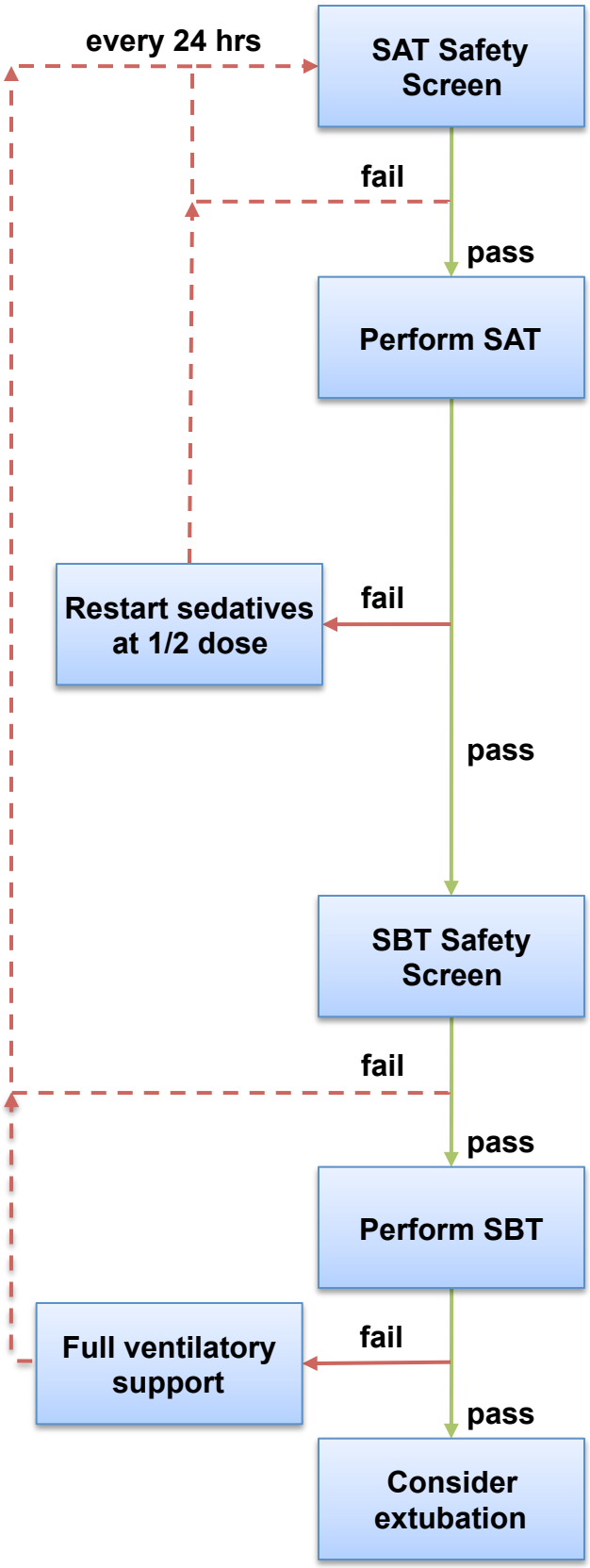
The ABCDE Bundle: Tools for Implementation

- “Wake Up and Breathe” Protocol
- Confusion Assessment Method for the ICU (CAM-ICU) Flowsheet
- Intensive Care Delirium Screening Checklist (ICDSC)
- Pediatric CAM-ICU – Worksheet for Daily Delirium Assessment
- Progressive Mobility Protocol
- Exercise/Mobility Safety Screen and Therapy
- Journal Club Exercises

"Wake Up and Breathe" Protocol
Spontaneous Awakening Trials (SATs) + Spontaneous Breathing Trials (SBTs)



SAT Safety Screen

- No active seizures
- No alcohol withdrawal
- No agitation
- No paralytics
- No myocardial ischemia
- Normal intracranial pressure

SAT Failure

- Anxiety, agitation, or pain
- Respiratory rate > 35/min
- Oxygen saturation < 88%
- Respiratory distress
- Acute cardiac arrhythmia

