Running Head: IMPLEMENTING CONFUSION ASSESSMENT METHOD
Implementing the Confusion Assessment Method to Improve the Care of Delirious Patients
Ву
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#### **Abstract**

**Background**: Delirium affects approximately fifty percent of adults aged 65 years or older. The prevalence of delirium can be as high as 74% in surgical patients and 11% to 42% in non-surgical patients. Delirium can go undetected in 72% of Intensive Care Unit (ICU) patients when routine neurological monitoring tool is not used but could be prevented in 30 to 40% of cases, if detected early. Using a valid and reliable delirium assessment tool in the ICU, is essential so early interventions can be initiated.

**Purpose**: The purpose of this scholarly project was to implement use of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) for delirium assessment at a hospital in the Mid-Atlantic region of the United States.

**Methods**: This quality improvement project was conducted with nurses that work in the intensive care unit. Informed consent was obtained by all nurse participants whose participation in the project was strictly voluntary. Pre and post-intervention questionnaires measured perceived self-confidence and comfort levels with providing ICU delirium care and delirium knowledge. The project involved three phases: pre-intervention questionnaire administration, inservice, case scenarios, brief videos and one-on-one training and implementation of the CAM-ICU tool in the ICU setting, and the administration of post-intervention questionnaire. Laminated CAM-ICU worksheet and flowsheet were placed at each bed space to provide cues to the nurses to complete their delirium assessment. Multiple modes of interventions were used for the implementation of the CAM-ICU. A total of 34 ICU nurses consented to the project.

**Results**: Thirty-four participants completed the pretest; 22 participants completed the posttest. The age of the participants ranged between 36 - 66 years, the average age was 53 years (SD = 7.94); years of ICU experience ranged between 3 - 40 years, average ICU experience was 20 years (SD = 9.09); 77% of participants had a Bachelor of Science degree. Comfort assessing ICU patients for delirium increased, t(21) = -2.339, p = .029, confidence providing accurate definition of delirium increased, t(21) = -3.052, p = .006, and nurses improved ability to identify interventions to prevent or decrease delirium, t(21) = -2.731, p = .013. There were statistically significant differences between the mean scores on the knowledge test from pre- to post-intervention, t(21) = -10.784, p < .001. Nurses age (p = .620), years of ICU experience (p = .352) and level of education (p = .129) did not influence the knowledge scores. Compliance in using paper CAM-ICU worksheet for documentation was 21%. Nurses scored 28% of the ICU patients screened as delirious.

Conclusion: This quality improvement project suggests that a formal training program for ICU nurses coupled with the use of in-service, one-on-one sessions, and videos for the implementation of the CAM-ICU tool, can result in increased awareness and knowledge of ICU delirium. The positive results have the potential to prompt treatment and improve outcomes for ICU patients who experience delirium. Adoption of the CAM-ICU into patient electronic health record is recommended for sustainability.

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# **Table of Contents**

Acknowledgements	iii
Overview	1
Background and Significance of the Problem	1
Problem Statement	3
The Purpose of the Project	3
Significance of the Project and Anticipated Outcomes	3
Theoretical Framework	4
Knowledge Creation	4
Identify, Review, and Select Knowledge	5
Identify a Gap in Knowledge	5
Adapt Knowledge to Local Context	6
Assess Barriers to Knowledge Use	6
Select, Monitor, Evaluate, and Sustain	6
Review of Literature	7
Evaluating the CAM-ICU Tool	8
Multifactorial Approach	10
Routine Delirium Assessment	11
Education and Training Nurses in Delirium Monitoring	13
Evidence Synthesis	15
Methodology	16
Design	17
Sample and Setting	17
Procedures and Measures	17
Data Collection and Analysis	20
Human Subjects Protection and Approval Processes	21
Results	21
Demographics	22
Self Confidence and Comfort Levels in Using CAM-ICU	22
Discussion	26
Translation Plan and Implication for Nursing Practice	29

Conclusion	33
References	34
Tables and Figures	38
Appendices	48

Implementing the Confusion Assessment Method to Improve the Care of Delirious Patients

Overview

# **Background and Significance of the Problem**

Delirium affects approximately fifty percent of adults aged 65 years or older and costs more than \$164 billion per year in hospitals within the United States (Inouye, Westendorp, & Saczynski, 2014). Care for delirium increases inpatient costs by at least \$2,500 per patient (Faught, 2014). There is a necessity for bedside nurses to recognize delirium (Boot, 2012) and be able to distinguish the neurological changes that occur as a result of disease progression versus the development of delirium (Flagg, Cox, McDowell, Mwose, & Buelow, 2010).

The definition of delirium is a syndrome where patients demonstrate disturbed behavior and lack of awareness. Delirium behavioral changes have a rapid onset and affect patients' cognition (Inouye et al., 2014). Delirium may be hypoactive (i.e., lethargy and reduced psychomotor functioning), hyperactive (i.e., agitation and hallucinations) or a combination of both (Inouye et al., 2014). When compared to non-delirious patients, those who develop delirium have worse outcomes (Holroyd-Leduc, Khandwala, & Sink, 2010). Delirium is associated with increased inpatient length of stay, the risk of hospital-acquired complications such as pressure ulcers, persistent cognitive deficits, and a higher rate of discharges to long-term care facilities (Holroyd-Leduc, Khandwala, & Sink, 2010).

The prevalence of delirium in the older adult population aged 65 years or older can be as high as 74% in surgical patients and approximately 11% to 42% in non-surgical patients (Holroyd-Leduc et al., 2010). In the elderly, the risk factors for delirium are often multifactorial due to the complex interactions between predisposing factors (i.e., cognitive impairment, functional impairment, history of stroke and alcohol use) and precipitating factors (i.e.,

psychoactive, sedatives or hypnotics drugs, physical restraint, use of bladder catheter, abnormal laboratory values, infection, any iatrogenic event, surgery, trauma or coma) (Inouye et al., 2014). In vulnerable patients with underlying dementia and co-morbidities, a sedative or hypnotic drug might trigger delirium while, in a young healthy patient, delirium might occur after exposure to multiple factors such as general anesthesia or sleep deprivation (Inouye et al., 2014). Looking at a risk factor will not treat delirium. Thus a multicomponent tactic will be most effective for both the prevention and treatment of delirium (Inouye et al., 2014).

On reviewing the literature and consulting with numerous experts, including the creators of the confusion assessment method (CAM), Ely et al. (2001) adapted the CAM tool for use in the intensive care unit (ICU). The adapted CAM-ICU is for ICU staff who have no formal psychiatric training. A validation study concluded that the CAM-ICU had a sensitivity of 93 - 100%, a specificity of 98 - 100%, and high interrater reliability ( $\kappa$  = 0.96) in detecting delirium (Ely et al., 2001). A reliability and validity study by Koga et al. (2015) determined that the CAM-ICU Kappa inter-rater reliability was ( $\kappa$  = 0.85) and Cronbach's alpha coefficient was 0.69 (95% CI: 0.57–0.79). In patients aged 65 years or older, suspected of dementia and those with the highest severity of illness, the CAM-ICU tool demonstrated excellent sensitivity, specificity, and interrater reliability (Ely et al., 2001).

Delirium can go undetected in as many as 72% of ICU patients when a routine neurological monitoring tool is not used (Andrews, Silva, Kaplan, & Zimbro, 2015) and can be prevented in 30 to 40% of cases if detected early (Inouye et al., 2014). Delirium is now being used as an indicator of healthcare quality for older adults (Inouye et al., 2014), hence the importance of educating bedside nurses on how to apply the CAM-ICU tool to assess for delirium accurately. The CAM-ICU tool is easy to use with an average assessment time for each

patient ranging between 2 and 5 minutes (Boot, 2012). Also, using the CAM-ICU tool will enable bedside nurses to improve their patients' quality of care since delirium assessment can be performed at least once every 8 to12 hours per shift (Boot, 2012). The Society of Critical Care Medicine and the American Association of Critical Care Nurses now recommend using a valid and reliable neurological assessment tool for the evaluation and routine monitoring of delirium (Andrews et al., 2015).

#### **Problem Statement**

In the intensive care unit of this project site, bedside nurses are not routinely documenting ICU delirium care. During rounding, an informal meeting with ICU nurses revealed that a formal training on using the CAM-ICU was lacking. Bedside nurses said they lacked knowledge of the CAM-ICU tool for delirium assessment and expressed interest in CAM-ICU tool use.

### The Purpose of the Project

The purpose of this scholarly project was to implement use of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) for delirium assessment, and measure the ICU nurses knowledge and confidence to assess for delirium using the CAM-ICU tool.

### **Significance of the Project and Anticipated Outcomes**

There are several outcomes following implementation of this educational training and tool. One was to increase the awareness and knowledge of ICU delirium. Another is an increase in delirium assessment in the ICU. This has the potential to decrease hospital length of stay, and improve patient satisfaction scores.

#### **Theoretical Framework**

The Knowledge to Action (KTA) framework (Straus, Tetroe, & Graham, 2013) was selected as a framework for the organizational structure for the design and methods used to implement this project. Permission was obtained from the author (Appendix A). The KTA cycle is an iterative cycle where both knowledge creation and translation are integrated together in each step of the process (Straus et al., 2013) (Appendix B).

Each component of the KTA contains different phases which overlap and can repeat (Straus et al., 2013). The action phases can be performed one after the other or together.

However, knowledge phases may have an impact on the action phases (Straus et al., 2013). The action cycle summarizes a process which represents the activities and action needed for knowledge use in practice. Knowledge can be adapted or adjusted to the local context such as the hospital, then barriers and facilitators to knowledge use are clearly assessed (Straus et al., 2013). Involving key stakeholders at the beginning and altering knowledge to the needs of the staff who are going to use this knowledge is also important (Straus et al., 2013). The knowledge creation process consists of these phases: 1. knowledge inquiry, representing primary literature review; 2. knowledge synthesis, representing the aggregation of existing knowledge; and 3. knowledge tools and products, representing the distillation of concise and user friendly formats of knowledge, such as guidelines or decision aids. The process of knowledge application includes seven phases, from identifying a problem and identifying, reviewing, and selecting knowledge (phase 1) to sustaining knowledge use (phase 7).

# **Knowledge Creation**

Based on the KTA model, the knowledge creation for this project began as knowledge inquiry of health research literature for best evidence on delirium assessment methods used in the

ICU. The question that arose from the inquiry was "will the use of the CAM-ICU for delirium assessment and educating bedside nurses to correctly apply the CAM-ICU improve the identification of delirium in patients aged 65 years or older in the ICU?" Knowledge synthesis involved current literature reviews for evidence similarities and differences between current delirium assessment methods. Operationalization of knowledge was by identifying and selecting a problem through gap analysis where stakeholders are involved. Synthesizing evidence was through rating its strength. The Johns Hopkins Nursing Evidence-Based Practice Appraisal tool was used to appraise the literature for delirium assessment methods used in the ICU (Dearholt & Dang, 2012). The knowledge products/tools stage involved refining knowledge where a determination made that the CAM-ICU was the tool that best addressed the question asked, thus the CAM-ICU tool was selected as the instrument of choice for ICU delirium assessment.

### Identify, Review, and Select Knowledge

Though several ICU neurological assessment tools are available in the literature, the CAM-ICU tool was selected due to its high interrater reliability ( $\kappa$  = 0.96) in detecting delirium (Ely et al., 2001). Findings that emerged from literature reviews reinforced the importance of educating bedside nurses to use a neurological assessment tool for delirium assessments (Straus et al., 2013).

### Identify a Gap in Knowledge

During rounding, an informal meeting with ICU nurses ensued where the investigator determined that patients' neurological assessments for delirium are performed without a valid tool. The CAM-ICU rows were embedded in the electronic ICU flowsheets and had to be downloaded into the electronic flowsheet for delirium assessment. ICU nurses confirmed they

lacked knowledge of using CAM-ICU for delirium assessment and expressed interest in CAM-ICU tool use.

### **Adapt Knowledge to Local Context**

Education and training helped adapt knowledge. Hospital intranet resources were available to facilitate quick access to appraised and summarized information on CAM-ICU tool usage. Additional learning sessions that are led by expert nurse educators helped provide opportunities for bedside nurses to practice new skills and achieve practice change (Straus et al., 2013).

# Assess Barriers and facilitators to Knowledge Use

Barriers to implementation were identified through ongoing stakeholders' meetings. Insufficient knowledge on delirium care was a primary barrier to CAM-ICU tool use. Other barriers included time allocation for implementing this education process, the commitment of staff and leadership, economic cost, and training those involved in the implementation process. There were also negative perceptions of the quality and clinical usefulness of CAM-ICU for delirium assessment. The bedside nurses felt overworked and worried that implementing the CAM-ICU would add more hard work to their workload. Facilitators was managerial and leadership support. The barriers identified highlighted the need for education and coaching of bedside nurses.

# Select, Monitor, Evaluate, and Sustain

Throughout the KTA process, knowledge use was monitored by incorporating care pathway through electronic/sticker tracking. The project investigator initiated a series of Plan-Do-Study-Act (PDSA) cycles. These cycles promoted the use of an iterative approach that uses small scale cycles to quickly assess change and adapt feedback thereby providing a flexible

approach to the CAM-ICU tool use. To monitor knowledge use and evaluate outcomes, audits and staff surveys were included to evaluate the implementation process (Straus et al., 2013). To establish a clear sustainable process where bedside nurses could accurately apply the CAM-ICU, support of stakeholders, including bedside nurses, ICU nurse managers, and the multidisciplinary team, was needed.

This foundational project disseminated research knowledge on delirium to bedside nurses. Nurses accurately utilized the knowledge for improvement in patient's outcome. For sustainability, future projects might grow from this work, such as creating policies and protocols on nurse education and the CAM-ICU. Additional projects might be to develop bedside nurses as leaders in delirium assessment and establish hospital delirium assessment champions who might act as resources for new staff (Straus et al., 2013).

CAM-ICU educational materials will be made available on the hospital SharePoint drive and remain open for the leadership to use and adapt, thus increasing the likelihood to sustain knowledge. This availability will increase hospital staff access to the implementation tools thus increasing the possibility of achieving successful permanency using the KTA framework for CAM-ICU tool implementation in an urban hospital environment.

#### **Review of Literature**

The literature review evaluated current evidence focused on educating and training bedside nurses to accurately applying the CAM-ICU for delirium assessment. There were several themes relating to the CAM-ICU and nurse education. Some evidence focused on a multifactorial program that looked at identifying delirium using a neurological assessment tool, some focused specifically on the CAM-ICU tool, some evidence assessed the problems that exist when a routine delirium assessment was lacking, and some focused on educating nurses to use

the CAM-ICU tool. The synthesis of similarities and differences of the studies evaluated is mentioned. A summary on the importance of training bedside nurses to apply the CAM-ICU tool for delirium assessment is included. The strength of the evidence and the quality of the evidence was rated using the Johns Hopkins Nursing Evidence-Based Practice Rating Scale (Dearholt & Dang, 2012; Newhouse, Dearholt, Poe, Pugh, & White, 2005) (Appendix D).

# **Evaluating the CAM-ICU Tool**

A prospective cohort study evaluated the CAM-ICU after its adaptation from the CAM tool by Ely et al. (2001). The adapted CAM-ICU was designed to be used by ICU staff with no formal psychiatric training (Ely et al., 2001). The study concluded that the CAM-ICU had a sensitivity of 93 - 100%, a specificity of 98% to 100%, and high interrater reliability ( $\kappa$  = 0.96) in detecting delirium. Delirium occurred in 83.3% of mechanically ventilated patients while they were in the ICU. In patients aged 65 years or older, suspected dementia and with the highest severity of illness, the CAM-ICU instrument retained excellent sensitivity, specificity, and interrater reliability (Ely et al., 2001). The strength of this study included a large number of patients evaluated, use of delirium experts for reference, standard ratings, and use of a standardized easily performed nursing assessment. The limitation was the convenience sample of patients from a single site. However, findings could be transferred to other healthcare organizations for practice change (Ely et al., 2001).

