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Pilot Study of a Two-Step Delirium Detection Protocol Administered By Certified Nursing Assistants, Physicians and Registered Nurses

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BACKGROUND

Delirium is common in older adults and leads to poor outcomes in hospitalized persons, including increased staff burden, decreased function, and heightened emotional distress (Morandi et al., 2015). In addition, delirium costs the United States \$164 billion annually in health care costs and can lead to physical and mental decline, nursing home placement, and death (Inouye, Westendorp, & Saczynski, 2014; Leslie & Inouye, 2011). Despite these poor outcomes, delirium is frequently not recognized, especially by busy healthcare professionals and hospital staff. This is particularly true for persons with hypoactive (quiet) delirium and for those with delirium superimposed on dementia (DSD) (Fick, Agostini, & Inouye, 2002; Inouye, Foreman, Mion, Katz, & Cooney Jr, 2001).

The Confusion Assessment Method (CAM) is the most widely used tool to assess for delirium worldwide and it has been extremely important in advancing delirium research. Moreover, there is a growing interest in integrating the CAM into clinical care; however, this process has presented some challenges. The CAM is a diagnostic algorithm, not a delirium assessment. Previous research has shown that asking registered nurses to complete the CAM without formal mental status testing and with minimal training results in poor sensitivity (Inouye et al., 2001; Lemiengre et al., 2006). A brief, structured assessment tool that includes mental status testing and that standardizes operationalization of the CAM algorithm might prove very valuable to facilitate widespread implementation of delirium screening. The Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) is an example

of an assessment tool that had facilitated widespread delirium screening in intensive care settings (Wei, Fearing, Sternberg, & Inouye, 2008). However, the CAM-ICU has limited sensitivity for assessing delirium in general medical and surgical patients (Kuczmarska et al., 2016). Filling this void is the 3D-CAM, a relatively new, brief diagnostic assessment for CAM-defined delirium that is optimized for general medicine and surgical settings, can be completed in 3 minutes, and has 95% sensitivity and 94% specificity when compared to a clinical gold standard (Marcantonio et al., 2014). Within the 3D-CAM, two items were identified (months of the year backwards and what is the day of the week?), that can serve as an ultra-brief screener to rule out delirium in less than 40 seconds (Fick et al., 2015).

Another key area in delirium screening is to identify the most effective and efficient clinician to conduct the screening and to determine how to integrate assessment and management of delirium into clinician workflow and the health system. In healthcare research, it is rare to examine how 3 different disciplines perform the same task. Usually, a task is assigned to a single discipline, either because of a unique skill set, or tradition. The evidence is not available for which discipline is most appropriate for delirium identification in the hospital setting, and no studies have compared physicians, nurses, and certified nursing assistants (CNA's). Each of these disciplines has unique daily responsibilities. Thus, in addition to measuring effectiveness and cost-efficiency of delirium screening, it is important to understand the specific barriers and facilitators of delirium assessment faced by each discipline. Doing comparative effectiveness studies using mixed methods allows us to understand the most effective and efficient manner to screen for delirium. This information can help guide decisions within healthcare systems on how to assure the best information is available to provide optimal care at the bedside. This information is critical to clinical systems implementation, priority setting, and policy making for delirium care (Pincus, 2011).

Thus, the purpose of this pilot study was to test the feasibility of a 2-step delirium detection protocol completed by clinicians using the ultra-brief screener followed by the 3D-CAM (Marcantonio et al., 2014) in those with a positive screen. This process will be part of a systematic delirium identification process that will be tested in a larger trial. First, the ultra-brief screener, consisting of two questions, "Please tell me the day of the week" and "Please tell me the months of the year backwards (MOYB) starting with December" is administered. Patients have to get the day of the week exactly correct and recite all 12 months backwards with no errors. They are allowed to look at a newspaper if it is nearby or a calendar on the wall. They are allowed to be prompted twice on the MOYB if they get stuck July, by saying for example, "Please tell me the month that comes before July?". If either or both of the questions in the ultra-brief screener is incorrect (or if the patient says "I don't know" or gives no meaningful response), then the physicians and registered nurses are instructed to move on to the 3D-CAM, and the CNA is instructed to notify the nurse. The 3-D CAM instrument can be accessed at the Hospital Elder Life Program website at <https://www.hospitalelderlifeprogram.org/delirium-instruments>

