patients currently on a VKA regimen take vitamin K supplements. It is suggested to refrain from pharmacogenetics testing when initiating VKA therapy. Patients with a consistently stable INR may lengthen the interval between INR testing to 12 weeks, rather than the recommended four. If the patient has an INR which deviates from the normal range by

0.5 in either direction, it is recommended to remain on the current dosage and be tested every 1-2 weeks or until the INR returns to the optimal 2.0-3.0 range. The authors are proponents of good communication between patients and their PCP, as well as good/ adequate patient education in regard to their condition, INR testing, and follow-up. When VKA therapy is to be discontinued, it should be abrupt, and not tapered down. VKA naïve patients may hemorrhage more than patients who have been on VKAs previously. Major bleeding associated with VKAs, may be reversed by four-factor prothrombin complex concentrate along with Vitamin K 5-10 mg, slow IV push. It is suggested to avoid concomitant VKA therapy with NSAIDs, aspirin, and/ or antibiotics.

Next PowerPoint (*Anticoagulants and Thrombolytic*). Biosynthesis of the 13 factors that make up the extrinsic and intrinsic pathways are dependent upon Vitamin K1 and K2.

- **Intrinsic Pathway:** all clotting factors within the blood vessel, slower clotting time, utilizes the activated partial thromboplastin test (aPTT).
- **Extrinsic Pathway:** initiating factor (tissue factor) is outside the blood vessel, faster clotting time (within seconds), utilizes the Prothrombin test (PT).

Heparin works on the activated factors of the intrinsic pathway (XIIa, XIa, IXa, Xa, Thrombin). VKA work on factors within both the extrinsic and intrinsic pathways (VII, IX, X, II [Prothrombin], as well as Proteins C, S, and Z).

- **Heparin** (parental anticoagulant) – inactivates clotting factors – venous thrombosis prevention – monitored via aPTT - 1-5 hour $t_{1/2}$
- **Warfarin** (OAC) – inhibits synthesis of clotting factors – venous thrombosis prevention – monitored via INR – 8-12 hour delayed onset – 36 hour clearance rate
- **Aspirin** (antiplatelet) – decreased platelet aggregation – arterial thrombosis prevention (prophylaxis for MI, stroke, heart valve replacement/ shunts) – inhibits cyclooxygenase (COX)
- **Streptokinase** (thrombolytic) – fibrinolysis – dissolves thrombi

Next PowerPoint (*Anticoagulants*). Calcium ions must be present for the thrombin system to begin.

Next PowerPoint (*A New Era in Anticoagulation Management*).

*****WEEK 11*****

Day 48: Monday 8/7/17

Started the day with a review of heparin (*Heparin*): Of low molecular weight and have a high affinity for activated Factor X (Xa), but less so of an effect on thrombin. To have its effect on Xa, heparin must interact with ATIII (Antithrombin III); heparin potentiates the actions of ATIII. To have an effect on thrombin, heparin must bind with ATIII as well as an enzyme. The heparin/ ATIII complex neutralizes the actions of Factors II (thrombin), IX, X, XI, XII, XIII. “Thrombin-induced activation of Factors Va and VIIIa is inhibited by the heparin/ ATIII complex.” Low concentrations (“mini-doses”) of heparin are sufficient to carry out anticoagulant functions. Platelet Factor IV (from endothelial cells) is a protein which can neutralize heparin. Anticoagulant effects of heparin disappear within hours of cessation of infusion.

Adverse Effects of Heparin:

- Heparin Induced Thrombocytopenia
- Heparin Induced Thrombocytopenia and Thrombosis
- Risk of potential osteoporosis

Low-molecular weight heparin is reversible with protamine (1mg per mg of LMWH).

Heparin Lab Monitoring:

- aPTT/ TCT: normal clotting time is 23-35 seconds. Therapeutic range is 50-70 seconds (1.5-2.0 times normal value). Evaluation of intrinsic pathway.

Heparin is the anticoagulant of choice for pregnant mothers as it does not cross the placenta, and has no untoward effects on the fetus.

Completed EPIC training via Parkland Pathways. Pursuant to this, my EPIC account should be activated within 48 hours.

