Comparative assessment of IV acetaminophen and conscious sedation for pain relief during invasive cardiac procedures

Zainab I. Alam

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COMPARATIVE ASSESSMENT OF IV ACETAMINOPHEN AND CONSCIOUS SEDATION FOR
PAIN RELIEF DURING INVASIVE CARDIAC PROCEDURES

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the
Graduate School of Biomedical Sciences
University of North Texas
Health Science Center at Fort Worth
in Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE
IN CLINICAL RESEARCH MANAGEMENT

By
Zainab I. Alam, B.S., B.S.
Fort Worth, Texas
March 2016
ACKNOWLEDGEMENTS

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<td>19</td>
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</tbody>
</table>
CHAPTER I
INTRODUCTION

Over the last decade, interventional cardiology procedures in the cardiac catheterization laboratory (Cath lab) have increased exponentially (Hamid, 2014). As such, exceptionally complex procedures are being performed in Cath labs that can sometimes entail several hours (Furniss et al., 2015). Safe sedation is fundamental to such procedures, yet only in 1996 did the American Society of Anesthesiologists issue a general guideline for safe moderate sedation for non-anesthesiologists (Gross et al., 1996). It has been even longer for any guidelines specific to cardiology. In 2012, the Society for Cardiovascular Angiography and Interventions (SCAI) released a clinical expert consensus statement on best practices in the Cath lab (Naidu et al., 2012).

While the consensus statement did create some consistency, the level of sedation, however, is left to the discretion of the physician and misadministration of procedural analgesics or over administration can lead to serious complications (Naidu et al., 2012). The United States Food and Drug Administration (FDA) has approved intravenous (IV) Tylenol for the management of mild to moderate pain as well as the management of moderate to severe pain with adjunctive opioid
analgesics (Malesker et al., 2015). There is now ongoing research being conducted in regards to IV Tylenol as a substitute for analgesics (Malesker et al., 2015).

CHAPTER II

BACKGROUND AND LITERATURE REVIEW

Pain is a uniquely unpleasant and multidimensional sensory experience (Woolf, 2004), and as such, the pathogenesis of pain is currently an emerging field of research (Woodcock et al., 2007). There are biological techniques that contribute to the analysis of pain mechanisms and have led to discovering new target sites, in order to provide highly specific analgesia (Woodcock et al, 2007). In addition, there are now different categorizations for pain that originate from the nature of source (Woolf, 2004). For example, a needle stick penetrates the skin and induces nociceptive pain, and inserting a catheter can result in tissue injury; leading to activation of inflammatory pain (Woolf, 2004). Depending on the source of the pain, different techniques are utilized to facilitate certain physiological approaches to decrease pain (Naidu et al., 2012; Woolf & Max, 2001).

Surveys conducted across the world have identified several conscious sedation protocols involving the use of an analgesic, benzodiazepine, and
antihistamine medications that aim to keep patients in an aware state of consciousness during diagnostic or interventional procedures (Beddoes et al., 2008), known as moderate sedation (Deftereos et al., 2013). The two most commonly used agents for moderate sedation are fentanyl and midazolam (Deftereos et al., 2013). Fentanyl is quickly distributed from the plasma to highly vascular tissues like the heart and brain, and provides its analgesic effect mostly at the site of insertion after crossing the blood-brain barrier (Peng & Sandier, 1999). Midazolam does not necessarily reduce pain, but instead, conceals it by means of inducing amnesia (von Delius et al., 2007).

As with any sedation, there are some concerns when it comes to moderate sedation. Benzodiazepines can cause significant hemodynamic instability due to decreased hepatic metabolism inducing an accumulation of the drug in the bloodstream (Laussen & Hansen, 2000). Unintentional advancement from moderate sedation to deep sedation is also a possibility (Hamid, 2014). There is also a documented delay in recovery time, which can lead to errors in monitoring the patients’ post procedural status (Furniss et al., 2015). This can lead to greater duration of hospital stay and ultimately less efficient patient treatment. With fentanyl being a narcotic opioid, respiratory depression leading to decreased oxygen saturation can often occur and be potentially life-threatening (Laussen & Hansen, 2000).

Intravenous potent short acting opioids, such as fentanyl, act specifically on central nervous system opiate receptors and produce a sedative effect by decreasing sympathetic activity and increasing parasympathetic activity (Donati et al., 2014).
Surprisingly, a recent placebo controlled study on the effects of fentanyl on procedural pain yielded no statistical significance in pain outcomes between the treatment and placebo groups (Samantaray & Rao, 2014). However, benzodiazepines, such as midazolam, potentiate the negative opioid effect of fentanyl by furthering respiratory depression, and at the same time reducing the analgesic effects leading to undesirable patient outcomes (Lu et al., 2013).

Intravenous (IV) administration of acetaminophen (Tylenol) has been approved by the FDA since November of 2010 (Malesker et al., 2015). IV Tylenol provides an analgesic effect by readily permeating the blood-brain barrier via passive diffusion (Malesker et al., 2015). IV infusion of Tylenol causes rapid elevations in plasma concentration of the drug, while avoiding the locally high drug levels in portohepatic circulation that lead to hepatotoxicity (Viscusi et al., 2012). Using IV Tylenol has been shown to result in significantly higher concentrations in cerebrospinal fluid (CSF) sooner than any other route (Singla et al., 2012), while maintaining duration of action for up to 6 hours (Malesker et al., 2015). It has been demonstrated that IV Acetaminophen improves pain management and reduces opioid requirements in surgical patients (Viscusi et al., 2012). IV acetaminophen may be preferable for less invasive procedures such as cardiac catheterization because, unlike other analgesics, it does not alter mental status, bleeding times, respiratory rate or renal function (Viscusi et al., 2012).

Scientific research indicates that pain perception varies by factors such as gender, race and age (Wandner et al., 2012). However, there is less consistent research on differences related to age (Wandner et al., 2012). Some studies indicate
that pain perception is dulled with age (Rittger et al., 2011), while others suggest that older adults suffer from an increased sensitivity to pain (Lautenbacher et al., 2005). A possible explanation for this discrepancy is the different pathways by which pain is registered have not always been taken into consideration since there is pressure-induced nociceptive pain as well as heat-induced nociceptive pain, which can both undergo summation that can alter responses (Lautenbacher et al., 2005). To prevent possible confounding in this practicum project, the age of patients was taken under consideration in creating the model for this experiment.

SPECIFIC AIM

The primary aim of this study was to compare pain perception during cardiac catheterization procedures reported by patients with moderate or conscious sedation compared with IV Tylenol infusion. Thus, the main goal of the study was to test the null hypothesis that the mean difference between pain ratings with moderate sedation and IV Tylenol is 0. The criterion for significance, alpha (α), was set at .05, and a two-tailed test of significance was selected.
SIGNIFICANCE

While moderate sedation is generally expected for those undergoing cardiac catheterization, there is much variability in the method of achieving such sedation (Conway et al., 2011). Depending on the type of procedure, there are different types of anesthetic agents that are administered (Hamid, 2014). Most commonly, moderate sedation consisting of a benzodiazepine and an opioid is administered with the help of the nursing staff according to institutional guidelines (Hamid, 2014). While many labs use varying doses of midazolam and fentanyl, some use diazepam and Benadryl (Kern, 2009). Other physicians choose to use morphine, and some labs administer no sedation (Kern, 2009). The standard pre-procedural medication at the Cath Lab at the Veterans Affairs North Texas Health Care system is 50 mcg of fentanyl with 1 mg of midazolam.

Despite awareness of potential negative outcomes for patients, there has not yet been a better alternative to the benzodiazepine and opioid cocktail (Beddoes et al., 2008). This practicum study can serve as a tool to provide a better understanding of the utility of IV Tylenol, while hopefully, causing a positive impact on the current standard of care by providing a safer alternative.
MATERIALS AND METHODS

Study Population

The population consisted of adult patients undergoing cardiac catheterizations at the Veterans Affairs North Texas Health Care system from October 22\textsuperscript{nd}, 2014 to September 15\textsuperscript{th}, 2015.

Data Collection and Screening

Data collection was done from Veterans Affairs North Texas Health Care System electronic medical records (CPRS). Patients were screened by date of procedure, age and type of procedure. The Cath Lab Procedure Reports are accessible in PDF format through VistA Imaging on CPRS and were used to attain patient arrival time, table time, procedure start and stop times as well as medication administration times and pain levels recorded by nurses. The “Notes” tab on CPRS was used to obtain “Cardiac Pre-Cath History & Physical,” “Cardiac Cath Procedure Reports,” and a variety of admission and discharge notes to record patient demographics.

Matching

This practicum project was a retrospective study with the treatment group consisting of 60 patients that received IV Tylenol, instead of fentanyl and
midazolam, during their catheterization. This group was matched based on age and type of procedure with a control group consisting of 60 patients that received moderate sedation consisting of fentanyl and midazolam. The type of procedure was subdivided into diagnostic catheterizations including left heart and right heart catheterizations as well as peripheral angiograms, right heart catheterizations (RHC) and percutaneous coronary interventions (PCI), which constituted the majority of cases. Three other categories (temporary pacemaker, impella and peripheral intervention) with one patient in each of the respective categories were matched to the control.

**Variables Recorded**

The patient records were classified as elective outpatient, inpatient, urgent and emergent procedures. Race, cardiac risk factors such as hypertension, hyperlipidemia, diabetes mellitus, chronic kidney disease and prior PCI were recorded, as well as indications for procedure such as coronary artery disease, heart failure, stable/unstable angina, non ST-segment elevation myocardial infarction/ST-segment elevation myocardial infarction (NSTEMI/STEMI) and congestive heart failure were collected. Procedural medications such as Tylenol, fentanyl, midazolam, morphine, Benadryl and codeine were also recorded along with dosage time. The administration of pain medications 12 hours prior to procedure was also recorded. For patients receiving PCI, the number of stents and the number of vessels were recorded in order to understand the extent and severity of the disease as both variables can affect pain outcomes.
**Pain Assessment**

The pain severity was measured and recorded by trained Cath lab nurses at varying intervals using a visual analogue scale (VAS), in which scores ranged from 0 (no pain) to 10 (worst pain possible) (Samantaray & Rao, 2014). When pain was detected, patients were asked to quantify their pain perception using the verbal rating scale (VRS) to assign a value from 0 to 10. The difference in pain recordings pre- and peri-procedurally were used to indicate the presence of breakthrough pain.

**Analysis**

Statistical analyses were performed using the Statistical Analysis System (SAS). Data are expressed as means +/- standard deviation, medians, or numbers, as appropriate. Since the control and treatment groups were matched, a univariate analysis was performed with the calculated pain differences using both a Wilcoxon Rank-Sum test and a two-sample t-test. Multiple logistic regressions using ANOVA was used to control for potential confounders such as race, cardiac risk factors, procedural medication, indications for procedure, and pre-procedural pain medication within 12 hours. Results were considered statistically significant with a 95% level of confidence and an alpha value less than or equal to 0.05.
RESULTS

STUDY POPULATION OVERVIEW

By Age

As previously stated, age has been known to affect pain sensitivity. This practicum study controlled for this variable by matching patients in the control group (receiving conscious sedation) and treatment group (receiving IV Tylenol) by age. *Figure 1* and Table 1 display the number of patients within certain age ranges and the descriptive statistics for the distribution of age amongst both groups, respectively. The spread of the ages ranges from 37 to 87 years of age with a median age of 65 for both groups. Controlling for age eliminated the possibility of it serving as a confounder.

![Figure 1. Age Distribution](image-url)
Table 1. Descriptive Statistics for Age (years) Distribution

<table>
<thead>
<tr>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
<th>Mode</th>
<th>Mean</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>65</td>
<td>87</td>
<td>67</td>
<td>64.87</td>
<td>10.28</td>
</tr>
</tbody>
</table>

**By Procedure**

The type of procedure was controlled by matching and is illustrated in *Figure 2*. The majority of the procedures were diagnostic catheterizations, followed by percutaneous coronary interventions (PCI) and then right heart catheterizations (RHC). There were three unique cases of an impella, temporary pacemaker and peripheral intervention, respectively that were matched between control and treatment groups. As such, the possibility of procedural confounding was removed.

