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The effect of a quality improvement intervention on perceived sleep quality and cognition in a medical ICU

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Abstract

Objective—To determine if a quality improvement (QI) intervention improves sleep and delirium/cognition.

Design—Observational, pre-post design.

Setting—A tertiary academic hospital in the US.

Patients—300 medical ICU (MICU) patients.

Interventions—This MICU-wide project involved a “usual care” baseline stage, followed by a QI stage incorporating multi-faceted sleep-promoting interventions implemented with the aid of daily reminder checklists for ICU staff.

Measurements and Main Results—Primary ICU outcomes were perceived sleep quality and noise ratings (measured on a 0-100 scale using the valid and reliable Richards-Campbell Sleep Questionnaire [RCSQ]) and delirium/coma-free days. Secondary outcomes included ICU and

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hospital length of stay and mortality. Post-ICU measures of cognition and perceived sleep quality were evaluated in an ICU patient subset.

During the baseline and sleep QI stages there were 122 and 178 patients, respectively, with >1 night in the ICU, accounting for 634 and 826 patient-days. Within the groups, 78 (63.9%) and 83 (46.6%) patients received mechanical ventilation. Over the 826 patient-day QI period, checklist item completion rates ranged from 86-94%. In multivariable regression analysis of the QI vs. baseline stages, improvements in overall RCSQ sleep quality ratings did not reach statistical significance, but there were significant improvements in daily noise ratings (mean \pm standard deviation: 65.9 ± 26.6 vs. 60.5 ± 26.3 , $P=0.001$), incidence of delirium/coma (odds ratio: 0.46; 95% confidence interval, 0.23-0.89; $P=0.02$), and daily delirium/coma-free status (odds ratio: 1.64; 95% confidence interval, 1.04-2.58; $P=0.03$). Improvements in secondary ICU outcomes and post-ICU outcomes did not reach statistical significance.

Conclusions—An ICU-wide QI intervention to improve sleep and delirium is feasible and associated with significant improvements in perceived nighttime noise, incidence of delirium/coma, and daily delirium/coma-free status. Improvement in perceived sleep quality did not reach statistical significance.

Keywords

Sleep; Intensive Care Unit; Quality Improvement; Richards-Campbell Sleep Questionnaire; Delirium; Cognition; Outcome Assessment

INTRODUCTION

Poor sleep is common in critically ill patients, and is characterized by frequent awakenings and approximately 50% of sleep occurring during daytime hours (1-4). Patients consistently report worse sleep quality in the ICU compared to home (2) and rank poor sleep as an important source of ICU-related anxiety and stress (5). Although poor sleep can be attributed to modifiable factors, such as noise (1,2,6-8), light (2,6), patient care interactions (9), and medications (3,10), few large-scale ICU sleep improvement studies have been attempted, possibly due to challenges with sleep measurement in this setting (11).

Nevertheless, interest in improving ICU sleep quality has increased, given its possible association with ICU delirium (12) and post-ICU neuro-psychological sequelae (13). Efforts to address these sequelae currently include avoiding deep sedation, preventing delirium, and introducing early physical rehabilitation (13); whether improving ICU sleep quality may be beneficial remains unknown. Thus, this project evaluated the effect of a multi-faceted intervention to improve sleep and delirium/cognition in a medical ICU (MICU).

MATERIALS AND METHODS

Project Setting and Design

This quality improvement (QI) project was undertaken in the Johns Hopkins MICU, which has a 1:2 registered nurse-to-patient ratio and 16 private rooms. This MICU-wide, pre-post evaluation was developed by a multi-disciplinary team with expertise in critical care, sleep, nursing, psychiatry, neuro-psychology, and pharmacology. The multi-faceted QI intervention targeted modifiable factors affecting sleep quality (1,2,4,14), and was implemented in three additive stages (described below), using a previously employed QI framework (15-17).

Baseline (January-February 2010): usual MICU care.

Stage 1 (starting March 2010): To decrease sleep disruptions, nighttime environmental interventions were implemented, including minimizing overhead pages, turning off patient televisions, dimming hallway lights, and grouping care activities (14,18). Daytime interventions to promote normal circadian rhythms and nighttime sleep included raising window blinds, preventing excessive napping, encouraging mobilization, and minimizing pre-bedtime caffeine.

