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There is a lack of consensus on best practice on pain management in patients with Traumatic Multiple Rib Fractures (TURFs). The objective was a pilot study to describe the use of pain management modalities for TURFs. Descriptive and statistical analyses were conducted on data from retrospective chart review. The number of rib fractures and length of stay (LOS) in the hospital, Trauma Intensive Care Unit (TICU), and on ventilator differed between treatment modalities. This demonstrates the need for a prospective, randomized control trial to determine best practice of pain management in patients with TURFs.

**Keywords:** continuous nerve block; epidural analgesia; opioids; pain management; regional anesthesia; rib fractures

CONTRASTING PAIN MANAGEMENT STRATEGIES IN A RETROSPECTIVE STUDY OF  
PATIENTS WITH TRAUMATIC MULTIPLE RIB FRACTURES (TURFs)

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CONTRASTING PAIN MANAGEMENT STRATEGIES IN A RETROSPECTIVE STUDY OF  
PATIENTS WITH TRAUMATIC MULTIPLE RIB FRACTURES (TURFs)

INTERNSHIP PRACTICUM REPORT

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For the Degree of

MASTERS OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

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## LIST OF ABBREVIATIONS

Abbreviations	Unabbreviated Term
AAST	The American Association for the Surgery of Trauma
CNS	Central Nervous System
COI	Conflict of Interest
CPNBCPB	Continuous Paracostal Nerve Block
CRF	Case Report Form
df	Degrees of Freedom
EA	Epidural Analgesia
EMR	Electronic Medical Record
EMS	Emergency Medical Services
GLF	Ground Level Fall
IRB	Institutional Review board
ISS	Injury Severity Score
MCC	Motorcycle Crash
MOI	Mode of Injury
MVC	Motor Vehicle Crash
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
PRO	Protocol
ROC	Research Outcomes Consortium
TBI	Traumatic Brain Injury
THFW	Texas Health Harris Methodist Hospital Fort Worth
TICU	Trauma Intensive Care Unit

## LIST OF ABBREVIATIONS CONTINUED

Abbreviations	Unabbreviated Term
TURFs	Traumatic Multiple Rib Fractures
TXA	Tranexamic Acid

## CHAPTER I

### INTRODUCTION

Texas Health Harris Methodist Hospital Fort Worth (THFW) annually admits approximately 3,000 trauma patients and 10% of these patients have rib fractures. Seventy-five percent (75%) of the patients who present with rib fractures have three or more rib fractures, which is defined as Traumatic Multiple Rib Fractures (TURFs). These patients with TURFs experience moderate to severe pain. The goal of patient care is to alleviate pain and prevent pulmonary dysfunction. Management of pain continues to be a challenge due to multiple modalities being available without best practice treatment guidelines defined for TURFs. The American Association for the Surgery of Trauma (AAST) states, “There is no specific treatment for rib fractures” (19). The frequency of various modalities chosen for pain management and rationale for the choice of treatment to alleviate pain was unknown at THFW. The results from this pilot study will serve as the foundation to design a prospective, randomized, controlled trial to find the optimal treatment modality of pain management for TURFs.

The primary objective of this practicum report was to perform a retrospective chart review for patients with TURFs and the types of pain management provided at THFW. The specific aims were to describe 1) the rationale, and 2) frequency of use of opioids alone versus opioids plus either epidural analgesia (EA) or continuous paracostal block (CPB) at THFW in the management of pain in patients with TURFs. A summary of the data is provided as a descriptive

and statistical analysis and the limitations of this pilot study are discussed. The practicum report provides information from previously published literature to establish an understanding of TURFs and pain management modalities. The specific aim and the significance section provide a further in-depth explanation. The materials and methods section details specific data collection procedures. The final part of the practicum report discusses the results, overall research outcome, and future directions.

## CHAPTER II

### RESEARCH PROPOSAL

#### **Background & Literature Review**

Patients with acute multiple rib fractures experience moderate to severe pain. An increase in the number of rib fractures increases the morbidity and mortality rates in patients with TURFs (2). The aim of treatment for these patients includes pain control and prevention of pulmonary dysfunction (17). Pulmonary dysfunction can include atelectasis, inability to clear secretions, pneumonia and adult respiratory distress syndrome (17). Pain management is individualized for each patient and administration may include one or more routes: oral, intramuscular, intravenous, via epidural catheter or continuous paracostal block (20). Types of pain medications given to patients include opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and acetaminophen (oral or intravenous). All the aforementioned analgesic modalities have effectively been shown to manage pain and increase pulmonary function in patients with TURFs (1, 2, 3, 7, 23).

#### *Pain medications*

Opioids are used in the treatment of pain with possible side effects that may include urinary retention, constipation, pruritus, nausea, cough suppression, central nervous system (CNS) depression and respiratory depression (11, 12). NSAIDs are used to relieve acute pain and reduce inflammation (2, 5). NSAIDs will present various side effects such as vomiting, nausea, constipation, depressed appetite, gastrointestinal ulceration, platelet inhibition, renal injury, gastrointestinal bleeding, induced hypersensitivity, and may prevent bone healing in many



patients (4). Acetaminophen may be administered orally or intravenously to relieve mild to moderate pain. However, use of acetaminophen is known to be associated with hepatotoxicity and other side effects (24).

### *Epidural Analgesia (EA)*

EA may be used to relieve pain by placing a catheter in the epidural space for the delivery of analgesics (2, 3, 14, 15, 16). Analgesic agents include anesthetics, opioids, or a combination of both. Patients with EA require catheter placement on hospital floors where specialized nurses are specifically trained to provide care for these patients (2, 19). Possible complications of EA include hypotension, a high or total spinal block (inadvertent injection into subarachnoid space), post spinal headache, infection, respiratory insufficiency, fever, or coagulation abnormalities (2, 13, 19). More recently, EA has become available as an alternative for pain management. The preferential use of EA in the management of TURFs has been supported in several publications with EA as a pain management modality in patients with blunt thoracic injury (1, 2, 3, 5, 7, 9, 12, 14, 15, 20, 26). A recently published retrospective study provided insight on which patients may benefit from epidural anesthesia; however, this study was unable to define optimal patient selection (26). The Eastern Association for the Surgery of Trauma (2004) published an evidence-based outcome evaluation with data suggesting that epidural administration of anesthesia as the preferred analgesic modality for patients with TURFs (20). Mackersie et al. (1991) provided evidence on the use of epidural analgesics in the relief of pain and increase in pulmonary function. According to this publication, patients receiving EA must be in a monitored setting with specialized implementation. In addition, there are many

contraindications for the use of EA (14). As a result, EA is not widely accepted as the standard of treatment by physicians treating rib fractures (7).

Yeh et al. (2012) reported that early EA placement did not decrease the length of hospital stay or the incidence of pulmonary complications in patients with rib fractures (7). Another study reported a lack of consensus in rationalizing the selection of pain management for the individual patient (26). The question has been raised that the anatomical location of rib feature(s) can be one of the key components in selecting the type of pain management in each patient. The number of rib fractures directly correlates with pulmonary dysfunction and, therefore, morbidity and mortality (1, 8). Patients with two or more fractures given thoracic epidural analgesia had a significant decrease in mortality (12, 15).

#### *Continuous Paracostal Block (CPB)*

CPB is a pain relief system that automatically infuses local anesthetic near the site of the rib fracture(s) (10). It has a specialized catheter with soaker technology. Pain scores with CPB were decreased compared to utilizing EA in a study by Grissinger (10). Problems associated with the use of CPB were overdose, improper placement, potential of infection, and inadequate pain control (10).

Historically, pain management for patients with TURFs has been the use of narcotics and later, narcotics used in combination with epidurals (1). THFW has used CPB as an adjunct with narcotics since 2010 due to the frequent challenges of the availability of physicians to place EA. CPB is a novel approach for managing pain in patients with TURFs. Providers may choose one of the five CPB devices currently available. A brief technical report of the five devices' flow

rates further aids in the selection of the device for regional analgesia delivery (25). A 2010 study included 102 patients with three or more rib fractures (22, 23). These studies indicate that pain management in patients with CPB improved since numeric pain scores decreased. This was associated with a corresponding increase in sustained maximal inspiration lung volumes, and decrease in respiratory rate with only two patients needing mechanical ventilation.

THFW has extensive experience since 2010 using the CPB as an adjunct with systemic narcotics, with rare catheter-related complications and efficacious dyspnea relief and early patient mobilization.

### **Specific Aim**

There is a lack of consensus among providers on the use of which analgesic modalities to use in the management of pain for patients with TURFs. There is a lack of evidence in the literature on the risks and benefits of CPB specifically for pain management for TURFs. The practice at THFW by one trauma surgeon has been the occasional use of CPB on patients with multiple rib fractures. The aim of this practicum project is to describe the experience at THFW with opioids alone, EA and CPB in the management of pain in patients with TURFs.

### **Significance**

All methods of pain management for multiple rib fractures have contraindications and complications. This practicum report contributes to the body of knowledge about pain management of rib fractures by describing the various methods of pain management in patients with TURFs, which is needed before a prospective study investigating best practices can be undertaken.

## **Materials and Methods**

### *Patient Selection and Data Collection*

This practicum project was a retrospective chart review with data collection from a 1-year period (June 01, 2013 to May 31, 2014) of patients with TURFs. The inclusion criterion was all patients presenting with 3 or more traumatic rib fractures. Local Institutional Review Board (IRB) approval was obtained from both THFW on October 28, 2014 and the University of North Texas Health Science Center (UNTHSC) on November 14, 2014 (Appendix: B). Data was abstracted from the electronic medical record (Care Connect) and the trauma registry (Trauma One). Anonymized information was maintained in a Microsoft Excel document that was password protected and encrypted on a password protected computer accessible only to study staff.

Separate reports were generated by the THFW Trauma Registrars from Trauma One including:

- Total trauma patients admitted from June 01, 2013 to May 31, 2014
- Total trauma patients with rib fractures admitted from June 01, 2013 to May 31, 2014
- Total trauma patients with three or more rib fractures admitted from June 01, 2013 to May 31, 2014
  - Patients that received CPB and opioids
  - Patients that received EA and opioids
  - Patients that received only opioids

Patient chart review in Care Connect was conducted from November 14, 2014 through January 2, 2015. Information on rib fractures was obtained from patient's Computerized Axial Tomography (CT) and Chest X-ray reports.

A Master Key for PRO5508 was designed to include only sequential patient identification number, account number and name. A separate Case Report Form (CRF) contained the raw data abstracted from Care Connect.

The results section includes both descriptive and statistical analyses.

The **descriptive analysis** included:

- Type of Pain Management (opioids alone, EA, CPB)
- Age (years)
- Sex (Male, Female)
- Mode of Injury (MOI)
  - Ground Level Fall (GLF)
  - Motor Vehicle Crash (MVC)
  - Motorcycle Crash (MCC)
  - Other: (Ladder, Fell from Commode, Fell from Step-Stool, Fell from Stairs, Building; Auto versus Pedestrian; Animal; Bicycle)
- Injury Severity Score (ISS): abstracted from Trauma One
- Information on rib fractures included:
  - Number of Rib Fractures
  - Unilateral or Bilateral Rib Fractures

- Rib Number(s) Hospital Length of Stay (days)
- Trauma Intensive Care Unit (TICU) Length of Stay (days) (if applicable)
- Days on Ventilator (if applicable)

The **statistical analysis** included:

- Chi-square test to examine whether following variables are independent of mode of treatment)
  - Age (under 59 years, 59 years and over): Majority of the trauma population admitted at THFW is 59 years and older.
  - Sex (Male, Female)
  - Total rib fractures (< 6, 7-10, >10)
  - ISS (over 14, under 14)
  - MOI (Ground Level Fall, Motor Vehicle Crash, Motorcycle Crash, Other)
  - Hospital LOS in days (1-3, >3)
  - TICU LOS in days (0, 1-6, >6)
  - On Ventilator (Yes, No)
- Mann-Whitney Test to examine whether ISS differed by type of pain modality.
  - ISS
- Logistic regression to test whether the following variables might predict the type of pain management selected:
  - Sex, race, ethnicity, MOI, age, ISS, total rib fractures, hospital LOS, TICU LOS, ventilator days

- Pearson Correlation coefficients to test for relationships between the following variables:
  - Age, total rib fractures, hospital LOS, TICU LOS, ventilator days

## **Results**

### *Descriptive Analysis*

Information extracted from Trauma One from June 01, 2013 to May 31, 2014 included 3,158 admitted trauma patients of which there were 348 patients with traumatic rib fractures. A total of 191 patients met the inclusion criterion of three or more traumatic rib fractures. Exactly 174 patients had pain managed with opioids alone, 16 patients received CPB, and 1 patient received EA. Because only a single patient was treated with EA, this patient was excluded from all data analyses to preserve patient confidentiality. Results therefore focus on contrasting the opioids alone versus the CPB groups.

Exactly 190 patients received opioids alone or CPB with opioids. The mean age was  $56.05 \pm 17.6$  years. There were 131 males (69%) with mean age of  $54.79 \pm 15.8$  years and, 59 females (31%) with mean age of  $58.86 \pm 20.9$  years (Figures 1, 2). One hundred and seventy-four (174) patients who received opioids alone had a mean age of  $55.81 \pm 17.3$  years. The average age per sex who received opioids alone was  $54.88 \pm 15.9$  years for males and  $57.92 \pm 20.3$  years for females. Sixteen (16) patients who received CPB had a mean age of  $58.69 \pm 20.5$  years. The average age per sex who received CPB was  $53.60 \pm 16.0$  years for males and  $67.17 \pm 25.8$  years for females.

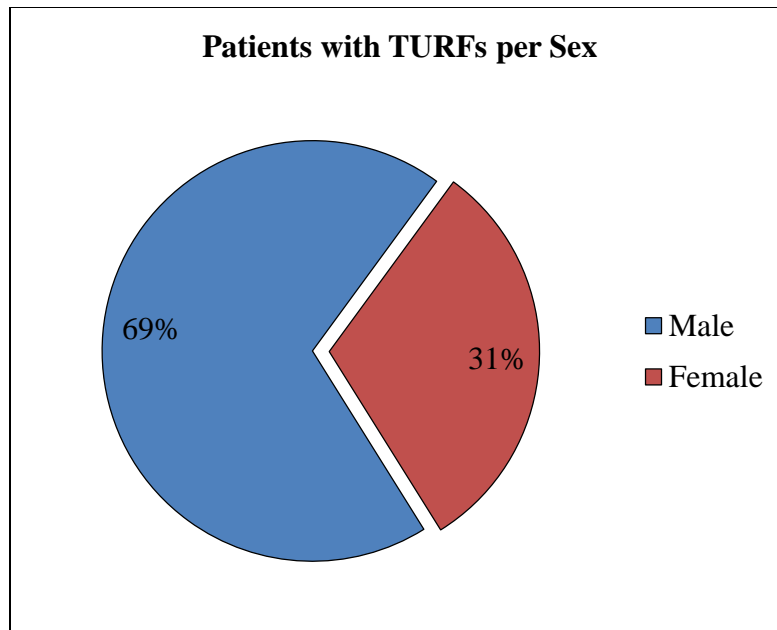


Figure 1: Total patients with TURFs per sex

TURFs = Traumatic Multiple Rib Fractures



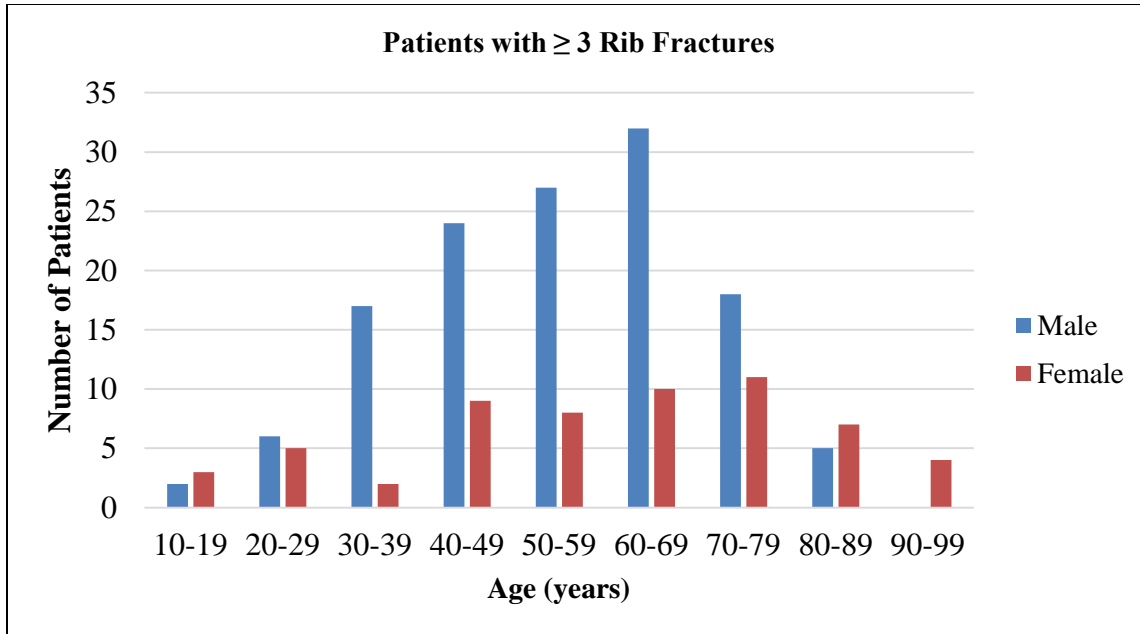


Figure 2: Age ranges of total patients with  $\geq 3$  rib fractures per sex

The average number of rib fractures of the 190 patients was  $6.18 \pm 3.4$ . Patients who received opioids alone had a mean number of rib fracture of  $6.26 \pm 3.4$ . The average number of rib fractures for males was  $6.37 \pm 3.5$  fractures and for females  $6.00 \pm 3.2$  fractures (Figure 3). Patients who received CPB had a mean of  $5.38 \pm 2.8$  number of rib fractures. The average male had a mean of  $5.90 \pm 3.3$  number of rib fractures and the average female had a mean of  $4.50 \pm 1.6$  number of rib fractures (Figure 4).

