

# Decrease in As-needed Sedative Use by Limiting Nighttime Sleep Disruptions from Hospital Staff

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**BACKGROUND:** Hospital routines frequently interrupt nighttime sleep. Sedatives promote sleep, but increase the risk of delirium and falls. Few interventional trials have studied sleep promotion in medical-surgical units and little is known about its impact on sedative use.

**OBJECTIVE:** To determine causes of sleep disruption, and assess whether decreasing sleep disruptions lowers sedative use in medical-surgical patients.

**DESIGN AND SETTING:** Interventional trial with historical controls on a medical-surgical unit of a community teaching hospital. Nurses, physicians, and patients were blinded to the measurement of as-needed sedative use.

**PATIENTS:** Consecutive eligible adults (n = 161 preintervention patients, n = 106 intervention patients).

**INTERVENTION:** We developed the “Somerville Protocol,” which included the establishment of an 8-hour “Quiet Time” that began with automated lights-off and lullaby; staff-monitored noise; and avoidance of waking of patients for routine vital signs and medications.

**MEASUREMENTS:** As-needed sedative use, responses to a patient questionnaire, and responses to a modified Verran Snyder-Halpern (VSH) sleep scale.

**RESULTS:** Preintervention, “hospital staff” was the disturbance most likely to keep patients awake. The intervention decreased the proportion of patients reporting it from 42% to 26%, a 38% reduction ( $P = 0.009$ ; 95% confidence interval [CI]: 0.0452–0.2765). Preintervention, 32% of patients received as-needed sedatives, compared to 16% with the intervention, a 49% reduction ( $P = 0.0041$ ; 95% CI: 0.056–0.26), with a 62% decrease in patients over age 64 years ( $P = 0.005$ ). VSH scores were unchanged.

**CONCLUSIONS:** Small modifications in hospital routines, especially in the timing of vital signs and routine medication administration, can significantly reduce sedative use in unselected hospital patients. *Journal of Hospital Medicine* 2010;5:E20–E24. © 2010 Society of Hospital Medicine.

**KEYWORDS:** patient safety, patient-centered care, sedatives, sleep, sleep fragmentation.

Additional Supporting Information may be found in the online version of this article.

Adequate sleep is important for health, yet the hospital environment commonly disrupts sleep.<sup>1–3</sup> Sleep improves after several days in the hospital.<sup>3,4</sup> Sleep deprivation increases cortisol levels<sup>5</sup> and sleep loss of greater than 4 hours may be hyperalgesic.<sup>6</sup> Even a few days’ suppression of slow-wave sleep worsens glucose tolerance.<sup>7</sup> Sleep disruption may cause irritability and aggressiveness,<sup>8</sup> impaired memory consolidation, and delirium.<sup>2</sup>

Noise may disrupt sleep. The World Health Organization recommends a maximum of 30 to 40 dBA in patients’ rooms at night.<sup>9,10</sup> Normal conversation occurs at 60 dBA. Medical equipment alarms are about 80 dBA.

Sedative use is common in the hospital.<sup>3</sup> Sedatives typically shorten sleep latency and suppress rapid eye

movement (REM) sleep. However, some sedatives cause delirium, falls, amnesia, and confusion, particularly in the elderly.<sup>11–13</sup>

Most research on sleep in hospitalized patients has been done in the critical care setting, often in sedated ventilated patients, where sleep disruption is well-described.<sup>14–16</sup> Only a few small studies have assessed the sleep of hospitalized patients outside critical care.<sup>17,18</sup>

A single blinded interventional trial assessed sedative use, but was a nonrandomized study.<sup>19,20</sup> As-needed sedative use was measured among hospitalized elderly patients as a secondary endpoint. The intervention, known as the Hospital Elder Life Program (HELP), included a protocol with noise reduction, massage, music, and warm drinks, as

well as rescheduling of medications and procedures; it resulted in a 24% reduction in as-needed sedative use. Another trial decreased noise and reduced overnight X-rays on a surgical unit, then measured staff and patient attitudes.<sup>21</sup> Two interventional studies in nursing homes reduced noise and light, and/or increased daytime activity and found no effect on most objective measures of sleep.<sup>22,23</sup> One descriptive study found most sleep disturbances in medical-surgical patients came from noise and sleeping in an unfamiliar bed.<sup>4</sup>

We hypothesized that an intervention designed to improve patient sleep through changes in staff behavior would decrease sedative use among unselected patients in a medical-surgical unit. We measured sedative use as our primary endpoint as a marker for effective sleep, and because decreased sedative use is desirable. We also hypothesized that the intervention would lead to improved sleep experiences, as measured by a questionnaire and Verran Snyder-Halpern (VSH) sleep scores as secondary endpoints.<sup>24</sup>

## Materials And Methods

### Study Design

This was a pre-post study assessing the effect of the intervention on as-needed sedative use, questionnaire responses, and sleep quality. It was an intention-to-treat analysis, and was blinded in terms of measurement of sedative use. The Institutional Review Board of Cambridge Health Alliance approved the study.