*Figure 2. Distribution of Procedures Performed*
UNIVARIATE ANALYSIS

**Pain Outcomes**

The variable of interest is the change in procedural pain score between both groups. Descriptive measures for the univariate non-parametric analysis were calculated using SAS, and values were recorded in Table 2. The mean ranked sum score was used as the measure for central tendency. The Wilcoxon Rank-Sum indicates that the mean score for the treatment group was 52.33; while the control group had a significantly higher mean score of 68.67. The results of the Wilcoxon two-Sample two-sided test indicate a p-value of 0.0004, which shows a statistical significant difference in breakthrough pain outcomes between the two groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Sum of Scores</th>
<th>Expected Under H0</th>
<th>SD Under H0</th>
<th>Mean Score</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tylenol</td>
<td>60</td>
<td>3140.0</td>
<td>3630.0</td>
<td>133.09</td>
<td>52.33</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>60</td>
<td>4120.0</td>
<td>3630.0</td>
<td>133.09</td>
<td>68.67</td>
<td></td>
</tr>
</tbody>
</table>

*SD= Standard deviation  Average scores were used for ties. 0.0004
Descriptive measures for the univariate parametric analysis of pain outcomes were calculated using SAS (Table 3). The mean pain difference score was used as the measure for central tendency because of assumed normal distribution. The two-sample t-test indicates that the mean score difference for the treatment group was -0.85; while the control group had a significantly higher mean score of 0.27. The results of the two-sample t-test indicate a p-value of 0.001, which still maintains a statistical significant difference in favor of IV Tylenol to reduce breakthrough pain outcomes between the two groups similar to the Wilcoxon Ranked Sum test.

Table 3. Univariate T-test Descriptive Statistics for Pain Differences

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Method</th>
<th>Mean</th>
<th>95% Confidence Level Mean</th>
<th>SD</th>
<th>95% Confidence Level Standard Deviation</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>60</td>
<td>0.27</td>
<td>-0.16</td>
<td>0.71</td>
<td>1.68</td>
<td>1.42</td>
<td>2.04</td>
</tr>
<tr>
<td>Tylenol</td>
<td>60</td>
<td>-0.85</td>
<td>-1.36</td>
<td>-0.34</td>
<td>1.96</td>
<td>1.67</td>
<td>2.40</td>
</tr>
<tr>
<td>Difference (1-2)</td>
<td>Pooled</td>
<td>1.10</td>
<td>0.47</td>
<td>1.78</td>
<td>1.83</td>
<td>1.62</td>
<td>2.09</td>
</tr>
</tbody>
</table>

*SD= Standard deviation
Statistical density estimation of pain differences amongst both groups was done using hypothesized probability density to produce a normal distribution curve as a parametric measure. A Kernel distribution curve was used as a nonparametric measure and used the known values averaged and spaced across the observed data. This allowed for a smoother curve for a nonparametric function, yet both curves displayed similar skews with the normal distribution curve illustrating the skews more obviously. These estimation curves are illustrated in Figure 3. Both approximation curves show the control group to be skewed right in the positive number direction in change of pain score, while the treatment group is skewed left towards an overall decrease in pain, indicating the positive effects of IV Tylenol on procedural pain compared with that of the moderate sedation group.

**Figure 3. Distribution of Pain Difference**

![Distribution of Pain Difference](image-url)
Race

As explained in the Chapter II, race can be a confounding variable (Wandner et al., 2012). In order to measure racial demographic variability, Fisher’s exact test was used in SAS due to the categorical nature of the variable. The racial demographics of the two groups are illustrated in Figure 4. The control group consisted of 13 African Americans and 47 Caucasians, while the IV Tylenol group consisted of 19 African Americans and 41 Caucasians. The Fisher’s exact test yielded a p-value of 0.30, which indicates no statistically significant difference in racial demographics, reducing the probability of race serving as a confounding variable.

Figure 4. Racial Demographics

*Fisher's Exact Test p-value=0.30
Pre-procedural Factors

Pre-procedural Medication

Pre-procedural pain was taken into consideration in order to account for possible analgesic potentiation (Tallarida, 2001). The descriptive measures for the categorical variable of pre-procedural administration of pain medication 12 hours prior to procedure were calculated using Fisher’s exact test in SAS to measure variability amongst the two groups. Figure 5 has the graphical representation of the number of patients receiving pre-procedural pain medication. Of the control group, 8 patients received pain medication prior to their procedures, while only 6 patients in the IV Tylenol group received pre-procedural pain medication. The Fisher’s exact test yielded a p-value of 0.78, which indicates no significant statistical difference in prior pain medication administration between both groups.

*Fisher’s Exact Test p-value=0.78
Procedural Factors

Number of Stents Placed

The number of stents placed can alter procedural pain outcomes (Jeremias et al., 1998). There were 13 patients in each study group that underwent percutaneous coronary intervention (PCI). Descriptive measures for the number of stents placed yielded identical minimums, maximums, medians and modes for the two groups. Values were recorded in Table 4, and the graphical breakdown of mean number of stents placed in Figure 6. The mean number of stents placed is comparable in both groups with the control group having a mean of 2.38, while the treatment group mean was 2.15. The standard deviations were similarly comparable with the control group yielding a standard deviation of 1.50 and the treatment group yielding a standard deviation of 1.52. Statistical analysis was performed using a t-test in SAS yielding a p-value of 0.70, which provided no statistical significance.

Table 4. Descriptive Statistics of Number of Stents amongst the Patients with PCI

<table>
<thead>
<tr>
<th>Group</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
<th>Mode</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Standard Error of mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>2.38</td>
<td>1.50</td>
<td>0.42</td>
</tr>
<tr>
<td>Tylenol</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>2.15</td>
<td>1.52</td>
<td>0.42</td>
</tr>
</tbody>
</table>

*Two-tailed T-test p value= 0.70
The number of vessels treated with stents can indicate the severity of disease with multi-vessel disease leading to greater procedural pain, a possible confounder (Kern et al., 2015). Of the 13 patients undergoing PCI in each group, the number of vessels in which stents were placed was compared. Descriptive measures were recorded in Table 5 yielding identical minimums, maximums, medians and modes for the two groups. The mean number of vessels used in patients undergoing PCI in the control group was 1.85, while the treatment group mean was 1.77. The standard deviations were similarly comparable with the control group yielding a standard deviation of 1.21 and the treatment group yielding a standard deviation of 1.24. The graphical breakdown of the mean number vessels used in the PCI procedures is in

Figure 6. Mean number of Stents Placed

*Standard Error
Figure 7. A t-test was performed using SAS to calculate the statistical difference. The p-value was found to be 0.87, providing no statistical significance.

Table 5. Descriptive Statistics of Number of Stents amongst the Patients with PCI

<table>
<thead>
<tr>
<th>Group</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
<th>Mode</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Standard Error of mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1.85</td>
<td>1.21</td>
<td>0.34</td>
</tr>
<tr>
<td>Treatment</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1.77</td>
<td>1.24</td>
<td>0.34</td>
</tr>
</tbody>
</table>

*Two-tailed T-test p value= 0.87
MULTIVARIABLE REGRESSION TO CONTROL FOR CONFOUNDERS

To examine factors impacting pain outcomes during cardiac catheterization in a more complete manner, multi-variable regression was performed using ANOVA with pain difference being the dependent variable. Treatment group, race, cardiac risk factors such as hypertension, hyperlipidemia, diabetes mellitus, chronic kidney disease and prior PCI, as well as indications for procedure such as coronary artery disease, heart failure, stable/unstable angina, non ST-segment elevation myocardial infarction/ST-segment elevation myocardial infarction (NSTEMI/STEMI) and congestive heart failure, procedural medications such as Tylenol, fentanyl, midazolam, morphine, Benadryl and codeine, the administration of pain medications 12 hours prior to procedure, stents in patients undergoing PCI as well as the number of vessels stented were all taken into consideration. The test model is displayed in Table 6, and the test results are displayed in Table 7. The results yielded no significant difference in pain for all factors except for with treatment group and diabetes mellitus. The p-value for statistical difference in procedural pain between both groups was 0.027, while the p-value for diabetes mellitus was 0.05. This indicates a very significant difference between the p-value of procedural pain (0.027) and the alpha value of 0.05.

Table 6. ANOVA Test Model for Dependent Variable of Pain Difference

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>Sum of Squares</th>
<th>Mean Square</th>
<th>F Value</th>
<th>Pr &gt; F</th>
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<tbody>
<tr>
<td>Model</td>
<td>18</td>
<td>103.56</td>
<td>5.75</td>
<td>1.77</td>
<td>0.039</td>
</tr>
<tr>
<td>Error</td>
<td>101</td>
<td>327.68</td>
<td>3.24</td>
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<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>119</td>
<td>431.24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variable</td>
<td>P value</td>
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<td>-----------------------------------------------</td>
<td>---------</td>
<td></td>
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<tr>
<td>Treatment Group</td>
<td>0.027</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pain Medication 12 hours Prior</td>
<td>0.88</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural Morphine</td>
<td>0.84</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural Benadry</td>
<td>0.39</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Procedural Codeine</td>
<td>0.17</td>
<td></td>
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<tr>
<td>Race</td>
<td>0.17</td>
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<tr>
<td>Number of Stents Placed</td>
<td>0.56</td>
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<td></td>
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<tr>
<td>Number of Vessels</td>
<td>0.57</td>
<td></td>
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<tr>
<td>Hypertension</td>
<td>0.56</td>
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<td></td>
<td></td>
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<tr>
<td>Hyperlipidemia</td>
<td>0.11</td>
<td></td>
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<td></td>
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<tr>
<td>Diabetes Mellitus</td>
<td>0.05</td>
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<tr>
<td>Chronic Kidney Disease</td>
<td>0.79</td>
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<tr>
<td>Prior PCI</td>
<td>0.80</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>0.91</td>
<td></td>
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<td></td>
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<tr>
<td>Heart Failure</td>
<td>0.07</td>
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<tr>
<td>Stable Angina</td>
<td>0.29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-ST Elevating Myocardial Infarction</td>
<td>0.36</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>0.53</td>
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</tbody>
</table>
DISCUSSION

The major findings of this practicum study were that not only does IV Tylenol have at least the same breakthrough pain outcomes, but also it provided better analgesia during cardiac catheterization procedures. No difference was found in demographic variables of race, pre-procedural and procedural rescue pain medication, indications for procedure, cardiac risk factors and procedural factors. An unexpected finding was the statistical significance of diabetes mellitus on pain outcomes, and its indication for a protective effect on pain. These findings support the hypothesis that IV Tylenol can possibly serve as a substitute for moderate sedation.

The positive effect of IV Tylenol on pain outcomes could potentially be explained in part due to its’ rapid diffusion and high permeability across the blood-brain-barrier. Fentanyl, on the other hand, needs additional time to provide an analgesic effect due to reduced onset of action (Peng, 1999). In fact, there is a significant temporal lag between plasma concentration and effect (Peng, 1999). Midazolam acts on GABA receptors, and also induces spinally mediate analgesia, and must first pass through the blood-brain barrier (Edwards et al., 1990). Although the exact mechanism of action of IV Tylenol remains unclear, it is thought to exert its analgesic activity by inhibiting the synthesis of prostaglandins in the central nervous system and blocking the generation of peripheral pain impulses (Anderson,
Another possible reason for IV Tylenol having greater efficacy at preventing breakthrough pain, could be the fact that fentanyl inhibits metabolism of midazolam via competitive inhibition (Oda et al., 1999).

Diabetes mellitus was shown to have a positive effect on pain outcomes. The protective effect on pain observed in this study can be explained by the phenomenon of diabetic neuropathy, where only 11% of patients have chronic pain, and others have macrovascular and microvascular changes that effect glucose metabolism (Argoff et al., 2006). These changes cause a decrease in response to stimuli like pain, inflammation and infection (Argoff et al., 2006). The decreased pain response in those with diabetes mellitus can be explained by the presence of such vascular alterations.

The administration of pain medication 12 hours before the procedure, the number of stents placed and the number of vessels they were placed in were not significantly different between groups and in reference to the dependent variable of pain. The number of vessels involved can be an indicator of the severity of heart disease, and can lead to less favorable pain outcomes (Beddoes et al., 2008), but in this case, the differences were not significant. The number of stents placed, could have effected pain outcomes if there was a significant difference between the groups, as more stents can lead to more pain (Hamid, 2014). The administration of pain medication 12 hours prior to the procedure, also, could have impacted pain outcomes by lessening them due to depressed pain sensitivity; however, that was not the case in this study (Lu et al., 2013).
The results of this study can lead to positive effects for both patients and practitioners alike. Patients can be spared a significant amount of procedural pain, while also, reducing the chances of procedural complications like respiratory distress and hemodynamic instability (Laussen & Hansen, 2000). This can lead to a reduced hospitalization time (Furniss et al., 2015) and expenses incurred (Myles et al., 2002). The implications of this study cover a wide variety of interest areas in present day research.
SUMMARY AND CONCLUSIONS

The primary objective of this internship practicum project is to establish the clinical relevance of IV Tylenol during cardiac catheterizations in order to assess its' impact on breakthrough pain and the need for narcotics and benzodiazepines. Under the supervision of the site mentor, Dr. Subhash Banerjee, I compared the pain scales and medication use of the treatment group, receiving IV Tylenol, as opposed to that of the control group, receiving moderate sedation. The hypothesis that was tested was the need for moderate sedation using narcotics and benzodiazepines will decrease, if replaced with IV Tylenol, and lead to better patient outcomes. Based on the results of this study, it is clear that IV Tylenol provides superior peri-procedural pain management compared to the combination of fentanyl and midazolam.