Gusmao-Flores, Salluh, Chalhub, and Quarantini (2012) conducted a meta-analysis of systematic reviews to evaluate the Intensive Care Delirium Screening Checklist (ICDSC) and the CAM-ICU for delirium assessment. Of 189 studies reviewed, only nine studies were evaluated for the CAM-ICU (n = 969 patients), and 4 (out of 33 studies) were evaluated for the ICDSC (n = 361 patients). The pooled sensitivity for CAM-ICU was 80.0% (95% confidence interval (CI)

[77.1, 82.6]), and specificity was 95.9% (95% CI [94.8, 96.8]). The diagnostic odds ratio was 103.2 (95% CI [39.6, 268.8]) (Gusmao-Flores et al., 2012). The pooled sensitivity for ICDSC was 74% (95% CI [65.3, 81.5]), and specificity was 81.9% (95% CI [76.7, 86.4]). The diagnostic odds ratio was 21.5 (95% CI [8.51, 54.4]). Regardless of the subgroup of patients evaluated, the meta-analysis showed CAM-ICU as an excellent tool for evaluating delirium in critically ill patients (Gusmao-Flores et al., 2012). Despite having a good performance, the ICDSC had a lower sensitivity and specificity when compared to the CAM-ICU. Gusmao-Flores et al. (2012) suggested that both CAM-ICU and the ICDSC can be used as screening tools for critically ill patients. Studies published in non-English languages were excluded which is a limitation since major information on delirium care was not available from those studies thereby excluding their use in the meta-analysis (Gusmao-Flores et al., 2012).

To ensure CAM-ICU delirium assessments were standardized and in accordance with validation studies, Soja et al., (2008) assessed the interrater reliability among nurse educators and expert evaluators. In their study, Soja et al., (2008) defined reliability as the agreement of CAM-ICU scores among bedside nurses and expert evaluator in the hospital. Their result showed an overall interrater agreement of  $\kappa = 0.77$  (95% CI [0.721 – 0.822], p < .0001). In mechanically ventilated patients, interrater reliability score was  $\kappa = 0.62$  (95% CI [0.534 – 0.704], p < .0001); among Traumatic Brain Injury (TBI) patients, reliability was  $\kappa = 0.75$  (95% CI [0.667–0.829], p < .0001).

Similarly, Flagg et al. (2010) mentioned CAM and CAM-ICU as tools routinely used in the ICU for delirium assessment due to their high sensitivity, specificity, and interrater reliability. In numerous studies, CAM-ICU tool had a sensitivity of 94% to 100%, specificity of 89% to 95%, and high interrater reliability (Flagg et al., 2010).

#### **Multifactorial Approach**

Several researchers used a multifactorial approach to study the benefits of educating bedside nurses to use a delirium assessment tool. The researchers Dilibero et al. (2016) conducted a quality improvement project at a hospital in Massachusetts. The aim of the project was to improve the accuracy of their delirium assessment to more than 80% among all their ICU patients. The CAM-ICU and the ICDSC tools were examined. The CAM-ICU had better clinical use and was selected by the staff nurses. The multifaceted delirium improvement project led by nurses included mandatory education. The education was hands-on use of the CAM-ICU, casebased education, and one-on-one coaching. Results from the project showed bedside nurses could attain delirium assessment accuracy of 62% to 92% after educational training. Also, bedside nurses' compliance with performing one delirium assessment per shift was 85% preeducational intervention with an improvement to 99% post-educational intervention. Preintervention assessment accuracy was 70.31% among all the ICU patients and 53.49% among sedated and agitated patients. Post-intervention assessment accuracy by nurses, improved to 95.51% for all patients and 89.23% among sedated and agitated patients. The results occurred due to the multifaceted approach of empowering frontline staff nurses through education, feedback, and one-on-one coaching at the bedside (Dilibero et al., 2016). Limitations of this study include the results were from a single hospital hence findings may not be generalizable to a larger population. However, results might be transferable to another institutional setting.

A quality improvement project by Adams et al. (2015) conducted at 21 hospitals under Kaiser Permanente in Northern California, evaluated clinical practice guidelines for CAM-ICU implementation. An approach was to educate ICU nurses on delirium assessment using PowerPoint presentations. Nursing management, including the Clinical Nurse Specialist (CNS)

and nurse educators, received education to use the CAM-ICU. Classes included comprehensive education on the use of the CAM-ICU and discussion of causative agents of delirium (Adams et al., 2015). The CNS taught delirium and CAM-ICU classes. Findings were benzodiazepine usage saw a reduction from 22% to 16%. Delirium detection rate improved from 5% in 2011 to 20% in 2014. CAM-ICU compliance increased to an average of 90% from 2011 to 2014. The limitation was that this study was conducted in 21 hospitals under Kaiser Permanente. Therefore, results may not be generalizable to other healthcare organizations. Strength was the numbers of hospitals involved in the study.

#### **Routine Delirium Assessment**

In two Midwestern hospitals, Flagg et al. (2010) used evaluated a convenience sample of nurses and assessed their abilities to recognize delirium in both ICU and the medical-surgical wards. Sixty one registered nurses participated in the study. Flagg et al. evaluated nurses' knowledge of symptoms associated with delirium, the negative sequelae associated with delirium, and the confidence levels of nurses to assess for delirium routinely. The researchers reviewed several cognitive assessment tools that can be used for identifying patients with delirium (Flagg et al., 2010). The instruments evaluated include the Cognitive Impairment Screening Tools, Psychomotor Skills Tests, Delirium Diagnostic Instruments, and Numeric Rating Scales. CAM and CAM-ICU were mentioned as commonly used tools for delirium assessments due to their high sensitivity, specificity and interrater reliability (Flagg et al., 2010). About 90% of the nurses identified the hyperactive symptoms of delirium, and 77% identified the hypoactive symptoms of delirium. The study also found that 83% and 90% of nurses could identify inattention as a sign of delirium (Flagg et al., 2010). The implication for nursing practice from this study included the recommendation to educate nurses on the importance of routine

delirium assessment and the importance of knowing the negative outcomes associated with delirium (Flagg et al., 2010). A similar study by Marino, Bucher, Beach, Yegneswaran and Cooper (2015) evaluated the importance of educating bedside nurses on using an ICU delirium assessment tool. The researchers conducted a quality improvement project to assess a nursing educational program for its critical care nurses using the validated ICDSC for use in the ICU and comparable to the CAM-ICU. Although the CAM-ICU tool was not the focus of this study, the project highlighted the need of having a nurse-led educational program for care of ICU delirious patients. Both studies confirmed that for a successful delirium program, nursing education was important (Flagg et al., 2010; Marino et al., 2015). Nurses should recognize the differences between neurological disease based changes in patients and the development of delirium when a valid and reliable tool is routinely used (Flagg et al., 2010). Weaknesses were the researchers in the Flagg et al. study did not individually score the cognitive and the neurological assessment tools used.

A prospective study was carried out at Vanderbilt University Medical Center. This study aimed to implement and evaluate nurses' compliance and reliability in using the CAM-ICU to assess for delirium in trauma patients (Soja et al., 2008). A web-based teaching module and group in-services were used to evaluate bedside nurses. Nursing compliance on using the CAM-ICU was the completion of a CAM-ICU and RASS score before an expert evaluator's assessment. The CAM-ICU tool was selected because it was routinely used by the surgical and medical ICUs at the Vanderbilt University Medical Center. During the education phase of the study, expert evaluators trained selected nurse educators and delirium champions on how to apply the CAM-ICU. The nurse educators eventually trained the bedside nurses (Soja et al., 2008). An overall compliance of 84% was obtained for CAM-ICU tool use. A post-

implementation nurse survey identified some barriers to delirium monitoring. Twenty-one percent of respondents mentioned time, 19% referred to the lack of feedback on performance, and 15% mentioned knowledge of delirium tool. Spot checks performed over a 2-week period showed continuous compliance of CAM-ICU at an overall rate of 92% (Soja et al., 2008).

#### **Training Nurses in Delirium Monitoring**

At a tertiary care medical center, Vasilevskis et al. (2011) carried out a prospective study to evaluate bedside nurses' recognition of delirium and sedation using validated tools. The CAM-ICU was used for delirium assessment, and the RASS score was used to measure sedation. Bedside nurses received education and competency assessment on how to apply the CAM-ICU and RASS tools. Delirium assessment was carried out once per 12 hours and every 4 hours for sedation. Vasilevskis et al. noted that delirium and sedation assessment using validated tools are reliable and sustainable in clinical practice. There was assessment agreement between bedside nurses and researchers. CAM-ICU delirium weighted kappa was 0.67 and RASS sedation weighted kappa was 0.66. Bedside nurses' delirium diagnoses were 0.81 and 0.81 respectively for sensitivity and specificity. In their discussion, Vasilevskis et al. recommended that ICU nurses should learn and prioritize delirium and sedation training as part of their regular clinical duties. Critical care providers can confidently use bedside nurses' assessment of delirium and sedation to help with appropriate medical decisions, quality, or research monitoring. The limitation of the study was the convenience sample of nurses used.

A performance improvement project by Andrews et al. (2015) evaluated the effects of implementing the CAM-ICU as a bedside nurse assessment. The staff selected the CAM-ICU due to their familiarity with the tool, support in the literature, and CAM-ICU availability in their electronic health record. The project focused on answering two questions. The first was the

effects of implementing the CAM-ICU assessment on the diagnosis of delirium, the duration of mechanical ventilation on patients, ICU length of stay, and the time spent on restraints. The second question was the barriers to performing delirium assessment in the clinical settings (Andrews et al., 2015). To answer both questions, ICU nurses received an hour mandatory education session. Nurses trained in understanding the consequences of delirium, identification of risk factors for delirium, and use of the RASS for sedation measurement and the CAM-ICU for delirium assessment. Education also provided videos that demonstrated patient assessments by experts who used the CAM-ICU. In the pre- and post-CAM-ICU implementation survey, 42 staff received the survey, and 20 (48%) responded. Ninety percent of the nurses stated that performing delirium assessment every 12 hours was not difficult. Reasons bedside nurses gave for easy adoption of this delirium assessment change was the education provided, the location of the assessment within the ICU charting flowsheet, and the availability of the delirium note cards (Andrews et al., 2015). Barriers to embracing the CAM-ICU included lack of confidence by nurses in performing the delirium assessment, difficulty using the CAM-ICU in ventilated patients, and lack of response by researchers to nurses' findings. Andrew et al. mentioned the need for a multidisciplinary team approach and the critical need for nurses to perform delirium assessment accurately and consistently. The researchers highlighted the need for continuous education for nurses, expert coaching provided at the bedside with real patients, and scenarios that highlight rare situations to help nurses adapt their new skill. An additional recommendation was ongoing training for nurses. A computerized learning system and follow-up demonstrations were also efficient in providing ongoing education to nurses (Andrews et al., 2015).

### **Evidence Synthesis**

In the studies reviewed, evidence from the literature showed more similarities than differences. Many studies recommended that bedside nurses receive mandatory education and training on how to apply the CAM-ICU for delirium assessment (Adams et al., 2015; Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011). Similarly, educating bedside nurses on the consequences of delirium and identifying risk factors for delirium was stated in a couple of studies (Soja et al., 2008; Vasilevskis et al., 2011).

Studies have also found educational training of nurses to be beneficial. One study showed an increase in delirium assessment accuracy after an educational training for bedside nurses (Dilibero et al., 2016). Education using videos that demonstrated assessments by expert clinicians using the CAM-ICU tool for individual patient assessment was encouraged by researchers as it helped nurses grasp the details of delirium assessment and encouraged compliance with delirium assessment (Andrews et al., 2015; Vasilevskis et al., 2011). Some evidence encouraged online based teaching modules and group in-services, which can be incorporated into nurse education and can be used to evaluate bedside nurses in their completion of a CAM-ICU delirium assessment (Andrews et al., 2015; Vasilevskis et al., 2011).

In a quality improvement project by Adams et al. (2015), ICU nurses were educated using PowerPoint presentations. For the 21 hospitals involved in the study, delirium detection rate improved. CAM-ICU compliance increased to an average of 90% from 2011 to 2014. Likewise, there was an increase in nursing compliance of CAM-ICU usage following nurse education (Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011).

Some of the evidence evaluated the CAM-ICU and found the tool to have high interrater reliability among nurse educators and expert evaluators (Soja et al., 2008); the CAM-ICU showed high sensitivity and specificity (Flagg et al., 2010). As a result, the CAM-ICU tool was selected by more bedside nurses for use due to its validity and reliability (Flagg et al., 2010; Soja et al., 2008).

Two studies used different ICU delirium neurological assessment tools with good validity and reliability and comparable to the CAM-ICU. Although the CAM-ICU tool was not the focus of those studies, the researchers were able to highlight the need for educating ICU nurses on how to apply a delirium assessment tool accurately. The studies proved that a formal educational training program for ICU nurses can result in increased awareness and knowledge of ICU delirium and can help critical care nurses accurately screen and treat delirious patients (Flagg et al., 2010; Marino et al., 2015).

In summary, to implement change and educate bedside nurses on how to apply the CAM-ICU tool for delirium assessment accurately, a multidisciplinary and a multifaceted approach to engaging and empowering bedside nurses through continuous education is necessary. Also, frequent feedback and one-on-one coaching at the bedside must be provided for this change to be successful, efficient and permanent (Adams et al., 2015; Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011).

### Methodology

The design, sample and setting, measurement, data collection and analysis and human subjects' protection plan are examined in this section.

### **Design**

In this quality improvement project, pre-test and post-test questionnaires on perceived self-confidence and comfort levels with providing ICU delirium care and a knowledge test to determine nurses' delirium knowledge were administered. This was to determine the effectiveness of a training program coupled with use of the CAM-ICU tool to identify delirium in the intensive care unit.

### Sample and Setting

The convenience sample came from a population of intensive care unit (ICU) registered nurses who work in a hospital in the Mid-Atlantic region of the United States The facility has 300 beds with 10 surgical ICU beds, 6 surgical ICU step-down beds, 12 medical ICU beds and 12 medical ICU progressive unit beds. The ICU has more than 50 registered nurses. All registered nurses who evaluated and documented ICU patient assessments were asked to participate. Attached to the pre-questionnaire were an informed consent and a Health Insurance Portability and Accountability Act (HIPAA) authorization forms which described the project. Nurses were required to complete and sign the consent forms for participation in the project. Project participation was strictly voluntary. No incentives were provided for participation.

#### **Procedures and Measures**

The project involved three phases: pre-test, educational training and tool use, and post-test. In the first phase, a pre-educational questionnaire on nurses' self-reported ratings of their perceived self-confidence and comfort levels with providing ICU delirium care was conducted (see Appendix E). Nurses were asked to rate their level of agreement with each statement on a 5-point Likert scale, with answers ranging from "strongly disagree" (1) to "strongly agree" (5) (Marino et al., 2015). A 15-item multiple choice knowledge test to determine nurses' delirium

knowledge before their training on ICU delirium care and using the CAM-ICU tool was also administered (Marino et al., 2015).

The second phase from January 15, 2017 to February 12, 2017 included educational training and use of the CAM-ICU. The educational training included an in-service on the importance of delirium assessment and case scenarios of ICU patients with and without delirium, as this allowed nurses the opportunity to collaborate and participate in the training. The training also included brief videos illustrating how to complete the CAM-ICU in clinical practice. The education package included laminated CAM-ICU worksheet and flowsheet placed at each bed space for reminders to provide cues to the nurses to complete their delirium assessment as this will refresh their knowledge and help sustain the completion of the CAM-ICU. The permission to use the CAM-ICU tool was received (Appendix F). The in-service training was conducted from 7 am to 9 am. Interested registered nurses from other shifts were asked to participate. Oneon-one training was provided to 10 nurses who missed the in-service training but were interested in learning to use the CAM-ICU. The educational training sought to enhance each nurse's knowledge of the importance of assessment and documentation of delirium in patient flowsheets. Demographic data of gender, the level of education, years of nursing experience was collected to understand the demographic characteristics of the ICU nurses population (Appendix G). Demographic information collected was stored in a locked location.

