Making the Shift from “Sedation” to Managing Pain: Implementing the 2013 SCCM Pain, Agitation & Delirium (PAD) Guidelines Reliably in an Open Community-based ICU

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Primary Intended Outcomes

1. Evolve the critical care practice culture around pain, agitation and delirium in ventilated adult patients, transitioning from traditional, deeper sedation goals using benzodiazepine-focused strategies to light sedation goals using analgesia-focused strategies as supported by the 2013 Society of Critical Care Medicine’s (SCCM) Pain, Agitation and Delirium (PAD) guidelines.
2. Develop a reliable process to support guideline-compliant PAD approaches.
3. Provide robust education supporting a reshaping of how each multidisciplinary team member thinks about, and thus applies, PAD strategies within their respective scopes of practice.

Relevant PAI Recommendations

B18. Pharmacists must be involved in identifying, developing, reviewing and approving new medication order sets.
B24g. Every pharmacy department should play a critical role in ensuring that the hospital or health system adheres to medication-related evidence-based practice guidelines.
B25e. In optimal pharmacy practice models, clinical specialist positions are necessary to advance practice, education and research activities.

Situation Analysis

SCCM released the most recent “sedation” guidelines in 2013, which were characterized by marked changes and a rebranding of “sedation” as “pain, agitation and delirium” to emphasize new understanding of the problem, clinical goals and approaches to management. The entire paradigm radically changed from the benzodiazepine-first, moderate-to-deep sedation strategies supported by the previous 2002 guidelines, as the evidence in the interim period bore three truths—(1.) that most “agitation” for which sedation had traditionally been used was likely associated with pain; (2.) benzodiazepines, in high dose strategies, were potentially harmful due to their association with delirium, the development of which is associated with increased ventilator duration and ICU and hospital length of stay as well as increased morbidity (as long-term cognitive dysfunction) and mortality; and (3.) patients experiencing light sedation measured by validated scales who survived...
the ICU had better cognitive outcomes than those who were deeply sedated and unable to formulate appropriate memories. Despite the acceptance of the evidence, the reversal in course required to comply with these new-found truths has been difficult to translate into practice as noted by several studies.3,4,5

RWJ Hamilton Hospital, a community hospital in a suburban setting in central New Jersey, recognized the need to evolve our “sedation” culture. The critical care unit was an open, 20-bed mixed-use unit in which various private practice attendings (including pulmonologists, internists, surgeons and cardiologists) were driving care. A group of intensivists provided consultation for 8 hours during the day, but often did not assume the lead role as the attending. Sedation strategies at this time often applied aggressive opioid and sedation combination therapy targeting moderate-to-deep sedation goals, most often through empiric infusion strategies initiated immediately upon intubation. We recognized that sustainable change was dependent on a cultural evolution of the entire team, from prescribers selecting therapy, to nurses performing routine assessments and applying prescribed strategies, to the respiratory therapist understanding the optimization of sedation and spontaneous breathing trials, to the pharmacists’ provision of expert consultation throughout. Without buy-in to the need for change, as well as the efficacy and safety of newer proposed strategies, cultural change would fail and traditional practices would persist.

A pharmacist-led interprofessional team was assembled to develop both a process to standardize initial PAD strategies that supported opioid-first, light sedation approaches as well as a robust educational and implementation plan to assure adoption of the proposed process.

Service Description

The interprofessional team developed an initial order set that became the mandatory empiric starting point for all intubated patients. The order set supported analgesia-first strategies but allowed intermittent benzodiazepines to address anxiety. To promote using the lowest effective dose to support appropriate pain management and light sedation goals, intermittent opioid strategies were preferred for all opioid-naïve patients (either confirmed or suspected in the case full histories were unavailable), with fentanyl infusions being permitted as initial therapy only for opioid-dependent patients. To support appropriate monitoring, conversion from scales traditionally permitted reflected in the 2002 SCCM guidelines to those endorsed by the current 2013 SCCM guidelines (namely the switch from Modified Ramsey Score [MRS] to the Richmond Agitation Sedation Score [RASS] and Critical Care Pain Observation Tool [CPOT]) was implemented during the same time period in which education and order set introduction occurred. To support opioid-focused regimens, senna was included as needed in the order set for bowel care.

