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Effects of Increased Confusion Assessment Method for the Intensive Care Unit Delirium Assessments on Patients in the Surgical Intensive Care Unit.

A DNP Project Submitted to the Graduate Faculty
of Jacksonville State University in Partial
Fulfillment of the Requirements for the
Degree of Doctor of Nursing Practice

By: William Ryan Lemon, MSN, AGACNP-BC

Jacksonville, Alabama

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ABSTRACT

Delirium is an acute syndrome of the central nervous system (CNS) that affects patients of all ages and all hospital areas. Furthermore, delirium can lead to frequent complications for these patients, especially those in intensive care units (ICU) (Kanova, Sklienka, Burda, & Janoutova, 2017). Nationally delirium affects 20-80% of patients that require ICU care (American Nurses Association, 2019). In the Surgical intensive care unit (SICU) at the acute care hospital used in the project, the average number of patients suffering from delirium is about 23%. The purpose of this project was to provide a more in-depth analysis of delirium, and to address the effects of four times a day assessments versus per shift assessments, or twice daily, which is the standard of care in the SICU. This project was a quality improvement initiative that incorporated a quasi-experimental design analyzing retrospective data collected on delirium incidences when two assessments were performed versus data collected over a four-month period where four assessments were performed. The project's results showed that the increase in frequency of the CAM-ICU assessments to four times a day yielded an average of 5.3-8.3% decrease in incidence of delirium in the SICU over four months and that the average incidences of delirium went from 23% to 16.7%. Nursing implications: This project provides evidence-based data showing that delirium assessment is vital to the quality of care provided to patients. Furthermore, it shows that the more aware both nurses and

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providers are of the risk factors for delirium, the more equipped they are to prevent the development of delirium.

Keywords: Delirium, CAM-ICU, Intensive Care Units, Delirium toolkit, Delirium statistics, Delirium Pathophysiology, and Geriatric Medicine.

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This manuscript is dedicated to the memory of my Father, Dr. William M. Lemon.

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Effects of Increased Confusion Assessment Method for the Intensive Care Unit delirium assessments on patients in the Surgical Intensive Care Unit.

Introduction

Delirium affects the central nervous system (CNS) and the patient's mental status explicitly. It is a syndrome of inattentiveness affecting patients of all ages and all hospital areas. Delirious patients can be grouped in one of two classifications. They can be identified as being in a state of hypoactive delirium or hyperactive delirium. Hyperactive delirium is characterized by (motor) agitation, restlessness, aggressive, and combative behaviors. Hypoactive delirium is characterized by motor retardation, apathy, slowing of speech, and patients can appear to be sedated (Lipowski, 1983). Both classifications of delirium will result in frequent complications for these patients, especially those in intensive care units (ICU) (Kanova, Sklienka, Burda, & Janoutova, 2017). Nationally delirium affects 20-80% of patients that require ICU care (American Nurses Association [ANA], 2019). In the SICU at the facility where this project was implemented, the average number of delirous patients is about 23%.

The incidences of delirium are hard to quantify because up to 70% of delirium cases go undetected (Grossman & Porth, 2014). However, Papadakis and McPhee (2019) estimate that delirium affected 29-64% of hospitalized older adults, persists in 25% or more, and was associated with worse clinical outcomes for the patient. These outcomes include higher inpatient and post-discharge mortality, increased length of stay, delayed or limited recovery of physical function, and a higher probability of placement in a skilled nursing facility (Papadakis & McPhee, 2019). Despite these statistics and the recommendations of professional societies and patient safety organizations, most ICU

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patients worldwide are not routinely monitored for delirium, preventing prompt prevention and management (Zoran et al., 2015). With this in mind, the importance of promptly and adequately addressing and treating delirium in all patients, especially those in the ICU setting, is essential. That, along with the statistics mentioned above, led to the development of the question; what are the effects of four times a day CAM-ICU delirium assessments compared to twice a day CAM-ICU delirium assessments?

Background

Delirium is an acute disorder that develops over hours to days, and is frequently seen in individuals admitted to ICUs and acute care hospital beds (Grossman & Porth, 2014). Delirium is often misconstrued with another disease, dementia, due to its ability to alter mental status, but there are distinct differences. Delirium is a disorder with rapid onset, a fluctuating course, and can be a presenting feature of another more ominous physical illness (Grossman & Porth, 2014). The primary deficit in delirium is attention rather than memory, and can be hyper or hypoactive (Papadakis & McPhee, 2019). The most crucial distinction is that delirium is temporary, and with the proper assessment and treatment, its effects can be curtailed.

Grossman and Porth (2014) note that the etiology of delirium is multifactorial; unfortunately, the exact reason delirium occurs is not apparent, but many risk factors contribute to cognitive decline (see Appendix A). These risk factors include a history of dementia, severe illness, depression, vision and hearing impairments, functional impairments, a history of transient ischemia or stroke, alcohol abuse, and advanced age (Kane, Ouslander, Resnick, & Malone, 2018). Unlike dementia, which is a gradual process, delirium is an acute disorder that develops over hours or days, and is frequently

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seen in hospitalized older adults (Grossman & Porth, 2014). While delirium can occur at any age, Maldonado (2017) notes that multiple studies have found that older age alone is an independent risk factor for delirium. These studies have shown that those younger than age 65 have a 3% chance of developing delirium during their hospital stay. These numbers only increase as individuals increase in age; the percentage jumps to 14% for those aged 65-74, and even higher for those 75 or older having a 36% chance of developing delirium (Maldonado, 2017). It is also important to note that delirium is not just a side effect of advanced age and hospitalization. There is up to a 15% prevalence of delirium in geriatric patients on admission to the hospital (Kane et al., 2017).