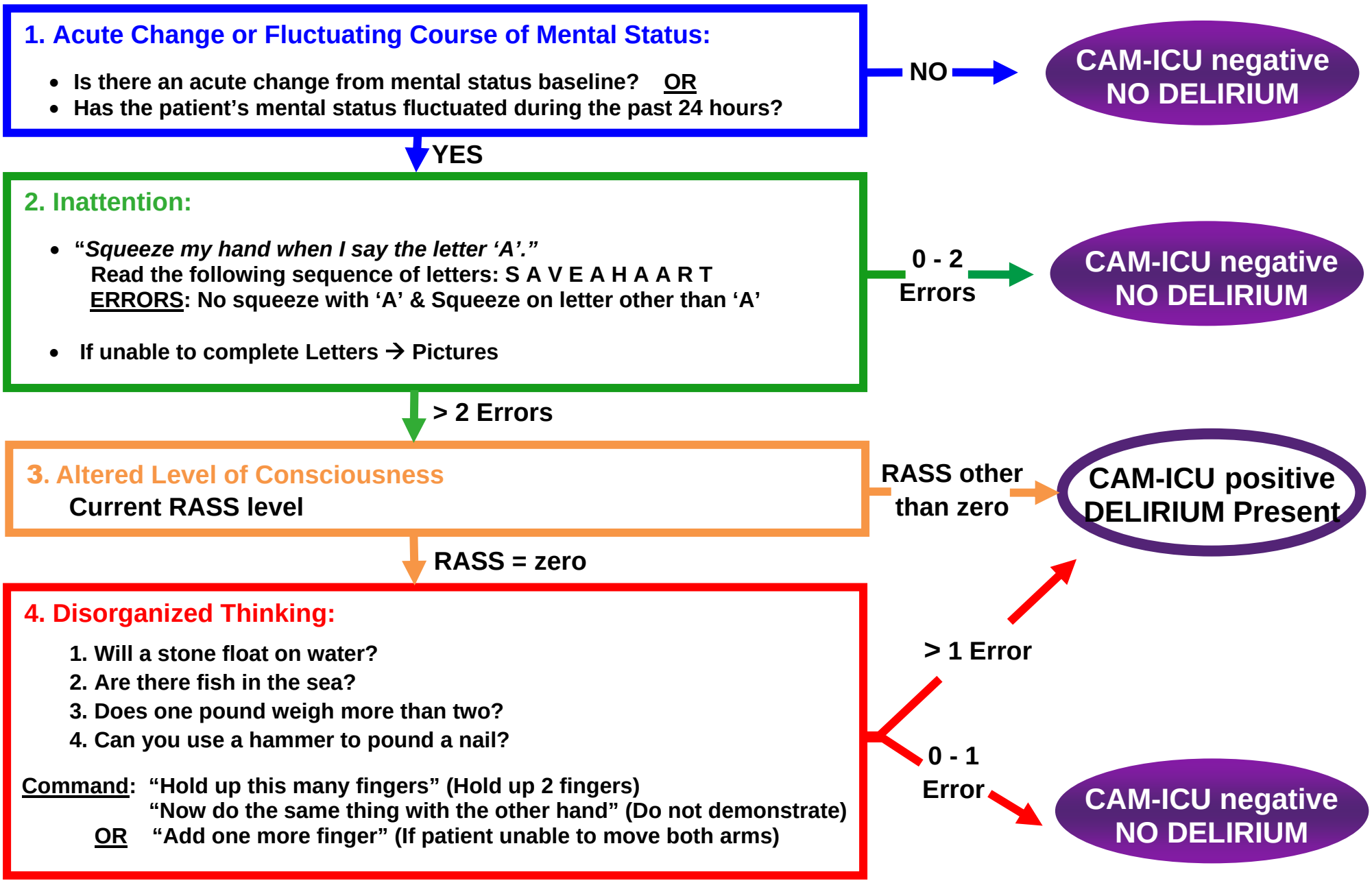
SBT Safety Screen

- No agitation
- Oxygen saturation ≥ 88%
- FiO2 ≤ 50%
- PEEP ≤ 7.5 cm H2O
- No myocardial ischemia
- No vasopressor use
- Inspiratory efforts

SBT Failure

- Respiratory rate > 35/min
- Respiratory rate < 8/min
- Oxygen saturation < 88%
- Respiratory distress
- Mental status change
- Acute cardiac arrhythmia

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



PATIENT EVALUATION	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
Altered level of consciousness* (A-E)					
If A or B do not complete patient evaluation for the period					
Inattention					
Disorientation					
Hallucination - delusion – psychosis					
Psychomotor agitation or retardation					
Inappropriate speech or mood					
Sleep/wake cycle disturbance					
Symptom fluctuation					
TOTAL SCORE (0-8)					

Level of consciousness*:		**Score**
	A: no response	none
	B: response to intense and repeated stimulation (loud voice and pain)	none
	C: response to mild or moderate stimulation	1
	D: normal wakefulness	0
	E: exaggerated response to normal stimulation	1

SCORING SYSTEM :
The scale is completed based on information collected from each entire 8-hour shift or from the previous 24 hours.
Obvious manifestation of an item = 1 point. No manifestation of an item or no assessment possible = 0 point.
The score of each item is entered in the corresponding empty box and is 0 or 1.

1. Altered level of consciousness:
A) No response or B) the need for vigorous stimulation in order to obtain any response signified a severe alteration in the level of consciousness precluding evaluation. If there is coma (A) or stupor (B) most of the time period then a dash (-) is entered and there is no further evaluation during that period.
C) Drowsiness or requirement of a mild to moderate stimulation for a response implies an altered level of consciousness and scores 1 point.
D) Wakefulness or sleeping state that could easily be aroused is considered normal and scores no point.
E) Hypervigilance is rated as an abnormal level of consciousness and scores 1 point.

2. Inattention: Difficulty in following a conversation or instructions. Easily distracted by external stimuli. Difficulty in shifting focuses. Any of these scores 1 point.

3. Disorientation: Any obvious mistake in time, place or person scores 1 point.

4. Hallucination, delusion or psychosis: The unequivocal clinical manifestation of hallucination or of behaviour probably due to hallucination (e.g. trying to catch a non-existent object) or delusion. Gross impairment in reality testing. Any of these scores 1 point.

5. Psychomotor agitation or retardation: Hyperactivity requiring the use of additional sedative drugs or restraints in order to control potential dangerousness (e.g. pulling out iv lines, hitting staff). Hypoactivity or clinically noticeable psychomotor slowing. Any of these scores 1 point.

6. Inappropriate speech or mood: Inappropriate, disorganised or incoherent speech. Inappropriate display of emotion related to events or situation. Any of these scores 1 point.

7. Sleep/wake cycle disturbance: Sleeping less than 4 hours or waking frequently at night (do not consider wakefulness initiated by medical staff or loud environment). Sleeping during most of the day. Any of these scores 1 point.