The second phase also included the implementation of the CAM-ICU tool in the ICU from January 19, 2017 to February 12, 2017. Paper based worksheets (see Appendix H) were placed in every patient chart. Data was de-identified by collaborating with a data statistician who used statistical methods to render the patients' and nurses' information not individually identifiable. The Richmond Agitation Sedation Scale (RASS) was already being used in this ICU

to assess for agitation and sedation and consists of the following rankings: +4 = combative; +3 = very agitated; +2 = agitated; +1 = restless; 0 = alert/calm;-1=drowsy; -2 = light sedation; -3 = moderate sedation -4 = deep sedation and -5 = unable to arouse (Appendix H). When a patient is assessed at a RASS of -4 or -5 the CAM-ICU tool is not used. RASS scores other than zero (alert/calm) trigger the use of CAM-ICU. The CAM-ICU was used once per 12-hour shift or every 4 hours if a patient was sedated or scored delirium positive. The CAM-ICU screening tool is not invasive and requires little of the patient or nurse's time to perform (Appendix H). The CAM-ICU evaluates the four "features" of delirium. Feature 1 is an acute change in mental status or fluctuation in the level of consciousness over the prior 24 hours; Feature 2 is inattention; Feature 3 is disorganized thinking, and Feature 4 is altered level of consciousness. Inattention and disorganized thinking are each assessed using brief, standardized testing specified by the CAM-ICU tool. The diagnosis of delirium requires a score of features 1 and 2 and either feature 3 or 4 to be present. Assessment results were recorded in the patient paper worksheets. ICU physicians were notified of patients scoring positive for delirium.

The third phase of the project was to evaluate the usefulness of education and implementation of the CAM-ICU tool through a repeat administration of the perception and knowledge surveys (post-test). The questionnaires were administered during the morning shift for a 2-week period from February 12, 2017, to February 24, 2017. The CAM-ICU worksheets were collected daily by the investigator during the 4 weeks of implementation and stored in a secure locked location. To protect participants' privacy, worksheet forms did not include any patient or nurse identifying information.

Permission to adapt the 15-item multiple choice knowledge test to determine nurses' delirium knowledge was sought from the author. Question 13 of the knowledge test was slightly

modified for RASS. The reason for the modification was because the Intensive Care Unit (ICU) at the project site does not use the RIKER Sedation-Agitation Scale for sedation measurement, which was in the original knowledge test. The modified knowledge test included replacement of the term "RIKER" with "RASS" (Appendix I).

#### **Data Collection and Analysis**

The sources of the data for analysis were the pre-test, and post-test responses to perception statements for nurse participants to self-report their perceived self-confidence and comfort levels with providing ICU delirium care. Also, used was data from the pre-test and posttest 15-item multiple choice knowledge test to determine nurses' delirium knowledge and CAM-ICU tool use. Intention was to audit the documentation of paper worksheets of all patients screened for delirium during the 4-week period of implementation, January 15, 2017, to February 12, 2017, to ascertain if participants were using the CAM-ICU by comparing the daily number of ICU beds occupied to the number of worksheets collected. However on January 19, 2017, five days into the implementation phase, the ICU electronic flowsheet was updated to include the CAM-ICU. Nurses were then documenting using the electronic flowsheet. Collection of paper worksheet was halted to avoid added documentation burden on nurses. Compliance in using the CAM-ICU tool was based on paper worksheets collected over a period of 5 days. Due to IRB restrictions, the newly added electronic flowsheet was not audited for this project. Secured data from CAM-ICU worksheet and the survey questionnaires were entered into a Microsoft Excel worksheet and transferred to the Statistical Package for Social Sciences (SPSS version 22.0, Inc., Chicago IL) for further analysis, with access limited to the project investigator only. Independent samples t tests were used to compare means for completed pre- and post-education surveys by age, ICU years of experience and education. Paired samples t tests were used to measure

differences in knowledge and confidence from pre to post educational training. For descriptive statistics, measures of central tendency were used for interval data and frequency distribution and percentages for nominal and ordinal data. Data were summarized and interpreted in a meaningful way to determine the effectiveness of a nursing education for CAM-ICU tool implementation in the ICU. All statistical tests were two-sided, and a p values of < .05 were considered statistically significant.

### **Human Subjects Protection and Approval Processes**

This project was submitted to the University of Maryland School of Nursing for approval and then to the Institutional Review Boards (IRB) of the University of Maryland and the institution where this project was conducted. The University of Maryland determined this project was not human subjects research. Not human research determination was granted. The project site determined this was an exempt from human research. An exemption was granted with requirement for informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from participating nurses (Appendix J). Data were de-identified as per HIPAA guidelines, thus protecting patients' and nurses' information. Data were stored securely in a password protected environment with restrictions. Access to information collected was limited to the project investigator, and the identity of participating nurses was kept confidential (Appendix J). The project was carried out and completed according to a set timeline (Appendix K).

#### **Results**

A total of 34 out of the 50 possible intensive care unit (ICU) nurses consented to the CAM-ICU educational training, thus representing 68% of the nurses. The pre- and post-test surveys were distributed to the consented nurses. Participants' age was retrieved from the

consent forms (Appendix J). Sixty-five percent of the participants who completed the pretest also completed the posttest.

### **Demographics**

Demographic data was analyzed using descriptive statistics (Table 1). The age of the participants ranged between 36 - 66 years, with an average age of 53 years (SD = 7.94). Thirty five percent of the participants were 56 years or older and 9% were 40 years or younger. More than half of the participants (56%) were between 41 and 55 years old. More females (82%) participated in the pretest than the males (18%). Participants' years of experience in the ICU ranged between 3 and 40 years, with 20 years average ICU experience (SD = 9.09). Eighteen percent had between 1 and 10 years of ICU experience, 24% between 11 and 15 years' experience, 35% between 16 and 25 years' experience, and 24% had more than 25 years' experience. Seventy-seven percent of the participants had a Bachelor's of Science degree as their highest level of education, 18% had a Master's of Science degree, and 6% an Associate degree.

### **Self Confidence and Comfort Levels in Using CAM-ICU**

Pre Training Questionnaire. Before the CAM-ICU training, a 5-item Likert scale of perception statements was distributed to the participants to self report their perceived self-confidence and comfort levels with providing ICU delirium care (Table 2). The first question asked if the participants were comfortable in assessing ICU patients for delirium. Twenty-seven percent strongly agreed, 32% agreed, 29% were neutral, 9% disagreed and 3% strongly disagreed. The second question asked how confident the participants felt in providing an accurate definition of delirium. Twenty-six percent strongly agreed, 38% agreed, 23% were neutral, 9% disagreed and 3% strongly disagreed. The third question asked how confident the participants were in communicating concerns about the presence of or risk for delirium to their patients'

critical providers care. Twenty-nine percent strongly agreed, 44% agreed, 18% were neutral, and 9% disagreed. The fourth question asked if the participants could identify at least two interventions that could be used to prevent or decrease the duration of delirium in ICU patients. Twenty-nine percent strongly agreed, 38% agreed, 21% were neutral, and 12% disagreed. The fifth question asked if the participants felt that assessing ICU patients for delirium daily is a worthwhile intervention. Forty-four percent strongly agreed, 38% agreed, 12% were neutral, 3% disagreed and 3% strongly disagreed.

Post Training Questionnaire. After CAM-ICU training and 4 weeks of use of CAM-ICU tool, the same 5-item Likert scale of perception statement questions was administered to each of the participants (Table 2). Twenty-two nurses (65%) participated in the post-educational training questionnaire and 12 nurses (35%) did not participate. The post-educational training questionnaire results were as follows: First question, 59% of participants strongly agreed, 36% agreed, 5% were neutral, and no participants either disagreed or strongly disagreed. The second question, 68% of participants strongly agreed, 32% agreed, no participants was neutral, or either disagreed or strongly disagreed. The third question, 59% of participants strongly agreed, 36% agreed, 5% were neutral, and no participants disagreed or strongly disagreed. The fourth question, 68% of participants strongly agreed, 32% agreed, and no participants were neutral, disagreed or strongly disagreed. The fifth question, 81% of participants strongly agreed, 14% agreed, 5% were neutral, and no participants disagreed or strongly disagreed.

To examine if the educational training made a difference in participants' perceived self-confidence and comfort levels with providing ICU delirium care, a paired sample *t* test was used to compare the means of the pre- and post-test responses for the 22 nurses with scores on both (Table 3). Nurses were significantly more comfortable in assessing ICU patients for delirium

(Q1) after the intervention than before, t(21) = -2.339, 95% CI [-0.86, -0.05], p = .029. Nurses were more confident in providing accurate definitions of delirium (Q2) on the post-test than the pre-test, t(21) = -3.052, 95% CI [-0.99, -1.88], p = .006. Nurses were more likely to be able to identify at least two interventions that could be used to prevent or decrease the duration of delirium in ICU patients (Q4) on the post-test than pre-test survey, t(21) = -2.731, 95% CI [-1.12, -0.15], p = .013. There were no significant differences in confidence in communicating concerns or risk for delirium to critical care providers (Q3), t(21) = -1.936, 95% CI [-0.94, -0.34], p = .066) or in feeling that assessing ICU patients for delirium daily is a worthwhile intervention (Q5), t(21) = -1.891, 95% CI [-0.76, -0.36], p = .073).

Pre and Post Knowledge Test. Thirty four nurses (n = 34) participated in the pre knowledge test, and 22 nurses (n=22) participated in the post knowledge test. Descriptive statistical analysis was used to examine the distribution of the scores (Table 4). The mean pre knowledge test score was 54% correct (SD = 15.74), ranging from 13% to 80%. Thirty eight percent of the participants scored between 1 and 49% correct, 47% scored between 50 and 69% correct, and 15% scored between 70 and 89% correct. No participants had 90% or more correct. Post-test knowledge score average was 91% correct (SD = 8.53), with 95% of the participants scoring between 80 and 100% correct and 5% of the participants scoring between 50 to 69%. The posttest knowledge score range was between 67 and 100%. A bar chart of the average performance of the participants on the pretest (54%) and posttest (91%) knowledge score is presented in Figure 1.

Paired samples *t* tests (Table 5) were used to examine if there were differences between the mean knowledge scores of the 22 participants who completed both tests; 12 nurses did not participate in the posttest so are not included in the comparison. There was a statistically

significant increase in the mean knowledge score from pre to posttest, t(21) = -10.784, 95% CI [-39.689, -26.856], p < .001.

To examine if participants' age had an effect on the exam scores (Table 6), an independent samples t test was used to compare the scores of those under 50 years of age to those over 50 years of age. On the pretest, there was no statistically significant difference in knowledge scores by age group; participants under 50 years old had a mean of 55.58% (SD = 12.75) and participants over 50 years old had a mean of 52.73%, (SD = 17.35), t(32) = 0.500, p = .620). There were no significant differences on the posttest knowledge score among participants under 50 years old (M = 94.00, SD = 7.00) and those over 50 years old (M = 88.23, SD = 8.95), t(20) = 1.618, p = .121.

To examine if ICU experience had an effect on the exam scores (Table 7), an independent samples t test was used to compare the scores of those with less than 20 years' ICU experience to those with more than 20 years' experience. There was no statistically significant difference on the pretest knowledge score among nurses with less than 20 years in ICU (M = 51.60, SD = 18.17) and nurses with more than 20 years in ICU (M = 56.79, SD = 11.35), t(32) = 0.094, p = 0.352). Years of experience did not affect posttest knowledge scores. There was no statistically significant difference among nurses with less than 20 years in the ICU (M = 92.23, SD = 7.06) and those with more than 20 years in the ICU (M = 88.22, SD = 10.28), t(20) = 1.088, t(20) = 1.088

To examine if level of education had an effect on knowledge scores (Table 8), independent samples *t* test was used to compare the scores of nureses with Bachelors degrees to those with Master's degrees (no participants with Associate degrees participated in the post knowledge test). There was no significant difference in pretest knowledge among nurses with a

Bachelor's Degree (M = 55.96, SD = 14.49) and those with a Master's Degree (M = 44.33, SD = 21.27), t(30) = 1.623, p = .115. There was no significant difference in the posttest knowledge score among nurses with a Bachelor's degree (M = 89.28, SD = 8.78) and those with a Master's degree (M = 96.5, SD = 4.04), t(20) = -1.585, p = .129.

CAM-ICU Paper Worksheet Compliance. The CAM-ICU paper worksheet explored the participants' compliance with the documentation of delirium assessment using the CAM-ICU (Table 9). One hundred and fifty paper worksheets were expected; only 32 worksheets were collected for a compliance rate of 21%. Nurses scored 28% of the ICU patients screened as delirious. The frequency of CAM-ICU features used for delirium assessment were Feature 1 (60%), Feature 2 (23%), Feature 3 (13%) and Feature 4 (4%). Compliance in using the electronic CAM-ICU Flowsheet was not accessed due to IRB restrictions.

#### **Discussion**

The importance of implementing a neurological screening tool such as the CAM-ICU to aid in the recognition of delirium as an organ dysfunction has been well documented (Adams et al., 2015; Andrews et al., 2015; Brummel et al., 2013; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011). Brummel et al. (2013) explained that the high occurrences of delirium in the ICU are often overlooked as healthcare providers are not using a well-organized approach for the routine monitoring of brain dysfunction.

Evidence-based gathering of information for an educational training began after an informal meeting with the intensive care unit nurses. Bedside nurses were lacking knowledge of delirium and confidence in using the CAM-ICU for delirium assessment. This led to the need for a practice change. Didactic-content, videos, and one-on-one sessions were used to teach bedside

nurses knowledge of delirium and increase confidence in using the CAM-ICU for delirium assessment.

The average age of the participants was 53 years; this was higher than ages reported in the literature, where ICU nurses were between 25 and 45 years old (Marino et al., 2015). The ICU nurse population was mostly female (82%), and the most had a Bachelor's degree (77%) as their highest degree. Gender and education distribution in this sample was in agreement with the literature (Marino et al., 2015). Data collected from the pre- and post-educational intervention questionnaires determined that the participants' demographic characteristics did not significantly influence the results of the knowledge scores. The result is in agreement with prior studies that showed no influence by demographics on education provided (Andrews et al., 2015; Brummel et al., 2013; Dilibero et al., 2016; Flagg et al., 2010; Marino et al., 2015).

In this quality improvement project, nurses were asked to self-report their perceived self-confidence and comfort levels with providing ICU delirium care. There was a statistically significant increase (p < .05) in comfort in assessing ICU patients for delirium, confidence in providing an accurate definition of delirium, and confidence in identifying at least two interventions that could be used to prevent or decrease the duration of delirium in ICU patients. The narrow 95% confidence intervals for all the confidence questions meant less margin of error in generalizing these project findings (Melnyk & Fineout-Overholt, 2011).

There was a statistically significant increase (p < .001) in delirium knowledge and CAM-ICU use after the educational training and implementation of the CAM-ICU tool. This knowledge increase could have occurred as a result of the one-on-one, video and didactic formal education regarding ICU delirium assessment and the CAM-ICU tool. The nurses' age (p = .620), years of ICU experience (p = .352), and level of education (p = .129) did not influence the

knowledge test. The result is in agreement with prior studies that showed no influence by demographics on education provided, but rather emphasized didactic, video and one-on-one education as an approach to implementing ICU delirium care (Andrews et al., 2015; Brummel et al., 2013; Dilibero et al., 2016; Flagg et al., 2010; Marino et al., 2015).

On January 19, 2017, five days into the education phase of this project, the ICU electronic flowsheet was updated with the CAM-ICU to include all four features of CAM-ICU application, including feature 1 through feature 4. Before adding the CAM-ICU into the electronic ICU flowsheet, 27 paper worksheets were collected to measure nurses compliance. An additional 5 paper worksheets were collected as nurse participants claimed to have their documentation in the new electronic CAM-ICU flowsheet. Worksheet documentation compliance was 21%; previous study mentioned CAM-ICU compliance increased to an average of 90% three years after implementation (Adams et al., 2015). Due to IRB and HIPPA restrictions, results of the electronic CAM-ICU compliance are not included in this project. Additional study will be needed to measure nurses compliance in using the electronic flowsheet.

The accomplishment and success of this implementation project are that confidence was increased as evidenced by increased utilization of the CAM-ICU on the unit at the project implementation site. This project demonstrated practice change at the unit level. Also, this project has allowed ICU nurses to increase their confidence level and gain knowledge in using a neurological assessment tool, the CAM-ICU for delirium assessment. In order to sustain this practice change, ongoing training and competency assessments will be provided to the ICU nurses. The ICU nurses now carry out delirium assessment once per 12-hour shift. Follow up study will be needed to establish the CAM-ICU tool usability in the electronic patient health

record system; previous studies stated that the CAM-ICU tool was selected by more bedside nurses for use due to its validity and reliability (Flagg et al., 2010; Soja et al., 2008).