Limitations

The key limitation of this study is that there is inter- and intra-provider variation for assessment of pain in patients. Another key limitation is the observational retrospective design, therefore affected by selection bias of the operators. The sample size and population is also limited. However, lessons learned from this project will help to initiate a randomized controlled clinical trial to compare pain outcomes in order to provide the best medical therapy in the future.
**Future Research**

This study can serve as a springboard for various areas of research in clinical effectiveness of IV Tylenol. A more specific study involving peri-procedural questionnaires instead of the use of the visual analog scale to indicate procedural pain can lead to more solid evidence in favor of IV Tylenol's utility. The duration of hospital stay can be studied to assess whether or not the usage of IV Tylenol decreases the post-procedural recovery period after cardiac catheterizations. The post-procedural complication rate or long term incidence of repeat revascularization can also be studied in a randomized controlled setting to evaluate patient outcomes. The post-procedural quality of life surveys and usage of pain medication can also be monitored in longitudinal studies. Total hospitalization cost along with the procedural medication cost can be studied to understand the cost effectiveness of IV Tylenol in comparison with the cocktail of medications that induce moderate sedation. These studies can be used get an overall better understanding of the potential outcomes for patients and hospitals alike when using IV Tylenol as a substitute for other medications during cardiac catheterizations.
BIBLIOGRAPHY


doi: 10.1097/MEG.0b013e3280ad4425


In addition to the practicum project described above, the general internship involved a wide variety of tasks. I had the opportunity to work under several clinical research coordinators in order to understand study initiation, patient enrollment and screening for various industry-sponsored projects. I received training in contracting, budgeting, grant writing, site-feasibility assessments as well as how to conduct team management activities. Data entry for pre-existing protocols, queries and regulatory paperwork was also performed. Initial IRB Submission packets with IRB title pages, Delegation of Authority forms, Investigator Abbreviated Protocols (IAPs), Informed Consent forms, HIPAA Authorization forms as Research Data Security Plans and Conflict of Interest forms were created, compiled and organized as well. I also gained proficiency in performing informed consents, following up with patients and continuing to have IRB communication.
APPENDIX A

INTERNSHIP JOURNAL
**Practicum Daily Activity Log**  
Masters of Science  
Clinical Research Management Internship  
Zainab Alam  
**Site:** Dallas VA, Department of Cardiology under Subhash Banerjee, Chief of Cardiology  
**Date of Internship:** August 17th, 2015 through Feb 2016

<table>
<thead>
<tr>
<th>Date</th>
<th>Activities</th>
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</table>
| July 1st, 2015| ADVISORY COMMITTEE MEETING  
• Met at VA North Texas Health Care System in the Department of Cardiology  
• Patricia Gwirtz, PhD, Jerry Simecka, PhD, Ranajit Chakraborty, PhD, Subhash Banerjee, M.D., Preeti Kamath, MHA, and myself discussed both the research and internship components of the 6 month internship  
• Preeti confirmed the length of time for HR processing and a start date sometime in August.  
• Discussed the prospect of publishing different research projects that are to begin in August 2015 and UNTHSC IRB Approval out of reciprocity. No specifics on ongoing research projects were given.  
• Dr. Simecka clarified the expectations of the student from the perspective of a Major Professor.  
• Master of Science Designation of Advisory Committee and Master of Science Degree Plan were reviewed and signed by the Dr. Banerjee and Preeti Kamath. The rest of the advisory committee signed the forms at a later date. |
| July 2nd, 2015-August 16th, 2015 | Prior to 8/17/15:  
• Contact with Preeti Kamath to:  
  o Discuss research component (co-authoring, content editing and collaborating with other co-authors for Dr. Banerjee’s “Manual of Peripheral Artery CTO Intervention”)  
  o Discuss day to day activities such as:  
    ▪ Working under two coordinators to understand study initiation, patient enrollment and screening for industry sponsored projects  
    ▪ Training in contracting, budgeting, grants, site-feasibility assessments and team management activities |
- Data entry for pre-existing protocols, queries and regulatory paperwork
- Performing Informed Consents
- Patient follow up and continued IRB communication
  - Complete necessary trainings before start date in order to gain computer access such as:
    - VA Privacy Information Security and Rules of Behavior (Completed 7/7)
    - HIPAA and Privacy Training (Completed 7/7)
    - History and Ethics of Human Subjects Research (Previously completed 3/30/15)
    - Introduction and Instructions to VA Biosecurity Concepts (Completed 7/6)
- Meeting with Dr. Simecka to:
  - Develop a rapport
  - Further understand the role of a Major Professor
  - Discuss how to go about Practicum Proposal with minimal information on the research component and received advice to wait until internship begins to further understand the proposed research assignment

August 17
th, 2015 (Mon) | FIRST DAY
- Learned of Dr. Banerjee’s absence this week, so no further information on research component.
- Communicated Proposal guidelines with Preeti in order to get more information from Dr. Banerjee after his return.
- Read different protocols particularly that of the “Commander” project to understand the magnitude of the ongoing research and learn what information is relevant to IRB forms
- Read informed consents to understand the approach with which information about a clinical trial is given to prospective patient
- At the end of the day, I was given a new protocol to read for the “Resolute Onyx” project because a CRC (Judi) was having a patient come in for screening the next morning.

August 18
th, 2015 (Tues) | • Followed another CRC (Swagata) who was doing a physical examination on a patient and learned how to
<table>
<thead>
<tr>
<th>Date</th>
<th>Activities</th>
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<tbody>
<tr>
<td>August 19&lt;sup&gt;th&lt;/sup&gt;, 2015</td>
<td>- Made a regulatory binder for the “Intrepid” project</td>
</tr>
<tr>
<td></td>
<td>- Made an IRB binder for the “Intrepid” project</td>
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<tr>
<td></td>
<td>- Organized IRB information to provide pharmacy with documentation to form a folder to allow drug dispensing for the “Intrepid” project</td>
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<td></td>
<td>- Attended a DVARC mini research forum where Data collection services made a presentation on how they can aid different teams for data analysis.</td>
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<tr>
<td></td>
<td>- Attended weekly (every Wednesday) team meeting in order for all the CRCs (Swagata, Puja, Michelle, Atif and Judi) to report on initiation, follow ups, informed consents and data collection/analysis.</td>
</tr>
<tr>
<td></td>
<td>- Used specific screening criterion of LVEF and BNP values to create a short list for potential patients who were eligible to join the “Paragon” project</td>
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<tr>
<td></td>
<td>- Began Start up Packet for “Intrepid” project</td>
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<tr>
<td></td>
<td>- Made enrollment note for “Intrepid” project</td>
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<tr>
<td></td>
<td>- Made Inclusion-Exclusion packet for “Intrepid” project</td>
</tr>
<tr>
<td>August 20&lt;sup&gt;th&lt;/sup&gt;, 2015</td>
<td>- Out of office - Sick</td>
</tr>
<tr>
<td>August 21&lt;sup&gt;st&lt;/sup&gt;, 2015</td>
<td>- Made Enrollment note for “Re-dual PCI” project</td>
</tr>
<tr>
<td></td>
<td>- Shadowed Judi and Preeti while they did informed consents for “Re-dual PCI” and “Resolute Onyx” and gained a better understanding of how to approach patients</td>
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<tr>
<td></td>
<td>- Began forming Start up Packet for “Re-dual PCI” by making an Inclusion-Exclusion packet</td>
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<tr>
<td>Date</td>
<td>Activities</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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| August 24th, 2015 (Mon) | • Attended Hawaiian themed VA Employee lunch party  
• Watched Cardiac catheterization on potential “Re-dual PCI” patient to perform a diagnostic in the hope of the patient returning for stent placement, but the patient had a left main blockage and was no longer a candidate for the study.  
• Edited and updated enrollment log for “TLG” binder through the use of both Excel and CPRS  
• Delivered IRB paperwork to pharmacy, medical services and to the laboratory  
• Made labels for “TLG” Consent Binder  
• Continued with “Re-dual PCI” startup folder: Edited Inclusion-Exclusion packet. Printed schedule of treatments and assessments as well as the study protocol. Created label for startup folder.  
• Assembled lab kits for patients first visits  
• Created Startup Packet for “Intrepid” using the Inclusion-Exclusion Packet I created last week, the printed schedule of assessments and a copy of the study protocol.  
• Picked up forms from the Laboratory and from the Pharmacy.  
• Added contact list to “Re-dual PCI” startup folder  
• Created a current study log with corresponding CRCs and placed them in different areas of the hospital  
• Printed out financial disclosure forms and got them signed by different members of the team for the “Voyager” project.  
• Prepared Protocol signature pages for the “Voyager” project  
• Began abridged version of “Commander HF” protocol for IRB submission |
| August 25th, 2015 (Tues) | • Spent most of the morning completing the abridged version of “Commander HF” protocol  
• Edited the Voyager Investigator abbreviated protocol as well.  
• Watched different peripheral cath lab procedures to open blockages due to peripheral artery disease (PAD) and learned about the steps taken to introduce the catheter as well as what to look for when looking for blockages  
• Waited for several potential patients to get on the table who had already consented to either the “Resolute” or “DIVA” studies to see if they were eligible for experimental intervention. |
- Dropped off blood samples to the lab with Judi
- Watched the beginning of several cardiac catheterizations
- Received computer access from Bettye and updated password information as well as picked up some forms from Becky in Medical Services
- Updated Correspondence folder for the “Intrepid” Regulatory binder
- Updated TLG study consent binder
- Went with Judi to Day Surgery unit to give copies of signed Informed Consent forms to patients who agreed to participate in the study, but unfortunately none of them qualified.
- Setup my VA e-mail

**August 26th, 2015 (Wed)**

- Submitted request for office key with Kyle now that I have official computer access
- Acquired Atif’s signature for the Financial Disclosure form for the “Voyager” project
- Filled out “Commander HF” startup documents for sponsor- particularly Financial disclosure forms
- Acquired signatures from the Principal Investigator (Dr. Banerjee), Co-Investigators (Dr. Brilakis and Dr. Grodin) and by the study coordinators (Preeti, Judi, Puja, Atif, Swagata, Michelle and myself) for the Financial disclosure form for the “Commander HF” project
- No access to “Banerjee Research” folder from my account and the woman to give me access is out of town
- Filled out FDA 1572 form for the local IRB for the “Commander HF project”

**August 27th, 2015 (Thurs)**

- Took different forms to Becky in Medical Services to get signed
- Also, met with Bettye in Medical Services to see if she could give me access to the “BANERJEE Research” folder since Vicky is out of town until Sept 2\textsuperscript{nd}, but Bettye was unable to do so. I spoke with Stephanie to see if she could and she also couldn’t. So, Stephanie put in a work order for me with the IT department.
- Preeti and I went to the Cath lab to meet with Dr. Banerjee to discuss research component, but a minute into the conversation; he got called into another case. So, we will reconvene later today. All I know so far is that there will be 9 authors and three have already sent chapters, but Dr. Banerjee will do
the majority of contributions to the “Manual of Peripheral Artery CTO intervention”.  
- For the “Resolute Onyx” study, I contacted Serena at Medtronic to schedule a training session on the protocol and EDC to be added to the trial as a coordinator.  
- Updated “Intrepid” Contracts and Correspondence folders.  
- Read up on Peripheral Artery Disease and Chronic Total Occlusion “CTO” as well as current treatments for it.  
- Met again with Dr. Banerjee to discuss details of research component to be able to start the Proposal.  
- Worked on my proposal  
- E-mailed Dr. Banerjee to clarify some questions that I was having  
- E-mailed the Project Coordinator (Prasad) at Springer Publishing to serve as liaison between Dr. Banerjee and Springer  
- Fixed a table for the Informed Consent form that was being revised for the “Commander HF study”

<table>
<thead>
<tr>
<th>August 28th, 2015 (Fri)</th>
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| - Replied to Serena about setting up my training for “Resolute Onyx” next Monday after meeting with Dr. Gwirtz  
| - Made copies of Investigator agreement and Investigator Brochure Acknowledgement form  
| - Spoke to Dr. Banerjee- received signatures, followed up on Publishing company’s e-mail about a manuscript completion date and asked Dr. Banerjee when we would be able to discuss my e-mail (later on today)  
| - E-mailed the Publisher contact to inform them of deadline for co-authors is the end of November and our projected manuscript completion date is in January.  
| - E-mailed Dr. Simecka updating him on my conversation with Dr. Banerjee.  
| - Printed out my e-mail to Dr. Banerjee and attached documents in preparation for the afternoon meeting  
| - Followed up with Dr. Simecka after I was informed that I had the wrong office number for him. Updated him on my internship activities and asked for some general suggestions to keep in mind while writing a proposal.  
| - Followed up with Stephanie from Medical Services to
see if she received any updates from the IT people in regards to my access to the shared folder.
- Made a binder label for the “DIVA” project
- Started going over “Resolute Onyx” protocol in preparation for training next week
- Made digital version of notes from meeting with Dr. Banerjee, so I have a backup since it is essentially the prompt and guidelines for my proposal.
- Preeti gave me assignments for Monday as she will be out of the office.
- Met with Dr. Banerjee. He only had a few minutes, so not much was clarified except for the idea that I should have two components to my research proposal. He said I could send him my school’s guidelines (which I already did) and we can build from there.