8. Symptom fluctuation: Fluctuation of the manifestation of any item or symptom over 24 hours (e.g. from one shift to another) scores 1 point.

Fig. 1 The Intensive Care Delirium Screening Checklist

Worksheet for Daily Delirium Assessments with the pCAM-ICU

FEATURE 1. Acute Change or Fluctuating Course of Mental Status →

A. Is there an acute change from mental status baseline? **Yes** or **No**

B. Has my patient's mental status fluctuated during the past 24 hours? **Yes** or **No**

*Evidenced by fluctuation on a sedation scale (RASS), GCS or previous delirium assessment.

If either answer Yes then I circle + → + / —

FEATURE 2. Inattention → **FEATURE POSITIVE** if **SCORE 0-7** on Vigilance "A" test **OR** ASE picture test.

Vigilance "A" Test:

I want my patient to squeeze my hand when I say ONLY the letter A.
I will read the 10 letter sequence in the same order every day, with my normal voice, saying each letter once every second.
Directions to patient: **"Squeeze my hand when I say the letter 'A'. Let's practice, 'A'."**

To score: When I say the letter "A" and the patient does not squeeze my hand, I subtract 1 point.
When I say the other letters and the patient squeezes my hand, I subtract 1 point.

A ____ **B** ____ **A** ____ **D** ____ **B** ____ **A** ____ **D** ____ **A** ____ **A** ____ **Y** ____

If the SCORE is 0 – 7 then I circle + → + / —

OR

ASE Pictures:

I will show the patient "**5 Memory Pictures**." I want the patient to remember the 5 '**Memory Pictures**' when shown a larger '**Deck**' of 10 pictures.

Directions to patient: **"I am going to show you 5 pictures that I want you to remember."** (Show 1 **Picture** every **3 seconds** and state object name.)
Directions if patient can **verbalize**: **"Say yes when you see one of those 5 pictures again."** (Show all pictures from **Deck** and state objects names.)
Directions to **intubated** patient: **"Nod your head yes when you see one of those 5 pictures again."**

OR

To score: If patient nods or says '**yes**' to ONLY the **5 Memory Pictures** they have completed this task successfully – SCORE 10/10.
If the patient does not nod or say '**yes**' to 1 of the **5 Memory pictures**, I will subtract 1 point.
If the patient nods or says '**yes**' to the **other** pictures in the **Deck**, I will subtract 1 point.
Memory Pictures: _____ / 5 Deck Pictures: _____ / 5

If the SCORE is 0 – 7 then I circle + → + / —

FEATURE 3. Altered Level of Consciousness → **FEATURE POSITIVE** if the current RASS score is anything other than '0'.

At time of Sedation Assessment the RASS score was _____ → + / —

FEATURE 4. Disorganized Thinking

Directions if patient can **verbalize**: **"I am going to ask you 4 questions, say "yes or no" to answer."**
Directions to **intubated** patient: "**I am going to ask you 4 questions, nod your head yes or no to answer.**"

Set A		**Set B**	
1. **Is sugar sweet?**	_____	1. **Is a rock hard?**	_____
2. **Is ice cream hot?**	_____	2. **Do rabbits fly?**	_____
3. **Do birds fly?**	_____	3. **Is ice cream cold?**	_____
4. **Is an ant bigger than an elephant?**	_____	4. **Is a giraffe smaller than a mouse?**	_____

5. Directions to patient: "**Hold up this many fingers**." (Examiner holds up 2 fingers for patient to see)
Directions to patient: "**Now do the same thing with the other hand**." (Do not show fingers again to patient)
Directions to patient if unable to move **both** arms: "**Now, add one more finger**."(Do not show fingers again to patient)

To score: If the patient answers a question incorrectly, I will subtract 1 point.
If the patient is not able to complete the command in #5, I will subtract 1 point.

If the SCORE is 0 – 3 then I circle + → + / —

Pediatric Delirium = Feature 1 _____ **+ Feature 2** _____ **+ EITHER Feature 3** _____ **OR Feature 4** _____

Present
Absent

Exercise/Mobility Screening and Therapy

Step 1: Exercise/Mobility Safety Screen (Patients must pass this safety screen in order to get therapy)

M – Myocardial stability
- No evidence of active myocardial ischemia (24 hrs)
- No arrhythmia requiring the administration of a new antiarrhythmic agent (24hrs)

O – Oxygenation adequate on
- $FIO_2 \leq 0.6$
- PEEP $\leq$10 cm H2O

V – Vasopressor(s) minimal
- No increase dose of any vasopressor infusion for at least 2 hours

E – Engages to voice
- Patient responds to verbal stimulation (i.e., RASS $\geq$ -3); range of motion may be performed in comatose patients, but will not be considered part of the Early Exercise Protocol (Some protocols may expand to include range of motion in comatose patients)