To sustain this project, a multidisciplinary and a multifaceted approach to engaging and empowering bedside nurses through continuous training by using the hospitals intranet training site is recommended. The training will ensure new nurses are competent in using CAM-ICU. All ICU nurses will be instructed to complete annual online competency training on delirium knowledge, this will enhance each nurse's confidence on delirium and CAM-ICU use. (Adams et al., 2015; Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011). There are currently ongoing discussions with the MICU and SICU nurse managers and nurses on forming nurse champions to ensure the sustainability of this implementation.

This project had some limitations. The participants were from a single hospital, and there were no participants from other hospitals or settings. The project was conducted in both MICU and SICU and did not include other units or wards. Follow-up project with other units in the hospital would help in sustaining delirium knowledge and increase confidence in using a neurological assessment tool. Additional study will be needed to evaluate the economic and budget impact of this implementation and make sure that this hospital has the budget to support expenses, such as compensating nurses for their time to ensure participation in all segments of the implementation training (Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011).

An additional limitation was the use of paper-based CAM-ICU worksheet for the compliance audit, which was time-consuming. Paper CAM-ICU worksheets were expected to be collected for four weeks. Update of the electronic health record with the CAM-ICU tool might

have impacted compliance rate as nurses were documenting delirium assessment using the electronic CAM-ICU. Thirty-two worksheets were collected for five days as the paper collection was halted to reduce added work burden on the nurses. Without the addition of the electronic CAM-ICU Flowsheet, it is uncertain if more than 32 CAM-ICU delirium worksheets would have been collected.

Another limitation was the number of nurses who willingly consented and participated in the project represented about 68% (34/50) of the ICU nurse population. More nurses would have participated in the quality improvement project without having to complete the consent forms which were a requirement of the IRB at the project site. Practice change is to carry out additional projects, audit the electronic CAM-ICU Flowsheet, and evaluate ICU nurses education and training through knowledge and confidence assessments.

### **Translation Plan and Implication for Nursing Practice**

The Knowledge to Action Framework was used to implement this project. This process framework was selected because of its practicality in facilitating the use of evidence-based practice and research knowledge among the multidisciplinary team and key stakeholders (Straus et al., 2013). Applying the two components of the KTA process (knowledge creation and action cycle), research questions were tailored to address the problem of ICU delirium and educating bedside nurses to apply the CAM-ICU for delirium assessment accurately. The action cycle began during an informal meeting when it was learned that bedside nurses were not familiar with applying ICU delirium screening tools. The usefulness of this knowledge was appraised through literature review and then adapted to the local context. The project investigator assessed the barriers and facilitators related to the knowledge to be adopted (implementing the CAM-ICU), the potential adopters (ICU nurses), and the context and setting in which the knowledge would

be used (ICU patients delirium assessment). Knowledge was implemented. Knowledge was then monitored for changes in practice. This is necessary to determine the effectiveness of the implementation. All through the KTA process, it was necessary to evaluate the impact of using knowledge to effect change. Finally, a sustainability strategy will be needed to ensure the continuous use of the knowledge, developing nursing champions and creating protocols is required to sustain this knowledge (Straus et al., 2013).

The success of the implemented practice change was measured by significant increase and improvement in post-test scores of confidence level and knowledge. Evidence based practice (EBP) implementation can be challenging and often needs approaches that address the complexity of systems of care, providers, senior leadership, and changing health care cultures (Rycroft-Malone & Bucknall, 2010). At the project site, when nurses have knowledge and confidence to assess for delirium, they can alert their providers for prompt patient treatment and discuss the possible causes of delirium during their daily multidisciplinary rounds. Also, the continuous monitoring of nurses performance to include the delirium assessment is vital to the success of this implementation (Adams et al., 2015). In addition, to provide reinforcement and encouragement to nurses, monthly reports will be created to show improved performance in knowledge and confidence of CAM-ICU use. To increase the compliance of CAM-ICU use, reports will be created to show areas that may need improvement. Changing the culture in this ICU is challenging and requires multiple tests of change to reach sustainability. Additional study will be needed to evaluate ICU cultural influence on this implementation effort (Adams et al., 2015).

Collaborating with key stakeholders allowed this investigator to identify challenges and correct them by revising the project plan (Rycroft-Malone & Bucknall, 2010). By evaluating the

evidence when the first ICU nurse participants completed the training and education and using information gathered during the evaluation phase of the KTA, we are able to identify new questions for system change implementation.

A motivation theory such as the cognitive theory will be used to motivate healthcare providers toward this system implementation. According to Liviatan and John (2014) "social cognitive methods of motivation and goals are mental processes represented in memory that constitute a desired state of affairs that one is committed to attain" (p. 98). Change is necessary for growth and organization's success. To sustain this change all stakeholders, including leadership, medicine, nursing, pharmacy and other healthcare providers involved in patient care will be brought together and trained to improve their knowledge of delirium. Guidelines and policy for evidence-based recommendations for the management of delirium will be provided. Hospital staff will be educated on quick triage of patients in the Emergency Department (ED) with quick allocation of hospital beds for symptom management. Email reminders, continuing education and training, including clinical audit will be developed. All staff involved with patient care such as doctors and nurses must remain compliant with annual competencies. Quarterly quality and performance improvement assessment through meetings with all stakeholders by reviewing the current quarter's death rates following delirium will be discussed. Feedback process regarding outcomes such as reduced length of stay and suggestions for improvements will be initiated. Committee and governance will be established to make certain the success of this system change implementation (Andrews et al., 2015; Dilibero et al., 2016; Flagg et al., 2010; Soja et al., 2008; Vasilevskis et al., 2011).

This project showed an improvement in nurses' delirium knowledge and confidence in providing delirium assessment using the CAM-ICU. This project determined that the benefits of

using didactic, one-on-one sessions and videos for the implementation of the CAM-ICU tool can result in increased awareness and knowledge of ICU delirium. The positive results have the potential to prompt treatment and improve outcomes for ICU patients who experience delirium. Adoption of the CAM-ICU into patient electronic health record is recommended for sustainability.

#### Conclusion

The Doctor of Nurse Practice Essential II (Organizational and Systems Leadership for Quality Improvement and Systems Thinking) states that the DNP must ensure accountability for the quality of health care and patient safety for the populations with whom they work (Chism, 2013; Zaccagnini & Waud White, 2014). The DNP graduates must understand principles of practice management, including conceptual and practical strategies for balancing productivity with the quality of care (Chism, 2013; Zaccagnini & Waud White, 2014). To translate this knowledge into practice, this project evaluated current literature for best evidence that could be used in practice to identify best nursing education strategy for the CAM-ICU.

The dissemination of findings from this project includes a presentation in the ICU and Evidence Based Practice Committee at the project site, manuscript publication in a peer-reviewed journal such as the American Journal of Nursing, and poster or presentations at conferences. In conclusion, a valid and reliable neurological assessment tool, the CAM-ICU was implemented in MICU and SICU. Educating and training ICU nurses on how to apply the CAM-ICU for delirium assessment showed compliance in the use of the tool. Continuous training, development of nurse champions, audit plan, policies, and protocol will ensure the sustainability of the CAM-ICU.

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# **Tables and Figures**

**Table 1**Demographic Characteristics of Participants (n= 34)

			Total	D			
		Count (n)	Count (n)	Percent (%)	Range	Mean	SD
Age (years)		Count (II)	34	(70)	30	52.88	7.94
	< 40	3		8.8			
	41-50	9		26.5			
	51-55	10		29.4			
	> 56	12		35.3			
Gender	Male	6	34	17.65			
	Female	28		82.35			
Highest	Associate	2		5.88			
Degree Held	BSN	26		76.47			
C	Masters	6		17.65			
	Doctorate	0		0.00			
	Others	0	34	0.00			
ICU	1 - 5	3		8.82	37	19.74	9.09
Experience	6-10	3		8.82			
(years)	11-15	8		23.53			
	16-20	6		17.65			
	21-25	6		17.65			
	26-30	4		11.76			
	31-35	3		8.82			
	36-40	1	34	2.94			

Note: Abbreviation: SD, Standard Deviation SEM, Standard Error of the Mean

**Table 2**Pretest (n= 34) and Posttest (n=22) Percent (%) of Responses to Self-Report of Perceived Self-Confidence and Comfort Levels with Providing ICU Delirium Care and Using CAM-ICU

		Strongly				Strongly
		Disagree	Disagree	Neutral	Agree	Agree
		(%)	(%)	(%)	(%)	(%)
Pretest	I'm comfortable assessing my ICU	2.9	8.8	29.4	32.4	26.5
Posttest	patients for delirium	0	0	4.5	36.4	59.1
Pretest	If asked, I'm confident that I can provide an	2.9	8.9	23.5	38.2	26.5
Posttest	accurate definition of delirium	0	0	0	31.8	68.2
Pretest	I'm confident in communicating my concerns about presence of	0	8.9	17.6	44.1	29.4
Posttest	or risk for delirium to my patients' critical care providers	0	0	4.5	36.4	59.1
Pretest	I can identify at least two interventions that can be used to	0	11.8	20.6	38.2	29.4
Posttest	prevent or decrease the duration of delirium in ICU patients	0	0	0	31.8	68.2
Pretest	I feel that assessing ICU patients for	2.9	2.9	11.9	38.2	44.1
Posttest	delirium daily is a worthwhile intervention	0	0	4.5	13.6	81.8

Note: 12 nurses did not participate in the posttest questionnaire so are not included in the posttest results

**Table 3**Paired t-test Analysis Comparing Perceived Self-Confidence and Comfort Levels with Providing ICU Delirium Care and Using CAM-ICU Pretest to Posttest (n=22)

		Mean	Paired Differ	rences							
	95% Confidence Interval of the Difference										
	Mean	SD	SEM	Lower	Upper	t	df	p			
Pretest Question 1 -	-0.455	0.912	.19437	85876	05033	-2.339	21	.029			
Posttest Question 1											
Pretest Question 2 - Posttest	-0.591	0.908	.19361	99355	18827	-3.052	21	.006			
Question 2 Pretest	-0.455	1.101	.23473	94269	.03359	-1.936	21	.066			
Question 3 - Posttest Question 3		11101	120 170	.J <u>_</u> 0,5	10000	1,700					
Pretest Question 4 - Posttest Question 4	-0.636	1.093	.23304	-1.12100	15172	-2.731	21	.013			
Pretest Question 5 - Posttest Question 5	-0.364	0.902	.19234	76362	.03635	-1.891	21	.073			

Abbreviation: SD, Standard Deviation

SEM, Standard Error of the Mean

Question 1: "I'm comfortable assessing my ICU patients for delirium"

Question 2: "If asked, I'm confident that I can provide an accurate definition of delirium"

Question 3: "I'm confident in communicating my concerns about presence of or risk for delirium to my patients' critical care providers"

Question 4: "I can identify at least two interventions that can be used to prevent or decrease the duration of delirium in ICU patients"

Question 5: "I feel that assessing ICU patients for delirium daily is a worthwhile intervention"

**Table 4**Descriptive Statistics Showing Percentage Correct Responses on Pretest (n=34) and Posttest

(n=22) 15-item Knowledge Test to Determine Nurse Participants' Delirium Knowledge On ICU

Delirium Care and Using The CAM-ICU Tool

	Knowledge		Percent					
	Score	<b>Participants</b>	Correct					
	(%)	(n)	(%)	Mean	Median	Range	SD	SEM
Pretest	1-49	13	38.24	53.74	53	67	15.74	2.70
	50-69	16	47.06					
	70-79	4	11.76					
	80-89	1	2.94					
	90-100	0	0.00					
Posttest	1-49	0	0.00	90.60	93	33	8.54	1.82
	50-69	1	4.55					
	70-79	0	0.00					
	80-89	8	36.36					
	90-100	13	59.09					

Abbreviation: SD, Standard Deviation

SEM, Standard Error of the Mean

Note: 12 nurses did not participate in the posttest and were excluded from the scores

**Table 5**Paired t-test Comparing Pretest and Posttest Scores on the 15-item Knowledge Test (n=22)

Pretest	Posttest				95% Cor	nfidence				
Mean	Mean	Mean			Interval	of the				
Scores	Scores	Paired		Paired	Differ	rence				
(%)	(%)	Difference	Paired SD	SEM	Lower	Upper	t	df	p	

<sup>12</sup> nurses did not participate in the posttest knowledge survey, so were excluded from the paired t test.

 Table 6

 Independent Samples t-test Comparing Knowledge of Delirium Assessment by Age Group

		Count								
	Age	<b>(n)</b>	M	SD	SEM	Lower	Upper	t	df	p
Pretest (n=34)	< 50 years	12	55.58	12.75	3.68	-8.779	14.491	0.500	32	.620
	> 50 years	22	52.73	17.35	3.70					
Posttest (n=22)	< 50 years	9	94.00	7.00	2.33	-1.669	13.207	1.618	20	.121
	> 50 years	13	88.23	8.95	2.48					

Note: Levene's test for equality of variances: Pretest F = 0.242, p = .626; Posttest F = 0.296, p = 0.592, indicating equal variances for both pretest and posttest.

Table 7

Independent Samples t-test Comparing Knowledge of Delirium Scores by Years of Experience

(< 20 years and > 20 years)

	ICU Years of	Count				95% Con Interval Diffe	l of the			
	Experience	(n)	M	SD	SEM	Lower	Upper	t	df	p
Pretest (n=34)	< 20 years	20	51.60	18.17	4.06	-16.37	6.00	-0.944	32	0.352
	> 20 years	14	56.79	11.35	3.03					
Posttest (n=22)	< 20 years	13	92.23	7.06	1.96	-3.68	11.69	1.088	20	0.290
ζ/	> 20 years	9	88.22	10.28	3.43					

Note: Levene's test for equality of variances: Pretest F = 2.811, p = .103; Posttest F = .721, p = .406, indicating equal variances at both pretest and posttest.

 Table 8

 Independent Samples t test Comparing Knowledge of Delirium Scores by Education Level

						Interv	onfidence al of the erence			
		Count				Lower	Upper	-		
	Degree	(n)	Mean	SD	SEM			t	df	p
Pretest (n=34)	Bachelors	26	55.96	14.49	2.84	-3.01	26.26	1.623	30	0.115
	Masters	6	44.33	21.27	8.68					
Posttest (n=22)	Bachelors	18	89.28	8.78	2.07	-16.73	2.28	-1.585	20	0.129
. ,	Masters	4	96.50	4.04	2.02					

Note: No nurses with Associates degrees completed the posttest.

Levene's test for equality of variances: Pretest F = 1.166, p = .289; Posttest F = 1.550, p = .227, indicating equal variance at both pretest and posttest.

 Table 9

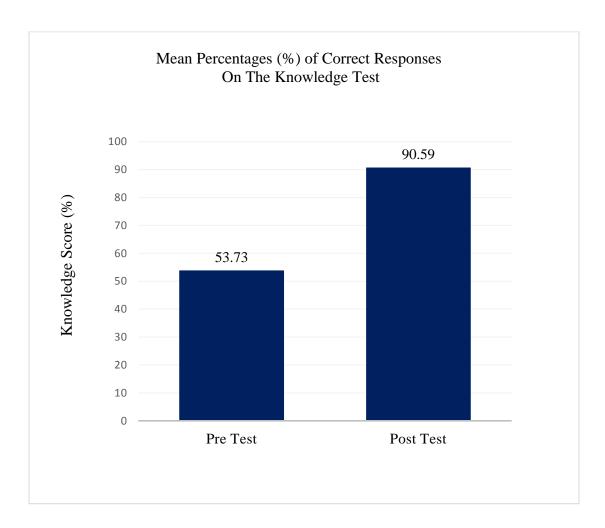
 Variables of the CAM-ICU Paper Worksheet Documentation Collected From Nurse Participants

CAM-ICU Worksheet Paper		
Documentation	n=32	%
Overall CAM-ICU Score		
CAM-ICU Posit	ive 9	28.13
CAM-ICU Negat	ive 23	71.88
CAM-ICU Feature Score		
Feature 1	32	60.38
Feature 2	12	22.64
Feature 3	7	13.21
Feature 4	2	3.77
*Paper Worksheet Compliance		Compliance (%)
Expected	150	
Collected	32	21.33

Note: The electronic CAM-ICU Flowsheet documentation was not audited due to the project site IRB/ HIPPA limitation.