Changes were approved through the institutional committee hierarchy. Educational planning began once approved at Critical Care Committee, the first committee in the process, after which dates were tentatively scheduled for training in anticipation of final by Medical Executive Committee (MEC). Upon MEC approval, a robust series of sessions was initiated, occurring over an intensive 3-month period. Sessions were provided collaboratively by the clinical pharmacist and the clinical nurse educator to both assist with content delivery but also to avoid the perception that the program was the unilateral initiative of one discipline alone. The target audience included ICU and ED staff nurses, pharmacists, respiratory therapists and attending physicians in both the ICU and ED; attendance of the nurses and pharmacists was mandatory, with targeted education for physicians provided through section meetings if they were unable to attend the unit-based educational sessions. The invitation was open to the entire team; we had social workers and dietitians electively attend.

The content of the educational series focused on four major areas: (1) creating a foundation of evidence to justify the need for the practice change; (2) building core knowledge; (3) how to competently conduct CPOT/RASS assessments; and (4) appropriate application of the prescribed order set to the individualized assessments. To support acceptance for the need to change existing practices, the underlying literature that evolved between the 2002 and 2016 guidelines was
summarized to tell the story of how it reshaped our understanding and the current guidelines.
Knowledge development focused on several key items. Firstly, there was a focus on key medication pearls that were designed to support appropriate selection and application of specific agents. Historically, we noted that nurses administered both opioid and benzodiazepine intermittent doses together or titrated sedative and opioid infusions (when they co-existed) simultaneously without differentiation of each agent’s unique role within the spectrum of management. Thus, we targeted segregating the actions and potential limitations of agents so that each agent could be thought of as a distinct tool within the nurse’s preverbal PAD tool box. Lastly, we provided education on new scales for both pain (e.g., CPOT) and agitation (e.g., RASS), including basic instruction on the scale details and how to conduct the assessment, as well as applying that knowledge to case-based examples. In an effort to relate to what was comfortable, we compared and contrasted RASS to MRS throughout so that the team would understand how the newer scoring systems were more specific.

Finally, to link this knowledge to bedside practice, we provided case examples that required learners to critically assess a clinical scenario and determine the appropriate action. Learners were provided with copies of the order set and CPOT and RASS scales to support their real-time use of the tools. We began by asking learners to anticipate which of the available four options within the order set (i.e., opioid-naïve adult; opioid-naïve geriatric; opioid-dependent; benzodiazepine-dependent), would be most appropriate for a newly intubated patient based on history and demographics, after which CPOT/RASS and medication administration trends were provided. Learners then critically assessed how to individualize decisions in applying the order set. For example, when presented with a 55 year old patient with no home opioid or benzodiazepine use, one would anticipate the intermittent sedation order set for those under 65 years old to be empirically selected; we wanted the group to understand this to support conversations for cases in which there appeared to be a mismatch between what was prescribed and the individual’s anticipated need. If this patient then had a CPOT 1 (indicating no need for pain medication) and a RASS +1 (agitated), we walked through the thought process of eliminating identifiable causes (such as hypoxemia or delirium) and, once addressed or ruled out, the justified and limited use of a midazolam bolus per the order set. In some scenarios we also provided data that demonstrated the need to escalate empiric doses to meet demonstrated needs, as well as situations in which routine, optimized intermittent strategies supported escalation to an infusion. We were careful to highlight excluded populations, such as sedative infusions used for managing status epilepticus or alcohol withdrawal delirium or as part of continuous paralytic therapy. Together, this provided the ability to illustrate why the order set was structured as it was, the anticipated thought process to match patients to their empiric needs to start, and fostered conversation regarding concerns or challenges to the underlying rationale or approach. We felt this full process was necessary to induce and foster the cultural evolution surrounding PAD that correlate to sustainable change. After initial implementation, real patient examples were brought back on a routine basis to the staff, either through vignettes on rounds or through inservices, to illustrate successes or share questions that had arisen. We also allowed extended conversation surrounding PAD during rounds to reinforce real-time decision making, goal setting and team cultural evolution.