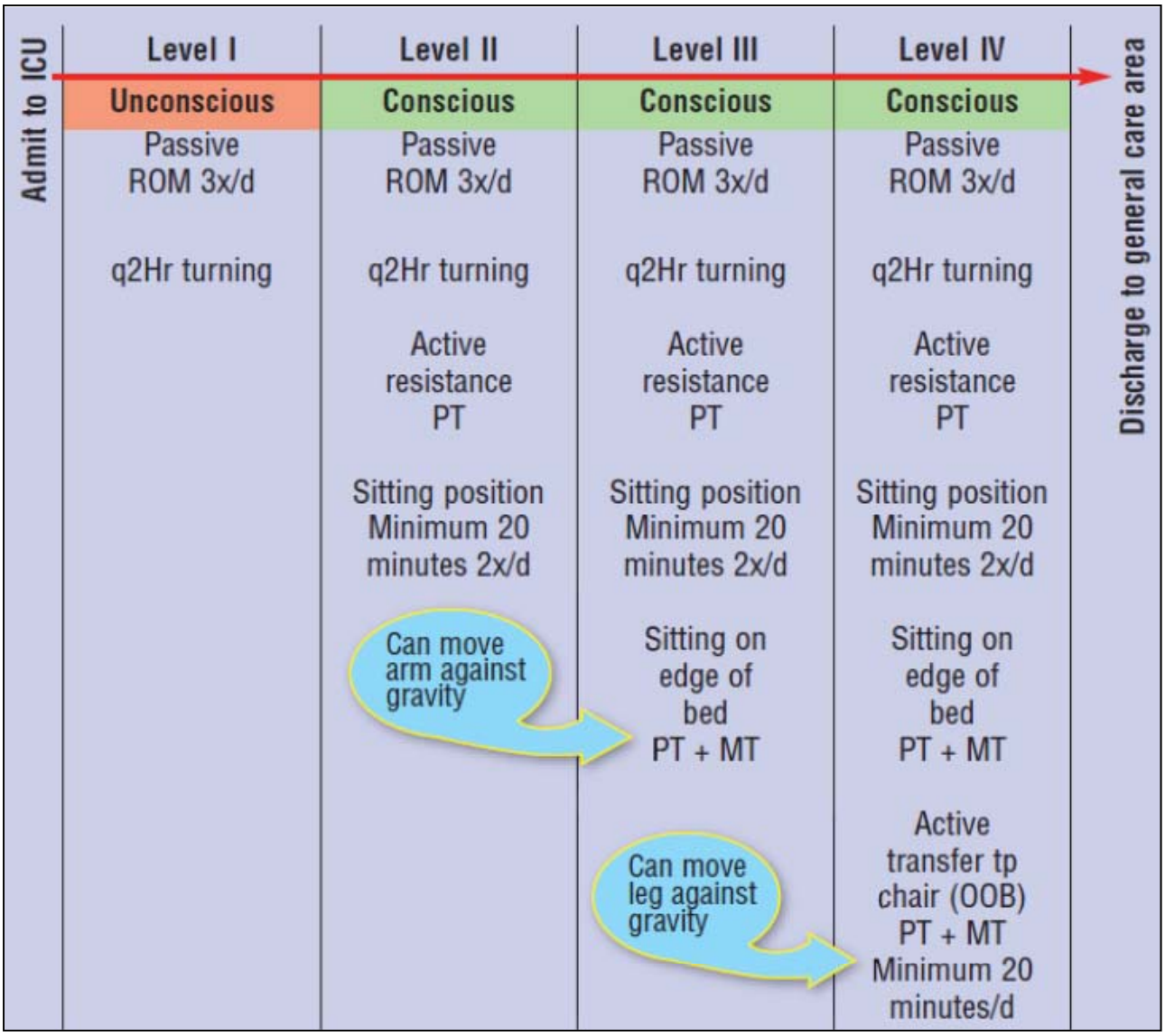
If the patient fails the Exercise/Mobility safety screen→If a patient does not meet all of the criteria above then he/she fails the safety screen and should not have the Exercise/Mobility protocol performed. In essence the patient is to critically ill to tolerate exercise and/or movement.

If the patient passes the Exercise/Mobility safety screen→ If a patient meets all of the safety criteria then he/she may move to Step 2: Exercise/Mobility Therapy

Step 2: Exercise/Mobility Therapy Once patients pass the safety screen they mayprogress to have therapy performed. Therapy should be started at Level 1 (see listing below) and progress as the patient tolerates to Level 4; however, completion of any activity listed below is considered compliant with Exercise/Mobility Therapy. All events can be performed with assistance. The activities can be performed by bedside staff, including but not limited to the RN, PT, and OT as well as family members and patients themselves.

Levels of Progressive Mobility:
Level 1: Active ROM exercises in bed and/or sitting position in bed; this includes bed adjustment, passive transfer, or with lift assistance
Level 2: Dangling
Level 3: Transfer to chair (active), includes standing without marching in place
Level 4: Ambulation (marching in place, walking in room/hall)

Progressive Mobility Protocol



Passive range of motion (ROM) therapy is started on day 1 of protocol (level I). As patients demonstrate consciousness and increased strength, they move to the next higher level. Physical therapy (PT) is first attempted at level II. Intervention is ceased as patient transfers to general care area; patients within both “protocol” and “usual care” groups receive usual care mobility therapy (MT) as dictated by physician teams in general care areas. OOB = out of bed.

Ross AG, Morris PE. *Crit Care Nurse.* 2010;30(2 suppl):S11-S13.

Journal Club Exercises

- **Anne S. Pohlman, APN-CNS, FCCM,** Critical Care Clinical Nurse Specialist, Department of Medicine, Section of Pulmonary and Critical Care, University of Chicago, Chicago, Illinois
- **Brenda T. Pun, RN, MSN, ACNP,** Program Clinical Manager, Vanderbilt University Medical Center, Nashville, Tennessee

During our session at the 2012 AACN NTI, we reviewed the ABCDE bundle and highlighted interventions to overcome barriers to implementing this strategy. One of the common barriers to implementing any change in practice involves staff education – specifically, familiarity with the current literature. Journal Clubs have been found to foster a culture of research appreciation, enhance familiarity with current literature, and promote enthusiasm for participation in research.