### Setting and Patients

The site was the only medical-surgical unit of Somerville Hospital, a small urban community teaching hospital that is part of Cambridge Health Alliance. The hospital unit was chosen for its architectural characteristics, and is organized spatially as 3 U-shaped pods surrounding nursing workstations. Hence, patient rooms were nearly equidistant from the nurses' stations, unlike a hallway design where distant rooms are quieter. Six rooms were private; 11 were semiprivate. Most of the unit's 28 beds are used for medical patients covered by the hospitalist service. Residents see a minority of patients. A hospitalist is available around the clock. Few agency nurses are used.

Preintervention patients were recruited between April and August 2007. The intervention was planned and implemented from September 2007 to January 2008. Intervention patients were recruited between February and June 2008. The most common principle diagnoses on the unit were chest pain (11%), pneumonia (8%), congestive heart failure (CHF) (5.1%), and chronic obstructive pulmonary disease (COPD) flare (3%). Exclusion criteria ensured that no patient was ill enough to require intensive care unit (ICU)-level care or was actively dying. All consecutive hospitalized patients on the unit on Tuesdays through Fridays were potentially eligible and invited to participate unless they met exclusion

criteria. The limited days of the week ensured that technical support would be available during the intervention phase.

Exclusion criteria were: known sleep disorders; language other than English, Spanish, Portuguese, or Haitian Creole; surgery the prior day; arrival on the floor after 10 PM the prior evening; residence on the unit for more than 4 days; alcohol or drug withdrawal; end-of-life morphine drip; significant hearing loss; and blindness.

### Study Protocol

A single investigator surveyed patients in the morning about the prior night's sleep experience. The surveys consisted of the VSH sleep scale, as well as an 8-item questionnaire developed from informal pilot interviews with about 18 patients conducted by 1 of the investigators (M.B.) (Supporting Information Figure 1). The VSH scale is a visual analog scale using a 100-cm line,<sup>24</sup> which we modified with a 100-mm line to make it easier to collect data. The questionnaire and VSH scores of patients with cognitive impairment were not included in the final analysis. Cognitive impairment was determined by diagnoses present in chart review. Surveys and consent forms were available in 4 languages and trained interpreters were used as needed. Nurses, providers, and patients were blinded to the measurement of as-needed sedative use, and staff were unaware of which patients were study subjects.

### Measurements

Nighttime administration of any medication ordered "prn sleep" or "insomnia" was measured using the pharmacy dispensing equipment (Pyxis; Cardinal Health, Dublin, OH), then verified by reviewing the patients' medication administration records. VSH sleep scores were created by measuring the distance in millimeters from the lower end of the scale (0) to the location marked.

We also tracked adherence to some aspects of the intervention. The questionnaire recorded door closing. Chart audits measured the numbers of different prescribers, and the frequency of medication orders using flexible timing.

### Data Analysis

Medication use was analyzed as "any as-needed sedative use" vs. none. The proportions of patients who used sedatives preintervention and postintervention were compared using a 2-sample *Z* statistic, as were survey items. Mean VSH scores were compared with 2-sample *t* tests. The study had greater than 80% power to detect a difference in proportion of at least 0.14 at  $\alpha = 0.05$ .

### Design and Implementation of the Intervention

Preintervention, routine vital signs were taken every 8 hours: 8 AM, 4 PM, and midnight. Night nurses arrived at 11 PM, and typically turned off the hallway lights, but the practice was variable and occurred at no set time.