<table>
<thead>
<tr>
<th>August 31st - September 8th</th>
<th>Out of office due to sprained ankle</th>
</tr>
</thead>
</table>
| September 9th, 2015 (Wed)   | Sent Serena an e-mail to reschedule “Resolute Onyx” training  
|                             | Updated TLG study log since I finally have folder access!  
|                             | Went with Judi for an Informed Consent for “Resolute Onyx”  
|                             | Compared revised Sponsor and Site Informed Consent form for the “Voyager” study since the Sponsor did not track the edits  
|                             | Edited “Redual,” “Relax,” and “Intrepid” PowerPoint presentations using Investigator Abbreviated Protocol and Protocol for each to add a “Challenges” section.  
|                             | Followed up with “Resolute Onyx” patient in the Cath lab only to find that the patient had a Femoral Artery Dissection, so we could not get the stent put in today if needed.  
|                             | Updated TLG Consent Binder and added appropriate enrollments notes as well as updated the study log along with making copies of the Informed Consent forms to file with Marguerite (Research Compliance Officer)  
|                             | Began start up packets for “Relax” and “Reverse” studies with accompanying protocols and flow charts |
| September 10th, 2015 (Thurs)| Contacted Serena to reschedule my “Resolute Onyx” training for early next week  
|                             | Completed Inclusion Exclusion Sheet for “Relax AHF” |
| September 11<sup>th</sup>, 2015 (Fri) | Contacted Serena to see if we could connect today to complete the “Resolute Onyx” training as it has been hard to connect with her due to the time difference  
Completed the Informed Consent form using the VA template for a BMS AFib new study  
Updated the Certificates folder with Atif’s new training  
Confirmed noon today for the “Resolute Onyx” training  
Updated expired Certificates binder  
Underwent training for Resolute Onyx  
Screened for Redual PCI  
Made Prescription Sheet for Redual PCI  
Screened for Resolute Onyx |
| September 14<sup>th</sup>, 2015 (Mon) | Created IRB Title Page for “BMS AFib” Study  
Created HIPAA Authorization for “BMS AFib” Study  
Made folder of Templates for future IRB start up forms  
Completed the “Assessment of Clinical Impact (ACI)” form  
Created Abstract for “BMS Afib” Study  
Worked on Conflict of Interest form for Dr. Banerjee  
Started on Investigator Abbreviated Protocol  
Received e-mail from Dr. Gwirtz to submit rough draft for proposal |
| September 15<sup>th</sup>, 2015 (Tues) | E-mailed Serena to follow up about Oracle training  
Continued worked on the proposal  
Filled out an abbreviated CV form for Dr. Brilakis  
E-mailed Dr. Gwirtz and Dr. Simecka my rough draft for my Protocol, so I can edit it and send it to Dr. Banerjee for review  
Continued work on Investigator Abbreviated Protocol for “BMS Afib” study  
Received 45 min long Oracle and eCRF training from... |
<table>
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<tr>
<th>Date</th>
<th>Activities</th>
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<tbody>
<tr>
<td>September 16(^{th}), 2015 (Wed)</td>
<td>- Completed Training record for Resolute Onyx and sent it back to Serena</td>
</tr>
<tr>
<td></td>
<td>- Finished Investigator Abbreviated Protocol for “BMS AFib” study</td>
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<td></td>
<td>- Attended DVARC mini research forum where Data collection services made a presentation on recent paperwork updates and requirements</td>
</tr>
<tr>
<td></td>
<td>- Then completed Research Data Security Plan for “BMS AFib” study</td>
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<tr>
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<td>- Completed and put the new folder for “BMS AFib” study in the “BANERJEE RESEARCH” folder. Will go over folder with Preeti tomorrow</td>
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<td>- Went to the ER with Michelle to look for “Premier” study patients</td>
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<td></td>
<td>- Went to Cath lab to talk to Dr. Banerjee about details for proposal</td>
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<td>- Completed Suicidal Caller training that was required on TMS.</td>
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<td>- Began CPRS training</td>
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<td></td>
<td>- Received e-mail with edits on proposal from Dr. Gwirtz and followed up with her for more input</td>
</tr>
<tr>
<td>September 17(^{th}), 2015 (Thurs)</td>
<td>- Had a quick meeting with Preeti to discuss how I’m doing and was told I have surprised her with my knowledge base making it easier to give me directions</td>
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<td></td>
<td>- Continued working on Dr. Brilakis’ and Dr. Banerjee’s CV abbreviated forms for the “Commander HF” Study</td>
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<tr>
<td></td>
<td>- Went to Cath Lab to get Dr. Grodin to sign off on different Investigator sheets</td>
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<td>- E-mailed Dr. Simecka since I have not heard from him about my proposal</td>
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<td></td>
<td>- Made appropriate edits to the proposal as per Dr. Gwirtz’ instruction</td>
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<td></td>
<td>- Received an e-mail from Dr. Simecka that he is out of town and will look at my proposal when he can</td>
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<tr>
<td></td>
<td>- Sent updated Proposal to both Dr. Simecka and Dr. Gwirtz for further editing.</td>
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<td></td>
<td>- Ordered lab kit for “Redual PCI” Study</td>
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<td>- Judi taught me how to send EKG via phone line</td>
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<tr>
<td>September 18(^{th}), 2015 (Fri)</td>
<td>- Made minor edits on “BMS Afib” study startup documents</td>
</tr>
<tr>
<td></td>
<td>- Worked on CPRS training</td>
</tr>
</tbody>
</table>
| September 22\(^{nd}\), 2015 (Tues) | • Worked on Revised Proposal  
• Went to Outpatient Services to consent a patient for “Resolute Onyx”  
• Then went to Cath lab to put it on the schedule  
• Talked to Dr. Banerjee about when he would start sending me book materials to organize and updated him on my proposal progress  
• Waited for the blood work to be put in for the “Resolute Onyx” patient  
• Learned how to input lab orders in CPRS  
• Went to engineering to get my official keys  
• Took Rahel to Bettye in Medical Services to make her an appointment to get her ID since she just got her computer access today  
• Went to Cath Lab to check on the two “Resolute” patients, but neither of them qualified for the study  
• While I was there, Dr. Banerjee said he had a little project for me to work on that is a study on the effects of IV Tylenol vs Oral Tylenol and comparing patient outcomes in narcotic use. More details to come.  
• Went to Atif’s office to print out some research on IV vs Oral Tylenol  
• Worked on Accounts spreadsheet for Puja’s “Orbit” study  
• Made Accounts spreadsheet for “Compass” study  
• Scanned and uploaded “Compass” budget and payment schedule to the Banerjee research folder |
| September 23\(^{rd}\), 2015 (Wed) | • Created “PAD CTO Book” folder and make folders for respective chapter authors with subfolders for copyright, chapters and images  
• Printed study list from Judi’s donuts to go to the CCRU  
• Went over Springer Manuscript Guidelines and Key Style points  
• Read several articles on IV Tylenol vs Oral Tylenol in different patient populations in preparation for meeting with Dr. Banerjee after team meeting  
• Printed agenda and sign in sheet for team meeting  
• E-mailed Dr. Banerjee’s colleague a copy of DOD grant protocol  
• Attended team meeting with Dr. Banerjee where we discussed ongoing projects and improvements on patient screening techniques |
| September 24th, 2015 (Thurs) | • Met with Dr. Banerjee to discuss new research project as well as updates for the book. I need to edit the new chapters according to the publisher guidelines  
• Spoke with both nurses, Diana and Tina that will be involved on the new project. Asked Diana to e-mail me IV Tylenol patient spreadsheet.  
• Went to HR to get my picture taken, but there was a problem with Medical Services not submitting some paperwork, so I went there and Bettye wasn’t in the office |
| • Went to Medical Services and got Becky to submit and fix my HR paperwork  
• Went to HR and got my picture taken, but will not get my ID until I do a VA background check form  
• E-mailed Dr. Simecka for ask if he had a chance to look at my proposal since he said if he didn’t get back to me this week that I should e-mail him  
• Received an email from Dr. Gwirtz informing me that the proposal is due next week with full committee signatures  
• E-mailed Dr. Gurm to request his book chapters, but the email address that Dr. Banerjee sent me did not go through  
• E-mailed Dr. Armstrong and Dr. Abu-Fadel requesting their respective book chapters  
• Started the Electronic Questionnaires for Investigations Processing  
• Went to the lab to drop off blood samples  
• Completed eQIP form and had it released to the Jocelyn in the Personnel security department  
• Received Dr. Gurm’s chapter from Dr. Banerjee and uploaded it into the shared folder  
• Received my proposal edits from Dr. Simecka and updated it to send to Dr. Banerjee  
• Emailed Dr. Simecka to confirm proper proposal submission form  
• Confirmed the edits and sent e-mail with updates on the book, the new project and my proposal to Dr. Banerjee. |
| September 25th, 2015 (Fri) | • Called Dr. Gwirtz to see the proper procedure for getting the signatures for my proposal submission form  
• Scanned, organized and sent all the Regulatory documents for Voyager and sent them to the sponsor |
- Spoke to Dr. Banerjee about learning the computer software sometime today
- Went with Judi to provide informed consent for a patient, but the patient wanted time to look over the form
- Went to lunch with the team to Pei Wei to celebrate Preeti's birthday and then came back to the VA
- Checked in with the possible “Resolute Onyx” patient to see how he felt about the study and he wanted to ask Dr. Grodin some questions
- Went to the Cath lab to see how long it would be before the Resolute patient would be seen, but there were still two peripheral cases ahead of him.
- E-mailed Dr. Chakraborty and Dr. Simecka to see what day of the week I can go to submit my proposal with the appropriate signatures.
- The Cath lab was unable to see the patient and I spoke to Dr. Banerjee about getting back to me about my proposal as well as teaching me the computer software on Monday.
- Sponsor wanted more documents, so I sent those as well.
- Screened patients for Monday and found 3 potential patients.