Stage 2 (starting April 2010): In addition to Stage 1 interventions, previously studied non-pharmacological sleep aids were offered to non-delirious (as measured by a negative Confusion Assessment Method for the ICU [CAM-ICU] (19) assessment) patients, including earplugs (20,21), eye masks (21), and soothing music (22).

Stage 3 (May-July 2010): A pharmacologic guideline was implemented for patients unable to sleep despite the Stage 1 and 2 interventions. This guideline discouraged use of commonly prescribed sedating medications known to alter sleep and precipitate delirium (i.e. benzodiazepines, opiates, diphenhydramine, trazodone) (12,23,24), and recommended readily available alternatives: 1) zolpidem for patients without delirium, and 2) haloperidol or an atypical antipsychotic for patients with delirium.

In this pre-post analysis, we decided *a priori* to compare patient outcomes during the baseline stage versus stage 3, after all QI interventions had been incrementally adopted into routine practice. All involved MICU staff received extensive training regarding this project. A daily checklist (available from authors) reminded staff to perform sleep-promoting interventions (16).

ICU Outcome Measures

All patients spending 1 full night in the MICU were eligible for outcome measurement. There were two domains for the primary ICU outcomes: perceived sleep quality and noise ratings, and patient cognition.

Perceived sleep quality was measured using the Richards-Campbell Sleep Questionnaire (RCSQ) (25), a 5-item questionnaire, validated against polysomnography in MICU patients (25), evaluating these aspects of nighttime sleep: 1) depth, 2) latency (time to fall asleep), 3) number of awakenings, 4) efficiency (percent of time awake), and 5) quality. Responses are recorded on a 100-millimeter visual-analogue scale (VAS), with higher scores representing better sleep and the mean of these five items representing the overall RCSQ score (primary RCSQ measure). As in other studies (26,27), the RCSQ also included a sixth item, not included in the overall score, evaluating perceived nighttime noise (VAS range: 0 for “very noisy” to 100 for “very quiet”).

Each morning, MICU nurses asked patients to complete the RCSQ. If patients were “comatose” (i.e., Richmond Agitation-Sedation Scale [RASS] score of -4 or -5 (28)) overnight, the RCSQ was not completed due to inability to evaluate perceived sleep quality. For non-comatose patients with delirium (i.e., having a positive CAM-ICU assessment (19)), inability to complete the survey (e.g., did not understand English), or with major communication barriers (e.g., unable to write or point to answers), the patient’s nightshift nurse completed the RCSQ, based on previous studies demonstrating high patient-nurse agreement on the RCSQ (26,29).

Patient cognition was assessed using ICU delirium/coma-free status, based on nurses’ twice daily CAM-ICU (19) and RASS (28) assessment. As in prior studies (30,31), delirium/coma-free status was selected to provide a gross, but feasible, daily evaluation of the

incidence of “normal” cognition following each night’s sleep. Secondary ICU outcomes included MICU and hospital length of stay and mortality.

Within the context of the MICU’s ongoing QI efforts, and in accordance with Office for Human Research Protections (OHRP) standards, this project was deemed “quality improvement” by the institutional review board (IRB) chair at Johns Hopkins University (32). The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines were followed in reporting this QI project (33).

Post-ICU Outcome Measures

Shortly after ICU discharge, a sample of MICU patients present during the QI project and meeting eligibility criteria (below) were evaluated for perceived sleep quality and cognition. Since this post-ICU evaluation was not part of routine care, it was considered human subjects research and approved by the Johns Hopkins University IRB, with informed consent obtained from all participating patients or their proxies (if patient incapable of consent).

Inclusion criteria for the post-ICU evaluation were: age ≥ 18 years, ≥ 1 night in MICU, and discharge to an inpatient ward bed or pending discharge directly from the ICU. Exclusion criteria were: 1) ≥ 1 night in another ICU during the hospitalization; 2) pre-existing cognitive impairment in the medical record (including dementia, stroke, traumatic brain injury, hepatic encephalopathy, or sustained alcohol or drug abuse (34)); 3) inability to speak or understand English; 4) visual or hearing impairment; 5) inability to read or use a writing instrument; 6) cardiac arrest during the hospitalization; 7) moribund; 8) discharge from the MICU >96 hours prior to assessment; and 9) prior enrollment.