<sup>\*150</sup> CAM-ICU worksheets were expected based on patient's daily assessment of once per 12-hour shift and admission to the ICU between January 15, 2017 and January 19, 2017.

**Figure 1**: Figure Showing Mean Percent Correct Pretest (n=34) and Posttest (n=22) on the Test to Determine Participants' Delirium Knowledge of ICU Delirium Care and Using The CAM-ICU Tool



Note: Nurse Scores Pretest (n=34); Posttest (n=22)

## Appendix A

Permission to Use the Knowledge to Action Framework (KTA)

## CIHR KT - L'AC aux IRSC (CIHR/IRSC) (CIHR/IRSC)

Irene,

Please consider this email permission to use the knowledge to action framework for your project. We just ask that you ensure that it is cited appropriately in your work.

Regards,

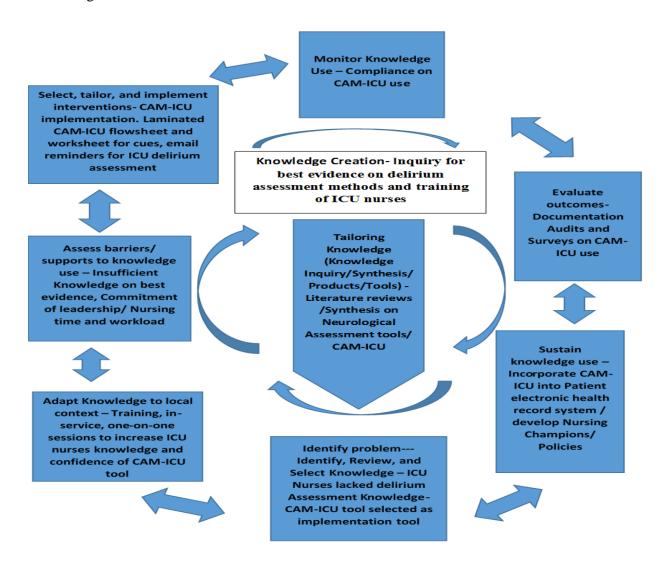
Liz Drake, MHA

Advisor, Knowledge Translation / Science, Knowledge Translation and Ethics Canadian Institutes of Health Research / Government of Canada <a href="mailto:elizabeth.drake@cihr-irsc.gc.ca">elizabeth.drake@cihr-irsc.gc.ca</a> / Tel : 613-948-5793

#### APPENDIX B

Figure A1.

Knowledge to Action Process



*Note.* Adapted from "The Knowledge to Action Framework" by Graham et al., 2006. *The Journal of Continuing Education in the Health Professions* p. 19.

Figure A2.

Applying The Knowledge to Action (KTA) Framework to Practice: Each component of the KTA contains different phases which overlap and can repeat (Straus et al., 2013).

Knowledge Creation (knowledge inquiry, knowledge synthesis, and knowledge tools and products)	Identifying the Knowledge -To-Action Gaps	Adapting Knowledge to Local Context	Assessing Barriers/Facilitat ors to Knowledge Use	Selecting, Tailoring, Implementing Interventions	Monitoring Knowledge Use	Evaluating Outcomes	Sustaining Knowledge Use
Began as knowledge	Bedside	Evidence	Barriers to	Lack of	Knowledge	The	Ongoing
inquiry of health research literature for best evidence on delirium assessment methods used in the ICU. PICOT question- P: Adult patients aged 65 years or older I: Training bedside nurses to improve knowledge and confidence in ICU	not routinely documentin g ICU delirium care. A formal training on using the CAM-ICU was	appraised and summarize d for best evidence on training nurses on knowledge and confidence in CAM-	implementation were identified through ongoing stakeholders' meetings. Insufficient knowledge and lack of awareness on delirium care was a primary barrier to CAM-	knowledge of CAM-ICU use was identified Theory: Cognitive theory on learning was used for training  Evidence-	monitored using documentat ion audit to observe the frequency of CAM-ICU use after multifacete d training	of outcome is an ongoing process that will include staff interviews and focus group on knowledge and	developme nt of a sustainabili ty action plan for developing nurse champions, attitudes of physicians, and other stakeholder
delirium tool use: Lack of awareness of delirium tool O: Improvement in self-confidence and knowledge of ICU delirium tool use T: Over a period of 12 months Products/tools stage: based on current evidence, determination was made to use multi modes of training to implement the CAM-ICU into practice.	lacking; Our understandi ng on how best to achieve this multi modes of training was limited.	ICU tool use for implementa tion.	ICU tool use. Other barriers included time allocation for implementing this process, the commitment of staff, leadership, economic cost, and training those involved in the implementation process. Facilitators was managerial and leadership support.	based intervention: make small changes to the implementatio n and training to improve knowledge and confidence on CAM-ICU tool use.	was provided.	confidence in using the CAM-ICU to assess ICU patients for delirium.	s toward the issue of nurses lack of knowledge on delirium and CAM- ICU use; Adoption of electronic CAM-ICU into patient electronic health record.

Note: This table was created by this investigator in an attempt to translate knowledge to practice using the KTA framework

## **APPENDIX C**

*Table A1*. Johns Hopkins Nursing Evidence-Based Practice Appraisal for Appraising the Delirium Confusion Assessment Method for the Intensive Care Unit (ICU) and Educating Nurses.

#	Author	Date	Evidence Type	Sample &	Results/ Recommendations	Limitations	RATING
				Sample Size			Strength
				Size			Quality
1	Flagg et al.	2010	Descriptive cross-sectional study using a convenienc e sample	N= 61	Nurse participants were asked to rate their level of confidence in identification of delirium, management of delirium, and the ability to explain delirium to a family. The mean scores for confidence were as follows: identifying delirium overall was 3.32 (SD, 0.76), management of delirium was 3.42 (SD, 0.80), and the ability to explain delirium to a patient's family was 3.25 (SD, 0.87). These scores suggest only a modest confidence in their ability to identify, manage, and explain delirium, because on the scale 1 = not at all confident and 5 = extremely confident	Identification and treatment of delirium require not only nursing perception change but also system change. The study looked at nursing behavior only.	
2	Marino et al.	2015	Quality improveme nt project	N = 49	Five nursing attitude and perceived confidence statements measured before and after the educational sessions showed a significant increase in positive perceptions overall (P <	Single hospital and study only looked at ICU nurses therefore might not be	VA

3	Adams et al.	2015	Quality Improveme nt Project	N=21 hospitals	.0001). Overall mean post education knowledge test raw scores showed a significant improvement from preeducational scores (70% ± 12.8% vs. 95% ± 6.9%; P < .0001).  ICU nurses were educated using PowerPoint presentations. The ICU nursing management including the Clinical Nurse Specialist and Nurse educators were educated on how to use the CAM-ICU screening tool. Classes included comprehensive education on the use of the CAM-ICU and discussion of causative agents of delirium. Clinical nurse specialists taught delirium and CAM-ICU classes. Findings were Benzodiazepine usage for the 21 hospitals in the quality improvement project saw a decrease in use from 22% to 16%. For the 21 hospitals involved in this study and based on positive CAM-ICU scores, delirium detection rate increased from 5% in 2011 to 20% in 2014. CAM-ICU	The study was conducted in 21 hospitals under Kaiser Permanente in Northern California. The result may not be generalizable to other healthcare organizations. Strength was the numbers of hospitals involved in this study	VA
	Dilibero et	2016	Quality	N = 8		Findings were not	VA
4	al.		Improveme	nurse	in the accuracy of delirium	generalizable to	

	1	1	T	T	TOTT 1		1
			nt Project	leaders	assessments in ICU patients by	other institutions	/
					providing a CAM-ICU educational	as it was a single	/
					program for its staff nurses.	center project.	/
					Compliance in performing one		/
					delirium assessment per shift was 85%		/
					at baseline and improved to 99%		
					during the post intervention period.		
					Baseline assessment accuracy was		/
					70.31% among all patients and		
					53.49% among sedated and agitated		
					patients. Post intervention assessment		
					accuracy improved to 95.51% for all		/
					patients and 89.23% among sedated		/
					and agitated patients		/
	Vasilevskis	2011	Prospective	N = 627	Six thousand one hundred ninety-eight	The limitation was	III A
5	et al.		cohort	nurses	CAM-ICU and 6,880 RASS	that study	/
			study		measurement pairs obtained on 3,846	performed at an	/
					patient-days. For CAM-ICU	academic teaching	/
					measurements, the agreement between	hospital, so	/ /
					bedside and research nurses was	findings may not	
					substantial (weighted kappa = $0.67$ ,	be generalizable to	/ /
					95% confidence interval (CI) = 0.66–	all settings,	
					0.70) and stable over three years of	although this	
					data collection. RASS measures also	single institution	
					demonstrated substantial agreement	represents a broad	
					(weighted kappa = 0.66, 95% CI =	population of	
					0.64–0.68), which was stable across	patients, across	
					all years of data collection. The	hundreds of	
					sensitivity of delirium nurse	individual nursing	/
					assessments was 0.81 (95% CI =	observation, and	/
					0.78-0.83), and the specificity was	includes MICUs	/
					0.81 (95%  CI = 0.78 - 0.85). The	and SICUs.	/
					conclusion was that Bedside nurse	Measures were	V

					measurements of delirium and sedation are sustainable and reliable	performed in the ICU and may not	
					sources of information.	generalize to a ward setting,	
6	Andrews et al.	2015	Retrospecti ve study	N= 42 nurses	Nurses used the CAM-ICU to screen for delirium 76.1% of the time expected (at least once per shift) during the 3-month period. RASS scores were recorded 83% of the time. Of the total RASS scores recorded, 85.3% were -1 to +1, and 5.4% were less than -3 (comatose). Paired observations were performed on 4 randomly chosen patients by the clinical nurse specialist and the pharmacist every other week during the 3-month period, yielding a sample of 21 (3 patients chosen were out of the unit during one of the observations). The precision of inter observer agreement was measured by calculating the kappa statistic. The results indicated substantial agreement between the ICU nurses and the clinical nurse specialist (K = 0.86), the ICU nurses and the pharmacist (K = 0.71), and clinical nurse specialist and the pharmacist (K = 0.78). Compared with patients who did not have delirium, patients who did had a longer mean length of stay in the ICU (137.3 hours vs 80.8 hours), longer	Not incorporating CAM-ICU results in a patient's treatment plan was a barrier and not using a multidisciplinary approach in initial study was also a limitation	

duration of mechanical ventilation (159.6 hours vs 46.9 hours), greater usage of restraints (80% vs 24.8%), and longer duration of restraint (150.8 hours vs 37.9 hours).  7 Soja et al. 2008 Prospective n=347 Observation all study  Nurses n=96  Nurses n								
Soja et al.   2008   Prospective   Patient n= 347   Observatio nal study   Nurses n=96   Nurses n=96   Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721−0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients κ = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704, p < 0.0001), and in TBI patients k = 0.62 (0.534−0.704								
and longer duration of restraint (150.8 hours vs 37.9 hours).    The expert   Patient n= 347   Observatio nal study   Nurses n=96   Nurses n=96   Soja et al.   2008   Prospective   Patient n= 347   Observatio nal study   Nurses n=96   Nurses n=96   Soja et al.   2012   Meta-analysis of Flores et al.   Post manufacture of the forest expert evaluation of the final analysis of Systematic Reviews   Post manufacture of the four features of the four features of the four features of the four features of delirium screen in the study.   111 A evaluator was a single expert and a licensed single expert and a licensed pharmacist. The authors did not include the use of the four features of delirium screen in the study.   111 A evaluator was a single expert and a licensed pharmacist. The authors did not include the use of the four features of delirium screen in the study.   111 A evaluator was a single expert and a licensed the four features of delirium screen in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%) Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721−0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534−0.704, p < 0.0001).   101 A point of the study.   102 A point of the study.   103 A po						(159.6 hours vs 46.9 hours), greater		
Soja et al.   2008   Prospective   Patient   n = 347   Compliance in completing the CAM-   Compliance was 84%   (849/1,011 observations). Compliance was 84%   (849/1,011 observations). Compliance was 83% (485/585) during the day shift, 86% (235/274) during the night shift, and 85% (129/152) during the weekend shift.   Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was \( \tilde{\text{e}} = 0.77 \) (95% confidence interval 0.721-0.822, \( p < 0.0001 \)). In mechanically ventilated patients \( \tilde{\text{e}} = 0.62 \) (0.534-0.704, \( p < 0.0001 \)), and in TBI patients \( \tilde{\text{e}} = 0.75 \) (0.667-0.829, \( p < 0.0001 \)). Studies published in non-English languages were evaluating the ICDSC (n = 361 analysis. The pooled sensitivity of the led to their non-						usage of restraints (80% vs 24.8%),		
Soja et al.   2008   Prospective   n = 347   Observation   nal study   Nurses n = 96   Nurses n = 96   Nurses n = 96   Suja et al.   Compliance in completing the CAM-ICU: Overall compliance was 84% (849/1,011 observations). Compliance was 83% (485/85) during the day shift, 86% (235/274) during the night shift, and 85% (129/152) during the weekend shift.   Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was \( \tilde{\text{P}} = 0.0001 \). In mechanically ventilated patients \( \tilde{\text{R}} = 0.62 \) (0.534-0.704, \( \tilde{\text{P}} = 0.0001 \)), and in TBl patients \( \tilde{\text{R}} = 0.62 \) (0.534-0.704, \( \tilde{\text{P}} = 0.0001 \)). Nine studies evaluated the CAM-ICU (including 969 patients) and four evaluating the ICDSC (n = 361 analysis. The pooled sensitivity of the led to their non-limitation analysis. The pooled sensitivity of the led to their non-limitation analysis. The pooled sensitivity of the led to their non-limitation compliance was 84% (849/1,011 observations). Compliance was 84% (849/1,010 today ob						and longer duration of restraint (150.8		
Nurses n=96						,		
Observatio nal study  Nurses n=96  Nurses n=16  Nurses n=	7	Soja et al.	2008	Prospective		1 0	<u> </u>	I11 A
nal study  nal stady				/	n= 347	ICU: Overall compliance was 84%	evaluator was a	/
National Study   n=96   Shift, 86% (235/274) during the day shift, and 85% (129/152) during the weekend shift.   Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was \kappa = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001). In mechanically ventilated patients \kappa = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients \kappa = 0.75 (0.667–0.829, p < 0.0001).				Observatio	Numana	(849/1,011 observations). Compliance	single expert and a	/
shift, and 85% (129/10tring the night shift. Host Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%) Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients κ = 0.75 (0.667–0.829, p < 0.0001).  8 Gusmao-Flores et al.  Gusmao-Flores et al.  Gusmao-Flores et al.  CAM-ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001), and in TBI patients κ = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients κ = 0.75 (0.667–0.829, p < 0.0001).  Nine studies evaluated the CAM-ICU (including 969 patients) and four evaluating the ICDSC (n = 361 languages were evaluation) led to their non-ICDSC (n = 361 languages were evaluation) led to their non-ICDSC (n = 361 languages were evaluation) led to their non-ICDSC (n = 361 languages were evaluation) led to their non-ICDSC (n = 361 languages were evaluation) led to their non-ICDSC (n = 361 languages				nal study		was 83% (485/585) during the day	licensed	/
weekend shift.   Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients κ = 0.75 (0.667–0.829, p < 0.0001).   Nine studies evaluated the CAM-ICU fincluding 969 patients) and four evaluating the ICDSC (n = 361 languages were excluded which led to their non-like the use of the four features of delirium screen in the study.					11=90	shift, 86% (235/274) during the night	pharmacist. The	/
Post Implementation Survey: The most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%)   Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients κ = 0.75 (0.667–0.829, p < 0.0001).   Sumao-Flores et al.   CAM-ICU analysis of Systematic Reviews   CDSC   Systematic Reviews   CDSC						shift, and 85% (129/152) during the	authors did not	/ /
most commonly identified barriers, in order of frequency, were: time (15/72, 21%), lack of feedback on performance (14/72, 19%), and knowledge (11/72; 15%) Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was κ = 0.77 (95% confidence interval 0.721–0.822, p < 0.0001). In mechanically ventilated patients κ = 0.62 (0.534–0.704, p < 0.0001), and in TBI patients κ = 0.75 (0.667–0.829, p < 0.0001).  8 Gusmao-Flores et al.  CAM-ICU studies published in non-English languages were evaluating the ICDSC (n = 361 patients) were included in the final analysis. The pooled sensitivity of the led to their non-						weekend shift.	include the use of	
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Systematic Reviews   CAM- ICU Sys						most commonly identified barriers, in	delirium screen in	
Systematic Reviews   CAM- ICU Sys						order of frequency, were: time (15/72,	the study.	/ /
knowledge (11/72; 15%) Reliability of agreement of CAM ICU scores between bedside nurses and expert evaluator: Overall interrater agreement was $\kappa = 0.77$ (95% confidence interval 0.721–0.822, $p < 0.0001$ ). In mechanically ventilated patients $\kappa = 0.62$ (0.534–0.704, $p < 0.0001$ ), and in TBI patients $\kappa = 0.75$ (0.667–0.829, $p < 0.0001$ ).  8 Gusmao-Flores et al.  CAM-ICU Ne (including 969 patients) and four evaluating the ICDSC (n = 361 patients) were included in the final analysis. The pooled sensitivity of the led to their non-							-	
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$\begin{array}{c ccccccccccccccccccccccccccccccccccc$						knowledge (11/72; 15%)		
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$\begin{array}{c ccccccccccccccccccccccccccccccccccc$						agreement was $\kappa = 0.77$ (95%		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$						confidence interval 0.721–0.822,		
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8 Gusmao- Flores et al.  Output  Output  Flores et al.  Output  Output						0.704, p < 0.0001), and in TBI patients		/
8 Gusmao- Flores et al.  Output  Output  Flores et al.  Output  Output						$\kappa = 0.75 \ (0.667 - 0.829, p < 0.0001).$		/
Systematic Reviews    Systematic Reviews   969   evaluating the ICDSC (n = 361   languages were patients) were included in the final analysis. The pooled sensitivity of the led to their non-	8	Gusmao-	2012	Meta-	CAM-		Studies published	1B /
Reviews ICDSC patients) were included in the final excluded which analysis. The pooled sensitivity of the led to their non-		Flores et al.		analysis of	ICU N=	(including 969 patients) and four	in non-English	/
ICDSC analysis. The pooled sensitivity of the led to their non-				Systematic	969	evaluating the ICDSC ( $n = 361$	languages were	/
analysis. The pooled sensitivity of the led to their non-				Reviews	ICDCC	patients) were included in the final	excluded which	/
N=361 CAM-ICU was 80.0% (95% inclusion in the						analysis. The pooled sensitivity of the	led to their non-	/
					N = 301	CAM-ICU was 80.0% (95%	inclusion in the	/

