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ABSTRACT

Introduction: Data collection is vital for the success of a clinical research project. The purpose of this practicum was to address the inadequate data collection by the Texas Emergency Medicine Research Associate Program (TEMRAP) research associates (RAs). The primary goal was to incorporate a more efficient training method to reduce the RAs' error rate in the documentation. The secondary aim of this experiment was to determine if RAs' knowledge of clinical research studies and/or their self-confidence when enrolling a patient had an effect on quality of data collection and if these variables could be improved by a new training method.

Methods: A randomized clinical trial was used to evaluate the efficacy of simulated clinical research enrollment training as a teaching and/or learning method to reduce the error rate in submitted research packets by RAs. The returning RAs were randomized into an intervention group with new training (simulations) and a control group with current training (didactic presentations). A self-confidence survey and a knowledge questionnaire were completed by RAs pre/post-training and one-month follow-up. Quality of data collection was measured by comparing the error rates of data collection in completed clinical research enrollment packets submitted by the RAs in the intervention group versus the control group.

Results: Results showed no statistically significant difference in the level of knowledge, confidence or error rates between the patient enrollment simulation (intervention) group and the didactic presentations (control) group after their respective training ($p > .05$). However, there

was a statistically significant increase in knowledge and confidence post-training in patient simulations group. A significant association was present between confidence and error rate but not between knowledge and error rate for research associates in either training group.

Conclusion: Clinical simulation training was not a significantly more effecting training method compared to current TEMRAP didactic presentation training. Even though knowledge and confidence did increase post-training there was no significant difference between the two types of training. Future experiments should explore the possibility of combining the two types of training and observing other potential variables affecting the quality of data, such as research associates' motivation. Additionally, the need for a larger sample size and enrolling participants with no prior research experience should be explored for significant results.

QUALITY ASSURANCE TRAINING: WILL NEW TRAINING
INTERVENTION IMPROVE DATA COLLECTION OF THE
TEXAS EMERGENCY MEDICINE RESEARCH ASSOCIATE
PROGRAM (TEMRAP)?

INTERNSHIP PRACTICUM REPORT

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For the Degree of

MASTERS OF SCIENCE
IN CLINICAL RESEARCH MANAGEMENT

By

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CHAPTER I.

INTRODUCTION

The primary purpose of this practicum project was to develop a solution to the Texas Emergency Medicine Research Associate Program (TEMRAP) Research Associates (RAs) problem of inadequate data collection by targeting their current training method. Clinical research relies greatly on using quality data in order to advance the field of medicine. Poor quality data with high error rates cannot be used as reliable data and is detrimental to the efficacy of clinical research studies. Previous knowledge pertaining to the importance of clinical data emphasizes that during a clinical research study, it is imperative to collect precise and concise data to develop the primary and secondary endpoints. A prior study carried out by Curcin, Vasa, et al, stressed that the quality of data has a direct impact on the values generated by the statistical plan (Curcin, Vasa, et al, 2014). A proposed new training to improve data collection and reduce error rates focused on the use of standardized patients (SP) with RAs completing a simulated patient enrollment interaction. Moreover, previous research investigating effective methods for training clinical employees suggested self-confidence and knowledge of related material are important in improving clinical competence (Culpa-Bondal, 2016; Baker, 2016). As such, RA's confidence during patient enrollment and knowledge of research studies were chosen to be analyzed throughout the experiment. The implementation of this new training program was formulated to: (1) Increase the confidence of Research Associates during subject enrollment as compared to the current training system. (2) Increase the amount of knowledge pertaining to the

clinical research studies as compared to the current training system. (3) Improve overall quality of data collection as compared to the current training system. In order to explore these goals, we devised a randomized control trial with RAs being separated among a control group with current training and an intervention group with new training. Additionally, the study sought to identify if the quality of data collection by TEMRAP RAs was significantly associated with knowledge of the study and if the quality of data collection by TEMRAP RAs is significantly associated with self-confidence. The results of the study were used to ascertain if clinical simulations were an effective training/learning method for RAs to improve their quality of data collection. This clinical research practicum was completed at the University of Texas Southwestern (UTSW) Medical Center over a six-month period, and Dr. Ava Pierce served as the Principal Investigator.

CHAPTER II.

BACKGROUND AND LITERATURE

Clinical research, as defined by the National Institutes of Health (NIH), involves human subjects partaking in patient-oriented research, epidemiological studies, behavioral or medical intervention studies, and health services research (NIH, 2017). The value of clinical research and the importance of patient participation originated from a need to develop, implement medical advances, and generate more efficacious treatment modalities (Tohid, *et al.*, 2017). Clinical research became the foundation for advancing our knowledge in diagnosing diseases and in the practice of preventative medical treatment (Niederhäusern, *et al.*, 2017). In the United States, the clinical research enterprise was prominent shortly after World War II because of the increasingly complex and sophisticated medical research designs. One of the earliest randomized control trials, the Salk polio vaccine field trial of 1954 among others led to an increasing demand in formal training for conducting clinical research. A concrete curriculum in the design and execution of clinical research only recently emerged in 1980 (Teo, 2009).

As the field of clinical research continues to grow the novelty of training programs leaves room for improvement and modification. A common goal among clinical research training is efficient patient enrollment into prospective studies, nurturing self-confidence for interacting with a variety of individuals and procurement of high-quality data (Mckenzie, Tilashalski, Peterson, & White 2017; Ioannidis, 2016). The insufficient patient enrollment into research studies has significant implications (Galli, *et al.*, 2014), such as loss of statistical power,

limited generalizability, and even increased duration of study (Burns, Magyarody, Jiang, & Wald, 2011). Many factors influence an insufficient accrual of patients into clinical research studies, such as inadequate staff efforts, investigator inexperience, or challenging logistics in protocol implementation (Ross, *et al.* 1999; Fayter, Mcdaid, & Eastwood, 2007). Overall, the “quality”, as it pertains to study design and implementation in clinical research, for academic purposes is diminished (Niederhäusern, *et al.*, 2017). The quality of data generated is also dependent on Clinical Data Management (CDM) and is a critical component to the outcome of the study. The process of collecting, cleaning, and managing subject data in accordance to ethical principles describes CDM (Krishnankutty, Kumar, Moodahadu, & Bellary, 2012). The investigator’s primary objective through CDM is to provide high-quality data by keeping the error rate and missing data as low as possible and gather maximum data for analysis (Gerritsen, M. G. et al 1993). The acquisition of low quality research may result in misleading findings but may also compromise safety and rights of subjects (Niederhäusern, Guyatt, Briel, & Pauli-Magnus, 2018; Juni, 2001).

A need for talented investigators may be met by fostering interest in clinical research at earlier stages (Teo, 2009). In an effort to do just that, the University of Texas Southwestern Medical Center’s Emergency Medicine Department created the Texas Emergency Medicine Research Associate Program (TEMRAP). The purpose of the program is to support clinical research activities of the UTSW Department of Emergency Medicine (DEM) and provide an educational experience in clinical research for undergraduate students and/or other individuals who have a future interest in medicine (UTSW, 2018). Research Associates (RAs) are tasked with recruiting patients and collecting data for active clinical studies at DEM. Since the establishment of TEMRAP at UTSW, RAs have been responsible for carrying out the duties of

screening potential subjects for clinical research, enrolling patients into clinical research studies, and successfully collecting valuable data for the clinical investigators. The expectation of the current training program is that it will be sufficient for RAs to complete their duties with minimal errors. Yet, many enrollment packets have been submitted with various types of error. Previous information gathered by UTSW employees involved in TEMRAP have identified the most common sources of errors emerge from: i) misinterpretation of study protocol, ii) inaccurate, ineligible, or incomplete data recording, iii) loss of data, and iv) inadequate training.

TEMRAP has three main phases (i. credentialing, ii. training, and iii. researching). Once the final stage of training is reached the RA can participate in clinical research. The opportunity for the RA to directly participate in the performance of clinical research, observe ED operations and interact with clinical personnel is a unique quality of this program. In return, the RA provides UTSW DEM Clinical Research Division assistance in identification, recruitment, consenting, and collection of data from patients in the ED. The training involved for these RAs is comprised of an all-day orientation, supplemented by PowerPoint lectures covering: expectations, professionalism, human subjects research protection, HIPAA, standard precautions, and research studies. A final quiz is given corresponding over the topics covered in the orientation to test the knowledge of RAs and as a standard for determining that the RAs are ready to work in a clinical setting. Supplemental training sessions are also provided to the RAs by their group leader as needed.

According to the National Training Laboratories' *Pyramid of Learning* (Appendix D), the individual only retains about 10-20% of information learned through lecture, reading and audiovisual. An individual involved in learning, where they partake in collaborative learning tends to improve the retention of information (Masters, 2013). Additionally, the problem with

educational material and didactic educational meetings is these interventions have been shown to have little to no effect in improving RA's performance of required tasks (Bero, *et al.*, 1998). Another problem with these type of training methods is they do not provide employees an environment to freely practice what they have learned and make mistakes with little consequences. Consequently, confidence in proper documentation and other techniques may also be affected during official shifts. The current training method of the TEMRAP, analogous to the previously mentioned interventions, may affect RAs performance of required tasks. As demonstrated in a 2017 survey of the TEMRAP RAs a number of them feel a lack of confidence when approaching patients, physicians, and nurses (Appendix C). Students are exposed to an unfamiliar environment, where a lack of confidence plays an important role in completing necessary duties (Karimollahi, 2012). The lack of self-confidence has been shown to be detrimental to communication skills and the attitudinal learning process (Geoffrion *et al.*, 2013). As such self-confidence has been reported as being a key component for effective clinical performance when interacting with patients (Porter, Morphet, Missen, & Raymond, 2013). The quasi-experimental pre-test/post-test design done by Culpa-Bondal and Baker identified an effective manner to measure self-confidence of health care employees (Culpa-Bondal, 2016; Baker, 2016). Additionally, the practicum's emphasis was in CDM because it is considered a critical phase in clinical research. Proficiency in CDM permits the generation of high-quality, reliable, and scientifically sound data from clinical trials. Yet, the improvement of such diverse skill sets cannot be done without a formalized curriculum or education (Teo, 2009).

A possible solution to address these previously mentioned issues is to modify TEMRAP training. Previous research has shown the most effective interventions with other clinical employees (nurses, medical resident, clinician technicians, etc.) involves interactive educational

meetings, where feedback is provided on clinical practices, with patient mediated interventions (Bero, *et al.*, 1998). Even in the 1960s researchers recognized the importance to having repeated practice opportunities combined with feedback (Motamedi & Sumrall, 2000). The use of human simulations in patient mediated interventions can be an educational strategy for the achievement of learning how to apply classroom education into clinical context because of the use of active learning (Cioffi, 2001). These simulations aim to replicate the reality of clinical situations, while offering skills-based clinical experience in a safe and secure environment (Fowler-Durham & Alden 2007). Christiaens *et al.* explain that role playing can easily be adapted to the clinical setting because of the flexibility of the technique. Furthermore, simulation education permits the student the ability to repeat practice in order to consolidate learning and develop competence (Issenberg *et al.* 2005, Hogg *et al.* 2006, Kardong-Edgren *et al.*, 2008), use instructor feedback and video debriefing (Fanning & Gaba 2007, Kuiper *et al.*, 2008). If the modified training intervention is effective, it could bolster the TEMRAP's curriculum and commitment in supporting clinical research activities at UTSW DEM (UTSW, 2018).

SPECIFIC AIMS

Training for employees working in a clinical setting can be a difficult topic to address and finding the most effective teaching/learning method can be complex. Each RA's goal during their weekly 4-hour shift is to enroll patients and correctly complete clinical research study data collection packets. The quality of the data collected is key to a project's success. There are multiple variables attributing to TEMRAP's RAs submission of study enrollment packets with errors. Even though there are various types of errors made by RAs, what could be the actual

cause of committing these discrepancies? A list of possible causes includes: i) lack of appropriate knowledge about the clinical research study being presented to a potential subject, ii) lack of confidence felt by RAs when interacting with a patient, iii) inadequate training, and iv) experience carrying out duties of an RA. The intended clinical experience simulation training was developed to explore the possibility of improving the quality of data collected by RAs. The main issues addressed were: 1) TEMRAP RAs' poor data collection by providing an evidence-based training method, 2) determine if confidence or, 3) knowledge correlates with error rates.

Hypothesis: The evidence-based simulation training is a more effective method than the standard training and will thus have a significantly lower error rate. Alternative hypotheses were the patient simulation training method would significantly reduce the number of: 1) data collection errors made by RAs, 2) increase their confidence, and 3) increase their knowledge of research studies as compared to the RAs who completed the didactic presentation training method. Moreover, there is a significant association between level of confidence and error rate as well as there is a significant association between level of knowledge and error rate. The null hypotheses of the project were no significant difference in the following data: 1) collection error rates, 2) level of confidence and 3) knowledge of research studies between the intervention (patient simulation) group and the control (didactic presentations) group. Additionally, there is no significant association between level of confidence and error rate as well as there is no significant association with level of knowledge and error rate.

Aim: The primary aim of this experiment was to determine if there is a significant association between the type of RA training method and the quality of data collection.

Secondary aims were to observe if confidence in interacting with subjects, and/or knowledge of the clinical research study affected the overall quality of data collected by the RAs. Other

features of the study were designed to determine if confidence or knowledge were increased by the new training method and if it correlated with error rates. The outcome of the study would determine if a significant difference existed in the error of RAs in the intervention training method versus the RAs in the control training method. If the simulation scenarios of clinical research enrollment assisted the RAs to collect higher quality data, it would increase the overall efficacy of clinical research studies' results. This training method could also apply to future RA training for any new students participating in TEMRAP.

The following research questions were addressed in this study:

1. How effective is standardized patient simulation training as a method of teaching and learning compared to current training system?
2. Does patient simulation training increase self-confidence?
3. Does patient simulation training increase knowledge over clinical research studies?
4. Does RAs' self-confidence affect error rates?
5. Does RAs' knowledge over clinical research studies affect error rate?

SIGNIFICANCE

The need for technical expertise is crucial for conducting clinical research as it has grown in complexity and scale. Examples of such skills include data analysis, writing skills and ethical conduct during interactions with an array of entities (such as human participants, healthy individuals or pharmaceutical companies) (Teo, 2009). This project implemented a new training method to address the problem of poor quality data collection with high error. The purpose of

the new training system was to improve the RAs confidence, knowledge and documentation skills. It would be beneficial for the quality of data and the continued development of clinical research for RAs to provide data that is accurate, reliable, and fit for use in clinical research studies. Even though there are many possible factors influencing a RAs' ability to collect high quality data this study targeted the type of RA training. In order to get a better understanding to the causes of poor data collection by RAs this study also examined the RA's confidence and knowledge. These factors were believed to be associated with data collection.

While increasing Emergency Department RA's quality of data collection is the focal point, providing clinical experience can foster the growth of clinical skills in students who desire to pursue a career in medicine. According to James Wyngaarden's influential article of 1979, "The Clinical Investigator as an Endangered Species," the number of clinical investigators has greatly decreased, threatening the future of biomedical research and the power of American medicine (Wyngaarden, 1979). Reducing the error rate in data collection can provide the Emergency Department increased resources for use in clinical research studies and advancement in the field of medicine. The Clinical Research Division of UTSW will have an enhanced enrollment profile to present to sponsors when consideration as a performance site for clinical trials is presented. There will be an increased capacity to collect valid data to be used for research by having a multitude of competent RAs. More importantly, the opportunity to mentor, train and educate future clinicians and researchers is important for advancing the medical field.

MATERIAL AND METHODS

a) Design

In this study, a randomized control trial (RCT) was used to test the efficacy of new subject enrollment simulation training versus current didactic educational presentation training on quality of data collection by the TEMRAP RAs. Since the study involved human subjects, official approval letters were obtained from the UTSW and UNTHSC IRBS (Appendix E). All of the RAs in this program were required to participate in a retraining as part of the TEMRAP orientations, thus convenience sampling was necessary. Verbal consent was obtained from RAs willing to participate in the study. Their involvement was voluntary and anonymous. Those who chose to participate in the study completed the confidence survey and the knowledge questionnaire. Prior to launching the study, three orientation days for the training were selected and two separate conference rooms were reserved at UTSW campus. Over the course of the three training sessions, the intervention training was held in one room and the control training was held in the separate conference room.

b) Population

The subject population was drawn from the TEMRAP RAs enrolled for the fall 2018 semester.

1. Inclusion Criteria:

- a. Texas Emergency Medicine Research Associate Program (TEMRAP) Research Associates (RAs) enrolled for the Fall Semester of 2018
- b. One+ semester(s) of research experience and are fully credentialed.

2. **Exclusion Criteria:**

- a. new incoming TEMRAP RAs
- b. Not fully research credentialed and cannot be trained during the designated orientation dates

c) Measurement Tools and Measures

A multiple-choice Knowledge Questionnaire was developed by researchers and TEMRAP leaders, covering the current research studies as well as general information about clinical research such as HIPAA, GCP, Professionalism, and Human Subject Research Protection (Appendix A). The maximum score was 23 or 100%. A score less than 18.4 or 80% was considered failing and a score greater than or equal to 18.4/23 or 80% was considered passing according to established TEMRAP standards. The Knowledge of Clinical Research Studies Questionnaire was distributed pre-training, post-training, and follow-up one month after having experience in a clinical setting to both control and intervention groups.

A confidence survey was developed by the researchers to evaluate the RAs' confidence during a pod shift patient enrollment interaction. A pod shift includes the standard patient enrollment tasks for an RA in the emergency department. The measurement was an adaptation from the confidence survey used in Culpa-Bondal and Baker SP Learning Outcome Assessment (Culpa-Bondal, 2016; Baker, 2016). The Confidence Survey (Appendix B) consisted of eight-item Likert Scale, responses ranging from 1 to 5, strongly disagree, disagree, neutral, agree and strongly agree. The maximum total score was 40 (very confident), scores indicating a low confidence were less than 24 and scores indicating a high confidence were greater than or equal to 24. Higher scores indicated a greater level of self-confidence. The self-confidence survey was distributed pre-training, post-training, and follow-up one month after having experience in a

clinical setting to both control and intervention groups. In analysis confidence score for individual RA was treated as a continuous number.

A method to measure quality of data collection was developed by the researcher to evaluate RAs' error rate after post-training. In order to obtain a measurement for quality of data, error rates were used, and an error was defined as any illegible data, inaccurate data, or incomplete data (Appendix C). The analysis of control and intervention groups study enrollment packets were examined for error rates as collected weekly post-training for a total of three weeks. The error rates were calculated by the number of packets with errors divided by the number of packets completed by an individual RA. A weekly mean value was then calculated weekly for RAs in both groups and data was sent to UTSW biostatistician for analysis.

d) Procedure

The RCT compared the number of error rates between two randomized groups of RAs. The participants were only randomized after verbal consent was obtained and inclusion/exclusion criteria were met for the study. The blocked randomization provided a better guarantee that the two groups were equal in the number of participants. In combination with blocked randomization a double blind was implemented to help avoid possible bias in the selection and allocation of patients arising from the predictability of treatment assignments (Deng & Graz, 2002). The RAs were blinded to which group they would be placed in as they were told they would be in either training group one or group two. During the data collection, de-identification was accomplished by removing names and replacing with numbers to ensure confidentiality and privacy. The most effective method to keep confidentially was reported as giving random numbers to participants to identify questionnaires for paired analysis (Culpa-

Bondal, 2016; Baker, 2016). The data was stored on to an excel sheet on a password-protected computer at UTSW.

The intervention training focused on RAs participating in SP clinical research enrollment simulations followed by constructive feedback from a TEMRAP leader with one+ years of clinical research experience. The training material used was a condensed versions of the fall 2018 clinical research studies (master packets) as a script. The master packets were created to be used for the patient enrollment scenario in the intervention group. The packets included current clinical research studies and specific tasks. Two different versions of these “master packets” were used and each pair of RAs were responsible for completing one of the two master study enrollment packets. The “master packets” included a one formal consent study with HIPAA authorizations forms, one verbal consent study, and corresponding fall 2018 research study tasks. Prior to the simulated patient enrollment encounters, RAs were debriefed about the new training and were demonstrated a role-playing scenario of patient enrollment with both master packets. The RAs were then paired up and each RA had a chance to play the role of simulated patient and RA during the training. The RAs playing the role of simulated patient were briefed about the scenario and the encounter.

The planned intervention with patient enrollment scenario was adapted from Cupla-Bondal and Baker experiment (Culpa-Bondal, 2016; Baker, 2016). The main reason for choosing this type of new training was previous studies revealed patient simulations have improved confidence and knowledge of employees in a clinical setting (Culpa-Bondal, 2016; Baker, 2016). RAs in the intervention group participated in a single simulation scenario of patient enrollment with subsequent feedback after the conclusion of their simulation. The TEMRAP leader was instructed to review the master packet submitted by the RA and give

feedback on presentation of material by RA as well as point out errors made in the study's task. Supplemental TEMRAP leaders were used as needed for observing the interactions between RA and simulated patient. The goal of this training was to successfully obtain UTSW Clinical Research Division standard for valid study information (Figure 4) during the approximately 30-45 minutes encounter. Once simulations were completed, the confidence and the knowledge test were administered to each RA.

The control group received the current training method which included reviewing didactic material as a PowerPoint presentation. The classroom lecture series covering each individual study with the RAs was led by a leader in TEMRAP with one+ year(s) of experience. The designated orientation leader reviewed each task of every clinical research study in rotation for the fall 2018 with the RAs. RAs who could not attend any of the training sessions were excluded from the study as to avoid any possible internal bias. An excel sheet was created to keep track of knowledge scores and confidence ratings. The RAs were assigned an identification number (S-number) used during the project. They used their S-number when completing the knowledge questionnaire, confidence survey, and when submitting research study packets, we made them de-identified.

Additionally, a pre-test/post-test design was used to investigate the impact of these training methods on RAs' self-confidence and knowledge over research study tasks across groups. Changes in the RAs' knowledge over the clinical research studies as well as self-confidence pertaining to the patient enrollment process were recorded using a knowledge questionnaire and self-confidence survey at three intervals during the study. These RAs completed a pretest self-confidence survey and knowledge questionnaire before respected exposure to either intervention or control training. Additionally, a post-test knowledge

questionnaire and confidence survey were distributed immediately after exposure to training and electronically one month after completing actual shifts in the hospital. The calculated values for knowledge and confidence were subsequently used to determine if a significant association existed between either or both these variables and error rate.

