ABCDEF Flagler Protocol for Patients on Ventilator

Awakening, Spontaneous Breathing, Coordination, Delirium, Early Mobilization, Family Engagement

Every patient on ventilator in the adult ICUs at Flagler Hospital will be eligible for this protocol. As with any protocol, this protocol serves to provide evidence-based, comprehensive recommendations to guide our multidisciplinary team in patient care, with the expectation that expert practitioners will modify and customize as necessary to meet individual patient needs. This protocol is not intended to replace the practitioner's judgment; it is intended to provide guidance to the physician for the group of patients described in the protocol.

Ventilator weaning and extubating are two distinct processes. The process of weaning ventilator parameters is dynamic and will be guided by a lung protective strategy:

- Use of tidal volume target 6 mL/kg PBW, with allowances for 4–8 mL/kg PBW to minimize asynchrony between the patient and ventilator.
- PEEP and FiO2 adjustments guided by the PEEP-FiO2 table to keep plateau pressure <30 and driving pressure <15 using the lowest FIO2 possible targeting a PaO2/FiO2 ratio >300, O2 Sat 90-96 % and PaCO2 37- 45 mmHg unless otherwise indicated.

The extubation planning will be applicable once the patient's respiratory status has improved and overall patient's clinical condition has stabilized.

Light target level of Sedation should be used to keep patient comfortable and promote liberation from the ventilator.

- Goal is a RASS scale of *0 to -1 (0: alert and comfortable, -1*: drowsy, not fully alert, but sustained awakening with eye contact to voice along with non verbal pain scale-revised (NVPS-R) ≤2 (relaxed and comfortable) with allowances for RASS +1 to -2 to prevent over or under sedation, facilitate ventilator synchrony and ameliorate stress response to pain and anxiety while the patient on ventilator (see RASS and BPS appendices and PAD algorithm)*:*
- Reassess Q4h to meet goal, document RASS and BPS Q4h

Maintenance of Pain/Agitation/Delirium (PAD) Protocol

For pain control will use a multi-modal analgesia approach including fentanyl at the lowest effective dose along with the simultaneous use of ketamine, acetaminophen, neuropathic agents, and nonsteroidal anti-inflammatory drugs (NSAIDs) based on specific patient's condition.

Once patient is intubated and placed on mechanical ventilatory support, will activate the ventilator bundle order set following the PAD protocol (see PAD algorithm):

Give fentanyl 50 mcg IV push immediately after intubation and initiate fentanyl IV infusion at 50 mcg/h and propofol IV infusion at 10 mcg/kg/min unless contraindicated as determined by the intensivist or advanced practice provider (APP). Assess NVPS-R and RASS at least q15min until stabilization is achieved. If nonverbal pain score-revised (NVPS-R) ≤2 and RASS ≤0, move to maintenance PAD protocol.

If NVPS-R >3 or RASS >0, bolus fentanyl IV 50 mcg q10min until patient is comfortable to a maximum of 200 mcg/h. If patient continues with NVPS-R >3 or RASS >0 despite above, increase fentanyl and propofol IV infusions to a maximum of 200 mcg/h and 50 mcg/kg/min respectively and notify intensivist/APP.

Consider scheduled Acetaminophen 650 mg q6h via OGT unless patient with acute liver injury or active alcohol drinker or need for detection of fever including patients with neutropenia.

Consider use of NSAID in patients with adequate renal function on no other nephrotoxic medications, absence of cirrhosis or inflammatory bowel disease, no history of GI bleed and no active hemorrhage or coagulopathy.

- Ketorolac: 15 mg IV q6hr PRN for BPS >3 or Ibuprofen 400 mg PO q6hr PRN for BPS >3. Discontinue the NSAID as soon as possible and avoid them for >5 days.

Consider use of Gabapentin 300-1200 mg q8hr or Pregabalin: 75-150 mg q12hr in patients with neuropathic pain. Both agents should be dose-reduced in renal dysfunction.

Encourage early mobilization and physical therapy.

After 4 hours of stability with NVPS-R ≤2 and RASS 0 to -1 with allowances for RASS +1 to -2 on individual basis, the patient will be a candidate for daily SAT/SBT screening criteria).