<table>
<thead>
<tr>
<th>September 28th, 2015 (Mon)</th>
<th>Started working on formatting Dr. Gurm’s chapter for the PAD CTO Intervention Book.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Obtained signatures from Dr. Banerjee and Preeti for my Proposal evaluation form</td>
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<tr>
<td></td>
<td>Finished formatting Dr. Gurm’s chapter</td>
</tr>
<tr>
<td></td>
<td>Received e-mail from Dr. Simecka to come to campus tomorrow to submit Proposal evaluation form</td>
</tr>
<tr>
<td></td>
<td>E-mailed Dr. Chakraborty and Dr. Simecka to confirm times that I could meet them tomorrow</td>
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<tr>
<td></td>
<td>Went to the Cath lab to check on some of the patients that I screened on Friday and Judi consented this morning. One of the was a screen fail during the procedure and the second one was a candidate, but we had to do a protocol deviation by adding two stents instead of one.</td>
</tr>
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<table>
<thead>
<tr>
<th>October 13th, 2015 (Tues)</th>
<th>Updated TLG Study enrollment list</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Printed down so unable to update enrollment notes for screen failure binder for Resolute Onyx and TLG study</td>
</tr>
<tr>
<td></td>
<td>Updated PAD CTO Book folder with the chapter from Dr. Armstrong</td>
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<tr>
<td>Date</td>
<td>Activity</td>
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<td>---------------------------------------------------------------------------</td>
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| October 14th, 2015  | • E-mailed Dr. Abu-Fadel to respond to his question about whether or not it was acceptable to wait until this week to send me his manuscript.  
                   • Emailed Prasad at Springer Publishing to clarify formatting guidelines for the manuscript  
                   • Updated TLG Consent binder with updated signatures on enrollment forms  
                   • Updated Resolute Onyx Screen Failure log with amended enrollment notes and signed inclusion exclusion sheets  
                   • Updated Resolute Onyx Device Accountability folder  
                   • Obtained signed EKGs for Resolute Onyx  
                   • Filled out Conmedication log for the most recent Resolute Onyx patient |
| October 14th, 2015  | **(Wed)**  
                   • Went to PIV office to check the status of ID badge and was told to check back next Wednesday  
                   • Looked through Resolute patients that need to be reconsented to find out if they have any upcoming appts  
                   • Screened patients for Resolute Onyx  
                   • Updated screening log for Resolute Onyx  
                   • Worked on formatting 2 chapters for PAD CTO book according to the publisher guidelines everything except for citations and tables  
                   • Had team meeting to touch base with other coordinators and learn about new upcoming projects  
                   • Preeti gave me more responsibilities for Resolute Onyx and Redual to take on the bulk of screening and consenting with Judi accompanying me for the next few weeks while Preeti is out of town  
                   • Instructed to confirm WOC paperwork changes with Becky in Medical Services tomorrow  
                   • Screened patients for Resolute and Redual for Thursday and Friday |
| October 16th, 2015  | **(Fri)**  
                   • Took on screening for the upcoming week for Resolute and Redual patients  
                   • Updated the list of patients that need to be reconsented for the Resolute study with their most recent list of appointments so we can reconsent them  
                   • Got many instructions on what to do in Preeti’s absence  
                   • Found the list of patients to look through to screen for Redual |
| October 20th, 2015  | • Began screening patients that are coming in on |
| (Tues) | Wednesday for Resolute Onyx  
- Received an e-mail from Dr. Banerjee to meet to discuss the book and the Tylenol paper  
- Called Dr. Banerjee to see when he was available to meet  
- Discussed the objective, criteria, organization and began making a template for the EDC  
- Continued screening patients  
- Went to Becky Robertson's office to discuss getting VistA Imaging access  
- Also spoke with Becky and Bettye in Medical Services to inquire about the status of the correction to my HR paperwork  
- E-mailed Vicky Robertson to request VistA Imaging access  
- Began preparing EDC for the Tylenol study |
| October 21st, 2015 (Wed) |  
- Arrived early to consent patient  
- Completed my first consent on my own for Resolute Onyx  
- Patient ended up being a screen fail due to low platelet count  
- Informed the patient of his ineligibility  
- Discussed with Dr. Banerjee about the eligibility of Hep C patient on Ribavirin and eligibility of patient with abnormal stress test but no angina for later this week  
- Spoke to Vicky Robertson and gained VistA Imaging Access  
- Screened another patient for Friday for Resolute  
- Obtained EDC access for Intelemage and Medtronic, but Medtronic login issues occurred  
- Spoke to IT for Medtronic, but they had no record of me  
- Attended Miniforum on Data and note entry for CPRS  
- Worked on form for Tylenol study  
- Printed consent and HIPAA forms for two potential patients tomorrow  
- Completed consent and HIPAA forms for the screen fail patient. |
| October 22nd, 2015 (Thurs) |  
- Obtained consent from two patients for Resolute Onyx.  
- Informed Dr. Banerjee of the possible patients and updated the procedure board.  
- Called the lab to add CK-MB and Troponin labs |
- Completed consent and HIPAA forms for the two consented patients.
- Learned how to make an enrollment note from Judi.
- Participated in a Web Conference Call with the team for the Viabahn stent.
- Filed the paperwork for the screen failure from yesterday since I was unable to make the enrollment note.
- Received a call from the Cath lab that the first patient went in and did not qualify.
- Went to the Cath lab to see if the second patient qualified.
- Patient qualified for a Resolute Onyx 2.0 mm stent.
- Obtained stent from Dr. Grodin’s office.
- Kept stent box for records.
- Filed historical enrollment note for the first patient that did not qualify.
- Filed first patient’s Informed Consent and HIPAA forms in Screen Failure binder.
- Filed enrollment and consent note for the patient that received the stent.
- Updated enrollment-consent list
- Signed the inclusion-exclusion sheets for the screen failures
- Helped Judi input lab orders for the enrolled patient.
- Called Attending Physician requesting that she not cancel our lab orders.
- Went to the Cath lab to ask Dr. Banerjee to put in lab orders for the possible patient tomorrow.

<table>
<thead>
<tr>
<th>October 23rd, 2015 (Fri)</th>
<th>Dr. Banerjee spoke to the patient about the trial and he declined.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I printed the signed enrollment notes for the screen failure binder since Dr. Banerjee signed them this morning.</td>
</tr>
<tr>
<td></td>
<td>Filed the enrollment notes in the binder.</td>
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<tr>
<td></td>
<td>Started working on the EDC information and making a file for the patient that enrolled yesterday.</td>
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<tr>
<td></td>
<td>Received an e-mail from the Voyager project sponsor in regards to missing documents.</td>
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<tr>
<td></td>
<td>I called him to clarify that medical license copies are not necessary for the coordinators and he said he would confirm with his team.</td>
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<tr>
<td></td>
<td>I e-mailed him the respective documents and am awaiting his response.</td>
</tr>
<tr>
<td>Date</td>
<td>Activities</td>
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<td>----------------------</td>
<td>-----------------------------------------------------------------------------</td>
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</tbody>
</table>
| October 26th, 2015 (Mon) | - Starting making the patient folder for the new enrolled Resolute patient.  
                           - Went with Judi to check on the patient and make sure he gets his lab work and EKG at the appropriate times.  
                           - Got my official PID card made.                                                                 |
|                       | **October 26th, 2015 (Mon)**  
                           - E-mailed updated and signed Banerjee CV to the sponsor for the Voyager study.  
                           - Sponsor still wants lab values which I sent last month.  
                           - Looked through old Resolute Onyx patients to find out which ones need to be reconsented.  
                           - Logged new stents in product accountability binder.  
                           - Brought new stents to Dr. Grodin’s office.  
                           - Took EKGs and inclusion exclusion sheets to Dr. Banerjee to sign.  
                           - Talked to Dr. Banerjee about CCSC class of angina for the newly enrolled patient who was discharged on Friday.  
                           - Went to Atif to learn how to make the form for the TYLENOL project on Access.  
                           - Printed and highlighted appropriate medical records to make patient folder for new patient.  
                           - Started screening Resolute patients for the week.                                                                 |
| October 27th, 2015 (Tues) | - Worked on TYLENOL EDC.  
                           - Emailed Bayer rep for Voyager Reg docs.  
                           - Screened patients for Resolute.  
                           - Found 3 potential patients for tomorrow.  
                           - Called Shibu and Linell to add CBC and chem8 for the potential patients tomorrow.  
                           - Updated Resolute onyx screening log.  
                           - Printed out HIPAA and Informed consent for tomorrow.                                                                 |
| October 28th, 2015 (Wed) | - Went up to the Cath lab to consent the first patient and he declined because he didn’t want to be a “test dummy”.  
                           -Returned back to the CRU to talk to Judi about potential questions about the status of the angina on another potential patient.  
                           - Went to the lab to drop of some samples with Judi.  
                           - Went to 4B to consent another patient who declined having any interest in research.  
                           - Went back to the Cath lab to consent another patient who also declined having any interest in research.  
                           - Followed up with Dr. Banerjee on the EDC Access.                                                                 |
| October 29th, 2015 (Thurs) | Form I made for the Tylenol study and he said he won’t be able to get to it today.  
- Stopped in the ER with Judi to see if there were any patients eligible for her or Michelle’s studies.  
- Updated the screening log with the 3 declined patients for today  
- Checked CPRS to see if the fellow Jay updated the Cath Lab Procedure report so I can finish the file on the enrolled patient from last week  
- Screened for Resolute patients for tomorrow. Found two potential patients  
- Called Shibu to add the CBC and Chem8  
- Went with Judi to consent a RELAX study patient, but found out he was being diagnosed as an NSTEMI so he became ineligible for the study |
| October 30th, 2015 (Fri) | Went to the Cath lab to consent a patient who rejected research when Swagata asked him about DIVA and said he wasn’t interested in research  
- Went to Day Surgery and consented a patient  
- Had Judi update the labs for CK-MB and Troponin  
- Came back to CRU to update screening log  
- Began filling out the rest of the consent form for the potential resolute patient  
- Had to reconsent a resolute patient that consented before the consent form was revised  
- Went to the Cath lab to inform them to give a loading dose of aspirin to the potential resolute patient  
- Went to Medical Services to get Beckye to insist that Bettye follow-up with me about my HR paperwork  
- Finished filling out the consent form and HIPAA form for the consented patient  
- Made copies for Marguerite.  
- Got Jay to update the Cath Procedure Report in CPRS but is awaiting signature by Dr. Banerjee  
- Consented patient did not qualify.  
- Created a historical enrollment note  
- Updated the enrollment-consented list and the screening log  
- Updated screen fail binder and awaiting Dr. Banerjee’s signature on the historical enrollment note as well as on the inclusion-exclusion sheet  
- Prescreened patients for next week for Resolute Onyx and Redual PCI  
- Got Atif to look at EDC for Tylenol |
- Attained Dr. Banerjee’s signature for the historical enrollment note for the screen failure from yesterday
- Obtained Dr. Banerjee’s signature for the fellow Jay’s Cath procedure report for last week’s enrolled patient
- Asked Dr. Banerjee about a potential patient with Hep C but not currently on medication for it and does not have a BMS recommendation anywhere in CPRS.
- Asked Linell to add the CBC and CHEM8 on that patient as Shibu was out of the office.
- Updated screen failure binder
- Updated screening log for Resolute Onyx

| November 3rd, 2015 (Tues) | • Started screening for Redual
• Received a call from Denise in the PIV office asking me to come in for finger prints
• I went in to get my finger prints and get advice on whether I should go to HR rather than wait on Bettye
• I went to HR and spoke with Deborah Thomas who said she never received an email from Bettye or Becky
• I went to Medical Services to follow up where Becky said she put it on Betty’s desk and Bettye said she didn’t know where it went so she would print a new one and scan it right away.
• Becky also asked me to give a WOC badge to a member of Bavana’s team so I went to the Cath lab to do that.
• I came back to the CRU and called Deborah in HR to inform her of the progress and she said there was a necessary document that I needed to sign that Bettye did not tell me about.
• Later, Bettye e-mailed me asking me to come back to the office to sign the letter for her.
• I went to Bettye’s office and signed the letter as well as made copies of the documents so I could hand deliver them to HR.
• I went to HR and delivered the documents to the gentleman at the front desk to deliver to Deborah.
• Called Deborah to confirm receipt of the documents, but she did not answer.
• Waiting on Bettye to scan and e-mail the official documents to HR.
• Screened patients for Wednesday and found 2 possible for Resolute and 1 for Redual
• Confirmed with Deborah that the HR files were
received and will take about a week to process, so I will follow up with her at ext 71216 next Wednesday.
- Printed consent and HIPAA for all three potential patients.
- Updated screening log for Resolute Onyx

| November 4th, 2015 (Wed) | • Consented two patients for Resolute.  
- The Redual patient is to be consented only after PCI.  
- Followed up with patients in the Cath Lab.  
- Got Judi to order CKMB and Troponins for prep procedures.  
- One patient qualified and received the last of the CORE study stents.  
- The other patient did not qualify.  
- Made copies of each patients respective EKGs.  
- Filled out the HIPAA and Consent forms  
- Made enrollment note for the enrolled patient and made a historical enrollment note for the patient that did not qualify.  
- Received Dr. Banerjee’s signature on the EKG.  
- Received Judi’s signature on both inclusion-exclusion logs.  
- Updated the enrollment-consent log  
- Made copies of the HIPAA and ICF of both patients for Marguerite and the one enrolled patient.  
- Learned how to make a copy of IVUS onto a DVD from Lauren in the Cath lab  
- Updated Screen failure binder  
- Updated screening log  
- Screened patients for Thursday and Friday |

