Spontaneous Awakening Trials (SAT) and Spontaneous Breathing Trials (SBT) Literature Synopsis

Summary
Spontaneous awakening trials (SAT) and spontaneous breathing trials (SBT) reduce the length of mechanical ventilation, thereby reducing the risk for developing ventilator-associated pneumonia (VAP). Since the guidelines were written in 2007, a groundbreaking article by Girard in 2008\(^1\) showed that SAT and SBT protocols result in faster extubation time and earlier discharge date. Most recently in 2012, a review article focusing on the findings of 14 studies recommended that weaning should be considered as early as possible, using a daily screening for readiness to wean protocol (SAT) that includes SBT (Luetz, 2012).\(^2\) In 2013, Mehta, et al,\(^3\) performed a randomized controlled trial to assess sedation with a protocol versus sedation with a protocol and a daily sedation vacation. The results did not support the use of a SAT, as there was no difference in time to extubation, the primary outcome. However, with the sedation vacation was a concomitant increase in the use of benzodiazepines.

Note: Literature supporting the guidelines is listed first, followed by literature published post-guidelines and an annotated bibliography.

Society for Healthcare Epidemiology of America
2014 - Strategies to prevent ventilator-associated pneumonia in acute care hospitals: 2014 update.\(^4\)

- Recommends the simultaneous use of daily sedation interruption (SAT) and daily assessment of readiness wean (SBT).
- Recommends management of ventilated patients with minimal sedation whenever possible and the avoidance of benzodiazepines.

American Thoracic Society
2004 - Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia.\(^11\)

- Recommends use of daily interruption or lightening of sedation (SAT) to avoid constant heavy sedation and to facilitate and accelerate weaning.
- Does not address SBT.

ZAP the VAP: Ventilator Associated Pneumonia
2008 - Canadian VAP Prevention Guidelines: Evidence-based, clinical practice guidelines for the prevention of ventilator-associated pneumonia\(^12\)

- Guideline excluded studies that evaluated SAT and SBT.

Center for Disease Control and Prevention
2003 - CDC Guidelines for preventing Health-Care-Associated Pneumonia; Evidence-based, clinical practice guidelines for the prevention of healthcare-associated pneumonia, including VAP.\(^7\)

- Does not address SAT and SBT, however supports weaning.

✓ **Recommends the simultaneous use of daily sedation interruption (SAT) and daily assessment of readiness wean (SBT).**

✓ **Recommends management of ventilated patients with minimal sedation whenever possible and the avoidance of benzodiazepines.**

2008 - Society for Healthcare Epidemiology of America Guidelines: A guideline of practical recommendations to assist acute care hospitals in implementing and prioritizing their ventilator-associated pneumonia (VAP) prevention efforts.⁵

✓ **Recommends the simultaneous use of daily sedation interruption (SAT) and daily assessment of readiness wean (SBT).**

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<th>Articles Cited in Guideline</th>
<th>Study Type and Author</th>
<th>Results - Details in Annotated Bibliography</th>
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<tr>
<td><strong>Quasi-Experimental Study</strong></td>
<td>(Resar, 2005)⁶</td>
<td><strong>PRO:</strong> This study did not specifically focus on weaning or sedation vacation, but the implementation of the IHI ventilation bundle. Findings showed that adherence to bundle led to a significant reduction of VAP. One of the items in the ventilator bundle was use of a sedation vacation protocol.</td>
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<td><strong>CDC Guideline -2003</strong></td>
<td>(Tablan, 2004)⁷</td>
<td><strong>PRO:</strong> Recommends the use of non-invasive ventilation as part of the weaning process from mechanically assisted ventilation to shorten the period of endotracheal intubation. (See CDC, below.)</td>
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<td><strong>Ventilator Management Protocol vs. Control</strong></td>
<td>(Marelich, 2000)⁸</td>
<td><strong>PRO:</strong> This article did not focus on sedation vacation intervention, but the use of Ventilator Management Protocol (VMP), including, a twice daily Spontaneous Breathing Trials (SBT).</td>
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<td><strong>Sedation Interruption vs. Control</strong></td>
<td>(Kress, 2000)⁹</td>
<td><strong>PRO:</strong> Study focused on adult medical patients who requiring mechanical ventilation and were receiving continuous infusion of sedative drugs. Findings showed that daily interruption of sedative drug infusions decreased the duration of mechanical ventilation and the length of stay in ICU.</td>
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<td><strong>Protocol-Directed vs. Non-Protocol</strong></td>
<td>(Brook, 1999)¹⁰</td>
<td><strong>PRO:</strong> Study focused on adult patients who were admitted into the medical intensive care unit. Findings showed that the use of protocol-directed sedation could reduce the mechanical ventilation, length of stay, and need tracheostomy among critically ill patients with acute respiratory failure.</td>
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| **(American Thoracic Society, 2005)**¹¹ | **PRO:** Recommends the use of daily interruption or lightening of sedation to avoid constant heavy sedation; and also recommends the
avoidance of paralytic agents as they can depress cough reflex which increases the risk of HAP.  
(See ATS, below)