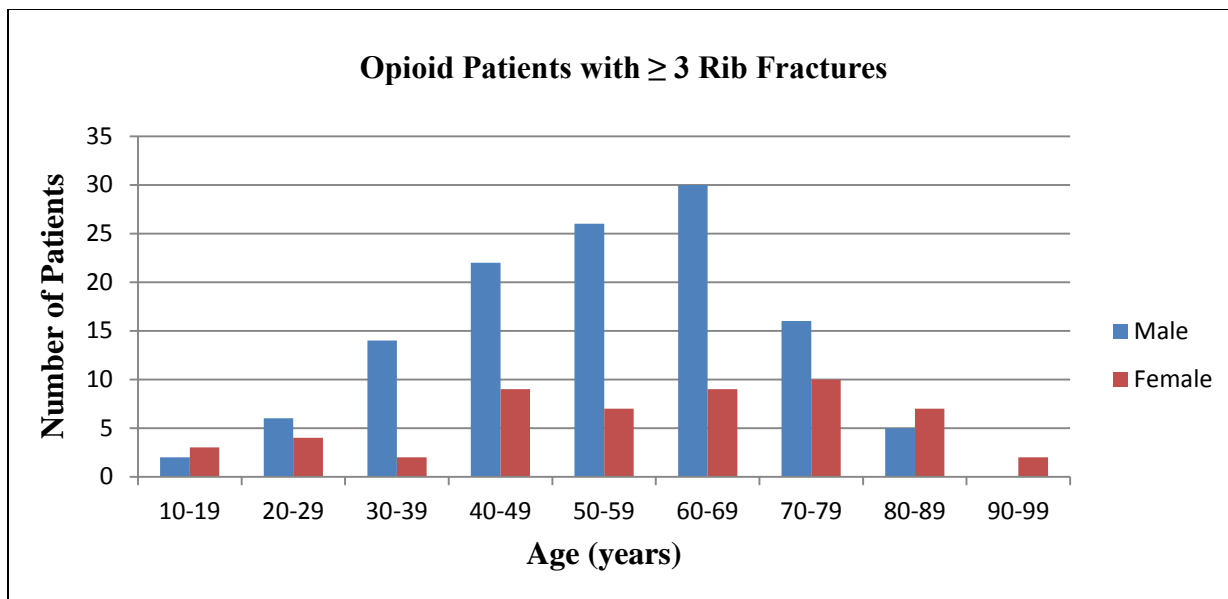


Figure 3: Patients given opioids alone with  $\geq 3$  rib fractures per sex

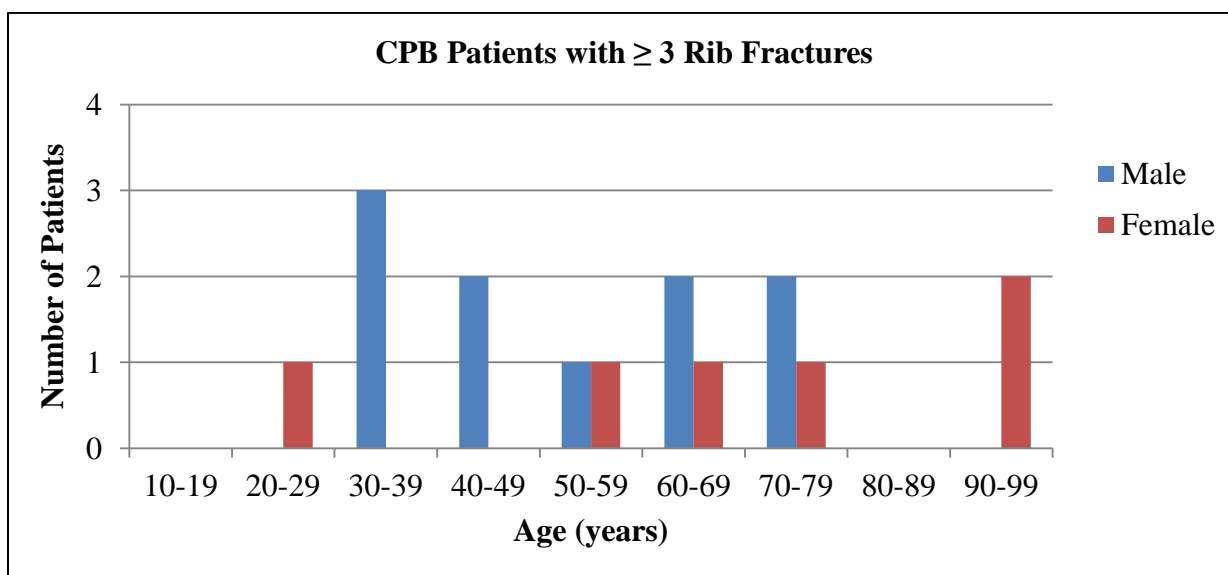


Figure 4: Patients given CPB with  $\geq 3$  rib fractures per sex

CPB = Continuous Paracostal Block

Patients with bilateral rib fractures who received opioids alone had a mean of  $9.59 \pm 4.1$  number of rib fractures. The average for males was  $9.75 \pm 4.5$  number of rib fractures and females with  $9.33 \pm 3.4$  number of rib fractures. Patients with unilateral rib fractures who received opioids alone had a mean of  $5.51 \pm 2.7$  number rib fractures. The average was  $5.07 \pm 2.9$  number of rib fractures for males and  $5.02 \pm 2.3$  number of rib fractures for females (Figure 5). Patients with unilateral rib fractures who received CPB had a mean number of  $5.27 \pm 2.9$  number of rib fractures. The average was  $5.90 \pm 3.3$  number of rib fractures for males and  $4.00 \pm 1.2$  number of rib fractures for females. There was only one female patient given CPB with bilateral rib fractures.

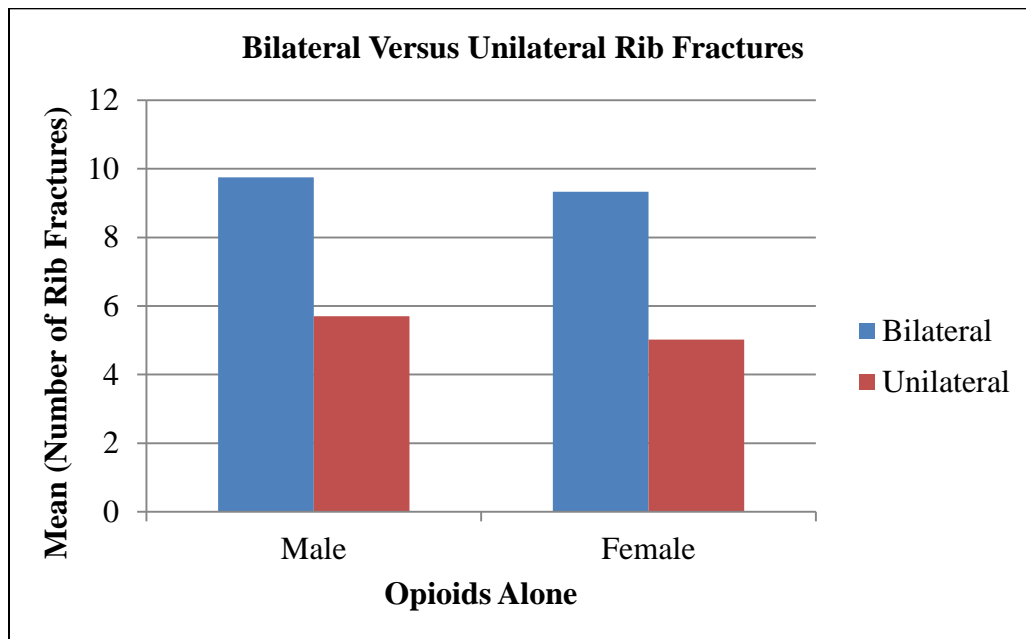


Figure 5: Patients with bilateral or unilateral rib fractures per sex

The mode of the fracture location in the 190 patients in this study was the left fifth rib and right sixth rib (Figure 6). The mode of the fracture location for a male was the left fifth rib and right fourth and fifth ribs. The left fifth rib and right seventh rib was the mode of fracture location for females (Figures 7, 8).

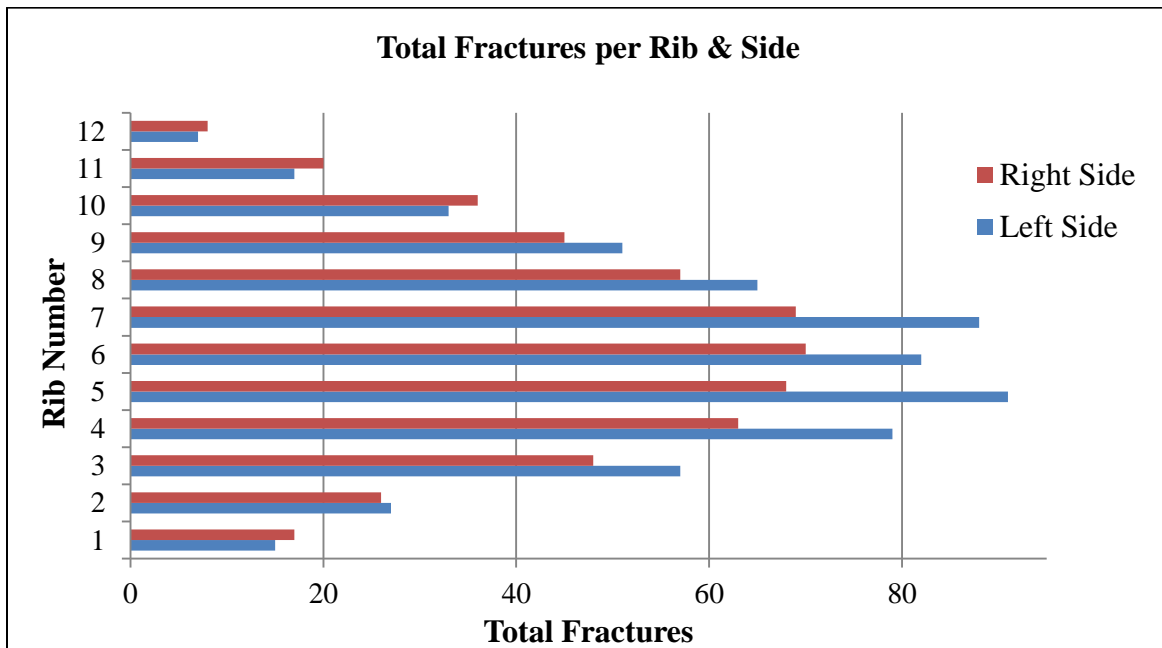


Figure 6: Total number of rib fractures per rib and side

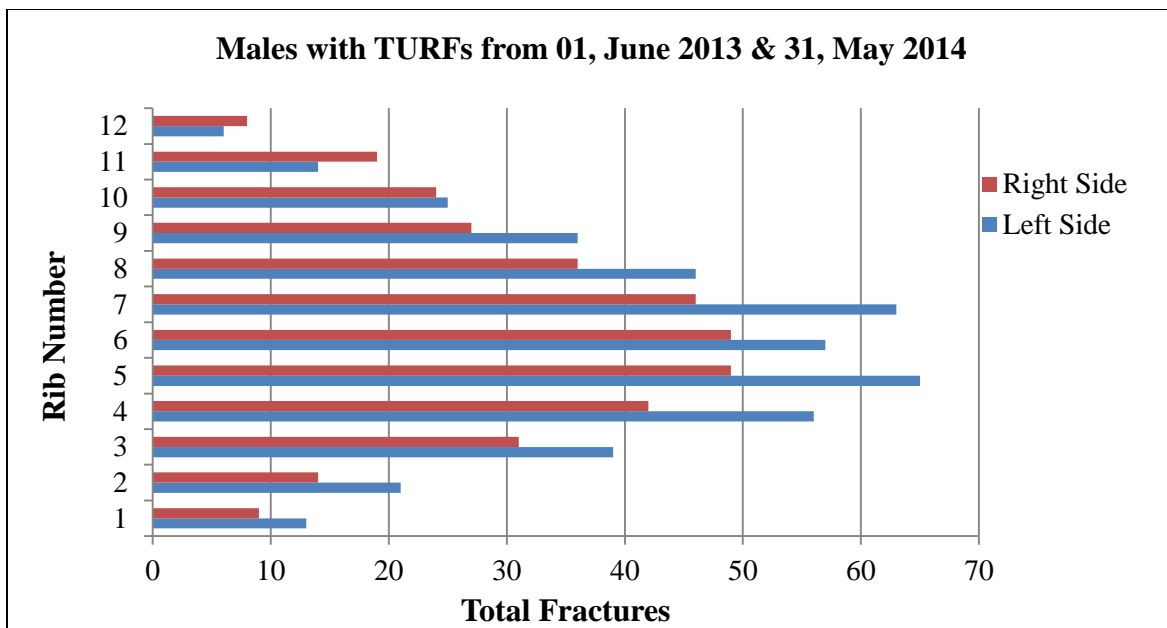


Figure 7: Total number of rib fractures for males

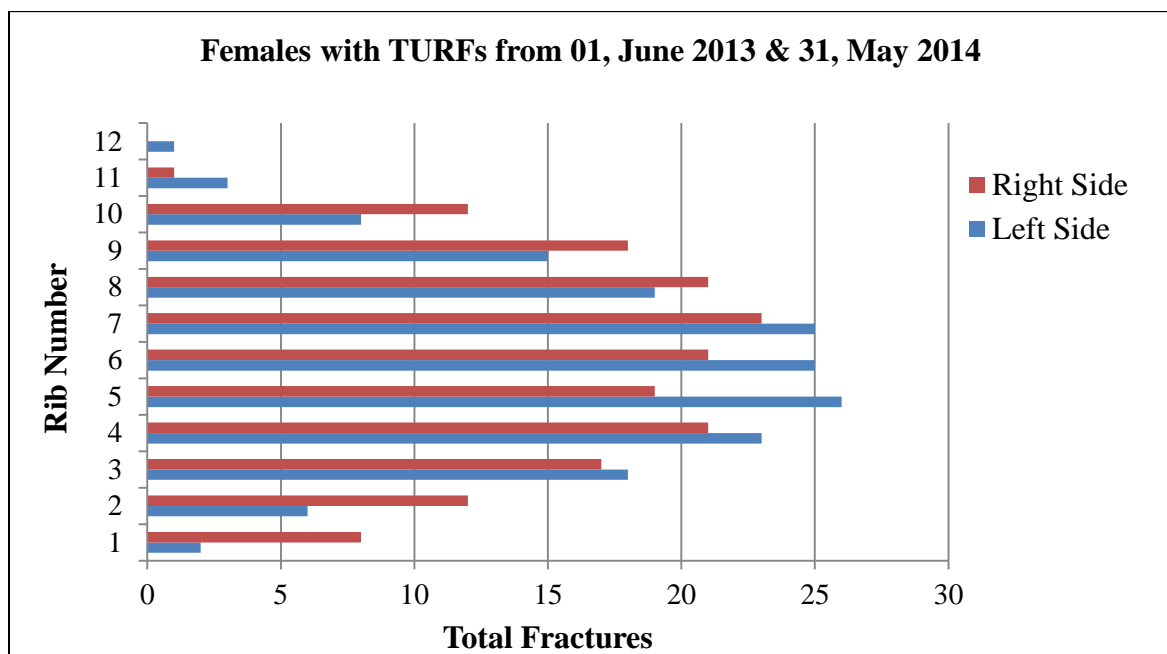


Figure 8: Total number of rib fractures for females

Patients who received opioids alone for pain management had a mean injury severity score (ISS) of  $9.08 \pm 3.9$  for ground level fall (GLF),  $15.36 \pm 8.6$  for motor vehicle crash (MVC),  $15.08 \pm 6.8$  for motorcycle crash (MCC) and  $14.30 \pm 8.9$  for other types of mode of injury (MOI) (Figure 9). Patients who received continuous paracostal block (CPB) for pain management had a mean ISS of  $11.50 \pm 5.0$  for GLF,  $16.50 \pm 3.5$  for MVC,  $14.00 \pm 4.7$  for MCC and  $19.67 \pm 13.0$  for the MOI category of other (Figure 9). The results were further stratified by type of MOI and type of pain management by sex. Females who received opioids alone had a mean ISS of  $9.90 \pm 4.0$  for GLF,  $12.36 \pm 5.4$  for MVC,  $16.33 \pm 15.5$  for MCC and  $17.71 \pm 15.4$  for other types of mode of injury (Figures 10-13). The average ISS of males who received opioids alone was  $8.21 \pm 3.6$  for GLF,  $16.86 \pm 9.5$  for MVC,  $14.91 \pm 5.6$  for MCC and  $13.91 \pm 7.2$  for other types of mode of injury. Females who received CPB had a mean ISS of  $9.90 \pm 0.0$  for GLF and  $24.00 \pm 18.2$  for other types of mode of injury. The average ISS of males who received CPB was  $14.00 \pm 7.1$  for GLF,  $14.00 \pm 4.7$  for MCC and  $15.33 \pm 6.1$  for other types of mode of injury (Figures 10-13).

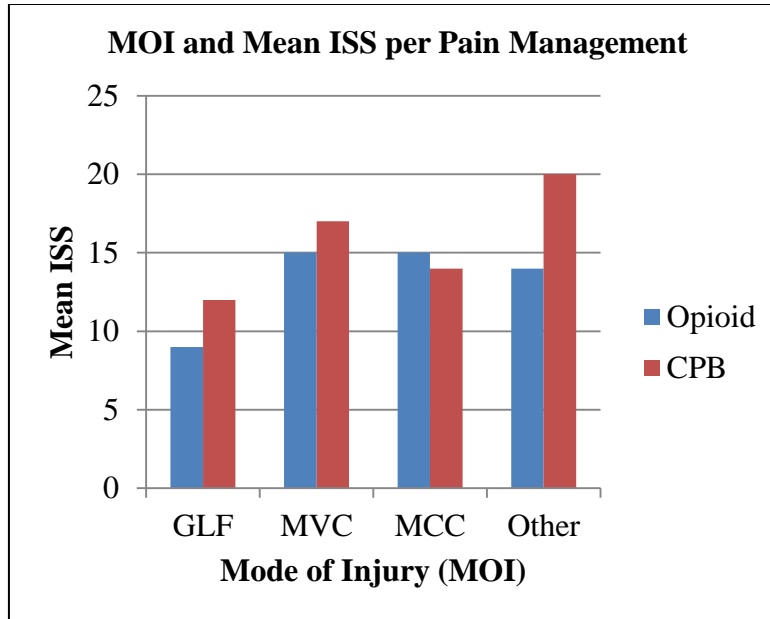


Figure 9: Mean ISS per MOI and pain management

ISS = Injury Severity Score; MOI = Mode of Injury;  
CPB = Continuous Paracostal Block

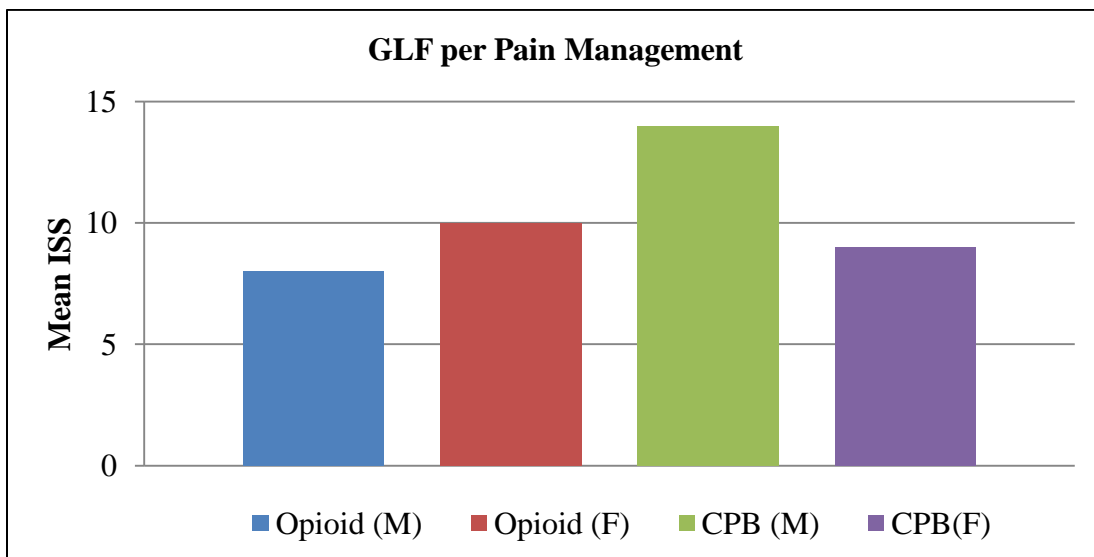


Figure 10: Mean ISS for ground level fall patients per sex

ISS = Injury Severity Score; M = Males; F = Females;  
GLF = Ground Level Fall; CPB = Continuous Paracostal Block