As soon as possible after ICU discharge, a trained investigator (B.B.K. or D.M.N.) administered the post-ICU evaluation. Perceived MICU sleep quality was assessed using an abbreviated Sleep in the ICU Questionnaire, a previously-published instrument (2) addressing ICU sleep quality and disturbances using a 1-10 scale. Cognition was measured using the CAM-ICU, along with these standardized tests: 1) Digit Span Forward and Backward to assess attention and short-term memory (35), and 2) Trail Making Tests A and B to assess attention and executive function (36). Education- and/or age-scaled cognitive test scores (35,37,38) were presented as standardized *T*-scores (Mean=50, Standard deviation (SD)=10) (39). Cognitive test scores were qualitatively classified as “mild to moderate” impairment if ≥ 1 and <2 SD below norm, and “severe” if ≥ 2 SD below norm.

Demographic and ICU variables

Demographic and ICU data obtained for this project included age, gender, race, ICU admission diagnosis, nightly mechanical ventilation status, daily administration of benzodiazepine and/or opiates via infusion and/or bolus, and nightly administration of pharmacological sleep aids. MICU patients (or proxy if patient incapable) completed a brief one-time home sleep quality survey (adapted from the Pittsburgh Sleep Quality Index (40)) inquiring about the presence of pre-existing sleep problems, home sleep quality, and frequency of sleep medication use. Data collection for the post-ICU patient subset included years of education, Charlson Comorbidity Index (41) and other relevant comorbidities, and ICU admission Sequential Organ Failure Assessment (SOFA) score (42).

Statistical Analysis

Data were summarized using median and interquartile range (IQR) for continuous variables and proportions for categorical variables. Unadjusted baseline versus sleep QI comparisons were performed using Wilcoxon rank-sum, chi-squared, and Fisher’s exact tests, as

appropriate. For patients with repeat MICU admissions, only the first MICU admission was included in statistical analyses.

ICU outcomes—Adjusted baseline versus sleep QI differences for the overall RCSQ and nighttime noise scores were determined using multivariable linear regression. All available covariates potentially influencing daily MICU sleep quality ratings were included in the regression model, including age, gender, home sleep survey responses, RCSQ rater (patient vs. nurse), location prior to ICU admission, ICU admission diagnosis, and mechanical ventilation status (measured each night). Because nurse raters performing sleep QI interventions may have influenced their own RCSQ responses, we created an interaction term for rater and project stage (i.e. baseline vs. QI) in the regression models, which was not significant and therefore not included in final models.

Analyses comparing ICU cognitive and secondary outcomes were conducted using multivariable logistic (delirium/coma-free status and mortality) and Poisson regression (length of stay), with adjustment for age, gender, overnight mechanical ventilation status, and four variables for bolus and infusion of benzodiazepines and narcotics. The Poisson models included standard error corrections for overdispersion based on the scaled deviance. Generalized estimating equations (GEE) were used in regression models incorporating repeated daily outcomes (RCSQ scores, delirium/coma-free status) to account for within-patient correlation of time-varying measures (43). Each of the two distinct primary outcome variables was evaluated using a significance level of 0.05. All other analyses of secondary outcomes were considered hypothesis-generating; hence, the p-value threshold used for statistical significance was not adjusted for multiple comparisons.

Post-ICU outcomes—Normality of post-ICU raw data was determined using Shapiro-Wilk tests. The Digit Span results were normally distributed and analyzed using linear regression. A transformed Trail Making Test B variable was calculated by subtracting raw time values from 180 to produce a right-skewed variable. The Sleep in the ICU Questionnaire responses, Trail Making Test A, and transformed Trail Making Test B results were right-skewed and analyzed using multivariable regression assuming a gamma distribution. To avoid overfitting the post-ICU regression models, we included covariates in the multivariable model based on bi-variable association (at $p < 0.10$) of the outcome and potentially relevant covariates, as selected, *a priori*, during design of the study based on prior research and consensus of the multidisciplinary QI team.