Problem Statement

Delirium negatively affects those that suffer from it, especially those in the ICU setting. It can lead to falls, increased length of stay, and increased morbidity and mortality (Grossman & Porth, 2014). In the SICU where the project was completed, the incidence of delirium was, on average, about 23%. The gap analysis led to developing a project that will address the effects of increased frequency of Confusion Assessment Method evaluations (CAM-ICU) to four times a day compared to two times a day.

Organizational Description of Project Site

The facility where the project was implemented is one of the largest metropolitan public hospitals in the southeastern United States. The hospital is an academic center and participates in research, and has medical training programs. It is a level one trauma center and includes a comprehensive transplant center. The facility has 1,157 inpatient hospital beds; these include acute care and critical care beds, including nine intensive care units. The facility also has many outpatient clinics to provide care for its patients

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through their care continuum. On average, this facility may admit and treat 35,000-40,000 patients per year. This facility provides a wide array of services which extend beyond the local metropolitan area, and support the state and southeastern United States.

Review of the Literature

This literature review consisted of searches from databases, including Medline, PubMed, CINAHL complete, Cochran Library, Joanna Briggs Institute database, and Nursing and Allied Health source. Key phrases used in the search consisted of ICU delirium, delirium assessment, delirium assessment tools, and frequency of delirium assessment. The search produced various peer-reviewed literature consisting of level one, level two, and level three studies. The 47 studies isolated based on the search criteria were decreased to 16 studies to support critical aspects of delirium assessment.

Defining the frequency of delirium assessments is a topic that has not garnered much attention from healthcare providers. There are varying schools of thought about delirium assessments, but what is apparent is there is a lack of research conducted on the effectiveness of assessment intervals and performance. Numan et al. (2017) noted that their use of three assessments a day yielded delirium incidences of 15%. On the other hand, Hamadnalla et al. (2021) used twice-a-day assessments on post-operative patients but would only assess them for the first four days. Stockholm, Steenholt, Csilan, Kjaer, and Christensen (2019) concluded that no absolute determination about the frequency of delirium assessments could be made from their study. What is not up for debate is that despite the recommendations of professional societies and patient safety organizations, most ICU patients worldwide are not routinely monitored for delirium, preventing prompt prevention and management (Zoran et al., 2015).

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The most crucial parts of a delirious patient's physical examination lie within observation and listening (talking with the patient) (Harrington & Vardi, 2014). Three main tools can be implemented during a physical examination to determine whether or not the patient has delirium. The first one is the Confusion Assessment Method (CAM). Faught (2014) notes that the CAM test has high sensitivity and specificity, but it does not provide a scale for judging the delirium's severity (see Appendix B). The second tool used to measure delirium is the Delirium Observation Screening (DOS). The DOS differs from the CAM because it offers a scale to judge the patient's delirium severity (Faught, 2014). The last tool that can be employed to detect delirium is the Neelan and Champagne Confusion Scale (NEECHAM). Like the DOS, the NEECHAM can offer both a determination of delirium and severity of the syndrome, but has a high negative predictive value of 79% (Faught, 2014).

The use of pharmacological agents for the treatment and prevention of delirium as a disorder itself is controversial. Many medications such as neuroleptics like haloperidol, risperidone, quetiapine, olanzapine, and other drugs such as dexmedetomidine, rivastigmine, and dexamethasone can be used in the treatment of symptoms of delirium. More recently, guidelines on the use of sedatives for agitation and delirium in critically ill patients do not recommend pharmacological agents to prevent the disorder (Tobar, Alvarez, & Garrido, 2017). On the other hand, because delirium is often a consequence of a severe illness or another physiological process, medications to treat the underlying illness are essential in delirium treatment (Papadakis & McPhee, 2019).

The use of non-pharmacological therapy in treating and preventing delirium seems to be the preferred method, and supportive devices can help in this process. One

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of the first and most critical supportive devices used to prevent and treat delirium is a delirium assessment tool. A tool like CAM is the first line of defense for the recognition and early treatment of delirium (Salvi et al., 2020). Another supportive device used is the delirium toolkit; these toolkits can have coloring books, stress balls, and playing cards. Not only are these patients given something they can focus on, but it is something that their family can do with them; this allows a family the opportunity to interact and reorient the patient. Reality orientation by family or caregivers, retention of activities of daily living, reduced use and doses of psychoactive drugs, early mobilization, promotion of sleep, maintenance of adequate hydration and nutrition, and provision of vision and hearing aids seem to be the most effective evidence-based strategies in the treatment and prevention of delirium (Salvi et al., 2020).

Evidence-based design, interventions, and data collection strategies should consistently be implemented when establishing new policies or practices (Melnyk & Fineout-Overholt, 2015). These practices provide confidence to the provider performing them, and can be sited to provide a resource for the patient (Melnyk & Fineout-Overholt, 2015).

Theoretical Framework

Florence Nightingale's environmental theory, Jean Watson's theory of human caring, and Edwards Deming's Plan, Do, Study, Act cycle guided the research done for this project to answer the PICOT question. The first and most influential is Florence Nightingale's environmental theory of nursing. In this theory, the focus on the patient's environment is essential for healing, preventing and detecting disease (Butts & Rich, 2018). Nightingale's theory has 13 canons that make up the environmental theory, with

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seven of those being instrumental in preventing and detecting delirium. These seven include proper ventilation and temperature control, pure water, control of noise, variety within the room's décor, bedding, lighting, and observation of the sick (Butts & Rich, 2018). These canons are vital because they could decrease delirium incidence if they can be appropriately controlled (Papadakis & McPhee, 2019). Also, Nightingale's insight into the observation of the sick is a cornerstone of delirium prevention and treatment. Those who carefully observe their patients will be more likely to notice subtle changes that may alert them that delirium is on its way (Nightingale, 1969).