The data collection spans three weeks in the fall 2018 semester. During active shifts for the fall 2018 semester each RA submitted research study data collection packets from pod shifts. Any mistakes found in submitted packets were recorded in an excel sheet and the entire corresponding packet was deemed as an error. A score of ≤ 0.2 was considered a low degree error rate, 0.25-0.4 was an intermediate degree error rate, and $\geq 0.5+$ was a high degree error rate was predetermined by UTSW Biostatistician. Regardless, all these packets were considered as poor-quality data and retraining for the individual RA was required only for those in the intervention training group. Once all the research study packets were received and designated as either correct (no mistakes made in data collection fields) or error, an error rate was obtained from the number of error packets divided by total number of packets completed by the individual RA. This data was handled by one designated TEMRAP leader. Additionally, this leader noted the type of errors made, the specific research study corresponding to the error, and total weekly errors. The error rate was calculated as a percent of the error ratio and a mean total was obtained for control and intervention groups. In order to assess the effectiveness of the patient enrollment simulation training, the mean error rates in data collection between the intervention group and the control group were obtained and analyzed further using a multiple variant statistical test as designated by the UTSW biostatistician. All collected survey packets received by October 3rd were considered for calculation of error rate.

e) Analysis

A fixed, convenience sample of Returning TEMRAP RAs were used in this study and no formal power analysis was performed because of small sample size. The RAs were randomized to either the control group or intervention group using blocked randomization program and a 1:1 allocation ratio. The program (<http://www.quantitativeskills.com/sisa/calculations/order.htm>) was run six times to get 36 assignments. Participant characteristics (intervention, control) and study outcomes (error rate, knowledge, and confidence) were summarized with descriptive statistics. Categorical variables were presented as frequency counts and percent and continuous variables were summarized as mean and standard deviation or median and percentiles.

To compare outcome measurements for pre, post and one-month follow up questionnaires/surveys between groups and within groups, mixed-effects linear model repeated measures analysis was performed. In the comparisons of one-month follow-up with pre or post-training scores only RAs with one-month values were included in the final analysis. These models have fixed effects for comparing the two groups and for comparing pre and post measurements within groups (knowledge and confidence). The students were modeled as a random effect. Pairwise comparisons, between and within groups, and 95% confidence intervals (CI) were derived from the differences of least square means (LSM) estimated from the mixed-effects model.

Non-parametric tests were used to analyze knowledge and confidence scores, since the data was not consistent with assumptions of normality that are needed for parametric tests. More precisely for knowledge and confidence data the Wilcoxon Rank Sum test was used to compare the pre-training and the differences between the two study groups and the Wilcoxon Signed-Rank test (a paired test) was used for within group comparison of the pre-training versus post-

training scores. In order to analyze any trends (worse, no change, or better) in the difference for the total pre, post, and one-month follow-up confidence scores for each individual item a Cochran-Armitage Trend was used, and the Fisher's Exact test was implemented to observe if a difference existed per item among the two study groups. A two-sided 0.05 significance level was considered statistically significant. Additionally, an analysis of participants race/ethnicity and gender was done using a Fischer's Exact Test and for age a Wilcoxon Rank Sum test.

The mean total error rates among the intervention group and control group were compared and analyzed using the non-parametric Wilcoxon Rank Sum Test. A further comparison of error rate per week among groups was done as well using the Wilcoxon Rank Sum Test. Since there was only one RA who submitted enrollment packets consecutively during the three-week collection period modifications to analysis were necessary. The UTSW Biostatistician used RAs in the first week (A) and RAs in the last week (B) to calculate the difference in the error rate (B-A).

To evaluate the association between RAs' confidence score and error rate or RAs' knowledge of clinical studies and error rate, the UTSW Biostatistician implemented a non-parametric Spearman Correlation Test.

RESULTS

a) Patient Demographics

The target population was research associates in the TEMRAP. A total of 115 research associates were enrolled in the TEMRAP for the 2018 semester (August 1- December 5). They were pre-screened and only 37% met the inclusion criteria for enrollment into the study. The

RAs are required to participate in a brief retraining upon returning to TEMRAP for a consecutive semester. The study took place over one semester, and total of 43 returning TEMRAP RA were identified to meet inclusion/exclusion criteria. By the time the training dates were set, 31 RAs were successfully enrolled for the study and informed consent was obtained verbally. However, once the study ended, a final sample of 25 RAs successfully completed the pretest, posttest surveys and questionnaires as well as submitted clinical research enrollment packets. Only 18 RAs completed follow up tasks in addition to pretest and posttest (Figure 1).

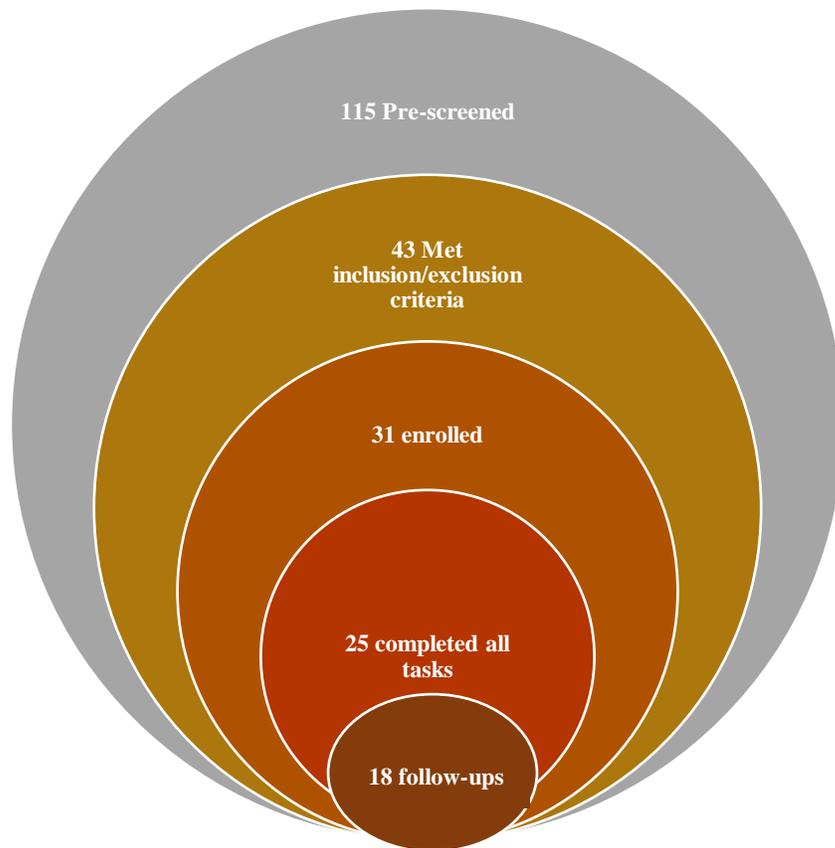


Figure 1: Subject Enrollment and Final Participation Profile

The mean age of participants in the intervention group was 21 with a standard deviation of 1.88 and for the control group mean age was 21 with a standard deviation of 3.01. Sixteen percent (16%) of the subjects in the intervention group and twenty-four percent (24%) in the control group were female equaling forty percent (40%) of total participants (Table 1 & Table 2).

In regard to race and ethnicity for all participants, about 40% were White, 4% were Black, 8% Mixed and 48% were Asian. 100% percent were of Non-Hispanic ethnicity. The analysis of demographic data by the Fischer’s Exact test demonstrated no difference between the intervention group and the control group in terms of gender (p=0.24), race and ethnicity (p=0.41). The Wilcoxon Rank sum test for age indicated no significant difference between the intervention group and the control group (p=0.39).

Table 1: Demographic Information for **Intervention** Participants

Variable	N	Mean	Std. Dev.	Median	Min	Max
Age (Intervention)	14	20.9	1.88	20.0	20	27
Gender	Frequency	Percent		Race/Ethnicity	Frequency	Percent
Female	4	29.0		NH-White	7	50.0
Male	10	71.0		Black	0	0
				Asian	6	43.0
				Mixed	1	7.0

Frequency indicates number of Subjects; N = number of subjects
 NH = Non-Hispanic

Table 2: Demographic Information for **Control** Participants

Variable	N	Mean	Std. Dev.	Median	Min	Max
Age (control)	11	21.7	3.07	21.0	18	28
Gender	Frequency	Percent		Race/Ethnicity	Frequency	Percent
Female	6	55.0		NH-White	3	27.0
Male	5	45.0		Black	1	9
				Asian	6	55.0
				Mixed	1	9.0

Frequency indicates number of Subjects; N = number of subjects
 NH = Non-Hispanic

The participants were allocated to either the intervention training group or the control training group by use of a blocked randomization program. Twenty-five knowledge questionnaires and confidence surveys were included in the analysis. The RAs whose information was collected and successfully used for the study included 16 (64%) males and nine (36%) females. The goal was to have at least 15 RAs in each group, but the set objective was not met because of drops from the program due to scheduling conflicts with other courses or inability to successfully make one of the offered training sessions.

1) Intervention Group - consisted of 14 returning RAs who all gave consent.

2) Control Group - consisted of 11 returning RAs who all gave consent.

b) Results

In regard to the error rates, a total of 23 RAs submitted 101 clinical research enrollment packets during a three-week data collection period. The median for each group was used rather than the mean to report the results of the data analysis because the data was not normally distributed. The median error rate for the intervention group was 0.30 and for the control group was 0.37. The distribution of error rates for the intervention group had a wider variation of errors (0-78%) as compared to control group (29-50%) (Figure 2).

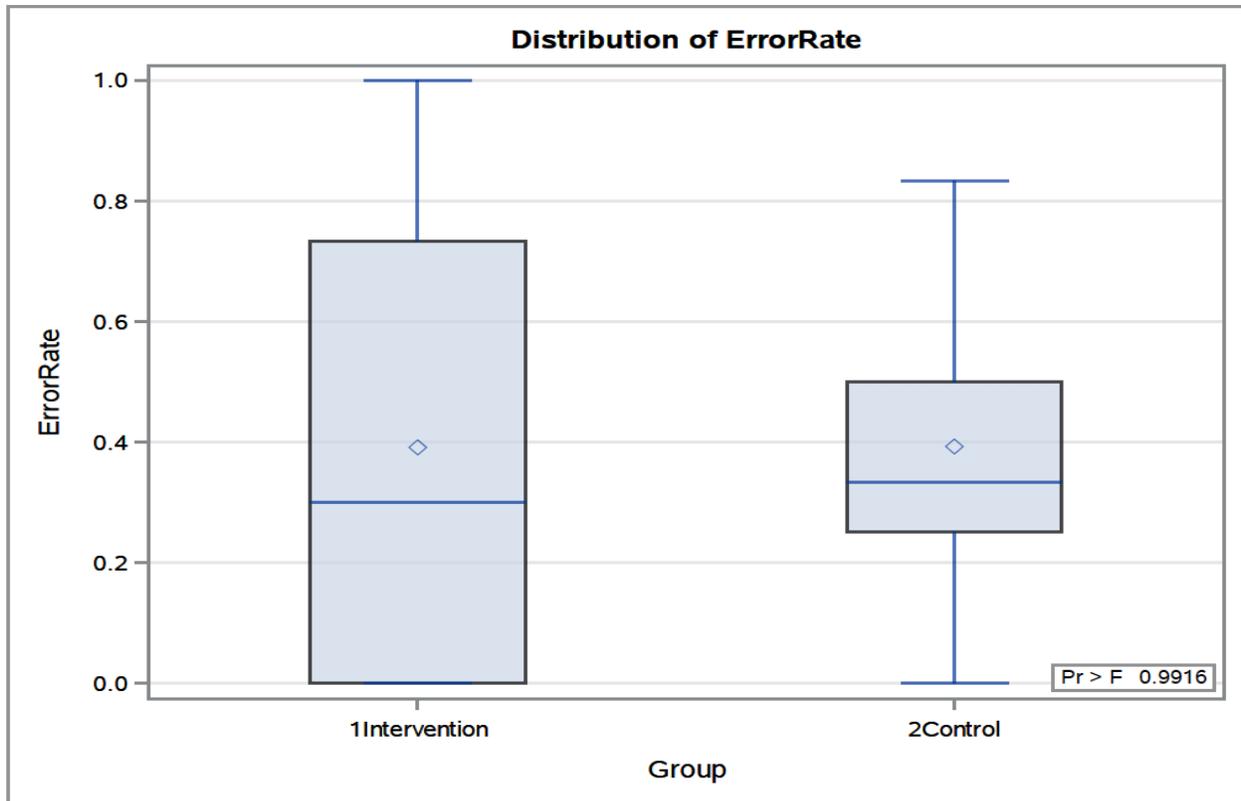


Figure 2: Error Rate Variation Range for Intervention vs. Control Groups

The results for the error rate data was no statistically significant difference existed across training groups ($p=0.77$). As for the participants in the study, 50% of the RAs in the intervention group demonstrated a low error rate and 33% made no errors in submitted packets. A total of forty-two percent (42%) exhibited an intermediate error rate, eight percent (8%) had a high error rate, and seventeen percent exhibited 100% error rate (Figure 3). As for the RAs in the control group eighteen percent (18%) demonstrated a low error rate and 1% scored a perfect score. A total of forty-five percent (45%) exhibited an intermediate error rate, 36% exhibited a high error rate, and zero of the participants had a 100% error rate (Figure 4).

High Error Rate vs. Intermediate Error Rate vs. Low Error Rate

Intervention (N=12)

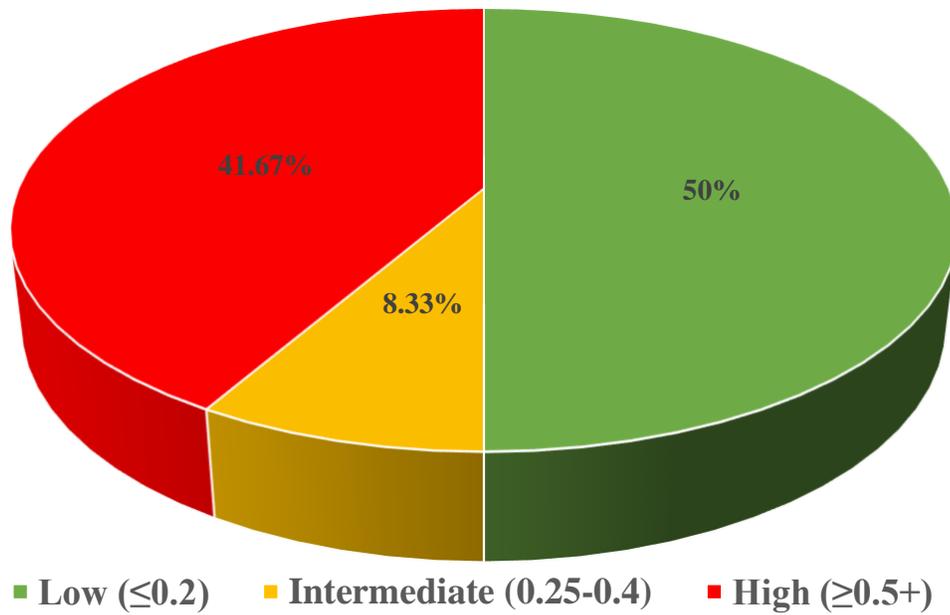


Figure 3: Intervention Group Degree of Error Rate

High Error Rate vs. Intermediate Error Rate vs. Low Error Rate

Control (N=11)

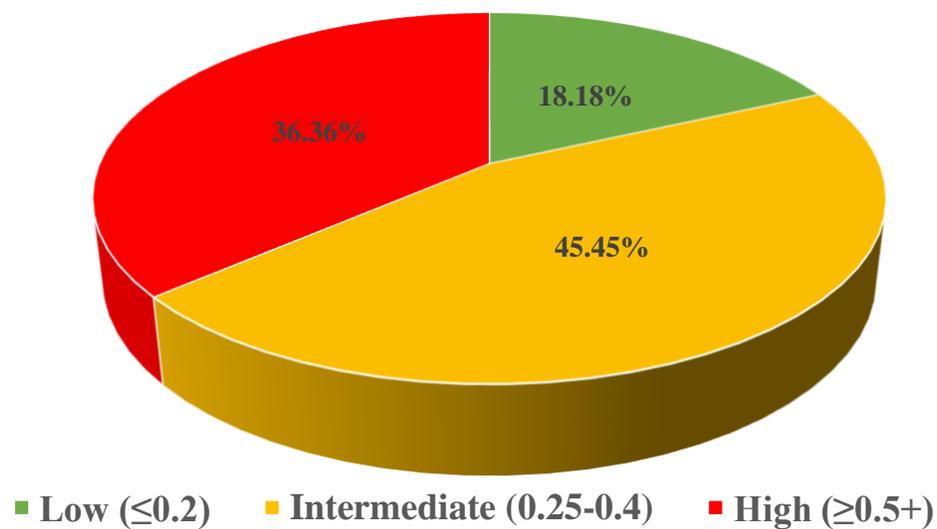


Figure 4: Control Group Degree of Error Rate

Results for the comparison of error rates per week (B-A) across training groups for the improvements (differences) were not statistically significant (Wilcoxon Rank Sum $p=0.72$). As for the within groups the paired differences are not quite significant. The intervention group had a median of -0.08 in the direction of improvement, with a borderline significant difference ($p=0.06$). The control group had a median of -0.33 indicating a similar but weaker improvement and a non-significant difference ($p=0.16$). For across training groups further data analysis for week one versus week two, week one versus week three, and week two versus week three was done by UTSW Biostatistician. The sample sizes for the within training groups were very small and as such there were no statistical differences or trends that were detectable.

Confidence

The modified confidence survey was used to demonstrate the confidence level of RAs in completing required tasks and enrolling patients into studies. The maximum score for each survey question is five and the lowest is zero. For the pre-training confidence survey participants in the intervention group had a mean score of 4.15 per question and the participants in the control group had a mean score of 4.19 per question, indicating a high baseline of confidence for both groups, thus limiting the capacity for improvement. There was no significant difference in pre-training confidence across the two training groups ($p=0.39$). For the post-training confidence survey participants in the intervention group had a mean score of 4.56 per question and the participants in the control group had a mean score of 4.61 per question. There was no statistically significant difference in post-training confidence scores across training groups ($p=0.62$) (Figure 5). The intervention group mean total pre-training confidence score was 33.14, with a standard deviation of 2.88, which increased significantly post-training to a mean of 36.50 with a standard deviation equal 2.56 ($p=0.02$). The control group had a mean total confidence

score of 34.36 with a standard deviation equal to 4.56 pre-training which increased significantly post-training to a mean of 36.91 with a standard deviation equal to 4.00 ($p=0.002$) (Figure 6).

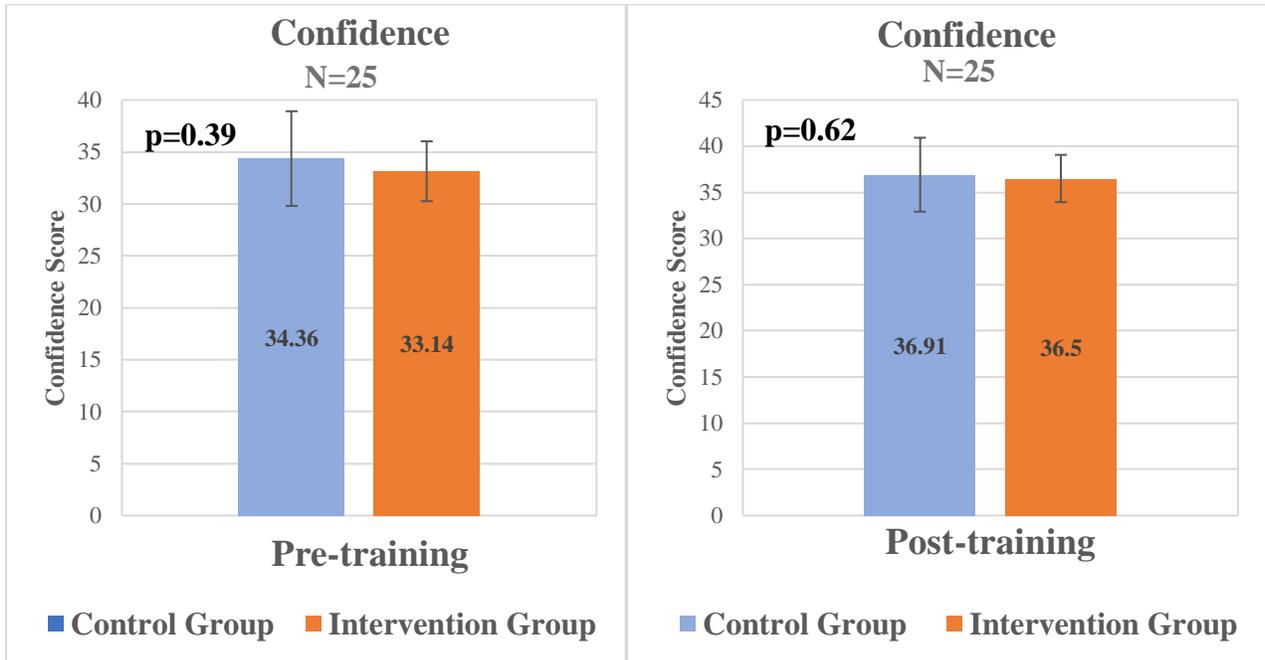


Figure 5: Comparison of Across Groups Confidence Survey Scores Before and After Designated Training

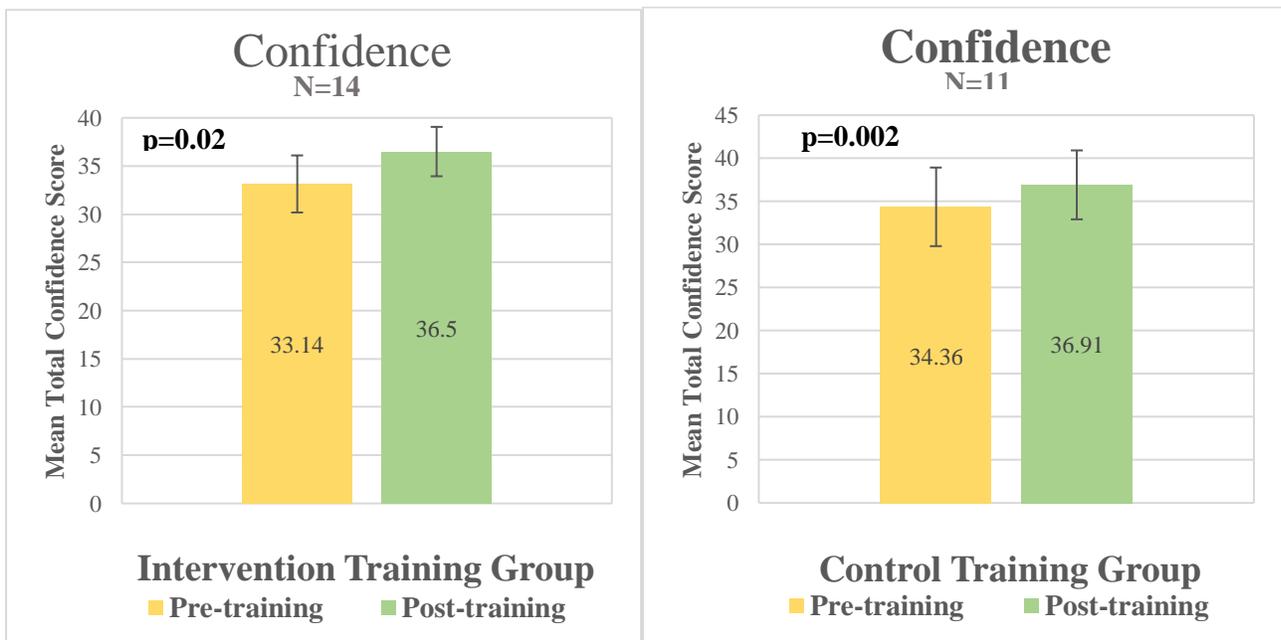


Figure 6: Comparison of Within Groups Confidence Survey Scores Before and After Designated Training

However, an item analysis revealed a significant post minus pre-training difference for participants in intervention group versus control group only for item two of the questionnaire (*RAs confidence in interacting with patients*) ($p=0.045$): intervention pre-training (mean of=4.00) and post-training (mean of=4.71). Control pre-training (mean of=4.36) and control post-training (mean of=4.55). In regard to the study's secondary aim, RAs confidence in accurately collecting data (item 6), no significant difference was observed after analysis ($p=0.80$): intervention pre-training (mean of=4.29), and intervention post-training (mean of=4.86). Control pre-training (mean of=4.46), and control post-training mean=4.73.