Day 49: Tuesday 8/8/17

Began review of *Blood Coagulation & Fibrinolysis*.

Attended weekly Emergency Medicine Department meeting. Discussed were the TXA study (drug study to measure effectiveness of decreasing ICH), as well as the ESETT study (drug study measuring the effectiveness of three drugs on status epilepticus refractory to benzo-diazepam).

Rehashed *Exception to Informed Consent* as well as *Community Consultation* protocols from last week. The latter is to be thought of as a “continuous process,” that evolves/ grows with time. Dr. Idris made the point that most people opt out of a study because they simply do not want to be involved without first giving their consent; they could care less about the nature of the study. Discussed a version of the Modified Rankin Scale (measures degree of neurological disability in daily activities secondary to stroke or other pathologies which would lead to such a deficit) for the ACCESS study.

Last week’s disparaging article “Watchdog” actually turned out to be a blessing: given its wide circulation and distribution (paper and internet), the article actually informed *more* people about the study and how to opt out of it if they want to (non-consent bracelet and necklace). Basically, it was free advertising.

Day 50: Wednesday 8/9/17

Continued reviewing *Blood Coagulation & Fibrinolysis*.

Had an introduction and data abstractor training session for the study *The Influence of Time-to-Diagnosis on Time-to-Treatment for STEMI Patients*. The study is a retrospective cohort study. The PI for the study is Dr. Maya Yiadom of the Emergency Medicine Department at Vanderbilt University. The study is looking at data from seven different medical facilities across the country for the years 2014-2016 (review of electronic health records for STEMI ED patients). The aim of the study is to determine the effect the time-to-diagnosis has on time-to-treatment for STEMI patients. Specifically, the study looks to compare two STEMI patient populations: those who receive the recommended timely diagnosis in 10 minutes or less, and those missed cases diagnosed after the recommended 10-minute cutoff. The study “will quantify the differences in the diagnosis-to-treatment interval,” in the two patient populations.

Day 51: Thursday 8/10/17

Continued reviewing *Blood Coagulation & Fibrinolysis*.

Samita and I worked through a patient's chart to extract information for the STEMI study. Practicing looking through EPIC requires a good bit of detective work and intuition. There are 9 instruments used to gather patient data: i) Hospitalization ii) Demographics iii) Emergency Department iv) Electrocardiograms v) Past Medical History vi) Initial Laboratory Results vii) STEMI Intervention viii) Ejection Fractions ix) Follow-up. Of particular importance, we are mostly looking for EKG diagnosis times and the time to the CATH-Lab (times and notes).

Day 52: Friday 8/11/17

Continued practice of taking extracted data from EPIC and recording it into RedCap for the STEMI study.

There is still data within the patient's EHR that we were not able to locate, especially some of the ED and CATH-Lab time-stamps. Past medical history, triage times, and a list of chief-complaints will require a little extra digging as well.

Attended office meeting regarding the IT side of things: How to utilize the touch screens in the conference rooms.

*****WEEK 12*****

Day 53: Monday 8/14/17

Began PowerPoint (*Drugs Used to Reduce Clotting*) as a review of i) anticoagulants ii) antiplatelets iii) Thrombolytics. As such, this pertained to the heparins and hirudin (leeches), warfarin, aspirin, and streptokinase. Essentially, the mechanism of action, structure, metabolism, $T_{1/2}$, dosing, as well as the requisite antidote in the event of bleeding were discussed.

In the afternoon, I proceeded to practice data extraction in EPIC for the STEMI study (pertaining to the time from diagnosis to time of treatment and the respective link to patient outcome). I am finding that the patient notes as well as the patient encounter, media file, labs, cardiopath file, and discharge form will prove to be the most helpful in finding the pertinent information for the study.

Day 54: Tuesday 8/15/17

Samita and I practiced extracting data from EPIC requisite to our training to be data extractors for the STEMI study. We then logged the information into REDCAP for our one respective practice “patients.”

