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Safety Measures in the Epilepsy Monitoring Unit: An Organizational Assessment

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Running head: SAFETY MEASURES IN THE EPILEPSY MONITORING

**SAFETY MEASURES IN THE EPILEPSY MONITORING UNIT: AN ORGANIZAITONAL
ASSESSMENT**

by

Tina R. Yates, BSN, MS, Post-Master's FNP Certificate

Doctor of Nursing Practice Final Scholarly Project

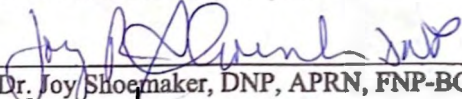
In Partial Fulfillment of the Requirements for the Degree


Doctor of Nursing Practice

Otterbein University

2022

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Executive Summary

Long-term video-electroencephalography (EEG) monitoring in the epilepsy monitoring unit (EMU) is an elective procedure and generally safe. Clinical experts determined the EMU protocols at a level-4 comprehensive epilepsy center were not followed correctly. The project is a retrospective chart audit incorporating Ray's Bureaucratic Caring theoretical framework with Donabedian's conceptual model. The project objective is to evaluate if safety measures protocols are implemented appropriately in the EMU and determine whether a need exists for quality improvements.

The project reviewed patients admitted to the EMU from September 2021 through November 2021 who developed a generalized tonic clonic (GTCs) seizure with electrographic epileptiform correlation. Data abstractors collected seizure safety indicators from eleven patients with fifteen GTCs. Of the fifteen GTCs, the seizure safety efficiency indicator revealed an average GTC was 92.7 seconds, and the time to responder response was 43.6 seconds. The GTC management and seizure precaution indicators showed (53%) had suction set up, (60%) suction initiated, (67%) vital signs recognized, (53%) no one called out vital signs, (40%) vital signs obtained, (60%) variation of a neurological assessment, (13%) of patients turned on their side, and (80%) had no objects to cause injury. Other indicators include (93%) had four side-rails up, (100%) no one called out bed in the low position, (13%) had continuous pulse oximetry, and (80%) had IV access and continuous telemetry. Interventions to stop seizure indicators include (67%) no one called out Ativan administration, (60%) no one called out notifying physician. During the postictal stage, (87%) variation of a neurological assessment, (73%) variation of vital signs, and (80%) postictal suctioning occurred. Medication change indicator revealed (80%) of antileptic drugs (AEDs) stopped and (20%) on AEDs. Of the fifteen GTCs, two GTCs, no one responded.

The project identified practice gaps in all seizure safety indicators, necessitating further investigation. Performance improvement efforts or quality improvement initiatives to lower EMU-related seizure emergencies, injuries, adverse events, and fatalities should be employed to prevent seizure safety concerns during an EMU evaluation.

Introduction

Long-term video-electroencephalography (EEG) monitoring in the epilepsy monitoring unit (EMU) is an elective procedure and generally safe (Atkinson et al., 2012; Lee & Shah, 2013). To accomplish diagnosis and best treatment, patients are admitted to the EMU and exposed to provocative measures like photic stimulation, hyperventilation, sleep deprivation, and tapering antiepileptic medications instead of preventative measures.

Clinical Problem

Provocative measures increase the risk for seizure emergencies, injuries, and significant adverse events, including falls, status epilepticus, and postictal psychosis (Atkinson et al., 2012). Although rare, fatalities such as sudden unexpected death in epilepsy (SUDEP) and near-SUDEP can occur (Atkinson et al., 2012; Lee & Shah, 2013; Ryvlin et al., 2013). Currently, no organizational data exists to support practice changes, which emphasizes the need for an organizational assessment.

Clinical Needs Assessment

Improving quality and safety concerns in the EMU is of utmost importance. Since the Institute of Medicine (IOM) (1999) publication “To Err is Human: Building a Safer Health System,” organizations strive to improve quality outcomes in healthcare settings. The literature on nursing practice guidelines for quality and safety in the EMU are scarce and heterogeneous (Sauro et al., 2016a; Sauro et al., 2016b). A level-4 comprehensive epilepsy neuroscience center in central Ohio referred to as the EMU. The EMU integrates a multidisciplinary approach within a state-of-the-art specialized inpatient unit, providing the highest level of individualized epilepsy care, extensive medical, neuropsychological, and psychosocial treatments, and the most advanced surgical treatment options for patients with a wide array of epilepsy syndromes. The EMU first opened in 2009 as a two-bed unit, then in 2016, as epilepsy prevalence increased to 1.2 percent of the United States have active epilepsy, around 3.4 million nationwide, a demand for additional beds emerged. The EMU is now an eight-bed unit, admitting ten patients per week, 40 patients per month, and on average 480 patients per year.

In 2014 the EMU joined the National Association of Epilepsy Centers (NAEC) and was accredited as a level-4 comprehensive epilepsy center. During project planning discussions with organizational key stakeholders, including epileptologists and the clinical outcomes manager, EMU seizure safety protocols were identified. EMU seizure safety concerns from two epileptologists, including the System Medical Chief of Epilepsy and an epileptologist recruited from Mayo Clinic comprehensive EMU, have witnessed incorrect or absent clinical use of the protocols. The epileptologist identified safety practice gaps during the review of EEG recordings and video monitoring that included delayed nursing and EEG technician response time, delayed time to airway, breathing, and circulation (ABC) evaluation, minimal to no neurological assessments, delayed time to initiation of seizure precautions, lack of safety measures for fall prevention, delayed time to initiation of seizure precautions, and no call out of Ativan administration or notifying the attending.

Problem Statement: PICO(T) Question

For EMU patients, does adherence to seizure safety measures compared to non-adherence of seizure safety measures influence the risk for seizure emergencies, injuries, and significant adverse events, including falls, status epilepticus, postictal psychosis, SUDEP, and near-SUDEP during the inpatient hospital evaluation?

Background and Significance of the Problem

The in-depth literature search examined the Cochrane Library, MEDLINE, a version of PUBMED, EBSCO, and Scholarly Google database using the keywords EMU patients as the problem, the risk for seizure emergencies, injuries, and significant adverse events, which include falls, status epilepticus, postictal psychosis, SUDEP, and near-SUDEP as the outcome, and the intervention using seizure safety measures. The Cochrane Library, MEDLINE, EBSCO, and Scholarly Google databases resulted in no hits for practice guidelines for SUDEP prevention or seizures safety guidelines in the EMU. The literature search concluded with 17 articles on the topic, and 13 articles were eliminated because there was no reference to safety measures and protocols in the EMU. The exhaustive literature search concluded with four articles for critical appraisal and synthesis.

Epilepsy is a common neurological condition, complex with a multitude of seizure syndromes. The EMU video electroencephalography (vEEG) is a resource to capture seizures for diagnostic purposes, quantify the frequency of seizures, optimize seizure medication management, and evaluate individuals for epilepsy surgery candidacy. The purpose of the EMU is distinctive compared to inpatient hospital admissions, as the EMU goals are provocation of symptoms by withdrawing antiepileptic drugs (AEDs) and utilization of activation methods such as sleep deprivation, photic stimulation, and hyperventilation. Ultimately, symptom provocation places individuals at serious risk for seizure emergencies, injuries, and significant adverse events, including falls, status epilepticus, postictal psychosis, SUDEP, and near-SUDEP (Sauro, et al., 2016a; Sauro et al., 2016b). A needs assessment is vital to complete a systematic data-driven process to identify safety gaps in practice by determining the existence, frequency, and contributing factors to seizure emergencies, injuries, postictal psychosis, SUDEP, and near SUDEP in the EMU.

According to Labiner et al. (2010), the NAEC emphasizes that safety protocols and guidelines in the EMU are incumbent for epilepsy centers worldwide, providing the impetus for epilepsy centers to develop a systematic, well-organized approach to developing safety measures and protocols in the EMU. The NAEC established the first set of safety protocols for epilepsy centers in 1990 with the latest recommendations in 2010 for epilepsy centers to become distinguished as a level-1 through level-4 comprehensive epilepsy center (Labiner et al., 2010). Several essential organizations disseminating the latest original epilepsy research include the International League Against Epilepsy (ILAE) and the American Epilepsy Society (AES). The NAEC, ILAE, and AES recommend that level 4 comprehensive epilepsy centers provide safety protocols which include nursing protocols regarding patient safety and assessment, guidelines for safety protection while in and out of bed, postictal psychosis protocols, status epilepticus protocols, and management protocols for seizure emergencies similar to cardiac arrest response (AES, 2021; Labiner et al., 2010; Velis et al., 2007).

Four articles were evaluated utilizing a general appraisal overview tool to evaluate relevancy, reliability, and validity related to the PICO(T) question. The articles that met most of the evaluation

criteria were synthesized and summarized (Appendix A, Table 1). The first article synthesized was the MORTEMUS systematic retrospective international survey by Ryvlin et al. (2013). The survey signified severe cardiac and respiratory function alterations during generalized-tonic-clonic seizures, leading to seizure emergencies and increased mortality risk leading to imminent death. The MORTEMUS study reported rare cases of SUDEP but emphasized SUDEP and near-SUDEP occurred in more than 10% of the studies surveyed and suggested the cause was non-adherence and incompetence of EMU staff. Thus, SUDEP prevention is a vital concern in the EMU. The survey concluded with recommendations of the importance of timely detection of cardiorespiratory distress, prompt and effective CPR, constant supervision with frequent nursing assessments, and continuous use of pulse oximetry with alarms and continuous telemetry. The MORTEMUS survey findings recommend that organizations assess for practice gaps in safety measures and develop seizure safety protocols in the EMU (Ryvlin et al., 2013).