Jean Watson's theory of human caring is a guiding influence because of the theory's emphasis on mutuality between the patient and the caregiver (Butts & Rich, 2018). According to Watson (1988), a caring occasion is the moment when the nurse and a patient come together in such a way that an opportunity for human caring is created. Building rapport between the patient and provider creates trust and familiarity that can give both parties the confidence to be honest with one another, which alone can lead to a better outcome (Butts & Rich, 2018). Mutuality also tends to let the provider have a better understanding of the patient's baseline behavior. This gives the provider a way to gauge any changes, no matter how subtle.

Although not a nursing theory, the final theoretical influence was Edwards Deming's Plan, Do, Study, Act (PDSA) model. The PDSA model is a systematic process for gaining valuable knowledge for the continual improvement of a product, process, or service (The W. Edwards Deming Institute, 2021). It is a quality improvement framework used for effecting change quickly (Butts & Rich, 2018). First, the planning phase includes studying a process to identify a problem and deciding what can be done to

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improve the situation. Next, the do phase tests the proposed change. Next, the study phase evaluates the change after the intervention has been performed, and the act phase is the full implementation of the intervention once it has determined that it will be effective (Butts & Rich, 2018). Butts & Rich (2018) also note that this cycle can be repeated to increase knowledge and change processes more rapidly and efficiently (see Appendix C).

Goals, Objectives, and Expected Outcomes

This project aims to improve the quality of care within the SICU by decreasing incidences of delirium. This goal can be achieved by increasing awareness about delirium staff-wide, improving the quality of the assessments performed, and ensuring the accuracy of delirium documentation. The project's expected outcome is that initially, the incidence of delirium may increase due to increased frequency and improved quality of assessments, but eventually, incidences of delirium will decline.

Project Design

The direction for the implementation plan for this project was gleaned from a quality improvement state of mind. Moran, Burson, and Conrad (2017) note that when the project's goal is to inspire and initiate change in the organization's practice via interventions, practice improvement, or implementation of a new model for care delivery, a quality improvement (QI) approach is the design of choice. Therefore, the design choice for this project was a quasi-experimental design. This approach was used because it does not require randomization or the use of a control group, it is capable of measuring changes in the outcomes after the treatment or intervention when it is not feasible to use an actual experiment, and it is practical and valuable in a clinical area (Moran et al., 2017).

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The foundation of the study focused on the proper and frequent use of a CAM-ICU assessment tool used in the SICU and its effects on delirium prevention and treatment. This tool provides an assessment that can determine whether the patient is suffering from delirium. In addition, it was chosen for its high sensitivity and specificity; other tools can provide both a determination of delirium and a level of severity, but they lack the CAM-ICU's precision (Faught, 2014).

The CAM-ICU was used in the SICU four times a day for the duration of the patient's stay. These assessments, along with the nurse's charting and provider's progress notes, gave insight into if this more aggressive method of assessing the patient led to a decreased incidence of delirium. At the end of the four months, the data was compiled, and the results were analyzed to see if this intervention was efficient (meaning not disrupting of nursing workflow), cost-effective, and had positive patient outcomes (decrease in incidence of delirium, or early diagnosis and treatment).

Project Site and Population

The site that the project was implemented was a surgical intensive care unit within a level one trauma center and acute care hospital. This ICU is a 20-bed unit serving a wide array of surgical patients including: vascular surgery, abdominal transplant, acute care surgery, surgical oncology, gastrointestinal surgery, orthopedic surgery, oral maxillary facial surgery, otorhinolaryngology surgery, thoracic surgery, and minimally invasive surgeries. In addition, the population of the unit was comprised of pre-operative and post-operative patients.

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Setting facilitators and barriers.

Stakeholders for this project include nursing staff, which aided in the assessments of the patients, along with the nurse manager of the unit, unit's nursing educator, physicians and advanced practice providers that work within the unit, nursing administration, and hospital administration.

Barriers to the project's implementation were based mainly around nursing workflow and ensuring that assessments were performed correctly and accurately documented. To remove this barrier, the principal investigator provided education to nursing staff that included performing and documenting the assessments. The principal investigator also stressed the importance of the assessments to the staff, and provided statistics about the incidence and effects of delirium that they were unaware of, which improved morale and confidence in the staff's ability and willingness to perform the assessments.

Implementation Plan and Procedures

The project was implemented in the SICU from February to May 2021. The CAM-ICU assessments were performed four times daily for every patient in the unit, and results were only used for those patients that had been in the SICU for two days or longer. In addition, the principal investigator provided education for the nurses working on the unit to reiterate the importance of performing the assessment accurately. This education included stressing the importance of the proper performance of delirium assessments, performing delirium assessments with the nursing staff, and documenting the assessments with the nursing staff to provide examples of proper documentation.

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Measurement Instruments

The CAM-ICU assessment was the only delirium assessment used during the project. The decision to use this tool was made because of the high sensitivity (94-100%) and specificity (94-95%) of the assessment (Yun Goa et al., 2021). Additionally, the assessment was already being employed in the SICU. Therefore, the nursing staff was already accustomed to performing this assessment.