Day 55: Wednesday 8/16/17

Helped out Shannon, Gail, KB, and Mario with the orientation for the Fall TEMRAP students’ orientation. The whole process included them getting their UTSW access badges, how they are to conduct themselves while in the ED, HIPAA, the role they may play in the upcoming quality improvement project (reducing the number of patients who leave the ED without being treated), and getting credentialed. Mostly, they are undergraduates from UTD, the majority being pre-med.

Before leaving for the day, KB and I went through my recruitment folder. Since I still have not gotten translated ICF and HIPAA authorization forms, I can only recruit English speaking patients at the moment.

Day 56: Thursday 8/17/17

Spent majority of morning screening patients in EPIC. Zero patients met all inclusion criteria or had at least one exclusion criteria.

In the afternoon, Samita, KB, and myself went to the ED to recruit a patient for Samita’s study. I observed the recruitment process as KB worked through the IFC and HIPAA authorization forms with the patient. Flow is important, as is being able to concisely answer the patient’s questions as they pertain to the study.

In total, screened 30 patients. None met inclusion criteria.

Day 57: Friday 8/18/17

Have been screening patients all morning with no real success. Even finding patients who have, or have had atrial fibrillation in the past is not occurring at the rate I initially thought it would. After screening patients from 0548 until 1257, I encountered maybe two patients with a past medical history including atrial fibrillation and concomitant warfarin therapy. In the ED, the criteria being used to evaluate whether or not a patient can participate in the study are their chief complaint along with signs and symptom, their ECG, and whether or not they are on oral anti-coagulants (OACs). Most patients have either undergone heparin injections to treat their present illness, or have had surgical ablation to treat the condition (a-fib).

In total, I screened 27 patients. None met inclusion criteria.

*****WEEK 13*****

Day 58: Monday 8/21/17

Spent the majority of the day screening ED patients. I screened 34, and not one met the requisite inclusion criteria for the study. I usually check for an INR score between 2.0-3.0, an ECG of atrial fibrillation/ flutter, the patient's past medical history, as well as current and past medications. Given how some signs and symptoms can be ambiguous and indicative of a myriad of ailments, I am beginning to lean more towards screening patients 40 years and older, as atrial fibrillation (along with other stroke risk factors) appears more in older patient populations. If nothing changes and recruitment remains low, we (Shannon and I) have discussed modifying the protocol via the IRB to screen for patients who have been admitted via the ED.

In total, I screened 34 patients. None met inclusion criteria.

Day 59: Tuesday 8/22/17

•AM: Ventured down to the ED in PMH with the intention of recruiting two patients. On the walk over, KB and I discussed the procedure of recruiting patients into a research study: Locate the POD in which the patient is located and approach the treating physician to find out whether or not the patient meets inclusion criteria as well as whether or not it is permissible to approach the patient (altered mental status, too sick, etc.), confirm the patient's identity, explain the study to them and their role in it, and ask if they would like to participate, thoroughly go through/ explain the IFC and HIPAA authorization forms and sign, patient demographics, and finally, complete the surveys of the study.

I located three patients in the ED who met inclusion criteria. When I approached their respective treating physicians as to whether or not the patients could participate in the study, I was informed that all were compliant in their anticoagulant medication regimens. As such, they were excluded from the study.

•PM: Screened ED patients in the EM office. Trying to be more methodical with how I screen for patients: I am starting to find that most atrial fibrillation patients are 50 or older, and that their INR score is a good indicator of whether or not they are compliant. "Chest pain and shortness of breath" are rather ambiguous symptoms that can be indicative of a wide array of illnesses.

In total, screened 25 patients.

Day 60: Wednesday 8/23/17

•AM: Screening patients.

•PM: Screening patients.

In total, screened 43 patients all day.

Day 61: Thursday 8/24/17

•AM: Screening patients. Recruited one patient.

•PM: Screening patients.

In total, screened 35 patients. Enrolled one.

Day 62: Friday 8/25/17

Helped out Shannon, Gail, and Mario with the orientation for the Fall TEMRAP students' orientation. The whole process included them getting their UTSW access badges, how they are to conduct themselves while in the ED, HIPAA, the role they may play in the upcoming quality improvement project (reducing the number of patients who leave the ED without being treated), and getting credentialed. Mostly, they are undergraduates from UTD, the majority being pre-med.