Once the order set was implemented, the clinical nurse educator and clinical pharmacy specialist assured broad availability to support all disciplines in real-time when adapting the new approach. One goal was to “hold hands” and demonstrate the benefit and safety of the order set; an inherent concern expressed during education by many nurses was that there would be reduced patient safety associated with self-extubation secondary to untreated agitation once intermittent regimens predominated over infusion strategies. Support was provided by both the clinical pharmacy specialist and the ICU satellite pharmacist, who was available from 0700 to 2300 on weekdays and 0700 to 1500 on weekends, in collaboration. During these times, pharmacists not only participated in bedside assessments but also worked with individual nurses in applying the order set to support building confidence. We
worked to ensure a consistent assignment of pharmacists so that enhanced training could be provided to support this role. On hours in which the satellite pharmacy was not opened, the centralized pharmacist was responsible for ensuring the appropriate order set was utilized at initiation and the clinical pharmacist remained on call 24/7 for any team member requiring guidance. This initiative was the igniting force of us formalizing a Critical Care Pharmacist (CCP) team to assure consistency in team cognitive support regardless of which pharmacist was present in the unit.

Throughout, the clinical nurse educator partnered strongly with the pharmacy team to add a strong nurse voice.

**Key Elements for Success**

1. Buy-in and commitment from physician, nursing, and pharmacy leadership to endorse processes to support sustainable change from historical sedation practices;
2. Implementing the initial order set as a mandatory starting place, but allowing for individualization of therapy as patients demonstrate needs. Importantly, the process needed to support pharmacists’ ability to push-back on non-order set prescriptions, including an escalation process (to the clinical pharmacy specialist 24/7 in our process) when an impasse was reached;
3. Robust and coordinated interprofessional education efforts, both prior to implementation and throughout the implementation period, with ongoing case-based education to demonstrate success;
4. Bedside clinical support from key clinical leaders (clinical pharmacist, nurse educator and critical care physician) to assist with adaptation of practices when staff is uncertain.

**Resource Utilization**

**Personnel:** No additional personnel required, but the clinical pharmacy specialist and clinical nurse educator need to be able to dedicate significant time in a condensed time period to provide robust education. For staff (nurses, pharmacists, physicians and respiratory therapists), educational time was approximately 2 hours/staff member over 3-month period. Education was provided in group in-service format, with anywhere between 5 and 15 staff members per group. Educational sessions lasted between 30 and 45 minutes.

Since nurse and pharmacist attendance was mandatory, attendance was tracked by the clinical nurse educator and clinical pharmacist, respectively, through sign in sheets.

**IT and other infrastructure:** No additional expense incurred. Time and informatics support for order set building in the clinical computer system required. In our organization, we had an informatics pharmacist in the department who could assist with order set construction and launch and informatics nurses who could build the appropriate nursing documentation components (such as RASS and CPOT assessments).

**Supply Expense:** None.

**Return on Investment:** Associated with reduced ventilator time and infusion patterns. Fewer infusions were used overall with justification and clinically appropriateness of infusions evaluated prospectively. This trend was anticipated to be associated with decreased costs, including direct cost of the agent, supplies such as IV tubing and personnel, as well indirect costs of patient adverse experiences, such as delirium.

**Recognized Intangible Benefits**

Per the current literature, one would anticipate less long-term cognitive deficits (such as Post-ICU Syndrome [PICS]) associated with lightly sedated patients.

The implementation of this process fostered more informed views regarding team members’ expertise and scope allowing for more effective interaction throughout patient care provision. It reinforced team dynamics and fostered constructive and routine interprofessional conversation.

**Outcome Measures**

After the first month of the order set’s implementation, the following were assessed:

1. Order set compliance during the first month, which was 100% with intervention of the pharmacists during order review;
2. A comparison of the following during the first month post-implementation versus the same month the year prior:
a. Type and appropriateness of drug administration strategies, with infusion strategies for sedatives (i.e., benzodiazepines and propofol) converting to predominantly intermittent strategies and infusions for all agents reserved for either those patients with known baseline tolerance/dependence or demonstrated need by optimized, frequent intermittent agent administration. As such, no patients started on an infusion without a specific reason and were not escalated from an intermittent to continuous regimen without the need demonstrated;
b. Infusion utilization, which revealed significantly fewer benzodiazepine (13 decreased to 2) infusions and propofol (19 decreased to 6) infusions and increased fentanyl (6 increased to 12) infusions.
c. Time to initiation of ventilator weaning/spontaneous breathing trials (SBTs), which decreased from 1.75 days to 1.1 days;
d. Ventilator days, which decreased from 4 days to 3 days;
e. Self-extubation rates (viewed as a surrogate for safety, as there was some concern that adapting light sedation goals would result in increased self-extubation), which remained the same in the two time periods compared.