Knowledge

The results of the knowledge questionnaire, indicating how well RAs understood the clinical research studies they would be enrolling patients indicated there was no statistically significant difference in pre-training knowledge scores ($p=0.67$) and post-training knowledge scores ($p=0.70$) across training groups (Figure 7). A total of 14 RAs' questionnaires were analyzed in the intervention training group and zero percent made a perfect score. The pre-training mean knowledge score was 75% or (17.3), standard deviation of 0.10, which increased non-significantly post-training to a mean score of 78% or (17.9), standard deviation of 0.16, ($p=0.14$). A total of 11 RAs' questionnaires were analyzed from the control training group and zero percent made a perfect score of 23. The pre-training mean knowledge score was 76% or (17.5) with a standard deviation of 0.09, which increased non-significantly post-training to a mean of 83% (19.1) standard deviation of 0.1 post-training ($p=0.11$) (Figure 8). The data indicated the average score of a participant after intervention training did meet the adequate requirement of 80% for passing the TEMRAP standards (78%), compared to participants after control training who made on average an adequate score (83%).

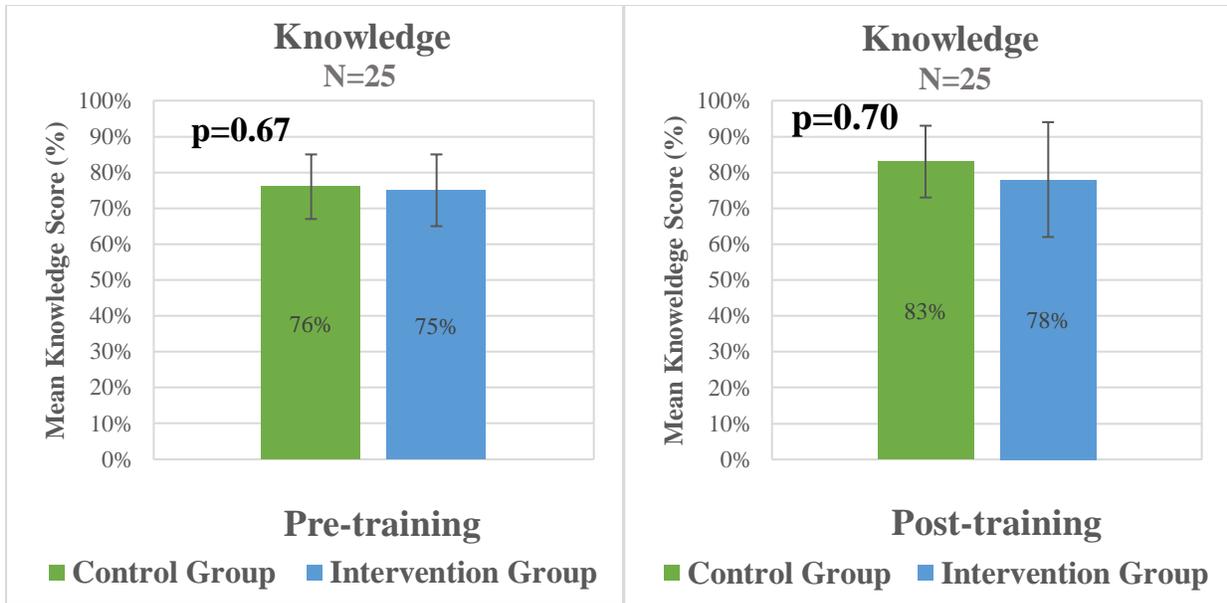


Figure 7: Comparison of Across Groups Knowledge Questionnaire Scores Before and After Designated Training

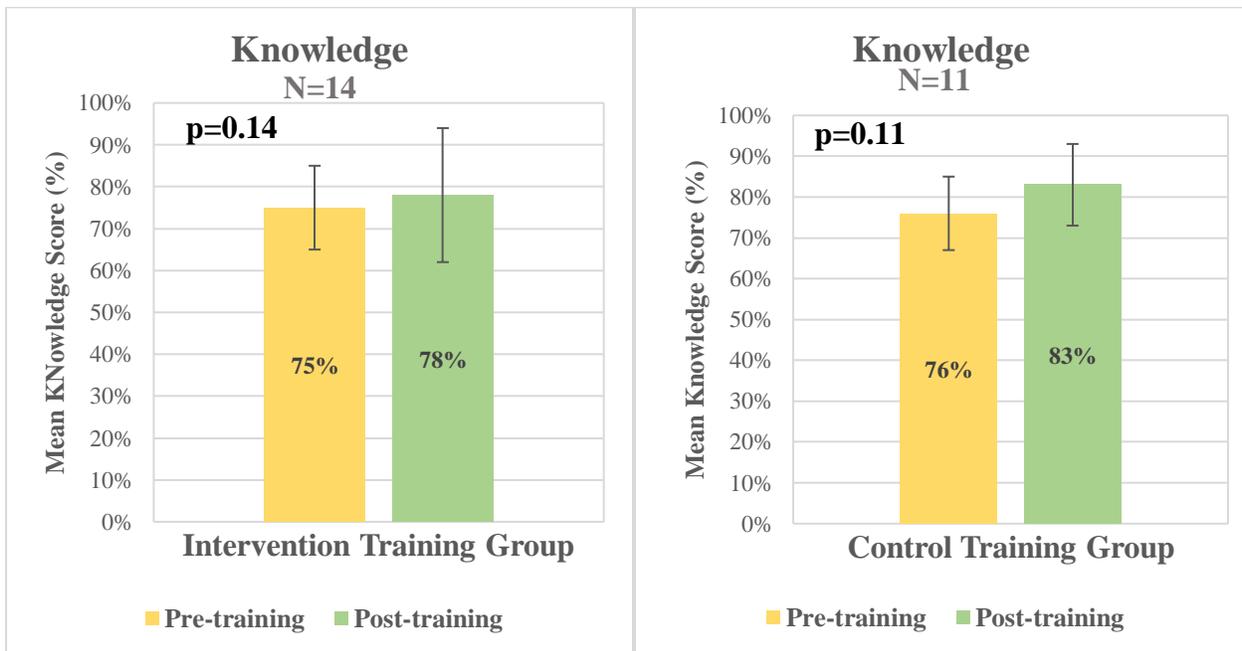


Figure 8: Comparison of Within Groups Knowledge Questionnaire Scores Before and After Designated Training

The one-month follow up results for knowledge score was statistically significant only for intervention within groups, paired difference of one month follow-up minus pre-training

knowledge ($p=0.049$) (Figure 9). For control within groups there was no significant difference ($p=0.09$) for pre-training vs one-month follow-up.

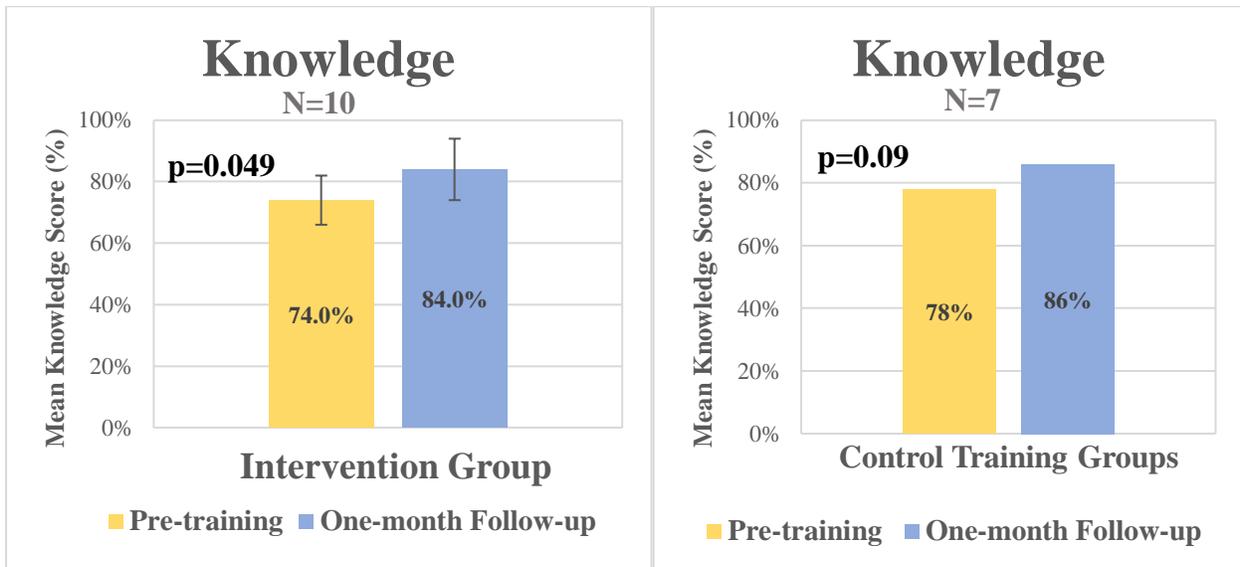


Figure 9: Comparison of Within Groups Knowledge Total (one-month follow-up minus pre-training) Difference

However, numerically the median difference was larger in the control group, but the sample size was smaller. The (net) differences between groups was non-significant ($p=0.72$). The post-training versus one-month was not significant between or within groups. As for confidence survey results, one-month compared to pre-training and post-training scores, all within and between group comparisons were non-significant.

In terms of visible association between error rates, knowledge, and confidence scores the Spearman Rho Test only found a statistically significant association for post-confidence versus error rate ($\rho=.47$, $p=.02$) when the participants in the intervention and the control group were combined as one sample (Figure 10). Indicating error rate and confidence were directly related in the positive direction (Spearman rho is positive >0), in other words an increase in RAs' confidence was associated with an increase in errors made by RAs. Additionally, there was a

tendency for error rate and knowledge scores to be inversely related (Spearman rho is negative, <0).

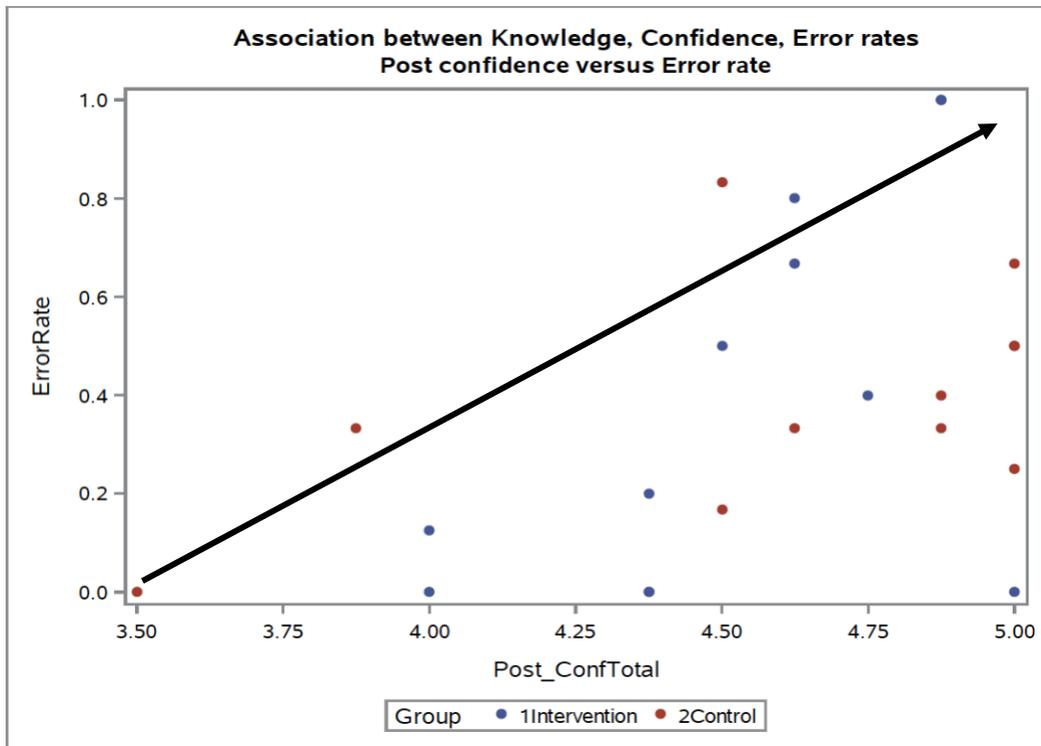


Figure 10: Association Between RA Error Rate and Post-Training Confidence (Combined Participants)

As for the by group analysis, there were no significant association for the intervention or control group when analyzed by the Spearman Rho Test because the sample sizes were too small to statistically detect any associations. Additionally, no other two variables tested displayed a significant relationship in by group or combined group analysis (pre-knowledge, post-knowledge, knowledge difference, pre-confidence, post-confidence, confidence difference, error sum, packet sum, and error rate).

DISCUSSION

A goal of the health care profession is to encourage a method of teaching and learning focused on enabling students to assimilate medical knowledge and skills from the classroom into the clinical settings (Cant & Cooper, 2009). The purpose of this study was to measure the effects of the current didactic presentations training versus the clinical patient enrollment simulation with feedback training on the reduction of error rate in submitted clinical research studies by RAs. It was further postulated that the clinical patient enrollment simulation training would increase the RAs' knowledge of clinical research studies and self-confidence scores. Subsequently, we assumed an increased score in either or both variables would result in higher quality collection of data with fewer errors. This was the hypothesis for this study, but as determined by the results most of these assumptions were found to not be statistically significant.

First, the data analysis of the error rate difference indicated no significant reduction in RAs' error rate ($p=0.72$). As such we failed to reject the null hypothesis and accept that the clinical patient simulation training with feedback was not a much more effective method than the classroom didactic presentations training in reducing errors committed by RAs. According to Bero *et al.*, interventions with didactic educational meetings, such as lectures, show little to no effect in dissemination of information. Yet, with the initial results, it is difficult to firmly conclude that either the patient simulation training or the didactic educational meetings training is a more effective learning and/or teaching tool. Even though no statistically significant difference existed across training groups, it was reassuring to observe a larger percentage (50%)

of total RAs in the intervention group, have a low degree error rate as compared to the total RAs in the control group (16.67%) because it reaffirmed that the intervention training would help reduce RA error rates over time (refer to figure 5). Additionally, referring to the variance in the distribution of error rate (figure 2), the large variance in the intervention training group can imply the improvement of these RAs over the three weeks of data collection is due to the feedback received. The small variance changes in the control training group could imply the RAs error rate was constant because no feedback was given over the three-week data collection period. It is promising to observe the borderline significant improvement in the within group results for the comparison of error rates per week committed by RAs in the clinical patient simulation training group ($p=0.06$). This further indicates the feedback cycle in place or the simulations had an effect on the improvement of the error rate over time as compared to the didactic educational presentations training. Conversely, the non-significant improvement of error rate per week for the didactic educational without feedback training group further implicates Cioffi prior findings of how the use of human simulations in patient mediated interventions can be an educational strategy for the achievement of learning how to fulfill required tasks in a clinical context.

Next, the results comparing the difference totals for the two training groups in terms of gains in confidence ($p=0.62$) and knowledge ($p=0.70$) led to a failure to reject the null hypothesis. The data analysis thus suggested no significant difference in the effectiveness of patient simulation training with feedback as compared to didactic presentations with no feedback training in terms of increasing RAs' self-confidence or increasing RAs' knowledge of clinical research studies. The results of the knowledge ($p=0.67$) and confidence ($p=0.39$) baseline data analysis indicated that neither group had an advantage over the other in terms of prior knowledge

or confidence. Yet, it is important to note the RAs in both training groups actually had a surprisingly high confidence score prior to experiencing their designated training, and this could attribute to the lack of statistical significance in the confidence total difference ($p=0.62$) between the two training groups. Nevertheless, we reject the idea about didactic educational training methods not providing employees enough confidence to carry out required tasks. In regard to the RAs' knowledge, the lack of significant knowledge total difference between the two groups, as shown by the Wilcoxon Rank Sum test, could be attributed to their prior experience as RAs. However, the results imply both groups tended to improve after their respective training. The increase in knowledge for the control group (7%) was greater as compared to the intervention group (2%), but this could be due to the control group trainer having the pre-training knowledge questionnaire prior to start of training. There could have been bias present during the trainer's lecture training series leading them to focus more time on topics covered in the questionnaire. Conversely, the main goal of the patient simulation training was to give the RA clinical experience with feedback on how to properly complete required task and not just focus on didactic material present on questionnaire.

To explore if patient simulation with feedback training (intervention group) increased self-confidence or knowledge of clinical research studies, we consider the within group results. The Wilcoxon Signed-Rank test results for RAs' self-confidence difference pre-training versus post training within the intervention group was statistically significant ($p=0.02$). This implies there is a significant increase in the RAs' confidence after completing the clinical patient simulation. These results endorse previous research that self-confidence could be a key component for effective clinical performance when interacting with patients (Porter, Morphet, Missen, & Raymond, 2013). As for the knowledge scores, within training groups, there was a

weak non-significant increase from a mean of 0.76 to a mean of 0.78 ($p=0.14$) for RAs after intervention training. Yet, it was reassuring to discover that the Wilcoxon Signed-Rank test results of the one-month follow up minus pre-training indicates an increase in RA's knowledge score only for the intervention group ($p=0.049$) and not for the control group ($p=0.09$). Even though premature, these results are promising, and they reinforce the conclusions made by Culpa-Bondal and Baker. In their 2012, study they revealed that clinical patient simulations with feedback improved confidence and knowledge of employees in a clinical setting. Nevertheless, the need for a larger sample size to increase power is necessary to firmly conclude these assumptions.

In terms of existing associations between confidence and error rate or knowledge and error rate, the results from the non-parametric Spearman correlation test for "all participants combined" and "by group" were unexpected. A significant association was found between error rate and confidence. It is important to point out this data analysis was only significant when the participants in both training groups were combined. As such the results reject the null hypothesis that there is no significant association between level of confidence and error rate but fail to reject the null hypothesis there is no significant association between level of knowledge and error rate. This implies an association is present between confidence and error rate but no association between knowledge and error rate. In regard to self-confidence affecting error rate, the results indicate there is a consequence of elevated self-confidence on error rate ($p=0.02$, $Rho=0.47$). The effect is contrary to the initial prediction of high self-confidence level reducing the RAs' error rate. Furthermore, according to Karimollahi, students who are exposed to unfamiliar environments will have a lack of confidence, and this plays an important role in completing necessary duties. However, my results contradict their findings, suggesting a positive and direct

relationship between error rate and confidence indicating a high level of confidence will cause a high level of error rates. This could mean a RA who is overconfident about their ability to complete tasks thus are not as vigilant when completing clinical research tasks.

On the other hand, the results of knowledge scores and error rates imply an inverse relationship. Even though not statically significant, it is promising to observe an association in line with the prediction, as RAs' knowledge scores increase the number of error rates decrease. Yet, with the current results it cannot be concluded that RAs' knowledge of clinical research studies affects their error rate. Overall, it is difficult to infer which type of training is responsible for the confidence and knowledge results, since the sample size for the intervention training and control training groups were so small. However, the intervention training group ($p=0.08$) did have a p-value closer to the designated alpha value compared to control training group ($p=0.15$) in terms confidence and error rate association. Nonetheless, it would be valuable to obtain a larger sample size for future studies.

Finally, it was interesting to note, while not a primary purpose of the study, a Spearman Rho value of -0.34 was present for the number of packets submitted by an RA and the number of errors made in submitted documents. Even though this was not statistically significant for the existence of a correlation, it is evident that more of a relationship existed in the intervention training group compared to the control training group. Thus, the more research packets a RA submitted the less errors they made in the consecutive research packets, but to a greater degree in the intervention training group probably due to the continual feedback. This could further indicate the feedback cycle in place for the clinical simulation training can cause an improvement in error rate over time as compared to the didactic educational presentations training. In as much as participant demographics is concerned, no statistically significant

findings were found. This indicates no major differences are present among the two training groups in terms of gender, age, or race and ethnicity.

a) Limitations

There were a number of limitations to this study, for which different controls were implemented to reduce their effects on the results. One such limitation which was controlled for was the possibility of randomizing participants unfairly into the two training groups. The initial non-statistical knowledge and confidence baseline difference between the intervention training group and the control training group was vital for demonstrating the fact participants were fairly divided with quick access to data collection. However, due to convenience sampling there was insufficient power to identify differences in the population subgroups and some selection bias was present. The designed training was created to study the target population of new research associates. Yet, the need for quick and easy results the use of returning TEMRAP RAs was necessary. Their prior experience could have had an effect on the error rate, confidence, and knowledge results, but their ability to quickly collect and submit patient enrollment data for error rate calculations made it possible to have readily accessible data to analyze. If the new RAs were used their data would not have been able to be analyzed in the allotted time frame for the study at hand. Another minor limitation was scheduling conflicts with RAs and the TEMRAP leader as such not there was variability in each student's experience resulting from not having consistent TEMRAP leaders present to give feedback to intervention training group or to lead the control training group. A confounding variable not tested for was did years of experience the TEMRAP leader giving feedback have on RA's results. Additionally, there was the potential for some selection threat to the study's validity; the researcher had no control over which returning research associate chose to participate.

It would have also been beneficial to pilot the knowledge questionnaire and confidence survey beforehand to limit the amount of threat to internal validity. I had to adjust the knowledge questionnaire from 25 questions to 23 questions because of flaws in the information only made evident after the first training session. The ability to blind the returning RAs from the intervention and control training was difficult because RAs talk amongst each other. Since the corresponding training did not all occur on the same day some RAs present at the later training sessions could have known there were different methods of training. We had RAs fill out a knowledge and confidence post survey immediately after training to help reduce this response bias. The use of non-crossover randomized control trial allows for the possibility of the different training groups to be unbalanced or some covariates may exist. Perhaps adjusting the design to allow participants to act as their own control would be beneficial to reduce the effect of any confounding variables. This could have disrupted the results for the confidence surveys or knowledge questionnaires.

The biggest obstacle to the study was the small sample size of participants and its effect on the power to identify any differences between the intervention and the control group. Furthermore, the short period of error rate data collection from submitted patient enrollment packets also limited the power of this study. The lack of follow up was detrimental to the study results as well. It was not expected to be so difficult to recruit Research Associates and have them complete follow up tasks.

b) Future Directions

There was no significant difference in the error rate between clinical patient simulation training and didactic educational presentations training but the small sample size as well as short data collection period impacted these results. The major changes to make for future studies is to

recruit a larger sample size of RAs as well as use RAs who do not have previous experience because this could be a confounding variable. Furthermore, allowing for a longer period to collect submitted clinical research enrollment packets may permit the detection of a significant difference in RAs' error rate and eventually determine if which training method is effective in reducing the number or errors in documentation.