For all regression analyses, multicollinearity was assessed using variance inflation factors (44), and addressed, when necessary, by re-categorizing or omitting less relevant collinear variables. A two-sided $p < 0.05$ defined statistical significance. All analyses were performed using STATA version 11.2 (College Station, TX).

Sample size calculation—The post-ICU evaluation sample size was calculated using the Digit Span test. A sample size of 38 patients in each of the baseline and sleep QI stages was selected to detect a moderate effect size of the intervention (45) (defined as a difference in Digit Span test score of 1.5 (46) given an expected SD of 2.3 (34)), with 80% power and a two-sided $p = 0.05$. Based on historical MICU admission rates, we calculated that the desired sample size was attainable within 8-weeks, the allotted time for the baseline and sleep QI stages.

RESULTS

During the baseline and sleep QI stages, respectively, 122 and 178 patients spent 1 night in the MICU and were therefore eligible for ICU outcomes analysis (Table 1). Overall, 34

baseline and 38 QI patients were enrolled in the post-ICU outcomes evaluation, with consent rates of 100% and 97%, respectively. There were no significant between-group differences in demographic characteristics, home sleep habits, or ICU admission diagnoses (Table 1). However, compared to the baseline group, fewer QI patients received mechanical ventilation during their ICU stay. In the post-ICU subset, there were no significant between-group differences in the additional covariates: years of education (median[IQR]: 11[13-15] vs. 12[13-16]; $P=0.67$), ICU admission SOFA score (6[4-9] vs. 5[3-7]; $P=0.15$), Charlson Comorbidity Index score (2[1-4] vs. 1[0-3]; $P=0.16$), and history of prior or current heavy drug and/or alcohol use ($n=10$ (29%) vs. $n=10$ (26%); $P=0.77$).

Sleep-promoting interventions

During the sleep QI stage, the daytime environmental, nighttime environmental and nighttime non-pharmacologic intervention checklist items were completed for 86%, 89%, and 94% of patient-days, respectively (summary in Table 2). Medications for sleep were given 60 times (9% of patient-days) during the baseline stage and 133 times (16%) during the QI stage after implementation of the pharmacologic sleep aid guideline ($P<0.001$). Of medications administered for sleep during the baseline and QI stages, respectively, 45% ($n=27$) versus 60% ($n=80$, $P=0.050$) were guideline-promoted medications given alone, 52% ($n=31$) versus 34% ($n=45$, $P=0.02$) were guideline-discouraged medications given alone, and 3% ($n=2$) and 6% ($n=8$, $P=0.44$) were given in combination.

ICU outcomes

Sleep quality—During 634 and 826 patient-days in the baseline and sleep QI stages, respectively, 110 (90%) and 160 (90%) patients completed at least one RCSQ assessment. During non-comatose days, 440 (89%) and 615 (87%) RCSQs were completed in the baseline and QI stages, respectively, of which nurse raters completed 193 (44%) and 279 (45%).

During the baseline versus sleep QI stages, mean (SD) ratings for RCSQ overall sleep quality were 54.5 (27.1) versus 53.2 (27.3) ($P=0.46$), with no significant improvement in multivariable regression models (adjusted difference=2.37; 95% CI, -1.66-6.40; $P=0.25$) (Table 3). However, mean RCSQ noise ratings were 60.5 (26.3) versus 65.9 (26.6) ($P=0.002$), respectively, and were significantly improved in multivariable models (7.06; 95% CI, 2.80-11.33; $P=0.001$) (Table 3). Similar adjusted differences for the RCSQ overall and noise ratings were observed in multivariable regression analyses stratified by patient (2.51 ($P=0.38$) and 6.75 ($P=0.02$), respectively) and nurse (2.09 ($P=0.47$) and 8.28 ($P<0.001$), respectively) rater. Patients with “somewhat or very bad” (vs. “very good”) home sleep quality had substantially worse RCSQ overall scores and noise ratings (Table 3).