PAD - special situations

For patients with suspect opioid induced tolerance, hyperalgesia, or complication from opioids, will use adjunct low dose ketamine. If RASS >1 despite fentanyl infusion at 200 mcg/h and propofol 50 mcg/kg/min, start ketamine IV infusion, unless contraindicated, at 2 mcg/kg/min to a maximum of 5 mcg/kg/min.

If patient remains with RASS ≥2 despite above regimen will consider the use of adjunctive sedation using lorazepam or midazolam 2 mg IV boluses q15min as needed x1h. If boluses are required for more than 2 consecutive hours, lorazepam or midazolam IV infusion can be started at 2 mg/h to a maximum of 10 mg/h.

For patients with prolonged use of fentanyl IV infusion for ≥7 days with acceptable oxygenation and plans for transition to pressure support in the next 24-48 hours will consider initiation of oral oxycodone or hydromorphone to help facilitate fentanyl IV infusion weaning. For patients with

chronic use of narcotics will consider the same approach regardless of the time on fentanyl IV infusion.

- Reduce infusion of fentanyl IV drip to ≤150 mcg/h
- Initiate Oxycodone 50 to 150 mg or Hydromorphone 20 to 60 mg: divide total dose in intervals every 4 or 6 hours
- Once oral replacement is initiated will attempt to reduce the fentanyl IV infusion by 25% or more daily to discontinue it. If a patient develops symptoms of withdrawal will use fentanyl IV boluses as needed.
- Once the fentanyl IV infusion has been discontinued it for ≥24 hours will initiate the weaning of the oral replacement (oxycodone or hydromorphone) by reducing the dose and the intervals progressively with the goal of discontinuing them in narcotics naive patients or to return to home dose in chronic users.

For patients on propofol IV infusion will monitor triglyceride at baseline, day 3 and then weekly. Will consider using alternative sedatives if triglyceride > 500.

For patients with intolerance to propofol, will use IV infusions of dexmedetomidine starting at dexmedetomidine at 0.4 mcg/kg/h to a maximum of 1.5 mcg/kg/h, or lorazepam or midazolam at the doses described above.

Use ketamine infusion at 1-5 mg/Kg/h – Off label use

- This may be necessary if everything as above fails especially in patients with profound hypotension, which limits the ability to give sedatives i.e., propofol, dexmedetomidine or benzodiazepines.
- After the patient is fully dissociated with ketamine, other sedatives and analgesics should be discontinued.

If NVPS-R ≤3 and RASS 0 to -1, reassess hourly. After 4 hours of stability once goal level of sedation is achieved, the patient will be a candidate for daily SAT/SBT screening criteria).

Protocol exceptions

For patients with the clinical conditions described below, the sedation goal will be RASS -4 or -5:

- Use of neuromuscular blockade (never to be initiated without prior adequate sedation)
- Life threatening hemodynamic instability
- Persistent PaO2/FiO2 ratio <100 on full mechanical ventilatory support or ventilatory dyssynchrony with O2 Sat <90% when attempting to decrease the level of sedation
- Intracranial pressure (ICP) >20 mmHg or suspected elevation of ICP
- Seizures within 24 hours
- Temperature targeted protocol for initial 24 hours

For patients with alcohol withdrawal syndrome, a modified PAD protocol will be followed.

Awakening - Registered nurse (RN) driven

Step 1: Safety Awakening Screen - All ventilated patients should be screened daily for appropriateness of a spontaneous awakening trial (SAT). Sedation should be weaned or removed daily unless contraindicated by the following **SAT exclusion criteria:**

- Active agitation with RASS ≥2
- Severe hypoxemia requiring FiO2 >60% unless directed by intensivist provider
- Deteriorating respiratory status
- Hemodynamic instability (e.g., Active titration of vasopressors)
- Active cardiac process (e.g., active ischemia/arrhythmia)
- Neuromuscular blockade
- Unstable airway or spine
- Active seizures within 24 hours
- Elevated ICP
- TTM protocol for initial 24 hours
- Planned OR/Procedure
- Comfort focus care

Step 2: SAT trial - **Hold sedation**
Usually, it will be performed in a sequential manner by decreasing the sedative/analgesic infusions rate with the goal to turn them off with exception of dexmedetomidine and ketamine, starting with propofol infusion by 10 mcg/kg/h every 10 - 15 minutes followed by decreasing the fentanyl by 25/mcg/h every 10 - 15 minutes until the patient is fully awake with assessment as needed of the patient's need for pain medications (see PAD algorithm protocol). Another alternative will be decreasing the fentanyl infusion by 25/mcg/h every 10 – 15 down to 25/mcg/h and then titrate down the propofol.