Another article synthesized was an observational, retrospective cohort study by Sanchez-Larsen et al. (2019). The article evaluated patients from a Spanish Epilepsy Reference Centre in Spain between 2010 and 2018. Of 1,250 epilepsy patients reviewed, 102 died during the study. The article used descriptive analysis for all variables, including demographics, seizure types, and other medical causes. Findings from the study concluded with four SUDEP patients found in the prone position with cardiac abnormalities, including a right bundle branch block and supraventricular asystole. Of these patients, three patients did not receive CPR, and one patient received ineffective CPR. The study findings indicate that organizations with comprehensive EMU care require highly specialized, educated, trained individuals providing prompt, safe, and effective epilepsy care (Sanchez-Larsen et al., 2019). Therefore, determining organizational compliance with safety measures and protocols is of urgency.

A rigorous systematic and meta-analysis article methodology by Sauro et al. (2016a) aimed to synthesize data regarding quality and safety in EMUs to develop quality indicators. The article presented the results of a succinct search using the Preferred Reporting and Items for Systematic Review and Meta-Analysis (PRISMA) statement. The data reviewed included demographics and quality and safety characteristics. The article concluded with 135 studies; 181,823 patients admitted to EMU from 1968 to

2016. The study mean quality 11 of 15 (standard deviation [SD] 2.5) or 73.3% with generalizability of nearly every article, 97.1%. Adverse effects proportion was 7% (95% confidence interval [CI] 5-9) with significant heterogeneity ($I^2=71.6\%$, $p < 0.001$), with the median proportion of adverse events 8.0% (interquartile range [IQR] 3.8%). Sauro et al. (2016a) article synthesized data finding a lack of nurse or staff response in clinical emergencies, which increases the risk of adverse effects, including SUDEP, and near SUDEP. Therefore, the article provides evidence to support the need for an organizational assessment to identify practice gaps in epilepsy care (Sauro et al., 2016a).

A quasi-experimental article by Sauro et al. (2016b) is the fourth article synthesized. The article developed evidence-based and consensus-driven quality indicators in the EMU using the methodology standards from the systematic review and meta-analysis by Sauro et al. (2016a). The article abstracted thirty-four quality indicators from 135 studies. Two additional quality indicators supplemented by expert opinion. The article used a modified Delphi technique to obtain a consensus of quality indicators among an EMU multidisciplinary quality improvement team. After two rounds of the Delphi technique, the authors developed 25 quality indicators for quality metrics through a 9-point Likert scale used for systemic data collection (Sauro et al., 2016b). The quality indicators could assist in standardizing safety measures and protocols in the EMU. Thus, an organizational assessment determining practice gaps in seizure safety is an integral step.

Significance of the Problem to Nursing

The lack of nursing awareness, knowledge, and confidence in caring for epilepsy patients in the EMU is a catastrophic risk for patients, families, organizations, and society. The literature search findings determined the failure of nursing knowledge, expertise, and confidence in utilizing timely detection measures. The failures included close monitoring and nursing assessments, inexperienced telemetry nurses, delayed CPR, lack of nocturnal nurse-to-patient supervision, and absence of continuous pulse oximetry with alarm use was associated with risk for seizure emergencies, injuries, status epilepticus, postictal psychosis, SUDEP or near SUDEP in the EMU.

Scaffolding the Project

Theoretical Framework

Marilyn Anne (Dee) Ray's Complex Holographic Theory of Bureaucratic Caring originated in 1981 and was selected as the theoretical framework for this project. According to Ray (1989), bureaucratic caring focuses on caring for individuals within the complexity of an organization. Ray's theoretical framework began as a grounded theory methodology with influences from phenomenology and ethnography, then evolved into a formal theory. As discussed in Coffman (2017), Hegel's theory is the interrelationship between thesis, antithesis, and synthesis and influenced the Bureaucratic Caring theory. Ray's theoretical framework focuses on the thesis of caring, the antithesis of bureaucracy, and synthesis, as the process repeats itself, evolves, and transforms. As Ray's theory continued to evolve, she discovered her theory fits with chaos theory and quantum physics of encouraging nurses to have creativity, innovative ideas within complex organizations, and nurses to discover embedded meanings within a dynamic, complex, holistic bureaucracy (Ray, 1989; Coffman, 2017; Ray & Turkel, 2018).

The aim of the project and aligning with the organization's mission and values are to provide spiritual-ethical caring to the epilepsy population by safe, individualized care through nurse-patient, physician-patient, and provider-patient relationships. According to Coffman (2017), Ray's theoretical framework focuses on nurses' awareness of viewing truth, seeing the good in others, the organization, and effective communication. Ray's theoretical framework' interconnectedness of concepts is the explicate order of spiritual-ethical caring surrounded by the implicate order of educational, physical, social-cultural, legal, technological, economic, and political factors. Spiritual-ethical caring is the dominant modality of the holograph as spiritual-ethical caring is both a part and a whole. The spiritual-ethical caring concept exemplifies moral obligations to others (Ray, 1989; Coffman, 2017; Ray & Turkel, 2018).

Ray's theoretical framework concepts provided the key concepts for the project's aim to identify practice gaps in seizure safety and provide recommendations for evidence and practice-based care during seizure response. The first concept is educational and relates to the meaning of spiritual-ethical caring by providing recommendations of formal and informal educational teaching ideas with different teaching modalities to the epilepsy staff. Another critical concept is political, which influenced the view of the

epilepsy nurses and responder's communications and decision-making. The legal concept relates to responsibility, accountability, guidelines, and protocols. Factors of the economic concept include money, budget, limitations, guidelines imposed by management organizations, and allocation of scarce resources. Physical is another concept relating to the physical state of being, which focuses on the physical state of the data abstractors and expands beyond nursing to other personnel staff based on the organizational assessment findings. Social-cultural is a concept that focuses on social interactions and support and understanding interrelationships involvement and intimacy with the epilepsy culture. Technological is the final concept, with factors including diagnostic tests, pharmaceutical agents, and the expertise of the individuals to utilize the resources (Ray, 1989; Coffman, 2017; Ray & Turkel, 2018).

Conceptual Framework

Donabedian conceptual model (1966, 2005) was the conceptual framework for this project. Avedis Donabedian, a physician and health services researcher at the University of Michigan, originally developed the conceptual framework in 1966, publishing the most frequently cited article, "Evaluating the Quality of Medical Care" (Berwick & Fox, 2016; Donabedian, 1966, 2005). The Donabedian conceptual framework provides a detailed process to evaluate for practice gaps in safety measure protocols in the EMU and to recommend quality improvement initiatives. According to Donabedian (1966, 2005), the framework's first quality indicator describes Structure Measures, which determine the structural components of the EMU, such as the location, size, environment, nurse-to-patient ratios, patient demographics, availability of technologies, and personnel training. Process Measures are another quality indicator describing how the organization works to deliver the desired outcomes, which provided the process of evaluating if epilepsy patients were receiving the seizure safety measures by completing the chart audit review compiled of indicators from epileptology experts to determine if nurses and EEG techs are following seizure safety protocols in the EMU (Berwick & Fox, 2016; Donabedian, 1966, 2005).

The final quality indicator described by Donabedian (1966) conceptual framework is Outcome Measures, which demonstrates if the project had achieved the aim. The project aim is a systematic-data-driven approach to identify significant safety gaps in practice and recommend implementation plans to

lower EMU-related adverse events, reduce EMU-related seizure emergencies, injuries, and adverse events, and optimize epilepsy care to improve early seizure recognition and outcomes. Furthermore, implement a plan to decrease the number of safety-related events, reduce hospital length of stay, and drive the implementation and sustainability of safety protocols in the EMU (Berwick & Fox, 2016; Donabedian, 1966/2005). Lastly, there is the potential to expand safety measures and develop seizure response protocols similar to cardiac arrest response across healthcare systems (Labiner et al., 2010). The project used the Donabedian conceptual model formatively and retrospectively (Hickey & Brosnan, 2017).

The Donabedian conceptual framework, three components approach, was used to effectively compile a systematic-data-driven organizational assessment process to evaluate if safety measure protocols are implemented appropriately in the EMU and to determine the need for quality improvements (Donabedian, 1966/2005). The project aims to ensure EMU patients receive high-quality, evidence-based epilepsy care from a multidisciplinary team of highly qualified experts through recommended sustainable practice changes and improve epilepsy services for the future to ensure quality health outcomes using the Donabedian conceptual framework. Thus, the project aim aligns with the IOM healthcare quality definition, “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (AHRQ, 2020, “What is quality” section). Additionally, using the Donabedian conceptual model encompasses the IOM “Crossing the Quality Chasm” domains to improve quality healthcare by providing safe, effective, patient-centered, timely, efficient, and equitable care (Donabedian, 1966/2005; IOM, 2001).

Project Objectives

The project objective was to complete a systematic data-driven process to identify safety gaps in practice by determining the existence, frequency, and contributing factors to seizure emergencies, injuries, and adverse events in the EMU as no organizational data exists to support practice change. The project aims to identify significant safety gaps in practice, provide recommendations for implementation plans to lower EMU-related adverse events, reduce EMU-related seizure emergencies, injuries, and

adverse events, and optimize epilepsy care to improve early seizure recognition and outcomes. Furthermore, suggest implementation plans to decrease the number of safety-related events, reduce hospital length of stay, and drive the implementation and sustainability of safety protocols in the EMU. Lastly, there is the potential to expand safety measures and develop seizure response protocols similar to cardiac arrest response across healthcare systems.