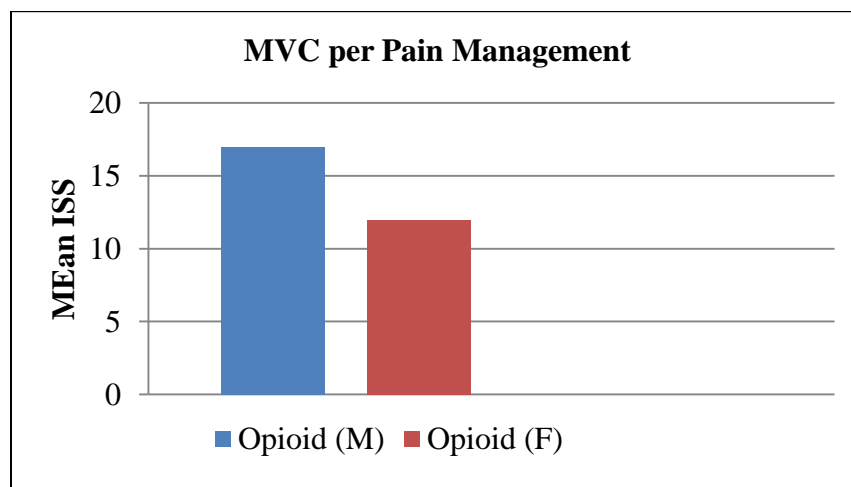


Figure 11: Mean ISS for motor vehicle crash patients per sex

ISS = Injury Severity Score; MVC = Motor Vehicle Crash;  
M = Males; F = Females

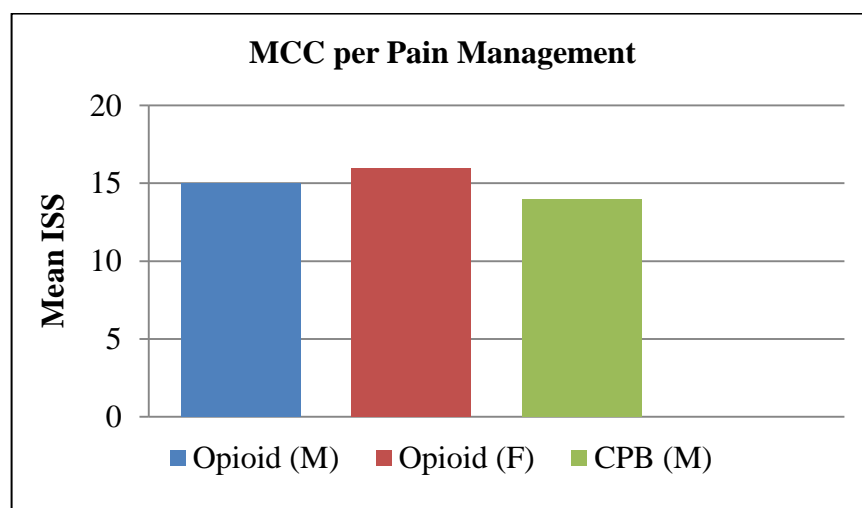


Figure 12: Mean ISS for motorcycle crash patients per sex

ISS = Injury Severity Score; M = Males; F = Females; MCC = Motorcycle Crash;  
CPB = Continuous Paracostal Block



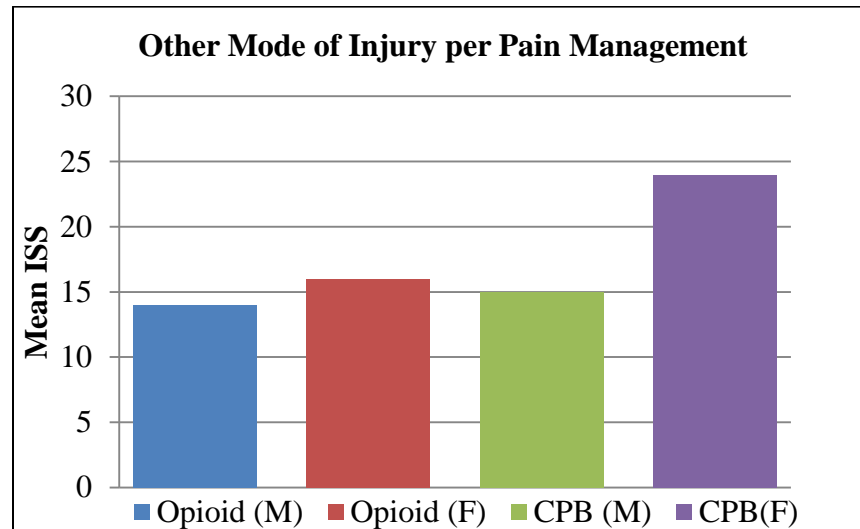


Figure 13: Mean ISS for Other MOI patients per sex

ISS = Injury Severity Score; M = Males; F = Females;  
CPB = Continuous Paracostal Block

Patients who were injured from MVC and received opioids alone had a mean of  $6.86 \pm 3.8$  number of rib fractures and  $7.50 \pm 0.7$  number of rib fractures for patients who received CPB (Figure 14). The GLF patients mean was  $5.42 \pm 2.8$  number of rib fractures for males and  $5.25 \pm 2.8$  number of rib fractures for females who received opioids alone. The GLF patients mean was  $7.50 \pm 6.4$  for males and  $5.00 \pm 1.4$  for females who received CPB. The MVC patients mean was  $7.11 \pm 4.1$  number of rib fractures for males and  $6.36 \pm 3.4$  number of rib fractures for females who received opioids alone. The MCC patients mean was  $6.26 \pm 3.6$  number of rib fractures for males and  $5.33 \pm 1.5$  for females who received opioids alone. The MCC patients mean was  $6.25$

$\pm 3.3$  number of rib fractures for males who received CPB. The other modes of injury of patients had a mean of  $6.03 \pm 3.0$  number of rib fractures for males and  $7.57 \pm 3.8$  for females who received opioids alone. Patients with other modes of injury had a mean of  $3.67 \pm 1.2$  number of rib fractures for males and  $3.33 \pm 0.6$  number of rib fractures for females who received CPB (Figures 15-18).

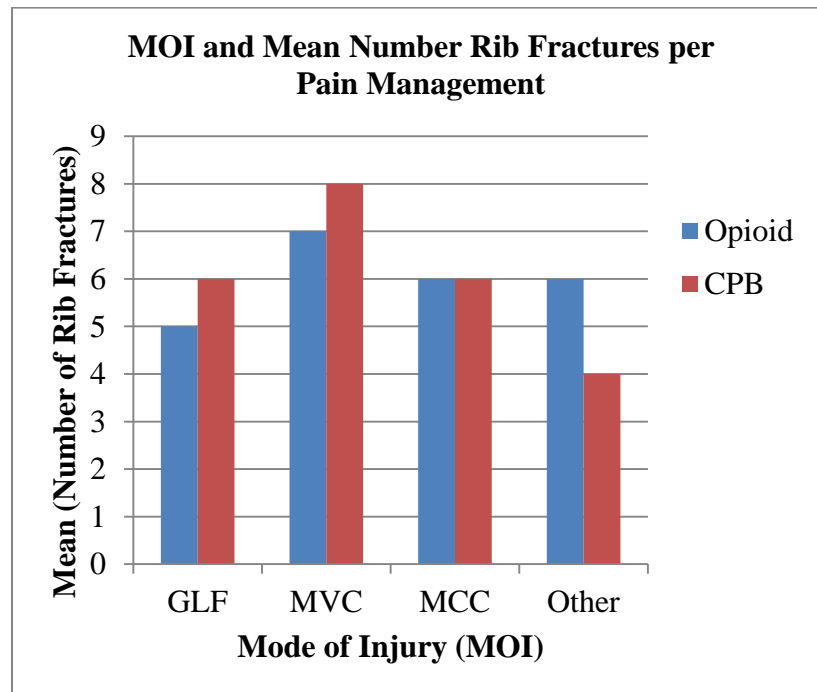


Figure 14: Mean number of rib fractures for each mode of injury per pain management

MOI = Mode of Injury; CPB = Continuous Paracostal Block; GLF = Ground Level Fall;  
MVC = Motor Vehicle Crash; MCC = Motorcycle Crash

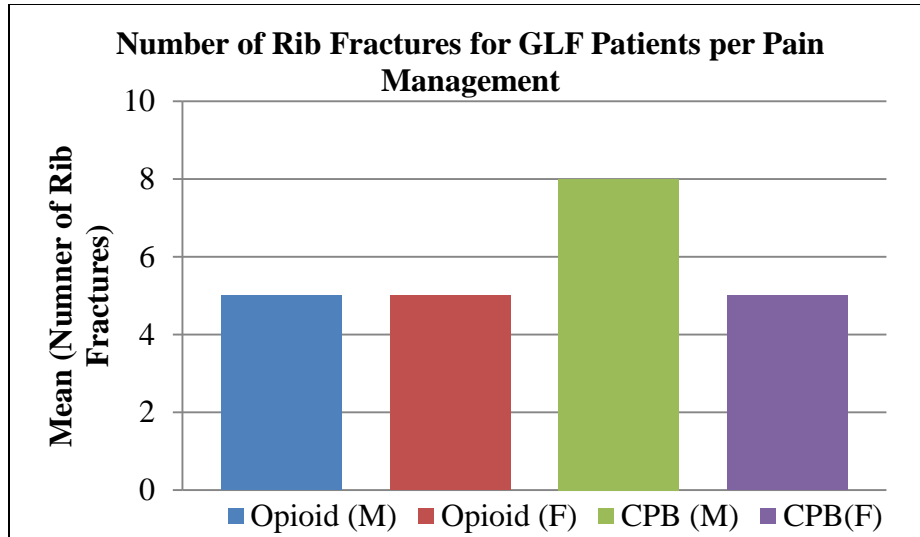


Figure 15: Ground Level Fall patients mean number of rib fractures per sex

M = Males; F = Females; CPB = Continuous Paracostal Block; GLF = Ground Level Fall

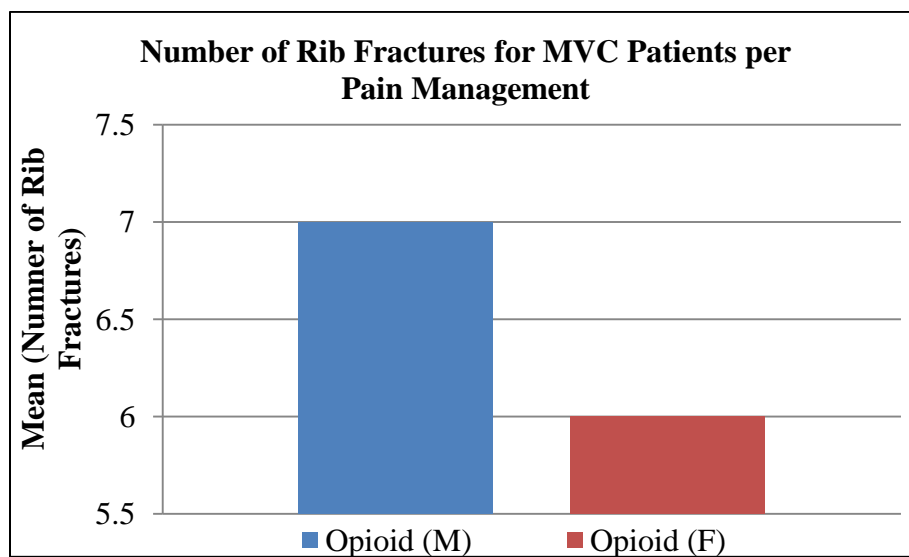


Figure 16: Motor Vehicle Crash patients mean number of rib fractures per sex

M = Males; F = Females; MVC = Motor Vehicle Crash

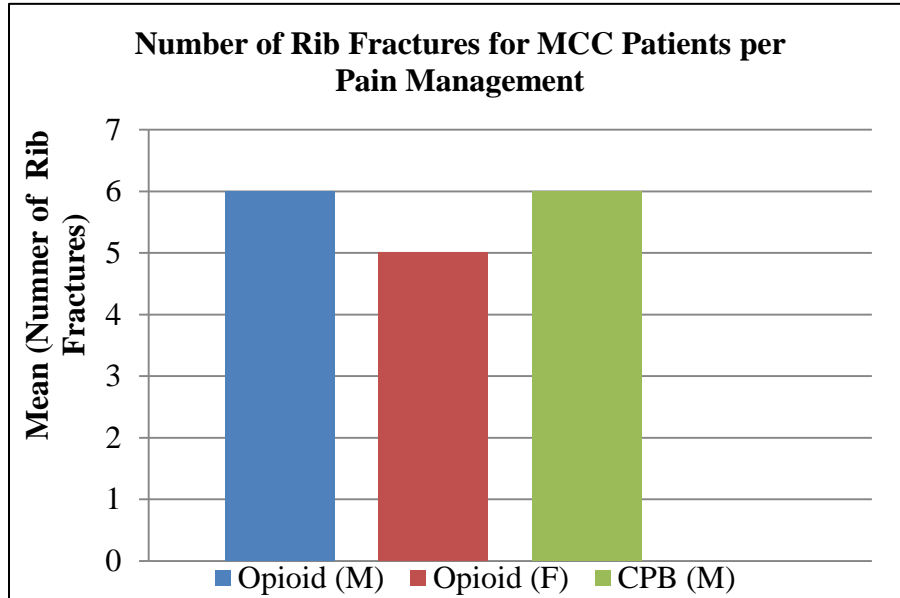


Figure 17: Motorcycle Crash patients mean number of rib fractures per sex

M = Males; F = Females; CPB = Continuous Paracostal Block; MCC = Motorcycle Crash

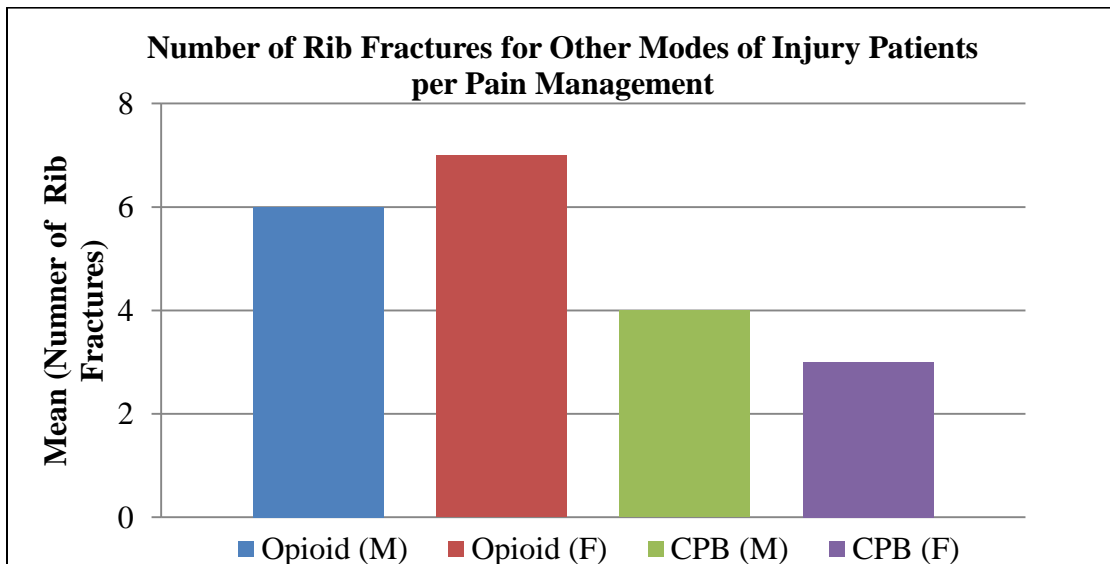


Figure 18: Other MOI patients mean number of rib fractures per sex

M = Males; F = Females; CPB = Continuous Paracostal Block

Patients who received opioids alone had a mean LOS of  $6.30 \pm 6.2$  days in the hospital,  $2.82 \pm 5.0$  days in TICU and  $1.31 \pm 4.1$  days on ventilator (Figure 19). The mean LOS for patients who received CPB was  $7.44 \pm 3.8$  days in the hospital,  $3.56 \pm 4.0$  days in TICU and  $1.56 \pm 3.0$  days on ventilator. Males who received opioids and females who received CPB had the highest mean hospital LOS. Both groups of males who received opioids or CPB had the highest mean for TICU LOS and ventilator days (Figures 20-22).

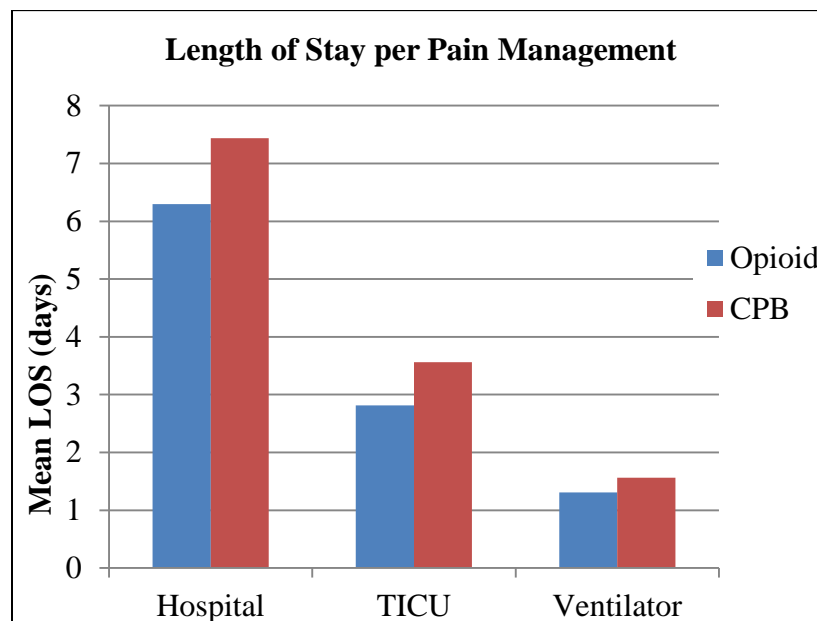


Figure 19: Mean hospital, TICU, and ventilator days per pain management

LOS = Length of Stay; CPB = Continuous Paracostal Block;  
TICU = Trauma Intensive Care Unit