0	Ely et al	2001	Drognostive	N-06	confidence interval (CI): 77.1 to 82.6%), and the pooled specificity was 95.9% (95% CI: 94.8 to 96.8%). The diagnostic odds ratio was 103.2 (95% CI: 39.6 to 268.8). The pooled area under the summary receiver operating characteristic curve (AUC) was 0.97. The pooled sensitivity of the ICDSC was 74% (95% CI: 65.3 to 81.5%), and the pooled specificity was 81.9% (95% CI: 76.7 to 86.4%). The diagnostic odds ratio was 21.5 (95% CI: 8.51 to 54.4). The AUC was 0.89.	meta-analysis.	
9	Ely et al.	2001	Prospective cohort study	N=96	this study confirmed the CAM-ICU, a 2-minute assessment instrument to have great accuracy, the study demonstrated a sensitivity of 93% to 100%, a specificity of 98% to 100%, and high interrater reliability ( $\kappa$ = 0.96) in the detection of delirium	Strength include the large number of patient evaluations, and use of delirium experts for reference standard ratings, use of a standardized, easily performed nursing assessment, Limitations was a selected population at a single site, need to evaluate the generalizability of performance across other	

		F	patient populations	
		i	including those	
		V	with a lower	
		l p	prevalence of	
		C	delirium	

Note: Dearholt, S.L., & Dang, D. (2012). *Johns Hopkins Nursing Evidence-Based Practice Model and Guidelines* (2nd Ed.). Sigma Theta Tau International, Indianapolis, Indiana

Table A2. Evidence Review Appraisal for Quality of Research Studies-Strengths/Weaknesses

Author	Study	Strengths	Weaknesses	Quality
and Date	objective/interventio	_		
	n or exposures			
	compared			
Flagg,	A descriptive cross-	Most participants (up to 90%) identified the hyperactive	The study was limited by	В
Cox,	sectional study using	symptoms of delirium (i.e., confusion, wandering,	both sample size and	
McDowell,	a convenience sample	verbal or physical aggression, etc.), 77% of the	sample location; findings	
Mwose,	to describe nurses'	participants were able to identify the hypoactive	are not generalizable.	
Buelow,	ability to recognize	symptoms of delirium. An exception was that of	Moreover, identification	
2010	delirium on both	inattention, which was identified by 83% and 90% of	and treatment of delirium	
	intensive care unit	the ICU and medical-surgical nurses, respectively.	require not only nursing	
	and medical-surgical		perception change but	
	units		also system change. The	
			study looked only at	
			nursing behavior.	
Marino,	Pre and post-	A sample of 49 nurses participated in the formal	The number of nurses	В
Bucher,	educational study. A	educational teaching sessions. All 5 nursing attitude	who voluntarily	
Beach,	didactic training	and perceived confidence statements measured before	participated in the formal	
Yegneswa	program for bedside	and after the educational sessions showed a significant	educational phase	
ran,	critical-care nurses	increase in positive perceptions overall (P < .0001).	represented	
Cooper,	was developed and	Overall mean post education knowledge test raw scores	approximately only one-	
2015	implemented. Upon	showed a significant improvement from pre-educational	third of the total critical-	
	completion of the	scores (70% $\pm$ 12.8% vs. 95% $\pm$ 6.9%; P < .0001).	care nursing staff of the	
	educational sessions,	Once-daily ICU delirium screenings and care bundle	facility. This may have	
	a daily bedside	interventions were initiated for all ICU patients; overall	ultimately contributed to	
	delirium screening	compliance during the measurement period was 56.3%	both poor staff	
	and care bundle	(598 of 1061 possible delirium screenings and protocols	compliance with delirium	
	protocol were	completed). Of all daily patient screenings performed,	screening and protocol	
	implemented for all	20.4% resulted positive for ICU delirium. All patients	implementation.	
	patients in ICUs	who received the care bundle interventions received the		
	throughout the	interventions uniformly, regardless of clinical delirium		

	facility.	status		
Adams, C. L., Scruth, E. A., Andrade, C., Maynard, S., Snow, K., Olson, T. L., et al., 2015	Implementing Clinical Practice Guidelines for Screening and Detection of Delirium in a 21-Hospital System in Northern California	ICU nurses were educated using PowerPoint presentations. The ICU nursing management including the Clinical Nurse Specialist and Nurse educators were educated on how to use the CAM-ICU screening tool. Classes included comprehensive education on the use of the CAM-ICU and discussion of causative agents of delirium. Delirium and CAM-ICU classes were taught by Clinical nurse specialists. Findings were that Benzodiazepine usage for the 21 hospitals in the quality improvement project saw a decrease in use from 22% to 16%. For the 21 hospitals involved in this study and based on positive CAM-ICU scores, delirium detection rate increased from 5% in 2011 to 20% in 2014. CAM-ICU compliance increased to an average of 90% from 2011 to 2014 for the 21 hospitals	The study was conducted in 21 hospitals under Kaiser Permanente in Northern California. The result may not be generalizable to other healthcare organizations. Strength was the numbers of hospitals involved in this study.	A
DiLibero, O'Donogh ue, DeSanto- Madeya, Felix, Ninobla, Woods, 2016	An Innovative Approach to Improving the Accuracy of Delirium Assessments Using the Confusion Assessment Method for the Intensive Care Unit. A quality improvement project	The study looked at the improvement in the accuracy of delirium assessments in ICU patients by providing a CAM-ICU educational program for its staff nurses. Compliance in performing one delirium assessment per shift was 85% at baseline and improved to 99% during the post intervention period. Baseline assessment accuracy was 70.31% among all patients and 53.49% among sedated and agitated patients. Post intervention assessment accuracy improved to 95.51% for all patients and 89.23% among sedated and agitated patients	Findings were not generalizable to other institutions as it was a single center project. Data collection was not systematically randomized; however, the collection of data as a convenience sample of the participants resulted in a semi-random nature to data collection, thereby minimizing this limitation.	A
Vasilevski s,	Delirium and Sedation Recognition	The sensitivity of delirium nurse assessments was $0.81$ (95% CI = $0.78$ – $0.83$ ), and the specificity was $0.81$	The study was performed at a large academic	A

Morandi, Boehm, Pandharip ande, Girard, Jackson, et al., 2011.	Using Validated Instruments: Reliability of Bedside Intensive Care Unit Nursing Assessments from 2007 to 2010: Prospective cohort study.	(95% CI = 0.78–0.85). The conclusion was that Bedside nurse measurements of delirium and sedation are sustainable and reliable sources of information.	teaching hospital, so findings may not generalize to all settings, although this single institution represents a broad population of patients, across hundreds of individual nursing observation, and includes MICUs and SICUs. Measures were performed in the ICU and may not generalize to a ward setting	
Andrews, Silva, Kaplan, Zimbro, 2015	To evaluate the implementation and effects of the Confusion Assessment Method for the Intensive Care Unit as a bedside assessment for delirium in a general intensive care unit in a tertiary care hospital- A retrospective Study	Nurses used the CAM-ICU to screen for delirium 76.1% of the time expected (at least once per shift) during the 3-month period. Paired observations were performed on 4 randomly chosen patients by the clinical nurse specialist and the pharmacist every other week during the 3-month period, yielding a sample of 21 (3 patients chosen were out of the unit during one of the observations). The precision of inter observer agreement was measured by calculating the kappa statistic. The results indicated substantial agreement between the ICU nurses and the clinical nurse specialist (K =0.86).	Not incorporating CAM-ICU results in a patient's treatment plan was a barrier and not using a multidisciplinary approach in initial study was also a limitation	В
Soja SL; Pandharip ande PP; Fleming SB; Cotton	Implementation, reliability testing, and compliance monitoring of the Confusion Assessment Method	The education phase for the bedside nurses was performed by expert evaluators. This study showed that having a well organized plan and continuing nursing education and support, delirium monitoring using the CAM-ICU is feasible and reliable in the trauma population. Nursing compliance rate with using the	The expert evaluator was a single expert and a licensed pharmacist. The authors did not include the use of the four features of delirium	A

BA; Miller LR; Weaver SG; Lee BT; Ely EW, 2008  Gusmao-Flores, D., Figueira Salluh, J. I., Chalhub, R. Á., & Quarantin i, L. C. 2012.	for the Intensive Care Unit in trauma patients  The confusion assessment method for the intensive care unit (CAM-ICU) and intensive care delirium screening checklist (ICDSC) for the diagnosis of delirium: A systematic review and meta-analysis of clinical studies	CAM-ICU was high, improvement in using the CAM-ICU was seen and sustained over time even with nurses' frustration at physician buy in. There was a compliance increase from about 85% during the data collection period to more than 90% during the post implementation phase despite the fact that there was no active monitoring by study staff during this phase.  Nine studies evaluating the CAM-ICU (including 969 patients) and four evaluating the ICDSC (n = 361 patients) were included in the final analysis. The pooled sensitivity of the CAM-ICU was 80.0% (95% confidence interval (CI): 77.1 to 82.6%), and the pooled specificity was 95.9% (95% CI: 94.8 to 96.8%). The diagnostic odds ratio was 103.2 (95% CI: 39.6 to 268.8). The pooled area under the summary receiver operating characteristic curve (AUC) was 0.97. The pooled sensitivity of the ICDSC was 74% (95% CI: 65.3 to 81.5%), and the pooled specificity was 81.9% (95% CI: 76.7 to 86.4%). The diagnostic odds ratio was 21.5 (95% CI: 8.51 to 54.4). The AUC was 0.89	Meta-analysis showed the CAM-ICU as an excellent tool for the evaluation of delirium in critically ill ICU patients regardless of the subgroup of patients evaluated. Regardless of having a good performance, the ICDSC presents lower sensitivity and specificity as compared to CAM-ICU. The study suggest that both CAM-ICU and the ICDSC can be used as a screening tool for the	В
			diagnosis of delirium in critically ill patients.	
Ely, E. W., Inouye, S. K., Bernard, G. R., Gordon, S.,	Delirium in mechanically ventilated patients: Validity and reliability of the confusion assessment method for the	Study confirmed the CAM-ICU, a two minute assessment tool to have great accuracy, the study demonstrated a sensitivity of 93% to 100%, a specificity of 98% to 100%, and high interrater reliability ( $\kappa$ = 0.96) in the detection of delirium	Strength include the large number of patient evaluations, and use of delirium experts for reference standard ratings, use of a standardized, easily	A

Francis,	intensive care unit	performed nursing
J., May,	(CAM-ICU).	assessment, Limitations
L., et al.		was a selected
(2001)		population at a single
		site, need to evaluate the
		generalizability of
		performance across other
		patient populations
		including those with a
		lower prevalence of
		delirium

Note. The rating quality of research studies is from Newhouse et al. (2005) quality rating scheme.

*Table A3.* Summary of Evidence rating

Level	#	Summary of Findings	Overall Quality
of	of		
Eviden	Studi		
ce	es		
1	1	Gusmao-Flores et al. (2015) meta-analysis of systematic reviews	B. CAM-ICU was described as a valid
		showed that the pooled sensitivity of the CAM-ICU was 80%, which	and reliable tool with high specificity
		proved that CAM-ICU had good performance for screening ICU	and a reliability.
		patients with delirium. After the first validation study, the CAM-	
		ICU was translated into and validated in many languages.	
III	5	Descriptive cross-sectional study using a convenience sample	A/B. There was improvement in the
		including observational study and a prospective cohort study with	accuracy of delirium assessments for
		retrospective study (Flagg, et al, 2010; Soja et al., 2008; Vasilevskis	ICU patients by ICU nurses when a
		et al., 2011,) concluded that bedside nurse's measurements of	CAM-ICU educational program for
		delirium using the CAM-ICU tool was sustainable and reliable for	staff nurses was used by the various
		patient care and for use in improving patient's stay in the hospital.	healthcare institutions in the study.
		Ely et al., (2001) cohort study confirmed the CAM-ICU, to have a	
		sensitivity of 93% to 100%, a specificity of 98% to 100%, and high	
X 7	2	interrater reliability ( $\kappa = 0.96$ ) in the detection of delirium.	A. D. ' I I.I CAM ICILI. I
V	3	Quality improvement project for the implementation of CAM-ICU	A. Project showed that CAM-ICU had
		in healthcare organization (Adams et al., 2015; Dilibero et al., 2016;	good performance for screening
		Marino et al., 2015) found that not including CAM-ICU assessment	patients with delirium in the ICU.
		tool in an ICU patient's treatment plan was a barrier and not using a multidisciplinary approach was also a limitation. By not using a	Hospital clinicians such as nurses need to become familiar with tools to
		delirium screening tool such as the CAM-ICU patients had a longer	identify delirium in order to initiate
		length of stay in the ICU. Bedside teaching was the most relevant	treatment and remove mitigating
		method for teaching delirium screening using the CAM-ICU tool as	factors early in patient hospitalization
		it combines both theory and practical application (Andrews et al.,	and prevent delirium. Nursing
		2015; Dilibero et al., 2016; Marino et al., 2015).	education was important in CAM-ICU
		2010, 2 mooto et an, 2010, maino et an, 2010).	delirium tool implementation.
			r · · · · · · · · · · · · · · · · · · ·

Note. The rating quality of research studies is from Newhouse et al. (2005) quality rating scheme.