1. Define “Quiet Time” between 10 pm and 6 am, during which any nonurgent procedures are minimized.
2. Change routine vital signs to 6 am (night shift), 2 pm (day shift), and 10 pm (evening shift.). Telemetry patients continue to get vital signs taken every 4 hours, as per hospital policy.
3. Educate physicians to order medications as Daily, BID, TID, QID, rather than as q24 hours, q12 hours, q8 hours, or q6 hours, when possible, so as to avoid waking patients for doses. Aminoglycosides and vancomycin are specifically exempt from this recommendation.
4. Do not administer standing doses of diuretics after 4 pm.
5. When possible, avoid blood transfusions during Quiet Time, as they require frequent monitoring.
6. Install a noise detection machine on the wall of the nursing station (Yacker Trackers®, Creative Toys of Colorado), set to flash warning lights at over 60 dBA during Quiet Time.
7. Play a lullaby over the public address system every night at 10 pm, to alert patients, staff, and visitors that it is bedtime.
8. Place overhead hallway lights on a timer set to turn off at 10 pm.
9. Encourage nurses to follow a bedtime routine: collect vital signs, administer bedtime medications, toilet the patient, and change the bag of IV fluids for those patients on IV fluids, so that an empty bag does not set off the alarm during the night, and finally, offer to close the patient’s door.
10. When possible avoid placement of intravenous catheters in the antecubital fossae, as occlusion is common which sets off an alarm on the pump. When possible, do not run IV fluids overnight.

**FIGURE 1.** The intervention protocol (the “Somerville Protocol”).

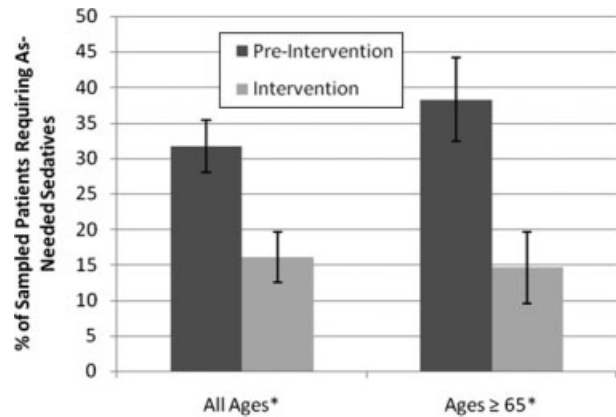
Patients in our informal pilot interviews identified vital signs, medication administration, noise, and evening diuretic administration as disrupting their sleep. After the preintervention phase, we spent 4 months designing and implementing the intervention. We solicited opinions from staff, who identified inflexible timing of medications as disruptive. The plan was discussed at routine staff meetings of all shifts.

The intervention, called the “Somerville Protocol” (Figure 1) created an 8-hour Quiet Time from 10 PM to 6 AM, when disruptions were minimized. Vital signs were taken 2 hours earlier (6 AM, 2 PM, and 10 PM); routine medication administration was avoided; and noise was reduced. As before, telemetry patients required vital signs every 4 hours. At 10 PM, hallway lights were turned off by a timer while the “Lullaby” by Brahms played overhead, signaling the start of Quiet Time to staff and patients. Inexpensive sound meters were installed in each nursing area. They flashed warning lights when 60 dBA was exceeded.

A physician and nurse served as champions. Educational signs were posted in the hospitalists’ call room and in the nursing areas. The champions used e-mail and “detailed” the intervention to staff. Because the staff played an active role in intervention planning, implementation went smoothly.

**TABLE 1.** Characteristics of Control and Study Patients

	Preintervention Patients (n = 161)	Intervention Patients (n = 106)	P Values for Difference
Mean age (years)	59.1	62.95	<i>P</i> = 0.146
Males, n (%)	79 (49.1%)	46 (43.4%)	<i>P</i> = 0.38
Hard of hearing, n (%) (self-report)	33/157 (21.0%)	14/103 (13.6%)	<i>P</i> = 0.128
English-speaking, n (%)	134 (83%)	83 (78.3%)	<i>P</i> = 0.34
Cognitive impairment, n (%)	4 (2.5%)	3 (2.8%)	<i>P</i> = 0.88
Surgical patients, n (%)	10 (6.2%)	2 (1.8%)	<i>P</i> = 0.089



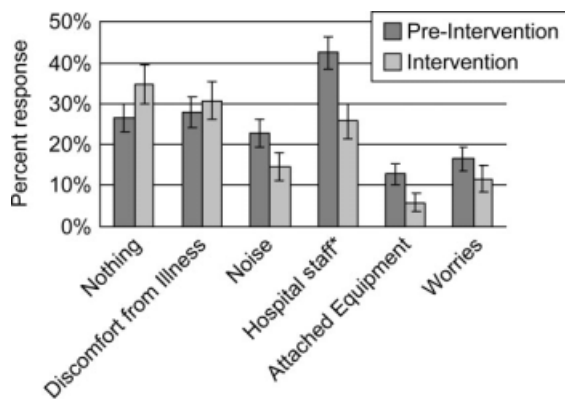
**FIGURE 2.** Any use of as-needed sedatives, per patient, on reference night. All ages: n = 161 patients preintervention; n = 106 intervention. Age ≥65 years: n = 68 preintervention; n = 48 intervention. Standard errors are shown. \*Indicates statistical significance between preintervention and intervention rates. Sedatives consisted of benzodiazepines and benzodiazepine-receptor agonists, sedating antihistamines, trazadone, mirtazapine, and antipsychotics, and tricyclic antidepressants.