To assist you with starting a Journal Club in your unit, we have selected key journal articles that correspond to the letters in the ABCDE bundle. The pages that follow are prepared templates to facilitate a Journal Club discussion for each of these articles. These helpful guides will make it easy for you or another nurse facilitator to lead discussions on each article's key points. We encourage you to distribute the journal articles to your ICU staff and set a series of dates for Journal Club discussions on this topic. Using the facilitator guides as a tool, your evidence-based discussions will be a success!

Journal Club tips:

- Finding the articles: Go to the AACN Web site (www.AACN.org) and open the Clinical Practice menu. You will find links to numerous sources of key information and articles related to clinical practice. You may also locate the articles using your hospital library resources.
- Distribute the articles to staff 2 weeks prior to the Journal Club session.
- Highlight the concept of ***evidence-based practice*** and make the Journal Club discussion relevant to practice in *your* ICU.
- Journal Club participants should include nurses from all shifts, and may include any of the multidisciplinary staff in the unit (RT, PT/OT, PharmD, MD).
- Leading the discussion: Follow the steps in each facilitator guide, and encourage staff participation throughout the discussion.
  - Describe the situation or clinical issue that attracted this article
  - Describe the study and review the research question
  - State the importance/relevance of the research question to your unit
  - Review the methods and results of the study
  - Review the validity and applicability of the study
  - Conclude with a discussion of the study's utility for your unit. Ask these important questions: ***What do we do now? Any ideas for change in our unit practice?***
- Make it easy to attend and participate: Short (15- to 30-minute) sessions!

Articles:

AB = Awakening and Breathing Trial coordination: Girard TD, Kress JP, Fuchs B, et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomized controlled trial. *Lancet.* 2008;371:126-134.

C= Choice of sedative: Riker RR, Shehabi Y, Bokesch PM, et al. Dexmedetomidine vs. midazolam for sedation of critically ill patients: a randomized trial. *JAMA.* 2009;301:489-499.

D = Delirium identification and management: Ely EW, Shintani A, Truman B, et al. Delirium as a predictor of mortality in mechanically ventilated patients in the intensive care unit. *JAMA.* 2004;291:1753-1762.

E = Early mobility: Schweickert WD, Pohlman MC, Pohlman A, et al. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomized controlled trial. *Lancet.* 2009;373:1874-1882.

Journal Club Facilitator Guide: ABCDE Bundle

Session 1 of 4

Publication: *Lancet.* 2008;371:126-134.

Title: **Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomized controlled trial.**

Authors: Girard TD, Kress JP, Fuchs B, Thomason JW, Schweickert WD, Pun BT, Taichman DB, Dunn JG, Pohlman AS, Kinniry PA, Jackson JC, Canonico AE, Light RW, Shintani AK, Thompson JL, Gordon SM, Hall JB Dittus RS, Bernard GR, Ely EW.

Discussion Points

I. Describe situation or clinical problem that attracted you to paper

- This is one of the primary publications for the **AB**CDE Bundle
- Implementing evidence-based practice in the ICU

II. Describe the study

Prospective, multicenter, randomized, controlled study to assess the efficacy and safety of a protocol of daily spontaneous awakening trials (SATs) paired with daily spontaneous breathing trials (SBTs) versus a standard SBT protocol in patients receiving patient-targeted sedation as part of usual care.

III. Describe the research question

Can routine daily SATs improve patient outcomes when combined with routine daily SBTs in adult mechanically ventilated patients?

IV. State the importance/relevance of the question

Recent studies have shown that implementing ventilator weaning protocols and sedation protocols in the ICU can decrease duration of mechanical ventilation (MV). Unfortunately, few patients are managed with these strategies due to ongoing disagreement among healthcare professionals with regard to benefits and risks, as well as challenges linked to implementation of these protocols by multidisciplinary healthcare providers. This protocol was designed to study outcomes related to these interventions done by bedside ICU nurses and respiratory therapists during the course of routine care.

V. Describe the methods giving detail on the question components

Adult patients from four large medical centers (one in Nashville, one in Chicago, and two in Philadelphia) were enrolled in this study. ICU patients who required MV for >12 hours were eligible for enrollment. Patients were excluded if they were admitted post cardiac arrest, had required continuous MV for >2 weeks prior to enrollment, were considered moribund in which death was perceived to be imminent, or if they had profound neurological deficits such as severe dementia or large stroke. Written consent was obtained from participants or their authorized surrogates.

- Enrolled patients were randomly assigned to 2 groups:
  Group 1: Control = usual ICU care including a daily SBT
  Group 2: Intervention = daily paired SAT + SBT

All patients received patient-targeted sedation, titrating sedative and analgesic doses to maintain the level of arousal and comfort deemed clinically appropriate by the ICU team for each patient. Beginning the morning after enrollment, the ICU nurses, respiratory therapists, and study personnel managed patients according to study treatment protocols (Figure 1 in manuscript). Defined safety screens for both SAT and SBT were assessed prior to initiating each daily intervention. Patients who passed the safety screen underwent interventions required for the study group. Patients who failed the safety screen were reassessed the following morning. Additional details of interventions and safety screens can be found in the manuscript.

- Interventions:
  SAT: All sedatives and analgesics (if used for sedation) were stopped and restarted at half of the previous amount if/when patient showed signs of needing them.
  SBT: Ventilatory support removed and patient changed to t-tube or CPAP 5 cm/H_2O.