If possible, and for this research to continue, more participants and a greater data collection period will be necessary to reach significance. Moreover, to increase the study's validity as well as generalizability to a broader healthcare professions population, more clinically associated groups (nurses, medical students, residents, etc.) should be incorporated into the study. Future studies investigating other possible variables affecting quality of data collection could be done such as motivation. Another possible training method which could be tested as a solution to address the problem of poor quality of data collection is to use a combined training session of clinical patient simulation and lectures reviewing the clinical research studies. Additionally, it would be useful to compare error rates of previous years with previous training and the current year with new training.

SUMMARY AND CONCLUSIONS

The overall goal of executing this practicum was to improve quality of RA data collection. In addition, possible underlying factors (confidence and knowledge) affecting RAs' poor collection of data were explored. According to the results, it is thought the patient

simulation training could effectively be used to train future RAs to collect data with high levels of confidence and knowledge. It is also believed that with the provision of regular feedback the quality of clinical research data collection will improve continuously over time. These beliefs are steadfast although results revealed that this particular training did not significantly enhance the measured variables as compared to normal training methods. This was concluded as the patient simulation training was equal to (confidence and knowledge) or better than the standard methods, as error rates significantly declined over the three-week period of data collection.

The results assisted TEMRAP in narrowing down a more effective method for bolstering RAs abilities to effectively collect research data in a clinical setting. However, the surprising result of increased confidence leading to increased error rate was contrary to our initial beliefs of increased confidence leading to decreased error rate. This would be interesting topic to further explore.

In summary, it was promising to observe a certain degree of effectiveness in the clinical simulation with feedback training on knowledge and confidence by comparing the pre-training, post-training and follow-up surveys and questionnaires. It will be beneficial to continue studying clinical patient simulation over a longer period to see if reduction in error rate is truly accomplished with future RAs. Eventually, the study could be refined by targeting new RAs as participants and combining patient enrollment simulation training with a brief didactic portion.

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CHAPTER III.

DESCRIPTION OF INTERNSHIP SITE

The clinical research practicum took place at the University of Texas Southwestern (UTSW) Medical Center over a six-month period, focusing on implementing quality improvement in data collection for Texas Emergency Medicine Research Associate Program (TEMRAP) Research Associates (RA). UTSW Medical Center at Dallas was formed in 1943 by the efforts of E. H. Cary, M.D. and the Southwestern Medical Foundation (“*Mission and History: 1943 to 1959*”). The mission of UTSW Medical Center is to promote health and a healthy society through education, research and healing enabling achievement of full human potential (“*Mission, Values, and History*”).

In 1986, a research facility was opened by The Howard Hughes Medical Institute concentrating on molecular biology. The new facility brought along a number outstanding scientist, who also head faculty positions in the basic science department in the Medical and Graduate schools. The UTSW Medical Center fosters multidisciplinary research and rigorous scientific training in both basic and clinical research (“*Mission and History: 2008 to Present*”). UTSW Medical Center is home to numerous labs, each focusing on its own areas of interest, yet all share a common goal of improving healthcare. The goal of the Department of Emergency Medicine is to improve patient care in emergency medicine as well as promote high quality research and education in emergency medicine-related topics.

The Director of the Department is Deborah B. Diercks, M.D., M.Sc. The Clinical Research Team that I worked with are Shannon McNabb, Mario Puentes, Khushbakht Bakhshi, Ava Pierce M.D., and Ahamed Idris M.D. TEMRAP along with the Department of Emergency Medicine, allowed qualified UTD students to participate in clinical research projects conducted within the Emergency Department (ED) at Parkland Hospital and William P. Clements, Jr, University Hospital.

INTERNSHIP EXPERIENCE AND JOURNAL SUMMARY

I started the first few weeks in May and June getting acquainted with the UTSW Emergency Medicine Department as well as working towards becoming fully credentialed with the UTSW. Luke and I embarked on a few tours with Mario and Holy in order to become oriented with the many facilities involved with clinical research. I was able to sit in on a few clinical research meetings, which would become a weekly occurrence for Luke and me, where the research team updated the primary investigator (PI) over the status of the ongoing clinical studies. I learned the importance of the IRB and its role in moving studies forward through the many phases. I was grateful to learn the process of writing a protocol and using the online software to navigate this intricate process.

In the next few months (June and July) of my practicum, I worked closely with the TEMRAP and became acquainted with the leaders involved in this program. I also attended several on-site pieces of training for the use of eIRB, Epic, and Velos patient registrations programs. These would come in handy when creating protocols for research but also for patient enrollment. I was given my project to work on and began to do research on the types of training

commonly used to prepare healthcare employees. In helping create a syllabus and program manual for TEMRAP throughout the first three weeks of the internship I become very familiar with the mission of purpose of this research experience. I learned research associates must be willing to talk to people from various backgrounds in order to recruit them into clinical research studies. As such, I began to formulate a plan for patient simulations, similar to what I had found in other scientific literature. By the time our presentation for the research proposal came, I was sure I would try and compare two types of training to test the efficacy of them as learning and/or teaching tools.

In the months of August and September, I was able to learn how clinical research work at UTSW and how to navigate the two important sites associated with the UTSW Emergency Medicine Research Team. I learned more about GCP practices and was even able to shadow Mario during patient enrollment and screening visit to Parkland Memorial Hospital. I learned it was important to update the sponsor and constantly be in communication with the IRB about clinical research progress. The other majority of my time during these months was spent helping TEMRAP credential students and executing my proposed training. I came to realize how difficult it was to manage a large group of research associates and the need for flexibility in this profession. In August I developed my patient simulation training and decided to use the didactic presentation as a control method of training. I created measurement tools (with the help of TEMRAP leaders) for knowledge and confidence to test participants in my study. The orientation dates were set for the months of August and September and this was where I collected my confidence and knowledge data.

During the last few weeks of September, I began to collect data for my primary variable, error rate. I was also in constant communication with my Major Professor and Site Mentor over

the progress of my written practicum. We meet on several occasions to review the formatting, content, and presentations. I also helped coordinate shifts for RAs as well as help finalize their credentialing at UTSW and Parkland Memorial Hospital. I was finally seeing how my protocol creation and executing of study plan had turned out.

In the Month of October, I spent the majority of my time analyzing my collected data and writing my practicum paper. I worked on finishing up my final draft to turn into my advisory committee throughout the rest of the week. In the final few weeks of my internship, I was a part of a few Site Initiation visits, witnessed study terminations, and a few studies open for enrollment. I was able to work closely with Ms. McNabb, site mentor, to create a presentation for my defense. Overall, the experience at UTSW was educational and amazing. My co-workers taught many lessons from GCP guidelines in action to proper communication with the IRB to what to do when I face challenges in life. They had taught me to be more knowledgeable in the regulatory field of the study, and also how to be a better person in life.

APPENDICES

APPENDIX A: KNOWLEDGE QUESTIONNAIRE

TEMRAP KNOWLEDGE QUESTIONNAIRE

1. A 43 year old female with a past medical history of typeII diabetes presents to the ED with the chief complaint of a headache. Does she qualify for T2D study participation?
 - a. Yes
 - b. No**
2. Which two studies do NOT include a **written** consenting process?
 - a. Afib & Anticoagulant non-compliance, Chest Pain: Patient Preferences
 - b. Chest Pain: Patient Preferences, VAS**
 - c. T2D, VAS
 - d. T2D, Afib & Anticoagulant non-compliance
3. Which of the following are general exclusion criteria for all ED studies?
 - a. Aged below 18
 - b. Pregnant
 - c. Prisoner
 - d. Doesn't provide verbal consent
 - e. All of the above**
4. Which of the following patients are not eligible for the VAS study?
 - a. 30 year old male complaining of R foot pain
 - b. 22 year old pregnant female complaining of abdominal pain**
 - c. 19 year old female complaining of general pain
 - d. 65 year old male complaining of hip pain
5. Which of the following is an exclusion criteria for the Anxiety/Chest pain & Hlit & Numeracy study?
 - a. ST Elevation Myocardial Infarction (STEMI)**
 - b. Complaining of chest pain
 - c. Complaining of shortness of breath
 - d. ER attending ordered an ECG
6. Does a patient have to state they have anxiety to be a candidate for the Anxiety CP study?
 - A. yes
 - B. no
7. What does the HADS measure?
 - a. Anxiety and Depression**
 - b. Electrical activity
 - c. Health literacy
 - d. Numeracy
8. What is the correct format of the Subject ID for your first patient when consenting?
 - a. XXX001**
 - b. XXXL1
 - c. 001XXX

- d. 1XXX
9. What is the proper procedure to handle the finished consenting paperwork?
- Hand the paperwork to the patient's doctor
 - Turn in the paperwork to your Head Trainer/ Team Leader
 - Drop off paperwork in lock box in Pod L
 - Drop off paperwork in lock box in Staff Lounge**
10. When is your pod and lobby shift data table due?
- At the end of your lobby shift
 - 9am on Saturday morning
 - 9pm on Saturday night**
 - 9am on Sunday morning
11. Which form was not administered for the Afib & Anti-coagulant Non-Compliance study?
- Morisky Scale
 - Perception Anticoagulant Treatment Questionnaire
 - Newest Vital Sign
 - Consent form
 - HIPAA
 - All of the above were administered**
12. Which of the following best describes "informed consent" as it applies to clinical trials?
- An ongoing process consisting of an exchange of information between the subject and the investigator.**
 - The IRB's approval of the research which is to be conducted.
 - A onetime event where the subject agrees to participate in clinical research.
 - A document detailing the study and the risks and benefits of participation in the study, signed by the subject and the investigator.
13. The most important responsibility of all researchers is to:
- Discover innovative and promising new therapies.
 - Conduct research efficiently to lower the cost of drugs in the marketplace.
 - Protect the rights, safety, and well-being of research subjects.**
 - Ensure high quality data.
14. Good Clinical Practice (GCP) can best be described as:
- Standards of ethical medical practice
 - Clinical research hypothesis testing
 - High quality medical care in accordance with evidence-based practice.
 - Standards for the conduct of clinical research**
15. What are the 2 specific inclusion criteria for the Afib study? (short answer)
- Currently prescribed anticoagulants (OACs) & past history of chronic heart failure
 - Past history of Afib and currently prescribed anticoagulants (OACs)**
 - Over the age of 18 and past history of hypertension

- D. Diagnosed with CHF during current visit & currently prescribed anticoagulants (OACs)
16. Which specific OACs can patients be on?
- a. Apixiban (Eliquis)
 - b. Dabigatran (Pradaxa)
 - c. Edoxaban (Savaysa)
 - d. Rivaroxaban (Xarleto)
 - e. Warfarin (Coumadin)
 - f. All of the above**
 - g. None of the above
17. What is Parkland Plus?
- a. Medicaid
 - b. Medicare
 - c. Self-pay
 - d. None of the above**
18. An example of what the presenting complaint must be for a patient to qualify for the T2D study is which of the following?
- a. Abdominal pain
 - b. Headache
 - c. Chest pain
 - d. Hyperglycemia**

Questions 21-22 can be answered using the following information.

For the SAHL-E task, 1 point is awarded for correct pronunciation and 1 point is awarded for correct association,

19. How many points do you give if the patient doesn't know how to say the word, asks you to say it for them, and they make a correct association?
- a. 2
 - b. 1**
 - c. 0
20. How many points do you give if the patient doesn't know how to say the word, asks you to say it for them, and they make an incorrect association?
- a. 2
 - b. 1
 - c. 0**
21. Which of the following are 2 inclusion criteria specific to the CP FU Compliance study?
- a. Only speaks, does not read English and presents to ED with ACS (acute coronary syndrome) symptoms
 - b. Spanish speaker and presents to ED with ACS (acute coronary syndrome) symptoms
 - c. Present to ED with ACS (acute coronary syndrome) symptoms and referred to ARC for follow up appointment**

- d. Spanish speaker and referred to ARC for follow up appointment
22. What is an example of a positive cardiac biomarkers?
- a. **elevated troponin levels, elevated CK levels**
 - b. Decreased troponin levels, elevated CK levels
 - c. Elevated troponin levels, decreased CK levels
 - d. Elevated troponin levels, decreased creatinine levels
23. Which of the following are paging only studies?
- a. Guided HF
 - b. Cardiac Biomarkers
 - c. AWARE II
 - d. **All the Above**

APPENDIX B: CONFIDENCE SURVEY

TEMRAP Patient Enrollment in POD Shifts Confidence Evaluation	Subject ID				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. I am confident in my ability to consent qualified patients accurately and efficiently.....	5	4	3	2	1
2. I am confident in my ability to generate responses to patient's questions regarding consent or research study.....	5	4	3	2	1
3. I am confident knowing when I have obtained enough information from a patient regarding study surveys	5	4	3	2	1
4. I am confident in dealing with difficult patients (e.g., difficult diagnosis, personalities).....	5	4	3	2	1
5. I am confident enrolling a diverse patient population into research studies (e.g, gender, age, race, culture, SES)	5	4	3	2	1
6. I am confident in my ability to collect and calculate accurate patient data acquired from surveys.....	5	4	3	2	1
7. I am confident in approaching clinical staff when obtaining patient information for study enrollment.....	5	4	3	2	1
8. I am confident in using appropriate professional language when interacting with patients and providers.....	5	4	3	2	1

APPENDIX C: SUPPLEMENTAL DATA

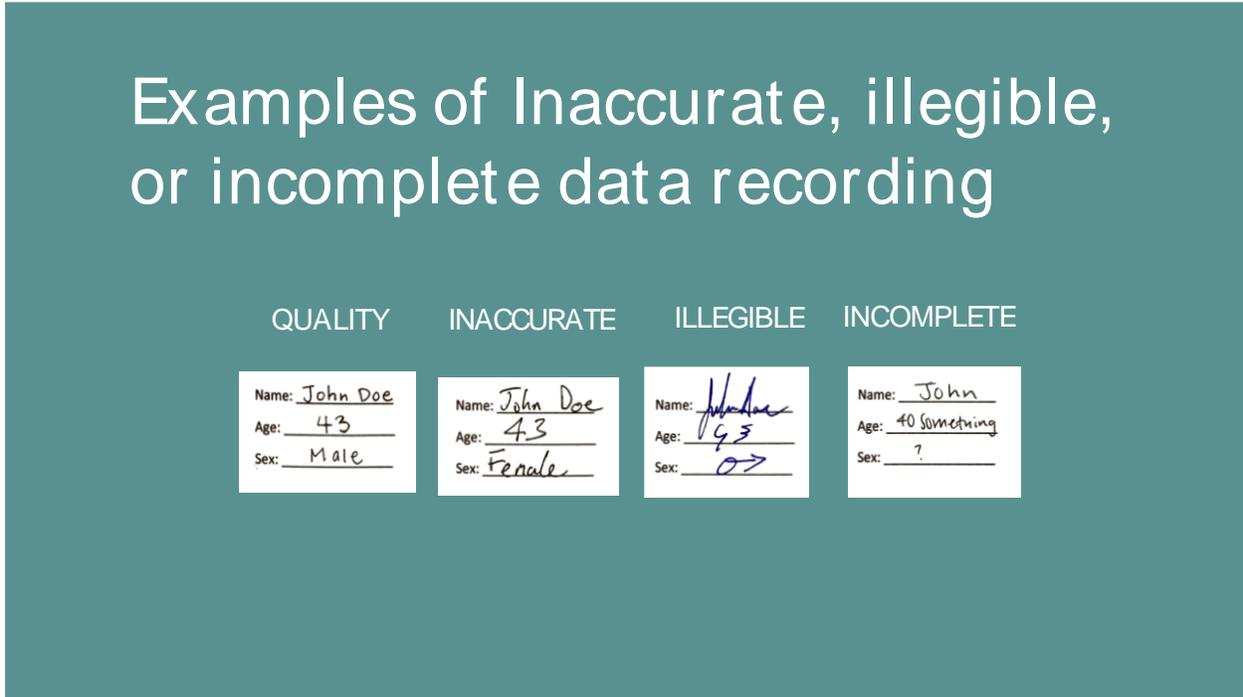


Figure 1A: Examples of Quality Data and Types of Errors for the Calculation of RAs Error Rate

- 33.78% said no (N=10)
- I feel comfortable interacting with the patients in the pods of the ED.
78.72% said yes (N=37)
21.28% said no (N=10)
 - I feel prepared to interact with patients in the pods of the ED.
78.72% said yes (N=37)
21.28% said no (N=10)
 - I would like more training for the pod shifts.
29.79% said yes (N=14)
70.21% said no (N=33)

Figure 2A: 2017 TEMRAP Confidence Survey of Research Associates

Table 1A: Statistics of Error Rate Across Training Groups

Wilcoxon Two-Sample Test	
Statistic (S)	137.0000
Normal Approximation	
Z	0.2791
One-Sided Pr > Z	0.3901
Two-Sided Pr > Z	0.7802
t Approximation	
One-Sided Pr > Z	0.3914
Two-Sided Pr > Z	0.7828
Exact Test	
One-Sided Pr >= S	0.3868
Two-Sided Pr >= S - Mean	0.7736
Z includes a continuity correction of 0.5.	

Kruskal-Wallis Test	
Chi-Square	0.0962
DF	1
Pr > Chi-Square	0.7565

Table 2A: Frequency Distribution of Error Rates in Participants (N=23)

ErrorRate	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	5	20.83	5	20.83
0.125	1	4.17	6	25.00
0.1666666667	1	4.17	7	29.17
0.2	1	4.17	8	33.33
0.25	1	4.17	9	37.50
0.3333333333	3	12.50	12	50.00
0.4	2	8.33	14	58.33
0.5	4	16.67	18	75.00
0.6666666667	2	8.33	20	83.33
0.8	1	4.17	21	87.50
0.8333333333	1	4.17	22	91.67
1	2	8.33	24	100.00

Table 3A: Distribution of Error Rates by Tertiles

Frequency Percent Row Pct Col Pct	Table of Group by ErrorRate				
	Group	ErrorRate			Total
		a.low <=.2	b.med .25-.4	c.high >=.5+	
	1Intervention	6 26.09 50.00 75.00	1 4.35 8.33 16.67	5 21.74 41.67 55.56	12 52.17
	2Control	2 8.70 18.18 25.00	5 21.74 45.45 83.33	4 17.39 36.36 44.44	11 47.83
	Total	8 34.78	6 26.09	9 39.13	23 100.00

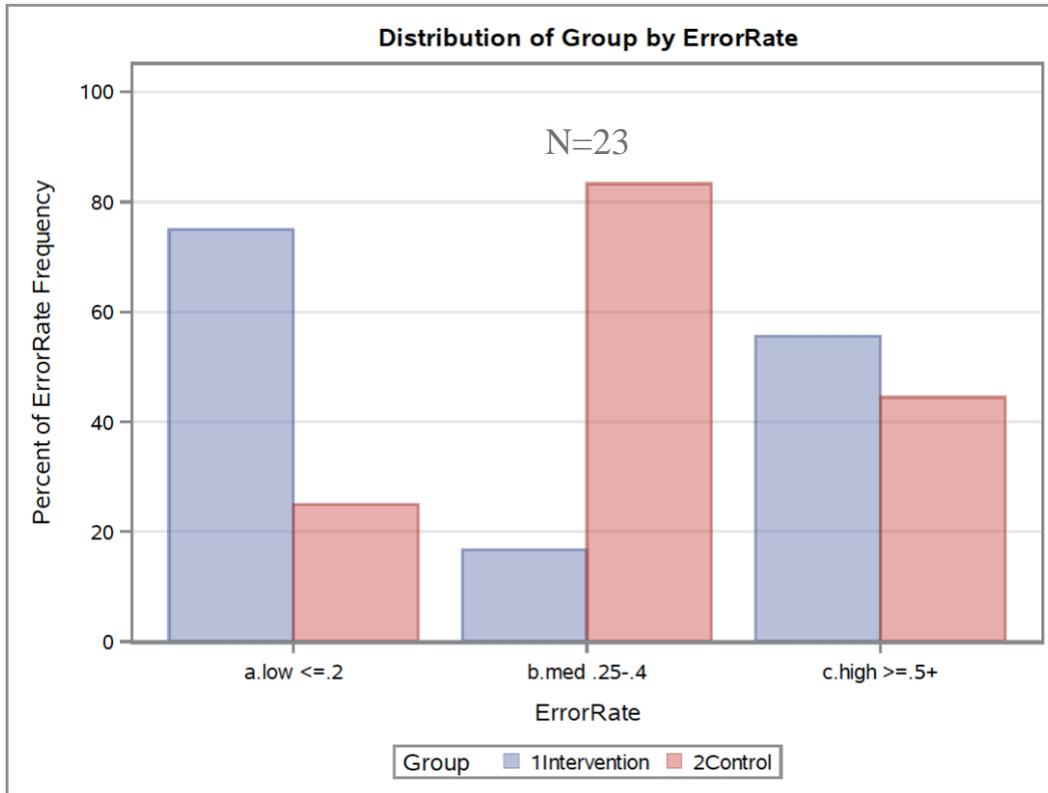


Figure 3A: Distribution of Error Rates by Group Intervention Training Versus Control Training

Table 4A: Statistics for Table of Tertile Groups by Error Rate
Statistics for Table of Group by ErrorRate

Statistic	DF	Value	Prob
Chi-Square	2	4.7433	0.0933
Likelihood Ratio Chi-Square	2	5.0719	0.0792
Mantel-Haenszel Chi-Square	1	0.5235	0.4694
Phi Coefficient		0.4541	
Contingency Coefficient		0.4135	
Cramer's V		0.4541	

WARNING: 100% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

Fisher's Exact Test	
Table Probability (P)	0.0157
Pr <= P	0.1231

comparing proportions between group.