Data Collection Procedure

The nurses' assessments were recorded in the patient's chart twice a day, as was the standard of care for the unit. The additional two assessments were performed by the principal investigator and nurses working in the unit. The assessments were recorded on paper forms and then transcribed onto an Excel form. All patients were deidentified; the Excel form used zero for patients that tested negative for delirium, one for those who tested positive for delirium, and two for those that were unable to be assessed.

Data Analysis

Previous statistics for the SICU showed that the average number of patients diagnosed with delirium was around 23%. In this previous data, 486 patients were assessed, with 106 of those patients testing positive. The analysis from data collected from January, one month before the project's implementation, found that 25% of patients tested positive for delirium. The following month of February, 90 patients were screened, with 15 of those testing positive (16%). In March, 101 patients were screened, with 19 patients testing positive (18%). April 114 patients were screened, with 16 testing positive (14%). Lastly, in May, 36 patients were screened, with seven testing positive (19%). It

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should be noted that data was only collected for the first two weeks in May (see Appendix D).

The total number of patients assessed during the four months was 342 patients (n=342). A Fisher's exact test was performed on the data; it was chosen due to its ability to analyze retrospective data and test the differences in proportions in a two-by-two table (Sylvia & Terhaar, 2018). Other statistical tests were considered, but Fisher's exact was the most appropriate. It resulted in a p-value of .07 and a confidence interval of 95% (see Appendices E & F). Thus, the project proved to be not statistically significant during this project's timeframe, but it should be noted that a comprehensive study may prove to be statistically significant (see Appendix G).

Throughout the project's implementation, the project showed that the diagnosis of delirium dropped from 23% to an average of 16.7% over four months. This is equivalent to a 6.3% average decrease in the incidence of delirium in the SICU from statistics gathered before January. From January to May, there was an average decrease in incidences of delirium of 8.3%.

Cost-Benefit Analysis/Budget

Nationally, delirium costs facilities and patients $32.9 billion a year (Yun Gou et al., 2021). If increased assessments led to decreased incidences, as shown in this project, it would save millions of dollars each year for facilities and patients. Not only is the quality of care improved so is the value for the patient.

This project's budget was minimal but efficiently utilized. The project did not accrue any revenue during any part of its implementation. Including its data collection, deciphering, or dissemination, neither patients nor staff were compensated for their

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participation. The monetary expenditures for this project were minimal. They only included stationary used for documentation, and this included writing utensils and paper. The main expenditure was the principal investigator and nursing's time.

The organization allowed the principal investigator to utilize the nursing staff to perform delirium assessments. The nursing staff's performance and allocated time for education were budgeted expenses of the facility. The organization funded $900 during the three-month implementation phase for nursing expenses.

Timeline

The project, from its planning stages to completion, ranged from September 2020 until August of 2021. The project planning phase took place from September to December of 2020, and included preparing and submitting a proposal evaluation and obtaining approval from the PERC committee at Jacksonville State University, and Institutional Review Board (IRB) submissions and approval. IRB approval was obtained from the facility on February 11, 2021, and IRB approval from Jacksonville State University was obtained on February 19, 2021 (see Appendices H & I). Both were exempt due to the project's use of secondary data. The project was implemented in the SICU from February to mid-May 2021. This included data collection, data analysis, and organization of data. May and June 2021 were used for the finalization of the manuscript and dissemination of results. This gave the principal investigator ten months to complete the project; one semester (ANP 797) for development and planning the project, one semester (ANP 798) for data collection and deciphering the data, and a half of a semester (ANP 799) to disseminate data.

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Ethical Considerations and Protection of Human Subjects

Ethical considerations and human subjects' protection are essential parts of projects that include humans. IRB approval was obtained by both the facility in which the project took place and Jacksonville State University with an exempt status as all data was secondary data. No patients or staff were identified in any way. Another crucial area of importance is to note that the project used an assessment tool that posed no physical or mental harm to the patient or the nursing staff performing the assessment. It is also important to note that the assessment done for the study was an assessment performed as part of the daily nursing care in the SICU; the only difference was the frequency in which the study was performed. Most importantly, both patients and staff had the ability and the right not to participate or not have their data used in the study.

Conclusion

Delirium is an insidious syndrome that affects anywhere from 20-80% of ICU patients (ANA, 2019). In the SICU, delirium affects, on average, about 23% of patients. While these statistics are daunting, there is light at the end of the tunnel. Delirium can be treated and even better prevented.

The increased frequency of the delirium assessments brought more attention to delirium and made providers and nursing staff more aware of the signs and symptoms. It also created room for discussions about how assessments were being performed and the impact that ICU delirium has on those suffering from it. This increase in attention was evidenced by the improved quality of delirium assessments performed by the nursing staff as the project progressed, and providers working in the SICU making a concerted

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effort to schedule nonurgent labs and other diagnostic studies during daytime or early evening hours to help promote the sleep-wake cycle.

While this project was not statistically significant (p-value .07), it showed that more frequent delirium assessments positively affected the incidence of delirium within the SICU. There was a 6.3-8.3% average decrease over the four months that the patients were assessed four times a day.

Some confounding factors must be mentioned and may affect the reproduction of the project in other units. The CAM-ICU assessment relies heavily on the person performing the assessment. It requires that the person performing it frame and ask the question correctly without leading the patient. Also, it is dependent on the patient's ability to participate, meaning those that are heavily sedated (Richmond Agitation-Sedation Score of negative two or less) cannot take part and should not be screened. Patients with hepatic encephalopathy were not screened or used in the study. Patients with COVID-19 were not screened due to the novelty of the disease and lack of understanding of how it can affect mental status.