Delirium/coma—Fewer patient-days of delirium/coma-free status were observed during the baseline (272, 43%) versus sleep QI (399, 48%) stage (unadjusted $P=0.04$), with an adjusted odds ratio of 1.64 (95% CI, 1.04-2.58; $P=0.03$) (Table 4). Among the 110 and 175 patients whose entire ICU stay occurred during the baseline or QI stage, respectively, 76 (69%) versus 86 (49%) had incident delirium/coma during their ICU stay (unadjusted $P=0.001$), with an adjusted odds ratio of 0.46 (95% CI, 0.23-0.89; $P=0.02$) (Table 4). To investigate whether differences in administration of pharmacologic sleep aids (as recommended by the pharmacologic guideline for insomnia) influenced this result, we included these medications in post-hoc multivariable regression analyses, and observed no material change in these results.

Secondary outcomes—In multivariable regression, there was no significant reduction in ICU or hospital length of stay or mortality (Table 4).

Post-ICU outcomes

The mean (SD) time to post-ICU testing after MICU discharge for the baseline and sleep QI groups was 23.3 (37.7) versus 7.8 (26.7) hours, respectively ($P=0.046$) (Table 5). On the Sleep in the ICU Questionnaire, QI patients recorded higher median ratings, representing better perceived sleep quality and disruptions, for 8 of 9 items (Table 5). In multivariable regression analysis, only ratings for disruptions due to medication administration were significantly improved ($P=0.009$) in the QI stage.

For neurocognitive testing, all but one patient (in the sleep QI group) were not delirious. Cognitive impairment was observed in almost all baseline and QI patients, with no significant differences in severity: no impairment, 12% vs. 21%; mild/moderate, 38% vs. 29%; and severe, 50% vs. 50% ($P=0.54$). Median (IQR) *T*-scores for the baseline vs. sleep QI groups were: Digit Forward: 49 (41-58) vs. 49 (44-57) ($P=0.96$); Digit Backward: 37 (33-41) vs. 41 (33-48) ($P=0.13$); Trail Making A: 36 (1-44) vs. 33 (16-53) ($P=0.31$); and Trail Making B: 35 (25-43) vs. 40 (26-53) ($P=0.27$). In multivariable models, neurocognitive test results were not significantly improved (Table 5), with no material change in a post-hoc sensitivity analysis adjusting for time to post-ICU testing.

DISCUSSION

Using a structured QI process, this single-site project involved a multi-faceted intervention for critically ill patients, with pre-post evaluation of its effect on perceived sleep quality and delirium/cognitive outcomes in the ICU and following ICU discharge. Implementation of sleep-promoting interventions as part of routine care was feasible and associated with significant improvements in perceived nighttime noise, incidence of ICU delirium/coma, and daily delirium/coma-free status in the ICU, along with non-significant improvements in sleep disruption ratings in a small post-ICU subset. Numeric differences reflecting improved perceived sleep quality in the ICU and post-ICU cognitive function in the QI stage were not statistically significant in multivariable regression models.

Given that interventions to improve ICU sleep have only recently gained widespread scientific interest (4), to our knowledge, there have been no previously published large-scale, multi-faceted QI projects in this area. This project followed other successful QI interventions within our MICU (47) and was conceived as a part of our ongoing efforts to change routine practice to reduce ICU-acquired functional impairments (13). Development of this sleep intervention was guided by prior studies demonstrating the feasibility of environmental noise and light reduction strategies (7,18,27,29), use of earplugs, eye masks, and music (20-22), and pharmacologic sleep aid interventions (48,49). Despite prior studies being limited by sample size (18,22,27,29,48,49), use of simulated ICU settings (20,21), or lack of well-recognized sleep measurement tools (7), they highlighted a spectrum of modifiable ICU sleep factors considered for this project.

Prior to QI implementation, sleep and noise ratings, prevalence of delirium/coma within our MICU, and post-ICU cognitive performance and noise ratings closely matched those of prior studies (2,8,14,25-27,30,34,50-52). Following implementation, the MICU sleep promoting interventions were associated with noise rating improvements paralleling those of a similar study (27). Furthermore, our QI effort was associated with delirium/coma reductions on par with those observed in a randomized clinical trial of dexmedetomidine (31). Despite these findings, however, we did not demonstrate a significant improvement in perceived ICU sleep quality, in contrast to two previous intervention studies (27,51), for several reasons. In contrast to our study, which included all patients spending 1 full night in the MICU, these prior studies selectively included post-operative patients with a lower acuity of illness (<4% received mechanical ventilation), and excluded patients receiving sedation, having pre-

existing sleep problems, and/or an ICU length of stay >3 days. Consequently, these patients may have experienced fewer sleep disruptions inherent to critical illness and been more sensitive to sleep promoting interventions. Furthermore, both studies had smaller sample sizes, did not adjust for potential confounders, and collected sleep ratings only once, on ICU day 3 (27) or after ICU discharge (51).