Methodical Approaches

A retrospective chart audit design was implemented using descriptive statistics and a mix of qualitative and quantitative approaches for data abstraction and analysis. Quantitative data included demographic information using a pie chart and a table with percentages and figures evaluating EEG tech and nurse response time and responder times. Qualitative data using tables and displaying seizure safety variables through a flow chart diagram and the development of a chart audit tool and chart procedure tool with descriptions were employed. Figures, a flowchart, and tables displaying seizure safety variables were employed. The project used the chart audit and procedure tools for data abstraction. The chart audit tool was developed through the Microsoft Excel data extraction software program for data input, quality control, and managing data (Appendix D and Appendix E). The chart audit procedure tool provides a list of each variable and explains how the variables were captured during data collection, providing explicit criteria for the abstractors, and increasing inter-rater reliability (Appendix F). Two meetings were held to discuss ambiguous and conflicting data as recommended by Gearing et al. (2006).

Target Population & Sample

The target population was a convenience sample of 102 patients admitted to the EMU between September 2021, October 2021, and November 2021. Of the 102 patients, 91 patients had no clinical seizures captured or experienced focal seizures without secondary generalization, and patients with psychogenic nonepileptic seizures (PNES) were excluded. Eleven patients (N=11) with a total of fifteen clinical generalized tonic-clonic seizures (GTCs) with electrographic epileptiform correlation were included for data abstraction.

The EMU is integrated into a general neurology unit and staffed by EMU nurses who also staff the general neurology unit. Unfortunately, during the retrospective chart review, the unforeseen global COVID-19 pandemic caused staffing shortages on the EMU, triggering reallocation of nurses, nurse ratio is usually 6-8 patients per shift. The patient support assistant (PSA) to patient ratio consists of 8-16 patients per shift. The EMU has 24-hour continuous live video EEG observation, with supplemental computerized real-time seizure software detection. There are 32 EEG technicians, around six are board-certified EEG technologists. EEG techs would notify nursing staff through a Vocera communication device when events occur. At the time of data abstraction, no protocols exist for the EMU nurses, EEG techs, and PSA's duties when responding to seizure GTCs.

All video EEG recordings include a single electrocardiogram monitor. Seizure safety protocols are padded side rails, and at the discretion of the physician is individualized patient mobility limitations. Tapering of Antiepileptic drugs (AEDs) occurs during the hospital evaluation, usually 24-48 hours after arrival and at the physician's discretion. Hospital length of stay is usually 3-5 days, surgical candidacy evaluation patient's length of stay can extend to 5-7 days.

Standard orders in the EMU include seizure precaution orders and IV access orders on admit. Further standard orders include IV benzodiazepine, Ativan for seizure rescue, and orders to notify the physician of seizures. A staff epileptologist is available 24 hours a day, and a certified nurse practitioner is available during the morning hours each day except for Wednesdays and on the weekends—no neurology fellows or residents.

Human Subjects Protection

The chart audit will not include protected health information (PHI) or any identifiable patient information. The level-4 comprehensive epilepsy center review Committee (Appendix B) and the Otterbein University Institutional Review Board approved this retrospective chart audit (Appendix C).

Instruments and Tools

The retrospective chart audit process of medical records and video EEG with data extraction used a simple, clear, uniform chart audit tool that systematically listed each indicator to enhance internal

validity and reproducibility and included demographic data collection. Two epileptologists who staffed the EMU provided quality indicators observed from previous EMU EEG recordings and video monitoring, in conjunction with the organizational protocols and best practice recommendations. The data abstractors reviewed the vEEGs together in collaboration with the epileptologist. The epileptologist reviewed the vEEG and marked the seizure start times and end times. The data abstractors reviewed each vEEG three times, observing during the first view, then writing on the chart audit tool the seizure start time, postictal time, and the end of the postictal stage. Lastly, the data abstractors recorded the chart audit variables (Appendix D and Appendix E). Each vEEG was reviewed until data abstractors determined the patient was becoming oriented, which became the postictal end time. Abstracting data through the chart audit tool was approved by the level-4 comprehensive epilepsy center with specific requirements to adhere to data extraction (Appendix B).

Timeline & Budget

Timeline

Project planning took longer than expected, approximately seven months (Appendix G). At the time, the development of the project team began in August 2021 through November 2021, obtaining important key stakeholder's support, identifying the target population, and allocating resources. According to AACN (2006), the recruitment of the project team included the project lead, project team leader, mentor, interprofessional team members, and identification of key stakeholders. The mentor was an expert Epileptologist from Mayo Clinic with influential connections and embodied mutual respect for the project leader. The interprofessional team included the System Chief of Epilepsy and Outcomes Office Manager. The two data abstractors were an experienced Advanced Practice Registered Nurse (APRN) and an Epilepsy Registered Nurse (RN). The project leader attempted to recruit the organization's Information Technology (IT) group and Statistician in January 2022 without success.

During the development of the project team, the project leader met with academic advisors at Otterbein University to discuss ideas for the project proposal process. In November 2021, the advisors provided input on developing the Chart Audit Tool and Chart Audit Procedure Tool. The project proposal

approval from the Otterbein University advisors occurred in December 2021. In the following months, approvals from the organizational IRB committee occurred in December 2021 and the Otterbein University IRB in January 2022. Completing the Student Research Fund Grant proposal occurred in February 2022. Partial funds were granted in March 2022 (Appendix H). However, the project cost was \$0.00 (Appendix I, Table 2). The data abstraction started in February 2022. In March 2022, the data analysis and interpretation were completed. Completion of the final project report occurred in March 2022. On April 14, 2022, dissemination of the DNP project occurred at the Otterbein Graduate Student Conference.

Budget

The project costs were initially estimated to include the cost for program software, projecting the cost to be \$100.00, and a statistician with a projected cost of approximately \$300.00. The final cost was \$0.00 as the project leader used Microsoft Excel for data analysis and interpretation, as the program is provided free for Otterbein University students. In collaboration with Otterbein University Professors and Epileptologists, deemed a statistician was not needed. The epileptologist, experienced RN, and outcomes office manager allocated time was approximately 100 hours each and is considered a productive time and compensated through hourly or salary wages through the organization. The project leader's time was estimated to be 300 donated hours to develop Chart Audit and Chart Audit Procedure Tools, the process for IRB approvals, data abstraction, data analysis, and interpretation. Additionally, planning, travel time, meetings, and dissemination of the project are considered (Appendix I). Upon completion, the project leader donated approximately 300 hours.

Analysis and Outcome Evaluation

Data Analysis

The project used descriptive statistics with qualitative and quantitative data. The project used Microsoft Excel to document in spreadsheets and calculate the measure of central tendency, including mean and mode for demographic data calculation and percentages for seizure safety indicators. An experienced RN and the project leader completed chart reviews and vEEG monitoring using the chart

audit and procedure tool in collaboration with the epileptologist. The data abstractors entered in Microsoft Excel demographic data and quality indicators in a non-identifiable format, discarding any written documentation with identifiable information in the organization recycle bins. The chart audit tool collected seizure safety measures, including evaluating efficiency, GTC management with seizure precautions, interventions to stop seizures, evaluation in the postictal setting, and any seizure medication changes (Appendix J).

As Gearing et al. (2006) recommended, the project leader conducted a pilot study. The pilot study of one patient, one GTC to accomplish reliability and feasibility of the chart audit and procedure tool, and the reliability of the individual data abstractor. The data abstractors completed a pilot study of one patient. The study determined a need to update the chart audit tool to reflect specific parameters for each indicator measured and provided the data abstractors the ability to review a vEEG to determine the reliability of the data abstractor's data collection strategies. Data extraction included two experienced abstractors to ensure reliability, including an experienced registered nurse (RN) previously practiced in the EMU and working in the outpatient Epilepsy Clinic. A certified nurse practitioner specializing in epilepsy with over 20 years of neurology experience, ten years of advanced practice registered nursing experience and six years of specialized experience in epilepsy. Discussions with a third data abstractor was an experienced epileptologist from Mayo Clinic. Lastly, the pilot study eliminated any ambiguous or conflicting data (Gearing et al., 2006).

Results

From 120 potential patients admitted to the EMU in September 2021 through November 2021, 102 patients were admitted and identified for chart review. The data abstractors identified eleven patients (N=11) with generalized-tonic-clonic seizures by reviewing medical records, including daily EEG procedure notes, the final EEG procedure note, daily epileptologist progress notes, and the discharge summary. Following chart review, the data abstractors identified fifteen GTCs (N=15) for vEEG review of the eleven patients.

Demographics. The abstractors collected demographic data from (N=11) patients, including age, developmental disability, ethnicity, employment, education, marital status, and seizure frequency. The age range of all patients was 22-69 years, mean of 44.3 years, the median age was 37.5, with a mode of distribution of 50 years. Of the patients, (n=3) patients (27%) were men and (n=8) patients (73%) were women, (Figure 1).