In this pilot, we determined feasibility and obtained preliminary estimates of the effectiveness of this protocol as implemented by physicians, nurses, and CNAs relative to a

trained researcher who served as a reference standard. We also collected qualitative data from these clinician groups.

METHODS

Study sample and setting

We utilized an embedded mixed methods design (Creswell & Plano-Clark, 2011). Our participants were recruited via screening consecutive hospital admissions to two general medicine wards of a large urban academic medical center and a rural community hospital. Eligibility criteria included: 1) general medicine (hospitalist) service admission, 2) age 70 or older, 3) expected hospital length of stay of 2 or more days, 4) ability to communicate adequately in English, and 5) not admitted for terminal care. Our protocol was approved by the Institutional Review Boards of all participating institutions.

Quantitative Data Collection Protocol

A series of four delirium assessments were conducted on enrolled participants, blinded to each other's results, within a 2-hour time window. Reference standard assessments for this pilot were conducted by senior research assistants with at least a master's degree. These assessors were trained in conducting the assessment utilizing both in person and video methods. Training was performed by research personnel with each clinician in a one to one manner. There were some slight differences between sites as clinicians were often on call and busy, but all were trained using a procedures manual with step-by-step instructions for the ultra-brief screener and the 3D-CAM (available from the author upon request). Registered nurses and physicians were trained for approximately 15–20 minutes and then administered a video post-test. Registered nurses at MNMC were given .5 CNE for the training. CNAs were trained in the 2-item ultra-brief screener for 5 minutes and did a practice administration to research personnel.

After obtaining informed consent from the patient or designated surrogate decision maker, trained researchers (TR) conducted the reference standard delirium assessment. This included cognitive testing using the Mini-Mental State Examination (MMSE, purchased from Psychological Assessment Resources) (Folstein, Folstein, & McHugh, 1975), supplemented with Digit Span for additional attention testing (Palmer & Meldon, 2003), the Delirium Symptom Interview (DSI) to elicit patient symptoms of delirium (Albert et al., 1992) and the Geriatric Depression Scale (Yesavage, 1988). Using data from the cognitive testing and DSI, the researcher completed the 10-item (long) Confusion Assessment Method (CAM), which generates both a diagnosis of delirium using the CAM diagnostic algorithm (Inouye et al., 1990), and a measure of delirium severity, the CAM-S long form (Inouye, Kosar, et al., 2014).

After trained researchers completed the reference standard delirium assessment, we asked physicians and registered nurses to complete the 2-step delirium identification protocol, which consisted of the ultra-brief 2-item screener ("Please tell me the day of the week" and "Please tell me the months of the year backwards starting with December"; for participants who got either of both of these questions incorrect (or who gave no response), physicians

and registered nurses were also instructed to administer the 3D-CAM. CNA's were asked to complete the ultra-brief screener only, and notify the nurse of an abnormal result. All assessments were timed for both components--the ultra-brief screener, and if necessary, the 3D-CAM

Qualitative Data Collection

After collecting patient quantitative data, researchers (n= 4 researchers; 2 at each site) focused on the actual delirium-screening event. Non-participant observation (direct observation when the researcher is not actively participating in the event they are observing) utilizing ethnographic methodology (Speziale, Streubert, & Carpenter, 2007) was used to observe the delivery of the delirium assessment protocol followed by brief interviews focused on the providers' perceptions of the protocol (e.g., How did the delirium screening go for you? What was the most difficult part? What did you like about it most?). These questions and observations addressed barriers and facilitators to bedside delirium screening. Observational data regarding the contextual features of the unit at the time of assessment (e.g., unit activities) were also collected. All data were recorded as field notes, then transcribed for analysis.