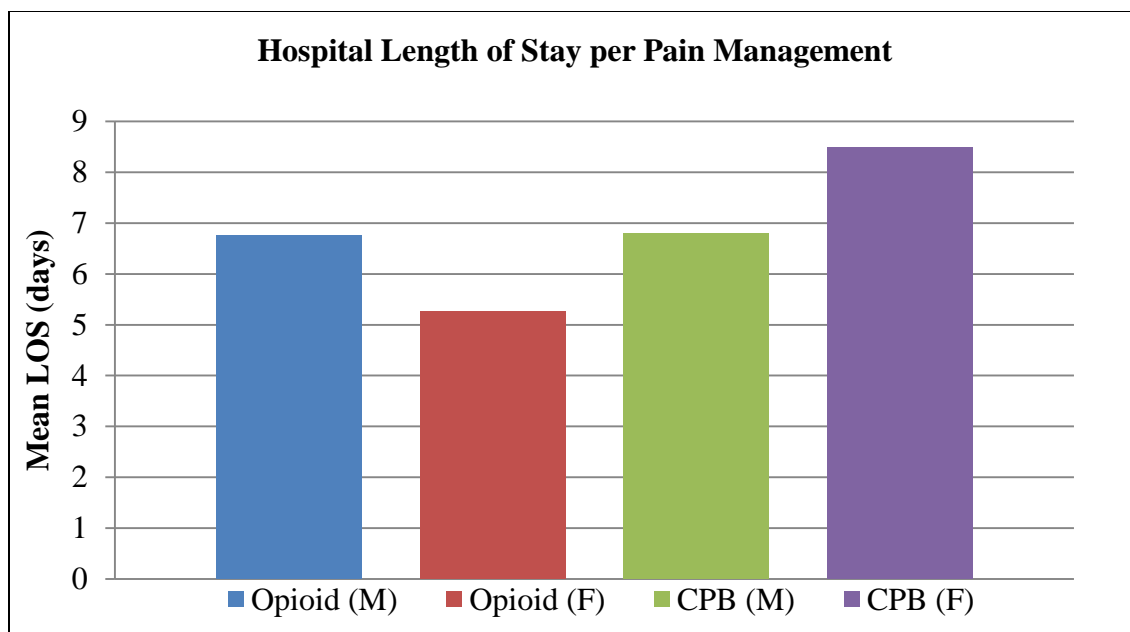


Figure 20: Mean hospital length of stay per pain management and sex

M = Males; F = Females; CPB = Continuous Paracostal Block; LOS = Length of Stay

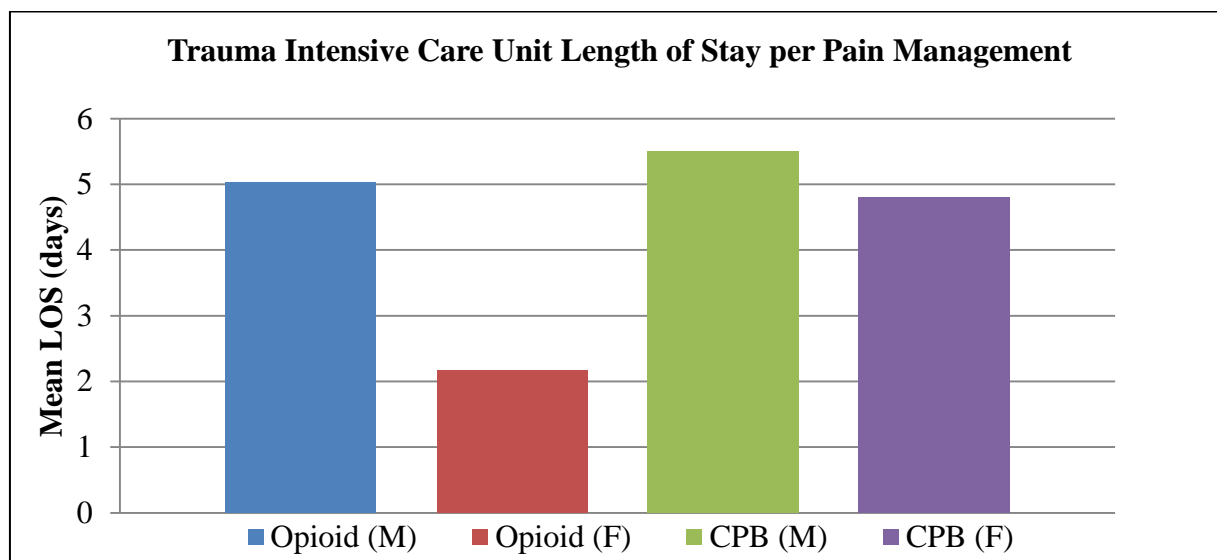


Figure 21: Mean TICU length of stay per pain management and sex

M = Males; F = Females; CPB = Continuous Paracostal Block; LOS = Length of Stay

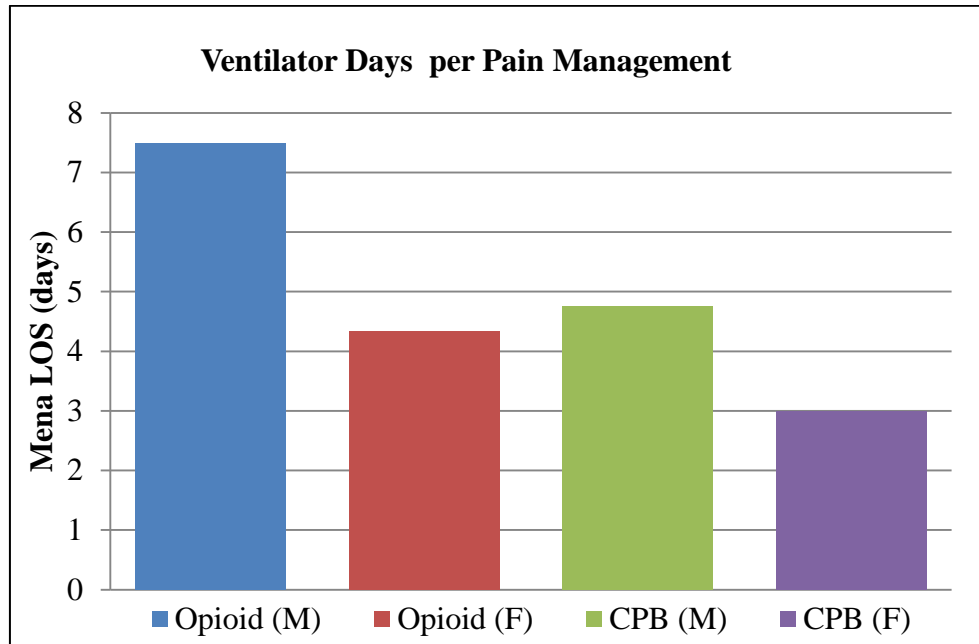


Figure 22: Mean number of days on ventilator per pain management and sex

M = Males; F = Females; CPB = Continuous Paracostal Block;  
LOS = Length of Stay

The age group with the highest mean for hospital LOS was 60-69 years of age, 30-39 years of age for TICU LOS, and 30-39 years of age for ventilator days (Figure 23). The highest mean for hospital LOS for patients who received opioids was in males 30-39 years of age and females 60-69 years of age (Figures 24, 25). Males 80-89 years of age and females 60-69 years of age had the highest TICU LOS mean in the group who received opioids (Figure 26). The highest mean for ventilator days of patients who received opioids was in males 50-59 years of age and females 60-69 years of age (Figure 27). The highest mean for hospital LOS of patients

who received CPB was in males 60-69 years of age and females 90-99 years of age (Figures 28, 29). The highest mean for TICU LOS of patients who received CPB was males 70-79 years of age and females 90-99 years of age (Figure 30). The highest mean for ventilator day of patients who received CPB was males 70-79 years of age (Figure 31).

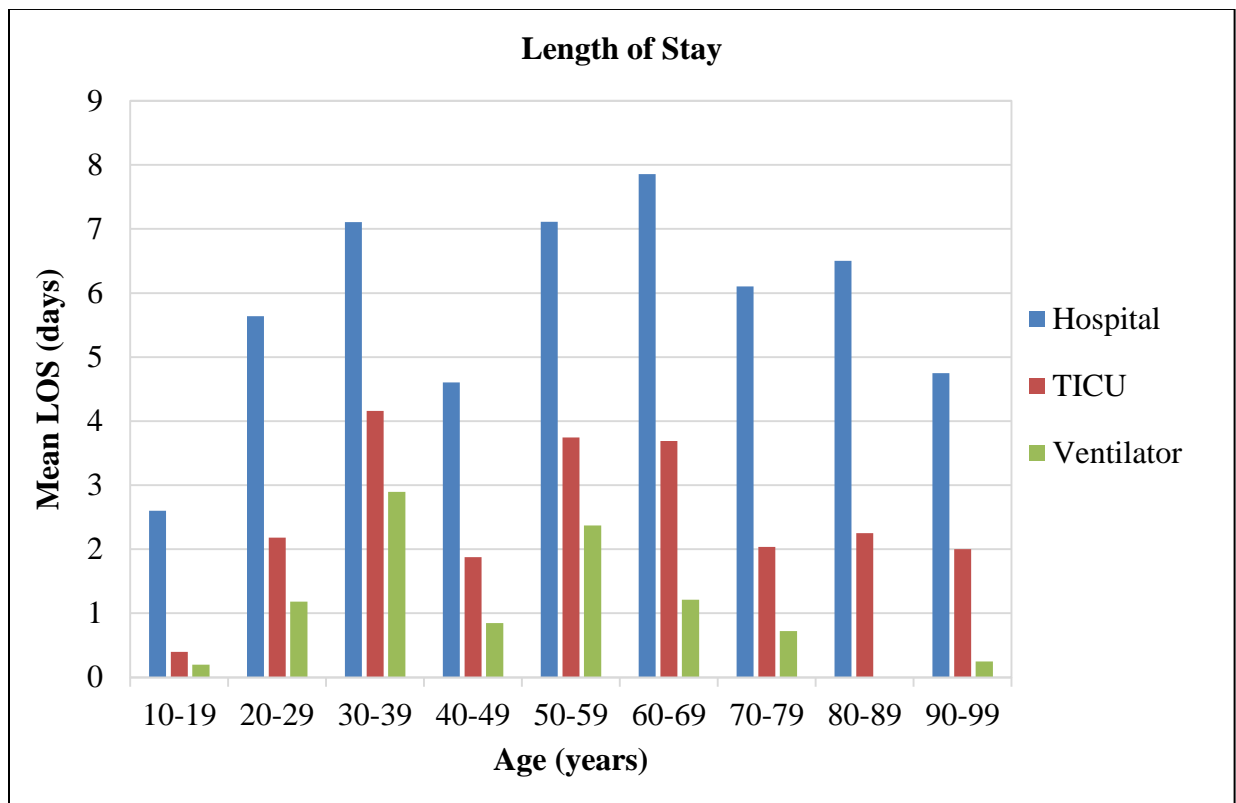


Figure 23: Mean hospital, TICU, and ventilator days per age range

LOS = Length of Stay; TICU = Trauma Intensive Care Unit



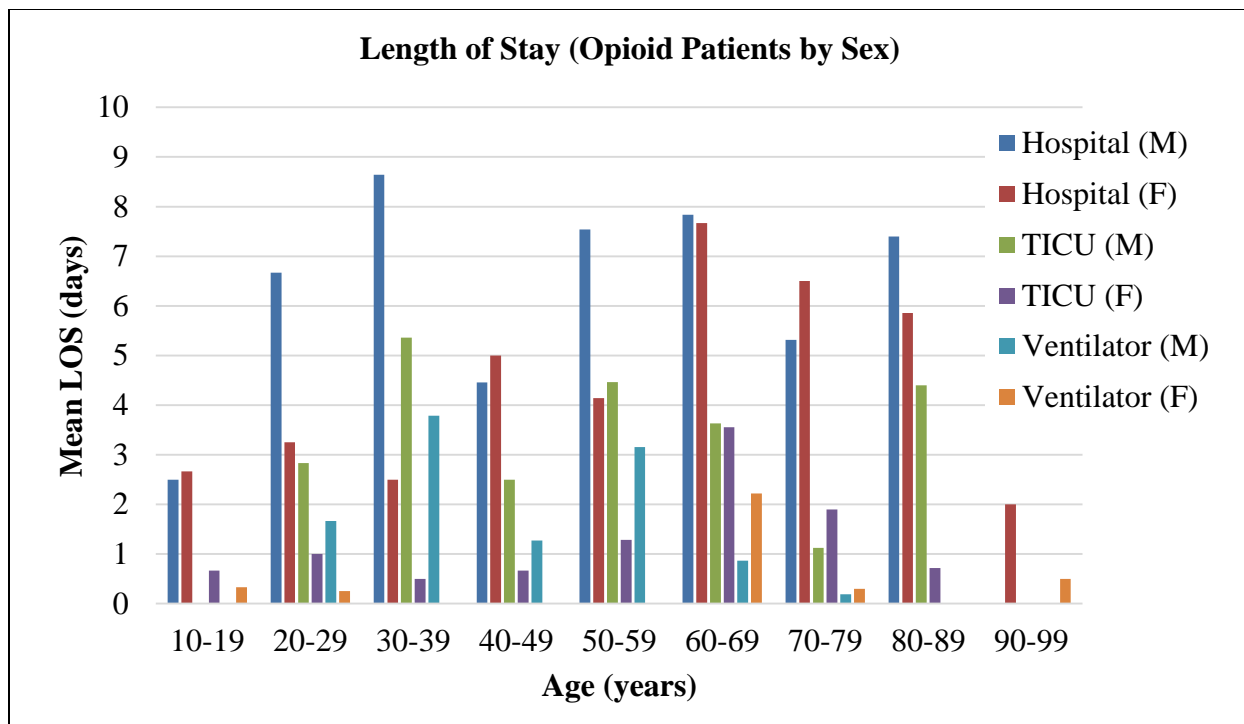


Figure 24: Opioid patients mean length of stay and on ventilator per age range and sex

M = Males; F = Females; TICU = Trauma Intensive Care Unit;  
LOS = Length of Stay

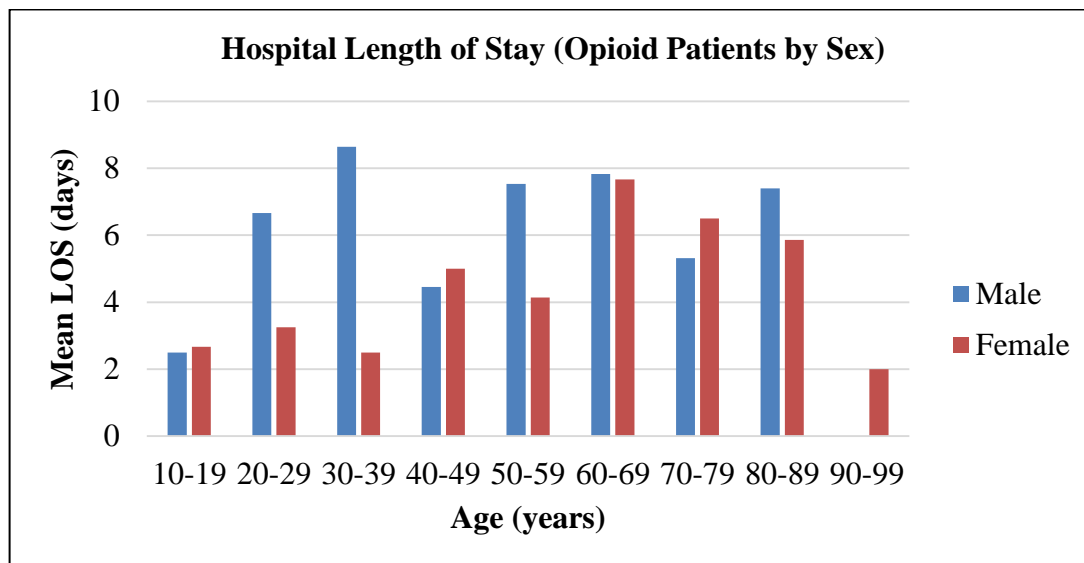


Figure 25: Mean hospital length of stay by sex

LOS = Length of Stay

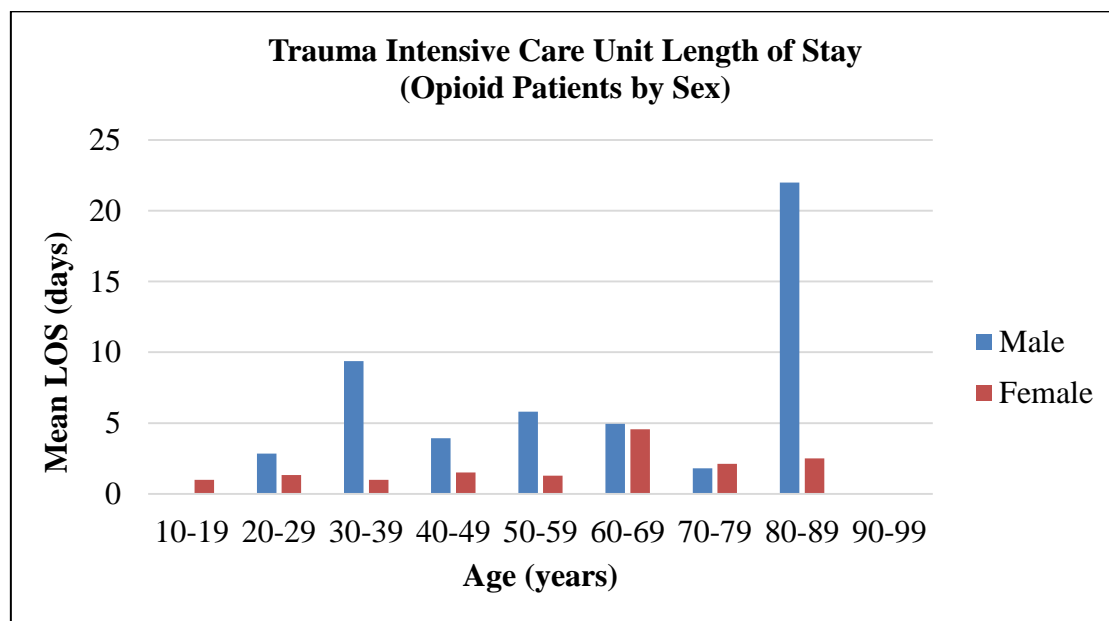


Figure 26: Mean TICU length of stay by sex

LOS = Length of Stay; TICU = Trauma Intensive Care Unit

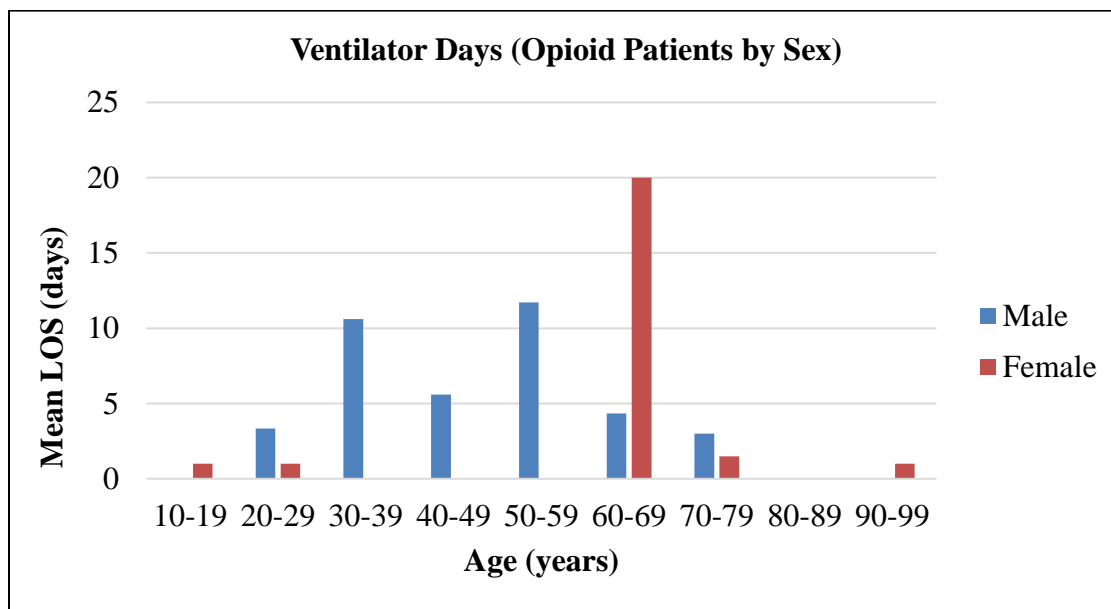


Figure 27: Mean days on ventilator by sex

LOS = Length of Stay

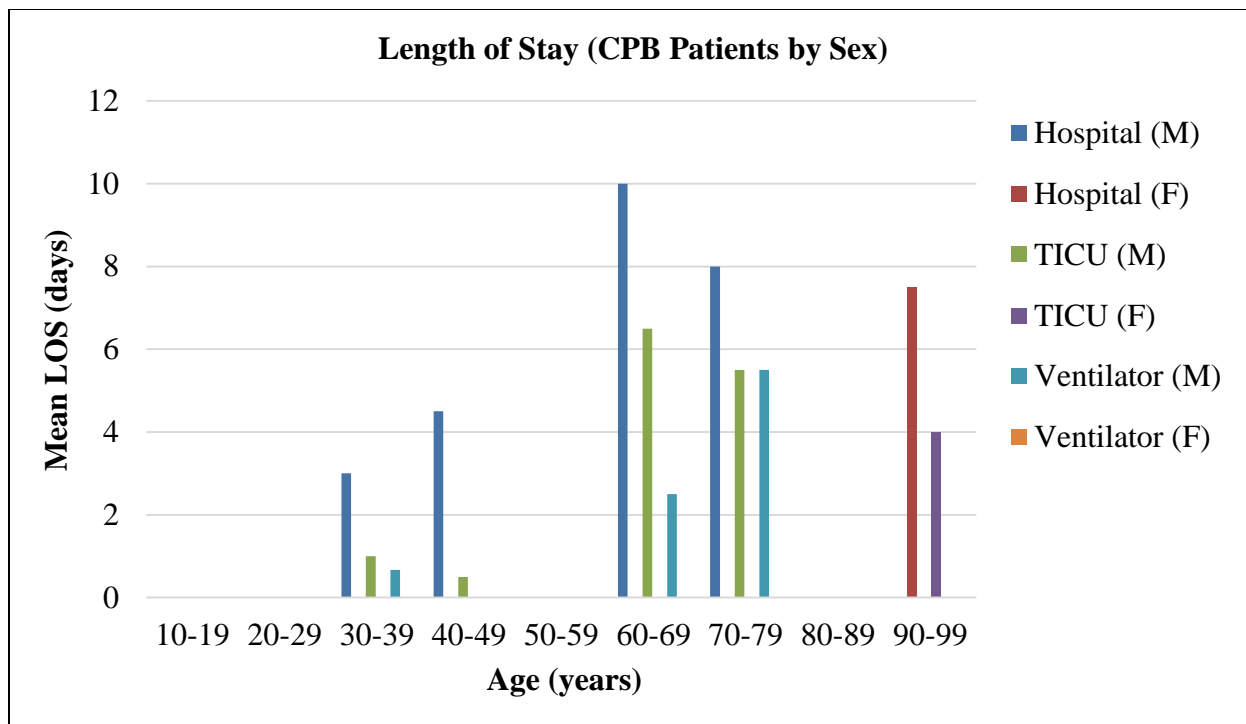


Figure 28: CPB patients mean length of stay and on ventilator per age range and sex