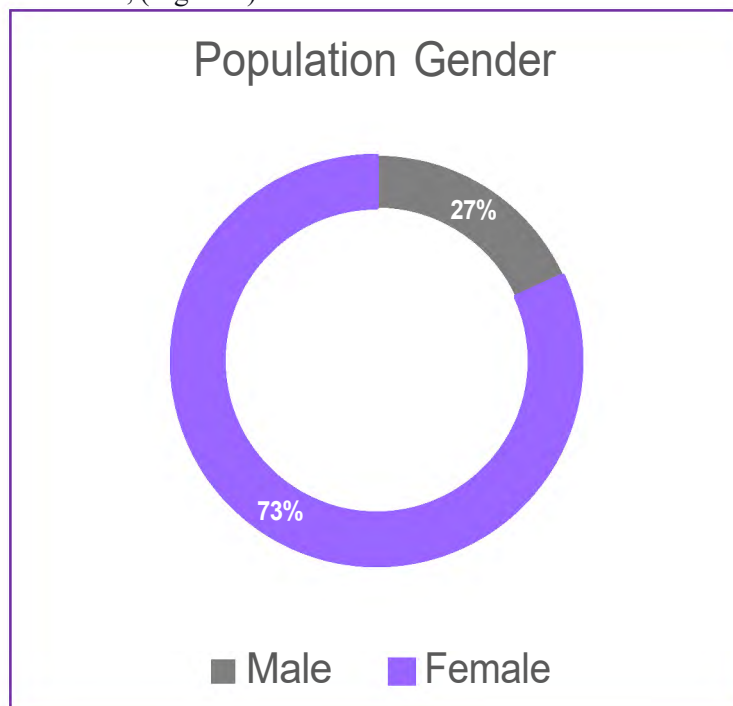


Figure 1. Demographic Characteristics of patients

Sixty-seven percent of patients have developmental disabilities, including cognitive and memory issues. Five patients (45%) primarily had seizure frequency from several times a month to three patients (27%) having several seizures weekly (Table 3).

Table 3
Demographic Data

Baseline Characteristics	n=11	%
Age		
20-29	2	18.2
30-39	3	27.3
40-49	1	9.1
50-59	3	27.3
60-70	2	18.2
Developmental Disability		
Cognitive	2	18.2
Memory	5	45.5
Attention	1	9.1
Unknown	5	45.5
Ethnicity		
African American or Black	4	36.4
American Indian or Alaska Native	1	9.1
Asian	0	0
Caucasian	6	54.5
Native Hawaiian or Other Pacific	0	0
I. slander	0	0
Two or more races	0	0
Declined to Specify		
Employment		
Unemployed	3	27.3
Employed	7	63.6
Retired	0	0
Disabled	1	9.1
Education		
Highschool or less	1	9.1
Some college	0	0
College graduate	0	0
Graduate school	1	9.1
Unknown	9	81.8
Marital Status		
Married	6	54.5
Single	4	36.4
Divorced	0	0
Widowed	1	9.1
Seizure Frequency		
Daily	1	9.1
Several daily	0	0
Weekly	1	9.1
Several weekly	3	27.3
Monthly	2	18.2
Several monthly	5	45.5
Unknown	1	9.1

Efficiency. The data extraction evaluated seizure onset to EEG tech response and time from seizure onset to nurse response (Figure 2). Out of the fifteen GTCs, one patient (7%) had two GTCs during their hospital admission, and during both GTCs, no EEG tech or nurse responded. During three (20%) of the GTCs, the EEG tech and nurse were already in the room. Another patient had a prolonged focal seizure alerting the EEG tech by pressing an EEG alert event button. Therefore, the nurse was present prior to the GTC event. During one GTC, the EEG tech provoked the patient with hyperventilation testing.

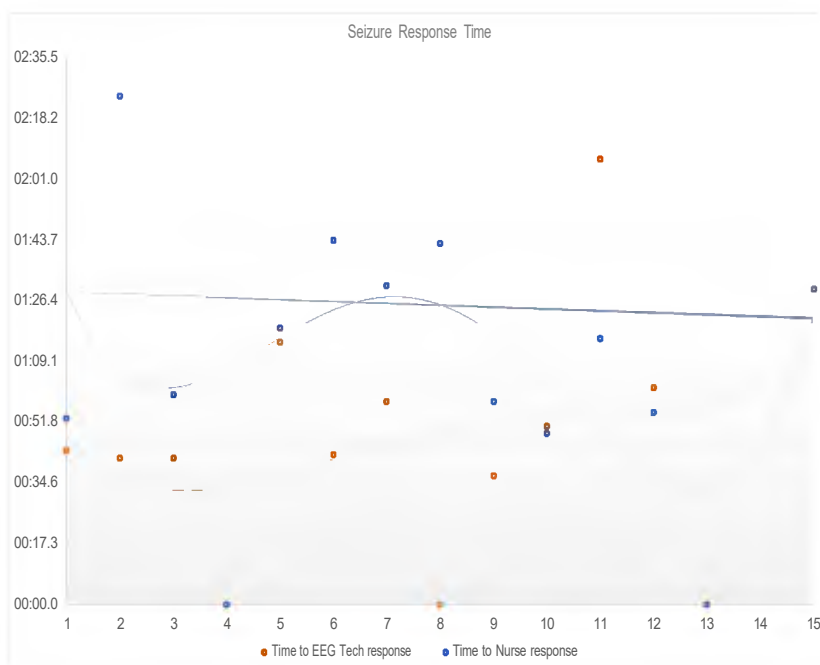


Figure 2. EEG tech and nurse response time

The abstractors identified during the chart audit efficiency section that the average length of GTC was 92.7 seconds. In comparison, the average time of the first responder was 43.6 seconds (Figure 3).

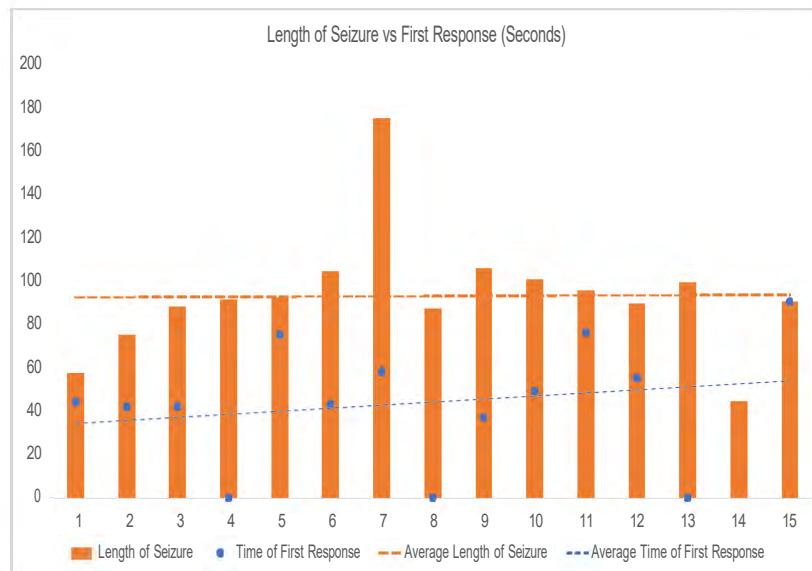


Figure 3. Length of GTC versus first response

During vEEG monitoring, time to the airway, breathing, and circulation assessment were reviewed (Appendix K, Table 4). Out of the (N=15) GTCs, eight (53%) of the rooms had suction set up during the GTCs, while nine (60%) of the responders-initiated suction. Although suction initiation averaged 86.4 seconds, improper suctioning occurred in three (20%) of the GTCs, and suction malfunction occurred in two (13%) GTCs. Of the (N=15) GTCs, four (27%) GTCs had oxygen set up in the rooms. Oxygen initiation occurred in three (20%) of the GTCs, with time to oxygen initiation averaging 123 seconds.

Other efficiency variables during data abstraction included the time of responders to recognize a need for vital signs or call out vital signs. Of the fifteen GTCs, ten (67%) of the responders recognized a need for vital signs, eight (53%) of responders did not call out vital signs, and six (40%) obtained vital signs. However, one (7%) did not complete a full set of vital signs, including blood pressure, heart rate, and oxygen saturation. Of the fifteen GTCs, one responder (7%) completed vital signs and called out vital signs. However, late during the postictal stage. Of the fifteen GTCs, two (13%) of responders did not respond to GTCs.

GTC Management and Seizure Precautions. Of the fifteen GTCs, the time of seizure onset to neurological assessment varied with who completed the assessment and what was considered a neurological assessment. Therefore, abstractors agreed to count the neurological assessment if the responder completed some nervous system evaluation. Out of the fifteen GTCs, eight (53%) of the nursing assessments were by the EEG techs and one (7%) by the nurses. Of the fifteen GTCs, five GTCs (33%) had no neurological assessment. Interestingly, two GTCs, no EEG tech or nurse responded despite having the supplemental computerized real-time seizure detection software.

Another seizure safety measure during GTC management and seizure precautions was determining how many patients were turned on their side during and following the GTC. Out of the fifteen GTCs, the EEG tech turned two patients (13%) on their side. During two GTCs, no EEG tech or nurse responded.

Data abstractors evaluated fall precaution measures of whether objects were moved to prevent injury, if side rails were up, and if responders called out if the bed was in a low position. Of the fifteen GTCs, during one (7%) GTC, the patient pressed the EEG activation event button, indicating a need for assistance, and the patient moved the bed table with belongings to the side before the onset of the GTC. During one GTC (7%), the EEG tech removed a game controller and personal belongings from the bed. Of the fifteen GTCs, one GTC (7%) a pillow was near the patient's face, and no one removed the object. The remaining twelve GTCs (80%) had no objects to cause injury. Of the fifteen GTCs, fourteen GTCs (93%) had four rails up, and one GTC (7%) had three rails up. However, after 20 seconds into the GTC, a nurse placed the fourth side rail up. During all, fifteen GTCs (100%) of the responders did not call out if the bed was in a low position.