| November 5th, 2015 (Thurs) | • Printed EKG for yesterday’s enrolled patient  
- Created blue folder for enrolled patient  
- Potential patient for today was passed to Bavana’s team  
- Screening patient for Re-dual  
- Will communicate with Preeti to sort out the Voyager situation  
- Printed out Tylenol EDC Word doc to work on it with Dr. Banerjee this afternoon  
- Went to MICU to check on patient from yesterday to give him his copy of the informed consent, but he was sleeping.  
- Went to Cath lab to inform Banerjee about patient we were giving to Bavana’s team and to update him on the high troponins of the patient from yesterday. |
| **November 9th, 2015 (Mon)** | • Went to Dr. Grodin’s office to find a stent that was lost and needed to be returned to Medtronic  
• Went through old binders and finally found the stent to update the log  
• Started making the Commander HF startup folder  
• Starting making inclusion exclusion sheet for Commander HF study  
• Got Dr. Banerjee to go over the Tylenol EDC with me and approve it  
• Learned how to burn IVUS CD for newly enrolled Resolute Patient  
• Checked in on Resolute patient as he had a post procedural MI |
| --- | --- |
| **November 9th, 2015 (Mon)** | • Consented a patient for Resolute 2.0 study as we completed the Core study last week  
• Organized papers from last week that I got signed by Banerjee to update the screen failure binder  
• Created Binder for last week Resolute’s patient  
• Followed up with Cath lab to find out that the patient was on the table  
• Patient had multiple lesions and needed a CABG  
• Went to take patient to CRU for a followup  
• Went back to the Cath Lab to follow up with Shibu about CCSC angina status of last week’s patient as Dr. Banerjee is out of town  
• Screened for Tuesday and the rest of the week  
• Continued working on Inclusion-Exclusion sheet for Commander startup folder  
• Received signatures from Dr. Grodin to file the informed consents in the screen failure log  
• Created a historical enrollment note for the patient that did not qualify today |
| **November 10th, 2015 (Tues)** | • Consented a patient for the Resolute 2.0 study.  
• The labs weren’t drawn in time, so the patient was a screen failure.  
• Created a historical enrollment note for the patient in the 2.0 study.  
• Continued working on the startup packet for the “Commander HF” packet  
• Checked in with Judi about the Voyager study updates.  
• E-mailed Dr. Anand Prasad on behalf of Dr. Banerjee to request additional images  
• Made a copy of the Informed Consent and sent it to
| November 12th, 2015 (Thurs) | Marguerite

- Attained more signatures from Dr. Grodin.
- Spoke to Atif who advised me to have the lab orders put under the 4B orders.
- Screened for patients for the rest of the week.
- Subsequently, went to Shibu’s office to ask him to out in the lab orders for 4B, so that the patients that qualify do not miss the proper labs.
- Spoke to Dr. Grodin about the SAE that occurred in the patient last week.
- Filled out the IRB Adverse Event submission form, but by then Dr. Grodin was gone.
- Judi advised me to fax it anyway and send it went an amended signature.

- It’s Preeti’s first day back from India and I updated her on the most recent activities.
- Sorted out IVUS files for Resolute study.
- Doing followup work for the SAE on the last Resolute Core patient.
- Updated Screen failure binder with the signed Historical research enrollment note.
- Received official WOC paperwork and uploaded it into the Banerjee Research shared folder.
- Found a potential inpatient for Resolute 2.0.
- Went to the ward to consent him and he consented.
- Went to Shibu to get the orders in for the CBC and CHEM8 and have it be text to nurse.
- Followed up with the nurse until she got the blood sample.
- Ran the blood sample to the lab.
- Went to the Cath lab to put it on the board that we have a potential Resolute patient.
- Asked Atif to put in an EKG order.
- Went to the ward to get the nurse to get the EKG done, but she told me to go to the tech.
- Got a copy of the EKG from the tech.
- Asked Atif and Bavana’s team to read the EKG because Dr. Brilakis, Dr. Grodin and Dr. Banerjee were unavailable and I wanted to make sure he didn’t have the exclusion criteria of a pre-procedural MI.
- EKG was cleared.
- Talked to Dr. Grodin about meeting in the late afternoon to discuss the last Resolute Core patient and get the remaining core stents. He said to come
back in the late afternoon.
- Went up to Cath and got the list of the inpatients for the next day
- Dr. Grodin said he would discuss the Adverse Event tomorrow
- Dr. Banerjee said he would give the patient to Dr. Brilika's study even though he had an eligible lesion
- Filled out a historical enrollment note

### November 13th, 2015 (Fri)

- Consented patient for Resolute 2.0
- Other qualifying patient was a no-show
- Spoke to Alex about paperwork issue and he said to come back later
- Went to CRU to get the Resolute binder
- Called Judi to find that consented patient did not qualify
- Filled out Informed Consent and HIPAA forms
- Screened inpatients for the rest of the day, none qualified
- Updated screen failure log
- Created historical enrollment note for non-qualifying patient
- Went to Cath to get updated procedural report from Alex and gave it to Latoya
- Went to Dr. Grodin's office to get signatures on screening logs and EKGs
- Will follow up with Dr. Grodin in the afternoon to report SAE to the VA IRB
- Worked with Hao to follow up with copies and original angios and IVUS reports for Resolute Onyx patients
- Sent copies of Informed Consents and HIPAAs to Marguerite
- Got Dr. Grodin to approve and fill out the rest of the SAE form to send to the VA IRB
- Faxed "Amended" SAE form to IRB

### November 16th, 2015 (Mon)

- Judi found a potential Resolute 2.0 patient with a possible Aspirin allergy
- Went to Dr. Banerjee to get his opinion on it. He said he would qualify.
- Went to consent the patient who was a screen failure due to an inability to consent from altered mental status
- Went to Cath to tell Preeti to let Banerjee know about the screen fail
| November 17th, 2015 (Tues) | Made sure patient labs were done.  
| | Asked Judi to put in EKG order.  
| | Made copies of Informed Consent and HIPAA to give to the patient and Marguerite.  
| | Sent copy of Informed Consent and HIPAA to Marguerite.  
| | Printed the signed enrollment notes for the TLG study that I got Ryan to sign yesterday  
| | Updated TLG Consent Binder  
| | Updated Resolute Onyx Screen failure binder | Made copies of TLG study Informed Consent and HIPAA and sent to Marguerite  
| | Filed the Informed Consent and HIPAA in the TLG Consent binder  
| | Need to talk to Banerjee about getting Adobe Acrobat pro Access for Tylenol Study  
| | Preeti informed me that Tylenol EDC needs to be changed into Excel  
| | There was a patient that screen failed for the PREMIER study, so I screened him for Resolute.  
| | Then went to consult Dr. Banerjee on some of the inclusion criteria and he still qualifies.  
| | Spoke to the Patient and he consented for both NET and Resolute 2.0  
| | Printed Enrollment note for TLG study patient to file in the binder  
| | Made list of patients with historical enrollment notes that are waiting on Dr. Grodin’s signature  
| | Called the lab to add labs to the consented patient  
| | Went through TLG study binder and found many notes Ryan the fellow needs to sign and another note that needs updating  
| | Updated screen failure binder for Resolute Onyx  
| | Checked list of patients that need to be reconsented and have some questions for Preeti  
| | Went to the Cath lab to see if patient qualified  
| | Talked to Ryan about the enrollment notes he needs to sign  
| | The patient enrolled in 2.0  
| | Filled out an enrollment note  
| | Called attending to make sure the labs aren’t cancelled  
| | Asked Michelle to check remotely to see if the patient’s labs were done |
- Made sure the IVUS and Angio CDs were in order. Will talk to Hao about getting copy and original of Angio for new enrolled patient
- Gave Preeti Originals and Copies of IVUS and Angio CDs
- First Resolute Patient is due for 6 month MPI so gave Judi contact info to make followup appointment
- Went to see yesterday's enrolled patient and gave him the copy of his informed consent
- Got a tech to do his EKG
- Went to Atif’s office to ask him to make the historical enrollment notes for one patient that screen failed and one that left the study.
- Got Dr. Banerjee to sign the patient's EKG.
- Asked Dr. Grodin to sign the Historical Enrollment Notes for 3 patients that he hasn’t yet signed, so I can update the screen fail binder.
- Went to the Cath lab to look for Ryan to find out which patient have completed the study.
- Asked Dr. Banerjee to sign enrollment note on CPRS and he said to come back around 3
- Added a chapter to the PAD CTO Manual book. Will work on editing it today
- Contacted Hao to make copies of Angios for yesterdays enrolled patient and he said he will come in tomorrow.
- Printed the notes that Dr. Grodin signed, so the screen failure log is now up to date.
- Dr. Banerjee signed the fellow report as well as the enrollment note, so the patient study folder is becoming more up to date.
- Went to Dr. Banerjee’s office to show him how Adobe Acrobat Pro could benefit the Tylenol study and he agreed to put in a request with Vicky Robertson.

| November 18th, 2015 (Wed) | Went to see a potential patient in the Cath lab, but had to stall him to wait for the lab results. |
|                          | Called the lab to rush the processing. |
|                          | Patient’s platelet count was too low. |
|                          | Added additional inpatients to the weekly list to screen. |
|                          | Spoke to Ryan about updating the TLG study list. |
|                          | Got a call from Atif about 2 new patients |
|                          | Screened both patients and they both qualify |
|                          | One was a screen failure due to inability to consent |
| November 19th, 2015 (Thurs) | • The other one I consented, but he did not have any qualifying lesions  
• Attained Dr. Banerjee’s signature on the EKG  
• Made a historical enrollment note for Dr. Banerjee to co-sign  
• Screened patients for Thursday and Friday and have some questions for Dr. Banerjee  
• Talked to Dr. Banerjee about some patients that I was screening  
• Asked Shibu to put in the 4B lab orders for the patients on Friday  
• Updated screening log for Resolute  
• Started sending some faxes for Puja before she leaves for India  
• Received new inpatient information from Cath Lab  
• Screen patient for Resolute  
• Patient qualified  
• Went to ward to consent patient and make sure proper labs were done  
• Walked a follow up patient of Judi’s over to the CRU  
• Filled out the Informed Consent and HIPAA  
• Scanned more documents for Puja, but then she told me that for the ones that she had noted as submitted to IRB were submitted incorrectly, so I re-did those as well.  
• Went to the Cath lab and there was a staff meeting going on.  
• Came back and finished the Compass faxing and copying.  
• Worked on Commander HF inclusion exclusion sheet.  
• Patient qualified for Resolute 2.0  
• Asked Judi to put in the orders for the blood work  
• Created an enrollment note for newly enrolled patient  |
| November 20th, 2015 (Fri) | • One possible patient from today was a no-show  
• I consented the other patient  
• The patient was a screen failure  
• Printed enrollment notes  
• Updated screen failure binder  
• Redacted patient records for patients 00266-001,002,003,105 to send to sponsor.  
• Went to the Cath lab to look for Dr. Grodin and Dr. Banerjee for signatures but they weren’t there.  
• Created historical enrollment note for screen fail |
<table>
<thead>
<tr>
<th>Date</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient from this morning.</td>
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<tr>
<td>• Made copies of yesterday’s enrolled patient’s Informed Consent to submit to RCO.</td>
<td></td>
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<tr>
<td>• Went to 5A Tele to give the patient a copy of the informed consent as well as attain a copy of the EKG from today.</td>
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<tr>
<td>• Filled out the informed consent and HIPAA for the screen fail patient, so I can make a copy and send it to Marguerite.</td>
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<tr>
<td>• Sent both ICs + HIPAAs to RCO office.</td>
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<tr>
<td>• Updated screen failure log.</td>
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<tr>
<td>• Screened patients for Monday, Tuesday and Wednesday.</td>
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<tr>
<td>November 21st, 2015 (Mon)</td>
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<tr>
<td>• Went up to 4B to consent a possible Resolute 2.0 patient.</td>
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<tr>
<td>• Patient wanted time to decide, so went to Dr. Grodin to get procedure note for patient 00266-104 added. Also, had Dr. Grodin fill out Clinically Significant lab values for the SAE on the last core patient 106.</td>
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</tr>
<tr>
<td>• Went to Shibu to ask him to add CK-MB and troponins to lab orders.</td>
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<tr>
<td>• Saw Barbara and she told me that the patient in 4B had consented for her study.</td>
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<tr>
<td>• Went to 4B to see if the patient was ready to consent and he was.</td>
<td></td>
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<tr>
<td>• Asked the nurse to draw labs because Shibu added new lab orders because he didn’t know CK-MB and Troponins could be added to CBC.</td>
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<tr>
<td>• Took the blood samples to the lab.</td>
<td></td>
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<tr>
<td>• Made a copy of the EKG.</td>
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<tr>
<td>• Dropped off the Clinically Significant lab values for the SAE patient to Judi and brought Resolute binder upstairs since the patient was being brought up to the Cath lab.</td>
<td></td>
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<tr>
<td>• Had Dr. Banerjee look at the EKG and he said it was normal.</td>
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<tr>
<td>• Screened in patients while the patient was in the Cath lab and none of them qualified because most of them were NSTEMIs.</td>
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<tr>
<td>• Updated enrollment consent list.</td>
<td></td>
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<tr>
<td>• Created a historical enrollment note for the screen failure patient from today.</td>
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<tr>
<td>• Printed addended procedure report for patient 104 and redacted that and the Cath lab report as well.</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Tasks</td>
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<td>----------------------------------------------------------------------</td>
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</tbody>
</table>
| December 1st, 2015 (Tues) | - Filled in IC and HIPAA form for the consented patient from this morning and made copies to send to RCO office.  
- Went to 5th floor to see if IVUS CD was burned on a patient. Had Atif check the CD and he said it was.  
- Went back to CRU and Preeti wanted to make sure the IVUS CD did not indicate that it was from the VA, so I confirmed it with Atif and returned the CD to Preeti in order for her to send it to the sponsor.  
- Started finishing up newly enrolled patient 004’s folder.  
- Screened patients for Tuesday and Wednesday.  
- Updated Screen failure log with screen failures from before Thanksgiving  
- Finished the Commander HF Inclusion-Exclusion sheet and start up folder  
- Printed Protocol, IRB approved informed consent, HIPAA and made the Inclusion-Exclusion sheet for the Harmony start up folder  
- Went to the IRB office to get boxes for Preeti  
- Worked on making the startup folder for Voyager but there was not folder to put the information in  
- Printed more screening logs and continued screening for the rest of the week  
- Went to Cath lab to see if there were any inpatients. Spoke to girls on Bavanas team about one possible patient, but he refused.  
- Went to Shibu and asked him to add CBC and CHEM8 to the 2 potential Resolute patients for tomorrow.  
- Screened other inpatients for this week  
- Talked to Rahel about turning in graduation paperwork since the deadline is this week  
- E-mailed Dr. Simecka to ask for specific deadlines for internship  
- Called Dr. Simecka to see if he will be available to sign my intent to graduate form  
- Rahel said Dr. Gwirtz will be available between 1-2 tomorrow, so I asked Preeti if I could go to turn in my intent to graduate form since it is due on Friday.  
- Spoke to Preeti about deadlines and says we can talk more in detail after I speak with Dr. Gwirtz tomorrow |
| December 2nd, 2015 (Wed) | - Consented qualifying patient.  
- Asked Judi to add troponin and CK-MB to lab orders.  
- Made copy of EKG. |
- Got loading dose of aspirin for the patient before angiography.
- Other patient was a no show.
- Patient will come back for planned PCI and then return 30 days later for Resolute Onyx stent.
- Made enrollment note.
- Talked to Dr. Banerjee about inclusion exclusion criteria and decided it would be a good idea to talk with the sponsor to clarify some of the criteria.
- Spoke with Preeti about things to talk to Dr. Gwirtz and Dr. Simecka about
- Checked 4 IVUS CDs in the Closet to see if they were de-identified
- Screened for next day and found 3 qualifying patients.
- Called Shibu to add the lab orders for the qualifying patients.
- Made copy of the informed consent and HIPAA for patient and spoke to the patient about it in detail.
- Made copy for Marguerite.
- Went to UNTHSC to discuss my practicum with Dr. Gwirtz and later met with Dr. Simecka.