M = Males; F = Females; CPB = Continuous Paracostal Block;  
TICU = Trauma Intensive Care Unit; LOS = Length of Stay

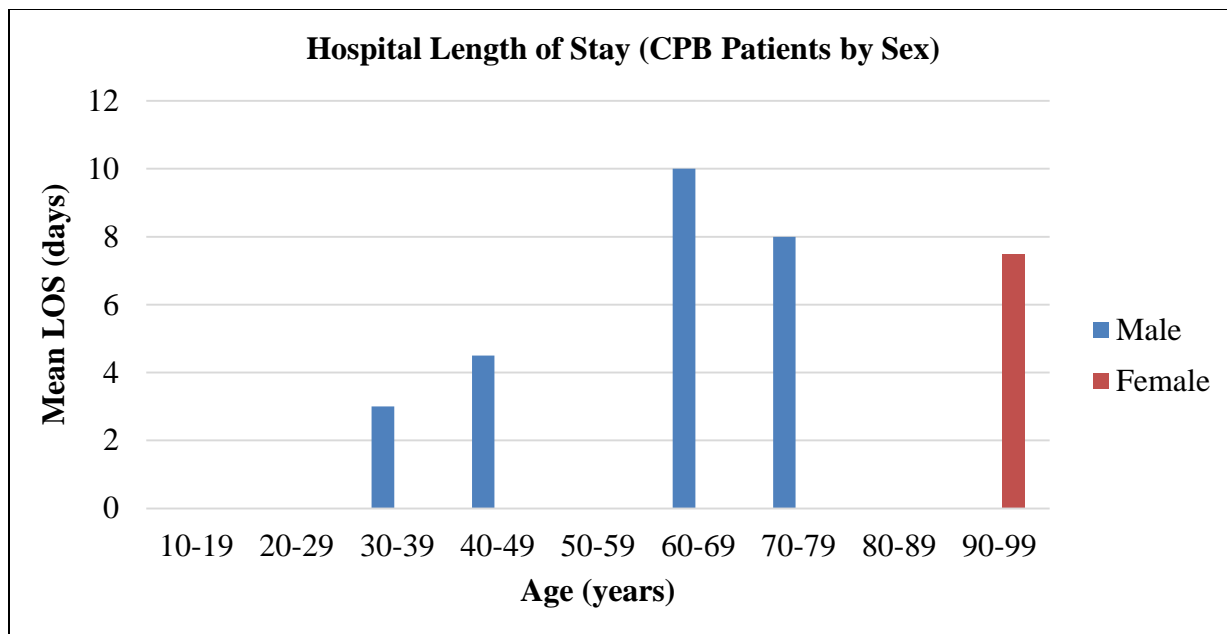


Figure 29: Mean hospital LOS by sex

LOS = Length of Stay; CPB – Continuous Paracostal Block

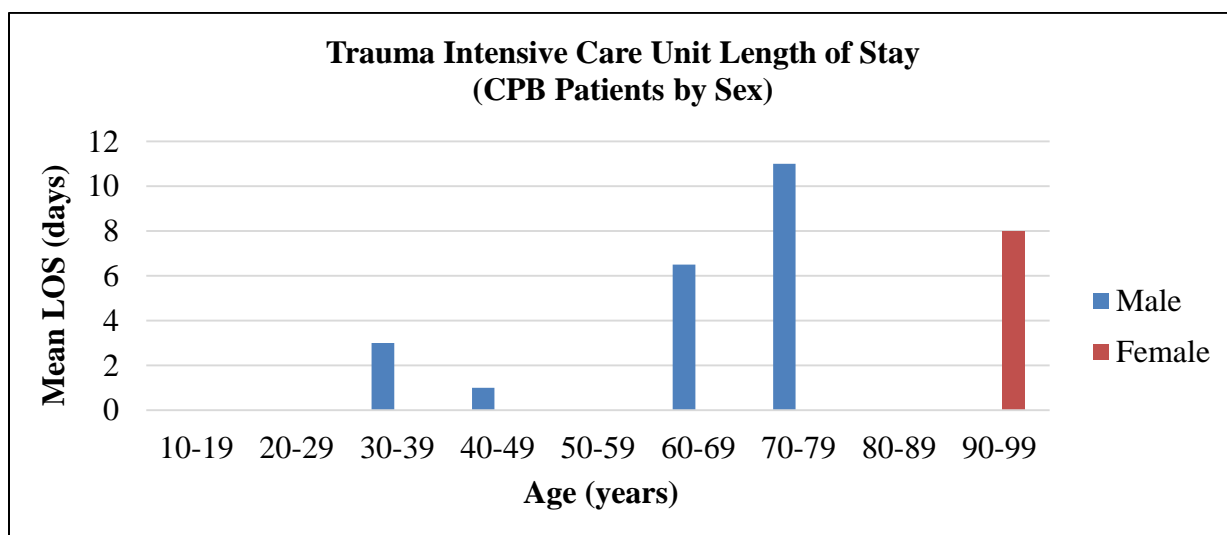


Figure 30: Mean TICU LOS by sex

LOS = Length of Stay; CPB – Continuous Paracostal Block; TICU – Trauma Intensive Care Unit

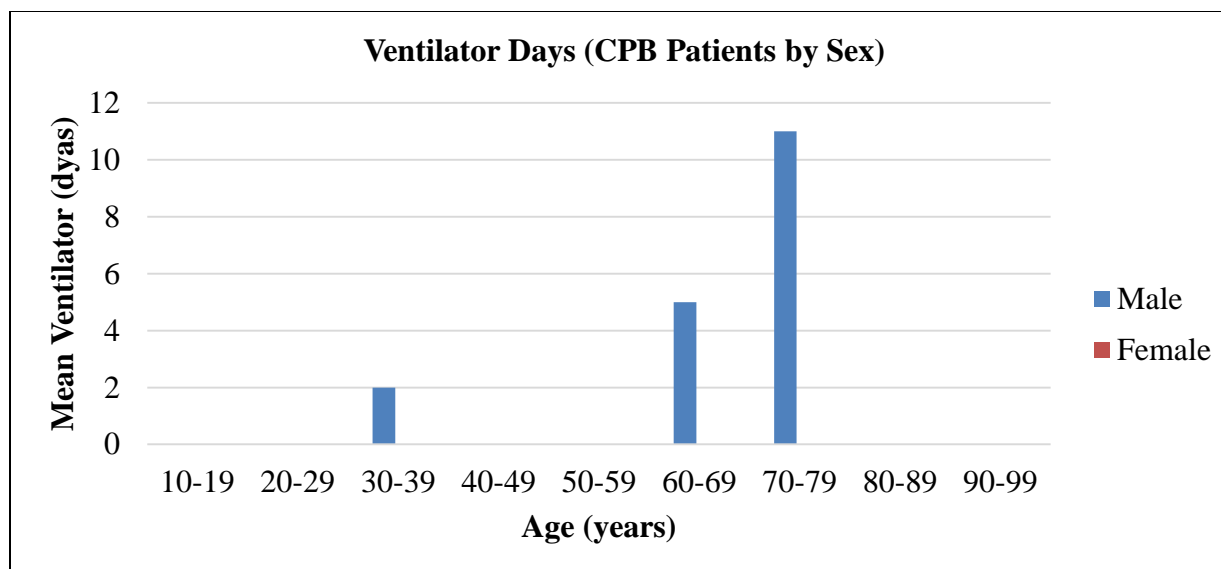


Figure 31: Mean days on ventilator by sex

LOS = Length of Stay; CPB – Continuous Paracostal Block

### *Statistical Analysis*

Chi-square tests did not reveal any significant differences in the variables on interest between the different modes of treatment. The test statistics for each variable tested are listed below:

- Age (under 59 years, 59 years and over):  $\chi^2 = 0.125$ , df = 1, P-value = 0.724
- Sex (Male, Female):  $\chi^2 = 0.339$ , df = 1, P-value = 0.560
- Total rib fractures (< 6, 7-10, >10):  $\chi^2 = 0.783$ , df = 2, P-value = 0.676
- ISS (over 14, under 14):  $\chi^2 = 0.902$ , df = 1, P-value = 0.342

- MOI (Ground Level Fall, Motor Vehicle Crash, Motorcycle Crash, Other):  $\chi^2 = 4.559$ ,  $df = 3$ , P-value = 0.207
- Hospital LOS in days (1-3, >3):  $\chi^2 = 3.437$ ,  $df = 1$ , P-value = 0.064
- TICU LOS in days (0, 1-6, >6):  $\chi^2 = 1.712$ ,  $df = 2$ , P-value = 0.425
- On Ventilator (Yes, No):  $\chi^2 = 3.086$ ,  $df = 1$ , P-value = 0.079

ISS is not different for patients in the two treatment modes ( $U = 1090.50$ ,  $Z = -1.442$ , P-value = 0.149).

The logistic regression model was not significant (parameter estimator = -2.386, standard error = 0.261, Wald = 83.450,  $df = 1$ , P-value 0.092). The predictors were also not significant ( $df = 1$ , P-value = 0.251).

The statistical results for Pearson Correlation coefficients showed a linear relationship between the total number of rib fractures ( $p < 0.05$ ) and with hospital LOS, TICU LOS, and ventilator days (Table 1). Ventilator days significantly correlated with TICU LOS (Table 1).

Table 1: Correlation coefficient test between age, total rib fractures, hospital LOS, TICU LOS, and ventilator days						
		Age	Total Rib Fractures	Hospital LOS	TICU LOS	Ventilator Days
Age	Pearson Correlation/ Fishers Exact test	1	0.017	0.063	-0.005	-0.104
	Sig. (2-tailed)		0.815	0.390	0.944	0.152
	n	190	190	190	190	190
Total Rib Fractures	Pearson Correlation/ Fishers Exact test	0.17	1	0.273**	0.178*	0.231**
	Sig. (2-tailed)	0.815		0.000	0.014	0.001
	n	190	190	190	190	190
Hospital LOS	Pearson Correlation/ Fishers Exact test	0.063	0.273**	1	0.860**	0.685**
	Sig. (2-tailed)	0.390	0.000		0.00	0.00
	n	190	190	190	190	190
TICU LOS	Pearson Correlation/ Fishers Exact test	-0.005	0.178*	0.860**	1	0.844**
	Sig. (2-tailed)	0.944	0.014	0.000		0.000
	n	190	190	190	190	190
Ventilator Days	Pearson Correlation/ Fishers Exact test	-0.104	0.231**	0.685**	0.844**	1
	Sig. (2-tailed)	0.152	0.001	0.000	0.000	
	n	190	190	190	190	190

\* Significant at  $\alpha = 0.05$ ; \*\* Significant at  $\alpha = 0.01$ ;

n = total number of patients; LOS = Length of Stay; TICU = Trauma Intensive Care Unit;

Sig. = level of significance



## **Discussion, Summary and Conclusions**

The aim of this practicum project was to describe the rationale and use of the various types of pain management modalities at THFW in patients with TURFs. There is a wealth of literature on the use of EA or opioids alone but, there is a lack of literature on the use of CPB modality of pain management for patients with TURFs. There are no published randomized control trials comparing the three pain management modalities for TURFs.

EA was only offered to one patient with TURFs. One physician irregularly used CPB for pain management in patients with TURFs. There are multiple variables for a physician to consider when making the decision in selecting the most appropriate type of pain management modality and it is individualized for each patient.

The results of this study indicate that there was significance between the number of rib fractures and length of stay in the hospital, the TICU and on the ventilator. Also, ventilator days significantly correlated with days in the TICU. These findings should be interpreted with caution since the types of pain management modalities were not randomized per patient. While it was not feasible to determine a rationale for the selection of pain management modality based on the results of this study, results suggest that further inquiry would be of interest, particularly with regard to how treatment design varies by number of fractures sustained.

## **Limitations**

This retrospective chart review had several limitations and biases. First, the treatment categories had unequal number of subjects. Second, the treatment already had been completed; therefore subjects were not randomized to a category of pain management modality. The design of the electronic medical record at THFW made it difficult to collect data. Fracture identification with CT or X-ray is a subjective process. Not all fractures were accounted for such as comminuted fractures and there can be a discrepancy in acute and chronic fractures.

## **Future Directions**

The few significant variables of the pilot study warrant confirmation by a prospective randomized control trial. Non-significant variables from the pilot study need to be readdressed in a prospective, randomized control trial. The results of this study will be utilized for the future development of a prospective randomized control trial to determine best practice of pain management in patients with TURFs.

## CHAPTER III

### INTERNSHIP EXPERIENCE

#### **Description of Internship Site and Experience**

Texas Health Resources is one of the largest nonprofit health systems in the United States (21). THFW in Fort Worth, Texas opened in 1930 striving to provide advance clinical services for Tarrant County and surrounding communities (21). The full-service medical facility with several specialized medical services includes oncology, trauma, cardiology, and women's services (21). Currently this facility has over 800 physicians and 726 beds (21). THFW is accredited by the American College of Surgeons as a Level II Trauma Center. On January 08, 2014, the Marion Emergency Care Center opened with 100 beds. The TICU with 20 beds provides care for acutely ill patients with traumatic injuries (21). It was awarded the Bronze Beacon Award for Excellence by the American Association of Critical-Care Nurses.

Current ongoing trauma research studies at this site include:

1. Near-Infrared Brain Imaging in Traumatic Brain Injury (NIRS)
2. Traumatic Brain Injury (TBI)-Intrepid
3. Platelets and Plavix
4. Hypo Resuscitation
5. Minimal Head Injury
6. Geriatric Functional Trauma Status (GFTS)
7. Vitamin D Levels in Trauma Patients 65 Years of Age and Older.

During the six month internship in Trauma Administration Department at Texas Health Forth Worth, I was able to perform the following duties:

- Interact with site personal: Trauma Registrars, Trauma Clinician's, Trauma Intensive Care Unit Nurse's, Principle Investigator, Emergency Medical Services (EMS), Other Physicians, Surgeons, Nurses and Allied Health Personnel.
- THFW Training certification included: Research Coordinator Review; Diversity and Inclusion 101; Information Security Awareness Training; Team STEPPS
- IRB Meetings: I was able to attend a Face to Face meeting that occurs twice a year between board members and principle investigators at Texas Health in Arlington, Texas.
- Meetings: Several meetings attended were at the University of Texas Southwestern and principle investigator, University of Texas Arlington and principle investigator, Research Outcomes Consortium (ROC), Budget Department, Clinical Research Management Internship with Committee Members, Restructuring and Formatting of electronic IRB website with Texas Health IRB, Office Rounds with Physicians and Trauma Administration Department, Multiple Disciplinary Rounds in TICU, and Staff Meetings.
- Maintenance of Documents: I was taught how to properly organize and, up-load documents to different types of electronic data capture per study type.
- Informed Consent: The Vitamin D study was my first observation on how to, screen for potential candidate(s), approach subject, enroll subject, complete informed consent process with subject or legally authorized representative, data management and, file all documents. After being added on as study staff, I was able to carry out all tasks for the

Vitamin D study. In addition, I had learned how to draft an informed consent and submit to IRB for review and approval.

- Study Design and e-IRB submission: I was able to create a new study and submit via the electronic IRB system for approval. There were several requirements for this research study such as, case report form, protocol submission, conflict of interest, answering all questions asked during the submission process. This research study had also required the approval from UNTHSC as well as other documentation.
- Amendment: During my internship I was shown how to make amendments on different studies and how to process them through the electronic IRB.
- Literature Review: I was also able to help with literature review for, manuscript submission, Journal Club and, trauma physicians' requests.
- Manuscript Submission: I was able to assist with a literature review, editing and formatting a manuscript which was submitted to the Wilderness & Environment Medicine. It was accepted for publication in early spring.

## **Journal Summary**

The clinical research internship was completed under the supervision of Ms. Cathy McNeill, MS, RN, CCRC, CCRP, Trauma Research Coordinator at THFW. My responsibilities and tasks involved during the six month internship on day to day were screening of daily trauma patients admitted in the TICU for potential enrollment following studies, Vitamin D, TBI-Intrepid and, TBI. The majority of the tasks and responsibilities I was involved with were that of a clinical research coordinator. I assisted and took part in several areas such as, data collection,

scanning and making copies, informed consent, amendments, continuing review submission, organize binders for site monitor, up-load data through electronic data capture, CRF, coordinate dates for site visits and, submit adverse event.

## APPENDICES:

### APPENDIX A: SUPPLEMENTAL TABLES

Table 1A: Total patients with TURFs per sex	
	n
Males	131
Females	59
Total Count	190

\*n = number of patients; TURFs -Traumatic Multiple Rib Fractures

Table 2A: Age ranges of total patients with $\geq 3$ rib fractures per sex			
Age (years)	Female (n)	Male (n)	Total Count (n)
10-19	3	2	5
20-29	5	6	11
30-39	2	17	19
40-49	9	24	33
50-59	8	27	36
60-69	10	32	42
70-79	11	18	29
80-89	7	5	12
90-99	4	ND	4
Total Count (n)	59	131	190

\*n = number of patients; ND = no available data

Table 3A: Patients given opioids or CPB with $\geq 3$ rib fractures per sex				
	Opioids alone		CPB	
Age (years)	Male (n)	Female (n)	Male (n)	Female (n)
10-19	2	3	ND	ND
20-29	6	4	ND	1
30-39	14	2	3	ND
40-49	22	9	2	ND
50-59	26	7	1	1
60-69	30	9	2	1
70-79	16	10	2	1
80-89	5	7	ND	ND
90-99	ND	2	ND	2

\*n = number of patients; ND = no available data;

CPB = Continuous Paracostal Block

Table 4A: Mean number of rib fractures per sex						
	Opioids alone		CPB		All Subjects	
	n	Mean	n	Mean	n	Mean
Males	121	$6.37 \pm 3.5$	10	$5.90 \pm 3.3$	190	$6.18 \pm 3.4$
Females	53	$6.00 \pm 3.2$	6	$4.50 \pm 1.6$		
Group	174	$6.26 \pm 3.4$	16	$5.38 \pm 2.8$		

\*n = number of patients; CPB = Continuous Paracostal Block



Table 5A: Mean bilateral or unilateral rib fractures per sex								
	Opioids alone				CPB			
	n	Mean Bilateral	n	Mean Unilateral	n	Mean Bilateral	n	Mean Unilateral
Males	20	9.75 ± 4.5	101	5.70 ± 2.9	ND	ND	10	5.90 ± 3.3
Females	12	9.33 ± 3.4	41	5.02 ± 2.3	1	*	6	4.00 ± 1.2
Group	32	9.59 ± 4.1	142	5.51 ± 2.7	1	*	6	5.27 ± 2.9

\*(Unable to calculate mean with n = 1); n = number of patients;  
ND = no available data; CPB = Continuous Paracostal Block

Table 6A: Rib numbers with total number of rib fractures per side													
	Rib Number												
Side	1	2	3	4	5	6	7	8	9	10	11	12	Total (FX)
Left (FX)	15	27	57	79	91	82	88	65	51	33	17	7	612
Right (FX)	17	26	48	63	68	70	69	57	45	36	20	8	527
Total (FX)	32	53	105	142	159	152	157	122	96	69	37	15	1139

FX = Rib Fractures

Table 7A: Total number of rib fractures per sex														
		Rib Number												
Sex	Side	1	2	3	4	5	6	7	8	9	10	11	12	Total (FX)
Male	Left	13	21	39	56	65	57	63	46	36	25	14	6	441
	Right	9	14	31	42	49	49	46	36	27	24	19	8	354
Female	Left	2	6	18	23	26	25	25	19	15	8	3	1	171
	Right	8	12	17	21	19	21	23	21	18	12	1	**	173
Male Total (FX)		22	35	70	98	114	106	109	82	63	49	33	14	795
Female Total (FX)		10	18	35	44	45	46	48	40	33	20	4	1	344
Grand Total (FX)													1139	