This QI project had several potential limitations. First, without a significant improvement in perceived sleep quality, we cannot necessarily attribute improvements in delirium/coma specifically to sleep. Instead, this improvement may have resulted from aspects of the multifaceted interventions that could affect delirium, such as the pharmacologic guideline for insomnia, provision of daytime sunlight (53), and promotion of daytime activity (47,53). However, since all aspects of the intervention are generally inexpensive, feasible to implement, and potentially beneficial, we suggest that all aspects of the entire multi-faceted intervention be considered together until further research is available. Second, given this pre-post design, we cannot be certain that the QI interventions caused the observed baseline versus QI differences. Other factors, not adjusted for in our analysis, including temporal or seasonal differences, could have influenced the results. Third, sleep was evaluated using the RCSQ instead of polysomnography (PSG), which is difficult to interpret and implement on a large-scale basis in the ICU (11). We selected the RCSQ in part because it had been validated against PSG in a MICU population (25). Fourth, there was no objective measure of noise and it is unclear whether the observed improvement in perceived noise was clinically important. However, in post-hoc multivariable regression analysis, there was a significant association between the RCSQ noise score and the overall RCSQ sleep ratings that excluded the noise question (0.38 point improvement in overall score for 1 point improvement in noise, $P < 0.001$), suggesting that improvements in perceived noise correlated with improvements in perceived sleep. We also have many anecdotal reports of marked reductions in overhead pages, unnecessary alarms, and nighttime television watching. However, we cannot demonstrate that improvements in perceived noise correlated with objective measurement and were clinically important. Fifth, it is possible that nurses' RCSQ ratings and delirium/coma assessments were biased by their own sleep-promoting actions (i.e. minimizing alarms, turning off televisions). However, RCSQ regression models including an interaction term for rater and project stage were not significant, suggesting no influence of the intervention stage on nurse RCSQ ratings. Furthermore, confounding of the delirium/coma outcome was minimized since the 8am assessments were completed by daytime nurses not performing nighttime sleep-promoting interventions, and the 8pm assessments were completed before the implementation of sleep-promoting interventions. Sixth, the post-ICU evaluation may have been underpowered to detect significant improvements in sleep quality and cognitive function. Moreover, despite efforts to perform the post-ICU evaluation immediately following ICU discharge, a longer time to cognitive testing in the baseline group may have allowed for recovery from ICU-acquired deficits (54), thus biasing the result toward the null. However, a post-hoc sensitivity analysis did not demonstrate any important differences in the results. Seventh, as a single-site study, generalizability of our findings may be limited. However, by having no exclusion criteria for the QI portion of the project, we examined a heterogeneous ICU patient population that included 161 mechanically ventilated patients, and observed baseline sleep quality ratings and cognitive outcomes similar to other ICU studies. Finally, as a multi-faceted QI project, we could not determine which specific sleep-promoting interventions were associated with the observed results. However, all facets of the intervention were inexpensive, easy to implement, and low risk. For this reason, and potential synergy between the interventions, we suggest the QI intervention remain bundled if implemented elsewhere.

In conclusion, using a structured process, we implemented a multi-faceted, multi-stage quality improvement intervention to promote sleep, demonstrating that such efforts were

feasible as part of routine ICU care and were associated with significant reductions in perceived nighttime noise levels and a substantial decrease in delirium/coma.