2004 - Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia.11

✓ **Recommends use of daily interruption or lightening of sedation (SAT) to avoid constant heavy sedation and to facilitate and accelerate weaning.**

✓ **Does not address SBT.**

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### Articles Cited in Guideline

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| Sedation Interruption vs. Control (Kress, 2000)³ | **PRO:** Study focused on adult medical patients requiring mechanical ventilation who were receiving continuous infusion of sedative drugs. Study findings showed that daily interruption of sedative drug infusions decreases the duration of mechanical ventilation and the length of stay in the intensive care unit.  
(***Cited by 2008 SHEA guideline²¹***) |
| Ventilator Management Protocol vs. Control (Marelich, 2000)⁶ | **PRO:** This article did not focus on sedation vacation intervention, but the use of Ventilator Management Protocol (VMP), which implemented a twice-daily Spontaneous Breathing Trials (SBT).  
(***Cited by 2008 SHEA guideline²¹***) |
| Protocol Directed vs. Traditional (Brook, 1999)¹⁰ | **PRO:** Study focused on adult patients who were admitted into the medical intensive care unit. Findings showed that the use of protocol-directed sedation could reduce the mechanical ventilation, length of stay, and need tracheostomy among critically ill patients with acute respiratory failure.  
(***Cited by 2008 SHEA guideline²¹***) |
2008 - Canadian VAP Prevention Guidelines: Evidence-based, clinical practice guidelines for the prevention of ventilator-associated pneumonia\textsuperscript{12}

✓ Guideline excluded studies that evaluated SAT and SBT.

2003 - CDC Guidelines for preventing Health-Care-Associated Pneumonia; Evidence-based, clinical practice guidelines for the prevention of healthcare-associated pneumonia, including VAP.\textsuperscript{7}

✓ Does not address SAT and SBT, however supports weaning.
### Post Guideline Publications

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<td><strong>Prospective, Cohort, Before-After Study</strong>&lt;br&gt;ABCDE vs. Usual Care (Balas, 2014)¹³</td>
<td><strong>PRO:</strong> States that patients managed with the Awakening and Breathing Coordination, Delirium monitoring/management, and Early exercise/mobility bundle spent 3 more days breathing without assistance, experienced less delirium and were more likely to be mobilized during their ICU stay than patients treated with usual care.</td>
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<td><strong>Guidelines for PAD Management</strong>&lt;br&gt;(Barr, 2013)¹⁴</td>
<td><strong>PRO:</strong> These guidelines provide a roadmap for developing integrated, evidence-based, and patient-centered protocols for preventing and treating pain, agitation and delirium in critically ill patients.</td>
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<td><strong>Review</strong>&lt;br&gt;(Luetz, 2012)²</td>
<td><strong>PRO:</strong> Study reviewed the findings of 14 articles to recommend that weaning should be considered as early as possible; a daily screening for readiness to wean should be implemented; and a weaning protocol including a SBT should be used.</td>
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<td><strong>Randomized, Controlled Trial</strong>&lt;br&gt;Protocolized Sedation versus Protocolized Sedation &amp; Daily Sedation Interruption (Mehta, 2012)³</td>
<td><strong>CON:</strong> Participants included 430 critically ill, mechanically ventilated adults in 16 tertiary care medical and surgical ICUs in Canada and the United States. 209 participants were randomized to control arm and 214 to the intervention arm. There were no significant differences between the two groups on median time to extubation or duration of ICU stay. Daily interruption was associated with higher daily doses of midazolam and fentanyl and more daily boluses of benzodiazepines.</td>
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<tr>
<td><strong>Concise Clinical Review</strong>&lt;br&gt;(Patel, 2012)¹⁵</td>
<td><strong>PRO:</strong> States that sedation and analgesia and important components of care the mechanically ventilated patient in the ICU. Objective assessments of pain, sedation, and agitation have been validated for use in the ICU for assessment and titration of medications. An evidence-based strategy for administering these drugs can lead to improvements in short-and long-term outcomes of the mechanically ventilated patient.</td>
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<td><strong>Systematic Review</strong>&lt;br&gt;(Blackwood, 2011)¹⁶</td>
<td><strong>PRO:</strong> Study focused on 11 RCT that evaluated the effect of weaning protocols on the duration of mechanical ventilation in 1,971 critically ill patients in ICU’s. Study findings showed that weaning protocol was associated with significant reduction for duration of mechanical ventilation, length of weaning, and length of stay in the ICU.</td>
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<td><strong>Randomized Clinical Trial</strong>&lt;br&gt;Pressure Support vs. Spontaneous Breathing (Gnanapandithan, 2011)¹⁷</td>
<td><strong>CON:</strong> Study focused on adult patients requiring mechanically ventilation for &gt; 24 hrs. Study findings show that weaning by gradual pressure support without an initial spontaneous breathing trial (SBT) was associated with better outcomes (in terms of higher weaning trial successes, shorter ICU stay and trend towards quicker time to extubation than weaning by PS-supported with Spontaneous Breathing Trials.</td>
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<td><strong>Systematic Review</strong>&lt;br&gt;(Jackson, 2010)¹⁸</td>
<td><strong>PRO:</strong> Study focused on 23 studies that reported data on the impact of sedation practice of adult patients, sedated and on mechanical ventilation in the ICU. Findings showed that the introduction of guidelines and protocols were associated with improvements in outcomes, including both ICU and hospital length of stay, duration of mechanical ventilation, costs, mortality and reduction of nosocomial</td>
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<tr>
<td>National Nursing Survey</td>
<td>(Guttormson, 2010)</td>
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<td>Survey of SCCM</td>
<td>(Tanios, 2009)</td>
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<td>Randomized Trial</td>
<td>SAT with SBT versus Standard of Care and SBT (Girard, 2008)</td>
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<tr>
<td>Quasi-Experimental</td>
<td>Nurse Implemented Sedation Intervention (Quenot, 2007)</td>
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   **PRO**: Literature Review. Article focused on the findings of 14 articles to recommend that weaning should be considered as early as possible; a daily screening for readiness to wean should be implemented; and a weaning protocol including a SBT should be used.