\*\* (True Zero); FX = Rib Fractures

Table 8A: Mean ISS per MOI and pain management								
	n	GLF	n	MVC	n	MCC	n	Other
Opioids alone	39	9.08 ± 3.9	66	15.36 ± 8.6	26	15.08 ± 6.8	43	14.30 ± 8.9
CPB	4	11.50 ± 5.0	2	16.50 ± 3.5	4	14.00 ± 4.7	6	19.67 ± 13.0

n = number of patients; CPB = Continuous Paracostal Block; MOI = Mode of Injury;  
ISS = Injury Severity Score; GLF = Ground Level Fall; MVC = Motor Vehicle Crash;  
MCC = Motorcycle Crash

Table 9A: Mean ISS per MOI, pain management and sex									
	Sex	n	GLF	n	MVC	n	MCC	n	Other
Opioids alone	M	19	8.21 ± 3.6	44	16.86 ± 9.5	23	14.91 ± 5.6	35	13.91 ± 7.2
	F	20	9.90 ± 4.0	22	12.36 ± 5.4	3	16.33 ± 15.5	8	17.71 ± 15.4
CPB	M	2	14.00 ± 7.1	1	*	4	14.00 ± 4.7	3	15.33 ± 6.1
	F	2	9.00 ± 0.0	1	*	ND	ND	3	24.00 ± 18.2

\*(Unable to calculate mean with an n = 1); n = number of patients; M = males; F = Females;  
CPB = Continuous Paracostal Block; MOI = Mode of Injury; ISS = Injury Severity Score;  
GLF = Ground Level Fall; MVC = Motor Vehicle Crash; MCC = Motorcycle Crash

Table 10A: Mean number of rib fractures per MOI and pain management								
	n	GLF	n	MVC	n	MCC	n	Other
Opioids alone	39	5.33 ± 2.8	66	6.86 ± 3.8	26	6.15 ± 3.4	43	6.23 ± 3.1
CPB	4	6.25 ± 4.0	2	7.50 ± 0.7	4	6.25 ± 3.3	6	3.50 ± 0.8

n = number of patients; CPB = Continuous Paracostal Block; MOI = Mode of Injury;  
GLF = Ground Level Fall; MVC = Motor Vehicle Crash; MCC = Motorcycle Crash

Table 11A: Mean number of rib fractures per MOI, pain management and sex									
	Sex	n	GLF	n	MVC	n	MCC	n	Other
Opioids alone	M	19	5.42 ± 2.8	44	7.11 ± 4.1	23	6.26 ± 3.6	35	6.03 ± 3.0
	F	20	5.25 ± 2.8	22	6.36 ± 3.4	3	5.33 ± 1.5	8	7.57 ± 3.8
CPB	M	2	7.50 ± 6.4	1	*	4	6.25 ± 3.3	3	3.67 ± 1.2
	F	2	5.00 ± 1.4	1	*	ND	ND	3	3.33 ± 0.6

\*(Unable to calculate mean with an n = 1); n = number of patients; M = males; F = Females; CPB = Continuous Paracostal Block; MOI = Mode of Injury; GLF = Ground Level Fall; MVC = Motor Vehicle Crash; MCC = Motorcycle Crash

Table 12A : Mean LOS and ventilator days per pain management				
		Mean (days)		
	n	Hospital LOS	TICU LOS	On Ventilator
Opioids alone	174	6.30 ± 6.2	2.82 ± 5.0	1.31 ± 4.1
CPB	16	7.44 ± 3.8	3.56 ± 4.0	1.56 ± 3.0

n = number of patients; LOS = Length of Stay; TICU = Trauma Intensive Care Unit; CPB = Continuous Paracostal Block

Table 13A: Mean LOS and ventilator days per pain management and sex					
			Mean (days)		
		n	Hospital LOS	TICU LOS	On Ventilator
Opioids alone	Male	121	6.75 ± 6.6	3.40 ± 5.6	1.67 ± 4.5
	Female	53	5.26 ± 5.1	1.47 ± 2.9	0.49 ± 2.8
CPB	Male	10	6.80 ± 4.3	3.30 ± 3.9	1.90 ± 3.6
	Female	6	8.50 ± 2.9	4.00 ± 4.5	1.00 ± 1.7

n = number of patients; LOS = Length of Stay;

TICU = Trauma Intensive Care Unit; CPB = Continuous Paracostal Block

Table 14A: Mean LOS and ventilator days per age range				
		Mean (days)		
Age (years)	n	Hospital LOS	TICU LOS	On Ventilator
10-19	5	2.60 ± 1.5	0.40 ± 0.5	0.20 ± 0.4
20-29	11	5.64 ± 4.6	2.18 ± 2.4	1.18 ± 2.1
30-39	19	7.11 ± 8.9	4.16 ± 7.3	2.89 ± 6.2
40-49	33	4.61 ± 4.6	1.88 ± 3.7	0.85 ± 2.6
50-59	35	7.11 ± 6.0	3.74 ± 6.0	2.37 ± 6.1
60-69	42	7.86 ± 6.2	3.69 ± 5.0	1.21 ± 3.5
70-79	29	6.10 ± 6.2	2.03 ± 3.0	0.72 ± 2.2
80-89	12	6.50 ± 5.6	2.25 ± 6.3	**
90-99	4	4.75 ± 4.3	2.00 ± 4.0	0.25 ± 0.5

\*\*(True Zero); n = number of patients; LOS = Length of Stay;

TICU = Trauma Intensive Care Unit

Table 15A: Opioids alone patients mean LOS and ventilator days per age range and sex									
			Mean (days)						
			Hospital LOS		TICU LOS		On Ventilator		
Age (years)	M (n)	F (n)	Male	Female	Male	Female	Male	Female	
10-19	2	3	2.50 ± 0.7	2.67 ± 2.1	**	0.67 ± 0.6	**	0.33 ± 0.6	
20-29	6	4	6.67 ± 5.6	3.25 ± 1.7	2.83 ± 3.1	1.00 ± 0.8	1.67 ± 2.7	0.25 ± 0.5	
30-39	14	2	8.64 ± 9.9	2.50 ± 2.1	5.36 ± 8.2	0.5 ± 0.7	3.79 ± 7.0	**	
40-49	22	9	4.45 ± 5.0	5.00 ± 4.2	2.50 ± 4.4	1.67 ± 0.9	1.27 ± 3.2	**	
50-59	26	7	7.54 ± 6.5	4.14 ± 2.7	4.46 ± 6.8	1.29 ± 0.5	3.15 ± 7.0	**	
60-69	30	9	7.83 ± 5.3	7.67 ± 9.7	3.63 ± 4.7	3.56 ± 6.6	0.87 ± 1.9	2.22 ± 6.7	

\*\*(True Zero)

n = number of patients; M = Males; F = Females; TICU = Trauma Intensive Care Unit;

LOS = Length of Stay

Table 16A: CPB patients mean LOS and ventilator days per age range and sex										
			Mean (days)							
			Hospital LOS				TICU LOS		On Ventilator	
Age (years)	M (n)	F (n)	Male	Female	Male	Female	Male	Female	Male	Female
10-19	0	0	ND	ND	ND	ND	ND	ND	ND	ND
20-29	0	1	ND	*	ND	*	ND	*	ND	*
30-39	3	0	3.00 ± 2.6	ND	1.0 ± 1.7	ND	0.67 ± 1.2	ND	0.67 ± 1.2	ND
40-49	2	0	4.50 ± 2.1	ND	0.50 ± 0.7	ND	**	ND	**	ND
50-59	1	1	*	*	*	*	*	*	*	*
60-69	2	1	10.00 ± 0.0	*	6.50 ± 2.1	*	2.50 ± 3.5	*	2.50 ± 3.5	*
70-79	2	1	.00 ± 4.2	*	5.50 ± 7.8	*	5.50 ± 7.8	*	5.50 ± 7.8	*
80-89	0	0	ND	ND	ND	ND	ND	ND	ND	ND
90-99	0	2	ND	7.50 ± 4.9	ND	4.00 ± 5.7	ND	**	ND	**

\*\* (True Zero); \* (Unable to calculate mean with an n = 1); ND = no available data; n = number of patients;  
 M = Males; F = Females; LOS = Length of Stay; TICU = Trauma Intensive Care Unit;  
 CPB = Continuous Paracostal Block

## APPENDIX B: IRB APPROVALS

Page 1 of 3



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### *Initial Approval Notice*

To: Stephen Rush  
CC: Sunny Patel  
From: Martin Berk, MD, IRB Chair  
on behalf of Texas Health Resources Institutional Review Board (THR IRB)  
RE: Study [Pro00005508](#)  
Date: Wed Oct 29 16:19:26 CDT 2014

An Expedited Review was conducted for this study under the provisions of 21 CFR 56.110 (a) (b) and 45 CFR 46.110 (b) (1) category (5).

The THR IRB Chair, or designee, has approved you to conduct research involving human subjects.\* Please review the following information summarizing the approval granted:

This study qualifies for waiver of process of informed consent under 45 CFR 46.116 (c) and/or (d); and waiver of documentation of informed consent under 45 CFR 46.117 (c) and/or 21 CFR 56.109 (c) (1).

This study qualifies for a waiver of authorization for the use of protected health information (PHI) under 45 CFR 164.512 (i) (1) (i).

This study qualifies to include pregnant women and children via 45 CFR 46 Subpart B and D.

Study No.: Pro00005508  
Study Title: A Retrospective Chart Review of Patients with Traumatic Multiple Rib Fractures (TURFs)  
Protocol Version: 1.2  
Protocol Date: 10/14/2014  
Approval Period: 10/28/2014 through 10/27/2015  
Approved Via: Expedited

Category 5 (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the

<https://cirb.texashealth.org/eIRB/Doc/0/V000ORTPFHG4174ULT9B1P8A47/fromString...> 11/18/2014

protection of human subjects. 45 CFR 46, 101(b)(4). This listing refers only to research that is not exempt.)

Risk Level:	Minimal Risk
Approved	200
Sample Size:	
Principal Investigator:	<a href="#">Stephen Rush</a>
Co-Investigators:	None
Other Study Staff:	Cathy McNeill
Funding Information:	Not Applicable
Documents Approved with this Review:	TURF IRB Protocol Submission TURFs 1.2 14 Oct2014 Revised; TURF CRF v.1.1 14 Oct 2014; TURF Master Key v1.0 14 Oct2014; Bill 1 TURFS eIRB Initial Submission Version 0.01 dated 9/24/14

To find the documents stamped with IRB approval for use in this research project, please follow the link below and click on the Documents tab. If not on this list, any documents to be used in the research must be reviewed and approved by the IRB before use in the research.:

[Pro00005508](#)

If your study involves waiving the authorization, please print out the approved study application and present it along with your approval letter when requesting access to protected health information (PHI).

The research may not continue beyond the end of the new approval period, as indicated by the expiration date above. In order for the research to continue beyond that date, the IRB must first conduct continuing review and designate a new approval period.

The IRB will send you a continuing review notice at least 30-60 days before the expiration date listed above. If not completely filled out, received, reviewed and approved by the IRB before the end of the expiration date above, enrollment of new subjects in the research must cease until IRB approval can be obtained. Continued involvement in the research of previously enrolled subjects may not continue unless explicitly approved by the IRB to prevent harm to subjects.

Based on human research regulations and THR human subject research policies, the IRB emphasizes the following requirements in granting approval for this research project:

1. Any changes, modifications, or amendments to any facet of the research must be reviewed and approved by the IRB before they can be initiated.
2. All reportable adverse events and unanticipated problems involving risks to subjects or others must be reported to the IRB according to THR IRB policy requirements. This includes reporting to this Committee any death or serious reactions(s) resulting from this study. Please consult the THR IRB Policy and Procedure Manual for specific definitions and reporting time-frames and requirements.
3. It is required to submit annual and terminal progress reports to the IRB and to receive continuing review of your activity annually by the IRB.



Failure to submit the above reports may result in severe sanctions being placed on Texas Health Resources. All research-related records and documentation may be inspected by the IRB for the purposes of ensuring compliance with THR policies and procedures and federal regulations governing the protection of human subjects. The IRB has the right and authority to suspend or terminate its approval if THR and Federal requirements are not strictly adhered to by all study personnel.

**If applicable, the JCAHO standards related to patients taking part in research require that they be informed about the benefits, risks, alternative treatments, research procedures and refusal to participate. This information is contained in each approved research consent form. All in-patients and out-patients that are actively taking part in clinical research must have a copy of their signed consent form on their open medical records.**

If you have any questions or concerns, please contact the IRB Office at (682) 682-6746 or [irb@texashealth.org](mailto:irb@texashealth.org). The IRB thanks you for your continued commitment to the protection of human subjects in THR research.


\*This submission was approved via electronic signature by the THR Chair or designee.

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612 E. Lamar Blvd., Suite 1212 \* Arlington, TX 76011 \* (682) 236-6746 \* Fax (682) 236-6756 \*  
[IRB@TexasHealth.Org](mailto:IRB@TexasHealth.Org) \* [WIRBTHR@TexasHealth.Org](mailto:WIRBTHR@TexasHealth.Org)

DATE: November 14, 2014

TO: Patricia Gwirtz, PhD (Associate Dean, GSBS)  
Clinical Research Management  
(Sunny Patel, Clinical Research Management student)

FROM: Chris Cooper, MPAS, PA-C   
UNTHSC Institutional Review Board (IRB) Chair

PROTOCOL: **IRB # 2014-153**  
**A Retrospective Chart Review of Patients with Traumatic Multiple Rib Fractures (TURFs)**

#### IRB BOARD ACTION AND NOTICE OF APPROVAL

This research project is a Texas Health Resources (THR) Institutional Review Board (IRB)-approved protocol (THR IRB protocol #: Pro00005508). The UNTHSC IRB Chair conducted a review of this project and concurs with the THR IRB's review. The UNTHSC IRB Chair acknowledges that this project meets the criteria to qualify as Expedited category research under the provision of 45 CFR 46.110 (b) (1), category (5).

UNTHSC IRB approval is effective November 14, 2014 through **November 14, 2015**.

Remember that you are responsible for complying with all UNTHSC requirements regarding projects involving human subjects and ensuring that the research is conducted as specified in the approved protocol. It is important that you use only the latest approved versions of all study documents and that all changes be approved by the IRB before they are implemented.

Any changes affecting the protocol upon which this certification is based must be reported to the Office of Research Compliance. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

Should your project period extend beyond this expiration date, you must submit a Progress Report for Continuing Review to the IRB. You must allow sufficient time for the renewal request to be reviewed and approved **before expiration of the current approval**. Be sure to *prepare for a renewal 2 months prior to the protocol expiration date*. If the project is finished before the approval expiration date, you may submit a final Progress Report (Continuing Review) either at the time the project is completed or before the expiration.

The Office of Research Compliance does their best to send out a reminder notice to send in your Progress Report (Continuing Review), but it is your responsibility to prepare such a report in order for continuing review to occur before the expiration date.

If you have any questions, please contact the Office of Research Compliance at 817-735-0409.

**UNT Health Science Center**  
**Office for the Protection of Human Subjects**  
**Institutional Review Board**  
**BOARD ACTION**

IRB Project #: 2014-158

Date Submitted: October 29, 2014

Principal Investigator: Patricia Gwartz, PhD (with Sunny Patel, Clinical Research Management student)

Project Title: A Retrospective Chart Review of Patients with Traumatic Multiple Rib Fractures (TURFs)

Sponsor Protocol #: N/A

Department: Clinical Research Management

Contact Info: sbp0051@live.unthsc.edu

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given, is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

- ☒ Project has received approval through: November 14, 2015
- ☐ Informed consent(s\*) approved as submitted on: \_\_\_\_\_


You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

\*Including: \_\_\_\_\_

- ☐ Study Protocol dated \_\_\_\_\_ approved as submitted.
- ☐ Investigator's Brochure \_\_\_\_\_ approved as submitted.
- ☐ Protocol Synopsis approved as submitted on: \_\_\_\_\_
- ☐ Amendment \_\_\_\_\_ to the protocol approved as submitted.
- ☐ Progress Report/Continuing Review completed, project has received approval through: \_\_\_\_\_
- ☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. **YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.**
- ☐ Project is disapproved for the reason(s) outlined (see attached).
- ☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).
- ☐ Completion of project is acknowledged and all required paperwork has been received.
- ☒ Special Findings/Other

This project is a Texas Health Resources IRB-approved protocol (THR IRB protocol #: Pro00005508). The UNTHSC IRB Chair conducted a review of this project, and the UNTHSC IRB Chair concurs with the THR IRB's review. Please see page 2.

  
Chairman, Institutional Review Board

  
Date \_\_\_\_\_ IRB Form 2 (revised September 2012)

**Board Action-page 2**

PI: Gwirtz, Patricia

IRB Project #: 2014-158

Date: 11/14/2014

**SPECIAL FINDINGS:**

- ☐ **CHILDREN:** The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:
- ☐ **45 CFR** ☐ **21 CFR**
- ☐ **COGNITIVELY IMPAIRED:** The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:
- ☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**
- ☐ **PREGNANT WOMEN:** The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**
- ☐ **FETUSES/NEONATES:** The Board found the involvement of fetuses/neonates to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR**
- ☐ **PRISONERS:** The Board found the participation of prisoners to be approvable under Subpart C of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**
- ☐ **OTHER:**

**OTHER**

☒ **Expedited Review Procedures (under 45 CFR 46)**

**Project** ☒ Approved ☐ Approved for Continuation ☐ Modifications approved **under the provisions of:**  
**45 CFR 46.110 (b) (1) category (5)**

☐ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

- ☒ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:

**Expedited Review Procedures (21 CFR 56.110 and 45 CFR 46.110)**

- ☒ **Informed Consent Waiver:** The Board finds this project qualifies for a **Waiver of Informed Consent** under the provisions of **45 CFR 46.116 (d) (1), (2), (3) & (4)**

☐ **Other IRB Approved Research Documentation Includes:**

☐ **Other Comments:**

## APPENDIX C: SAMPLE MASTER KEY AND CASE REPORT FORM

### SAMPLE MASTER KEY

Subject ID	Name	Account #
M1	Mickey Mouse	12345678
M2	Minnie Mouse	12345679
F1	Donald Duck	12345677
F2	Daisy Duck	12345676
M3	Pluto Smith	12345675
F4	George Jetson	12345674
F5	Elroy Jetson	12345673
F6	Judy Jetson	12345672
M4	Jane Jetson	12345671
M5	Rosie Smith	12345670

# SAMPLE CASE REPORT FORM

Subject ID	Age	Sex	Race	Ethnicity	Admission Date	MOI	ISS	Total Rib Fractures	Unilateral or Bilateral	Location of Rib Fractures	Rib Numbers	Type of Pain Management	Days on Ventilator	ICU LOS	Hospital LOS
M1	76	1	4	1	1/1/2014	1	12	3	1	A	R3,5,7	1	0	13	20
M2	69	1	4	2	1/5/2014	2	36	4	1	AL	L3-6	3	0	4	7
F1	92	2	3	2	1/5/2014	1	17	3	2	PL,P	R3,4,L1	1	2	3	6
F2	88	2	4	1	1/7/2014	1	23	3	2	P,L	R3,4,L1	1	8	2	8
M3	65	1	4	2	1/9/2014	2	29	5	1	A	R5-10	3	0	0	1
F4	72	2	4	1	1/10/2014	2	18	7	2	P,L	R3-5,L3-6	3	3	4	8
F5	82	2	1	2	1/13/2014	1	22	9	2	P,L	R2,4,7,L3-9	3	4	0	8
F6	83	2	3	2	1/15/2014	1	14	5	1	PL	L3-7	3	10	6	13
M4	74	1	1	2	1/15/2014	2	25	5	1	P	R1-5	3	0	4	8
M5	70	1	2	2	1/16/2014	3	56	3	1	PL	R8-10	1	0	5	9

Sex	RACE	Ethnicity	MOI	Unilateral or Bilateral Rib Fracture	Location of Rib Fractures	Type of Pain Management
1=Male	1=American Indian	1=Hispanic	1=GLF	1=Unilateral	A = Anterior	1=Opioids
2=Female	2=Asian	2=Non-Hispanic	2=MVC	2=Bilateral	AL= Anterolateral	2=Epidural
	3=African American		3=MCC		P = Posterior	3=Continuous Paracostal Block
	4=Caucasian		4=Other		PL = Posterolateral	
	5=Native Hawaiian				L = Lateral	

## APPENDIX D: DAILY JOURNAL

Tuesday, 22 July 2014

- First day to officially meet internship mentor (Ms. McNeill) at Texas Health Resources. Her office is located in Trauma Administration in the Jones Tower.
- Introduced to mentor's manager and other staff members in the department.
- Introduced to trauma surgeons in a meeting called, Office Rounds. There are two types of Rounds, Multiple Disciplinary TICU or Office. Office Rounds were daily meetings consisting of trauma research coordinator (Ms. McNeill), trauma program manager, trauma nurse clinician's, trauma performance improvement coordinator, injury prevention coordinator, and the trauma surgeons. Office Rounds are to discuss the current status of patients and newly admitted patients for on-coming doctors as well as input from all. Rounds Intensive Care Unit compared to Office Rounds has some similarities and its differences. TICU Rounds allow input from the team providing an opportunity to ask questions. Overall, round's continues to be very exciting and very educational each day. TICU Rounds allow input from the team providing an opportunity to ask questions. Overall, round's continues to be very exciting and very educational each day.