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Table 1

Patient Characteristics

Characteristic	ICU evaluation			Post-ICU evaluation		
	Baseline (N = 122)	Sleep OI (N = 178)	P value ^a	Baseline (N = 34)	Sleep OI (N = 38)	P value ^a
Age, median (IQR)	54 (43-63)	54 (44-66)	0.75	53 (41-61)	54 (34-62)	0.77
Female, n (%)	54 (44.3)	93 (52.3)	0.17	16 (47.1)	24 (63.2)	0.17
White race, n (%)	49 (40.2)	82 (46.1)	0.31	10 (29.4)	19 (50.0)	0.08
Living at home before ICU admission, n (%)	95 (77.9)	139 (78.1)	0.96	27 (79.4)	32 (84.2)	0.60
Home sleep questionnaire ^b						
Pre-existing sleep problems, n (%)	27 (22.1)	48 (27.0)	0.34	9 (26.5)	18 (47.4)	0.07
Describes sleep as, n (%)						
Very Good	34 (27.9)	40 (22.5)		12 (35.3)	13 (34.2)	
Somewhat good	40 (32.8)	50 (28.1)	0.24	16 (47.1)	15 (39.5)	0.82
Very bad/somewhat bad	15 (12.3)	36 (20.2)		5 (14.7)	9 (23.7)	
Unknown/not answered	33 (27.1)	52 (29.2)		1 (2.9)	1 (2.6)	
Taking Sleep Medications, n (%)						
>4 times per week	11 (9.0)	16 (9.0)	0.58	5 (14.7)	5 (13.2)	0.85
1-4 times per week	7 (5.7)	16 (9.0)		4 (11.8)	3 (7.9)	
Never or unknown	104 (85.3)	146 (82.0)		25 (73.5)	30 (79.0)	
ICU Admission Diagnosis, n (%)						
Respiratory failure (including pneumonia)	38 (31.2)	52 (29.2)		9 (26.5)	7 (18.4)	
Gastrointestinal	19 (15.6)	27 (15.2)		3 (8.8)	9 (23.7)	
Sepsis (non-pulmonary)	11 (9.0)	25 (14.0)	0.52	2 (5.9)	0 (0.0)	0.18
Cardiovascular	16 (13.1)	15 (8.4)		4 (11.8)	8 (21.1)	
Other	38 (31.2)	59 (33.2)		16 (47.1)	14 (36.8)	
Ever received mechanical ventilation overnight in MICU, n (%)	78 (63.9)	83 (46.6)	0.01	16 (47.1)	11 (29.0)	0.11

Abbreviations: ICU - Intensive Care Unit; QI - Quality Improvement; IQR - Interquartile Range; MICU - Medical ICU

^a Calculated using Wilcoxon rank sum for continuous variables, and chi-squared or Fisher's exact tests, as appropriate, for categorical variables.

^b Baseline sleep questionnaires could not be completed for 30 (25%) and 51 (29%) of baseline and sleep QI patients, and 1 (3%) and 1 (3%) post-ICU patients due to patient being moribund or comatose (without proxy), or other reasons.

Table 2
Implementation of Sleep Quality Improvement Interventions

Intervention	Completion
Patient daytime interventions (<i>N</i> =735 patient-days), n (%) ^{a,b}	
Blinds raised	578 (79)
Caffeine avoided after 3pm ^c	248 (54)
Less than 50% of day shift spent napping ^d	287 (45)
Patient nighttime interventions (<i>N</i> =826 patient-nights), n (%) ^a	
Room lights dimmed before 10pm	642 (78)
Room curtain closed before 10pm	528 (64)
Warm bath before 10pm	403 (49)
Unnecessary alarms prevented	640 (77)
Room temperature optimized	637 (77)
Pain appropriately controlled	559 (68)
Television off	486 (59)
Estimated number of nurse interruptions between 10pm-7am	
0-5 interruptions	231 (28)
6-10 interruptions	177 (21)
>10 interruptions	111 (13)
Not reported	307 (37)
Soft music offered and accepted ^e	62 (11)
Eye mask offered and accepted ^e	10 (2)
Earplugs offered and accepted ^e	5 (1)
Medication given per sleep guideline ^f	61 (13)
ICU-wide nighttime interventions (<i>N</i> =88 days), n (%)	
Hallway lights dimmed by 10pm	78 (89)
Overhead pages after 10pm	
None	13 (15)
1-3	32 (36)
>3	7 (8)
Unknown ^g	36 (41)

Abbreviations: ICU, Intensive Care Unit

^aMissing data for individual checklist items occurred for 6-15% of patient-days. In calculating proportions for checklist item adherence, items with missing data were considered not completed.