Data analysis

Sensitivity and specificity for both the 2-item screener alone (all 3 disciplines), and for the 2-step protocol (physicians, registered nurses only) were calculated for the quantitative analysis. Sensitivity was defined as percent that tested positive on the 2-step protocol among the gold standard positives, and specificity as percent that tested negative on the 2-step protocol among the gold standard negatives. Because of the pilot nature of this study, with limited sample size, confidence intervals were not calculated for sensitivity or specificity results. Analyses were conducted using commercially available software ("SAS Power Procedure," 2014).

Qualitatively, an iterative process of thematic analysis of the field notes was conducted. Two researchers (who were also data collectors) reviewed and independently coded the dataset. Preliminary coding was discussed to generate common themes, categorized as either barriers interfering with, or facilitators assisting with administration of the delirium screens. Multiple coders (data collectors from both sites) were then used to help validate the interpretation of the codes (Creswell, 2016). Lastly, two other research team members who were not involved in earlier stages of thematic analysis reviewed the dataset and confirmed the findings. A third independent rater who was not in the field performed inter-coder agreement.

RESULTS

Over a 2-week period, we identified 36 eligible patients at both study sites, and approached 34 (1 was on respiratory precautions, 1 was discharged before approach). Of these, we enrolled 24 (9 refused, 1 lacked capacity and we were unable to reach the proxy). We excluded one patient from the protocol because they deviated greatly from the protocol with an almost 4 hour gap (double the protocol) between delirium assessments and was noted to be fluctuating during this time. The analysis was conducted on 23 enrolled patients. All 3

clinical assessments were successfully completed in 100% of enrolled participants, and within the target 2-hour time window in 91%). The mean age of study patients was 81 with 52% of patient's male and 100% white (Table 1). Based on the reference standard rating, 5/23 patients (22%) had delirium. Seven physicians, 13 nurses, and seven CNA's participated in the assessments. Pilot study results in Table 2 suggest that the 2-item ultra-brief screener is very effective in identifying delirium, with high sensitivity and moderate specificity, as designed. Moreover, all three clinicians could administer the screener accurately. The full 2-step delirium protocol, performed by physicians and nurses, retained very good to excellent sensitivity and substantially improved specificity, as designed. Both physicians and registered nurses were able to administer the 2-step protocol effectively.

Qualitative analyses to identify barriers and facilitators of protocol implementation based on the field notes from the observations and interviews are summarized in Table 3. Seven themes emerged under barriers and facilitators, three facilitators and four barriers. The qualitative data revealed many positive comments about the ease of use of the screener. Some barriers were noted including finding the time to do the assessment and excessive encouragement or prompting by the clinical staff, time between training, interdisciplinary breakdowns in communication (instances when the CNA did not feel they had the power to report on cognitive changes), and challenges in screening older adults with severe cognitive impairment, impaired responsiveness, or anxiety about the cognitive testing.

IMPLICATIONS FOR PRACTICE AND RESEARCH

The identification of delirium in the hospital setting continues to be a challenge. In this preliminary work, we found that our two-step delirium identification protocol (ultra-brief screener followed in positives by the 3D-CAM) was feasible as administered by registered nurses and physicians, while the screener was feasibly administered by CNA's. Moreover, the protocol worked as designed, and achieved high sensitivity and specificity. Finally, the protocol was time efficient, taking less than 40 seconds for the ultra-brief screener, and three minutes for the 3D-CAM. Our qualitative research found that all three disciplines expressed enthusiasm and confidence in completing the 2-step protocol. We also identified some potential barriers to the larger study of this protocol such as time between training. Qualitative barriers and facilitators were also found that will aid in the eventual implementation of the protocol.