For patients at risk for hyperactive delirium requiring fentanyl and propofol IV infusions and meet criteria for SAT, in addition to the propofol and fentanyl infusions, start dexmedetomidine at 1 mcg/kg/h. After an overlapping of ½ hour, start decreasing the propofol and fentanyl infusions as described before. The dexmedetomidine infusion can be titrated up to a maximum of 1.5 mcg/kg/h.

Titrating patients off of Dexmedetomidine:

After a 4-hour period of stabilization with BPS ≤3 and RASS 0 to -1, titrate down the dexmedetomidine infusion as tolerated to discontinue it. Monitor for signs/symptoms of withdrawal: positive CAM-ICU, RASS > +1, tachycardia (HR >90), and hypertension (SBP > 140mmHg or MAP > 90).

Consider initiation of enteral clonidine 0.1mg every 6 hours (can titrate up to clonidine 0.3mg every 6 hours) either:

- As a treatment for dexmedetomidine withdrawal symptoms as described above
- As an option to preemptively facilitate transition of care for those being weaned off of a dexmedetomidine infusion in preparation for transfer out of ICU

Once patient weaned off of dexmedetomidine infusion, taper down dose of enteral clonidine by increasing dosing interval to ensure that clonidine is not inadvertently continued upon patient discharge (ex: for a clonidine maintenance regimen of 0.3mg every 6 hours, the dosing interval is increased to 0.3mg every 8 hours for 1-2 days, then 0.3mg every 12 hours for 1-2 days, then 0.3mg daily, then stopped).

SAT failure criteria: If after reducing or holding sedatives any of the following occurs for longer than 5 minutes (or less on case-by-case basis), the sedation will be resumed at a lower dose if possible:

- RASS ≥2
- SaO2 <90%
- RR >35
- Acute cardiac arrhythmia
- Two or more of the following:
    - HR increases >20 bpm
    - HR <55 bpm
    - Use of accessory muscles
    - Diaphoresis
    - Dyspnea

Spontaneous Breathing - Respiratory therapist (RT) driven

Step 3: Safety Spontaneous Breathing Screen. All ventilated patients should be screened daily for appropriateness of a spontaneous breathing trial (SBT). If the patient passes the SAT, the RN will communicate with the RT to proceed with screening for spontaneous breathing trial (SBT) unless contraindicated by the following **SBT exclusion criteria:**

- PEEP greater than 8 cm H2O
- FiO2 more than 0.50
- pH less than 7.35. If no recent ABGs available, consult with MD or advanced practice provider (APP) for clarification
- Labored breathing
- Hemodynamic instability and active ectopy/ischemic changes. The use of vasopressors does not specifically contraindicate SBT attempts unless there is need for increasing dose

Step 4: SBT trial - If there are no exclusion criteria, an SBT* will be performed and documented in the patient's record by the RT.

*** SBT**:

- Patient will be placed on pressure support 7 and PEEP 5
- The SBT should be continued for a maximum of 30 min unless ordered otherwise.

- If not tolerated, stop the trial at any point.
- If tolerated, review assessment with MD or APP to evaluate the patient's ability/readiness to extubate.
- Patients can be extubated while on dexmedetomidine or ketamine IV infusions.

SBT failure criteria: If any of the following occurs for longer than 5 minutes (or less on case-by-case basis), the SBT should be stopped at any time:

- RR >35
- RR <8
- SaO2 <90%
- HR >140
- SBP >180 or <90 mmHg
- ICP >20 mmHg
- Mental status changes
- Acute cardiac arrhythmias

Step 5: Extubation If the patient passes the SBT, the RT will communicate with the RN and MD/APP for consideration of extubation. The following criteria should be met prior to extubation **(extubation criteria):**

- Resolution or improvement of the condition leading to acute respiratory failure
- No IV sedation infusion except for dexmedetomidine or ketamine
- RSBI ≤105*
- CXR stable or improving
- Effective clearance of secretions and adequate airway protection. The patient should be awake and following commands
- Cuff leak test if patient has risk factors for laryngeal edema and post extubation stenosis**
- Repeated clinical assessment remains crucial and should not be replaced by any single parameter
- Confirmed with MD or APP and CPOE order in place

* An RSBI ≥105 breaths/min/L is better at identifying patients who will fail weaning than an RSB <105 breaths/min/L is at identifying patients who can be successfully weaned.