Wednesday 23, July 2014

- Schedule a date and time between all advisors for the Committee Meeting at Texas Health Resources on Tuesday 29, July 2014 at 1:30pm.

- My e-IRB account was activated after submission and completion of resume, Policies Verification Form, Human Subject Research Training (HCCS), Health Insurance Probability and Accountability Act training (HIPAA) and Conflict of Interest (COI) modules.
- Attended Trauma Outcome Performance Improvement Committee (TOPIC) meeting with representatives from orthopedic, emergency department, anesthesia, neurology and others with invested interest to discuss opportunity for improvement in patient care.

Thursday 24, July 2014

- All activities including meetings were on hold and rescheduled until the contract between University of North Texas Health Science Center and Texas Health Research and Education was in place.

Friday 25, July 2014

- The contract between University of North Texas Health Science Center and Texas Health Research and Education was approved and signed by Texas Health Research and Education.

Tuesday 29, July 2014

- During the Committee Meeting both Master of Science- Degree Plan and Designation of Advisory Committee forms were handed over to Dr. Gwartz. The advisory committee discussed the expectations and focus of the internship practicum of clinical research management program at Texas Health Resources with Ms. McNeill.

Wednesday 30, July 2014



- A study site monitor arrived to audit the Traumatic Brain Injury (TBI) study including, source documents, case report forms (CRF), adverse event (AE) forms, confirm the signed consent forms and correspondence.
- Attended Journal Club meeting to learn about blunt splenic injury and pseudo-aneurysm; to watch or remove the spleen.

Thursday 31, July 2014

- TBI study site monitor addressed changes and corrections to be made in the company designed electronic data capture (EDC). Ms. McNeill showed how to correctly make changes and how to input data.

Friday 1, August 2014

- Today logged into My Talent Learning Assignment to finish training and certification for Texas Health Research and Education (THRE).

Monday 18, August 2014

- Attended Multiple Disciplinary Rounds in TICU.
- Attended Face-to-Face with CEO Doug Hawthorne's last town hall meeting with a surprise visit from Mayor Price to honor Mr. Hawthorne's vast amount of time and dedication to Texas Health Resource.
- Attended Office Rounds with doctors and trauma department.

Tuesday 19, August 2014

- Attended meeting with another nurse researcher for insight on poster accepted for Society of Clinical Research Associates (SoCRA).

- Attended Office Rounds with doctors and trauma department.

Wednesday 20, August 2014

- Attended Office Rounds with doctors and trauma department.
- Observed how to approach patient's family to obtain subject consent or legally authorized representative (LAR) consent for Vitamin D. Study.

Thursday 21, August 2014

- Attended Office Rounds with doctors and trauma department.
- Learned how to submit amendment and COI for a study on e-IRB.

Friday 22, August 2014

- Multiple disciplinary rounds in TICU.
- Staff Meeting: American College of Surgeons Level II Trauma Recertification Preparation.
- Attended Office Rounds with doctors and trauma department.
- Learned how to fill out the trauma registry data request form for access to data.
- Research project may involve a retrospective study chart review in patients with multiple rib fractures pain management.

Saturday 24, August 2014

- Attended Clinical Research Coordinator Review certification class and Clinical Research Coordinator Review evaluation was completed to receive contact hour certificate.

Monday 25, August 2014

- Attended Multiple Disciplinary Rounds in TICU.
- Attended Office Rounds with doctors and trauma department.

Tuesday 26, August 2014

- Attended the ROC meeting at MedStar for Tranexamic Acid (TXA) study update and budget review.
- Started working on literature review search for practicum project over retrospective chart review of patients with TURFs.
- Confidentially statement was signed and submitted to Texas Health Resources and COI submitted on eIRB for Near Infrared Spectroscopy (NIRS) study.

Wednesday 27, August 2014

- Literature review for trauma surgeons over amniotic fluid embolism due to blunt abdominal trauma.
- New budgeting cost report for Texas Health Research and Education created and discussed for TXA study.
- Attended Office Rounds with doctors and trauma department.
- Exchanged contact information with ON-Q representative.
- Webinar: Successful FDA Inspections (how to prepare for inspection, manage activities during and after inspection, and fundamental elements for a successful inspection).

Thursday 28, August 2014

- Attended Office Rounds with doctors and trauma department.

- Completed amendment for Vitamin D study including COI.
- Submitted Continuing Review for Platelets and Plavix study.
- Attended meeting with Texas Health Research and Education Budget manager and research contract specialist regarding TXA study.
- Helped mentor with poster preparations for SoCRA.

Friday 29, August 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued with poster preparations for SoCRA.
- Medical device representative from ON-Q sent some information over quality assessment process used for un-official study.

Monday 1, September 2014

- Labor Day (Holiday).

Tuesday 2, September 2014

- Unable to attend work during the time of visit from American College of Surgeons Recertification for THFW.
- Performed literature search in various data bases for upcoming research proposal.

Wednesday 3, September 2014

- Unable to attend work during the time of visit from American College of Surgeons Recertification for THFW.
- Submitted COI for Continuing Review: Vitamin D in Trauma Patients.

- Performed literature search in various data bases for upcoming research proposal.

Thursday 4, September 2014

- Completed registration for Research Outcome Consortium, uploaded COI Form, and Data Entry Training/Quiz.
- Met and assisted the IRB internal auditor over ongoing near infrared spectroscopy (NIRS) study.
- The Research Outcome Consortium granted permission for data entry and editing.
- Office Rounds with doctors and trauma department.
- Logged online to the FDA Webinar on Investigational Devices that FDA recently issued a final guidance document (FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations).

Friday 5, September 2014

- Attended a Face to Face IRB meeting was held at the Texas Health Resource in Arlington that only occurs twice a year or every six months.
- Continued to assist the IRB internal auditor over the ongoing near infrared spectroscopy (NIRS) study.
- Attended both Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued working on literature search for TURFs retrospective study.

Monday 8, September 2014

- Attended both Office Rounds and Multiple Disciplinary Rounds in TICU.

- Continued to search and gather literature for TURFs retrospective study.
- Worked with mentor on research proposal and the e-IRB submission protocol.

Tuesday 9, September 2014

- Attended Office Rounds with doctors and trauma department.
- Reviewed Trauma Patient List for possible subject enrollment for vitamin D study.
- Completed influenza education training at Texas Health Resources (THR) on My Talent online.
- Registered on trauma.org to obtain resource access for articles which may contribute towards TURFs research proposal and study.
- Contacted Ms. Whitehead at UNTHSC on how to properly cite information if, unable import a specific file format in RefWorks.
- Contacted advisor Dr. Gwartz regarding possible requirements and processes to obtain approval from UNTHSC IRB for retrospective study.

Wednesday 10, September 2014

- Worked with Dr. Gwartz and mentor on research proposal.
- Continued working on literature search for TURFs protocol and proposal.
- Attended Office Rounds with doctors and trauma department. Meeting with Dr. Rush and Ms. McNeill on the retrospective study.

Thursday 11, September 2014

- Attended Office Rounds with doctors and trauma department.

- Continued working on literature search for TURFs research proposal and protocol.

Friday 12, September 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Contacted Ms. Whitehead requesting to schedule a meeting next week in the morning for database search at UNTHSC.

Monday 15, September 2014

- Meeting with Ms. Whitehead at UNTHSC on different databases that are potential areas for literature search, properly cite information if unable to use cite manager file format, registered with National Center for Biotechnical Information (NCBI) to save literatures and export them to RefWorks and how to request articles or journals. In addition, her help was extremely useful in acquiring electronic prints of articles that required special permission and access.
- Contacted Ms. Morrow who works with the I-flow company in the information department regarding any recent publications or articles on a specific device for the retrospective study.
- Contacted U.S. National Library of Medicine (NLM) for access to specific article and guidelines.
- Continued working on literature search with the help of Ms. McNeill; Contacted THR in obtaining articles from databases that UNTHSC did not have access.

Tuesday 16, September 2014

- Attended Office Rounds with doctors and trauma department.

- Interviewed an in- patient with traumatic multiple rib fractures to see how the injury occurred, pain level at admittance, what was given for the management of pain, and how beneficial it was to the patient.
- Attended certification class on adverse events at THR research instructed by Ms. McDonald.

Wednesday 17, September 2014

- Attended Office Rounds with doctors and trauma department.
- Continued working on literature search with the help of Ms. Whitehead and Ms. McNeill obtaining articles that required special permission.
- Attended certification class on informed consent at THR research instructed by Ms. McDonald.

Thursday 18, September 2014

- Attended Office Rounds with doctors and trauma department.
- Discussed the protocol and literature searches with Dr. Rush and received his input.
- Attended certification class research privacy and confidentiality at THR research instructed by Ms. McDonald.
- Continued working on proposal and protocol.

Friday 19, September 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued working on research proposal and protocol for finalization.



- Requested an extension for submission of proposal due to the absence of Ms. McNeill.
- Submitted study to Dr. Rush and Ms. McNeill for any changes or corrections needing to be made before submission to Dr. Gwartz for review and finalization by committee members.

Monday 22, September 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Research proposal submitted to advisor to Dr. Gwartz.

Tuesday 23, September 2014

- Attended Office Rounds with doctors and trauma department.

Wednesday 24, September 2014

- Attended Office Rounds. Reviewed protocol with Dr. Rush with minor changes.
- Started e-IRB submission process for THR.
- Generated case report form (CRF) and blank Bill for e-IRB application.

Thursday 25, September 2014

- Attended Office Rounds with doctors and trauma department.
- Finished and submitted the eIRB protocol for Retrospective TURFs study with an assigned protocol number PRO00005508.
- Completed COI for TURFs study.
- TURFs PRO00005508 approved by entity reviewer.

Friday 26, September 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Contacted IT department with an issue opening .dat files from THR secure webmail.
- Simulation lab meeting on how to implement in improvement of certain areas noted by the American of College of Surgeons.
- Sufficient resources identified, and scientific merit approved for PRO00005508.

Monday 29, September 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Appointment at UNTHSC student health clinic.
- Organized study binder for The Retrospective TURFs study (PRO00005508).

Tuesday 30, September 2014

- Ms. McNeill reviewed, approved, and submitted research proposal to Dr. Gwartz and Dr. Kirchhoff.
- Attended Office Rounds with doctors and trauma department.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Literature review search for Dr. Smith, “Massive Transfusion with Tranexamic Acid”.
- Update IRB process notification over PRO00005508 stated, “IRB Analyst Assigned”.
- Attended meeting at THR Arlington on an action plan to identify evaluate and implement options intended to provide a timely IRB review process for research conducted within THR.

Wednesday 1, October 2014

- Attended Office Rounds with doctors and trauma department.
- TBI consenting, prequalification and procedures of patients.
- TXA corrections for IRB analysts on e-IRB.
- Literature search for Dr. Smith, “Pneumonia & Alcohol Morbidity and Mortality.”
- Contacted THRE IRB for timeline flow chart on approval of study.
- Edit proposal paper after reviewed by Dr. Gwartz.

Thursday 2, October 2014

- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Reviewed literature search for Dr. Smith, TXA & Massive Infusion, and Pneumonia & Alcohol.
- Contacted Ms. Whitehead for advice over bibliography and citing references correctly.
- UNTHSC IRB requested a letter from Principle Investigator (PI) Dr. Gwartz regarding my involvement along with all the approved PRO00005508 documentations from THFW IRB.

Friday 3, October 2014

- Ms. Whitehead stated the proposal has correctly cited references and had a well-organized bibliography.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

Monday 6, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Received notification from THFW IRB requesting corrections & clarifications on PRO00005508. Corrections & clarifications were completed as requested by THFW IRB and resubmitted.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.

Tuesday 7, October 2014

- Attended Office Rounds with doctors and trauma department.
- Video interview of Ms. McNeill's poster, "Development of a Geriatric Functional Trauma Status (GFTS) Score".
- THFW IRB phone meeting with Ms. Cline.
- Finished summarizing literature searches for Journal Club on the Role of Tranexamic Acid (TXA) in the Massive Transfusion Protocol (MTP).
- Organized SoCRA Folder.
- Up-dated my calendar with upcoming training, meeting and events.
- Uploaded and submitted to e-IRB: Revised PRO00005508 v1.1 and Pre-Reviewed 07 Oct 2014 with corrections.

Wednesday 8, October 2014

- Organized and completed SoCRA Folder.

- Organized Neuron (Intrepid Study) Folder.
- Attended Office Rounds with doctors and trauma department.
- Helped problem solve technical issues with outlook mail.
- Attended TOPIC (Trauma Outcomes Performance Improvement Committee) meeting.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Prepared questions to ask Dr. Gwartz regarding: forms, proposal, formatting, etc... for clarification.
- Completed and submitted, Intrepid Financial Disclosure Agreement for Neuron Traumatic Brain Injury Study (TBI).

Thursday 9, October 2014

- Attended Office Rounds with doctors and trauma department.
- Meeting with Dr. Gwartz for answers to all my questions.
- Revised Research Proposal and resubmitted to all committee members.
- Worked on flyers for Journal Club Meeting on Wednesday 29, October 2014.

Friday 10, October 2014

- Assisted with completion of amendment for TXA Study.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.

- Continued literature search for any new articles over Continuous Paracostal Block (CPB).
- Requested a phone meeting with Dr. Kirchhoff to discuss research proposal.

Monday 13, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Discussion of research proposal over the phone with Dr. Kirchhoff and Ms. McNeill.
- Attended meeting over Variations in Intervention in Trauma Department.

Tuesday 14, October 2014

- Attended Office Rounds with doctors and trauma department.
- Filled out and dropped off M.S. Research Proposal Evaluation for second signature.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Phone meeting with new chapter chair for SoCRA, how to transfer chair chapter currently held by Ms. McNeill, and the possibility of holding meetings in both Dallas and Fort Worth.
- Scheduled meeting date with Dr. George Alexandrakis and fellow colleagues at UTA for NIRS study and training on how to properly use the device.

Wednesday 15, October 2014

- Attended Office Rounds with doctors and trauma department.
- TXA Study web conference with ROC.
- Attended planning meeting for the 2015 Trauma Conference.

- Ms. McNeill and I posted up flyers for The Journal Club.

Thursday 16, October 2014

- Attended Office Rounds with doctors and trauma department.
- Picked up the signed M.S. Research Proposal Evaluation form.
- Research Proposal has been finalized and ready for submission.
- Dropped off Intent to Graduate and M.S. Research Proposal Evaluation forms with correct signatures at UNTHSC.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Helped translate information from nurse and patient in native speaking language Gujarati.
- Prepared statistics from Vitamin D Study for presentation to Trauma Research Committee.
- Evidence Based Practice & Research Council Meeting.

Friday 17, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Completed preparation of statistics from Vitamin D Study for presentation to Trauma Research Committee.
- Attended workshop, “Health Literacy why is it Important?” presented by Ms. Carbajal-Diaz from UNTHSC Public of Health for the Department of Trauma Administration.

- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Attempted to deliver copy of signed consent and/ results of Vitamin D study to subject; discharged and mailed to subject.
- Assisted with Family Planning Meeting in TICU with explanation and translation of information in native speaking language Gujarati.

Monday 20, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Began draft of Standard Operating Procedure (SOP) for Vitamin D Study.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Attended Critically Appraising an Article that Reports a Randomized Controlled Trial Class with certification earned.

Tuesday 21, October 2014

- Attended Office Rounds with doctors and trauma department.
- Obtained lab results for Vitamin D study, made copies, and delivered to patient.
- Completed SOP for Vitamin D Study and submitted to mentor.
- Attended lunch meeting presented by Cubist, “Are you prepared to Battle Resistances.”
- Discussed shipping of material to and from Intrepid (TBI) study monitor. Began preparation to ship frozen Biomarkers in cryovials to sponsor.



- Volunteered as a Model for the Advanced Trauma Life Support (ATLS)/ Advanced Trauma Certified Nurse (ATCN) Certification Courses.

Wednesday 22, October 2014

- Attended Office Rounds with doctors and trauma department.
- Trauma Research Committee Meeting.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Attended Trauma Research Committee Meeting and presented Report on Vitamin D.
- Unable to attend a SoCRA Meeting at University of Texas Southwestern (UTSW), Dallas, Texas.

Thursday 23, October 2014

- Attended Office Rounds with doctors and trauma department.
- Attended lunch meeting presented by Pharmaceutical Rep, "Lovenox."

Friday 24, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

Monday 27, October 2014

- Did not go into work. Appointment with student clinic at UNTHSC for treatment of severe allergies and upper respiratory infection.

Tuesday 28, October 2014

- Attended Office Rounds with doctors and trauma department.

- Contacted THRE IRB when to expect protocol study approval by email.
- Trained another student with the presence of Ms. McNeill, on how to correctly enroll and obtain consent from subject or legally authorized person in TICU for Vitamin D study.
- Meeting with the sponsor of the NIRS study at University of Arlington (UTA).

Wednesday 29, October 2014

- Attended Office Rounds with doctors and trauma department.
- Finished up-data collection and organizing my binder.
- Assisted Dr. Witham and Ms. McNeill in literature search for Snakebite study.
- Drafted LETTER/MEMO for Dr. Gwartz to sign and was submitted to the research department to the UNTHSC IRB where all approved THR IRB PRO00005508 documents will be submitted to UNTHSC IRB.
- Attended Journal Club meeting to learn and discuss Massive Transfusion Protocol.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.

Thursday 30, October 2014

- International Airline Transport Association (IATA) all day training and certification class.
- Attended Research Poster Reception at THR.

Friday 31, October 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Training on how to submit a manuscript for the Snakebite study.
- Continued literature search and helped edit the Snakebite manuscript.
- Started formatting blank word document for Practicum report.
- Approval of PRO00005508 has moved out of IRB Review and now Pending Institutional Approval by THR IRB.

Monday 3, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Received email from THR for the Approval of PRO00005508 and the Approval Letter from THR IRB. All the required documentation from the UNTHSC IRB was gathered and submitted in person to UNTHSC IRB.
- All the THR IRB approved documents were printed out and placed in study binder.
- Observe the placement of the CPB in-patient with TURFs.

Tuesday 4, November 2014

- Attended ROC meeting at University of Texas Southwestern for the TXA study.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Continued formatting blank word document for Practicum report.

Wednesday 5, November 2014

- Attended Office Rounds with doctors and trauma department.
- Continued formatting blank word document for Practicum report.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent.
- Submission of Revised Snakebite manuscript to the Wilderness & Environment Medicine and was listed as a Co-Author due to my work on references and the manuscript.
- Ms. McNeill forwarded an email received from Open Forum Digest with the discussion topic, “Rib Fractures Protocol.” Downloaded and printed out the guidelines that were posted on the forum. Also reached out to each trauma managers from forum by email. Download and printed post on the forum for additional references that may contribute to working practicum report.

Thursday 6, November 2014

- Attended Office Rounds with doctors and trauma department.
- Phone conference with Trauma Program Manager from Genesis Health Care System from the Rib Fracture Protocol posted on the Open Forum Digest for the Society of Trauma Nurses.
- Organized TURFs binder in preparation of study.
- Mentor and I discussed the practicum report outline and formatting.
- Continued working on formatting the black document for Practicum report.