Daily study intervention success and failure measures are defined in the manuscript. SAT/SBT success – ICU team notified to determine decision to extubate. SAT failures – restart sedatives at 50% of dose, titrate to goal. SBT failures – return to MV settings used prior to trial. Resume care and re-evaluate the next day.

VI. Describe primary results

- 336 patients were enrolled and randomized. 168 patients in each study group.
- Main outcomes are found in Table 3 of manuscript.
  - ⇒ **Efficacy**: Paired sedation and ventilator weaning protocol consisting of daily SATs plus SBTs resulted in patients spending more time off MV, less time in coma, and less time in ICU and hospital. Additionally, for every 7 patients treated with this intervention, one life was saved.
  - ⇒ **Safety**: More patients in the SAT + SBT group self-extubated than in the control group; however, the number of patients requiring re-intubation was similar between groups.

VII. Appraisal of study validity

Patients were prospectively randomized and analyzed with an intention-to-treat approach. The two study groups were similar at baseline (results found in Table1 of manuscript). The patients and critical care communities that participated were heterogeneous. Patients were analyzed in the groups to which they were randomized. Clinicians were not blinded to study group. Follow-up survival data are reported at 1 year.

VIII. Why results can be applied to the situation or clinical problem

The multicenter study design included enrollment from both community and university hospital settings. This study enrolled only nonsurgical patients because of their potential need for continuous analgesia. Additional studies are needed to test this intervention in this population. Clearly defined safety screens for both SAT and SBT interventions are provided in the protocol. Defined success and failure endpoints for the interventions are given in the manuscript. The protocol was designed to be done by bedside nurses and respiratory therapists during the course of routine care.

IX. Utility of study in your practice

Results of this study suggest that the use of a paired daily SAT with daily SBT for the management of MV ICU patients results in better outcomes and should become routine practice. Bedside ICU nurses and respiratory therapists need to become familiar with the results and details of this trial to optimize patient outcomes in their own units.

Journal Club Facilitator Guide: ABCDE Bundle

Session 2 of 4

Publication: *JAMA.* 2009;301:489-499.

Title: **Dexmedetomidine vs. midazolam for sedation of critically ill patients: a randomized trial**

Authors: Riker RR, Shehabi Y, Bokesch PM, Ceraso D, Wisemandle W, Koura F, Whitten P, Margolis BD, Byrne DW, Ely EW, Rocha MG.

Discussion Points

I. Describe situation or clinical problem that attracted you to paper

- This is one of the primary publications for the AB**C**DE Bundle
- Implementing evidence-based practice in the ICU

II. Describe the study

Prospective, multicenter, double-blind, randomized trial to compare the efficacy and safety of prolonged sedation (>24 hours) with dexmedetomidine vs. midazolam for mechanically ventilated (MV) patients.

III. Describe the research question

Can a sedation strategy using dexmedetomidine (DEX) result in improved outcomes in MV ICU patients compared with midazolam (MZ)?

IV. State the importance/relevance of the question

Sedation is an integral component of bedside care in the ICU. Current sedative agents can be problematic when used long term. Selection of the best sedative agent, route, and dose to optimize patient comfort has challenged bedside practitioners for decades. Few studies have compared the GABA receptor agonists (including propofol and benzodiazepines, such as midazolam) with other drug classes. This protocol is designed to compare DEX (an α_2 agonist) with MZ (a GABA receptor agonist), focusing on the percentage of time the subject remains within the targeted sedation range RASS (-2 to +1).

V. Describe the methods, giving detail on the question components

MV adult patients from 68 medical centers in 5 countries were enrolled in this study. Patients on MV for <96 hours and anticipated to remain on MV and sedation for at least 3 more days were eligible for enrollment. Patients were excluded if they were admitted for trauma, burns, dialysis, pregnancy, serious CNS pathology, liver disease, unstable angina, acute MI, heart block, and hypotension despite use of vasoactive drugs. Written consent was obtained from participants or their authorized surrogates.

- Enrolled patients were randomly assigned in a 2:1 ratio to 2 groups.
  Group 1: DEX infusion 0.2-1.4 μg/kg/hr
  Group 2: MZ infusion 0.02-0.1 mg/kg/hr

All patients had the sedative infusions titrated for light sedation (RASS –2 to+1). Infusions were administered for up to 30 days. (Note: Dex is currently approved for a maximum dosage of 0.7μg/kg/hr for 24 hours, so this study investigated it outside of package labeling). All patients underwent daily arousal assessments and drug titration every 4 hours. Analgesia with fentanyl bolus doses could be administered as needed for pain. Patients in either group not adequately

sedated by study drug could receive open-label MZ bolus doses. Sedation infusions were stopped for extubation. Additional details of interventions can be found in the manuscript.

VI. Describe primary results

- 375 med/surg patients were enrolled. DEX = 244; MZ = 122.
- Main outcomes found in Table 2 of manuscript.
  - ⇒ **Efficacy**: There was no difference in percentage of time within the target RASS range between groups. At comparable sedation levels, DEX-treated patients spent less time on MV and experienced less delirium. The duration of study drug treatment was shorter with DEX, mostly because DEX patients were extubated more rapidly. Open-label MZ was administered to more DEX patients.
  - ⇒ **Safety**: 30-day mortality was not different between groups. DEX-treated patients developed more bradycardia (HR <60 bpm), but were equal to MZ-treated patients in clinically signficant bradycardia that required intervention (HR <40 bpm). MZ-treated patients had a higher incidence of tachycardia and hypertension. Analysis of both drugs in patients with renal dysfunction concluded the effects of both drugs were prolonged.