Both registered nurses and physicians report that lack of time and deciding who is responsible for delirium screening are barriers to assessing and managing delirium (Steis & Fick, 2008). Delirium screening that is quick, simple, highly sensitive, validated in persons with hypoactive delirium and in those with underlying dementia, and that requires little training is urgently needed.

The current study extends our prior work where we developed and validated the 3D-CAM (Marcantonio et.al. 2014) and identified the ultra-brief delirium screen from secondary data analysis. The best 2-item screener was the combination of the items "Please tell me the months of the year backwards" and "Please tell me the day of the week" with a sensitivity of 93% (95% CI: 81%-99%) and specificity of 64% (95% CI: 56%–70%) (Fick et al., 2015).

Based on these two studies, we developed the two-step delirium identification protocol, which consists of administering the ultra-brief screener first, and in “positives”, going on to administer the 3D-CAM. Our study is one of the first to pilot test a two-step protocol in a prospective sample and to test the real-world administration of this approach by registered nurses, and physicians, and the ultra-brief screener by CNA’s.

Many previous screeners have not been as sensitive when used in the actual practice setting with clinicians as opposed to trained researchers. Testing the protocol as administered by the actual personnel who would implement it clinically is an important contribution. If our protocol proves to be efficient and effective in a larger sample, it has the potential to greatly streamline and individualize delirium screening and should be attractive to leaders of healthcare systems who may be searching for practical tools to identify delirium.

Although other studies have found time to be a barrier in delirium identification, the dilemma of who is most efficient and effective at delirium identification and whose responsibility it should be to screen is an unanswered question in the field of delirium and in practice (Morandi et al., 2017). There are two issues: 1) which discipline can administer the protocol most effectively, that is achieving closest concordance with a reference standard; 2) which discipline can administer the protocol most efficiently, that is in the shortest amount of time, and at lowest cost. Our planned larger study addresses both of these critical questions.

This pilot study demonstrated the feasibility of our proposed study approach, which we are currently testing in a new NIH funded interdisciplinary study “Researching Efficient Approaches to Delirium Identification” (READI) which will enroll 450 older adults 70 and over and approximately 75 clinicians in Pennsylvania and Massachusetts. This study will use a protocol very similar to this pilot, except that delirium will be assessed on two consecutive days in enrolled patients (assuming they are not discharged). Comparative effectiveness work such as this is critical for providing better information on delirium identification to patients, providers and policy makers.

This pilot study had some inherent limitations, such as small sample size, and a non-diverse sample, which may limit generalizability. However, this study also has several important strengths and provided key information for proving feasibility of this complex, interdisciplinary protocol. Key feasibility metrics included: 1) successful enrollment of older hospitalized patients, 2) assessments completed by clinicians from all three disciplines with minimal training, 3) favorable comparison of the ultra-brief screener and 2-step protocol with the reference standard, and 4) identification of barriers and facilitators using our direct observation qualitative methods. Notably, we conducted this study at two distinct study sites (a large, urban academic medical center and a small, rural, non-teaching community hospital) that should help to address protocol effectiveness, efficiency, and implementation challenges across diverse settings, facilitating future large-scale implementation efforts.

In summary, registered nurses and other healthcare professionals play a key role in bedside delirium identification. The ultra-brief screener followed by the 3D-CAM is a promising and innovative approach to improve delirium identification by clinicians. This pilot study

provided valuable results to guide our future work. We now plan to replicate this pilot in a much larger sample, collecting the data necessary to inform future widespread implementation, and furthering our goal of translating research into the real world of clinical practice.