Cochran-Armitage Trend Test	
Statistic (Z)	-0.7398
One-sided Pr < Z	0.2297
Two-sided Pr > Z	0.4594

no consistent trend

Sample Size = 23

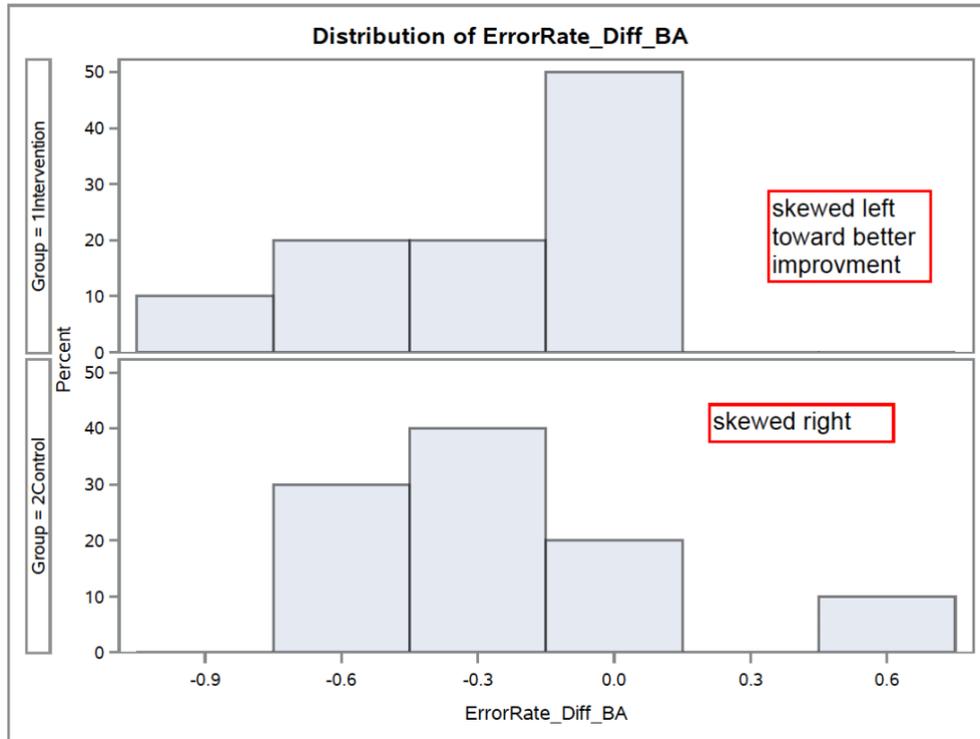


Figure 4A: Distribution of Error Rate Difference (Last Week (B) – First Week (A)) by Training Groups

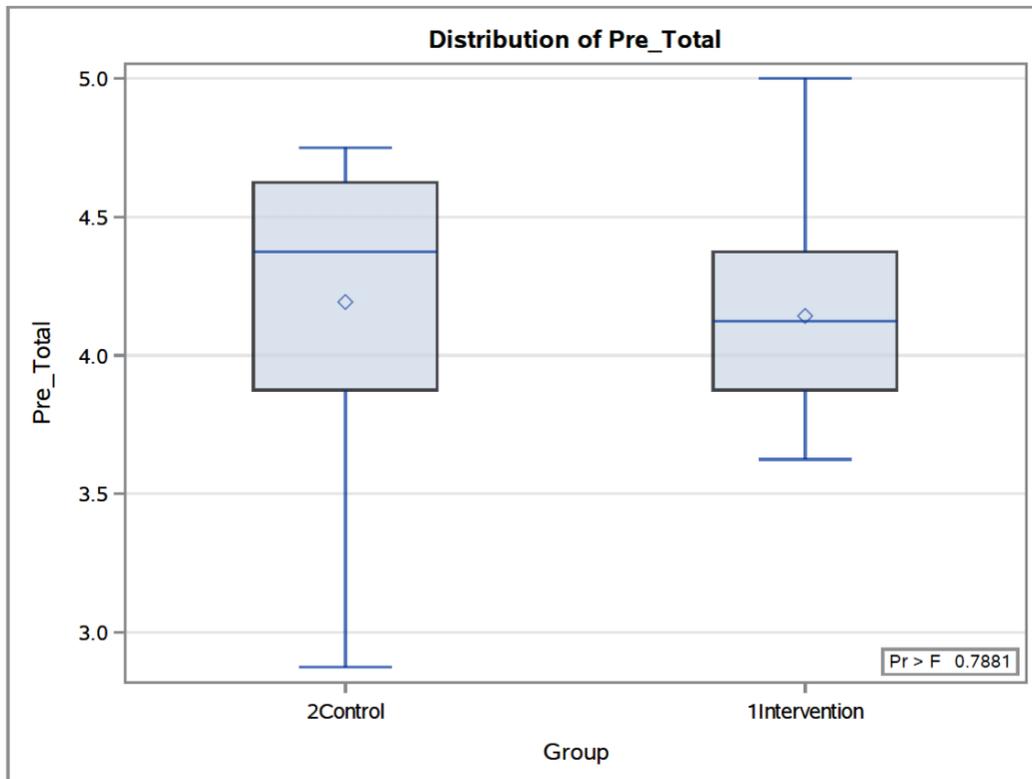


Figure 5A: Distribution of Pre-training Confidence Scores by Training Groups

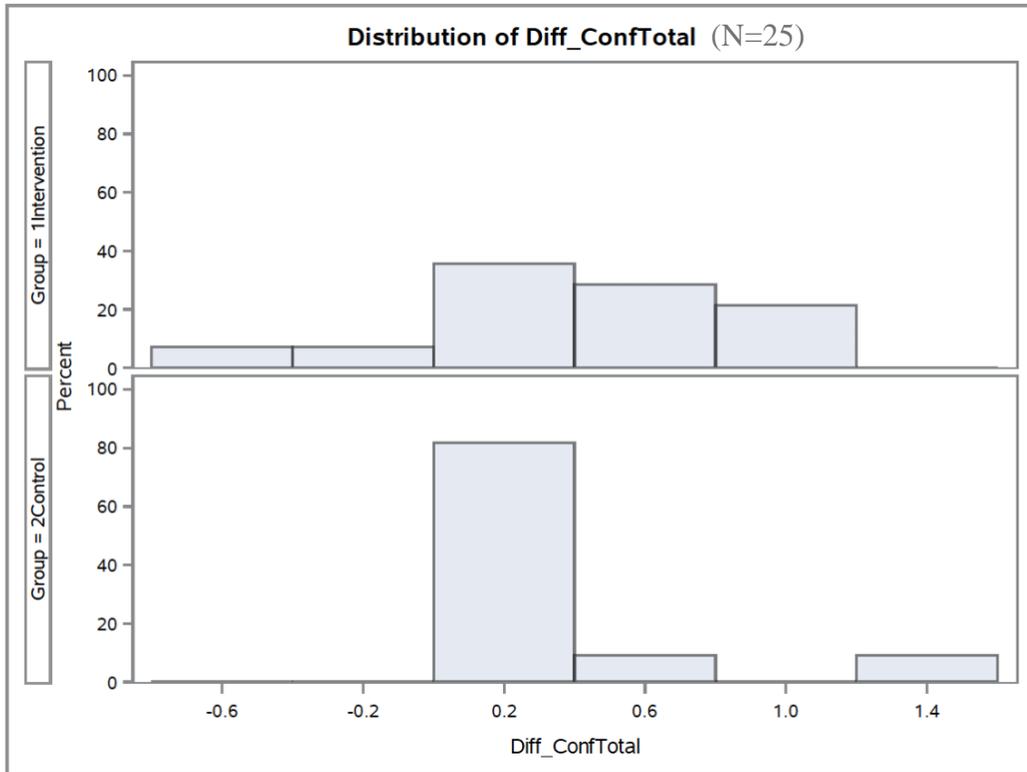


Figure 6A: Distribution of Confidence Scores Total (paired pre- versus post-training) Difference by Groups

Table 5A: Statistics for Table Across Groups for Total Confidence Difference (Item 2)

Statistics for Table of Group by Diff_Conf2

Cochran-Armitage Trend Test	
Statistic (Z)	2.0029
One-sided Pr > Z	0.0226
Two-sided Pr > Z	0.0452



Sample Size = 25

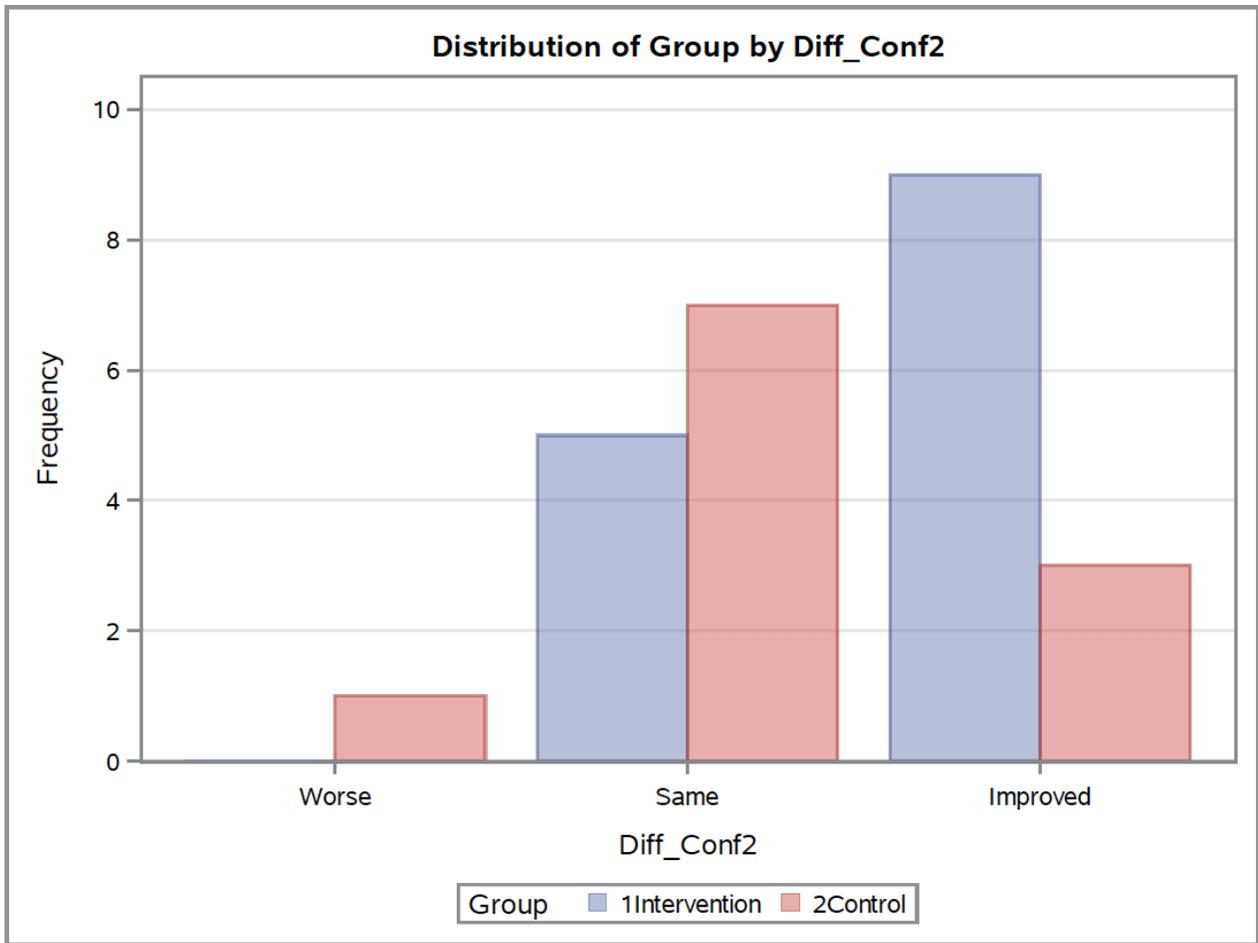


Figure 7A: Distribution of Total Confidence Scores Difference Across Groups (Item 2)

Table 6A: Statistics for One-Month Confidence Score Difference Across Training Groups

Wilcoxon Scores (Rank Sums) for Variable Mon1_ConfTotal Classified by Variable Group					
Group	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
2Control	7	56.50	56.0	8.610072	8.071429
1Intervention	8	63.50	64.0	8.610072	7.937500
Average scores were used for ties.					

Wilcoxon Two-Sample Test	
Statistic (S)	56.5000
Normal Approximation	
Z	0.0000
One-Sided Pr < Z	0.5000
Two-Sided Pr > Z	1.0000
t Approximation	
One-Sided Pr < Z	0.5000
Two-Sided Pr > Z	1.0000
Exact Test	
One-Sided Pr >= S	0.4897
Two-Sided Pr >= S - Mean	0.9790
Z includes a continuity correction of 0.5.	

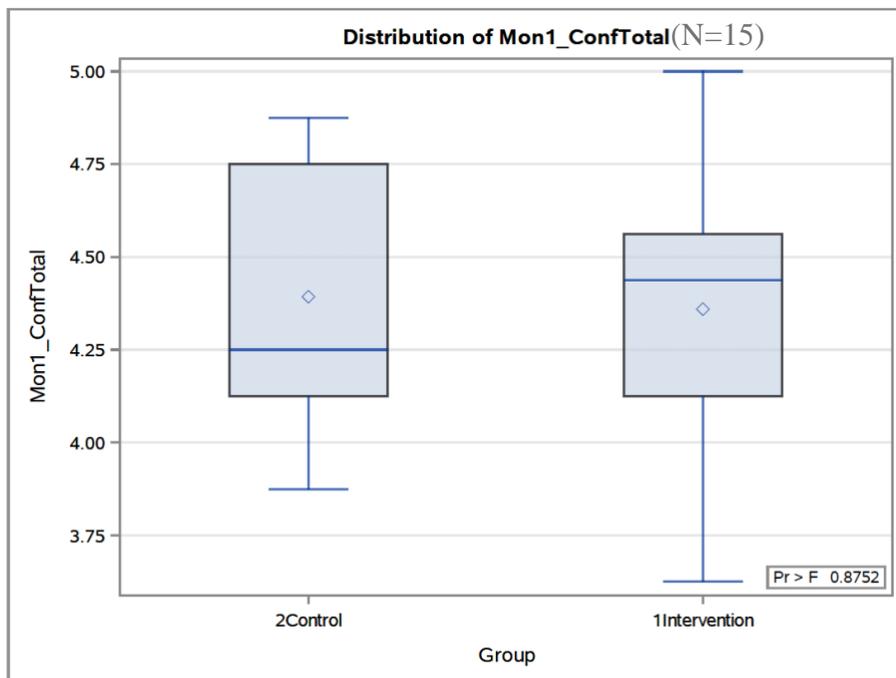


Figure 8A: Distribution of One Month Follow-up Confidence Scores by Training Groups

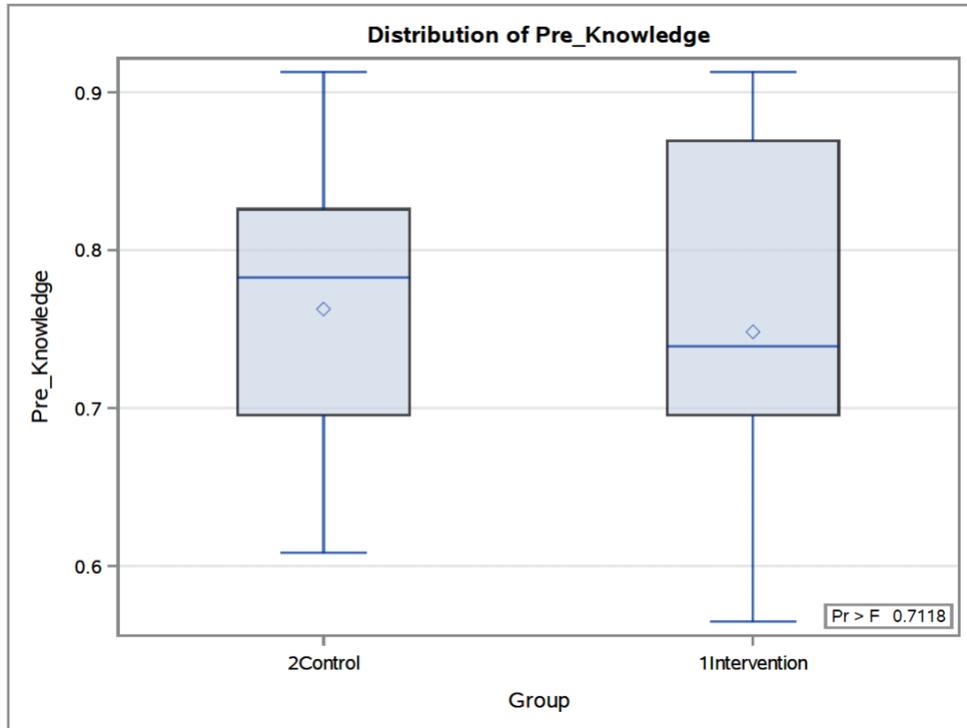


Figure 9A: Distribution of Pre-training Knowledge Score by Training Groups

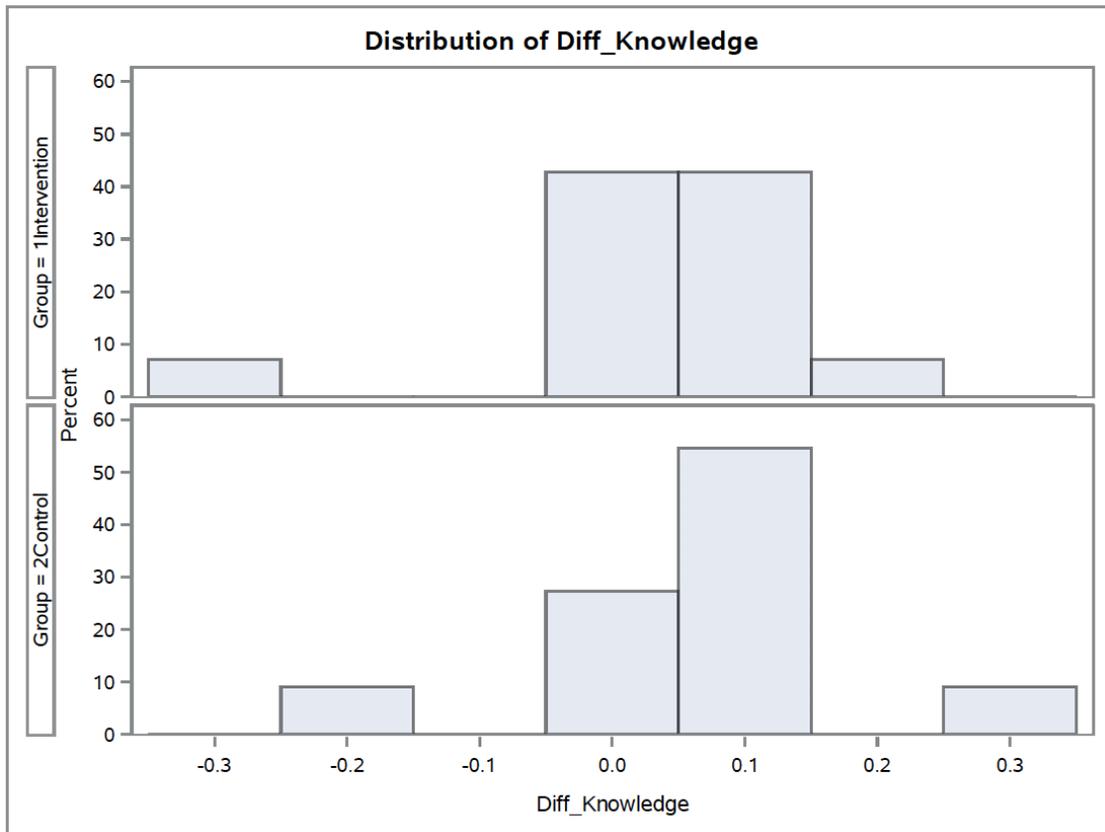


Figure 10A: Distribution of Knowledge Total (paired pre- versus post-training) Difference by Training Groups

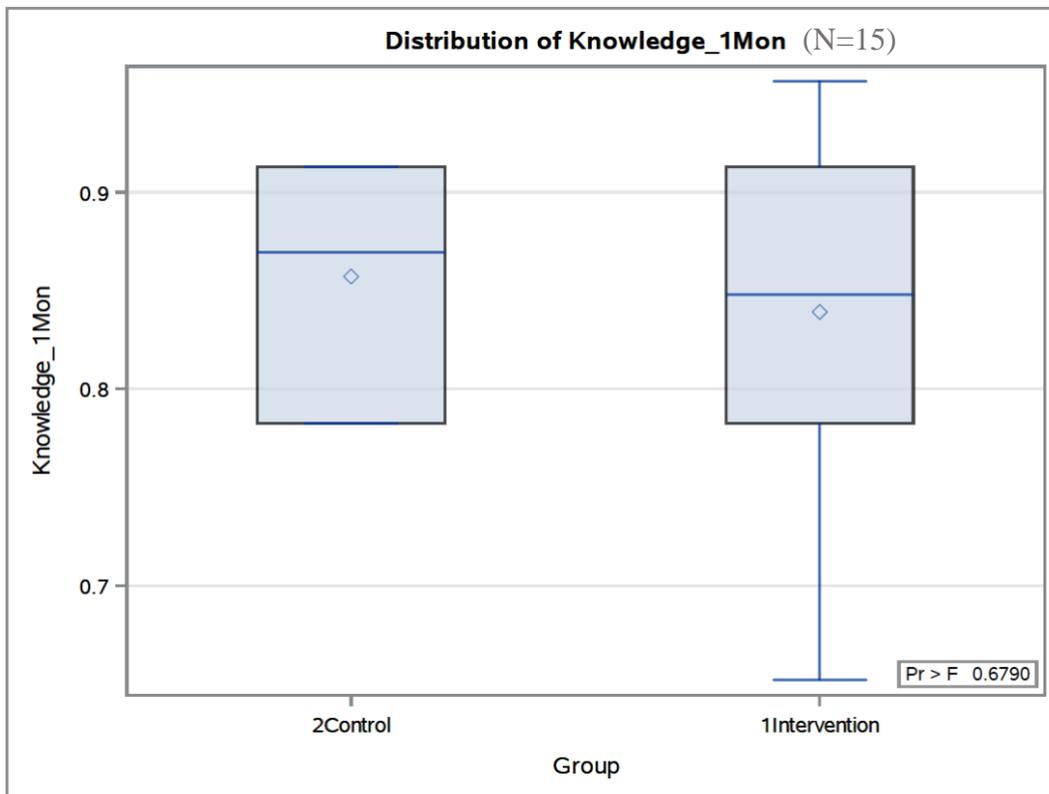


Figure 11A: Distribution of One-Month Follow-up Knowledge Scores by Training Groups

Table 7A: Statistics for Associations between Knowledge, Confidence, and Error Rates for All Participants Combined

Spearman Correlation Coefficients Prob > r under H0: Rho=0 Number of Observations						
	Pre_Knowledge	Post_Knowledge	Diff_Knowledge	Pre_ConfTotal	Post_ConfTotal	Diff_ConfTotal
Errorsum	-0.19729 0.3669 23	-0.22990 0.2913 23	-0.17962 0.4122 23	0.31027 0.1496 23	0.40972 0.0522 23	0.06151 0.7804 23
PacketSum	-0.00484 0.9825 23	-0.20655 0.3444 23	-0.24605 0.2578 23	0.37774 0.0756 23	0.01405 0.9493 23	-0.18402 0.4006 23
ErrorRate	-0.22955 0.2920 23	-0.13437 0.5410 23	0.02571 0.9073 23	0.02523 0.9090 23	0.46981 0.0237 23	0.29223 0.1760 23

APPENDIX D: LEARNING PYRAMID

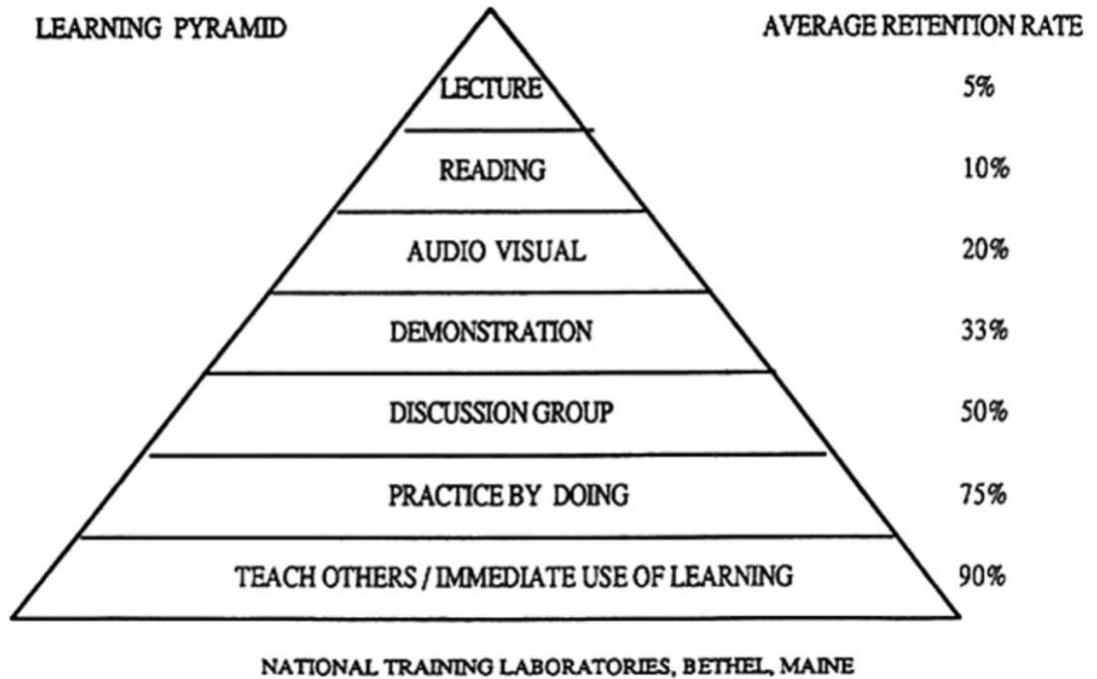


Figure : The NTL Learning Pyramid (Masters 2013)
(<https://www.tandfonline.com/doi/pdf/10.3109/0142159X.2013.800636?needAccess=true>)

APPENDIX E: IRB APPROVAL LETTERS

UTSouthwestern
Medical Center

eIRB System

From: [Kelavor Lewis](#)
Institutional Review Board Designated Reviewer
IRB - 8843

To: [Ava Pierce](#) , [Miguel Saldana](#) , [Shannon McNabb](#)

Date: Wednesday, August 08, 2018

Re: Exempt

IRB Number: [STU 072018-017](#)

Title: Quality Assurance Training: Will New Training Intervention help improve data collection of Texas Emergency Medicine Research Associate Program (TEMRAP) Research Associates?