## Results

During the preintervention phase, 334 patients were screened, 294 were eligible, and 54.7% of eligible subjects were enrolled (n = 161). During the intervention phase, 211 patients were screened, 188 were eligible, and 56.3% of eligible patients were enrolled (n = 106). The mean patient age was 60.6 years. The preintervention and intervention groups did not differ significantly in enrollment rate, age, gender, cognitive impairment, surgical status, or hearing deficiencies (Table 1). Over 93% of patients were nonsurgical.

## Sedative Use

Preintervention, 31.7% of patients received nighttime as-needed sedatives, versus 16.0% of the intervention group, a 49.4% reduction (*P* = 0.0041; 95% confidence interval [CI]: 0.056-0.26) (Figure 2). In patients aged 65 years or older, 38.2% received nighttime as-needed sedatives preintervention, and 14.6% did postintervention, a 61.2% reduction (*P* = 0.0054; 95% CI: 0.084-0.39).



**FIGURE 3.** What keeps patients awake? \*Indicates statistical significance.

### Questionnaire Results

Preintervention, “hospital staff” was by far the biggest factor keeping patients awake, with 42.4% of patients reporting it (Figure 3). This dropped to only 25.7% with the intervention, a 39.3% decrease ( $P = 0.009$ ; 95% CI: 0.0452-0.2765). Preintervention, 19.2% of patients selected “voices” as the noise most likely to “bother” them at night, and this dropped to 9.9% with the intervention, a 48% decrease ( $P = 0.045$ ; 95% CI: 0.0074-0.1787). No other significant differences were found.

### VSH Sleep Score Results

We found no improvement in any measure of the VSH sleep scale. However, 75% of our patients were unable to use the modified VSH scale, generally because they felt too ill, and were then prompted by the surveyor to choose a number between 1 and 10 that reflected their experience.

### Protocol Adherence

Changes in unit routines resulted in complete adherence to the new vital signs schedule and avoidance of routine evening diuretics. The closing of patients’ doors did not change. An audit of 40 charts found that the percentage of medication orders written with appropriate flexible timing increased from 82% ( $n = 228$ ) to 95.5% ( $n = 200$ ) ( $P = 0.001$ ; 95% CI: 0.077-0.192). From 20 to 30 different providers wrote orders during each phase.

### Discussion

Our trial found that hospital staff was the factor most responsible for patient sleep disruption, and that behavioral interventions on hospital staff can reduce use of as-needed sedatives. The only previously reported intervention to reduce sedative use, the HELP strategy, involved a complex intervention requiring extra staff, with adherence ranging from 10% to 75%.<sup>19,20,25</sup> In contrast, our protocol can be easily replicated at minimal cost.

Our results are consistent with those of Freedman et al.,<sup>26</sup> who found that noise was not the primary factor responsible for sleep disruption in ICU patients, and that staff

activities were at least as important a factor. The study is also consistent with the nursing home studies in which decreases in noise and light did not improve sleep.<sup>22,23</sup> It refutes the study that showed that most sleep disturbance in medical-surgical patients comes from noise and sleeping in an unfamiliar bed.<sup>4</sup> Our results call into question the use of the VSH scale in hospitalized patients, which was designed for use in healthy subjects.

Limitations of this study were as follows: moderate size, lack of refined measures of disease severity, and, as in previous studies,<sup>19,21-23</sup> the lack of randomized concurrent controls. Evaluation of secondary endpoints was limited by lack of validation of the questionnaire with objective observations, and inability to use the modified VSH scale. Self-reports of sleep may correlate imperfectly with objective measures, such as polysomnography.<sup>27</sup>

A larger concurrent trial randomizing similar units at multiple hospitals would be ideal. Future research is needed to determine whether improving sleep in the hospital improves other outcomes, such as recovery times, delirium, falls, or cost.

The need to reduce as-needed sedatives is an important safety issue and similar interventions in other hospitals may be helpful. Simple changes in staff routines and provider prescribing habits can yield significant reductions in sedative use.

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