The remaining seizure safety measures include whether patients had prior to the GTC continuous pulse oximetry, IV access, continuous telemetry, and if the camera was in line with the patient. Of the fifteen GTCs, during two GTCs (13%) had continuous pulse oximetry in place, three GTC's (20%) responders initiated continuous pulse oximetry, two GTCs (13%) the video quality was obscured, and eight GTCs (53%) did not have continuous pulse oximetry in place. Data abstractors identified that 12

GTCs (80%) had IV access and continuous telemetry, and three (20%) were unknown secondary to camera quality obscured, except data abstractors could hear telemetry alarms. Abstractors observed camera visibility to the patient during 14 GTCs (93%). One GTC (7%) EEG tech provided verbal reminders to responders to move out of the way of the camera.

Interventions to Stop Seizure. During the data extraction, data abstractors measured time to Ativan administration during the GTC, time to nurse recognizing a need for Ativan, and the time between response and Ativan administration. Along with evaluating if the nurse or EEG tech called out notifying the attending. Of the fifteen GTCs, ten GTCs (67%) no nurse called out administering Ativan, one GTC (7%) nurse reported a need for Ativan. The time from seizure onset to the administration of Ativan for two GTCs was 304 seconds, and the second GTC, Ativan, was administered prior to the start of the GTC as the patient had a prolonged focal seizure activating the EEG event button prior to the GTC. The time it took between response to Ativan administration, abstractors observed Ativan given with only two GTCs (13%). One GTC had a prolonged period of 20 minutes from the recognition to administer Ativan to administration. The second GTC had a short period of 20 seconds of the EEG tech verbalizing notifying the attending to the administration of Ativan. During the fifteen GTCs, nine GTCs (60%) no one called out notifying attending. Two GTCs (13%) no one responded. One GTC (7%), the attending, was already in the room. Another GTC, the EEG tech, called out attending requesting Ativan administration. One GTC (7%), the EEG tech, called out attending notified. Lastly, the EEG tech called out during one GTC (7%), reporting a need to call the physician again.

Postictal Setting. During data extraction, the postictal setting indicators include when the postictal stage began, if some nervous system evaluation (neurological assessment), the frequency of vitals, time of suctioning, and the end time of the postictal stage. Out of the fifteen GTCs, thirteen (87%) had some variation of a neurological assessment. Two GTCs (13%), no one arrived in the room until after the second GTC, and variation of a neurological assessment was after the end of the postictal stage. The frequency of vital signs occurred in variation in eleven (73%) of the GTCs. Three GTCs (20%) no vital signs were taken—vital signs obtained after the postictal stage for one GTC (7%). Data abstractors

noticed two GTCs (13%) with prolonged time to obtain blood pressure because of the wrong blood pressure cuff size. One GTC (7%), the video audio obscured data abstractors from hearing if responders called out vital signs. Time to postictal suctioning occurred in twelve GTCs (80%). However, observed four GTCs (27%) with late suctioning, two GTCs (13%) were improper suctioning, two GTCs (13%) had a suction malfunction, and no one initiated suctioning for two GTCs until during the postictal stage.

Medication Changes. Data abstraction evaluated if patients were on AEDs during the GTC or stopped. Twelve GTCs (80%) AEDs were stopped. Three GTCs (20%) were on AEDs when GTCs occurred.

Conclusions & Recommendations

Conclusions

In the retrospective chart review, of (N=11) patients, with a total of (N=15) GTCs, an array of pertinent safety measure concerns were revealed and are consistent with the literature emphasizing prompt reassessment of safety protocols in the EMU to minimize seizure emergencies, injuries, and significant adverse events including falls, status epilepticus, and cardiac arrhythmias (Atkinson et al., 2012). Although SUDEP and near-SUDEP are rare, fatalities in the EMU do occur (Atkinson et al., 2012; Lee & Shah, 2013; Ryvlin et al., 2013).

The results are alarming, as the retrospective chart review revealed what the epileptologist had observed a lack of nursing response time to GTCs. Of the fifteen GTCs, nurses were the first responder during 33% of the GTCs. The project identified that the average length of GTCs for the (N=11) was 92.7 seconds. According to Pan et al. (2015), a retrospective chart review of (N=153) patients determined the mean GTCS duration per patient was around 74.6 seconds. The abstractors determined the length of the first responder's mean response time was 43.6 seconds, and during seven GTCs (47%), the EEG techs responded. The data extraction identifies suboptimum GTC response time. The findings indicate a need to improve nursing seizure response time.

The suboptimum nursing response time leads to the next seizure safety measure concern, evaluating airway, breathing, and circulation. The data indicate a lack of suction and oxygen set up in rooms prior to

GTCs and improper suctioning and malfunction of suctioning equipment. Minimal initiation of oxygen by responders was noted. If responders-initiated suctioning or oxygen, the average time to suctioning, and oxygen initiation was 103.8 seconds, while the average length of GTC for the fifteen GTCs was 92.67 seconds. During this time, it also became evident the importance of continuous pulse oximetry. During three GTCs (20%), the responders had difficulty obtaining spontaneous pulse oximetry prolonging evaluation. Additionally, responders reported some patients with oxygen saturation percentages in the 70-80 range once responders obtained oxygen saturation levels is another important variable during GTC response. One patient had two GTCs (13%) that occurred within 24 hours, and during both GTCs, oxygenation saturation percentage was in the 70 range. Evidence suggests there are no communication or checks and balances to ensure rooms have suction and oxygen set up with functioning equipment.

Turning patients on their side during and after a GTC is another imperative seizure safety measure in preventing seizure emergencies, injuries, adverse events, and fatality in the EMU. Turning patients on their side opens the airway prevents asphyxiation and aspiration (Shafer et al., 2012). The project findings were frightening, as responders only turned three patients (20%) on their side during GTCs.

Of the fifteen GTCs, twelve (80%) had continuous telemetry in place prior to the GTC. However, vital signs were obtained less than 50% and varied regarding the type of vital signs taken. During data extraction, GTCs occurred where EEG techs and nurses called out the heart rate, but no one called out regarding the type of heart rhythm, or there was no witnessed observation of nursing monitoring for heart arrhythmias during the GTC. The comprehensive, retrospective study by Ryvlin et al. (2013) evaluated cardiorespiratory arrests observed during GTCs and concluded cardiorespiratory compromise occurs during the GTC, and the postictal stage leading to terminal apnea followed by cardiac arrhythmias and cardiac arrest. The data findings indicate imminent concerns for seizure emergencies and fatalities during an EMU evaluation.

During data extraction and observations concerns surfaced for the delay and lack of or variation of neurological assessment during a GTC seizure and during the postictal stage from the nursing staff. Data abstractors suspect the cause of the delay and lack of neurological assessment is complex and multifaceted,

suggesting a need for a quality improvement initiative examining cause and effect. Abstractors assume the delay in neurological assessment is secondary to no seizure alert alarm for nursing staff. The lack of neurological assessment during and after the GTC is possible caused by nursing's lack of knowledge of epilepsy, their role in seizure response, and the alarming nurse-to-patient and PSA-to-patient ratio are contributing factors. These concerns are likely vital components for imminent seizure emergencies, injuries, adverse events, and fatalities.

An ongoing commonly reported incident in acute hospitals settings is falls (Morris & O'Riordan, 2017). Falls are especially concerning during an EMU evaluation as patient exposure to provocative measures for diagnostic evaluation and patients with GTCs can develop postictal confusion and psychosis. The demographic data revealed 72.8% reporting one or more cognitive, memory, and attention issues, further increasing the patient's risk for falls. Evaluation of fall precautions occurred during data extraction. All four side rails were up during GTCs except one, and abstractors observed the nurse raising the fourth side rail within 20 seconds of arrival to the room. Visual obscuring during vEEG extraction did not allow abstractors to confer if the patient's bed was in a low position. No responder called out bed in the low position, raising safety concerns. Abstractors evaluated whether responders removed objects during GTC that could cause injury and falls. The project identified one patient who had his pillow near his face without removal from responders. A rare entity in the EMU, but literature reported a case of a GTC where the patient had forced head version causing his face to turn into the pillow for 79 seconds before nursing staff arrived at the room, indicating a potential risk for adverse events and injury (Atkinson et al., 2012).

Other seizure safety measures evaluated during the fifteen GTCs include IV access, continuous telemetry, and visibility of patients during EMU video monitoring. Essentially, the project found patients with IV access, continuous telemetry, and camera visibility. However, visual camera quality limited the abstractor's ability to evaluate.

Recognition from nursing staff regarding Ativan administration during GTCs is an essential standard of care for GTCs and is standard on the admission orders for the EMU nurses caring for patients in the EMU. After data extraction, the GTC duration for the fifteen GTCs was 92.67 seconds, indicating

seizures lasting approximately 1 minute and 33 seconds. Therefore, based on the standard admission orders, nurses administer Ativan if the seizure is greater than 5 minutes or a cluster of seizures. However, nurses verbalized to EEG techs asking for the seizure start time for GTC or when the GTC ended and when the postictal stage began. EEG techs suggested to nursing staff on one occasion to call the physician to discuss Ativan administration given seizure duration, clustering, and findings on EEG recordings. Also, EEG tech educated nursing staff regarding seizure resolution and timing of the postictal stage. The data findings indicate a lack of nursing knowledge and nursing uncertainty of GTC start time and response time to determine when to give Ativan.

During the postictal stage, after a review of fifteen GTCs, it became clear there were variations in nursing assessment and vital signs among responders, delays in blood pressure recordings as two patients required different size blood pressure cuffs. Similar findings as previously discussed, evaluating suctioning during the postictal stage included delayed suctioning, improper suctioning, and suction malfunction.

Finally, the majority of the fifteen GTCs, patients were off their seizure medications, and three patients had GTCs despite being on seizure medication. Therefore, educating nursing staff and responders regarding the time of seizure onset, seizure duration, postictal stage, and clustering of seizures can decrease the risk for seizure emergencies such as status epilepticus.