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TABLE 1**PATIENT CHARACTERISTICS**

		All Sites	MA site	PA site
Patients (N=23)		23	14	9
Mean Age (SD)		80.7 (7.1)	79.4 (7.5)	82.7 (6.3)
Gender N (%)	Male	12 (52%)	7 (50%)	5 (56%)
	Female	11 (48%)	7 (50%)	4 (44%)
Race N (%)	White	23 (100%)	14 (100%)	9 (100%)

TABLE 2**SENSITIVITY AND SPECIFICITY RESULTS BY CLINICIAN TYPE**

Clinician Type	2 Item Ultra-Brief Screener				2-Step Delirium Identification Protocol			
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
Physicians	80% (4/5)	56% (10/18)	33% (4/12)	91% (10/11)	80% (4/5)	83% (15/18)	57% (4/7)	94% (15/16)
Nurses	100% (5/5)	67% (12/18)	45% (5/11)	100% (12/12)	100% (5/5)	89% (16/18)	71% (5/7)	100% (16/16)
CNA's	100% (5/5)	61% (11/18)	42% (5/12)	100% (11/11)	N/A	N/A	N/A	N/A

TABLE 3

BARRIERS AND FACILITATORS OBSERVED DURING THE BEDSIDE DELIRIUM SCREENING

Facilitators	
Providers expressed confidence using the protocol with patients.	
<i>"I think the 2-item form is just as sensitive as the long form, I really like it...I've started doing it on several of my patients not in your study." (Hospitalist)</i> <i>"What I liked best was the first 2 questions and how quick and reliable it was and I liked knowing there was a process with the next form---if she didn't pass it that I would be confident in the step of the 3D-CAM." (RN)</i>	
Providers rapidly gained comfort administering the protocol.	
<i>"You can do it the first thing in the morning when you get the vital sign, it is just very easy to stick the 2 questions in." (RN)</i> <i>"She (CNA) said it was very easy and she felt comfortable doing the interview, and she didn't have any questions." (Researcher field note)</i>	
Majority of staff were enthusiastic and positive about the protocol.	
<i>"I liked working with you guys. You made it easy for me by handing me a clipboard. I felt comfortable with the questions, even though it is just my first day." (Hospitalist)</i> <i>"I just loved it! I was really happy to be able to do it (smiling)" (RN)</i>	
Barriers	
Too much time between training and first use.	
<i>"I (Researcher) had to correct the CNA on the 'what is the day of the week?' question; this is the first time for the CNA to do the study and the training was a few weeks ago. The next time she did the assessment, she did it correctly." (Researcher field note)</i>	
Communication: Excess encouragement or prompting & breakdowns in inter-professional communication, communication between clinicians and CNA.	
<i>"I wish I could ask these questions [as part of routine clinical practice—not just for a research study]. Sometimes I ask someone else to do them, like the nurse or physical therapist. I notice the confusion because I'm often one of the first people to notice it as I am taking care of the patient." (CNA)</i> <i>"There is not good communication [among nurses and CNAs] about the patients." (CNA)</i> <i>"I noticed the nurse praised the patient several times saying, 'good, that is right' and 'that is wrong' sort of thing. She didn't notice that she was doing this (correcting the patient). (Researcher field note)</i> <i>"Sometimes, a family member in the room tried to give patient hints." (Researcher field note)</i>	
Clinician difficulties in engaging patients who were more challenging or less responsive.	
<i>"The patient has severe dementia and was almost non-responsive and the physician was not exactly sure what to do when the patient was not answering..." (Researcher notes)</i> <i>"The CNA was not confident with how to communicate with a patient who was actively delirious and not answering all of the questions..." (Researcher notes)</i> <i>The patient, an older woman, began to cry during the assessments saying she already answered these questions twice and she just wanted to go home..." (Researcher field note)</i>	
Busy unit, busy patient room traffic and competing priorities.	
<i>"I can do this-but first I have to do all the blood sugars for this side of the hallway and I have not had lunch and its 11:15 already." (CNA to RA)</i> <i>"I'll try and let you know when I have time to do this" (sighed twice and put hand on head and holding 2 intravenous lines in other hand). (RN to RA)</i> <i>"Many people coming and going throughout assessments (e.g. to check patient's vital signs or blood glucose, visitors or medical staff attending to roommate, etc." (Researcher field note)</i>	