*****WEEK 14*****

Day 63: Monday 8/28/17

•AM: Screening patients. Attempted to recruit a patient meeting inclusion criteria. They declined to participate.

•PM: Screening patients.

In total, screened 34 patients today.

Day 64: Tuesday 8/29/17

•AM: Screening patients. Recruited one patient.

•PM: Screening patients.

In total, screened 27 patients. Enrolled one in the study.

Day 65: Wednesday 8/30/17

•AM: Screening patients.

•PM: Went down to the ED around 11:30AM, and did not leave until around 5:30PM. I was able to recruit four patients. Working on a better bedside manner and not getting too hoarse during the process is something I am trying to take more into account as I continue to speak with and recruit patients. Also better interaction with ED staff is key!

In total, screened 34 patients. Enrolled four.

Day 66: Thursday 8/31/17

Screening patients. Entered those already recruited into Velos (links patients enrolled in studies by UT Southwestern to their Parkland medical records number).

WEEK 15

Day 67: Tuesday 9/5/17

•AM: Screening patients.

•PM: Went down to the ED to recruit. Had difficulty locating patients, as a mass casualty incident (MCI) moved them around the ED to different pods/ rooms. The one patient I was able to locate was not currently on anticoagulants; therefore, they did not meet the less-restrictive inclusion criteria of the original UTSW study protocol. Frustrating afternoon to say the least.

In total, screened 47 patients. Enrolled zero.

Day 68: Wednesday 9/6/17

•AM: Screening patients. Successfully screened, consented, and enrolled one patient.

•PM: Office meeting pertaining to different aspects of team work. We went through a team building exercise with Lego/ building blocks and utilized different aspects of leadership and teamwork to correctly build the Lego structure in the allotted amount of time.

Went down to ED to attempt a patient enrollment. The patient met inclusion criteria, but their vision was impaired, and without their glasses, they would not have been able to complete the visual component of the NVS survey which requires the patient to read and interpret a nutrition label and then answer questions based on the information found therein. As such, the patient could not be enrolled.

In total, screened 21 patients. Enrolled one.

Day 69: Thursday 9/7/17

•AM: Screening patients.

•PM: Went to ED to enroll. Was able to get two patients, one requiring a Spanish interpreter. Attempted to reenroll a third. Half-way through the process, the patient informed me they were tired and wanted to take a break and that I should come back later. Not a problem I said, and left to enroll other pre-screened patients. Upon returning to this patient's room, I found that they had been discharged about 20 minutes before I got there (I was enrolling the Spanish speaking patient at the time).

From now on, I will include in my recruitment packet two copies of the ICF and the HIPAA authorization so as to not need to make copies and use PMHED resources. This way, I can always provide the patient with their copies of the ICF/ HIPAA authorization whether or not they finish the study or decide half-way through they no longer wish to participate.

Screened 23, enrolled two.

Day 70: Friday 9/8/17

•AM: Screening patients. Considering today or Monday emailing Dr. Gwartz to inform her that I am now a little afraid I am not going to reach power for the study unless my enrolling/ recruiting drastically improves.

•PM: Data extraction for the STEMI study from Vanderbilt.

Screened 17. Enrolled zero.

*****WEEK 16*****

Day 71: Monday 9/11/17

•AM: Screening patients.

•PM: Screen four potential patients for inclusion criteria and proceeded to the ED to enroll them into the study. Upon speaking with either the patient or the treating physician, three of the four were eliminated from possible enrollment for a number of reasons: i) one patient had cataracts which impeded his ability to read the nutrition label and participate in the NVS ii) another patient was severely impaired due to a previous CVA iii) another patient had new onset atrial fibrillation (or they had it for a while and did not know) and was not

currently on any OACs to the best of their knowledge. The last patient was successfully screened for inclusion, consented, and enrolled into the study.

In total, I screened 37 patients today for possible enrollment, and was only able to approach four, and only one was enrolled.

Day 72: Tuesday 9/12/17

- AM: Screening patients. Was able to recruit one patient in the morning.

- PM: Recruited another patient in the afternoon. Further screening yielded no patients meeting inclusion criteria.