VII. Appraisal of study validity

Patients were prospectively randomized 2:1 to the DEX group to obtain safety data for long-term use. The two study groups were similar at baseline (Table1 of manuscript). Clinicians were blinded to study group.

VIII. Why results can be applied to the situation or clinical problem

This was a large multicenter study with enrollment in both community and university settings around the world. It is unknown whether the benefits of DEX would be seen in these patients. Clearly defined medication administration protocol is provided in the manuscript.

IX. Utility of study in your practice

This study shows that when elements of best sedation practice (including daily arousal, consistent light-to-moderate sedation level, and delirium monitoring) are used for all patients, the choice of DEX for sedation further improves these important outcomes. It also confirms that DEX infusion rates up to1.4 μg/kg/hr for up to 30 days provide sedation similar to MZ, are safe, and are associated with improved outcomes. Bedside ICU nurses and clinicians need to become familiar with the results and details of this trial to optimize patient outcomes in their own units.

Journal Club Facilitator Guide: ABCDE Bundle

Session 3 of 4

Publication: *JAMA.* 2004;291:1753-1762.

Title: **Delirium as a predictor of mortality in mechanically ventilated patients in the intensive care unit.**

Authors: Ely EW, Shintani A, Truman B, Speroff T, Gordon SM, Harrell FE, Inouye SK, Bernard GR, Dittus RS.

Discussion Points

I. Describe situation or clinical problem that attracted you to paper

- This is one of the primary publications for the ABC**D**E Bundle
- Implementing evidence-based practice in the ICU

II. Describe the study

Prospective, observational cohort study to determine if delirium in the ICU is an independent predictor of 6-month mortality and length of stay among patients receiving mechanical ventilation (MV).

III. Describe the research question

Can delirium in the ICU predict 6-month mortality and length of stay outcomes among patients receiving MV?

IV. State the importance/relevance of the question

Delirium is a common yet underdiagnosed form of organ failure. While the published incidence of delirium is substantial, different studies have yielded rates varying from 32% to greater than 80%. In the absence of data linking delirium to patient outcomes, few ICUs routinely monitor for delirium. Valid and reliable instruments are available to measure both level of arousal (e.g., RASS, SAS) and delirium (e.g., CAM-ICU, ICDSC) in ICU patients. Using the RASS and CAM-ICU, this protocol tests the hypothesis that delirium in the ICU is an independent predictor of 6-month mortality and length of stay.

V. Describe the methods, giving detail on the question components

Adult MV patients admitted to the medical or coronary ICUs of a university hospital were enrolled in this study. Patients were excluded if they had a primary neurologic disease, were unable to speak or understand English, were extubated prior to enrollment, or refused consent to participate. Written consent was obtained from participants or their authorized surrogates.

- Enrolled patients were assigned to 2 groups based on daily neurologic assessments.
  Group 1 = delirium: If the patient ever had delirium while in the ICU.
  Group 2 = no delirium: If the patient never had delirium while in ICU.

Patients' neurologic status was assessed daily by the study nurses and defined as normal, delirious, or comatose using a 1- to 2-minute neurologic assessment that objectively measured patient arousal and delirium status. Arousal = Richmond Agitation-Sedation Scale (RASS); Delirium = Confusion Assessment Method for the ICU (CAM-ICU). Additional details of interventions and data collection can be found in the manuscript.

VI. Describe primary results

- 275 patients were enrolled. 51 patients never woke up from coma and experienced 100% mortality. The remaining 224 patients were included in this analysis.
- Group 1 Delirium, n= 41; Group 2 No Delirium, n=183.
- Main outcomes found in Table 3 of the manuscript.
  - ⇒ Overall, patients spent 21.6% of their ICU days as normal, 43.1% as delirious, and 35.3% as comatose. Of the patients who were alert or easily arousable as measured by a RASS score of 0 or –1, more than half (54.5%) were delirious.
  - ⇒ Patients who developed delirium had a higher 6-month mortality rate and spent 10 days longer in the hospital than those that never developed delirium.
  - ⇒ Development of delirium in MV patients was associated with a 3-fold increase in risk of death after controlling for pre-existing comorbidities, severity of illness, coma, and use of sedative and analgesic medications.

VII. Appraisal of study validity

This single-center observational study was not designed to prove a cause-and-effect relationship between delirium and clinical outcomes. This study demonstrates an important clinical association as well as the need for further examination. The two study groups were similar at baseline (Table 1 of manuscript). Clinicians were not blinded to study group. Six-month mortality data is reported in the manuscript.

VIII. Why results can be applied to the situation or clinical problem

This prospective study included enrollment of consecutive MV patients admitted to adult medical and coronary ICUs of a university hospital. Patients were followed daily for development of delirium over 2158 ICU days. Additional studies are needed to incorporate other types of ICU patients, such as those with trauma or underlying neurologic disease. The neurological assessments were designed to be done by bedside nurses during the course of routine care.

IX. Utility of study in your practice

Results of this study suggest that delirium was an independent predictor of higher 6-month mortality and longer hospital stay, even after adjusting for relevant covariates, including coma, sedatives, and analgesics in patients receiving MV. The study raises the question of how diligently delirium should be monitored in acutely ill patients. Bedside ICU nurses and clinicians need to become familiar with the results and details of this trial to optimize patient outcomes in their own units.

Journal Club Facilitator Guide: ABCDE Bundle

Session 4 of 4

Publication: *Lancet.* 2009;373:1874-1882.