Limitations

Convenience sampling may cause a risk for sampling error (Moran et al., 2020). Another limitation was determining the best ways to manage incomplete or missing data within the medical record. The short time frame allotted for this project was another limitation. Lastly, abstractors were not blinded to the study purpose and had difficulty managing confounding factors (Gearing et al., 2006).

Facilitators

An important facilitator for this project was organizational support. Another vital facilitator was the formal and informal discussions with several epileptologists expressing interest in the project idea. Developing the right team for data extraction was another facilitator. The project leader exemplified

excellent facilitator skills by communicating succinctly, timely with prompt feedback, and maintaining sensitivity to the abstractor's needs (Moran et al., 2020).

Recommendations

Identification of practice gaps in seizure safety protocols in all the chart audit categories, indicates need to improve processes and practices using performance improvement efforts or quality improvement initiatives. Use of fishbone cause and effect diagrams, Pareto analysis charts, and root cause analysis (RCA) may identify possible causes and effects of seizure safety practice gaps in the EMU, provide quantifiable data, and identify the most vital components to consider in quality improvement implementation plans. The project demonstrated a need for role clarification the EMU as responders did not know their duties during GTCs. Providing formal and informal education to nursing staff, EEG techs, patient care assistants, and anyone responding to seizures and developing step-by-step nursing-driven protocols, providing face-to-face real-time feedback discussions, and developing debriefing opportunities are additional recommendations. Lastly, consideration of a multidisciplinary EMU committee regularly evaluates seizure safety concerns in the EMU and develops ways to sustain change.

Quality improvement implementation plans are ideal for lowering EMU-related adverse events, reducing EMU-related seizure emergencies and injuries, and optimizing epilepsy care to improve early seizure recognition and outcomes. Furthermore, to decrease the number of safety-related events, reduce hospital length of stay, and drive the implementation and sustainability of safety protocols in the EMU. Lastly, there is the potential to expand safety measures and develop seizure response protocols similar to cardiac arrest response across healthcare systems. The project aligns with the IOM, AHRQ, NAEC, ILAE, and AES recommendations of providing high-quality, evidence-based, practice-based epilepsy care (AES, 2021; AHRQ 2020; IOM, 2001; Labiner et al., 2010; Velis et al., 2007).

Summary

The retrospective chart audit identified practice gaps in seizure safety measures in the EMU and generated hypotheses of the existence, frequency, and contributing factors causing seizure emergencies, injuries, adverse events, and fatalities. Throughout the project, from the planning stage to completion, the

aim of the project evolved and during the evolutionary process, providing spiritual-ethical caring for the EMU population within the complexity of the organization required creativity, innovative ideas, and aligning the project aim with the organizations' mission. Donabedian's conceptual framework provided the foundational framework in determining the EMU patient's demographic characteristics to compiling the seizure safety measurements pertinent to the EMU culture and quality improvement initiative recommendations established from the project outcomes.

A chart audit tool using Microsoft Excel evaluated seizure safety measures with two epileptologists, in conjunction with organizational protocols and best practice recommendations. The retrospective chart review identified (N=11) patients and (N=15) GTCs through a systematic data-driven approach. A small-scale pilot study was conducted and provided valuable missing seizure safety measure variables. Video EEG monitoring identified practice gaps in all categories of the chart audit tool, including efficiency, GTC management, seizure precautions, interventions to stop seizures, and evaluation during the postictal setting identifying detrimental concerns. The project findings should prompt the organization further to investigate performance improvement efforts or quality improvement initiatives.

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Appendix A

Summary of Evidence and Synthesis Table

Table 1

Summary of Evidence and Synthesis Table

Citation	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
Study I								
Ryvlin et al. (2013)	Systematic review and Meta-analysis.	N-147	Independent Variables: EMU, VEEGs.	Non-conditional logistic regression model.	Total patient-years spent in units.	29 cardiorespiratory arrests reported.	*Level I Systematic Review and Meta-Analysis.	Small number of cases of SUDEP reported.
Incidence and mechanism of cardiorespiratory arrest in epilepsy monitoring units (Mortemus): A retrospective study.	Retrospective Study.	International study identifying EMUs in Europe, Israel, Australia, and New Zealand. Data ranged from January 1, 1968, to December 29, 2009.	Dependent Variables: Mortality Census, number of VEEGs done during this period, proportion of adult patients and epilepsy surgery assessments, average length of stay, average duration of monitoring during presurgical VEEG, and	Mixed-effect logistic regression model. Random effect for inter-patient variability using the glmmPQL function of R software.	Average duration of stay calculated by 95% CI. Two investigator independent evaluation.	16 SUDEP, half definite and half probable, nine with near SUDEP. All fatal and near SUDEP cases occurred at night. CPR was undertaken in 11 of the 16 cases with delayed CPR exceeding 10 minutes after initial apnea.		Missing pathological data in half of SUDEP cases. Missing or suboptimum ECG and respiratory data. Assessment of postictal respiration through video extraction raises substantial concern, despite high inter-rater agreement. Lack of data on blood pressure, cerebral perfusion, oximetry, and partial pressure of CO ₂ .

Citation	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
Study II			number of cardiorespiratory arrests, average length of stay, average duration of monitoring during presurgical VEEG, and number of cardiorespiratory arrests.			CPR was initiated within 3 minutes of the near SUDEP cases. All SUDEP cases were in setting of GTCS. 14 patients prone during cardiorespiratory arrest.		Hypoxia could have been caused by patients in prone position. Respiration is withheld during GTCS, which resulted in hypoxemia in 33% of the cases. Therefore, brain dysfunction is possible already compromised Cardiorespiratory arrest occurred in all patients within 3 minutes postictally.
Sanchez-Larsen et al. (2019)	Observational, retrospective study.	All patients between October 2010 to October 2018. N=1250 evaluated. N=102 died.	Independent variables: Epilepsy Dependent variables: Dead/alive status	Statistical Package for Social Sciences, Windows.	Descriptive analysis for all variables.	7 patients diagnosed with SUDPE/near-SUDEP. Represented 6.8% of all deaths, affecting 0.56% of all participants. Four patients in prone position.	Level IV Cohort Study	Selection bias. Resistant epilepsy and not generalized to the general population. Some patients possible overlooked. Feasibility of implementing a practice guideline to provide nursing knowledge, define nursing responsibilities, and

Citation	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
						3 patients received no CPR, 1 patient received ineffective CPR.		develop practice guideline emphasizing prompt nursing response in EMU.
						3 patients abnormal telemetry findings.		
Study III								
Sauro et al. (2016a)	Systematic review and Meta- analysis.	N-135	Independent variables: EMU.	Cochrane Q test.	Descriptive Statistics.	Quality and safety data studies reported 181, 823 patients admitted EMU 1968-2016.	*Level I Systematic Review and Meta- Analysis.	Publication based and possible missed articles.
Quality and safety in adult epilepsy monitoring units: A systematic review and meta- analysis.	Predetermin ed protocol Preferred Reporting and Items for Systematic Review and Meta- Analysis (PRISMA) statement.	Two independen t viewers. Kappa statistic used.	Dependent variables: Quality and safety metrics. Exclusion criteria: Subpopulations not representing EMU. Population, less than 20 patients. Duplicate date.	I2 statistic. Metaprop and mean packages for STATA 12.0. Begg's and Egger's statistics.		Most significant finding, considerable variability in EMU limiting comparisons and developing benchmarks.		Heterogeneity in reporting. Study highlights the need for practice guidelines in the EMU.

Citation	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
			Inclusion criteria: Used the most rigorous studies.					
			Use of modified STROBE checklist for case-controlled, cohort, and cross-sectional studies.					
Study IV								
Sauro et al. (2016b)	Quasi- experimental study	Quality improvement team members including N=6	Independent variables: Quality and safety indicators	9-point Likert scale.	Descriptive Statistics.	34 quality and safety indicators from 135 studies with 2 additional quality indicators added.	*Level I Systematic Review and Meta- Analysis.	Publication bias.
Quality indicators for the adult epilepsy monitoring unit.	Use of systematic review Sauro et al. (2016a) (a) quality and safety methodology.	epileptologists, N=2 fellow/trainees, N=2 neurosurgeons, N=1 psychologist, N=1 nursing staff, N=2 EEG	Dependent variables: Delphi Technique, EMU.	Delphi technique Round 1 and 2.		Round 1: 16 participants (88.9% response rate) 67.6 % consensus in 34 variables.		Limited generalizability for public use but beneficial for using quality indicators in developing practice guidelines and increasing nursing knowledge.

Citation	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
		technologists t, N=1 managemen t, N=1 QI consultant, N=1 patient representati ve.				Round 2: 9 participants (response rate of 56.3%), 10 additional indicators agreed. 25 indicators plus 9 adverse effects were developed into metrics.		
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> * Highest Level of Evidence </div>								

Note. Studies in alphabetical order by first author last name: I, Ryvlin, II Sanchez-Larsen, III Sauro (a); IV, Sauro (b). EMU=Epilepsy Monitoring Unit; SAS= Statistical Analysis Software; STROBE= Strengthening the Reporting of Observational Studies in Epidemiology; SUDEP=Sudden Unexpected Death in Epilepsy; SNPR= Swedish National Patient Register; vEEG= Video Electroencephalography. Otterbein University adapted with permission from Evidence-based practice in nursing and healthcare. (p. 520), by Melnyk, Bernadette, Mazurek, and Ellen Fineout-Overholt. Lippincott Williams & Wilkins, 2011.