In total, I screened 27 patients for possible enrollment. I approached two, and enrolled those two.

Day 73: Wednesday 9/13/17

- AM: Screening patients. Went down to the ED and attempted to enroll two patients. Was not successful:

One patient was asleep (I checked on them twice an hour apart, and they were out both times). The other patient required a Spanish interpreter. At that particular moment in the ER, the interpreters were spread rather thin and I did not want to impinge their clinical duties.

- PM: Screening patients. Returned to the ED and successfully enrolled one patient. The patient was Spanish speaking and required the help of a certified PMH interpreter.

Screened 25 patients. Only two met criteria. Was able to approach and successfully enroll one.

Day 74: Thursday 9/14/17

- AM: Screening patients. Two met inclusion criteria

- PM: Screened patients. Went down to ED to approach and enroll the two prescreened patients. Approached one patient to discuss the study. The patient stated that they wanted to leave soon and were going to wait to speak with the doctor before they left. Therefore, they declined to participate in the study. But they did state, "Maybe next time."

Approached the nursing staff in a separate pod about possibly enrolling the other patient. Per our discussion, the patient was short of breath and had just been taken off of a breathing treatment. At that time, the nurses states that the patient was somewhat altered and confused and surrounded by ED staff. Taking into account the

nurses' statements and the clinical condition of the patient, it was deemed by all present (myself included), that now was not a good time to approach the patient.

Screened a total of 27 patients, two meeting inclusion criteria. I attempted to approach these two patients.

One declined to participate, and the clinical staff for the other deemed that the patient's present condition was not conducive to their ability to participate in the study.

Day 75: Friday 9/15/17

•AM: Worked on the Vanderbilt STEMI study and continued data abstraction.

•PM: Attended meeting for the TEMRAP trainers. Filled them in on the recruiting procedures for the A-Fib Study.

Sent email to Dr. Gwartz regarding enrollment numbers and my concern that the study will not reach power.

The following numbers were sent in the email:

Table 3: Enrollment Trend at Four Weeks

Sean's study											
Start Date: Aug 17, 2017	#	%	per day	per week							
Business Days	21										
Weeks	4										
Patients Pre-Screened	523		25	131							
Patients Meeting Inclusion Criteria	23	4%	1	5	eligibility rate						
Patients Approached	21	91%	1	5	approach rate (of those eligible)						
Patients who remained eligible after screening	14	67%			eligibility rate						
Patients Enrolled	13	93%	1	4	enrollment rate (of those approached)						
Patients refused	1	7%			refusal rate (of those approached who remained eligible after screening)						
Rate	2.49%										
Patients Enrolled per Week	3.25										
Expected Enrollment in the Six Week Period	19.5 (+/-)										

Based on the present numbers, I have pre-screened on average 25 patients per day, 131 per week. Of those patients pre-screened, 23 (4%) have met the inclusion criteria. Of those, 21 (91%) have been approached, with 14 (67%) remaining eligible. Of those remaining eligible after screening, 13 (93%) have been enrolled; the one patient (7%) refusing participation.

As such, my enrollment rate is in the 90th percentile of those meeting the inclusion criteria. The issue at hand is that the number of those meeting the inclusion criteria is much lower than we expected. Another unforeseen barrier was the one week suspension of enrollment near the end of the enrollment period.

*****WEEK 17*****

Day 76: Monday 9/18/17

- AM: Cannot screen/ enroll patients in A-Fib Study until the site approval is granted. Worked on the Vanderbilt STEMI study and continued data abstraction.

- PM: Worked on the Vanderbilt STEMI study and continued data abstraction.

Day 77: Tuesday 9/19/17

- AM: Worked on the Vanderbilt STEMI study and continued data abstraction.

- PM: Worked on the Vanderbilt STEMI study and continued data abstraction

Day 78: Wednesday 9/20/17

- AM: Worked on the Vanderbilt STEMI study and continued data abstraction.

- PM: Worked on the Vanderbilt STEMI study and continued data abstraction.