Title: **Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomized controlled trial.**

Authors: Schweickert WD, Pohlman MC, Pohlman A, Nigos C, Pawlik AJ, Easbrook CL, Spears L, Miller M, Franczyk M, Deprizio D, Schmidt GA, Bowman A, Barr R, McCallister KE, Hall JB, Kress JP.

Discussion Points

I. Describe situation or clinical problem that attracted you to paper

- This is one of the primary publications for the ABCD**E** Bundle
- Implementing evidence-based practice in the ICU

II. Describe the study

Prospective, multicenter, randomized controlled study to assess the efficacy of combining daily sedation awakening trial (SAT) with early physical and occupational therapy (PT/OT) on functional outcomes in ICU patients receiving mechanical ventilation (MV).

III. Describe the research question

Can adding early PT/OT to daily SAT interventions improve functional and neuropsychiatric outcomes in ICU patients receiving MV?

IV. State the importance/relevance of the question

Recent studies have shown improved outcomes and survival rates for ICU patients receiving mechanical ventilation. As patients survive acute illness, long-term complications, such as ICU-acquired weakness and delirium secondary to critical illness, have become more apparent. Weakness is a frequent complication, is associated with major disability, and often requires protracted rehabilitation. ICU staff focus on treating circulatory, respiratory, and renal function to ensure survival. As a result, maintaining patients on life-sustaining equipment and interventions often requires long periods of unconsciousness and immobility. This protocol is geared to study outcomes related to optimizing daily sedation combined with early mobilization interventions by PT/OT.

V. Describe the methods, giving detail on the question components

Adult patients from two university hospitals (Chicago and Iowa) were enrolled in this study. Neither site routinely provided PT/OT for MV patients, nor had a dedicated therapist for such practice prior to the study. ICU patients who had been on MV <72 hours and were expected to stay on for >24 hours, and who met criteria for baseline functional independence, were eligible for enrollment. Independent functional status was defined as "the ability to perform six activities of daily living and the ability to walk independently." Patients were excluded if they were admitted post cardiac arrest, had increased intracranial pressure, had a rapidly developing neuromuscular disease, or had an irreversible disorder with 6-month mortality estimated at more than 50%. Written consent was obtained from participants or their authorized surrogates.

- Enrolled patients were randomly assigned to 2 groups.
  Group 1: Control = usual care, daily SAT, therapy services as ordered by the ICU team
  Group 2: Intervention = Early PT/OT during daily SAT

All patients received goal-directed sedation guided by the Richmond Agitation-Sedation Scale (RASS) and underwent daily SAT. All patients were weaned from MV using SBT weaning protocol and received protocolized enteral feedings and glucose monitoring. After enrollment, ICU nurses and study personnel managed patients according to study treatment protocols. Defined safety screens for both SAT and PT/OT were assessed prior to initiating each daily intervention. Patients who failed the safety screen were reassessed the following morning. Additional details of interventions and safety screens can be found in the manuscript.

In the intervention group, daily SAT was initiated and, once patient interaction was achieved, PT/OT sessions began. Therapy sessions began with active-assisted exercises and progressed to bed mobility activities, sit-stand transfers, and finally walking. Progression of activities was dependent on patient tolerance and stability. Daily study intervention success and failure measures are defined in the manuscript. PT/OT staff providing daily therapy interventions was different from those assessing study outcomes. Blinded PT/OT staff assessed patients every 48 hours for strength, ability to perform ADLs, and ability to walk. Research staff, bedside RNs, and PT/OT staff monitored safety continuously during the study.

VI. Describe primary results

- 104 patients were enrolled and randomized. Control group, n=55; intervention group, n=49.
- Main outcomes found in Table 3 of manuscript.
  - ⇒ **Efficacy**: Daily interruption of sedation combined with PT/OT from the start of critical illness resulted in an improved return to independent functional status at hospital discharge compared with standard care. Patients in the intervention group had shorter duration of ICU-associated delirium and more ventilator-free days than control patients.
  - ⇒ **Safety**: Early PT/OT intervention was found to be safe. There was one serious adverse event (i.e., desaturation <80%) in 498 therapy sessions. Discontinuation of therapy as a result of patient instability occurred in 19 sessions (4%), most commonly for perceived patient ventilator asynchrony.

VII. Appraisal of study validity

Patients were prospectively randomized and analyzed with an intention-to-treat approach. The two study groups were similar at baseline (Table 1 of manuscript). The patients and critical care communities that participated were heterogeneous. Patients were analyzed in the groups to which they were randomized. Clinicians performing outcome assessments were blinded to study group.

VIII. Why results can be applied to the situation or clinical problem

This study design included enrollment of ICU patients from the MICU with a variety of diagnoses, including acute lung injury, sepsis, and asthma. Prior to ICU admission, these patients had a baseline functional independence as measured by the Barthel Index score. Additional studies are needed for application to other types of ICU patients. Adherence to protocol results can be found in Table 2 of the manuscript. The protocol was designed to be completed by bedside nurses and PT/OT therapists during the course of routine care.

IX. Utility of study in your practice

Results of this study suggest patients assigned to early PT/OT during SAT had a shorter duration of delirium and left the hospital with better functional status than the control group. Early activity is feasible and safe. This study highlights the robust outcomes that can be achieved with the coordinated efforts of multiple disciplines dedicated to the survival and mental and physical recovery of critically ill patients. Bedside ICU nurses and therapists need to become familiar with the results and details of this trial to optimize patient outcomes in their own units.