**December 3\(^{rd}\), 2015 (Thurs)**

- Dr. Banerjee and Dr. Grodin weren’t in the Cath lab, so I couldn’t consent the first patient for this morning.
- There was another patient that was admitted but became a screen fail due to his kidney function.
- Asked Shibu to add lab orders to one of the inpatients.
- The patient other patient that qualified declined the “NET” trial because he is already enrolled in another study, so I did not consent him.
- Went to Vicky Robertson to see what happened with Adobe Acrobat Pro being installed on my computer.
- Went down to the Cath lab to add names for the inpatients and one patient qualified.
- Came back to CRU and talked to Preeti about the new inpatient and she advised me to talk to Dr. Grodin.
- In the meantime, Tom from IT came down to install Adobe Acrobat Pro 11 on my computer, so I waited for him to finish that before going to see Dr. Grodin.
- Met with Dr. Grodin and he wanted to see the films.
- Discussed with Dr. Brilakis and Swagata and decided the patient should be consented for DIVA.
<p>| | |</p>
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</table>
|   | • Sent the copies I made yesterday to Marguerite.  
|   | • Left a voicemail for Serena at Medtronic to discuss the inclusion-exclusion criteria.  
|   | • Updated the screening log.  
|   | • Made an EDC pdf for Tylenol paper  
|   | • Made pain tables on Excel.  
| December 4<sup>th</sup>, 2015  
(Fri) | • Talked to Preeti about job opportunities at the VA.  
|   | • E-mailed Dr. Banerjee the EDC pdf and the Excel pain tables so that I can get started on the data entry.  
|   | • Went to the Cath lab to see if Dr. Grodin was in to be able to Cath for Resolute.  
|   | • On the way, Judi asked me to get a sample of blood from a PREMIER patient.  
|   | • I got the sample and took it to the lab.  
|   | • The lab said it wasn’t labeled and to go back up to Cath to get it labeled.  
|   | • I went back up to Cath and Dr. Grodin was there and said go ahead and consent the patient.  
|   | • I got the label for the blood.  
|   | • I consented the patient and made a copy of his EKG.  
|   | • I asked Shibu to add CK-MB and Troponin to his labs.  
|   | • I went back to the lab to give them the blood work, but they said there was no order for the blood and they would hold it for me and to call them back.  
|   | • I went to the CRU to get the Resolute folder for the patient and tell Judi about what happened with the blood sample.  
|   | • She said she wanted me to bring it back to the CRU and put it in the refrigerator.  
|   | • She also said that the CK-MB and Troponin labs on the guy that Shibu put in weren’t there and she had a bad feeling about that guy and to just get the blood from the lab and come back.  
|   | • Went to the lab and brought the sample back to the CRU.  
|   | • Updated Resolute Onyx screening log.  
|   | • Started screening patients for next week.  
|   | • Found a potential patient that had a diagnostic Cath last week and went to the Cath lab to look at the images and ask the fellow if any of the patient’s lesions were ≥2.0, but there were no eligible lesions.  
|   | • Continued screening for the next week.  
|   | • Made a spreadsheet for the enrolled Resolute Onyx patients to keep track of followup.  

| December 8<sup>th</sup>, 2015 (Mon) | Went to Cath lab to see if there were any inpatients. Found 2 that were possibly eligible.  
One was a re-screen who did not have chest pain but is possible for Re-dual because he has CHF and is on Warfarin  
Told Judi he was eligible for Re-dual  
The second was a screen fail because his creatinine was too high.  
Added screened patients to the screening log  
Asked Preeti when Dr. Banerjee would be free, so I can go over the primary objectives of the Tylenol paper to get started on my proposal. She said after 10.  
Talked to Judi about the CCSC class for an old Resolute patient.  
Went up to the Cath lab to see if Dr. Banerjee was free, but a STEMI just came in so he wasn’t.  
Attended Cardiology lunch. Dr. Banerjee was busy so I couldn’t clarify objective for the proposal.  
Started organizing documents for background on my proposal  
Went up to see Dr. Banerjee and he said he was not in the state of mind to think about right now.  
Found out that Dr. Banerjee will be out of the office for the rest of the week. |
| December 9<sup>th</sup>, 2015 (Tues) | Went to the Cath lab to screen inpatient list.  
Found two eligible patients, but both ended up being screen fails.  
Screened for Thursday.  
Got an email from Dr. Banerjee about him wanting the EDC to be in Excel, so I started working on that  
VISTAlmaging was not working  
Had to reconsent a patient.  
Filled out the form and made a copy of the form for the patient.  
Made a copy to Marguerite and sent it to the RCO Office.  
Put the updated consent in the patient binder.  
Updated the enrollment consent log  
Made a mistake in making the addendum to the enrollment note and had to e-mail NTX health record modification to fix that.  
Made an Excel Spreadsheet version of the EDC and was unable to fill it in with patient data due to |
| Date: December 10th, 2015 (Wed) | - VISTAImaging malfunctioning.  
- Prepared consent forms for potential patient for tomorrow.  
- Talked to Preeti about dates for my thesis defense and about screening criteria for Re-dual.  
- I went up to the Cath lab to see if Dr. Grodin was available to cath today and it turned out that the potential patient for today was a no show.  
- I screened the inpatients for this morning.  
- The NTX health record modification people emailed me about more information for the addendum to the enrollment note.  
- I emailed back providing more specific details so they knew what exactly to delete.  
- Started screening for Redual PCI since Judi isn’t here today.  
- Couldn’t find any patients that have Afib to qualify for Redual this week.  
- One potential Resolute patient for tomorrow.  
- Had Shibu add the orders for the patient  
- Screened for Resolute for Friday and found one potential patient.  
- Called Linell to add a CBC and CHEM8 for him.  
- Updated screening log.  
- Started data entry on Tylenol Excel EDC  
- Worked on some of the background section for the proposal when the 4th patients data on VISTAImaging wasn’t showing up. |
|---|---|
| Date: December 14th, 2015 (Mon) | - Went to the Cath lab to add inpatients to screen  
- Dropped off paperwork to the Lab Chief office and to Becky in Medical Services  
- Started working on Avery Tab templates as well as XLPAD Trace Binder labels  
- Needed to help Hattie and Atif burn CDs for an upcoming paper.  
- Finally spoke to NTX health record modification on the phone to fix the reconsent issue for the reconsented patient.  
- Screened inpatients and found one potential patient.  
- Went to 5A Tele to consent him. He agreed to participate in the study.  
- Asked Judi to put in an order for the EKG.  
- Duwaine from the Cath lab came to get him and said we could get the EKG done in the Cath lab. |
- Called Swagata to come up to get the blood sample so we could have his troponins in one time.
- Got the EKG done and received a copy of it.
- Swagata was having trouble getting the blood sample, so I asked Alex to help.
- Got the blood sample and ran it to the lab.
- In the meantime, Preeti texted me to pick up the paperwork from Medical Services.
- Went to Medical Services to get the paperwork and brought it down to the CRU.
- Couldn’t find the Resolute Startup Packet, but Judi had already brought it upstairs for me.
- Went up to the Cath lab and waited for the procedure to start.
- I was running late for a doctor’s appointment and Judi came to stay and see if the patient qualified, which he did.