While more research into the frequency of assessments is needed, the project did provide enlightenment into nursing's attitude and competency in performing the CAM-ICU assessments. A future study is needed to assess nursing's performance of the CAM-ICU and their effects on incidences of delirium. The study also brought to light some novel nursing implications. These implications include the necessity of delirium assessments and their role in improving the quality of care provided to patients. The project also showed that the more aware both nurses and providers are of the risk factors for delirium, the more equipped they are to prevent the development of delirium.

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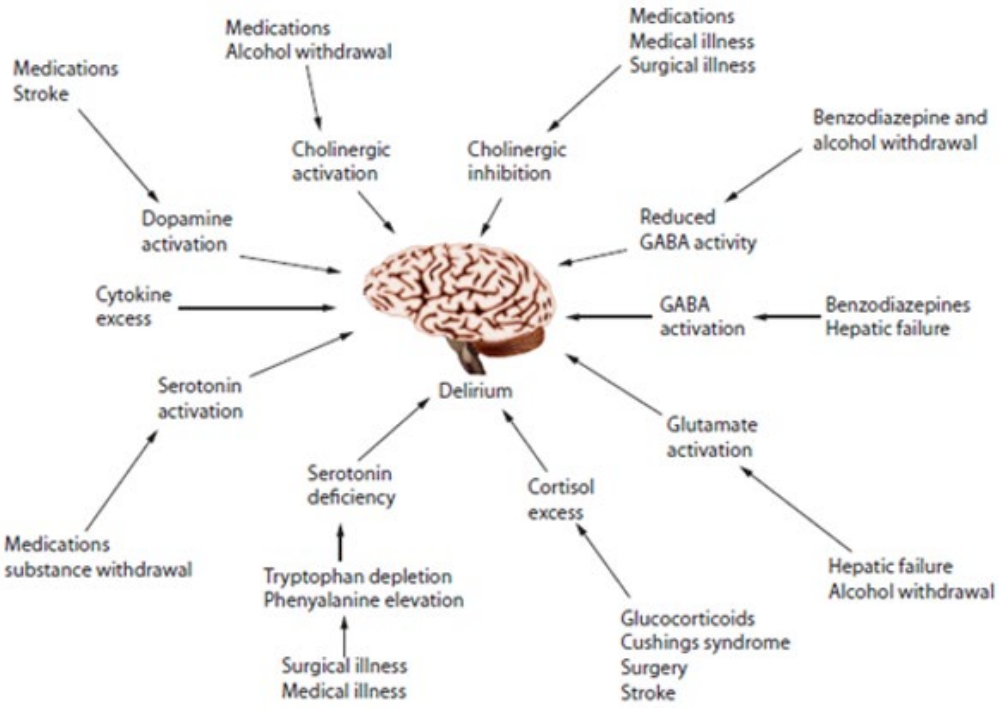
Appendix A

Figure 1. Risk Factors for delirium



Source: Jesse B. Hall, Gregory A. Schmidt, John P. Kress: *Principles of Critical Care*, 4th Edition:
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Figure 1. This is an illustration showing the different factors that may contribute to a patient developing delirium.

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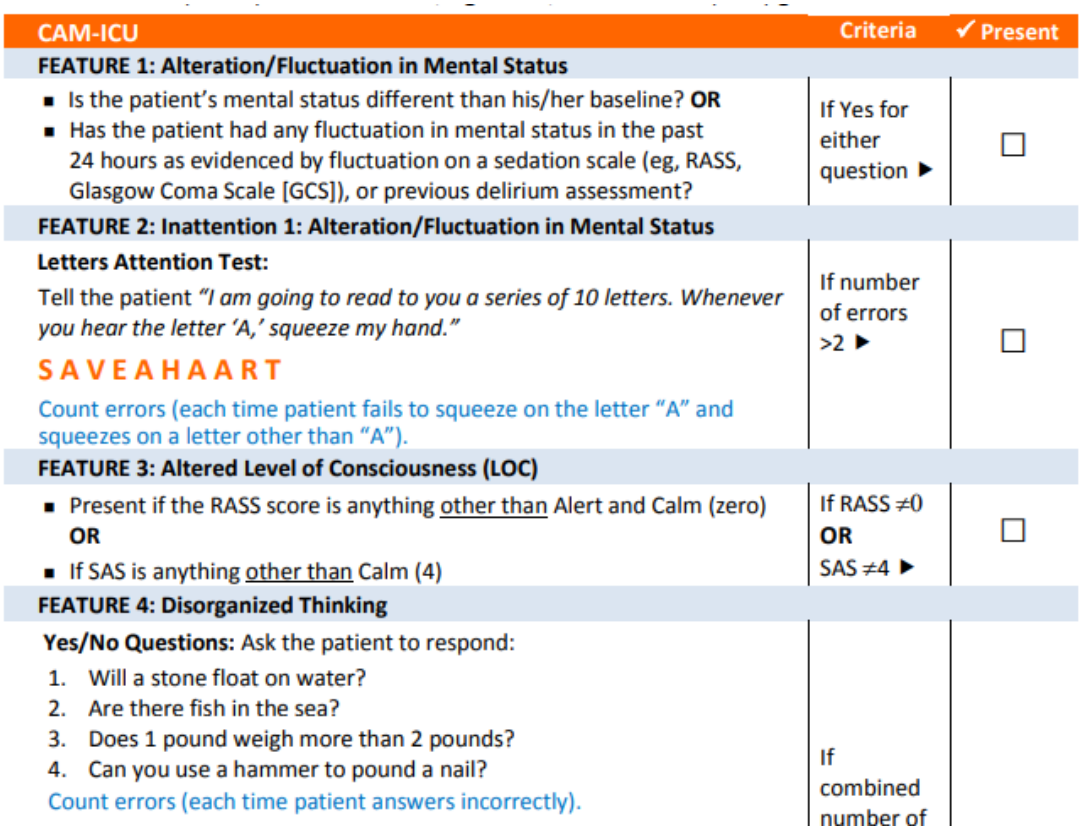
Appendix B