   **CON**: Randomized Controlled Trial of 430 critically ill, mechanically ventilated adults in 16 tertiary care medical and surgical ICUs in the United States and Canada. Patients were randomized to protocolized sedation or protocolized sedation plus daily sedation interruption. Main outcome measure was time to successful extubation. Secondary outcomes included: Duration of stay, doses of sedatives and opioids, unintentional device removal, delirium and nurse and respiratory therapist clinical workload. Results: **Median time to successful extubation was 7 days in both the interruption and control groups (median [IQR], 7 [4-13] vs 7 [3-12]; interruption group hazard ratio, 1.08; 95% CI, 0.86-1.35; P=.52). Duration of ICU stay (median [IQR], 10 [5-17] days vs 10 [6-20] days; P=.36) and hospital stay (median [IQR], 20 [10-36] days vs 20 [10-48] days; P=.42) did not differ between the daily interruption and control groups, respectively. Daily interruption was associated with higher mean daily doses of midazolam (102 mg/d vs 82 mg/d; P=.04) and fentanyl (median [IQR], 550 [50-1850] vs 260 [0-1400]; P=.001) and more daily boluses of benzodiazepines (mean, 0.253 vs 0.177; P=.007) and opiates (mean, 2.18 vs 1.79; P=.001). Unintentional endotracheal tube removal occurred in 10 of 214 (4.7%) vs 12 of 207 patients (5.8%) in the interruption and control groups, respectively (relative risk, 0.82; 95% CI, 0.36-1.84; P=.64). Rates of delirium were not significantly different between groups (53.3% vs 54.1%; relative risk, 0.98; 95% CI, 0.82-1.17; P=.83). Nurse workload was greater in the interruption group (VAS score, 4.22 vs 3.80; mean difference, 0.41; 95% CI, 0.17-0.66; P=.001). Patients managed with protocolized sedation and a daily sedation interruption did not have any significant differences in duration of mechanical ventilation or length of ICU stay. However, as noted above, the use of midazolam, fentanyl, benzodiazepines, and opiates increased in the patients with daily sedation interruption.**


**PRO:** Systematic Review. This review did not specifically sedation vacation protocol, but reviewed the use of the IHI ventilator bundle. Review focused on 21 teaching hospitals 40 community hospitals that were made up 44 medical ICU’s and 12 surgical ICU’s. Data from 35 units showed a decrease in VAP rated with increased adherence to ventilator bundle. One of four bundle items was the use of a sedation vacation protocol.