**Risk factors for post extubation stenosis include traumatic intubation, intubation > 6 days, endotracheal tube size ≥8.5, female sex, and reintubation after unplanned extubation. A repeat cuff leak test is not required following the administration of systemic steroids.

Coordination

In addition to the mandated communications regarding SAT, SBT and readiness for extubation, the RN and RT can consult with each other and with MD/APP for clarification at any time.

If the SAT or SBT were deferred, the reason must be documented in the chart by the RN and RT respectively.

Delirium - RN driven

All ICU patients including those not on ventilator should be screened for delirium using the CAM-ICU scale (see appendix) every shift and after any change in mental status.
The RN will document in the chart the CAM-ICU Q12h and when any change in mental status

Taking into consideration that uncontrolled pain is a common trigger for hyperactive delirium, pain assessment should also be performed when CAM-ICU is positive.

General measures to prevent delirium

- Pain: Monitor and/or manage pain using modified Behavioral Pain Scale (mBPS, see appendix)
- Orientation: Talk about day, date, place; discuss current events; update white boards with caregiver names; use clock and calendar in room
- Sensory: determine need for hearing aids and/or eyeglasses
- Sleep: Provide & encourage sleep preservation techniques like noise reduction, day-night variation, "time-out" to minimize interruptions of sleep, promoting comfort & relaxation

Management of patient's CAM positive

- Minimize medication known to cause delirium including benzodiazepines
- Maintain lowest effective analgesic/sedative to achieve effective pain control and goal RASS
- For hyperactive delirium will consider
    - Dexmedetomidine IV infusion at 0.4 mcg/kg to a maximum of 1.5 mcg/kg/h, and/or PRN
    - Haloperidol 2.5-5mg IV Q6hr providing not prolonged QTc (< 500msec)
    - Quetiapine 25-50mg qhs by NGT providing not prolonged QTc (< 500msec)
    - Olanzapine 2.5-5 mg qhs by NGT for patients with prolonged QTc (>500msec)
    - The routine use of antipsychotics is however discouraged
- For hypoactive delirium will maintain lowest effective analgesic/sedative and optimize nonpharmacological interventions

Early mobilization - RN, RT, and physical and occupational therapists (PT-OT) driven

All ICU patients including those not on ventilator should be screened for early mobilization. The following will be considered **mobilization/exercise exclusion criteria:**

RASS < -3, FiO_2 >60%
PEEP >10cm H_2O
Increasing dose of vasopressors

MI in last 24hrs or unstable arrhythmia
Chest tube on suction (OK for OOB in chair but no ambulation); *If CTS follow their orders
Injuries in which mobility is contraindicated (e.g., unstable fracture)

If no contraindication, the RN, and RT should communicate with the PT-OT team to proceed with mobilization/exercise mobility plan. If patient fails, the PT-OT team will document it in the chart and re-evaluate in 24 hours. During the morning round, the intensivist team will implement specific procedures to achieve the mobility goal and identify and address any barriers if applicable.

Levels of therapy

- Active range of motion exercises in bed and sitting position in bed
- Dangling
- Transfer to chair (active), includes standing without marching in place
- Ambulation (marching in place, walking in room/hall)

Family engagement - Multidisciplinary intensivist group driven

Family involvement is a key element in every phase of the patient care process. In addition to sharing with family clinically relevant changes in patient status, family members will be encouraged to attend the daily ICU multidisciplinary rounds.

APPENDIXES:

Richmond Agitation Sedation Scale (RASS)

Score	Term	Description
+4	Combative	Overtly combative, violent, immediate danger to staff
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive
+2	Agitated	Frequent non-purposeful movement, fights ventilator
+1	Restless	Anxious but movements not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact to *voice* (> 10 seconds)
-2	Light sedation	Briefly awakens with eye contact to *voice* (< 10 seconds)
-3	Moderate sedation	Movement or eye opening to *voice* (but no eye contact)
-4	Deep sedation	No response to voice, but movement or eye opening to *physical* stimulation
-5	Unarousable	No response to *voice or physical* stimulation

Procedure for RASS Assessment

1. Observe patient
   a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
   d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by
   e. shaking shoulder and/or rubbing sternum.
   f. Patient has any movement to physical stimulation. **(score –4)**
   g. Patient has no response to any stimulation. **(score –5)**

Non Verbal Pain Scale - revised

Scoring

The NVPS - revised is based on observations, with zero to two points assigned for each of the five areas.