## APPENDIX D

## JOHNS HOPKINS NURSING EVIDENCE-BASED PRACTICE RATING SCALE

	STRENGTH of the Evidence
Level I	Experimental study/randomized controlled trial (RCT) or meta analysis of RCT
Level II	Quasi-experimental study
Level III	Non-experimental study, qualitative study, or meta-synthesis.
Level IV	Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
Level V	Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

QUALITY of the Evidence									
A	High	Research	consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence.  well-defined, reproducible search strategies; consistent results with sufficient numbers of well defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions.						
		Summative reviews							
		Organizational	well-defined methods using a rigorous approach; consistent results with sufficient sample size; use of reliable and valid measures						
		Expert Opinion	expertise is clearly evident						
В	Good	Research	reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence						
		Summative reviews	reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.						
		Organizational	Well-defined methods; reasonably consistent results with sufficient numbers; use of <b>reliable and valid</b> measures; reasonably consistent recommendations						
		Expert Opinion	expertise appears to be credible.						
C	Low	Research	little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn						
	quality	Summative	undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn						
	or major	reviews							
	flaws	Organizational	Undefined, <b>or</b> poorly defined methods; insufficient sample size; inconsistent results; undefined, poorly defined or measures that lack adequate reliability or validity						
		Expert Opinion	expertise is not discernable or is dubious.						

Note. \*A study rated an A would be of high quality, whereas, a study rated a C would have major flaws that raise serious questions about the believability of the findings and should be automatically eliminated from consideration.

#### APPENDIX E

1. 5-item Likert scale perception statements for nursing staff participants to self-report their perceived self-confidence and comfort levels with providing ICU delirium care.

The 5-item Likert scale has 25 possible choices. Only one choice per question with a total of five possible answers allowed. A question cannot have two responses.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	Question	1	2	3	4	5
1	I'm comfortable assessing my ICU patients for Delirium					
2	If asked, I'm confident that I can provide an accurate definition of delirium					
3	I'm confident in communicating my concerns about presence of or risk for delirium to my patients' critical care providers					
4	I can identify at least two interventions that can be used to prevent or decrease the duration of delirium in ICU patients					
5	I feel that assessing ICU patients for delirium daily is a worthwhile intervention					

Content Reliability of the 5-item Likert Scale Perception with Intensive Care Unit (ICU) Delirium Care and the 15-Item Multiple Choice Knowledge Test To Determine Nurses and Providers Knowledge of Delirium showed a significant increase in positive perceptions overall (P < .0001). Overall mean post education knowledge test raw scores showed a significant improvement from pre-educational scores (70% +/- 12.8% vs 95% +/- 6.9%; P < .0001). The knowledge assessment tool and the Perception of ICU delirium care were newly developed and thus was validated only for content and not for statistical reliability

Implementation of an Intensive Care Unit Delirium Protocol: An Interdisciplinary Quality Improvement Project. Marino, Jessica; DNP, AG-ACNP-BC; Bucher, Donald; DNP, ACNP-BC; Beach, Michael; DNP, ACNP; Yegneswaran, Balaji; Cooper, Brad; PharmD, FCCM, Dimensions of Critical Care Nursing. 34(5):273-284, September/October 2015. DOI: 10.1097/DCC.000000000000130. Reprinted with permission from Wolters and Kluwer Health Inc. All rights reserved

# 2. Nurses 15-Item Multiple Choice Knowledge Test of Intensive Care Unit Delirium 15 questions with 50 possible choices. Nurses can only pick one correct choice per question. Only 15 answers are correct.

For each question, please choose the most correct response:

- 1) True or False: Delirium is an acute change in mental status associated with physical or mental illness
  - a. True
  - b. False
- 2) Which of the following is the "cardinal sign" of delirium?
  - a. Fluctuation in symptoms
  - b. Inattention
  - c. Hallucination
- 3) True or False: There is no diagnostic blood, electrophysiological, or imaging test for delirium.
  - a. True
  - c. False
- 4) Delirium that develops during an ICU stay has been associated with:
  - a. Increased ICU length of stay
  - b. Increased hospital length of stay
  - c. Increased mortality after discharge
  - d. Long term cognitive impairment
  - e. A, B, and C
  - f. All of the above
- 5) True or False: Once delirium is resolved during a hospitalization, there are no long-term-term effects
  - a. True
  - b. False
- 6) All of the following practices have been shown to prevent or shorten duration of delirium except:
  - a. Early mobilization
  - b. Daily spontaneous breathing trials
  - c. Daily awakening trials (sedation holiday)
  - d. Increasing sedation at night to promote sleep
- 7) Which of the following patients cannot be screened for delirium?
  - a. A patient having active hallucinations
  - b. A patient who is intubated
  - c. A patient who is comatose
  - d. A patient who has had a stroke
- 8) True or False: A patient who is drowsy most of the day cannot screen positive for delirium.
  - a. True
  - b. False
- 9) All of the following are risk factor for delirium except:

- a. History of dementia
- b. History of smoking
- c. Comatose state at any point during admission
- d. History of alcoholism
- 10) A patient who meets some criteria for delirium but does not score high enough for a positive delirium screening is deemed to have signs of:
  - a. Hyperactive delirium
  - b. Hypoactive delirium
  - c. Subsyndromal delirium
  - d. Partial delirium
- 11) Which of the following three pharmacological agents for sedation is associated with decreased incidence of delirium
  - a. Dexmedetomidine hydrochloride (Precedex)
  - b. Lorazepam (Ativan)
  - c. Midazolam (Versed)
- 12) True or False: All patients generally require continuous sedation while receiving mechanical ventilation
  - a. True
  - b. False
- 13) An appropriate target RASS score for most patient receiving continuous sedation is:
  - a. RASS 3-4 (drowsy but arousable, or alert and calm, and able to follow commands)
  - b. RASS 2-3 (drowsy and arousable to stimuli, but may not be able to follow command)
  - c. RASS 1-2 (minimal response to stimuli, and will not follow commands)
  - d. None of the above
- 14) The pharmacological agent of choice for treatment of delirium is:
  - a. Haloperidol (Haldol)
  - b. Olanzapine (Zyprexa)
  - c. Quetiapine (Seroquel)
  - d. Risperidone (Risperdal)
  - e. No agent has been shown to be superior in the treatment of delirium
- 15) All of the following are appropriate interventions to promote sleep except:
  - a. Darken the room at night
  - b. Administer Ativan at HS
  - c. Decrease noise level at night
  - d. Cluster care and interventions at night to minimize interruptions in sleep

*Note*. Implementation of an Intensive Care Unit Delirium Protocol: An Interdisciplinary Quality Improvement Project. Marino, Jessica; DNP, AG-ACNP-BC; Bucher, Donald; DNP, ACNP-BC; Beach, Michael; DNP, ACNP; Yegneswaran, Balaji; Cooper, Brad; PharmD, FCCM Dimensions of Critical Care Nursing. 34(5):273-284, September/October 2015. DOI: 10.1097/DCC.000000000000130. Adapted with permission from Author.

#### **APPENDIX F**

#### Permission for the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

We have obtained copyright for the CAM-ICU and its educational materials and have deliberately made it unrestricted in terms of use. We ask that you include the copyright line on the bottom of the pocket cards and other educational materials, but do not require you to obtain a written letter of permission for implementation and clinical use.

Copyright line: "Copyright © 2002, E. Wesley Ely, MD, MPH and Vanderbilt University, all rights reserved"

# APPENDIX G

# Demographic Data

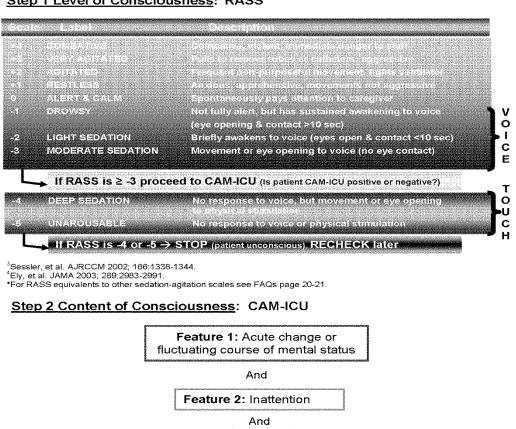
This Form is Voluntary –Information provided will be kept in confidence
Please do not Provide Your Name or Unit where you work
Gender: Male Female
Years of Nursing Experience in the ICU:
Degree Information - Please list highest degree(s) earned:
Associate/Diploma Degree
Bachelors of Nursing Degree
Master's Degree
Other

#### APPENDIX H

Figure A1. RASS and CAM-ICU

#### Assessing Consciousness: Linking Level of Consciousness & Delirium Monitoring

#### Step 1 Level of Consciousness: RASS\*



<sup>6</sup>Inouye, et. al. Ann Intern Med 1990; 113:941-948. <sup>7</sup>Ely, et. al. CCM 2001; 29:1370-1379. <sup>8</sup>Ely, et. al. JAMA 2001; 286:2703-2710.

Feature 3: Altered level of

consciousness

Page 6

Feature 4: Disorganized

Thinking

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Or

Figure A2. CAM-ICU Worksheet

#### **CAM-ICU Worksheet**

Feature 1: Acute Onset or Fluctuating Course	Score	Check here If Present
Is the patient different than his/her baseline mental status?  OR  Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation/level of consciousness scale (i.e., RASS/SAS), GCS, or previous delirium assessment?	Either question Yes →	
Feature 2: Inattention		
Letters Attention Test (See training manual for alternate Pictures)		
<u>Directions</u> : Say to the patient, "I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand." Read letters from the following letter list in a normal tone 3 seconds apart.	Number of Errors >2 →	
SAVEAHAART or CASABLANCA or ABADBADAAY		
Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A."		
Feature 3: Altered Level of Consciousness		
Present if the Actual RASS score is anything other than alert and calm (zero)	RASS anything other than zero →	
Feature 4:Disorganized Thinking		
Yes/No Questions (See training manual for alternate set of questions)		
Will a stone float on water?     Are there fish in the sea?     Does one pound weigh more than two pounds?     Can you use a hammer to pound a nail?		
Errors are counted when the patient incorrectly answers a question.	Combined number of	
Command Say to patient: "Hold up this many fingers" (Hold 2 fingers in front of patient) "Now do the same thing with the other hand" (Do not repeat number of	errors >1→	
fingers) *If the patient is unable to move both arms, for 2 <sup>nd</sup> part of command ask patient to "Add one more finger"		
An error is counted if patient is unable to complete the entire command.		

	Criteria Met →	
CAM-ICU		
Positive		Overall CAM-ICU
(Delirium Present)		
	Criteria Not Met →	Feature 1 plus 2 and either 3 or 4 present = CAM-ICU positive
CAM-ICU		
Negative (No Delirium)		
(No Delirium)		

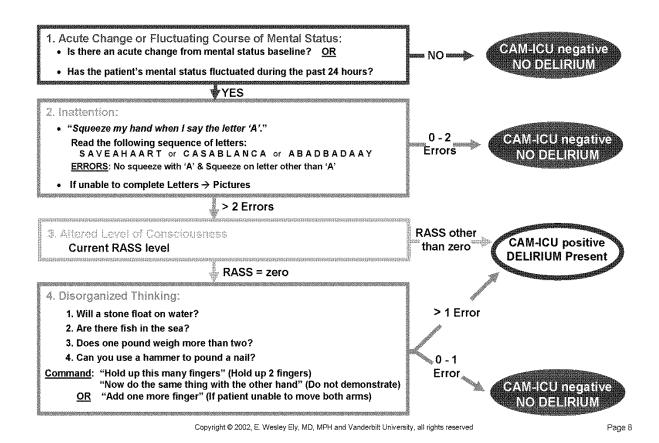
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Page 7

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Figure A3. CAM-ICU Flowsheet

#### Confusion Assessment Method for the ICU (CAM-ICU) Flowsheet



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#### APPENDIX I

# Permission to Use and Adapt Likert scale Confidence Level and Perception Statement and Knowledge Test

Mon, Apr 4, 2016 Good morning Ms. Akande,

You certainly have permission to use any of our materials from the article, so long as they are properly cited when used. I would be very interested to hear the outcomes of your capstone project when it is complete. Feel free to email me back here if you can.

Ms. Akande,

You can use the RASS scale as needed for your project in place of RIKER if this is more appropriate.

Jessica Marino, DNP, AG-ACNP, CCRN UPMC Hamot Erie, Pennsylvania 814-877-6000

Title: Implementation of an Intensive Care Unit Delirium Protocol: An Interdisciplinary Quality Improvement Project.

Author: Marino, Jessica; DNP, AGACNPBC; Bucher, Donald; DNP, ACNPBC; Beach, Michael; DNP, ACNP; Yegneswaran, Balaji; Cooper, Brad; PharmD, FCCM Publication: Dimensions of Critical Care Nursing Publisher: Wolters Kluwer Health, Inc. Date: Jan 1, 2015 Copyright © 2015, Copyright (C) 2015 Wolters Kluwer Health, Inc. All rights reserved.

Logged in as: Irene Akande

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Licensed Content Title Implementation of an Intensive Care Unit Delirium Protocol: An Interdisciplinary Quality Improvement Project. Licensed Content Author Marino, Jessica; DNP, AGACNPBC; Bucher, Donald; DNP, ACNPBC; Beach, Michael; DNP, ACNP; Yegneswaran, Balaji; Cooper, Brad; PharmD, FCCM Licensed Content Date Jan 1, 2015 Licensed Content Volume 34 Licensed Content Issue 5 Type of Use Dissertation/Thesis Requestor type Individual

# **APPENDIX J Institutional Review Board Approval**

#### Human Studies Subcommittee (IRB) Washington DC VA Medical Center

Washington, DC

#### IRB APPROVAL - Initial Review

Date: December 8, 2016

From: Cynthia L. Gibert, M.D., Chairperson

Investigator: Heidi Maloni, PhD, RN

Protocol: Implementing the Confusion Assessment Method to improve care of delirious patients

ID: 01843 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 12/05/2016 meeting:

- Consent Form Version Dated 11/22/2016 (12/01/2016)
- Financial Disclosure Form Akande, Irene (10/03/2016)
- Financial Disclosure Form Maloni, Heidi (10/03/2016)
- HIPAA Worksheet (10/03/2016)
- Initial Review Submission Form (10/03/2016)
- Personnel Roster Investigator Roster (10/03/2016)
- Project Data Sheet w/ Abstract (10/03/2016)
- Protocol Face Sheet (10/03/2016)
- Scientific Review Response to Scientific Review (10/25/2016)
- Scientific Review Scientific Review #2 (10/24/2016)
- Scientific Review Scientific Review #1 (10/20/2016)
- HIPAA Authorization (12/01/2016)
- Protocol (10/25/2016)

Revised per Scientific Review

Training Manual (10/25/2016)

#### **CAM-ICU**

- Appendix A. Likert Scale perception (10/03/2016)
- Appendix B. Multiple choice survey (10/03/2016)
- Appendix C. Permission to use tool (10/03/2016)

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU tool)

- Appendix D. Demographic Data (10/03/2016)
- Checklist for Reviewing (ISO/PO) (10/03/2016)
- Information Security Plan (10/03/2016)
- PI Certification for Researcher's Eligibility (10/03/2016)
- Privacy and Data Security Plan (10/03/2016)
- Quality Improvement worksheet (10/03/2016)
- Request for waiver of Consent (10/03/2016)
- Request for Waiver of HIPAA Authorization (10/03/2016)
- University of Maryland, Baltimore IRB (10/03/2016)

Exempted (Not Human Research Determination)

Conditions of Approval are attached. These conditions are further detailed in the HHS, FDA, and VA regulations, which are available in the Research Office.

The following Human Studies Subcommittee (IRB) members recused themselves (or were otherwise excused) from deliberations and did not vote: Heidi Maloni, PhD, RN.

Approval is granted for a period of 12 months and will expire on 12/04/2017. Your Continuing Review is scheduled for 11/13/2017, and the requirements are attached.

The protocol was determined to have the following level of risk: Minimal Risk

#### "REMINDERS"

"The most current IRB-approved stamp version of Informed Consent Form for each study must be used as the informed consent form."

Records will be maintained until the end of the study and until disposition instructions are approved by the National Archives and Records Administration.