Lessons Learned
1. Cultural change is hard, but achievable, when there is reliable interprofessional support of the solution.
2. Collegiality and recognition of the importance of routine interprofessional approaches in which all team members are accountable for their full scope of practice is essential to avoid conflict and support practice integration.
3. Early successes are important to reshape how team members think and feel about the new treatment approaches they are being asked to implement.
4. It is easy to revert to “old habits,” so ensuring persistent and reliable support of all disciplines. Avoidance of gaps of time when support in unavailable is important. For this, we provided and encouraged 24/7 consultative support to assist with real-time decision making. Allowing expanded discussion during rounds when “old habits” emerge to redirect the thought process is key to adapting practices.
5. Key clinical leaders who are providing education and supporting the change during implementation should be well versed in the topic and comfortable “standing their ground” against argument, as a certain subset of the group will likely be late adopters and resistant to evolving practice approaches.
6. Ensuring team members, particularly nurses, understand the different roles of various scales (e.g., RASS for agitation vs. CPOT for pain) and how that influences drug selection from the order set is key to optimize appropriate application and patient response. Equally important, the culture needs to use these validated assessment when the topic is discussed so that it becomes integral within the culture. We refer to it as “talking RASS” or “talking CPOT” with our team.
7. When using a mandatory initial order set based on empiric dosing, it is important to ensure the team understands the need to escalate the empiric intermittent doses when patient assessment and response support the need prior to converting to an infusion. While fentanyl doses are most commonly the focus of dose escalation due to the role and focus on pain management, this can apply to benzodiazepine therapy as well for patients exhibiting a significant anxiety component (i.e., CPOT negative/RASS positive assessment with delirium ruled out).
8. When opioid utilization is increased and bowel regimens are included only on an “as needed” basis, it is key for the pharmacist to assess utilization and need daily to foster early recognition and treatment of opioid-induced constipation. We did not appreciate how the
primary focus of the nurses on PAD drug selection would distract from this consideration, a gap identified by and filled by the pharmacists early in the process.

Other Considerations
Depending on the established dynamic between the pharmacists and prescribers, some pharmacists may be hesitant, even when supported, to push back on non-order set strategies. Persistent reinforcement and partnering of the clinical pharmacy specialist with all disciplines within the team (i.e., nurse, physician, pharmacist and respiratory therapist) is required to support and sustain this change. Likewise, it is pivotal that nurses also question orders outside the standard analgesia-first strategies to reinforce best practices for their patients; thus the team takes ownership for following best practices instead of one discipline taking full accountability. Bringing periodic case studies back to the interprofessional team that illustrate successful application of the protocol or illustrate questions that arose during consultant, builds confidence in both individual decision making as well as of the effectiveness of the protocol itself and, ultimately, reinforces long term transformation and adoption of 2013 PAD standards.

Suggestions for Other Hospitals/Health Systems
Cultural change that seeks to reverse the course of a long-established practice is truly a marathon and not a sprint. All team members with a vested interest must participate in developing new standards and approaches and believe in the need for those changes. Gaps in compliance are most likely to occur when new or periodic (e.g., per diem) team members enter the process, reinforcing how key it is that all team members have the same expectations and will question inconsistent approaches.

Helpful References

Team Members
- Natalie Jones, M.S.N. Ed., R.N., CCRN, Critical Care Nurse Educator, RWJ Barnabas Health
- Nina Roberts, M.S.N., R.N., CCRN, NEA-BC, Director of Critical Care, RWJ Barnabas Health
- Suzanne Caravella, Pharm.D., R.Ph., BCPS, Senior Pharmacist, RWJ Barnabas Health
Initial Sedation Orders for Mechanically Ventilated Patients

INITIAL SEDATION ORDERS FOR MECHANICALLY VENTILATED ADULTS (SELECT ONE)
See treatment algorithm in CC-039 (“Sedation and Analgesia in the Critically Ill, Mechanically Ventilated Adult, Including Sedation Vacations and Spontaneous Breathing Trials”) for guidance.