Day 78: Thursday 9/21/17

- AM: Still waiting to have “officially” been given site approval from Parkland. As such, worked on the Vanderbilt STEMI study and continued data abstraction. Will have completed 12 out of the 50 MRNs by this morning. The afternoon/ evening I intend to do a once over of the completed packets for editing and verification of information. I also need to begin printing the source documents for each MRN data packet. The tentative plan is for Shannon, Samita, and myself to do as many as possible over the weekend.

- PM: Worked on the Vanderbilt STEMI study and continued data abstraction.

Day 79: Friday 9/22/17

•AM: Worked on the Vanderbilt STEMI study and continued data abstraction.

•PM: Worked on the Vanderbilt STEMI study and continued data abstraction. Got performance site approval from Parkland, so now I can get back down into the ED next week and hopefully make up for lost time enrolling.

The plan is to come in tomorrow (Saturday), and help with STEMI study.

Day 80: Saturday 9/23/17

Came in with Mario and Samita to help Shannon out with the STEMI study. Printed off the source documents for the MRNs already completed. Thus far, I have completed 18 MRNs, and have printed the source documents for nine.

*****WEEK 18*****

Day 81: Monday 9/25/17

•AM: Now officially have site approval at Parkland, so I will try to make up for lost time. Screening for prospective patients to enroll into Afib Study.

•PM: Screening patients.

Screened 35 patients. Two met inclusion criteria. I approached one, and enrolled one.

Day 82: Tuesday 9/26/17

•AM: Screening for prospective patients to enroll into Afib Study. Went down to ED to enroll. Prescreened four patients who met inclusion criteria and approached three. One patient declined to participate, and the other two wanted some time to think about it. Essentially, zero enrolled in the AM.

•PM: Screening patients. Went down to try and enroll a patient encountered earlier in the ED. Upon going through the ICF and HIPAA Authorization, the patient decided they no longer wished to participate in the study. I thanked the patient for their time, asked if there was anything I could do for them before leaving, and left their room.

Screened 34 patients all day. Four met inclusion criteria. I approached three, and all three declined to participate. Zero enrolled for the day.

Day 83: Wednesday 9/27/17

•AM: Screening for prospective patients to enroll into Afib Study. Prescreened one patient meeting inclusion criteria. Patient was Spanish speaking, and with the assistance of an interpreter I approached the patient.

Patient declined to participate in the study as they said they needed to speak to/with Medicare/ Medicaid first?

•PM: Completed Parkland Pathways training: Emergency Operations for 2017 and Abuse & Neglect.

Total patients screened: 29. Prescreened patients meeting inclusion criteria: one. Patients approached: one.

Patients enrolled: zero.

Day 84: Thursday 9/28/17

•AM: Screening for prospective patients to enroll into Afib Study.

•PM: Screening for prospective patients to enroll into Afib Study.

Went to ED to enroll the one patient found meeting inclusion criteria. Located patient in the trauma pod of the ED, spoke with treating physicians and was able to approach the patient. Asked patient if they would like to participate in the study, and they answered in the affirmative. After going through the ICF, the patient, informed me that they were in too much distress to continue. I assured them there was no problem and thanked them for their time and left. Screened patients for the remainder of the afternoon with no success finding patients meeting inclusion criteria.

Total patients screened: 53. Prescreened patients meeting inclusion criteria: one. Patients approached: one.

Patients enrolled: zero.

Day 85: Friday 9/29/17

•AM: Assembled recruitment packet pdf for the TEMRAP students and assembled two folders with the study materials to be available down in the ED for TEMRAP students should they be able to locate and enroll potential patients.

•PM: Went to the Parkland to drop folders off in the ED for the TEMRAP students as well as went by Language Services to service the Alvin Unit (mobile translating device).

*****WEEK 19*****

Day 86: Monday 10/2/17

•AM: Screenign patients. Went down to ED to enroll patients.

Prescreened a possible 28 patients. Three met inclusion criteria. I approached all three meeting the criteria and enrolled one patient. Of the two who were not enrolled, one patient had possibly altered mental status and could not be brought to focus on the study, and the other did not wish to participate after we had gone through the ICF together.

Two other prescreened patients did not meet inclusion criteria as they either a) were diagnosed with atrial fibrillation but were not on oral anticoagulants, or b) they were prescribed oral anticoagulant, but were diagnosed with atrial flutter rather than atrial fibrillation.