**PRO:** VMP Protocol vs. Control. This article did not focus on sedation vacation intervention, but the use of Ventilator Management Protocol (VMP) that used Spontaneous Breathing Trials (SBT). Study findings were based on 335 patients from the medical and surgical ICU’s that required mechanical ventilation. The duration of mechanical ventilation for patients was decreased from a median of 124 hours for the control group to 68 hours in the Ventilator Management Protocol group (p = 0.0001).


**PRO:** Sedation Interruption vs. Control. Study focused on 128 adult patients who were receiving mechanical ventilation and continuous infusions of sedative drugs in a medical intensive care unit. *In the intervention group, the sedative infusions were interrupted until the patients were awake, on a daily basis; in the control group, the infusions were interrupted only at the discretion of the clinicians in the intensive care unit. The median duration of mechanical ventilation was 4.9 days in the intervention group, as compared with 7.3 days in the control group (P=0.004), and the median length of stay in the intensive care unit was 6.4 days as compared with 9.9 days, respectively (P=0.02).* Findings show that daily interruption of sedative drug infusions decreased the duration of mechanical ventilation and the length of stay in the intensive care unit.


**PRO:** Protocol-Directed vs. Non-Protocol Directed Sedation. Study was focused on 321 adult patients who were admitted into the medical intensive care unit. The median duration of mechanical ventilation was 55.9 hours (95% confidence interval, 41.0-90.0 hours) for patients managed with protocol-directed sedation and 117.0 hours (95% confidence interval, 96.0-155.6 hours) for patients receiving non-protocol-directed sedation. Kaplan-Meier analysis demonstrated that patients in the protocol-directed sedation group had statistically shorter durations of mechanical ventilation than patients in the non-protocol-directed sedation group (chi-square = 7.00, p = .008, log rank test; chi-square = 8.54, p = .004, Wilcoxon’s test; chi-square = 9.18, p = .003, log test). Lengths of stay in the intensive care unit (5.7 ± 5.9 days vs. 7.5 ± 6.5 days; p = .013) and hospital (14.0 ± 17.3 days vs. 19.9 ± 24.2 days; p < .001) were also significantly shorter among patients in the protocol-directed sedation group. Among the 132 patients (41.1%) receiving continuous intravenous sedation, those in the protocol-directed sedation group (n = 66) had a significantly shorter duration of continuous intravenous sedation than those in the non-protocol-directed sedation group (n = 66) (3.5 ± 4.0 days vs. 5.6 ± 6.4 days; p = .003). Patients in
the protocol-directed sedation group also had a significantly lower tracheostomy rate compared with patients in the non-protocol-directed sedation group (10 of 162 patients [6.2%] vs. 21 of 159 patients [13.2%], p = .038).


**PRO:** This was an 18-month, prospective cohort, before and after study in 5 adult ICUs, one step-down unit and one oncology/hematology/special care unit. A total of 296 patients (146 pre-bundle and 150 post-bundle) were enrolled. 187 of these were mechanically ventilated. For the mechanically ventilated patients, outcomes included the association of bundle implementation and ventilator-free days. **Patients in the post-implementation period spent three more days breathing without mechanical assistance than did those in the pre-implementation period (median [interquartile range], 24 [7–26] vs 21 [0–25]; p = 0.04).** After adjusting for age, sex, severity of illness, comorbidity, and mechanical ventilation status, patients managed with the Awakening and Breathing Coordination, Delirium monitoring/management, and Early exercise/mobility bundle experienced a near halving of the odds of delirium (odds ratio, 0.55; 95% CI, 0.33–0.93; p = 0.03) and increased odds of mobilizing out of bed at least once during an ICU stay (odds ratio, 2.11; 95% CI, 1.29–3.45; p = 0.003). Critically ill patients managed with the Awakening and Breathing Coordination, Delirium monitoring/management, and Early exercise/mobility bundle spent three more days breathing without assistance, experienced less delirium, and were more likely to be mobilized during their ICU stay than patients treated with usual care.


**PRO:** Use either a daily sedation interruption or titrate sedative medications to maintain light levels of sedation. Suggest using non-benzodiazepines rather than benzodiazepine infusions for sedation. Use sedation protocols and daily checklists to integrate and to facilitate management of pain, sedation and delirium in all ICU patients.


**PRO:** (Sedation control) Consensus guidelines for sedation management for mechanically ventilated patients in the ICU. Sedation and analgesia are important components of care the mechanically ventilated patient in the ICU. Objective assessments of pain, sedation, and agitation have been validated for use in the ICU for assessment and titration of medications. An evidence-based strategy for administering these drugs can lead to improvements in short- and long-term outcomes of the mechanically ventilated patient.