Appendix B

OhioHealth Approval



Tina Yates
Otterbein University December 22, 2021

RE: Organizational Assessment Proposal: Safety Measures in the Epilepsy Monitoring

Dear Ms. Yates:

The Nursing Evidence-Based Practice Review Committee (NEBPRC) has reviewed the proposal referenced above. You have adequately addressed all concerns from the pre-review and the revisions are accepted. You may conduct the organizational assessment data as stated except for the following variables. You may **NOT** collect age, admission, or discharge dates, or living location as those data are considered protected health information. Lastly, remove the section from the data collection sheet that states "Any nurse assessment" since that is too vague.

The NEBPRC has determined that the project proposal you submitted does not meet the Federal definition of research as cited in CFR 45-46:102. According to the Federal Code, research is defined as:

(1) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

You have permission to implement the organizational assessment with the exceptions listed above, providing that the unit manager at the intended intervention site agrees. Upon completion of the project and before dissemination (poster or manuscript), you must submit the results so that the OhioHealth can review the presentation to ensure Health Insurance Portability and Accountability Act (HIPAA) compliance.

Congratulations on your progress towards this worthy endeavor.

Unit

Teresa Wood PhD, RN NEA-BC
Teresa Wood PhD, RN, NEA-BC Program Manager, Nursing Research

Appendix C

Otterbein IRB Approval



INSTITUTIONAL REVIEW BOARD

- ☒ Original Review
☐ Continuing Review
☐ Amendment

Dear Dr. Shoemaker,

With regard to the employment of human subjects in the proposed research:

HS # 21/22-38

Shoemaker, Hotler & Yates: Safety Measures in the Epilepsy Monitoring Unit: An ...

THE INSTITUTIONAL REVIEW BOARD HAS TAKEN THE FOLLOWING ACTION:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Approved | <input type="checkbox"/> Disapproved |
| <input type="checkbox"/> Approved with Stipulations* | <input type="checkbox"/> Waiver of Written Consent Granted |
| <input type="checkbox"/> Limited/Exempt/Expedited Review | <input type="checkbox"/> Deferred |

*Once stipulations stated by the IRB have been met by the investigator, then the protocol is APPROVED.

1. As Principal Investigator, you are responsible for ensuring all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol.
2. It is the responsibility of the Principal Investigator to retain a copy of each signed consent form for at least four (4) years beyond the termination of the subject's participation in the proposed activity. Should the Principal Investigator leave the university, signed consent forms are to be transferred to the IRB for the required retention period.
3. If this was a limited, exempt, or expedited review, there is no need for continuing review unless the investigator makes changes to the proposed research.
4. If this application was approved via full IRB committee review, the approval period is one (1) year, after which time continuing review will be required.
5. You are reminded you must promptly report any problems to the IRB and no procedural changes may be made without prior review and approval. You are also reminded the identity of the research participants must be kept confidential.

Signed: Noam Shpancer
IRB Chairperson

Date: 1-28-22

[illegible]

Chart Audit Tool Continued

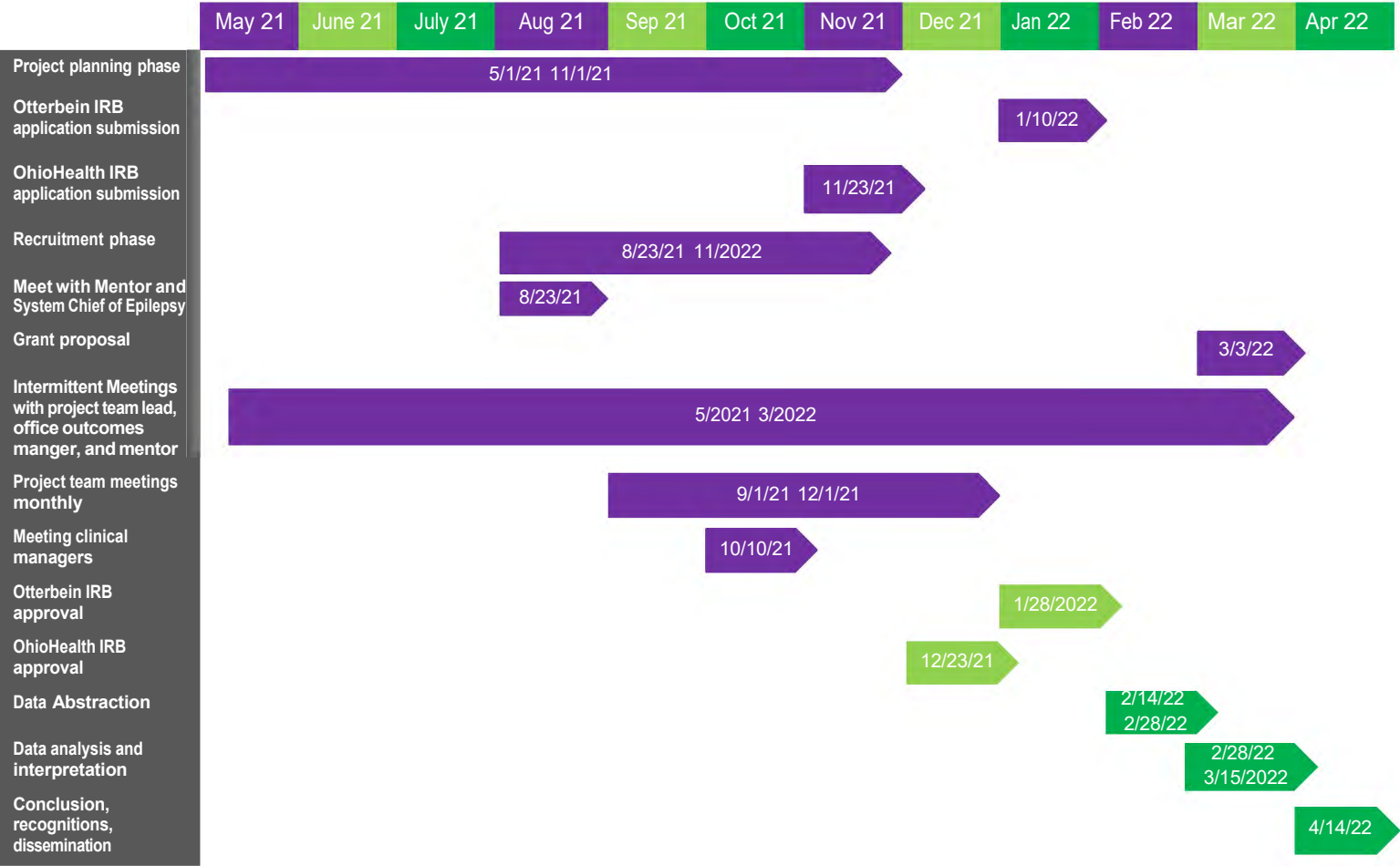
Patient ID	Seizure #	t Demogr	Efficiency						Postictal Setting		
		Gender	Seizure Start time	EEG to Tech Response	Time to EEG Tech response	Nurse to Response	Time to Nurse response	Time of First Response	Start time of Postictal Stage	Length of Seizure	Postictal Stage Ends
1	1	Female	2:56:10 PM	2:56:54 PM	00:44.0	2:57:03 PM	00:53.0	44	2:57:07 PM	57	15:03 starting to answer questions appropriately.
2	2	Male	11:55:20 AM	11:56:02 AM	00:42.0	11:57:45 AM	02:25.0	42	11:56:35 AM	75	Long posictal states, unsure of end time. Stopped data abstraction when pateit responds to nurse.
	3		1:27:29 AM	1:28:11 AM	00:42.0	1:28:29 AM	01:00.0	42	1:28:57 AM	88	Long posictal states, unsure of end time. Stopped data abstraction when patient responds to nurse.
3	4	Female	4:55:29 PM	already in room.	00:00.0	Nure already in room.	00:00.0	0	4:57:00 PM	91	17:08:13
4	5	Female	4:03:15 AM	4:04:30 AM	01:15.0	4:04:34 AM	01:19.0	75	4:04:47 AM	92	4:30:15
5	6	Female	12:53:34 PM	12:54:17 PM	00:43.0	12:55:18 PM	01:44.0	43	12:55:18 PM	104	13:03:54
6	7	Female	3:29:38 AM	3:30:36 AM	00:58.0	3:31:09 AM	01:31.0	58	3:32:32 AM	174	03:49:07 stopped observing after Ativan given.
7	8	Female	1:31:35 AM	1:31:35 AM	00:00.0	1:33:18 AM	01:43.0	0	1:33:02 AM	87	1:58:27
	9		2:46:32 AM	2:47:09 AM	00:37.0	2:47:30 AM	00:58.0	37	2:48:17 AM	105	2:54:19
8	10	Female	7:12:33 PM	7:13:24 PM	00:51.0	7:13:22 PM	00:49.0	49	7:14:13 PM	100	19:21:15
9	11	Male	2:05:19 AM	2:07:26 AM	02:07.0	2:06:35 AM	01:16.0	76	2:06:54 AM	95	2:17:41
	12		2:34:04 AM	2:35:06 AM	01:02.0	2:34:59 AM	00:55.0	55	2:35:33 AM	89	02:43:57 EEG techs call out allowing patient to rest.
10	13	Female	7:52:35 AM	7:44:10 AM	00:00.0	7:50:06 AM	00:00.0	0	7:54:14 AM	99	8:04:59
11	14	Female	4:57:23 AM	No EEG tech response. No one arrived until postictal stage.		No RN response. No one arrived until postictal stage.			4:58:07 AM	44	No postictal stage, went into second event.
	15		4:58:08 AM		01:30.0		01:30.0	90	4:59:38 AM	90	5:03:48

Appendix F						
Seizure Safety Measures in the EMU						
Table 4	Seizure Safety Measures in the EMU					
	Seizure Safety Measures in the EMU					
GTC Average Percentages	Suction				Oxygen	
	Suction Set Up on Arrival to Room	Time to Suction Initiation	Improper Suctioning	Suction Malfunction	Oxygen Set Up on Arrival to Room	Time to Oxygen Initiation
1	-	-	-	-	-	-
2	+	68 s	-	+	+	-
3	-	70 s	-	-	+	-
4	-	77 s	-	-	+	-
5	+	58 s	-	-	-	-
6	+	-	-	+	-	-
7	+	-	-	-	-	185 s
8	-	125 s	+	-	-	-
9	-	98 s	+	-	+	76 s
10	+	108 s	-	-	-	109 s
11	+	92 s	-	-	-	-
12	+	-	+	-	-	-
13	+	85 s	-	-	-	-
14	-	-	-	-	-	-
15	-	-	-	-	-	-
Average Percentages	53%	86.4s	20%	13%	27%	123.3s

- No
+ Yes
s Seconds

Note: Average time from seizure onset to suction and oxygen initiation. Percentage of suction setup, improper suctioning, suction malfunction, and oxygen setup. EMU=Epilepsy Monitoring Unit; GTC=Generalized Tonic-Clonic Seizure.