Day 87: Tuesday 10/3/17

Spent majority of day inputting data into spreadsheet/ Excel format.

Met with the biostatistician in the afternoon and discussed the specific aims of our respective studies.

Day 87: Wednesday 10/4/17

Edited original research proposal to now be in the past tense.

Got together with Samita to discuss a game-plan on how to approach completing our respective projects. The plan we have is to work on the Power Point slides that we can until Beverly the biostatistician returns the results of our data. As such, we will work on a Definition of Terms, The Introduction, The Background, The Methods, and the References. This will occur during the week of October 9th through the 13th.

We should receive the results of our data by the 15th of October. Therefore, the week of October 16th through the 20th, Samita and I will work on the slides for The Abstract, The Results, and The Summary/ Conclusion.

Day 88: Thursday 10/5/17

The plan for the day is to begin working on the Power Point slides that I am able. They will be worked on in Word before being put into the slide show.

Was able to type/ copy and paste the content for the Introduction, Background, and Method sections. Began/ created the initial slides for the public thesis presentation.

Plan for tomorrow is to begin typing up the summary of my internship experience, as well as looking up references for the Power Points I used to study hemostasis.

Day 89: Friday 10/6/17

Spending the morning reading through and summarizing my journal entries into one document. The plan for the afternoon is to hopefully print out primary source documents for a few of the MRNs for the STEMI study.

*****WEEK 20*****

Day 90: Monday 10/9/17

•AM: Tentative plan for the morning is to complete the next one-third of the summary for my daily journal entries. Upon completion of this task, I will begin working on the Power Point presentation for thesis defense.

Day 91: Tuesday 10/10/17

Went to the UNTHSC and turned in the Intend to Defend form to Carla. Spoke with all Advisory Committee professors with the exception of Dr. Peirce. We discussed where I was in the process of writing my thesis: research proposal put in the past tense, introduction, methods, and background section put into a format which can be injected into the body of the thesis as the body of the whole comes together. All profs appeared satisfied with my progress, as well as giving input on how to proceed and how to address the low enrollment numbers.

Day 92: Wednesday 10/11/17

Plan for today is to work more on summarizing my daily journal, see what is possible to do with the Power Point, and possibly begin working on a limitations section. Dr. Gwartz sent me a template example of how to write the body of a thesis. I will look this over and compare it to my own progress.

Day 93: Thursday 10/12/17

Received my data back from Beverly. Will look this over and discuss how to interpret it with her as well as with Shannon. The plan for today is to do more journal summary, complete what I can on the Limitations section, and input that into the PowerPoint.

Day 94: Friday 10/13/17

Plan for today is to look through patient demographic information and type up a summary of the results. To that end, I will continue to work on the daily journal summary.

*****WEEK 21*****

Day 95: Monday 10/16/17

Worked on completing patient demographics charts and began hammering out the results section.

Day 96: Tuesday 10/17/17

Working on the results section. Begin putting sections into a sequential format.

Day 97: Wednesday 10/18/17

Made charts of data.

Day 98: Thursday 10/19/17

Working on edits for limitations, discussion, and results sections.

Day 99: Friday 10/20/17

Worked on thesis and charts. Emailed sections to Dr. Gwartz for review.

*****WEEK 22*****

Day 100: Monday 10/23/17

Implemented edits from Dr. Gwartz, formatted thesis into a single document via template. Sent to Dr. Gwartz for review.

Day 101: Tuesday 10/24/17

Work on edits from Shannon and Dr. Gwartz. Continue to work on the format of the completed document.

Met with Beverly to discuss the data, why Fisher's Exact Test was used, possibly seeing if we came closer to power than initially thought as we focused on only one aim instead of three. This could explain why marginal significance was found between NVS and patient motivation. Review/ explored the validity of the MMS.

Day 102: Wednesday 10/25/17

Implement edits into draft from Dr. Gwartz. Work on formatting. Resubmit to Dr. Gwartz.

Day 103: Thursday 10/26/17

Completed the appendices of the thesis document. Submitted thesis to Advisory Committee.