**PRO**: Systematic Review. Study focused on 11 RCT that evaluated the effect of weaning protocols on the duration of mechanical ventilation in 1,971 critically ill patients in the ICU. Study findings showed that weaning protocol was associated with significant reduction in the mean duration of mechanical ventilation by 25% (95% confidence interval 9% to 39%, P=0.006; 10 trials); the duration of weaning was reduced by 78% (31% to 93%, P=0.009; six trials); and length of stay in the intensive care unit by 10% (2% to 19%, P=0.02; eight trials).


**CON**: Randomized Clinical Trial. Study focused on 120 adult patients requiring mechanically ventilation for > 24 hours to evaluate the effectiveness of weaning by gradual pressure support (PS) with initial spontaneous breathing trial (SBT) versus PS-supported SBT. Findings show that weaning by gradual reduction of PS without an SBT was associated with better outcomes in terms of higher weaning trial successes, shorter ICU stay and trend towards quicker time to extubation than weaning by PS-supported with SBTs. The median duration of ventilation prior to weaning was 80.2 (50.5-175.6) hours. The baseline characteristics were similar in the two groups except the PaO(2)/FiO(2) ratio, which was significantly higher in SBT group. The rates of successful weaning trial (89.7% versus 69.4%) were significantly higher in the PS group. The median duration of weaning (66 hours versus 81.5 hours, P=0.05) and the median duration of ICU stay (8 days versus 9.4 days, P=0.027) was lower in the PS group.


**PRO**: Systematic Review. Study focused on 23 studies that reported data on the impact of sedation practice of adult patients, sedated and mechanically ventilated in the ICU. The introduction of guidelines and protocols, or daily interruption of sedation, was associated with reduction of length of ventilation from 10% to 70%, weaning times, length of stay in the ICU from 35% to 65%, length of hospital stay and sedation duration from 39% to 50%.


**PRO**: Study surveyed 423 members of the American Association of Critical Care Nurses to describe factors that influence nurse sedation administration to mechanically ventilated patients and to identify individual or workplace characteristic that impact sedation practices. Self-reported sedation administration subscale scores were higher for respondents using a sedation assessment scale (median: 3.67, IQR: 3.33-3.89) than those without (median: 3.56, IQR: 3.33-3.79); z(407) = -2.565, p=.01). Respondents that utilized sedation scale indicated stronger agreement that three items indicated under sedation: reaching for endotracheal tube (ETT) or lines, tachypnea and ventilator dysynchrony. The majority of nurse respondents felt that sedation was necessary for patients’ comfort and characterized mechanical ventilation as uncomfortable and stressful. The attitudes influence nurses’ self-reported sedation administration.


**PRO**: Study focused on surveying 916 physician, nurse, and pharmacist members of the Society of Critical Care Medicine. The goal was to determine current use of sedation protocols and Daily Sedation Interruption (DIS), along with the perceived barriers to each. Of 64% having sedation protocol, 78% used it for >50 % of ventilated patients. Reasons for lack of protocol use include no physician order (35%), lack of nursing support (11%) and fear of
over sedation (7%). Daily sedation interruption was used by only 40%. Barriers to DSI included lack of nursing acceptance (22%), concern about risk of patient imitated device removal (19%), and inducement of either respiratory compromise (26%) or patient discomfort (13%). Clinicians who prefer propofol were more likely to use DSI than those who prefer benzodiazepines.


**PRO:** Study focused on 423 adult patients requiring mechanical ventilation for ≥ 48 h and infusion with either midazolam or propofol. The incidence of VAP was significantly lower in the nurse-implemented protocol (NIP) group compared with the control group (6% and 15%, respectively, p = .005). By univariate analysis (log-rank test), only use of a NIP was significantly associated with a decrease of incidence of VAP (p < .01).

Additionally, NIP was found to be independently associated with a lower incidence of VAP after adjustment on Simplified Acute Physiology Score II in the multivariate Cox proportional hazards model (hazard rate, 0.81; 95% confidence interval, 0.62-0.95; p = .03). The median duration of mechanical ventilation was significantly shorter in the NIP (4.2 days; interquartile range, 2.1-9.5) compared with the control group (8 days; interquartile range, 2.2-22.0; p = .001), representing a 52% relative reduction. Nurses used dosage table to administer medication by weight for initial and adjustment of sedatives. Level of sedation was determined using Cambridge score used to assess consciousness levels every 3 hours.