Appendix G
Timeline



Appendix H

Student Research Fund (SRF) Approval



1 South Grove Street Westerville, OH 43081

OTTERBEIN
UNIVERSITY

TEL: (614) 823-1556

FAX: (614) 823-1335

www.otterbein.eduOFFICE OF ACADEMIC AFFAIRS Tina Yates tina.adkins@otterbein.edu

March 3, 2022

Dear Tina,

On behalf of the Student Research Fund Committee, I am pleased to inform you that your proposal, "Safety Measures in the Epilepsy Monitoring Unit: An Organizational Assessment, has been approved for a \$100.00 SRF Research Grant. This funding is to be used towards your budgeted item of a software license to assist with your data collection and analysis (Minitab, SPSS, other preferred software). The committee has declined the funding of a statistician, as SRF funds are not intended for stipends or payments for editors, statisticians, or others who contribute intellectually to the project.

Student Research Fund recipients are competitively selected based upon the quality of their proposed research and/or creative endeavor. Congratulations on this achievement!

Your advisor, Joy Shoemaker, will be informed about your award. The Administrative Assistant for your department, Maureen Kaiser, can most likely assist you in expensing or requesting reimbursement for costs incurred after the award approval. The expenses for your SRF grant should be charged to fund STURES.

Your unique SRF code should also be included – 729586. For any publications or conference applications that involve that acknowledge this grant, please note that this funding is from: "Student Research Funds." Please visit the [SRF webpage](#) for help with Claiming Expenses or contact Academic Affairs (x1556 or

Finally, we would like to let others know of your good work. When you submit your final invoice for payment on the award, please also submit an abstract that is suitable for publication and addresses the significance of the research, the methodology, and the conclusion you reached. This 200 word abstract should include your name, your advisor's name, the title of your research or presentation, and the signature of your advisor.

Should you have questions, please feel free to contact the SRF Team at

[SRF webpage](#)
academicaffairs@otterbein.edu). academicaffairs@otterbein.edu Best wishes with your project.

Dr. Kathryn M. Plank

Associate Provost for Curriculum, Teaching & Learning, and Mission

kplank@otterbein.edu 614.823.1556Sincerely, 

Appendix I**Budget****Table 2***Budget*

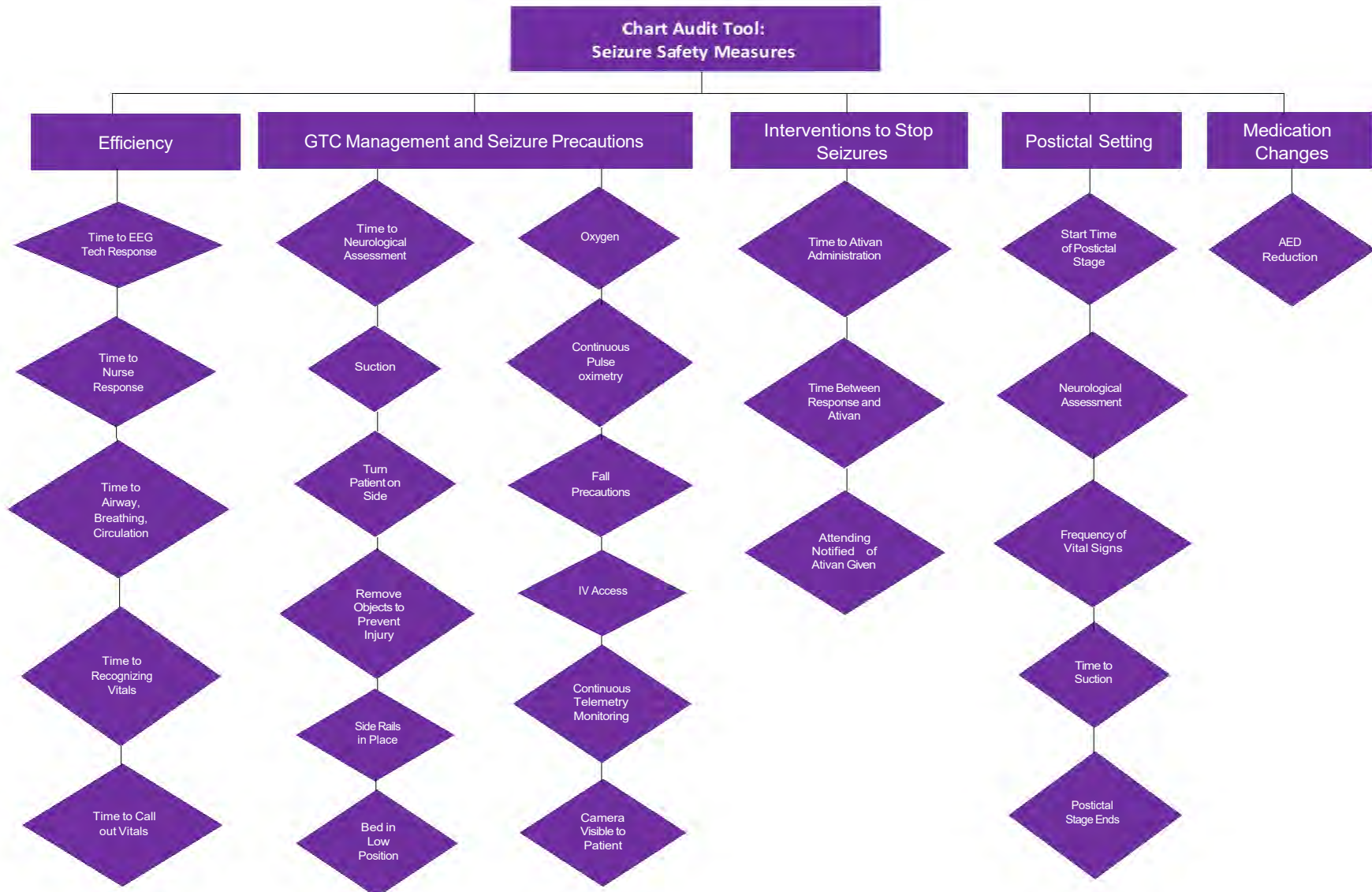
Expenses	SRF Fund Request	Projected	Actual
Licensed Software/Excel/Minitab	\$100.00	\$100.00	\$0.00
Statistician	\$300.00	\$300.00	\$0.00
Experienced Epilepsy RN	\$0	100 donated hours	100 Donated hours
Epileptologist, Outcomes Office Manager	\$0	• 100 productive hours	• 100 Productive hours
Project lead donated hours	\$0	300 donated hours	300 donated hours
Totals	\$400.00	• \$400.00 + 400 donated + 100 productive hours	• \$0.00 + 400 donated + 100 productive hours

• Per Individual

Note. Hours-project lead donated hours. RN-Registered Nurse; EMU-Epilepsy Monitoring Unit

Appendix J

Chart Audit Tool: Safety Measures



Appendix K

Seizure Safety Measures in the EMU

Table 4
Seizure Safety Measures in the EMU

	GTC Average Percentages	Suction			Oxygen		
		Suction Set Up on Arrival to Room	Time to Suction Initiation	Improper Suctioning	Suction Malfunction	Oxygen Set Up on Arrival to Room	Time to Oxygen Initiation
1	-	-	-	-	-	-	
2	+	68 s	-	+	+	-	
3	-	70 s	-	-	+	-	
4	-	77 s	-	-	+	-	
5	+	58 s	-	-	-	-	
6	+	-	-	+	-	-	
7	+	-	-	-	-	185 s	
8	-	125 s	+	-	-	-	
9	-	98 s	+	-	+	76 s	
10	+	108 s	-	-	-	109 s	
11	+	92 s	-	-	-	-	
12	+	-	+	-	-	-	
13	+	85 s	-	-	-	-	
14	-	-	-	-	-	-	- No + Yes s Seconds
15	-	-	-	-	-	-	
Average Percentages	53%	86.4s	20%	13%	27%	123.3s	

- No
+ Yes
s Seconds

Note: Average time from seizure onset to suction and oxygen initiation. Percentage of suction setup, improper suctioning, suction malfunction, and oxygen setup. EMU=Epilepsy

Monitoring Unit; GTC=Generalized Tonic-Clonic Seizure.