Select ONE of the following depending on whether the patient is opioid and benzodiazepine DEPENDENT or NAÏVE:

If patient is Opioid and/or Benzodiazepine NAÏVE, please select the appropriate set of orders:

☐ INTERMITTENT SEDATION, PATIENTS AGED >65 YEARS
- Fentanyl 25 mcg IVP q1h PRN moderate pain (pain score 4-6 and CPOT >3) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Fentanyl 50 mcg IVP q1h PRN severe pain (pain score 7-10 and CPOT >3 unresponsive or incompletely treated by lower Fentanyl dose) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Fentanyl 25 mcg IVP q30 min PRN titration dose for RASS >0 AND has not responded to fentanyl q1h PRN standard dose x3. Instructions: Use PRN q1h standard dosing to achieve RASS 0 to -2. If unable to achieve RASS of 0 to -2 after q1hr PRN dosing x3, then proceed with q30 min titration dose. Call MD to clarify q1h dose to equal cumulative dose that achieved RASS goal if titration doses were required.
- Midazolam 2 mg IVP q2h PRN RASS >0 associated with anxiety and NOT relieved by fentanyl
- Senna 5 ml per GT BID PRN constipation

If no BM in 24 hours after start of Senna, start Docusate solution 100 mg per GT BID PRN constipation.

☐ INTERMITTENT SEDATION, PATIENTS AGED <65 YEARS
- Fentanyl 50 mcg IVP q1h PRN moderate pain (pain score 4-6 and CPOT >3) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Fentanyl 75 mcg IVP q1h PRN severe pain (pain score 7-10 and CPOT >3 unresponsive or incompletely treated by lower Fentanyl dose) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Fentanyl 50 mcg IVP q30 min PRN RASS >0 AND has not responded to fentanyl q1h PRN standard dose x3. Instructions: Use PRN q1h standard dosing to achieve RASS 0 to -2. If unable to achieve RASS of 0 to -2 after q1hr PRN dosing x3, then proceed with q30 min titration dose. Call MD to clarify q1h dose to equal cumulative dose that achieved RASS goal if titration doses were required.
- Midazolam 4 mg IVP q1h PRN RASS >0 associated with anxiety and NOT relieved by fentanyl
- Senna 5 ml per GT BID PRN constipation

If no BM in 24 hours after start of Senna, start Docusate solution 100 mg per GT BID PRN constipation.

If patient is Opioid and/or Benzodiazepine DEPENDENT, please select the appropriate set of orders:

☐ OPIOD DEPENDENT INITIAL SEDATION ORDER SET: FOR PATIENTS ON CHRONIC OPIOID-BASED PAIN MANAGEMENT REGIMENS
- Chronic Regimen: Fentanyl 2.5 mg/250 mL infusion at ______ mcg/hr. Instructions: Do NOT titrate or taper. Provides coverage of established chronic pain management regimen.

  Dosing information: Convert the chronic 24h opioid utilization to fentanyl equivalents and prescribe as an hourly rate. Pharmacist is available for assistance in converting daily doses to hourly rates. For opioid dependence associated with illicit agents for which there are no available conversion (e.g. heroin), initiate at 100 mcg/hr and adjust to 200 mcg/hr if withdrawal symptoms persist despite IVP.

- Acute Regimen: (prescriber to select one option)
  - For hourly rates of 50 mcg/hr or less: fentanyl 50 mcg q1h PRN pain 4/10 or RASS >0 associated with pain
  - For hourly rate >50 mcg/hr, match the PRN dose to the hourly rate: fentanyl ______ mcg q1h PRN pain 4/10 or RASS >0 associated with pain
- Senna 5 ml per GT BID PRN constipation.
  If no BM in 24 hours after start of Senna, start Docusate solution 100 mg per GT BID PRN constipation.

☐ BENZODIAZEPINE DEPENDENT INITIAL SEDATION ORDER SET: FOR PATIENTS ESTABLISHED ON ALPRAZOLAM ≤4 mg/d, CLONAZEPAM ≤3 mg/d, OR LORAZEPAM ≤4 mg/d
- Lorazepam 1 mg IVP q6h (indication: chronic benzodiazepine requirement)
- Midazolam 2 mg IVP q1h PRN RASS >0 associated with anxiety and NOT relieved by fentanyl
- Fentanyl 50 mcg IVP q1h PRN moderate pain (pain score 4-6 and/or CPOT >3) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Fentanyl 75 mcg IVP q1h PRN severe pain (pain score 7-10 and/or CPOT >3 unresponsive or incompletely treated with lower Fentanyl dose) or RASS >0 associated with pain (e.g., coughing on or reaching for endotracheal tube)
- Senna 5 ml per GT BID PRN constipation
  If no BM in 24 hours after start of Senna, start Docusate solution 100 mg per GT BID PRN constipation.

Physician Signature: ___________________________ Date/Time: ______________________
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