The following other committee reviews are scheduled:

Research & Development Committee [12/16/2016]

Approval for study initiation is contingent upon your:

- (1) Receipt of written notification from the ACOS R&D that documents approval by the R&D Committee and authorizes the initiation of this research, and
- (2) Compliance with the requirements of the Research Service for the conduct of studies involving human subjects.

#### Research & Development Committee Washington DC VA Medical Center

Washington, DC

#### **APPROVAL - Initial Review**

Date: December 16, 2016

From: Joao L. Ascensao, MD, PhD, FACP, Chairperson

Marc R. Blackman, M.D., ACOS/R&D

Investigator: Heidi Maloni, PhD, RN

Protocol: Implementing the Confusion Assessment Method to improve care of delirious patients

ID: 01843 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 12/16/2016 meeting:

- Consent Form Version Dated 11/22/2016 (12/01/2016)
- Financial Disclosure Form Akande, Irene (10/03/2016)
- Financial Disclosure Form Maloni, Heidi (10/03/2016)
- HIPAA Worksheet (10/03/2016)
- Initial Review Submission Form (10/03/2016)
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- Scientific Review Response to Scientific Review (10/25/2016)
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- Scientific Review Scientific Review #1 (10/20/2016)
- HIPAA Authorization (12/01/2016)
- Protocol (10/25/2016)

#### Revised per Scientific Review

Training Manual (10/25/2016)

#### **CAM-ICU**

- Appendix A. Likert Scale perception (10/03/2016)
- Appendix B. Multiple choice survey (10/03/2016)
- Appendix C. Permission to use tool (10/03/2016)

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU tool)

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- Privacy and Data Security Plan (10/03/2016)
- Quality Improvement worksheet (10/03/2016)
- Request for waiver of Consent (10/03/2016)
- Request for Waiver of HIPAA Authorization (10/03/2016)
- University of Maryland, Baltimore IRB (10/03/2016)

Exempted (Not Human Research Determination)

#### YOU MAY NOW INITIATE RESEARCH.

Approval by each of the following is required prior to study initiation: Human Studies Subcommittee (IRB) [Approval Granted 12/05/2016] Research & Development Committee

Joao L. Ascensao, MD, PhD, FACP, Chairperson

Date

Marc R. Blackman, M.D., ACOS/R&D

Date





University of Maryland, Baltimore Institutional Review Board Phone: (410) 706-5037 Fax: (410) 706-4189

Email: hrpo@umaryland.edu

#### NOT HUMAN RESEARCH DETERMINATION

Date: September 23, 2016

To: Veronica Gutchell RE: HP-00071952

Name: Implementing the Confusion Assessment Method to improve care of delirious patients

This letter is to acknowledge that the UMB IRB reviewed the information provided and has determined that the submission does not require IRB review. This determination has been made with the understanding that the proposed project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge **OR** a human participant (see definitions below).

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are human subject research in which the organization is engaged, please submit a new request to the IRB for a determination.

#### Definitions -

Human Research: Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by FDA and involves "Human Subjects" as defined by FDA ("FDA Human Research").

**Research as Defined by DHHS:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Research as Defined by FDA:** Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

**Human Subject as Defined by DHHS:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- Intervention means physical procedures by which data are gathered (for example, venipuncture)
  and manipulations of the subject or the subject's environment that are performed for research
  purposes.
- Interaction means communication or interpersonal contact between investigator and subject.
- Private Information means information about behavior that occurs in a context in which an
  individual can reasonably expect that no observation or recording is taking place, and
  information which has been provided for specific purposes by an individual and which the
  individual can reasonably expect will not be made public (for example, a medical record).
- Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

<u>Human Subject as Defined by FDA:</u> An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or <a href="https://hrp.doi.org/hRPO@umaryland.edu">https://hrp.doi.org/hrp.do

ADepartment of Veterans Affairs	VA RESEARCH CONSENT FORM Washington VA Medical Center	
Subject Name:		
Last 4 SSN	Date:	
<b>Title:</b> Implementing the Confusion A patients	Assessment Method to improve care of de	elirious
Principal Investigator: Heidi Malo	oni, PhD VA	AMC: 688
SECTION I: PURPOSE		

#### **SECTION II. PROCEDURES**

If you consent to participate in this research study, you will complete two questionnaires, one before you receive educational training at week 1 and one after receiving your educational training at week 3.

benefits to which you were otherwise entitled. We are conducting an educational training for ICU nurses on how to correctly use the CAM-ICU to accurately assess for delirium and improve on future delirium assessments at the Washington DC VAMC. Approximately, fifty subjects will be enrolled in this study.

The educational training will include a 30 minute PowerPoint in-service on the importance of delirium assessment, and case scenarios of ICU patients with and without delirium, this will give you the opportunity to collaborate and participate in the training. Also included will be a five-minute online video illustrating how to complete the CAM-ICU tool in clinical practice (<a href="www.icudelirium.org/delirium/monitoring.html">www.icudelirium.org/delirium/monitoring.html</a>).

CAM-ICU flowcharts will be placed at each bed space for reference. The education will enhance your knowledge on the importance of assessment and documentation of delirium. Your demographic data of gender, level of education, years of nursing experience will be collected to understand the demographic characteristics of ICU nurse's population. Demographic information collected will be stored in a locked cabinet with access available to the principal investigator and the co-investigator only.

Version 11/22/2016

Washington DC VAMC IRB APPROVED December 5, 2016

Updated by IRB office: 3/13 VA FORM 10-1086

### ADepartment of Veterans Affairs

## VA RESEARCH CONSENT FORM Page 2 of 4

These questionnaires consist of a 5-item Likert scale of perception statements to self-report your perceived self-confidence and comfort levels with providing ICU delirium care. You will be asked to rate your level of agreement with each statement on a 5-point scale, ranging from "strongly disagree" (1) to "strongly agree" (5). The 5-item Likert scale has 25 possible answer choices and only one answer per question is allowed with a total of five possible answers. In addition, there will be a 15-item multiple choice knowledge tests to determine your delirium knowledge prior to your training.

In week 2, you will be provided with paper based CAM-ICU worksheets to enhance your delirium screen. Patient's information will not be collected.

In week 3, the post educational questionnaire will consist of a similar copy of the pre-educational questionnaire. Paper-based forms will be stored in a secure locked cabinet. To protect your privacy paper forms will not include any of your identifying information. The timeline for formal data collection during this phase will be 3 weeks. You do not have to answer all questions for the pre and post educational questionnaire.

#### SECTION III. RISKS

This project will provide you with education on how to use the CAM-ICU tool for delirium assessment. There are no anticipated potential risks. This project will not use or disclose any protected health information and this project involves no more than minimal risk of demographic data collected for gender, years of nursing experience in the ICU and level of education. This project has adequate plan to protect your demographic data from improper use and disclosure as data will be stored in a locked cabinet with access to the principal investigator and the co-investigator only.

#### SECTION IV. BENEFITS

The benefit would be that you are able to accurately identify delirium. Your participation may benefit others in the future by contributing to the understanding of delirium assessment at the Washington DC VAMC.

#### SECTION VI. PRIVACY & CONFIDENTIALITY

VHA will maintain the confidentiality of your records if information is shared with others, the VHA will require that your records will be kept confidential. Federal and local regulations may require review of our medical and research records by representatives of Food and Drug Administration (FDA), Government Accountability Office (GAO), the VA, Office of Human Research Protection (OHRP), Office of Research Oversight (ORO), VA Office of the Inspector General (OIG), and the Institutional Review Board of this medical center. Refer to the accompanying HIPAA authorization for further information regarding Privacy and Confidentiality.

## **A**Department of Veterans Affairs

# VA RESEARCH CONSENT FORM Page 3 of 4

#### SECTION VII. RESEARCH RESULTS

- 1. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.
- 2. We will maintain your privacy and the confidentiality of the research record and no information by which you can be identified will be released or published without your authorization <u>unless required by law</u>. Dr. Maloni will have possession of all data including questionnaires. Other research staff members will have access to them but they will be stored in a secure location in accordance with the record control schedule. At that time they will be destroyed. There is a possibility that the Food and Drug Administration (FDA) may inspect the records.

#### SECTION VIII. SPECIAL INFORMATION

- 1. You are not required to take part in this study: your participation is entirely voluntary.
- 2. You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment, if you are a patient.
- 3. There will be no costs to you for any of the treatment or testing done as part of this research study. Any additional costs to the participant that might result from participation in the research, such as travel expenses, will be reimbursed according to normal VA travel procedures.
- 4. You will receive no payment for your participation.
- 5. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
- 6. If you are injured as a result of taking part in this study, the VAMC will provide necessary medical treatment at no cost to you. However, the VAMC has the right not to provide treatment for injuries resulting from your noncompliance with study procedures.
- 7. Additional compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation may be obtained from the Patient Advocate Office at this VA Medical Center.
- 8. If you would like talk to someone unaffiliated with the research to discuss problems, concerns, and questions, including questions about your rights. If you have problems, concerns or complaints, or think you have been injured you can contact the Associate Chief of Staff for Research & Development, Dr. Marc Blackman, at 202-745-8133 or the Chairman of the Human Studies Committee, Dr. Cynthia Gibert, at 202-745-2238. You can also call them if you want more information, want to offer a suggestion, or want to provide input.

#### **AFFIRMATION FROM SUBJECT**

Dr. Maloni or Ms. Akande has explained the study to me and answered all of my questions. I have been told of risks or discomforts and possible benefits of the study.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my identity will not be revealed unless required by law.

# VA RESEARCH CONSENT FORM **A**Department of Veterans Affairs Page 4 of 4 In case there are medical problems or questions, I have been told I can call Ms. Akande at (202-745-8680) during the day. If any medical problems occur in connection with this study the VA will provide emergency care. I understand the explanation of my rights as a research subject, and I voluntarily consent to participate in this study. I understand the explanation of what the study is about and how and why it is being done. I will receive a signed copy of this consent form. Participant's Signature Date I have informed the participant of the intent, nature benefits and risks of the research project. I judge that he/she understood my explanation and that his consent was given freely. Consent Informant Signature Print Name Date

Department of Veterans Affairs	Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research		
Subject Name (Last, First, Middle Initial	):	Subject SSN (last 4 only):	Date of Birth:
VA Facility (Name and Address): WASHINGTON DC VETERANS AFFAIRS MI 50 IRVING STREET NW, WASHINGTON, DC			
VA Principal Investigator (PI): HEIDI MALONI, PHD		PI Contact Information: 202-745-7873	
Study Title: Implementing the Confusion Assessment Method	d to improve care of delirious patio	ents	
Purpose of Study: This is a scholarly capstone quality improvement Assessment Method for the Intensive Care Unit (			he Confusion
USE OF YOUR INDIVIDUALLY IDENT Your individually identifiable health infoinformation that would identify you such to allow the VA Principal Investigator (F present health information in addition to investigators of this study are committe your health care.	rmation is information about	you that contains your health	information and b. VHA is asking you use your past or med above. The mation related to
Signing this authorization is completely participate in this study. Your treatment whether or not you sign this authorization	voluntary. However, your au t, payment, enrollment, or eli on.	nthorization (permission) is negitive the gibility for VA benefits will not	ecessary to be affected,
Your individually identifiable health info	rmation used for this VA stud	dy includes the information m	arked below:
☐ Information from your VA Health F findings	Records such as diagnoses,	progress notes, medications,	lab or radiology
☐ Specific information concerning:			
☐ alcohol abuse ☐ dru	ıg abuse 🔲 sickle cell	anemia 🔲 HIV	
<ul> <li>☑ Demographic Information such as nat</li> <li>☐ Billing or Financial Records</li> <li>☐ Photographs, Digital Images, Video, ot</li> <li>☑ Questionnaire, Survey, and/or Subject</li> <li>☐ Other as described:</li> </ul>	or Audio Recordings		
VA FORM SEPT 2015 10-0493 Version Date	<u>:</u>		Page 1

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research			
Subject Name (Last, First, Middle Initial):	Subject SSN (last 4 only):	Date of Birth:	
USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: ( optional research activity, complete page 5 and leave this section blank. If I and/or "Specimen" for future use or if "Not Applicable" is selected, remove p  ☑ Not Applicable - No Data or Specimen Banking for Other Resea An important part of this research is to save your  ☐ Data	panking is a required research a age 5 in its entirety.)		
☐ Specimen			
in a secure repository/bank for other research studies in the future. If yand/or specimen for future studies approved by the required committe will not be able to participate in this study.			
<b>DISCLOSURE:</b> The VA research team may need to disclose the infor institutions that are not part of VA. VA/VHA complies with the requiren Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other protect your privacy. The VHA Notice of Privacy Practices (a separate we protect your information. If you do not have a copy of the Notice, the	nents of the Health Insuranc applicable federal laws and i document) provides more in	e Portability and regulations that of the properties of the proper	
Giving your permission by signing this authorization allows us to disclepersons as noted below. Once your information has been disclosed or by federal laws and regulations and might be re-disclosed by the pers	utside VA/VHA, it  may no lo	nger be protected	
☐ Non-VA Institutional Review Board (IRB) at who will monitor the study			
Study Sponsor/Funding Source:  VA or non-VA person or entity who takes responsibility for; initiates	s, or funds this study		
☐ Academic Affiliate (institution/name/employee/department): A relationship with VA in the performance of this study			
☐ Compliance and Safety Monitors:  Advises the Sponsor or PI regarding the continuing safety of this st	tudy		
Other Federal agencies required to monitor or oversee research (s	uch as FDA, OHRP, GAO):		
☐ A Non-Profit Corporation (name and specific purpose):			
Other (e.g. name of contractor and specific purpose):			
VA FORM SEPT 2015 10-0493 Version Date:		Page 2	

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research				
Subject Name (Last, First	, Middle Initial):	S	ubject SSN (last 4 only	: Date of Birth:
Oversight (ORO), the Office of General Counse information in the perform	/HA that are responsible for over- ice of Research and Developmer of, the VA IRB and Research and nance of their VA/VHA job duties.	nt (ORD), the I Development :	VA Office of Inspector G t Committee may also h	General, the VA ave access to your
While this study is being of				
☐ will have access to you	r research related health records	s		
will not have access to	your research related health rec	cords		
	A healthcare including your doctory to have access to the research			
	n this authorization you may cha s in writing and must send your v			
which you are entitled will continue to use or disclos	your permission, you will no long I NOT be affected. If you revoke the the information that it has alreate earch team has relied upon for the 's Principal Investigator.	(take back) yo ady collected	our permission, the rese before you revoked (too	arch team may k back) your
<b>EXPIRATION:</b> Unless you your information will:	u revoke (take back) your permis	ssion, your aut	horization to allow us to	use and/or disclose
☐ Expire at the end of this	s research study			
	vill expire at the end of this research future research will not expire.	n study. Any st	udy information that has b	een placed into a
☐ Expire on the following	date or event:			
☐ Not expire				
WEST				
VA FORM SEPT 2015 <b>10-0493</b>	Version Date:			Page 3

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research				
Subject Name (Last, First, Middle Initial):	Subject SSN (last 4 only):	Date of Birth:		
TO BE FILLED OUT BY THE	TO BE FILLED OUT BY THE SUBJECT			
<b>Research Subject Signature.</b> This permission (authorization) has be opportunity to ask questions. If I believe that my privacy rights have I facility Privacy Officer to file a verbal or written complaint.				
I give my authorization (permission) for the use and disclosure of my described in this form. I will be given a signed copy of this form for m		h information as		
Signature of Research Subject	Date			
Signature of Legal Representative (if applicable)	Date			
To Sign for Research Subject (Attach authority to sign: Health Care or Next of Kin if authorized by State Law)	Power of Attorney, Legal Gua	ardian appointment,		
Name of Legal Representative (please print)				
VA FORM SEPT 2015 10-0493 Version Date:		Page 4		

#### **APPENDIX K**

#### **Proposal Timeline**

- Submit Proposal to committee members by April 2016.
- Present Proposal to committee members by May 2016.
- Submit project proposal to UMB and Hospital Institutional Review Boards (IRBs) for review by September 2016.
- Conduct interviews and survey from December 2016 February 2017
- Analyze and evaluate data by March 2017.
- Submit final scholarly project manuscript to the committee for review by March 2017.
- Present final scholarly project report to Committee by April 2017.