Figure 2. CAM-ICU Delirium assessment



CAM-ICU	Criteria	✓ Present
FEATURE 1: Alteration/Fluctuation in Mental Status		
▪ Is the patient's mental status different than his/her baseline? **OR** ▪ Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation scale (eg, RASS, Glasgow Coma Scale [GCS]), or previous delirium assessment?	If Yes for either question ▶	☐
FEATURE 2: Inattention 1: Alteration/Fluctuation in Mental Status		
Letters Attention Test: Tell the patient *"I am going to read to you a series of 10 letters. Whenever you hear the letter 'A,' squeeze my hand."* S A V E A H A A R T Count errors (each time patient fails to squeeze on the letter "A" and squeezes on a letter other than "A").	If number of errors >2 ▶	☐
FEATURE 3: Altered Level of Consciousness (LOC)		
▪ Present if the RASS score is anything other than Alert and Calm (zero) **OR** ▪ If SAS is anything other than Calm (4)	If RASS ≠0 **OR** SAS ≠4 ▶	☐
FEATURE 4: Disorganized Thinking		
Yes/No Questions: Ask the patient to respond: 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does 1 pound weigh more than 2 pounds? 4. Can you use a hammer to pound a nail? Count errors (each time patient answers incorrectly).	If combined number of	

Figure 2. This is an example of a CAM-ICU delirium assessment used during the project. It includes all four features used in the full assessment.

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Appendix C

Figure 3. Deming's PDSA model

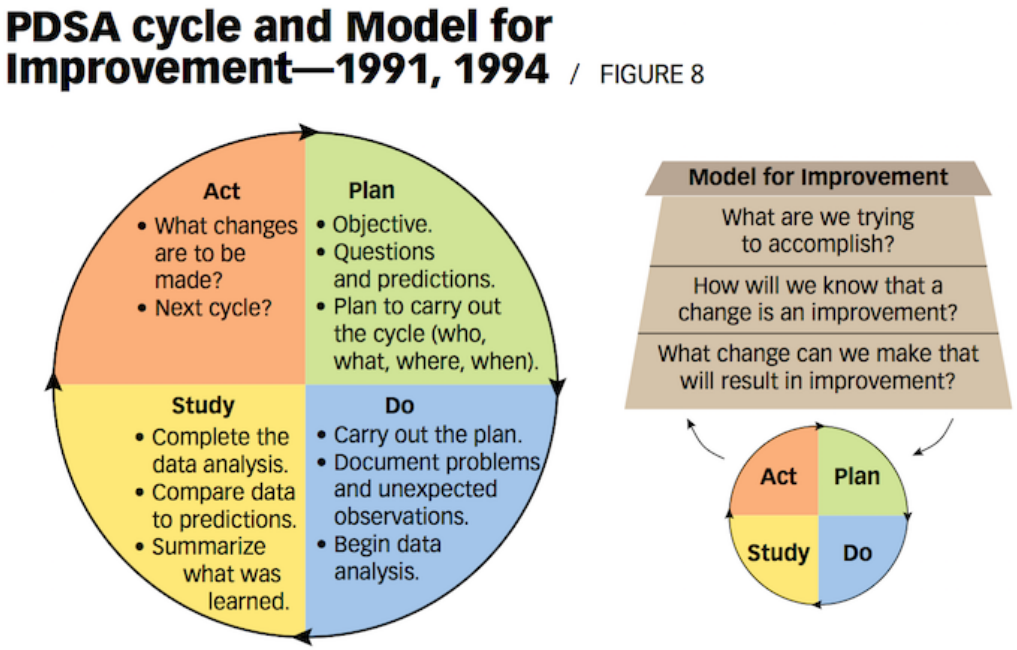

Figure 3. This is an example of Deming's Plan, Do, Study, Act (PDSA) model. This model is used to implement change quickly and efficiently within an organization.

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Appendix D

Figure 4. Data analysis table.