Documents: Protocol

The UT Southwestern Institutional Review Board (IRB) Designated Reviewer determined on Wednesday, August 08, 2018 that this research is exempt in accordance with 45 CFR 46.101(b). Further review of this study by the IRB is not required unless the protocol changes in the use of human subjects. In that case, the study must be immediately resubmitted to the Board. Please inform the IRB when this research is completed.

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

NOTE(S) TO PI:

Current HRPP policy is that education must be refreshed every three years in [CITI](#) to ensure the most up-to-date knowledge. **Please note that enforcement of this policy will begin January 2018.** Please contact Joshua Fedewa at 214-645-5486 or at Joshua.Fedewa@UTSouthwestern.edu if you have any questions about this requirement.

Thank You

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

University of Texas Southwestern Medical Center
Institutional Review Board

5323 Harry Hines Boulevard
Dallas, Texas 75390-8843
phone: 214-648-3060
fax: 214-648-2171

DATE: 10 August 2018 (Revised; Initial Letter sent 9 August 2018)

TO: Stephen Mathew, PhD
(CRM Intern Project: Miguel Saldana)

FROM: Tania C. Ghani, MS, CIP *T.C. Ghani*
Assistant Director, North Texas Regional Institutional Review Board

PROTOCOL: **2018-145**
Quality Assurance Training: Will New Training Intervention Help Improve Data Collection of the Texas Emergency Medicine Research Associate Program (TEMRAP) Research Associates?

NOTICE OF DETERMINATION / APPROVAL

The Office of Research Compliance, on behalf of the North Texas Regional Institutional Review Board (NTR IRB) has reviewed your protocol and has determined this protocol to meet criteria for **EXEMPT** status (as specified in Federal Regulations 45 CFR 46 101(b) in one or more of the following categories, as initialed below:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of... instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office...
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs...
- (6) Taste and food quality evaluation and consumer acceptance studies...

You are responsible for complying with all North Texas Regional Institutional Review Board (NTR IRB) policies, decisions, conditions and requirements regarding projects involving human subjects. You are responsible for insuring that the research is implemented as specified in the protocol. In addition, you are required to use **ONLY** the reviewed and approved documents, materials and/or procedures designated for this protocol that were acknowledged by the North Texas Regional Institutional Review Board (NTR IRB).

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

If you have any questions, please contact the North Texas Regional Institutional Review Board (NTR IRB) at (817) 735-0409.

APPENDIX F: JOURNAL

First Week

Tuesday, May 29, 2018

I met Holy, she introduced me to the clinical research team and the responsibilities of each team member. We talked about the two possible projects available to Luke and myself. Later in the day, I was able to attend clinical research meeting led by Dr. Idris

Department meeting key points:

Reviewing studies being implemented (grant phase)

May 15 - MATH(pt registry of pts with blood clots being treated)- active and ongoing- screening is still going

Ortho Vitros Cardiac biomarkers (June 1st-possible activation)

Stago Trust-IRB reviewing currently

ENERGIZE- i-stat received and working on order set, badge buddy approved. Possible enrollment problem because of the lengthy process

ECHO - Mario received echo images and was able to send CDs (May 15-18) learned issues with FedEx delivering specimens because difficult to find drop off room

Access- Need to submit a service agreement to PMH before final approval (study focuses on pt resuscitated and ST elevation)- Learned about door to balloon time (done within 30 min)- has to do with ST-elevation MI- Dr. Idris able to come up with new amendments for training (Pt criteria pt been resuscitated from VFib or VTach only in Parkland end of June start)

HOBIT (Siren)- still in internal review, need to have own contract approved before Baylor contract

BOOST III (SIren)- sometime in June (writer) changes at data, safety, monitoring level

AWARE II- IRB stips addressed and resubmitted

AURORA- the PI changed from ALB to DD. more Stips need to be done

ADHF- approved with stips

Observational study- Ventilation during continuous chest compression

the study was done for ventilation during chest compression

TRansformative EMergency Dispatch Protocols for Multifold Increase of Survival Rate- To

develop devices and protocols that enable dispatcher assistance during bystander CPR-

contact students to volunteer-25 dollars- the UTD students

I was given a tour of Parkland Hospital and shown the daily tasks assigned to clinical research coordinators. I was shown the two main processes of recruiting patients, including the lobby area and the ED pods. Mr. Puentes taught us the approach taken to find suitable participants for studies.

Wednesday, May 30, 2018

In the Morning spoke with Ms. Holy Chou about possible thesis project involving TEMRAP students analyze. What parts of the program are working well, what parts need to be improved, the overall success of the program. We had a meeting with Dr. Idris (12pm-1pm). We spoke with him about gathering information about TEMRAP program. We formulated a prospective study-quality improvement for data collection, improving the overall program for collecting the data from patients (Lobby shift-talk with pts in the waiting room/ Pod shift- talk to pt in pods and screen to see if they fit in criteria). The proposed problem was (QI-problem) data is poorly collected as such we must look for an improvement. The students from previous years and experience will serve as the basis for data. I will be in charge of implementing a new training for

research associates to talk to patients. I will test how effectively they collect data, will divide them into two groups.

I was given a tour of Clements hospital the other site where clinical research studies are done.

We learned about the subject recruitment process at this private hospital and how it compared to Parkland. The main focus of two prominent studies currently involving recruitment of subjects for:

1) GUIDED-HF: CHF study at Parkland ED. Pretty straightforward. You will be able to use EPIC to screen.

2) MATH-VTE: This one is the PE/VTE study. It's a list that we want to collect to see eliquis works at home.

Thursday, May 31, 2018

The first day we were able to shadow Ms. Holy Chou on a patient screening who fit the inclusion/exclusion criteria. We learned the best way to approach the subject and how to give the informed consent. Even though the patient refused to participate in the study we observed Ms. Chou be transparent and follow protocol/GCP guidelines. In the office, we helped organize the current study surveys collected from TEMRAP students. We organized the patient surveys based on the individual clinical study. We worked on creating an appendix for reference of local resources for a psychiatric study at UTSW. We included mental health resources for both Parkland Memorial hospital and Clements Hospital.

I attended Daily meet with Dr. Diercks, team talked about current clinical projects and status of each, discussed about improvements or any hardships encountered, updated Dr. Diercks with TEMRAP students, how to educate residents awareness of clinical research, witness the process

of going over new application for clinical study coordinator - summarize strength and weaknesses of each candidate:

-Updated on Access- startup end of June

-ADASUVE- budget estimated and will be sent for approval

-ADHF: approved since yesterday, needing an amendment for protocol

-AURORA: under IRB review

-AWARE II-

Friday, June 1, 2018

I reviewed the TEMRAP syllabus to get a better idea of the program I will be studying. I spoke with Ms. Holy about some changes to my proposal including using the controls as previous students who did not have any previous clinical research experience instead of using second-year students in the program. I will be comparing these students and how they collected data to this upcoming year's students once they have new training/manual I put together. We were also able to accompany Ms. Holy on another subject referral, but unfortunately, after explaining the study to the possible patient, they denied wanting to participate. We were notified that badges would be ready next week and are responsibilities once we have access to Parkland Medical and Clements Hospital. We also learned about the additional classes and online training we must do to become credential at these two other sites.

Second Week

Monday, June 4, 2018

I spoke with Ms. Holy today about getting the survey data from the TEMRAP students from the previous years. I will get the information tomorrow and start looking through the student's collected data. I went through the student handbook for TEMRAP and the syllabus and got a

better idea about the program goals, expectations, and orientation. My goal is to find a possible solution or come up with a plan to improve data collection. I investigated today some possible sources for improving the quality of data collection, did not find much. I was able to read a few medical journals and scientific articles about improving data collection and how high the quality of data corresponds to effective clinical research. I spoke to the team about our meeting tomorrow and I was notified that Dr. Pierce will be in the office on Thursday to meet with me about the TEMRAP student program.

Tuesday, June 5, 2018

We received our ID numbers today and will be able to get our UTSW badges in the afternoon. I spoke again with Ms. Holy about my project proposal ideas. I suggested using electronic means (I pads or tablets) of obtaining data from patient surveys but after some discussion realized it would be expensive and impractical. We spoke further about the training the students go through at the start of the program and I learned they only do one day of training and it was ineffective. I will speak with Mrs. McNabb when she returns to the office, as she is in charge of the training.

For study proposal: I am deciding if the solution should be some kind of training/ or implementation of the guidebook

-Problem: quality of data collection by TEMRAP students, due to insufficient confidence and/or understanding of clinical study assigned. Interns

-Solution: I want to help students/patients in collection data of survey, so research coordinators can use valid data for studies.

-Purpose: improving the quality of data collection can help the overall purpose and results of the clinical research study. With correct data, the hypothesis can be better tested, and better data sets collected and shared.

Meeting with Dr. Idris:

The updated team on the current progress of several studies. The team responsible for each study updated Dr. Idris on the state of several current clinical research projects, including IRB status, funding status, and whether subjects are ready to be recruited. Luke and I talked to Dr. Idris about TEMRAP students and possibility of us helping recruit them for ventilation study.

Wednesday, June 6, 2018

We received our UTSW badges today but still waiting on further credentialing to have access to the office door and other buildings. We accompanied Ms. Holy to enroll and consent 2 new patients but after further discussion with providers, the patients were not eligible. Attended the monthly departmental meeting today. We were introduced to the rest of the department of emergency medicine, we learned about administrative updates, financial news (acceptance of new budget) and plans for the rest of the month. We learned how the recruiting process worked in detail. How to use the Epic system and look for inclusion/exclusion criteria for possible subjects.

Thursday, June 7, 2018

Met with Dr. Pierce today and went over a proposal for TEMRAP students. I will be receiving more information in the future about protocol and training involved. I will also work on setting up committee meeting with here. She informed me she wants to have a quality and assurance changes in TEMRAP program. I accompanied Ms. Holy to another subject recruitment for Guided-HF study, she was able to recruit a new patient. I was able to witness the informed consent process and HIPAA presentation to the patient. I observed the questioning process and how to present the survey information. In the afternoon attended Dr. Diercks meeting, updating about the current status of various clinical research studies.

I was able to think up more ideas for the proposal of the project, such as using a new method of building confidence in interviewers to help collect data from patients: Spoke to Dr. Diercks about the proposal and she suggested very good ideas, such as Situation Videos that grow through a series of interviews with multiple answers. One correct answer would advance the story, while incorrect answers would play out situation but then explain why it was incorrect. Ultimately a narrative building up to one message, the goal would be to help build confidence in students. I could use a survey with validated confident scales in two groups: one control with regular training and another group would be study group with the proposed new training. She recommends using modern methods (social media methods), since the study population is younger and more adept to current technologies. I could use a statistic program for quick calculations.

Friday, June 8, 2018

Observed Ms. Holy continue the process of data entry for enrollment of HF-Guided clinical study. Learned about the process of data entry through the multiple platforms, converting survey data into electronic records. Finished going through the TEMRAP orientation day training, noticed much of the training is done via PowerPoint. It is a good general overview of clinical research and why it is done. A possible method for improving data collection by students could be using an interactive video of clinical research. I found video from the U.S Department of health and services, it includes four distinct roles in clinical research (PI, IRB chair, CRA, and CRO) and how the decisions they make can have a big impact on the overall success of research study. I am still looking for some other method for getting information across that is more relevant to TEMRAP undergraduate generation. <https://ori.hhs.gov/research-clinic>. I spoke again with Ms. Holy and realized it would be better to use returning students for study proposal

because of the timeline of research too short to use untrained new students. I learned to return students will go through a retraining process, so I can implement my new training to half of those students.

Third Week

Monday, June 11, 2018

I accompanied Holy on patient recruitment for Guided-HF study and was able to observe patient consent and HIPAA process. I learned about clinical research interaction with physician and other providers. I organized and stored several of the TEMRAP student surveys. I went through different study surveys and looked for any missing information. I arranged the data collected by the specific study they pertained to and successfully stored them in filing cabinets. I was able to meet with Mrs. McNabb today and finalize 1st CRM committee meeting. We had a group huddle with her and discussed expectations of the job, duties of the intern, and signed credentialing paperwork. I got a better idea of my proposal and what to expect for future responsibilities. I learned further detail about the training of TEMRAP students and the main focus is to familiarize students with the specific clinical studies they are responsible for during course. I have been tasked to work on a syllabus and student handbook manual to help improve the course. I am still working on finding what kind of new training I will implement to help the quality of data collection.

Tuesday, June 12, 2018

Luke and I finished organizing the TEMRAP VAS study data into portfolios and stored them with other clinical research studies. We were sent the templates for last year's intern's proposals and had a chance to review them. Weekly meeting with Dr. Idris, we were updated on the current status of several research studies. Key point:

Discussed the financial aspects of two studies, waiting for confirmation of submitted payment for invoices. I Learned about monetary awarding process for a budget of specific clinical studies and how sub-ledgers work.

MATH is active and still enrolling. Problems with enrollment due to not falling into inclusion/exclusion criteria

Discussed the possibility of using UTSW social media page as a method of outreach instead of taking an ad out in the newspaper. This method of recruitment could reduce the cost of expenses for an overall research study.

Worked on credentialing paperwork for Parkland Memorial Hospital including signing up for IRB orientation in class, Velo's online training in class and eIRB and Velo's courses.

I sat in on interview discussion meeting, where team huddled to consider top candidates with Mrs. McNabb. I assisted Mrs. McNabb in creating the new list of TEMRAP students as well as remove the students who are not coming back for the fall semester. Thought of a new idea for research thesis: best way to recruit patients for the study, using old methods IRB approved posters placed around the hospital or using social media outlets such as Twitter, Instagram or Facebook (probably has to be IRB approved as well). I looked into UTSW twitter and Instagram, surprisingly not many followers.

Wednesday June 13, 2018

I worked on a summary of my project and was able to determine population size, type of study I will be performing (randomized clinical trial), my hypothesis, and statistical analysis involved. I worked on parts of the proposal rough draft, but still have to find more sources. I worked on proposal PowerPoint to present at the first CRM meeting, where I will pitch my idea for my thesis. I completed two trainings needed for UTSW credentialing, specifically HPI and conflict

of interest. I helped Ms. McNabb plan for TEMRAP schedule in fall and finalize the list of students. I discussed with Mrs. Kate Hoke about credentialing returning students as to proceed with thesis project in a timely manner. I signed up for the final credentialing orientation necessary for Parkland and UTSW. I was officially added to the MATH study today and am awaiting further credentialing to being enrolling patients as a research associate. I complete a conflict of interest statement online for UTSW as well for the first time.

Thursday June 14, 2018

I checked my UTSW email and was contacted by TEMRAP student leader to help with syllabus and student handbook. I looked over the google document containing the student hand book and made some edits before the afternoon meeting.

Later in the day I attended a meeting with Ms. McNabb, Dr. Pierce and the TEMRAP leaders to discuss plans for Fall enrollment, orientation of new and returning students, the syllabus, student handbook, and discuss my thesis. As for my thesis we talk about my goals of creating a new training program which will help returning and new students collect higher quality data. After some brainstorming the current TEMRAP leader helped me come up with the idea of doing an interactive roleplaying training followed by a series of quizzes. We also talked about using other forms of social media, such as a blog, discussion board, and email chains to help the students throughout the program. We discussed a plan of action for implementing my intervention group. I will be taking over a group of 22 returning students and be having them undergo my new training. There will be 3 other groups each led by a team leader. The control group will be another 21 returning students, and the other two groups will be new students and will not be participating in the randomized controlled trials.

-My current sources I found today are linked below:

https://journals.lww.com/academicmedicine/Fulltext/2013/06000/Social_Media_Use_in_Medical_Education_A.36.aspx

Friday June 15, 2018

I continued to work on my proposal rough draft and PowerPoint presentation. I explained to Holy my idea for the new training being an interactive roleplaying session. One student will play a patient with a script and another student will play the research associate role. The RA will interact with the patient according to one of the current studies being used and hopefully this will help the both students know about the study, as well as have increased confidence when approaching and interacting with patients. Holy thought it was a good idea but recommended I keep looking for sources that can be referenced for this type of training. My goal for today is to find more sources relevant to my proposal and in general how to properly conduct clinical research. Found source validating fact for need of complete and high-quality data in clinical research. <https://www.bmj.com/content/338/bmj.b2393.extract>

Fourth Week

Monday June 18, 2018

I continued to research articles for history of clinical research, importance in field of medicine and how it helps advancement of patient care. I was looking for articles specifically identifying the need for specialized positions for enrolling positions (such as RAs) and correlation to improved clinical research enrollment in hospitals. I read a couple of articles on the patient's perspective about clinical research as well as found some sources to back up why I am using a t-test to analyze my data. I worked on finishing my PowerPoint for the proposal of my thesis this week and continued to add to my background information. I spoke with Holy today about a

PowerPoint she sent, which she uses for the TEMRAP students for training. The purpose of the PowerPoint is to educate students on good data collection and how illegible data can have a profound effect on clinical research. She showed me good examples of previous student enrollment data and I got to see first-hand the difference between good, valid data and poor-quality surveys.

Tuesday June 19, 2018

I continued working on my proposal PowerPoint for my CRM meeting Thursday. I am now research credentialed at UTSW. I am still awaiting credentialing for Parkland Memorial Hospital access and spoke with Mrs. Kocurek. I attached and sent her the missing documents. I was subsequently credentialed at Parkland later this afternoon, now I just need to attend a few in class orientations about eIRB, Velos, and Epic. I am awaiting emails with further instructions from Parkland Memorial Hospital.

We attended The Research Division weekly meeting at 12:15, we were informed he will be out of town starting tomorrow attending conferences.

-MATH study: no patient enrollment so far but had 11 possible candidates. There was one possible subject which fit criteria was at the middle of the night when no CRA were on duty.

Continued discussing updates on the rest of the current studies, currently numbering at 21. Spoke with Dr. Idris after the meeting and we volunteered to enroll as subjects for a ventilation study.

Later in the afternoon Ms. McNabb reviewed my Proposal PowerPoint for my first CRM meeting on Thursday. She made some really good edits and helped me prepare for possible questions about my topic.

Wednesday, June 20, 2018

I revisited the PowerPoint over data quality given to TEMRAP students during orientation. I was able to get a better idea of what error rate could be defined as for my proposed project. I was able to present a mock proposal presentation to Ms. McNabb. She gave me feedback on many areas of my presentation. We looked at possible questions to answer for tomorrow CRM committee meeting. Especially focused on defining error rate and what confidence and knowledge surveys I would be using. I spent some extra time reviewing and editing my proposal in order to have a final product for tomorrow. I enjoyed an ice cream social with the Emergency Medicine Department. I emailed committee directions and confirmed a time for tomorrow's meeting.

Thursday, June 21, 2018

Today we had our 1st committee meeting with my Major Professor, site mentors, and Director of the program. I was able to explain to them the purpose of my project and why it was significant. They asked to describe what TEMRAP was as well as give more details about the surveys I would be giving. Some really good advice was taking two post surveys of the students, one right after training and then another one later after some clinical experience. I was able to make some revision after the meeting and talk to Dr. Pierce about the biostatistician and her input on my proposal. I was told my Major Professor would be going out of town next Wednesday, so I had the deadline changed. I was updated about the Dr. Diercks meeting today by Holy, they went through the studies again and updated her. I continued to research for a validated confidence survey which would be relevant to my project.

Friday, June 22, 2018

I read my emails today to look for my Parkland credentialing information. I have still not received any email and notified Mrs. Kocurek about it. My colleague Luke has already obtained his P-number and we turned in the forms about the same time. I continued to work on my

proposal. My goal for today was getting a validated Likert scale confidence survey, knowledge quiz (which will act as the survey for knowledge portion of intervention) and find more sources for my background. I have a meeting at UNT at 1:45 and will also be going to campus to get my last committee members signature. I will contact Kelly Clark to get more information about my Parkland access.

Fifth Week

Monday, June 25, 2018

I continued to work on proposal rough draft especially on the background section. I was able to finally find a suitable confidence survey to use for my practicum project. I continued to work on the knowledge quiz I would be giving the students. I received information from Vice Chief of TEMRAP over the current knowledge quiz for returning RAs, an orientation outline, and current training modules. I was able to complete the summary, significance, problem and hypothesis section of my proposal. I found more references to back up my idea of using patient simulations to improve confidence and knowledge of RAs. I gave Ms. McNabb a copy of my current proposal rough to take home and make some edits.

Tuesday, June 26, 2018

I received Ms. McNabb's edits and began to implement them into my proposal. I continued working on a proposal, background info, methods and began investigating current training practices. I was able to get some useful feedback about my PowerPoint presentation from Ms. McNabb over the topics covered during orientation day. The outline summarized the main points of current training and what it involved, the mostly didactic material presented by staff members of the DEM Research Division. I asked Holy for advice on how to present my materials and methods sections because I was having trouble deciding how to incorporate the figures for the

actual survey/questionnaires. I was able to meet with the Biostatistician today and go over the type of test I would be running for my thesis. She mentioned she could have a summary of the information to me by Friday. I helped Holy with STAND-UP Spanish translation of HIPPA form.