<table>
<thead>
<tr>
<th>December 15(^{th}), 2015 (Tues)</th>
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<tbody>
<tr>
<td>Went to the Cath lab to see if there were any qualifying inpatients.</td>
</tr>
<tr>
<td>Made an enrollment note for the patient from yesterday.</td>
</tr>
<tr>
<td>Judi put in EKG orders which I will make sure get done before the patient is discharged.</td>
</tr>
<tr>
<td>Updated screening log.</td>
</tr>
<tr>
<td>Updated enrollment and consent list.</td>
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<tr>
<td>Checked to make sure labs were drawn according to protocol for newly enrolled patient.</td>
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<tr>
<td>Filled out the rest of the informed consent and HIPAA forms for the new patients.</td>
</tr>
<tr>
<td>Made copies for the RCO (Marguerite) and the patient.</td>
</tr>
<tr>
<td>Went to get the EKG done for the patient.</td>
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<tr>
<td>Found out about a team lunch that we have today.</td>
</tr>
<tr>
<td>Added follow up dates to the spreadsheet for the enrollment consent list.</td>
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<tr>
<td>Gave the patient the stent information and follow up card.</td>
</tr>
<tr>
<td>Tried to get signatures on the EKGs and screening log from Dr. Banerjee, but he was in a meeting.</td>
</tr>
<tr>
<td>Went for a team lunch.</td>
</tr>
<tr>
<td>Started making a patient folder for the newly enrolled Resolute Onyx patient.</td>
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<tr>
<td>Spoke to Dr. Banerjee about the Tylenol paper outcomes and received necessary signatures.</td>
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<tr>
<td>Date</td>
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<td>-----------------------</td>
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</table>
| December 17<sup>th</sup>, 2015 (Thurs) | - Went to the Cath lab to look for new inpatients.  
- Continued making patient folder for the new patient using the notes in CPRS.  
- Registered for Dallas CVI  
- Started screening patients for Friday.  
- No qualifying patients.  
- Updated screen failure binder for consented patients.  
- E-mailed Dr. Gwirtz about dates for my defense and she said my main focus right now should be the proposal before being allowed to start on the actual project.  
- Reminded Judi of the 30 day updates that are due for the two patients from last month.  
- Preeti is now looking at the dates to see which dates are most suitable for her and Dr. Banerjee.  
- I will subsequently email a shortened list of dates to Dr. Simecka and Dr. Chakraborty to finalize a defense date.  
- Created XLPAD Trace binder labels and saved them on the shared server.  
- Found the Avery binder tap templates but it wouldn't open on my computer. I tried it on Erum’s and Puja’s and the only one that it works on is Preeti’s, so I will remind her of that tomorrow. |
| December 18<sup>th</sup>, 2015 (Fri)   | - Worked on Proposal from home                                               |
| December 21<sup>st</sup>, 2015 (Mon)   | - Received an e-mail from Preeti requesting that all data entry be completed by January 15<sup>th</sup> in order for my site to support my requirements for graduation  
- Continued data entry. |
| December 22<sup>nd</sup>, 2015 (Tues)   | - Continued data entry and noticed that some categories may had needed to be added to the EDC like AFib as an “Indication”; Nitrates, Antiarrhythmics, Diuretics, muscle relaxers and barbiturates as relevant medications to take into consideration.  
- Went for a team lunch to wish Puja the best for her new job.  
- Went back over the patients I had already entered and added the information for the new categories. |
| December 23<sup>rd</sup>, 2015 (Wed)    | - Picked up papers from Medical Services.  
- Checked the Cath Lab to see if Dr. Grodin was in his office.  
- Picked up papers from the Lab for two new studies. |
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<tr>
<th>Date</th>
<th>Notes</th>
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| December 24th, 2015     | • Worked with Hattie to arrange columns on the Excel document to make it easier to analyze  
                        | • Asked Dr. Banerjee about my reviewing my proposal and he wanted me to have data before writing a proposal.  
                        | • Tried calling Dr. Gwirtz to ask her what to do about my proposal, but she didn’t answer.  
                        | • Continued doing data entry                                           |
| December 28th, 2015     | • Mentioned the proposal again to Dr. Banerjee and he said focus on the data entry.  
                        | • Continued doing data entry.                                           |
| December 29th, 2015     | • The office was very cold and Hattie was in her office, so I asked if I could work with Hattie to figure out the best way to arrange the pain tables.  
                        | • Continued data entry.                                                |
|                         | • Received a message from Preeti asking me if my proposal was submitted to the program and I told her about Dr. Banerjee’s opinion last week.  
                        | • She said I should send the proposal to her.                           |
|                         | • Focused my attention on the proposal when I got home.                 |
| December 30th, 2015     | • Finished the last of what was left of the proposal and submitted it to Preeti to get to Dr. Banerjee.  
                        | • Asked Atif some questions about the data because the pain outcomes aren’t checked at regular intervals and the data doesn’t seem very promising, but he said just get it done.  
                        | • Continued data entry.                                                |
| January 1st, 2016       | • Continued data entry.                                                |
| January 4th, 2016       | • Emailed Dr. Gwirtz to update her on the delays for my proposal.       |
|                         | • Continued data entry.                                                |
|                         | • Finished up most of the data entry for the Tylenol leg.               |
|                         | • Threw away expired boxes that had needles in them, so I separated the needles to dispose of them appropriately.  
                        | • Started making formatting edits to the EDC.                           |
|                         | • Wanted to discuss some formatting questions with Hattie, but she isn’t here today.  
                        | • Discussed progress of my practicum report.                            |
|                         | • Spoke with Dr. Grodin as he wanted to catch up after                  |
- Sent the list of Cath lab patients for today and tomorrow to Judi.
- Spoke with Dr. Banerjee about medical schools and how to rank them.
- Picked up an ACI from the Lab Administration office for Preeti.
- Went to see Vicky Robertson in Medical Services to see how she is recovering from her accident and to see the status of Michele and Atif’s computer access.
- Went through the list of all the enrolled Resolute Onyx patients that had a positive stress test to find out what type of stress test they had and added it to the excel spreadsheet in the shared folder.
- Edited Resolute Onyx enrollment-consent sheet to add formulas for the 30 day, 6 month, 8 month, 1 year, 2 year and 3 year followups.
- Preeti said Dr. Banerjee would have my proposal edits completed by tomorrow.
- Asked Latoya to print me out the list of all Cath lab patients from 10/22/14-9/15/15.
- With Atif’s help, I figured out what categories to sort out the matched control group into.
- Went through the Cath lab fellow reports for October 2014 through the middle of November 2014 and found 13 patients that matched the control group qualifying criteria after going through more than 400 patients just by name and social to find out their age at the time of the procedure and type of procedure to see if they could be matched.

**January 6th, 2016 (Wed)**

- Received Dr. Banerjee’s edits to the proposal from Preeti.
- Informed Preeti of the back and forth for the editing and approval process of the proposal.
- E-mailed Dr. Gwirtz to update her on my progress thus far and balancing the proposal with data entry.
- Found out that a Resolute Onyx patient is in the ER, which is an adverse event.
- Will go see the patient with Judi later on today.
- E-mailed myself proposal edits to work on from home, so I can focus on data entry while on site.
- Spoke to Dr. Brilakis about sending me the inpatient procedures since the list from Latoya is only outpatient procedures and is a hard copy list.
- Emailed Dr. Brilakis the list of dates that I need the
Cath lab patient log for.
- Went through the Cath lab fellow reports for the rest of November 2014 through the middle of February and found 24 more patients that matched by age and type of procedure.

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| January 7th, 2016 (Thurs) | - Dr. Brilakis e-mailed me about what folder to put the list of inpatients from the Cath lab in.  
- I e-mailed him back asking him to put it in the Brilakis Research folder, so Preeti could put it in the Banerjee research folder to get it to me.  
- Preeti gave me documents to give to Becky in Medical Services.  
- Went to Medical Services and gave Becky the paperwork.  
- Spoke with Dr. Brilakis about how and where to put the patient list document.  
- Received confirmation from both Preeti and Dr. Brilakis about the location of the file.  
- Instead of hand writing and going through the list from Latoya, I decided to use Dr. Brilakis’ list and start from the top which is the most recent, thereby making it easier to find the reports and go through them. |
| January 8th, 2016 (Fri) | - Started data entry for the 47 patients that I matched, so I could meet the deadline for January 15th. |
| January 11th, 2016 (Mon) | - Continued data entry for the matched patients. |
| January 20th, 2016 (Wed) | - Had submitted the EDC for approval for the treatment and the 47 out of the 60 matched for the control and received approval from Preeti to finish up data entry as per Dr. Banerjee’s approval.  
- Met with Dr. Gwirtz to discuss my defense and gained a better understanding of what is expected for the thesis defense seminar since I was unaware of the presentation I would have to make and that the deadline to submit the thesis is two weeks before the defense.  
- Stopped by Dr. Chakraborty’s office to see if he was in to confirm the 7th or 9th of March for my defense since Dr. Banerjee, Preeti, Dr. Simecka and Dr. Gwirtz were on board for those dates. He was not in his office, so I subsequently emailed him to check his availability. |
| January 21st, 2016 (Thurs) | - Dr. Chakraborty confirmed the 9th of March for my defense. |
- Matched 9 more patients.

**January 22nd, 2016 (Fri)**
- Entered the data for the 9 matched patients.
- Continued to look through cath lab reports and CPRS for the last 4 patients to match from the digital CART-CL list with just patient name and date of procedure.
- Spoke to Preeti about a time for the defense to get the site’s preference before confirming with the rest of the committee.
- Spoke to Michelle about the patients I had to match and she informed me that the nurses keep a monthly log with the type of procedure.
- Spoke to Don the head of nursing and he said to ask Smitha.
- Obtained the list of Cath patients with their type of procedure in order to find the last four patients.

**January 26th, 2016 (Tues)**
- Helped Erum with some SAE related questions she had in terms of categorizing the severity of the event.
- Found the last four patients and

**January 27th, 2016 (Wed)**

**January 28th, 2016 (Thurs)**
- Worked remotely on my thesis.

**February 1st, 2016 (Mon)**
- Took the day off to spend Match day with my family since my mom came in town from San Antonio.

**February 2nd, 2016 (Tues)**
- Checked in with Preeti as I entered the office and she told me to keep Dr. Banerjee up to date with the thesis progress. I told her I was waiting on Hattie’s input on how to statistically analyze the data and once the analysis was done I would follow up with Dr. Banerjee.
- Spoke with Hattie about how to arrange the data for it to be analyzed and discussed the different tests we would run to assess statistical significance. We decided on a matched pair t-test and Wilcoxon ranked sum two sample test.
- Started arranging the data to calculate the differences to make a spreadsheet for Hattie to use in the SAS software program.

**February 3rd, 2016 (Wed)**
- Finished the spreadsheet for Hattie, but we had to reformat it for analysis and created the associated tables.
- We performed the Wilcoxon ranked sum test and found the p value to be 0.0008 and made the associated distribution of scores graph.
- We then performed descriptive statistics to assess differences in mean, median, standard deviation as well as upper and lower quartiles.
- To be thorough we also performed the t-test and found the p value to be .002.
- Could not get a hold of Dr. Banerjee to tell him the good news, so I decided to e-mail him about the significant progress and ask for any possible hypothesis for such specific results.
- Dr. Banerjee replied saying that the results were encouraging and that he would follow up with Hattie to see if the significance holds under multi variable analysis.

| February 4\(^{th}\), 2016 (Thurs) | - In the pre-treatment spreadsheet for both groups, I tried to accommodate for confounding effects of medications by listing the time of the last dose, but it would be easier to analyze that if I made it a yes or no type of data subset for sedatives, benzos, narcotics, Tylenol, codeine or Benadryl within a certain time interval
- Spoke to Atif as Dr. Banerjee was unavailable and he said 24 hours.
- Erum told me Dr. Banerjee was available and I spoke to him about the multiple variables he wanted to look at and we decided on an interval of 12 hours.
- Completed interval spreadsheet and updated the info for the EDC.
- Spoke to Hattie about best way to analyze. |
| February 5\(^{th}\), 2016 (Fri) | - Researched articles on the mechanism of action of fentanyl and midazolam. |
| February 8\(^{th}\), 2016 (Mon) | - Completed 12 hour interval medication dosage column for the control group.
- Spoke to Hattie about the restrictions on VA information for use on UT Southwestern computers.
- Brought Hattie down to the CRU to clarify with Preeti what is allowed and what isn’t in terms of privileged information and allowing Hattie shared folder access.
- Since dates are protected information, had to make 4 new columns to analyze duration of stay for both the Tylenol arm and the control group.
- Made de-identified copies of the patient list and EDC.
- Sent the de-identified copies as well as data analysis document title “Tylenol_pain” where I have 6 sheets, one for pain, one for medication 12 hours prior, one |
for the combination of fentanyl and midazolam, one for fentanyl, one for midazolam and one for Benadryl.

February 9th, 2016 (Tues)
- Worked on editing formatting the proposal into the required format for thesis submission.
- Spoke to Dr. Simecka about sending him a draft of my thesis.

February 10th, 2016 (Wed)
- Worked on arranging the data the way that Hattie wanted it because she initially misunderstood the intent behind the data analysis.
- Did multivariable regression using SAS with Hattie, and found the results to be very statistically significant.

February 11th, 2016 (Thurs)
- Worked more on the thesis because I wanted to have some of the results section completed before sending anything to Dr. Simecka or Dr. Gwirtz in order to have a more complete abstract, introduction and background.

February 12th, 2016 (Fri)
- Continued research on pain receptors for fentanyl and midazolam as well as the competitive inhibition fentanyl has of midazolam.
- Also needed to research possible reasons for the presence of protective

February 15th, 2016 (Mon)
- Informed Preeti o
- Worked all night and put together a rough draft minus commentary on the the Results and the discussion section.

February 16th, 2016 (Tues)
- E-mailed my draft to Dr. Gwirtz and Dr. Simecka.

February 17th, 2016 (Wed)
- Received Dr. Gwirtz’ edits and commentary.
- Started adjusting my thesis accordingly.

February 18th, 2016 (Thurs)
- Dr. Simecka will be out of town until Tuesday, so will try to get as much done before then.
- Asked Atif for his input and advice.

February 19th, 2016 (Fri)
- Adjusted my thesis according to what I saw in scientific journals in terms of structure and verbage.

February 22nd, 2016 (Mon)
- Spoke to Dr. Simecka over the weekend about what needed to be done and confirmed a meeting for Wednesday at 1 pm.

February 23rd, 2016 (Tues)
- Received Dr. Banerjee’s insights and input on my thesis and adjusted it accordingly before the meeting with Dr. Simecka tomorrow.