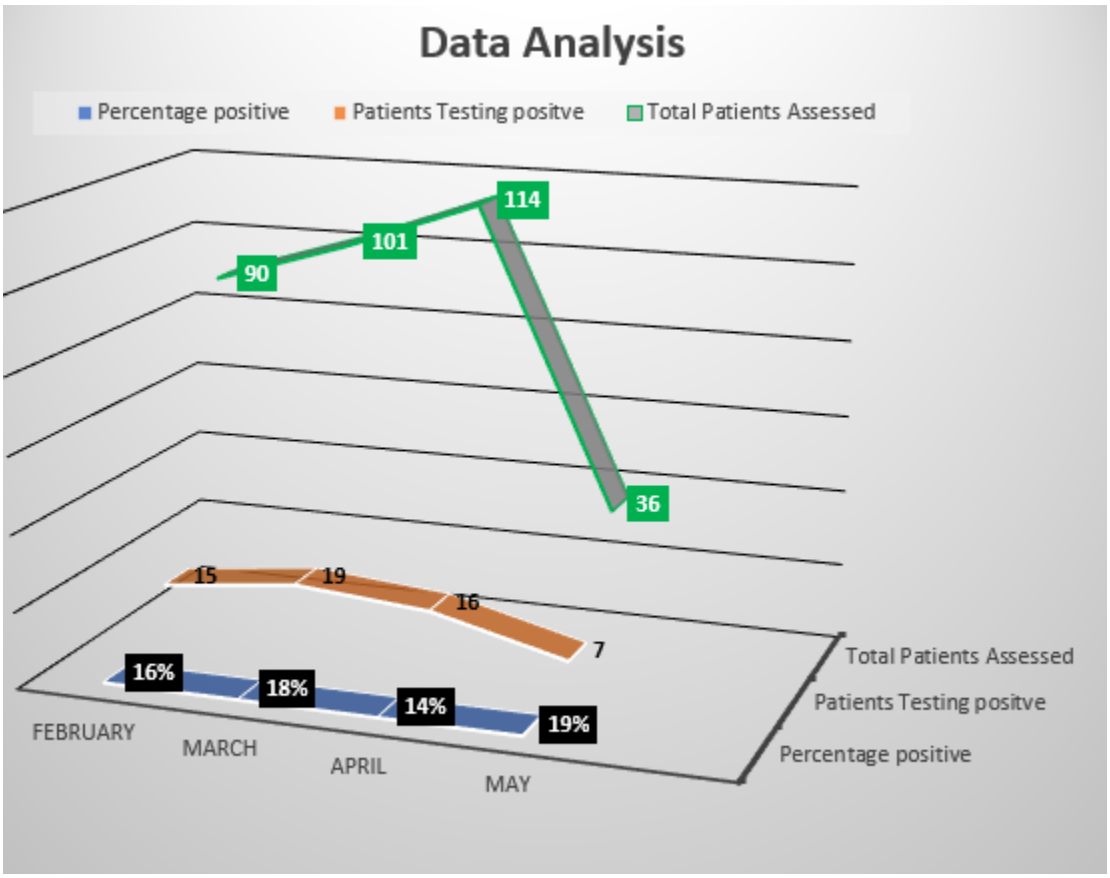

Figure 4. This is a data analysis table showing the total number of patients assessed for delirium (top line in grey and green). The number of patients that tested positive for delirium (middle line in orange). Finally, the percentage of patients that were delirious during those months (bottom line in blue).

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Appendix E

Figure 5. Fisher exact test

Table format: Contingency		Outcome A	Outcome B
		Delirius	Not Delirius
1	2 day assess	106	380
2	4 day assess	57	285
3	Title		

Figure 5. This is the Fisher's exact test performed during this project. It shows the number of patients assessed twice a day (line #1) and the number of patients assessed four times a day (line #2).

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Appendix F

Figure 6. Fisher's exact test graphic data

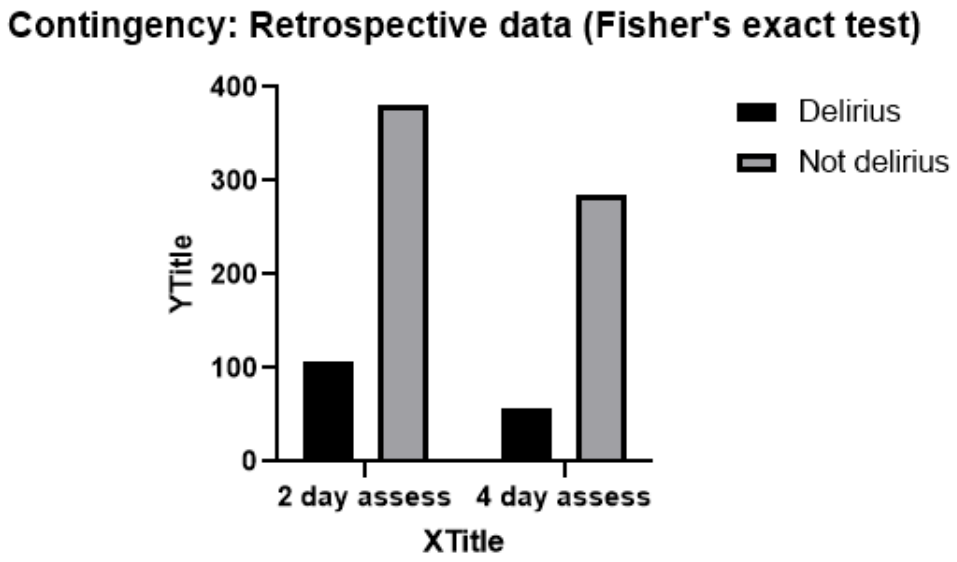

Figure 6. Fisher's exact test graphic data shows the number of assessed patients before and after the intervention and the number of patients that tested positive.

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Figure 7. Results of Fisher's exact test

1	**Table Analyzed**	Contingency: Retrospective data (Fisher's exact test)	
2			
3	**P value and statistical significance**		
4	Test	Fisher's exact test	
5	P value	0.0758	
6	P value summary	ns	
7	One- or two-sided	Two-sided	
8	Statistically significant (P < 0.05)?	No	
9			
10	**Effect size**	**Value**	**95% CI**
11	Relative Risk	1.309	0.9818 to 1.752
12	Reciprocal of relative risk	0.7642	0.5706 to 1.019
13			
14	Attributable risk (P1 - P2)	0.05144	-0.005598 to 0.1059
15	NNT (reciprocal of attrib. risk)	19.44	
16			
17	Odds ratio	1.395	0.9794 to 2.005
18	Reciprocal of odds ratio	0.7170	0.4986 to 1.021
19			
20	Sensitivity	0.6503	0.5744 to 0.7193
21	Specificity	0.4286	0.3915 to 0.4665
22	Positive Predictive Value	0.2181	0.1837 to 0.2570
23	Negative Predictive Value	0.8333	0.7902 to 0.8691
24	Likelihood Ratio	1.138	
25			
26	**Methods used to compute CIs**		
27	Relative Risk	Koopman asymptotic score	
28	Attributable risk (P1 - P2)	Newcombe/Wilson with CC	
29	Odds ratio	Baptista-Pike	
30	Sensitivity, specificity, etc.	Wilson-Brown	
31			
32	**Data analyzed**	**Delirius**	**Not Delirius**	**Total**
33	2 day assess	106	380	486
34	4 day assess	57	285	342
35	Total	163	665	828
36			
37	**Percentage of row total**	**Delirius**	**Not Delirius**	
38	2 day assess	21.81%	78.19%	
39	4 day assess	16.67%	83.33%	
40			
41	**Percentage of column total**	**Delirius**	**Not Delirius**	
42	2 day assess	65.03%	57.14%	
43	4 day assess	34.97%	42.86%	
44			