Wednesday, June 27, 2018

I was not feeling well today and did not go into work. I did, however, work a little more on my material and methods section later in the day. I was defining what each survey would include and how they will be done. I hope to finish a rough draft by tomorrow afternoon. I was also sent my information to begin the Parkland credentialing process. The first wave of in-class training will be in the month of July. The orientations will be focusing on Velos, IRB, and Epic training.

Thursday, June 28, 2018

Attended the weekly meeting with Dr. Diercks, where staff updated her on the progress of each active study and those in development. Mario gave an update on the first study on the itinerary, the training stage has begun for nurses and staff. Holy updated the group on her studies, one of which she is having trouble with obtaining stips. Once the team finishing updating Dr. Diercks on the progress, Luke and I spoke about the progress of our projects. Final remarks were made about the funding of a couple of specific studies and confirmation of next week's meeting. I continued to work on the final revisions my proposal and setting up my calendar with training dates

Friday, June 29, 2018

I worked on finishing up my rough draft proposal and incorporating the edits made by Ms. McNabb. I also received a revised version from my Major Professor and worked on fixing the recommended edits. I was able to finalize all my sources and add my figures into my proposal. I

had a lunch meeting with Dr. Raymond Fowler around 12:30 pm and we discussed some aspects of clinical research in the Emergency Medicine Department as well as the involvement of medical students in clinical research. He also inquired about the progress of my research proposal and what exactly it entailed. I ended the day by taking the UTSW shuttle to the bass center close to my apartment complex because I have training next week in this building. I got a good idea where the IRB, Velos, and epic training for credentialing in Parkland would be taking place.

Sixth Week

Monday, July 2, 2018

I completed my edited version of my thesis proposal and my Major Professor approved of the overall thesis. She instructed me to convert my thesis into a pdf document and send it out to the rest of my committee. I sent out the approved practicum thesis proposal to the remaining committee members and will wait for a response. Dr. Krishnamoorthy responded to my email and notified me he will have his edits back to me by Friday. I started the IRB submission form, sent to me by Ms. McNabb. I was able to complete the Parkland badge access form and send it to Ms. Anna Barden. The access will allow me to get into Parkland hospital and the observation unit on the 9th floor as well as the emergency pods.

Tuesday, July 3, 2018

I continued working on IRB submission form and sent a rough draft version to Ms. McNabb to edit. I Attended Dr. Idris weekly meeting where clinical research team updated him on the progress of each study. We were shown a mock video for one of the studies in progress. I received an email from Ms. Barden about some issues with my request to have badge access for Parkland Memorial Hospital. I have to go through EPIC training modules and speak with Ms.

McNabb about what steps to take next. I have signed up to take an in-class training for Velos and eIRB Study Registration, Velos Patient Registration and Epic Integration, and Epic for Research Coordinators.

Wednesday, July 4, 2018

Fourth of July holiday no work today!

Thursday, July 5, 2018

I read emails pertaining to training and future requirements for getting fully credentialed as a study coordinator. Attended weekly meeting with Dr. Diercks, clinical research team updated her on the current research studies.

-ACCESS & ADHF/STAND UP pending IRB approval at the moment. Plan to start ACCESS enrollment in August.

-AWARE II waiting on stips.

-ECHO & ESETT waiting for payment and invoicing.

-MATH we are still screening patients and have not yet enrolled any subjects yet.

-Spoke about future workflow in following months and discussed plans for enrollment once rest of studies are in enrollment phase. In the month of July currently, have MATH and GUIDED-HF studies.

We discussed further the interview candidates for the Clinical Research Coordinator position.

The department is need of a late shift and swing shift candidate. I had a meeting with a few TEMRAP leaders at 2 pm today. We went over the scenario and script for the intervention training group. We outlined an itinerary for the TEMRAP orientation and well as set dates for it.

We finalized the confidence survey to be used in the study and continued to work on the knowledge questionnaire. I received an email from my Major Professor, notifying me she will be

getting a copy of the electronic form to be signed by my committee members for approval of my proposal.

Friday, July 6, 2018

I finished up a final proposal, emailed my Major Professor about any final edits, and sent out an email to my committee members for final review. According to my Major Professor, she sent an electronic form to be signed by CRM committee members for approval of research proposal to be sent to the Graduate School Biomedical Science office. I continued contact with Major Professor and at the end of the day she notified me that my CRM committee members had signed the form approving my final proposal. I continued communicating with TEMRAP leaders and Ms. McNabb over the rough draft outline of TEMRAP orientation and dates. We continued to work on the logistics of TEMRAP orientation, deciding how many orientation days would be provided and which days to meet to go over the type of training for the control group in my research practicum. We also decided to use my email as a source for getting TEMRAP credentialing papers until the program email TEMRAP@UTsouthwestern.edu was accessible by the TEMRAP leaders.

Seventh Week

Monday July 9, 2018

Today we had in class training for Velos and eIRB presentations and registering patients onto the Velos system. The in-class training was from 8am-12pm and we learned very useful information on how Velos is a study management tool used to help investigators manage the set up and daily activities of clinical research at UT Southwestern. We also learned how Velos works when one starts screening and enrolling patients into a study. I found it useful to learn that Velos associate's patients with studies in Epic and dissociates patients from studies in Epic once certain

criteria are met in Velos. I learned that eIRB is a paperless submission and document routing system that is used to submit new studies, continuing reviews, modification, study closures, and anything related to human research studies and IRB. This information was actually very useful because now that I have gotten my research proposal approved I must use eIRB to submit my protocol. The steps were confusing until I used the tip sheet provided from Kimberly Taylor our trainer for these two training sessions. Later in the day, I communicated with TEMRAP Vice Chief RA and Ms. McNabb to set final dates for the orientation. We were able to book the big conference and small conference rooms for August 10, 17, 31, and September 7. I continued to process TEMRAP student credentialing information and upload files to USB specific for the program. We set a date to have a meeting to discuss the student manual, it will be on July 12 at 2pm.

Tuesday July 10, 2018

I arrived in time for Dr. Idris' meeting, clinical research teams updated him on research studies. Mario updates on MATH: study is active and still enrolling, missed another possible patient because they came in overnight.

I was in contact with TEMRAP leaders and discussed the students who have emailed me their credentialing paperwork. I was able to upload the documents into a USB specific for TEMRAP files and will be passing this along to the Vice Chief. We also discussed the updates to the knowledge questionnaire and other possible questions to ask RAs. I was able to make an updated confidence survey and knowledge questionnaire to be uploaded to eIRB. Once I was reviewed the eIRB submission form with Ms. McNabb, I will be able to have it reviewed by the IRB. Shannon emailed Dr. Pierce, the PI on the project, about the draft submission and if she could review it.

Wednesday July 11, 2018

I attended the monthly departmental meeting led by Mr. Colbey Walker. He opened the meeting with department updates, such as an intranet system. He followed up with scheduling changes for the following months and especially focused on revamping the social media presence. He mentioned hiring a content creator for the department's online appearance. Joanie mentioned we would be receiving questionnaires to give feedback on what we would like to see being implemented in the new intranet system. In regard to the Education Division, a lot of new fellows have started at UTSW. Simulation fellowship has been continued to be worked on in order to be formally recognized, with the hope of getting the program accredited. Jock updated the department on finance, hiring new position, and mentioned new updates to PeopleSoft. He recommends the department try and sign up for some of the training sessions. He mentioned regarding the budget no new feedback. Ms. McNabb updated the department about two new positions for clinical research coordinators and updated department on TEMRAP status. Joanie reminded the department about the benefit fair. Asked Mario about Parkland credentialing training.

Thursday July 12, 2018

I attended a morning meeting with UTD representatives, we discussed the TEMRAP schedule, plans for improvement, and application process. Afterwards I attended Dr. Diercks weekly meeting, clinical research team updated her on status of research studies:

- ACCESS, spoke about enrollment and a new amendment being added
- ADHF approved -5/30/18
- AURORA-still having smartphone issues and ISAC approval.
- ENERGIZE- awaiting site approval.

-Guided-HF- continued enrollment, data cleaning report in progress.

-MATH- 174 pts screened, no patients enrolled as of yet.

-final remarks about expectation for the following week were made and I updated Dr. Diercks on the progress of my research study.

Finally, at the end of the day I Had a meeting with Ms. McNabb and TEMRAP leaders over the student manual as well as other changes to the TEMRAP program. We made many new policy changes, which we hope will improve the overall experience of the program. We discussed changes to knowledge questionnaire as well, settling on 40 quality questions pertaining to RA assigned clinical research studies and IRB.

Friday, July 13, 2018

I discussed with the TEMRAP Vice Chief about the knowledge questionnaire and changes made with Ms. McNabb and other TEMRAP leaders. I was informed of a couple of major implementations, such as including TEMRAP as part of the orientation. We established talking about this at a later date once we know how many returning students would be attending which orientation date. As of now, we establish the major dates for returning student orientation is August 10, 17, & 31. We have set up an electronic method to sign up for orientations. We have been able to establish the total number of TEMRAP leaders for the upcoming orientation, eight total at the moment. We talked further about how to randomize students and we agreed to use an online randomizing program.

I am will be waiting for confirmation of all students who will actually be part of TEMRAP before I start the process of randomizing. So far, we have about 35 returning students but there are still a few missing documentations according to Vice Chief. I have received a few more emails of students credentialing material, which were originally due on July 11. I further

discussed with Vice Chief about how many leaders to assign to each group (New students, Control returning, and Intervention returning). We decided to wait until the final list of attendees to orientation is made before we start designating leaders to groups.

Eighth Week

Monday, July 16, 2018

I had to go to UNTHSC today to get my Intent to Graduate form signed by my Major Professor, Program Director and then turn it into the Graduate School of Biomedical Science. My Major Professor took the time to meet with me and talk about our timeline for the following months. She explained to me what dates I should set my defense for as well as send out a doodle poll for my committee. She also told me about the tip and expectations for defense date, such as bringing a snack, water, and dressing professionally. I was also able to pick up my updated TB physician exam for the current year. I took the time to turn in some more paperwork. I was able to get back to the office in the late afternoon and work a few hours on how to randomize the RAs. Later in the night, I had a dinner meeting with both the Chief and the Vice Chiefs of the TEMRAP program. We discussed logistics and set up more meeting dates. We set up a date, so I could shadow them in the ED on Thursday. We set the date to go over the control training with the RA leader. As well as discussed, the possibility of meeting at UTD and doing a mock trial of the scenario and script for the intervention group.

Tuesday, July 17, 2018

I continued working on randomizing my two groups for the control and intervention. I found a research randomizer online but went ahead and emailed the internal biostatistician Mrs. Beverly Huet about the best approach to randomize these two groups of RAs. She sent me a list of resources as well as explaining to me, to make sure the program I end up using offers “blocked”

randomization which ensures that the allocation is balanced after enrolling every 6 (or 4 or 8) subjects. I went ahead and used a blocked randomization of 6 groups of 6. I emailed the Vice Chief RA on the randomization of each RA according to their S-number (I did not have names with corresponding S-numbers at my disposal in order to reduce possible break of blinding). I spoke with Ms. McNabb about my meeting last night with TEMRAP leaders and how we plan to do a mock run of intervention scenario at UTD before the start of the orientation. I also discussed with her about adding an informational about lobby shift and changes before we split up groups into two arms.

Wednesday, July 18, 2018

I spent most of the day doing the Parkland Pathways training, it took about 5 hours to complete.

I cc'd an email with remaining students needing to sign up for the TEMRAP orientation.

I spoke with Ms. McNabb about getting access to O-drive and it takes about a week before I can upload my files of TEMRAP

Thursday, July 19, 2018

I had a meeting with TEMRAP Vice Chief and Chief. I was able to shadow the TEMRAP students in the ED today. I had a meeting about students who are planning to return and RA who have dropped from the program. The new count for returning RA is now 41, still working on randomizing RA into two arms for the study. We also spoke with Ms. McNabb about our future plans and unanimously agreed to not include knowledge questions pertaining to lobby shift.

However, we will be having a 10-minute presentation about what the lobby shift entails and announce the major changes. The presentations will be right before we split the two groups into control and intervention.

Friday, July 20, 2018

I worked on planning my defense and looking over the requirements for my presentations. I continued to work on setting a date for the defense and so far, have only gotten responses from both my site mentors. I was in touch with Vice Chief of TEMRAP to notify her of my randomization and went ahead with forwarding her this information. We also talked about planning a mock run for the intervention testing during the last weekend of July and before the first orientation. We spoke about the meeting on July 27 over the control training and what I could expect.

Ninth Week

Monday, July 23, 2018

I worked on my IRB submission edits, will need to speak with Ms. McNabb for further advice.

The following is from the IRB review and what needs to be changed:

Please describe the recruitment procedures including a) how subjects will be identified (ex. class roster) and b) who will have responsibility for recruitment?

How will the study be announced (i.e. via email, flyer)? Any recruitment material must include elements that participation is voluntary and will not affect grades, performance appraisals or employability - if applicable.

Include recruitment script in Item 6.3.1

I worked on UNTHSC IRB training and completed it in order to have UNTHSC IRB approval. I communicated with the Vice Chief of TEMRAP and set up the date to have the mock intervention training with TEMRAP leaders on July 31 at 5:30 pm. I was able to get a response from all my mentors and have two dates to choose from to set my defense.

Tuesday, July 24, 2018

I spoke with Ms. McNabb today about the IRB requests for changes to the protocol. I worked on a recruiting script and sent it to her for review. We will discuss further tomorrow how to address the changes required by IRB. I worked on the TEMRAP quiz with Vice Chief we were able to get it down to twenty-five questions. We discussed what we will be talking about on Friday (quiz/control training/what to discuss in a combined orientation session). We discussed what we are planning (mock scenario/getting mock scenario written up/getting a rubric written for feedback).

Wednesday, July 25, 2018

This morning I printed out my journal to be signed by Shannon and the IRB stipulations. Shannon helped me write up a recruitment script and answer the questions of the IRB. I was able to upload the new information and emailed Dr. Pierce the form was ready for re-submission.

Thursday, July 26, 2018

I continue to work on the student manual with the Vice Chief of TEMRAP. We edited and finalized the first 10 pages of the document.

The updates included: rearranging the order of presented material, such as having the program overview towards the beginning followed by roles and expectations of RAs.

I continued to receive credentialing emails and drug test result emails from the new RAs. I uploaded the data into folders on a USB for TEMRAP. I was on a group text with the TEMRAP leaders and we talked about our meeting tomorrow at 2 pm with Ms. McNabb. One of the leaders will be presenting what he plans to do with the RAs in the control group. We will also be having a preliminary meeting at noon to discuss our plans for the student manual, the credential of new students, and finalization of orientation agenda.

Friday, July 27, 2018

This morning I finished transferring the emails with information regarding the TEMRAP credentialing paperwork and drug testing results to the TEMRAP USB. We had our preliminary meeting at noon to discuss our plans for the student manual, the credential of new students, and finalization of orientation agenda.

Tenth Week

Monday, July 30, 2018

I emailed the IRB member in charge of reviewing my research proposal. I asked if I could do anything to help speed up the process because I still need to have my project go through the UNTHSC IRB. I spoke with Ms. McNabb about the new email account for student leaders and the other email for RAs. We have both username and passwords finally set up. I spoke with Vice Chief RA about our upcoming meeting this week. We will meet on Wednesday night at 8:30 PM to go over the scenario, script and run a mock intervention. I will also be meeting the rest of the TEMRAP leaders and let them know about my plans as well as the expectation for a research study.

Tuesday, July 31, 2018

I sent emails to returning RAs with temporary username and password in order for them to sign into their UTSW account.

I worked on creating a master packet of the studies to be used in TEMRAP intervention group. I discussed with the Vice Chief about which pages from what studies to include in the master packet. We decided to include the consent and HIPAA from Afib study. We included the health literacy task, the SAHL-E task, Patient Demographics, Numeracy Task, HADS, Data collection sheet, and Trust in Physician Task.

Wednesday, August 1, 2018

I continued to work on the credentialing information for new TEMRAP Research Associates. I continued to help Vice Chief send out temporary passwords and S-numbers to returning TEMRAP RAs. We had a meeting with TEMRAP leaders at UTD. We spoke about expectations for the program this year:

Welcome to TEMRAP leadership! On behalf of leadership, we are excited to be working with you all during the Fall 2018 semester. This leadership guide has been condensed to give you a look at your roles and responsibilities for your position. If you have any questions or need advice we are always here to help. Once again welcome to the team!

Leadership expectations:

1. Student privacy: all information and personal data of RAs must be kept secure and undiscussed with other students or unauthorized individuals. Violation may result in disciplinary action.
2. Leadership confidentiality: matters discussed in all Leadership exclusive meetings and group messaging must remain confidential and may not be discussed among other RAs
3. Communication & punctuality: Leaders must regularly check UTSW emails and other communication lines and respond within a reasonable time frame. Punctuality is a big aspect of leadership especially with data submissions and other requested information
4. Student Resource: as a group leader you are the first point of contact for students in your group. To the best of your ability, please answer any questions or refer them to the right person/resources. Be supportive/helpful throughout the training process and the entirety of the semester.

Responsibilities:

1. Weekly compilation of data & submission: all data retrieved by RAs will be sent to the student leaders by 9 pm every Saturday evening in a template excel format. Leaders are to compile all data and submit to the Research Coordinator by Sunday evening every week. (POD shift data pending)
2. Maintain RA records: student leaders may be asked to maintain a record of RA completions and/or compliance expiration dates (i.e. module completions, TB skin test renewal dates, etc.)
3. Training sessions: facilitate and organize training sessions for new and/or returning RAs accordingly in addition to continuing education sessions/shifts
4. Performance feedback: with leaders having the most direct interaction RAs, they may be asked to provide unbiased feedback regarding the performance of a student for CRA/VCRA and/or UTSW administration
5. Leadership meetings: group leaders may be asked to attend leadership meetings held at the UTSW campus in addition to bi-weekly conference calls to discuss program-related progress

Thursday, August 2, 2018

I spoke with Dr. Pierce about progress with intervention and other projected related goals. I had a 10 AM meeting with Ms. McNabb and TEMRAP leaders. We discussed the changes to RA program manual and I got great feedback from Ms. McNabb. She suggested instead of having a rubric for feedback, the leader should read through the RA packet after simulation and give feedback on data collection. I spent the rest of the day helping Vice Chief upload credentialing documents of new TEMRAP RAs onto the USB.

Friday, August 3, 2018

I spent most of the day in the huddle room working with Vice chief and the credentialing specialist of TEMRAP. We worked on getting new students credentialing information. I was

organizing the emails from new RAs. We made folders specific for each student and made sure to include their immunization record, UTSW paperwork, Parkland paperwork, and CITI training certificates. Afterward, The Vice Chief and Credentialing Specialist sent emails for each student with attached documents to Mrs. Kocurek.

Eleventh Week

Monday, August 6, 2018

I worked on finalizing the syllabus for TEMRAP and once I finished it I emailed a copy to Ms. McNabb and Dr. Pierce for revision. Later in the day, I worked on creating a PowerPoint presentation for the combined session of training for the upcoming TEMRAP orientation. I asked the Vice Chief for more details about the pod and lobby shift changes. I completed the IRB portion and I will be adding a few more details tomorrow regarding other major changes to the program. I continued sending emails with temporary passwords to the returning students. I spoke to Ms. McNabb about master packet change for intervention. I was able to determine a more effective manner of presenting the patient simulation. I decided to have two separate master packets, (master packets include the studies the RA will be presenting to the other student playing the patient role). Since students will be paired off in groups of two I believe it was more effective to have two scripts per pair. The first student will present the first study packet (two master packets: one will have Anxiety CP + CP PP and the other packet will be Afib + VS, both will include all formal consent study tasks) and the second student will present the other packet.

Tuesday, August 7, 2018

First thing I worked on today was creating a task sheet for the master packets. The task sheets will separate the different parts of each master packet and notify the RA of the task they are performing to the corresponding clinical research study. I worked on the TEMRAP student

manual with Vice Chief and Chief of the program. We made changes to the manual of operations section pertaining to lobby shifts. We edited the application timeline section as well as the student conduct policies.

Wednesday, August 8, 2018

I continued working on the credentialing of new TEMRAP RAs. I was checking the immunization records, TB test, Drug test, and Flu shot records with the information recorded by the TEMRAP Vice Chief on an excel sheet. I was able to get through twenty-two RAs today and will continue tomorrow. I continued to prepare my script and scenario for Friday's first day of TEMRAP orientation. I emailed Ms. Lewis, the IRB committee member in charge of reviewing my clinical research proposal, to see if she need anything else to push forward the review process. I continued working on prepping for Fridays Orientation.

Thursday, August 9, 2018

I initially wrote out a list of tasks needed to be completed before tomorrow. I started by editing and finishing up the PowerPoint presentation for our combined session of returning TEMRAP RAs. We included slides on IRB, major program changes for Fall 2018, and all the paging studies for this fall with inclusion as well as exclusion criteria.

Friday, August 10, 2018

Today was the first orientation day. We started the day by trying to get badges for the new RAs and updating the badges for the returning RAs. Unfortunately, there was an issue with the RAs' profiles not being created in the system. We had to contact HR and see if they could manually input the RAs information. They told us this could take some time and to wait at least 48 hours before calling again. During the rest of the day, the RAs attended several orientation presentations until lunch time. After lunch, they split up into their designated groups and me as

well as the Vice Chief gave a PowerPoint presentation to the all the returning RAs before splitting them up into the two groups. I took the intervention group upstairs and one of the other TEMRAP leaders took control down to the library room. The research study went well I believe and I am looking forward to next week.

Twelfth Week

Monday, August 13, 2018

I was feeling unwell today and did not go into the office today.

Tuesday, August 14, 2018

I was still feeling unwell today and went to the clinic to get some medicine for my allergies. In the afternoon I felt a little better and I worked on sending emails. I sent new RAs emails with temporary passwords, so they can eventually register their accounts in the UTSW system. I also worked on verification of new RAs' immunizations and drug screening dates were inputted correctly.

Wednesday, August 15, 2018

I read my emails from RAs and TEMRAP leaders. I sent a few emails to returning RAs with temporary password information. I spoke to Ms. McNabb over the problem with getting new RAs badge profiles created and into the UTSW system. She told me she had emailed IR about the problem, but I told her I could go to HR and talk to them. So, I went to the Bass building on North Campus to talk to HR about creating badge profiles for new RAs. I was able to get them a list of all the RAs with username and they told me they could input the information into their system by this afternoon. They told me the RAs should be able to get their badges by Friday. Later in the day, I received an email confirming the RAs badge profiles had been created and were ready to get badges. I finished sending the temporary password emails to list an of 30 new

RAs, which I received from the Vice Chief. Towards the end of the day, I continued working on verification of immunizations of new RAs.

Thursday, August 16, 2018

I focused on getting all the materials for orientation tomorrow prepared and so I printed out 30 copies of the TEMRAP syllabus, student manual, and presentations. I made sure to get the combined session PowerPoint up-to-date to present to returning RAs. I had to make copies of my enrollment packets to be used for returning RAs as well as additional confidence surveys. I made sure to print 20 copies of the knowledge surveys for both intervention and control groups. I spent the rest of the day finishing up the verification of immunizations for new RAs.