Patients who are awake : Observe for at least 1-3 minutes.
Patients who are asleep : Observe for at least 5 minutes or longer.

Observe legs and body uncovered.
Reposition patient or observe activity.
Assess body for rigidity and tone.
Initiate consoling interventions if needed, then assess again.

Interpretation

- 0: Relaxed and comfortable
- 1 to 3: Mild discomfort
- 4 to 6: Moderate pain
- 7 to 10: Severe discomfort/pain

By recording the NVPS - revised score periodically, healthcare providers can evaluate and document whether someone's pain is increasing, decreasing, or stable.

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

1. Acute Change or Fluctuating Course of Mental Status:

- Is there an acute change from mental status baseline? OR
- Has the patient's mental status fluctuated during the past 24 hours?

NO → CAM-ICU negative NO DELIRIUM

YES

2. Inattention:

- *"Squeeze my hand when I say the letter 'A'."*
  Read the following sequence of letters: S A V E A H A A R T
  ERRORS: No squeeze with 'A' & Squeeze on letter other than 'A'
- If unable to complete Letters → Pictures

0 - 2 Errors → CAM-ICU negative NO DELIRIUM

> 2 Errors

3. Altered Level of Consciousness
Current RASS level

RASS other than zero → CAM-ICU positive DELIRIUM Present

RASS = zero

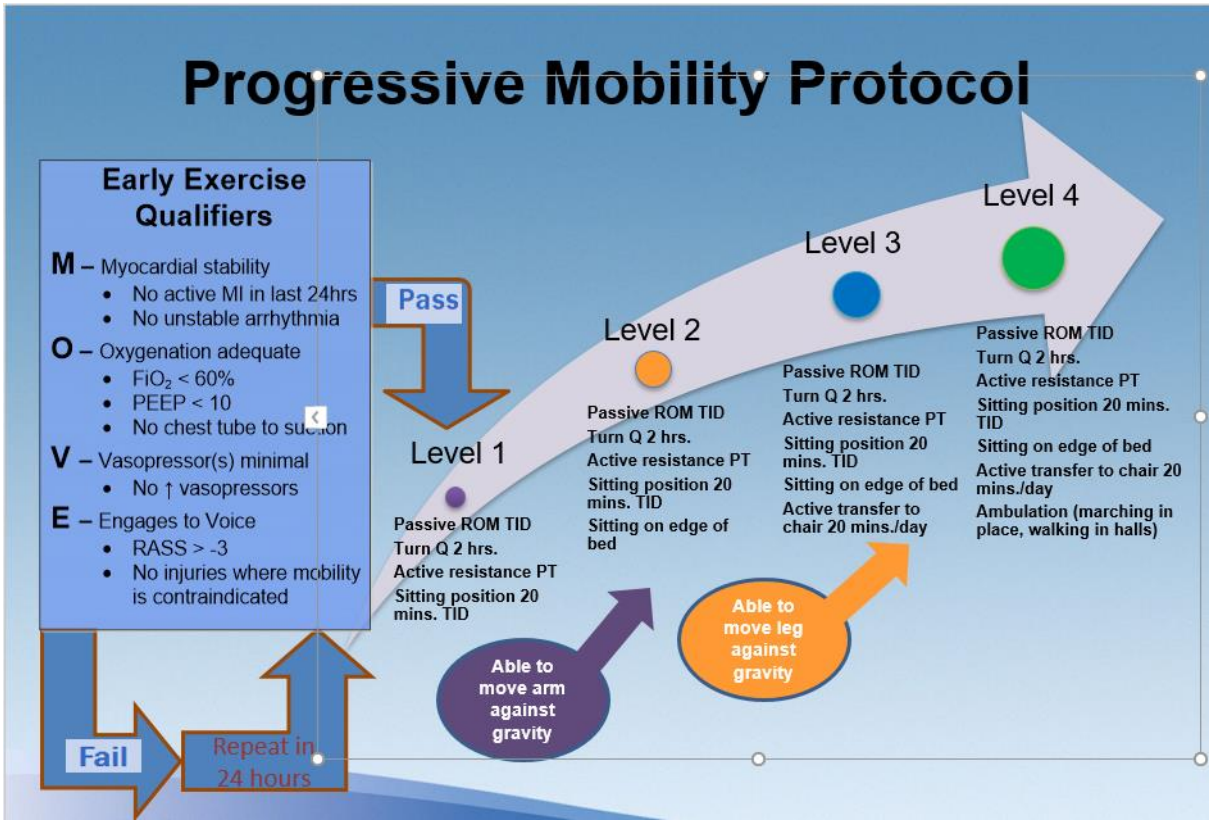
4. Disorganized Thinking:

1. Will a stone float on water?
2. Are there fish in the sea?
3. Does one pound weigh more than two?
4. Can you use a hammer to pound a nail?