Figure 7. This table shows the results of Fisher's exact test. It shows that the project has a p-value of 0.07 with a confidence interval of 95%. It also provides sensitivity and specificity, positive predictive value, and percentages of delirious and non-delirious patients twice a day and four times a day assessments.

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Appendix H

Figure 8. Jacksonville State University IRB approval

February 19, 2021

Dear William Lemon:

Your proposal submitted for review by the Human Participants Review Protocol for the project titled: "Effects of Increased Confusion Assessment Method for the Intensive Care Unit Delirium Assessments on Patients in the Surgical Intensive Care Unit", has been reviewed and approved as exempt. If the project is still in process one year from now, you are asked to provide the IRB with a renewal application and a report on the progress of the research project.

Sincerely,

Joe Walsh
Executive Secretary, IRB

Figure 8. IRB approval received from Jacksonville State University, showing that the project was approved under an exempt status.

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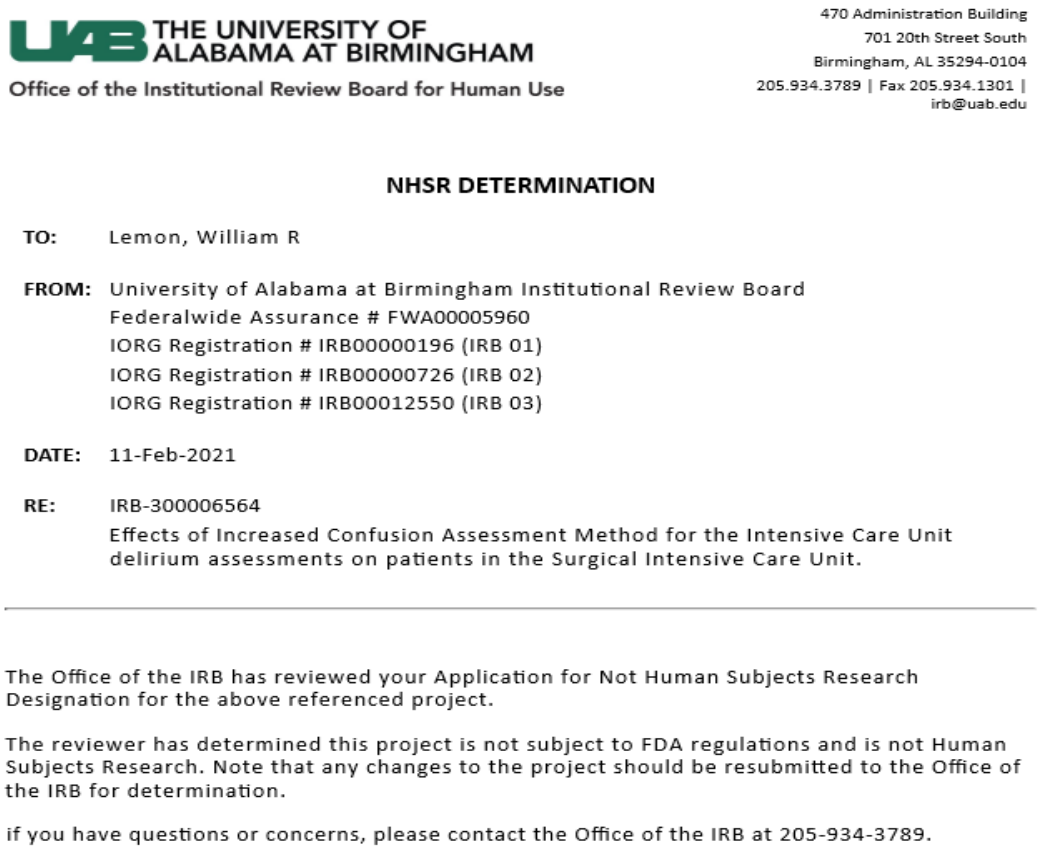
Appendix I

Figure 9. University of Alabama Birmingham Hospital IRB approval



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 |
irb@uab.edu

NHSR DETERMINATION

TO: Lemon, William R

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)
IORG Registration # IRB00012550 (IRB 03)

DATE: 11-Feb-2021

RE: IRB-300006564
Effects of Increased Confusion Assessment Method for the Intensive Care Unit delirium assessments on patients in the Surgical Intensive Care Unit.

The Office of the IRB has reviewed your Application for Not Human Subjects Research Designation for the above referenced project.

The reviewer has determined this project is not subject to FDA regulations and is not Human Subjects Research. Note that any changes to the project should be resubmitted to the Office of the IRB for determination.

if you have questions or concerns, please contact the Office of the IRB at 205-934-3789.

Figure 9. IRB approval received from the University of Alabama Birmingham hospital, showing that the project was approved under an exempt status.

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