Friday, August 17, 2018

Today was the second day of TEMRAP orientation and I arrived in the office around 7:45. I prepared to meet the RAs for orientation in the visitor center. I made sure to print out sheets of paper for the new RAs, which included their S-number, so it would be easier to get their badges. I initially helped organize the students at the visitor center to get new badges. I printed out sheets of paper for the new students with S-number in case they did not remember it. For the first half of the day, I spent preparing to present about the IRB to returning students as well as gather my material for my training intervention. After lunch, the returning groups joined me and the TEMRAP leaders for a 30-minute combined information session. I presented information on the IRB and Good Clinical Practice, while the Vice Chief updated the RAs on the major program changes as well as the new paging studies. Afterward, I gave verbal consent to the students about using their information for my proposal, I told them if they did not want their information to be used they could let me know. I received unanimous consent from the RAs and we continued with the experiment. The RAs were split into their groups and the intervention group stayed with me

in the small conference room, while the control group went downstairs into a library conference room. I instructed the leader of the control group to go through the studies as they normally have in the past but to make sure to pass out the confidence survey and knowledge questionnaire before and after the training. In my group, we began training by doing a demonstration of what was expected when enrolling a patient. I used the master packets I created which included formal consent and task from ongoing research studies. Myself along with the Vice Chief described how to fill out tasks and how to properly give a patient consent. Afterward, I told the RAs we would be breaking up to pre-assigned pairs and begin the training. One person would play the role of an RA and enroll the other person playing the part of the patient. I randomly assigned each person a master packet to go through with their partner. Once they finished enrolling a TEMRAP leader assigned to observe would go through the packet. They would give the RA feedback on performance and quality of data collection. I began to notice RAs would act to make mistakes or would be unsure about certain parts. I saw RAs ask questions and be engaged in learning the enrollment packet material. Once the RAs took the confidence survey and knowledge questionnaire after training they were allowed to go home.

Thirteenth Week

Monday, August 20, 2018

I went through orientation paperwork and I organized the confidence surveys as well as the knowledge questionnaires. I did some grading and found some commonly missed questions. I spoke to the Vice Chief about these discrepancies and made note of why these questions could have been missed. I spoke to Ms. McNabb about the verification of all RAs immunizations and how I have gone through them to make sure the dates were correct.

Tuesday, August 21, 2018

Today I spoke to Ms. McNabb about doing a community outreach program with the TEMRAP RAs. We will be working a UTSW tent for the American Heart Association annual Heart Walk. Later in the day, I was assigned to a GroupMe chat group for a group of TEMRAP RAs. I would be the leader of a group of 20 students and would act as a liaison for any questions they may have for TEMRAP student leaders.

Wednesday, August 22, 2018

I worked on compiling emails from RAs into folders according to the subject. I made folders in my outlook inbox for flu shot information, Taleo training certificates, and any other miscellaneous documents RAs sent to me. I spoke to the Vice Chief about any changes to next week orientation and we worked on updating the knowledge questionnaire for next week.

Thursday, August 23, 2018

I continued updating the excel spreadsheet with students who emailed me completed Taleo training certificates and updated flu shot records. I updated the combined training session PowerPoint with new material for next week orientation of returning RAs. I received from my Major Professor a finalized schedule of due dates for my final proposal paper. Since my defense date is set up for Oct. 29, 2018, I must try and have a rough draft of my paper by Sept. 17, 2018.

Friday, August 24, 2018

I worked on verifying the TEMRAP RAs Taleo training certificates and putting the information in an excel spreadsheet for the credentialing specialist. I continued to receive emails regarding temporary password for UTSW email access.

Fourteenth Week

Monday, August 27, 2018

I was in contact with TEMRAP Chief and Vice Chief throughout most of the day. We spoke about the topics to discuss at Wednesday meeting and about any current RA concerns. I was asked to create confidence survey for lobby shift training session tonight. The survey was similar to the one I created for my proposal. I continued monitoring my email for RAs Taleo certificates and flu shot records for the credentialing process.

Tuesday, August 28, 2018

I accompanied Mario to the Clinical Research lab to process blood specimens collected for a study and he demonstrated the proper blood techniques. I was shown the proper attire to wear when dealing with blood samples as well as how to use the equipment in the lab.

I continued working on my defense rough draft. I continued getting emails for Taleo certificates and flu shots. I included these items in an excel document I created to verify the student and their completed tasks.

Wednesday, August 29, 2018

I shadowed Mario for most of the day today. We started off going to Parkland to screen for patients for actively enrolling studies. I was able to learn about the administrative duties of a clinical researcher. I was taught one must be able to split time between enrolling patients from the sites as well as responding to sponsors.

In the afternoon met with TEMRAP Vice Chief and Chief to discuss credentialing plans, and current status of patient enrollment start date (when RAs will be in the ED to recruit patients)

I also discussed meeting with Michelle, who is in charge of gathering study data and calculating error rates. Lastly, we had a team meeting with Dr. Pierce and Ms. McNabb discussing the addition of a new study (Frailty study) as well as the plans for TEMRAP.

Thursday, August 30, 2018

I Continued working on the credentialing emails from RAs, which included Taleo certificates and flu shot records. I worked on my defense further adding new figures and discussion. I made sure to print out the lecture PowerPoints for the RAs attending tomorrow's orientation. I printed extra copies of knowledge questionnaire, confidence survey and a roster sheet for RAs to know what training group they will be in tomorrow.

Friday, August 31, 2018

Today was the third day of TEMRAP orientation and the final day for returning RAs to attend training. During the day, the RAs attended several orientation presentations until lunch time. After lunch, they split up into their designated groups and me as well as the Vice Chief gave a PowerPoint presentation to the all the returning RAs before splitting them up into the two groups. I took the intervention group upstairs and one of the other TEMRAP leaders took the control up to the library room. The research experiment went well and there was a lot of positive feedback by returning RAs.

Fifteenth Week

Monday, September 3, 2018

Labor Day Holiday

Tuesday, September 4, 2018

I went to the Bass building around noon to pick up shirts for the AHA "Heartwalk." I will be participating in this volunteer opportunity with a group of TEMRAP students and Ms. McNabb this coming Saturday morning. Monthly Departmental meeting: We discussed the "reboot" new introduction of PeopleSoft software. Department head announced fiscal year surplus and discussed the budget for the Emergency Medicine Department. A good candidate for content coordinator has been found and more discussion will occur tomorrow. Education spoke about

residency recruitment in the coming months. Finance introduced a new employee and spoke about the main difference in the reboot of a software system.

Wednesday, September 5, 2018

I separated my data from the training experiment. I made an excel sheet with the knowledge questionnaire scores for each RA in the control and intervention groups. I made sure to calculate the average and the mean difference between each group. I further separated the data with scores before and after training. I made a second excel sheet with the confidence survey data. I created an item list analysis for the 8 questions asked from the confidence survey. I calculated the average for each question with a range of 1 to 5. I then separated the data into the control and intervention groups and a before and after training. I calculated the mean difference between the intervention group and the control group for each question. I then calculated the mean difference of total confidence before and after training. I followed up with calculating the mean difference of total confidence for the control and intervention groups.

Thursday, September 6, 2018

I continued creating an outline for the discussion and results portion of my thesis today. I also printed out material for tomorrow's final TEMRAP orientation day. The materials included handouts of each powerpoint presentation. Two important documents covering the confidentiality of data and attestation of TEMRAP to be filled out by students. I made sure to make copies of the program manual and syllabus as well.

Friday, September 7, 2018

I met students in the visitor center to start with the badge process, but the office did not open until 9 am. We had to take the students up to the office to start orientation early. We decided to take students into groups to get badges once the offices opened at 9 am. During the didactic

portion of orientation, I worked on my data sets to send to the UTSW biostatistics. I worked in excel making a confidence sheet and a knowledge sheet. I was able to finish it by lunchtime when I realized there were some errors with the S-numbers corresponding to students actual scores. I had accidentally mixed up some students and placed them in the wrong experimental group. Later in the day, I printed out Access clinical study awareness brochures to pass out tomorrow at the annual AHA "Heartwalk."

Sixteenth Week

Monday, September 10, 2018

In the morning I responded to emails dealing with TEMRAP credentialing. I was in contact with the TEMRAP Vice Chief and sent her some missing files for new RA. I had a mock interview later in the day with my major professor at UNTHSC. I meet with Dr. Hodge to also talk about my upcoming practicum deadlines. We spoke about what is expected in my first draft due September 17. She explained to me the difference between the results and discussion portions. I told her I would not have all my results in by this time because I am still working on obtaining research study packets from students. The returning students going to pod shift to enroll patients started on August 31 and only two students per shift are allowed to work. I was able to obtain 15 study packets to review for errors so far and I am expecting more later this week. Overall Dr. Hodge gave me good ideas on how to outline my first draft and I will continue to work on updating the practicum paper.

Tuesday, September 11, 2018

In the morning I checked the Groupme forum, where students can text the TEMRAP leaders about any questions, problems or concerns they may have during an off shift. Last night a few issues came up with the pod shift studies, a few were missing data collection sheets. This sheet is

an important aspect of clinical research studies where patient information is obtained. It includes the MRN or the number given to a patient when they present to the emergency room. Two students noted on the GroupMe several anxiety/chest pain studies were missing this form. Luckily the Vice Chief was able to come up with a quick solution. The students went ahead and wrote on the cover each packet, “missing the data collection sheet” to signify those incomplete study packets. The TEMRAP leader responsible for keeping the packets up to date and fully stocked told me he will be going into Parkland on Thursday to get those packets. He will be checking if any other packets are missing data collection sheets. Later in the day I sent a few more credentialing emails to the TEMRAP Vice Chief and spent a few hours editing my practicum. I was able to create an outline of the abstract page, acknowledgments page, introduction, and table of contents.

Wednesday, September 12, 2018

In the morning I asked Mario to if he would be going to Parkland Hospital to screen for patients. I accompanied him in order to pick up the enrollment packets from RAs pod shifts. The lockbox was full of studies and I was able to bring back a lot of enrollment packets with valuable information for my study. Later in the day the TEMRAP leader responsible for going through the packets to verify if RAs completed the studies they stated in an email to Mario. The leader also went through to check for error rates and uploaded them to an excel sheet for me to send to the biostatistician for analysis. I continued working on my paper adding an outline of the appendix, tables, and figures. I made sure to update the information in each section as well as new changes. In the evening I had a conference call with Ms. McNabb and the TEMRAP leader to talk about any concerns during the first two weeks of RA shifts as well as new changes.

Thursday, September 13, 2018

I continued working on my practicum paper creating an introduction and cleaning up the materials and methods sections. I was able to talk to Ms. McNabb about setting up a meeting with the UTSW biostatistician Mrs. Beverly Huet. Ms. McNabb reviewed the statistical information sent by Mrs. Huet covering the knowledge and confidence data sets. Later in the day we discussed the results briefly and realized there was not much difference in confidence or knowledge between the control or intervention group. We did, however, notice there was an overall improvement in both knowledge and confidence in both groups after their designated training.

Friday, September 14, 2018

I emailed the TEMRAP Vice Chief regarding final credentialing documents of a few new RAs. We also spoke about the following weeks and how many RAs will be expected to shift in the pods. The data from the pods will be used to calculate the error rates and the overall effect of both pieces of training on quality of data collection. I was able to message the leader in charge of calculating error rates about her availability next week. She will be coming in on Wednesday again to continue calculating error rates for the enrollment packets completed by RAs. Finally, Ms. McNabb and I were able to send an appointment with the UTSW biostatistician to go over the test she did on my data sets I collected the previous weeks. We will be meeting on Monday at 10:30 am to discuss the results and what they mean.

Seventeenth Week

Monday, September 17, 2018

I worked on revising my paper for most of the morning. I ended up altering the title of my practicum as well as modifying the material and methods sections. Around 10:30 am Ms. McNabb and I met with Mrs. Huet to discuss the statistical analysis of my data sets. Mrs. Huet

explained to me why she chose the test she did for the knowledge and confidence scores. She did a great job of explaining the results of the test and what this means for the intervention as well as control groups. In the afternoon I added some more information to my methods and materials section. I outlined the results and discussion portion. I worked on making an online version of my confidence survey and knowledge quiz to get RAs to fill out for the post-1-month test. I set up an excel sheet for demographic information of participants to be filled out later this week. I forwarded the data sets for pod data error rates collected up to date to Ms. McNabb.

Tuesday, September 18, 2018

This morning I continued working on my practicum paper to get it turned into my Major Professor by Friday. I cleaned up the background and literature section. I found some more useful sources as well for my introduction and methods section. I kept gathering demographic data to send to the UTSW biostatistician.

Wednesday, September 19, 2018

I came into the office in the afternoon because I was in the library researching the different statistical test used for my data sets and understanding how my results relate to my proposed thesis. I met up with the TEMRAP Vice Chief in the afternoon to talk about how to distribute my knowledge questionnaire and confidence survey to participants for the one-month period. We recreated the questionnaire and survey onto a google form. We then sent a like to all the participants to complete these forms and additionally to answer some demographic questions. I informed them the deadline was Friday to turn in the responses.

Thursday, September 20, 2018

I finished the background and literature review section of my thesis today. I added an outline of the results, discussions, limitations, summary & conclusion, and the abstract sections of my

paper. I focused on cleaning up and updating my methods section today. I spoke to Ms. McNabb about sending her a draft of my paper this afternoon. She took home a copy and told me she would look over it. Afterward, I continued reviewing my results from the knowledge and confidence data sets.

Friday, September 21, 2018

In the morning Ms. McNabb returned to me a copy of my edited thesis. I took the time to review it and made the necessary changes to my thesis. I sent my draft to Dr. Hodge around lunchtime after I finished my major edits. I then asked Ms. McNabb for a copy of her notes over the confidence and knowledge datasets she took when speaking with the UTSW biostatistician. I spent the rest of the day finishing my introduction and methods section. At the end of the day, I asked Ms. McNabb for advice on what graphs to include in my results section. She gave many helpful tips and I will work on finishing those sections this weekend.

Eighteenth Week

Monday, September 24, 2018

I received feedback from my Major Professor, Dr. Hodge about the first draft of my practicum. She brought up some good points about the experimental methods and results. They were lacking accurate descriptions and the overall flow of the presentation of the material was all over the place. She asked me questions about how exactly I did the confidence and knowledge analysis and how I planned on doing the error rate analysis. These questions brought to light some missing components of my practicum. Later in the day, I went into the office and was able to meet with the UTSW biostatistician. I was able to ask her about these components of my practicum and she did a really good job of clearing up how exactly the analysis of knowledge, confidence, and error rate worked in my experiment. As for the error rate data analysis, she told

me she would be able to use A Wilcoxon Rank Sum test. I was able to talk to Ms. McNabb as well about my changes and I asked her for her opinion on these aspects of my thesis. Towards the evening I was able to make many changes to my draft and I gave my version 2 to Ms. McNabb to review.

Tuesday, September 25, 2018

I came into the office and worked on editing my practicum. I was able to update parts of the background and methods sections. I received an edited version of my practicum from Ms. McNabb. I worked on changing the grammatical mistakes I made as well as working on creating figures and tables. I spoke to Mario about going to the Emergency Department staff lounge to pick up enrollment packets completed by RAs. He told me we could meet at 9 am tomorrow to go over to Parkland Hospital. I briefly spoke to the error rate RA and set up a time for her to come by tomorrow to verify the enrollment packets. I was also in contact with the TEMRAP leader responsible for printing packets and set up a time for him to come by the office to print more enrollment packets.

Wednesday, September 26, 2018

I was in the office early to meet with Mario and go to Parkland Hospital. He had a conference call with a clinical research sponsor and so I took the time to continue working on my practicum paper to send another updated version to Dr. Hodge. Afterward, I accompanied Mario and the new Clinical Research Coordinator Riley to Parkland Hospital. I was able to pick up the data enrollment packets from the safe and counted number of enrollment studies in the ED. I confirmed with the Error Rate Leader and she was in the office around 3.

Thursday, September 27, 2018

I continued working on editing my practicum paper. I was able to send an updated version to Dr. Hodge by the end of the day. Ms. McNabb, Mario, and Riley were out of the office today and will be gone until Monday for a conference in New Orleans. I added some more information into my results section and reread my paper for grammatical errors.

Friday, September 28, 2018

None of the team was in the office today and as such, I worked on my practicum for most of the day. I was able to clean up the procedures section of material and method as well as finish up a summary of the internship site. I am hoping to have my data analyzed by Mrs. Huet the biostatistician by next week. I sent her a final copy of my data sets for the error rate with the total mean between the intervention and control groups.

Nineteenth Week

Monday, October 1, 2018

Today I worked remotely from home and did not come into the office. I continued editing my paper in preparation of my meeting with Dr. Hodge. I fixed the grammatical edits in the introduction and background literature made by Ms. McNabb. I started putting together my demographic data table from participants and noticed only 19/25 had responded. I received an email from the UTSW biostatistician to remind her early this week about reviewing my error rate data set.

Tuesday, October 2, 2018

I had a meeting with Dr. Hodge today to review my version 3 of my practicum reports. We spent an hour and a half talking about formatting, grammatical, and overall fluidity of practicum paper. Dr. Hodge gave me a lot of good tips on how to prepare for my defense and what to focus on weekly. After explaining to Dr. Hodge about my predicted timeline and how I still waiting for

some data sets to be analyzed, she suggested I wait to send out a final draft of my practicum a week prior to my defense. I sent out an email to my committee and Dr. Mathew, luckily, they were all willing to grant me approval. In the afternoon I came into the office and updated Ms. McNabb on my suggested timeline for the rest of the month as well as updated her my meeting with Dr. Hodge. Ms. McNabb also suggested I email the UTSW biostatistics reminding her about analyzing my datasets for error rate. I got a response an hour later, stating it will be ready by tomorrow morning.

Wednesday, October 3, 2018

I was able to get my committee's approval for an extension on my final date for submitting my practicum to them. I continued working on my practicum, adding more to my results section and modifying my data. I was able to get in touch with the UTSW biostatistician and she sent me the error rate data. I examined it and wrote out any questions I had to ask her later in the week. I spoke with Ms. McNabb and set up a meeting next week to spend time editing my practicum. We set up a meeting for Wednesday, Oct. 10.

Thursday, October 4, 2018

I made an outline for the rest of my results and Discussion section. I formulated a plan for the types of figures to include in my practicum and how to present the statistical data. The rest of the day of I focused on incorporating the error rate data into my results section.

Friday, October 5, 2018

I ask Ms. McNabb if I could work in the library today and she approved. I continued writing my practicum in the library today because the office was busy. I focused on adding the rest of the discussion section regarding the error rate data. I made an outline for the type of figures to include for my knowledge and confidence data. I emailed Mrs. Huet (biostatistician) asking her

for help over further analysis of some of my data. I was wanting to find out which statistical test would be best for seeing if a correlation existed between two variables. More specifically, I wanted to see if a statistically significant correlation existed between the RAs' knowledge and error rate or RAs' confidence and error rate.

20th Week

Monday, October 8, 2018

I began compiling data into excel to make figures and tables for knowledge, confidence, and error rates data. After discussing with Ms. McNabb, she recommended making bar graphs for the knowledge and confidence results. I also asked her if pie charts would be useful for presenting the error rate data and the frequency of errors made by RAs. I ended up making the bar graphs and a histogram for the error rate. Making the excel graphs took a little longer than intended and thus I will work on the pie charts at a later day.

Tuesday, October 9, 2018

The clinical research team was very busy today because of a site visit from a monitor. I was able to observe how site visits work and spoke to Mario about what is expected when a monitor comes to a site. The site visit was at Clements University Hospital and it was for the study STAND UP. Later in the day, I spent a few hours working on my discussion portion before my meeting tomorrow with Ms. McNabb

Wednesday, October 10, 2018

I spent most of the day in a meeting with Ms. McNabb, reviewing my practicum paper so far. I was able to ask her several questions about formatting my information. I decided to place most of my figures in the appendix and we discussed which ones I should include from the data analysis done by Beverly. We also talked about how to present my discussion and to make sure

to answer my questions I stated in the specific aims section. She told me to also make sure to keep a running order of how my information is presented through my paper. I should talk about my main goal first in each section and then follow up with my secondary aims. The priority will be error rate discussion followed by a discussion of confidence data than knowledge data.

Luckily later in the afternoon, Ms. McNabb had a meeting with Beverly and I was able to ask all my data analysis questions. She also brought me the data for investigating if any correlations existed between knowledge and error rate or confidence and error rate. In the evening we had our biweekly TEMRAP leader call meeting. We discussed any updates from the past week and any new information. Ms. McNabb stated the community outreach went well and we also heard from the TEMRAP Chief about students' surveys. Most students were really satisfied with the program and a couple complimented the efficacy of my new training. There were a few complaints, but they were constructive criticism.

Thursday, October 11, 2018

In the morning I worked on compiling the data for the one month follow up knowledge and confidence surveys. I was able to finish them and send the information to Beverly for analysis, along with the demographic data. I spent the rest of the afternoon adding new graphs and tables for my results sections. I was able to get an updated rough draft version to Ms. McNabb to review.

Friday, October 12, 2018

There was another site visit this morning, so I spent the morning at the library working on my thesis practicum. I continued to add in new graphs and figures as well as compose a presentation for my defense. I was able to get the final data analysis from Ms. Huet, regarding weekly error rate comparison across and within training groups.

21st Week

Monday, October 15, 2018

I was at UNTHSC campus today early to work on my defense PowerPoint before my meeting with my Major Professor, Dr. Hodge. We spent an hour and a half reviewing my PowerPoint, starting with my introduction through the summary and conclusion. Even though I was not completely done with summarizing all my results it was very helpful to get a template set up. Dr. Hodge has me very good insight on the type of formatting to have throughout my presentation as well as etiquette tips for the day of my defense. We talked about what to expect from the public and private defense. I was not able to time myself on how long it would take to give my defense because we had a lot to talk about, but she reassured me it would be under 45 minutes. After our meeting, I sent her a copy, so she could edit it and send me back additional feedback. I stayed at UNTHSC for the rest of the day to continue working on my practicum report and adjust my presentation.

Tuesday, October 16, 2018

In the morning I meet with Ms. McNabb and I was able to set up a timeline with her to practice my PowerPoint presentation. I took the time to send the presentation with my Major Professor edits. We further discussed how my progress was going for my practicum and I told Ms. McNabb, I was close to finishing. I finished writing out most of my results and discussion section, but I still need to clean up my figures and tables.

Wednesday, October 17, 2018

I spent most of the day working on my final draft, specifically the limitations, future direction, and summary/conclusion sections. I was able to complete a preliminary draft of these sections

and make it flow in the order of my results. I plan to polish up the rest of my paper tomorrow and will have a meeting with Ms. McNabb to discuss my timeline again.

Thursday, October 18, 2018

I spent the entire day cleaning my final rough draft as well as going over a bit of my PowerPoint presentations. I was able to finish up everything except the journal summary section of my practicum paper. I am planning to finish my paper this weekend and send a copy to Ms. McNabb tomorrow to review. I am still working on finalizing my PowerPoint for my Defense in a few weeks.

Friday, October 19, 2018

I was able to send a rough draft final copy to Ms. McNabb to review for formatting issues and content. I was in touch with my major professor as well to set up another practice defense date. I worked in the library today in order to be able to look up any final resources.