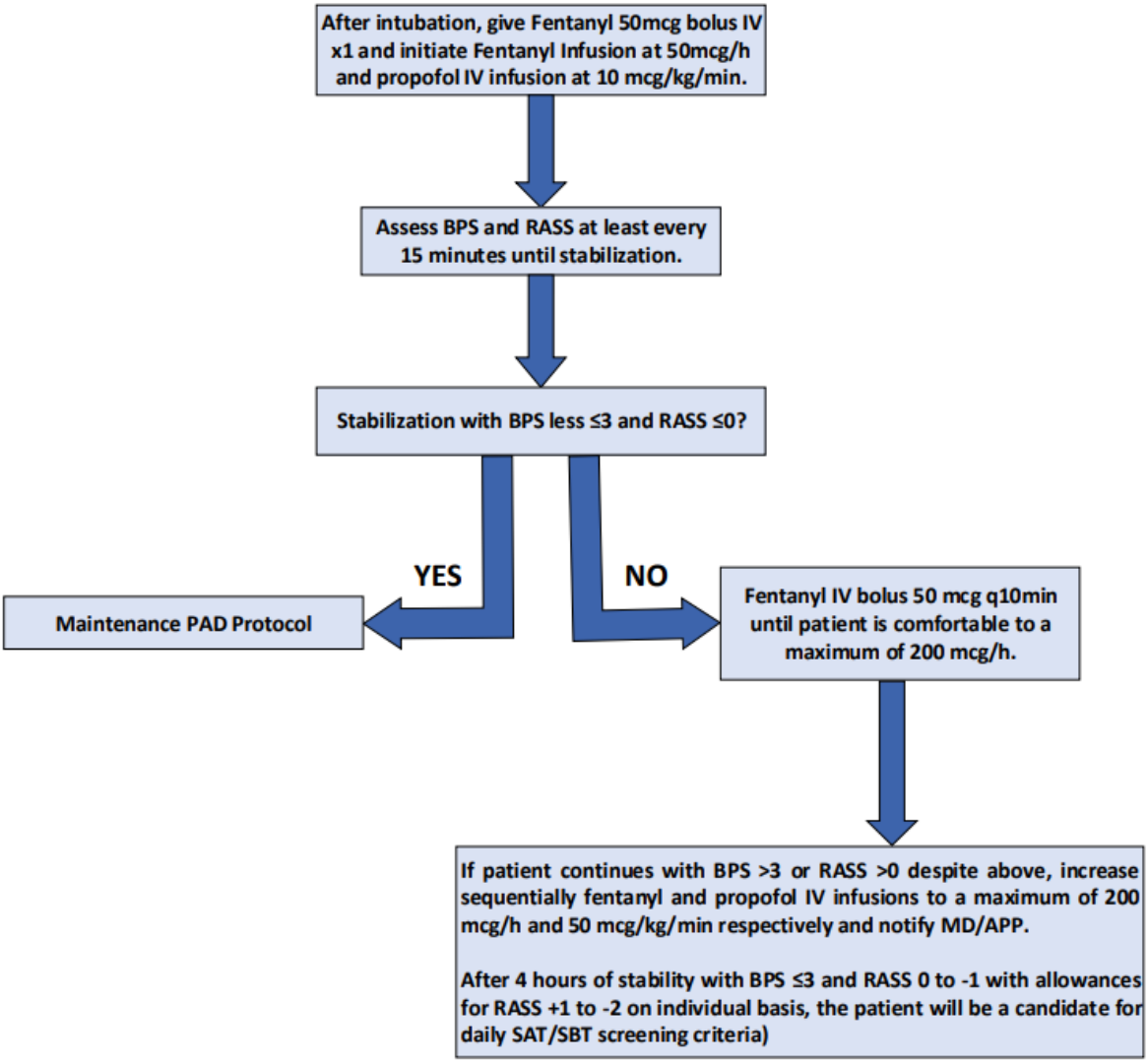
Command: "Hold up this many fingers" (Hold up 2 fingers)
"Now do the same thing with the other hand" (Do not demonstrate)
OR "Add one more finger" (If patient unable to move both arms)