- I was complemented by the Director of Nursing Restorative Care who was looking into the development of a protocol for best practices of multiple rib fractures.

Friday 7, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Literature Review search for, Dr. Witham on, “Traumatic Subarachnoid Hemorrhage Vasospasm & Transcranial Doppler”, including any current guidelines, protocols, articles, etc....
- THR-IRB meeting was unable to attend due to automotive issues.
- Unable to enroll patient in TICU for Vitamin D.

Monday 10, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent. Subjects enrolled and available at time were provided a copy of lab results.
- Approached patient as translator in native language, Gujarati, and offered assistance including translation with the medical team.
- Contacted help desk for Trauma Administration Department with technical issues with receiving and calling out on new phones.
- Continued formatting word document for practicum report.
- Spoke to Ms. Johnson at UNTHSC about spring enrollment.
- E-mailed UNTHSC IRB for up-date on when PRO00005508 will be approved.

- Completed formatting blank word document to prepare practicum report.

Tuesday 11, November 2014

- Attended Office Rounds with doctors and trauma department.
- Called THR IT to setup new phone to send and receive both internal/external calls.
- Called UNTHSC IRB Ms. Oglesby for update on the submission of THR approved protocol PRO00005508. Ms. Oglesby stated Executive Director will be back in office by mid-week to discuss the submission of the study. I will call back Friday 14, November 2014 if no response has been received from UNTHSC IRB.
- Scanned the daily list for new patients in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Approached subject or legally authorized person in TICU for Vitamin D study enrollment and consent. Subjects enrolled and available were give results back to them.
- Begun drafting the acknowledgement section for practicum report.
- Completed updating MyRecord Tracker for UNTHSC.
- Helped with literature search for Journal Club topic, “Junctional Tourniquets”.

Wednesday 12, November 2014

- Attended Office Rounds with doctors and trauma department.
- Helped troubleshoot internet connection and application of software up-date to the Nicolet EEG machine after receiving approval from the Traumatic Brain Injury study tech support.

- TOPIC lunch meeting with representatives from orthopedic, emergency department, anesthesia, neurology and others with invested interest to discuss opportunity for improvement in patient care.
- Contacted subjects at initial 30 days prior to enrollment in Vitamin D study.
- Started working on poster presentation project for Dr. Mathe for current Vitamin D study and data accumulated thus far.
- Membership Forms for both Association of Clinical Research Professionals (ACRP) and SoCRA were completed and submitted.

Thursday 13, November 2014

- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented in-patient subject in TICU. Ms. McNeill provided step-by-step instructions to properly gather and file all information specifically for the enrolled subject.
- Made new signs to for EEG monitor for the Intrepid Study.
- Attended Office Rounds with doctors and trauma department.
- Submitted both completed COI agreement for Dr. Gwartz and I for UNTHSC IRB.
- Attended Trauma Talk at THR Use of Simulation Lab in Trauma.

Friday 14, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Submitted New Membership ACRP application.

- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented in-patient subject in TICU.
- TICU nurse needed my assistances in moving medical equipment under her supervision.
- Dr. Rush, Ms. McNeill and I discussed future prospective TURFs study and meeting data.
- Continued to work on Practicum report.
- Attended Adam Stewart in presenting the Internship Practicum Report at UNTHSC.
- Created labels for Lab Papers and made copies of consents for Vitamin D study.

Monday 17, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented in-patient subject in TICU. After the PI signed the consent I had scanned and made two copies in which one copy was given to the subject.
- Acquired signature on the Safety Monitor form for Intrepid Study from Dr. Mathe.
- Received UNTHSC approval for PRO00005508 by email.
- Acquired data report by the Trauma Register for PRO00005508 over all patients with rib fractures from 01 June 2013 to 31 May 2014.
- Scheduled to Attend Cooks IRB meeting and the Research Council Meeting for this week.
- Completed internship practicum enrollment for spring 2015 at UNTHSC.



Tuesday 18, November 2014

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Reviewed data report for patients that meet the inclusion criteria with greater than or equal to three rib fractures. Subjects with unspecified number of rib fractures were searched in Care Connect by Ms. Cathy McNeill.

Wednesday 19, November 2014

- Volunteered for the Disaster Drill in the Emergency Department at THR.
- Continued working on Master Key List while reviewing data reports.
- Helped two members resolve issues with printing quality.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.

Thursday 20, November 2014

- Attended Office Rounds with doctors and trauma department.
- Attended Cooks IRB meeting.
- Attended Research Council meeting at THR.
- Continued gathering data for Master Key List.

Friday 21, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Continued gathering data from data report for practicum report.
- Completed required UNTHSC Training and Annual Disclosure Statement.

Monday 24, November 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued data collection from data report for practicum report.

Tuesday 25, November 2014

- Attended Office Rounds with doctors and trauma department.
- Continued data collection from data report for practicum report.
- “Rebound Coagulopathy in Patients with Snakebite Presenting with Marked Initial Coagulopathy” was accepted for publication in Wilderness & Environmental Medicine.

Wednesday 26, November 2014

- Attended Office Rounds with doctors and trauma department.
- Continued data collection from data report.

Thursday 27, November 2014

- Thanksgiving Break.
- Completed UNTHSC courses that include: Reporting Child Abuse on Campus; HIPPA Privacy and Security TX; and Active-Shooter Preparedness.

Friday 28, November 2014

- Continued review of medical charts.

Monday 1, December 2014

- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued data collection from data report with the help of mentor.
- Up-dated mentor's calendar with mine.
- Submitted practicum report for formatting approval to Dr. Kirchhoff committee member.

Tuesday 2, December 2014

- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Continued working on Master Key List and, specific International Classification of Diseases Clinical Modification codes (ICD-9-CM).

Wednesday 3, December 2014

- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Attended teleconference for Intrepid TBI study.

- Mentor and I continued gathering data through Care Connect.
- Requested data report from Trauma Registrar for admits with the specific ICD-9-CM codes from 01 June 2013 to 31 May 2014 with multiple rib fractures.
- Completed enrollment for student health insurance.

Thursday 4, December 2014

- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Attended Trauma Performance Improvement (PI) Stimulation Research meeting.
- Continued review of data report with help of mentor and trauma registrar.
- Attended Trauma Simulation Research Meeting.

Friday 5, December 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU. I gave the correct diagnosis addressed by physician during Office Rounds.
- Continued data collection with the help of mentor & principle investigator.

Monday 8, December 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued working on data collection with mentor.
- Certificate received for Using Simulation in Trauma Education.

Tuesday 9, December 2014

- Attended Office Rounds with doctors and trauma department.
- Continued review of medical charts for data collection.
- Attended Trauma call meeting with Resuscitation Outcomes Consortium (ROC) and TXA study update.

Wednesday 10, December 2014

- Mentor was out of the office.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Attended Employee Holiday Party.
- Organized current data collected.
- Approached physician to choose a Planning Meeting Date “Planning for the 2015 Trauma Conference” and to notify committee member to schedule as soon as possible.

Thursday 11, December 2014

- Mentor was out of the office.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Continued organizing the data collected.

Friday 12, December 2014

- Mentor was out of the office.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Organized data collected.
- Requested help from IT service with technical issues.

Monday 15, December 2014

- Mentor was out of the office.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Organized binders containing data collected.

Tuesday 16, December 2014

- Mentor was out of the office.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Continued data collection.

Wednesday 17, December 2014

- Mentor was out of the office.

- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Attended Office Rounds with doctors and trauma department.
- Requested Practicum Report Committee Meeting date with all members regards to current status, discussion, input and suggestions for, data analysis, defense date, practicum report, and all other questions.

Thursday 18, December 2014

- Attended Office Rounds with doctors and trauma department.
- Attended Streamlined EIRB Training.
- Continued data collection with mentor and trauma registrar. Later data collection was continued with investigator.
- Scheduled Practicum Report Committee Meeting with Dr. Kirchhoff, Mentor and I for December 22, 2014; Dr. Gwartz, Mentor and I for January 6, 2015. Invite were sent to all committee members.

Friday 19, December 2014

- Enrolled subject in TBI study.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

Monday 22, December 2014

- Attended Practicum Report Committee Meeting with Dr. Kirchhoff to discuss data analysis.
- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

- Attended Trauma Conference Topics/Objectives meeting.

Tuesday 23, December 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued organizing data for analysis.

Wednesday 24, December 2014

- Holiday.

Thursday 25, December 2014

- Holiday.

Friday 26, December 2014

- Continued organizing data for analysis.

Monday 29, December 2014

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

Tuesday 30, December 2014

- Attended Office Rounds with doctors and trauma department.
- Continued organizing data in preparation for analysis.

Wednesday 31, December 2014

- Attended Office Rounds with doctors and trauma department.
- Attended teleconference with Intrepid Study Site Call.
- Continued organizing data in preparation for analysis.

Thursday 1, January 2015



- Holiday (New Year's Day).

Friday 2, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued organizing data for analysis.

Monday 5, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

Tuesday 6, January 2015

- Practicum Report Committee Meeting with Dr. Gwartz.
- Attended Office Rounds with doctors and trauma department.
- Attended Trauma Performance Improvement Simulation meeting.

Wednesday 7, January 2015

- Attended Office Rounds with doctors and trauma department.
- Continued working on practicum report and data analysis.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patients declined to enroll.

Thursday 8, January 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.

Friday 9, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.

Monday 12, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.

Tuesday 13, January 2015

- Attended Office Rounds with doctors and trauma department.
- Helped Mentor draft informed consent for new study.
- Continued working on data analysis.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.

Wednesday 14, January 2015

- Attended Office Rounds with doctors and trauma department.
- Attended TXA study meeting.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patients declined to enroll.
- Continued working on data analysis.

Thursday 15, January 2015

- Attended Office Rounds with doctors and trauma department.
- Attended Best of Class IRB Tasks/Activities meeting.
- Continued working on data analysis.
- Attended Trauma Administration Department meeting.

Friday 16, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Data analysis “Results Review 1” was submitted to all committee members to review, revise, and suggestions for further analysis or changes.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.

Monday 19, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued working on practicum report.

Tuesday 20, January 2015

- Attended Office Rounds with doctors and trauma department.
- Administered Mayo-Portland Adaptability Inventory for Traumatic Brain Injury (MPAI-4) & Extended Glasgow Outcome Scale (GOS-E) with TBI study LAR.

- Submitted “Results Review 2” all committee members to review, revise, and suggest any further analysis on data.
- Continued working on practicum report.

Wednesday 21, January 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. Eligible patient declined to enroll.
- Helped organize the Intrepid TBI, NIRS and, TBI regulatory and study binders.
- Submitted Results Review 2 to PI for input and suggestions.

Thursday 22, January 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Continued working on practicum report.
- Results Review 2 was printed out for trauma physicians to discuss.

Friday 23, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Double checked data analysis for PRO00005508.

- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.

Monday 26, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Received Pre-Review from committee members over, “Results Review 2” and addressed changes and corrections to the results.
- Completed an outline for the Biostatistics Consulting Class on Thursday at UNTHSC as a key speaker.

Tuesday 27, January 2015

- Attended Office Rounds with doctors and trauma department.
- Attended ROC meeting for all study updates including TXA.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Continued working on data analysis for practicum report.
- Helped review and edit flyers for community consultation.

Wednesday 28, January 2015

- Attended Office Rounds with doctors and trauma department.
- Key speaker for the Biostatistics Consulting Class.
- Results were reviewed with changes to be made.
- Attended Trauma Research meeting.

Thursday 29, January 2015

- Attended Office Rounds with doctors and trauma department.
- Changes to the results were corrected and ready to draft. Started drafting the results section for the practicum report.
- Attended Association of Clinical Research Professionals: Great and Meet meeting.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.

Friday 30, January 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Continued working on Materials and Methods section.

- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.

Monday 2, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Helped neuron site monitor with TBI study.
- Attended Trauma staff meeting.
- Continued drafting result section for practicum report.

Tuesday 3, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Helped neuron site monitor with TBI study.
- Revised the figures, results, and method section of report.
- Attended Trauma Staff meeting.

Wednesday 4, February 2015

- Attended Office Rounds with doctors and trauma department.

- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Revised the figures, results, and method section of report. Started to draft an outline for the discussion, conclusion, introduction, and abstract sections.

Thursday 5, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Drafted the discussion, conclusion, introduction, and abstract sections. Revised the past sections drafted.
- Attend THFW ROTEM meeting.

Friday 6, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Reviewed and revised the discussion, conclusion, introduction, and abstract sections.

Monday 9, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.



- Continued job search and application process.
- Up-dated calendar with all meeting and events occurring this month.

Tuesday 10, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Attended meeting with PI and study staff for Platelets and Plavix study.

Wednesday 11, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Attended Trauma Outcome Performance Improvement Committee (TOPIC) meeting with representatives from orthopedic, emergency department, anesthesia, neurology and others with invested interest to discuss opportunity for improvement in patient care.
- Attended SoCRA meeting in Fort Worth.

Thursday 12, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll. Up-dated all subject binders currently enrolled.

- Continued working on results section.
- Attend meeting with sales representative at THFW.
- Attend Trauma Talk at THFW.

Friday 13, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Quick discussion with future PI and pharmacist for the RCT TURFs study.

Monday 16, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Helped colleague with flow chart.
- Continued making changes to practicum report.

Tuesday 17, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.

Wednesday 18, February 2015

- Attended Office Rounds with doctors and trauma department.

- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Meeting with director of marketing and sales representative and drafted one page synopsis for them.
- Started budget for RCT for TURFs.

Thursday 19, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Continued drafting RCT for TURFs study.
- Attended public relation meeting for ideas on community consultation.
- RSVP for next ACRP chapter meeting.
- Per-review received from committee member.

Friday 20, February 2015

- Attended America Heart Associations in Fort Worth for community consultation on emergency medicine.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Intend to defend form submission and signatures acquired.

- Continued to make changes to practicum report.

Monday 23, February 2015

- School closed and was instructed by mentor to stay home.
- Worked on practicum report.

Tuesday 24, February 2015

- School closed and was instructed by mentor to stay home.
- Worked on practicum report.

Wednesday 25, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Revised practicum report after receiving corrections and revisions from committee member.
- Contacted Mr. Smith to schedule room and time for defense.

Thursday 26, February 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Continued making revisions and formatting changes to tables and figures in practicum report.

- Job search.

Friday 27, February 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Literature review for OPT study.
- Reviewed and revised the discussion, conclusion, introduction, and abstract sections.
- Interview for employment opportunity with Children's Hospital Association.

Saturday 28, February 2015

- Attended UT Southwestern Career Fair for possible job openings and opportunities for interview.

Monday 2, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Contacted the director of THR Budgeting to further enhance my knowledge on the requirements needed in the preparation of a contract.
- Continued drafting result section for practicum report and possible questions that maybe asked during defense.
- Contacted HR department at UT Southwestern for interview over phone.

- Continued to draft the RCT for TURFs.

Tuesday 3, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Helped update the Trauma bulletin board.
- Helped neuron sit monitor with TBI study.
- Helped revise power point slide for TOPIC with current on-going research studies with inclusion criteria. Attended Trauma Outcome Performance Improvement Committee (TOPIC) meeting with representatives from orthopedic, emergency department, anesthesia, neurology and others with invested interest to discuss opportunity for improvement in patient care.
- Helped colleagues troubleshoot in excel and word documents.
- Attended TRACK meeting.
- Sent out meeting invite to all committee members with date, time, room, and location of my defense.

Wednesday 4, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.

- Helped prepare shipping of biologics to PI.
- Attended intrepid study site teleconference call.
- Continued working on practicum report.

Thursday 5, March 2015

- Continued working on practicum report.
- Literature review for verified and approved observation score system for the OPT study.
- Continued working on making minor edits to practicum report.

Friday 6, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Continued working on practicum report and formatting power point for defense.

Monday 9, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Helped with literature review and manuscript submission criteria for Platelets and Plavix study.
- Continued drafting result section for practicum report.

Tuesday 10, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Helped neuron sit monitor with TBI study.
- Revised the figures, results, and method section of report.
- Attended Trauma Staff meeting.

Wednesday 11, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Completed continuing review for NIRS study.
- Attended Trauma Outcome Performance Improvement Committee (TOPIC) meeting with representatives from orthopedic, emergency department, anesthesia, neurology and others with invested interest to discuss opportunity for improvement in patient care.
- Received hospital directory from various sites to contact the main trauma manager at each site to send brochure for all employees to register and attend the 17<sup>th</sup> Annual Trauma Conference.

Thursday 12, March 2015

- Attended Office Rounds with doctors and trauma department.



- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Contacted all THR sites for the upcoming Trauma Conference to disperse brochure through email. Contacted the conference coordinator for the availability and accessibility of presentations to the attendants; current count of attendants; selection of menu; which speakers have already submitted power point.
- Submitted a COI reminder to complete to all study staff on the NIRS study.
- Attended meeting with Dr. Newcomb to discuss the simulation study and reliability of scoring system during the study.

Friday 13, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Face to face meeting with committee member for question and answer on practicum report review.
- Pre-review from committee member received and started to make changes.
- Reached out to pharmaceutical sales representative for samples of the products in the upcoming randomized control trial.

Monday 16, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Attended simulation lab meeting.
- Completed, “Binge drinking for injured patient screening” flow chart.
- Continued revising practicum report.
- Attended simulation PI meeting for all study staff to complete CITI Training.

Tuesday 17, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Attended ROCK meeting.
- Practicum report review with committee member.

Wednesday 18, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Reviewed practicum report and resubmitted to committee members.

Thursday 19, March 2015

- Attended Office Rounds with doctors and trauma department.

- Reschedule subject site visit for 3 months for study.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Attended trauma simulation PI meeting for the OPT study
- Scheduled job interview with the HR at UT Southwestern.
- Prepared documents for study subject to complete and return by mail.
- Attended nursing symposium and poster seminar at THFW.
- Drafted the discussion, conclusion, introduction, and abstract sections. Revised the past sections drafted.

Friday 20, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Completed list of forms and surveys for UNTHSC.
- Reviewed new templates from THR e-IRB.
- Continued revising practicum report.
- Completed Survey for, “Does it even matter”.
- Attended speaker dinner for IV Acetaminophen.

Monday 23, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.

- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Continued revising practicum report.

Tuesday 24, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Started to draft abstract to submit to the research symposium at THFW.

Wednesday 25, March 2015

- Attended Office Rounds with doctors and trauma department.
- Reviewed thesis and power point outline for defense with major professor. Made all corrections, scanned and emailed copy to major professor as requested.
- Resubmitted practicum report to all committee members.
- Helped a colleague troubleshoot problems with power point that was due by noon.

Thursday 26, March 2015

- Attended Office Rounds with doctors and trauma department.

Friday 27, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Submitted resume to Alcon for possible job opening.
- Continued working on case report form for the OPT study.

- Continued making power point outline for defense.

Monday 30, March 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Continued working on power point for defense and making minor adjustments on practicum report.

Tuesday 31, March 2015

- Attended Office Rounds with doctors and trauma department.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Three month subject visit for ongoing study.
- Continued working on power point presentation for upcoming defense.

Wednesday 1, April 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Phone interview with Baylor Hospital.
- Continued working on power point presentation for upcoming defense with major professor at UNTHSC.
- Attended teleconference meeting with Intrepid site call.
- Attended faculty dinner with all guest speakers for the 17<sup>th</sup> annual trauma conference.

- Reviewed defense presentation with major professor.

Thursday 2, April 2015

- Attended and volunteered at the 17<sup>th</sup> annual trauma conference.
- Received per-reviewed practicum report from committee member and made all corrections or adjustments.
- Continued working on power point for defense.

Friday 3, April 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily inpatients list in TICU for the Vitamin D study. There were no eligible patients to enroll.
- Continued revising and editing power point for defense.

Monday 6, April 2015

- Attended Office Rounds and Multiple Disciplinary Rounds in TICU.
- Scanned the daily in-patients list in TICU that meet inclusion and exclusion criteria for Vitamin D Study. Consented subject in TICU, acquired all required signatures, scanned & made two copies of consent, and provide one completed consent to in-patient subject.
- Practice run for defense at UNTHSC with major professor.

Tuesday 7, April 2015

- Filled out all Forms and obtained all required signatures.
- Defense at UNTHSC.

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