> 1 Error → CAM-ICU positive DELIRIUM Present

0 - 1 Error → CAM-ICU negative NO DELIRIUM



ANALGOSEDATION PROTOCOL



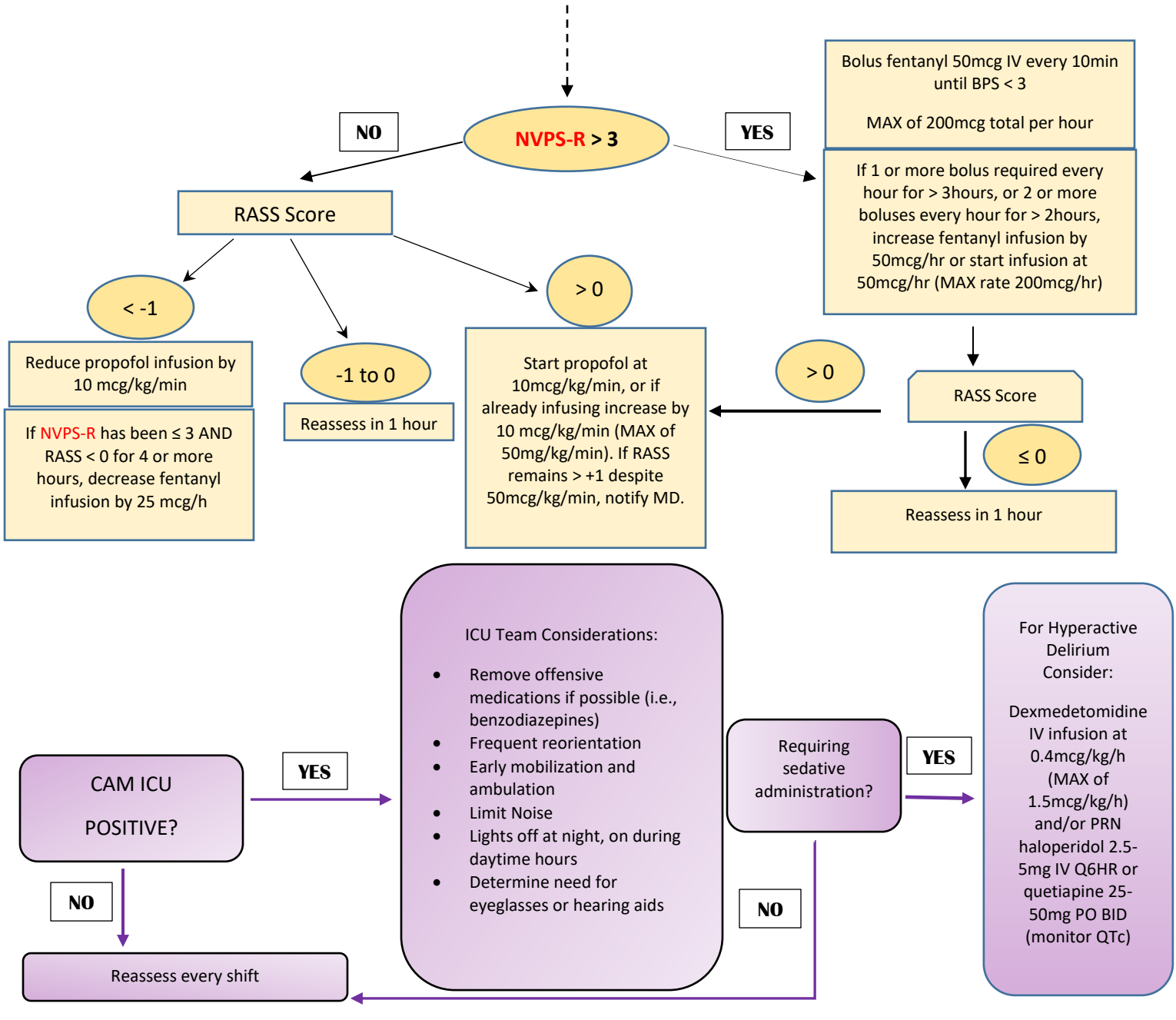
Goal: RASS 0 to -1 with NVPS-R <3; Reassess every 4 hours to meet goal. Document RASS and BPS Q4HR

Assess BPS and RASS at least every 1 hour if NVPS-R ≤ 3 and RASS 0 to -1; if stable 4 hours, assess SAT/SBT

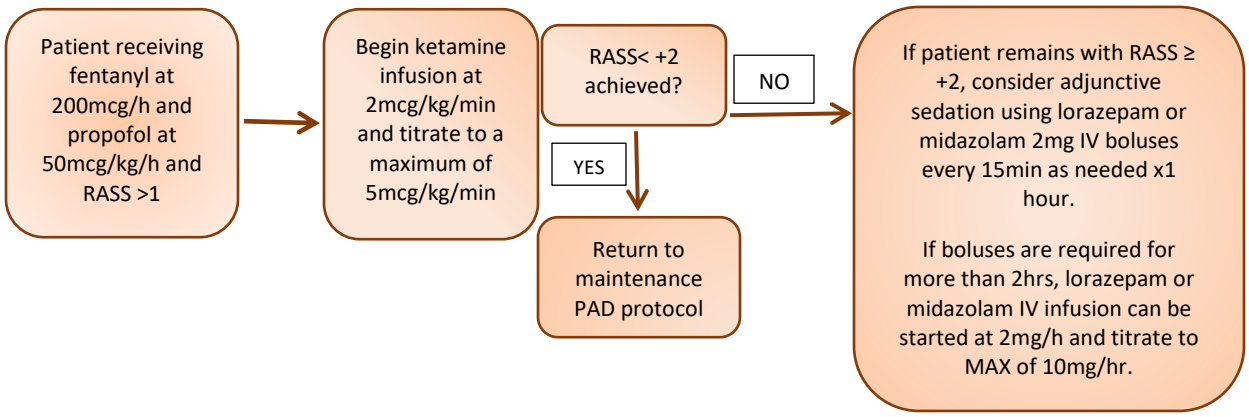
Assess CAM-ICU every shift (chart Q12HR) and after any change in mental status

Protocol Exceptions: Patients meeting the following criteria will have goal RASS -4 or -5

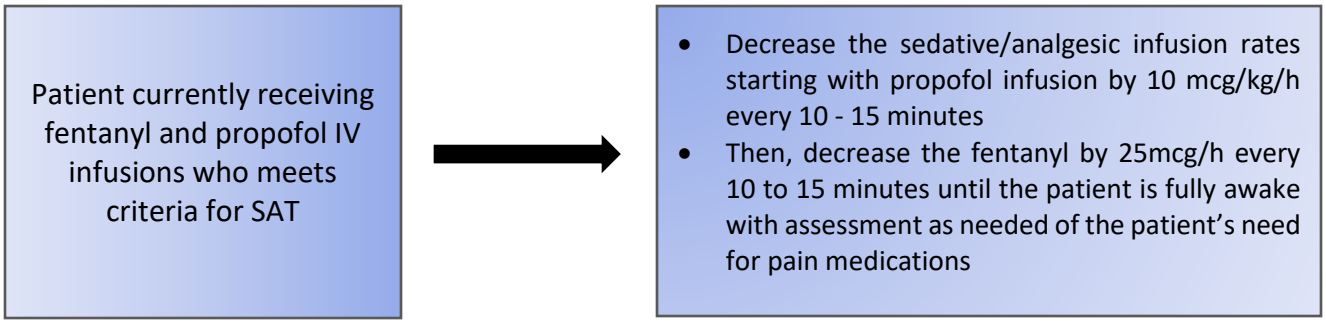
- Use of neuromuscular blockade (never to be initiated without prior adequate sedation)
- Life threatening hemodynamic instability
- Persistent PaO2/FiO2 ratio < 100 on full mechanical ventilatory support or ventilatory dyssynchrony with O2 sat <90% when attempting to decrease the level of sedation
- Intracranial pressure (ICP) >20mmHg or suspected elevation of ICP
- Seizures within 24 hours



Difficult to sedate patients with suspected opioid tolerance, hyperalgesia, or complications from opioids



Holding Sedation



For patients at risk for hyperactive delirium who meet criteria for SAT