^bExcludes 91 patient-days that occurred on day of MICU admission, after daytime interventions could be performed.

^cProportion calculated after exclusion of 278 patient-days (38%) where patients' clinical status prohibited oral intake.

^dProportion calculated after exclusion of 92 (13%) patient-days where activities to promote wakefulness were not promoted due to sedation status (RASS -4 or -5).

^eProportions calculated after exclusion of 260 (31%) patient-days where nonpharmacologic interventions were not applicable due to sedation status (RASS -3, -4 or -5). Soft music, eye masks, and earplugs were offered but declined by patients 159 (28%), on 150 (27%), and 150 (27%) patient-days, respectively, and not offered to patients (due to patient already sleeping, clinical instability, other clinical duties) on 280 (49%), 323 (57%), and 326 (58%) patient-days.

^fMedications included low-dose antipsychotics and zolpidem for patients with and without delirium, respectively.

^gUnknown because staff not present to complete the checklist, or the checklist not completed.

Table 3
Sleep quality and nighttime noise results

Covariate	Adjusted change (95% CI) in score ^a			
	Total sleep quality	P value	Noise	P value
Sleep QI vs. baseline stage	2.37 (-1.66, 6.40)	0.25	7.06 (2.80, 11.33)	0.001
Nurse vs. patient completing questionnaire	1.75 (-3.60, 7.09)	0.52	3.32 (-2.09, 8.72)	0.23
Age, per year	-0.01 (-0.14, 0.12)	0.91	-0.06 (-0.20, 0.07)	0.36
Male	-1.60 (-5.99, 2.78)	0.47	1.54 (-3.05, 6.12)	0.51
Living at home prior to ICU admission	3.05 (-2.47, 8.57)	0.28	7.71 (0.82, 14.60)	0.03
Self-reported history of sleep problems	-1.01 (-6.58, 4.56)	0.72	4.96 (-1.02, 10.93)	0.10
Self-reported home sleep quality				
Very good	REF		REF	
Somewhat good	-3.87 (-9.12, 1.38)	0.15	-7.67 (-12.92, -2.42)	0.004
Somewhat/very bad	-13.96 (-19.79, -8.12)	<0.001	-9.21 (-16.31, -2.11)	0.01
Unknown/not answered	-0.54 (-6.50, 5.43)	0.86	-4.90 (-11.16, 1.35)	0.12
Home sleep medication frequency				
Never/unknown	REF		REF	
1-4 times per week	-9.17 (-17.56, -0.79)	0.03	-8.07 (-16.36, 0.21)	0.06
>4 times per week	3.91 (-3.42, 11.23)	0.30	0.20 (-8.08, 8.48)	0.96
ICU admission diagnosis				
Respiratory (including pneumonia)	REF		REF	
Gastrointestinal	-3.89 (-10.72, 2.94)	0.26	-1.92 (-10.37, 6.54)	0.66
Sepsis (non-pulmonary)	-4.70 (-13.05, 3.65)	0.27	-1.15 (-11.38, 9.09)	0.83
Cardiovascular	3.04 (-5.98, 12.05)	0.51	1.91 (-7.27, 11.08)	0.68
Other	-6.35 (-13.44, 0.73)	0.08	-2.75 (-11.55, 6.04)	0.54
Receiving mechanical ventilation overnight	2.96 (-1.77, 7.69)	0.22	-2.38 (-7.00, 2.25)	0.31

Abbreviations: QI - Quality Improvement; CI - Confidence Interval

^aScoring done using a 100 millimeter visual-analogue scale, with higher scores representing better overall sleep quality and less overnight noise for the Total Sleep Quality and Noise results, respectively. P values calculated using multivariable linear regression analysis using generalized estimating equations (GEE) to account for within-patient clustering of repeated daily timevarying measures.

Table 4
ICU cognitive and secondary outcomes

ICU outcome	Baseline N = 110 patients, 634 patient- days	Sleep QI N = 175 patients, 826 patient- days	Adjusted QI vs. Baseline (95% CI)	P Value
Delirium outcomes				
Daily delirium/coma-free status in MICU, no. patient-days (%) and Odds Ratio	272 (43)	399 (48)	1.64 (1.04-2.58)	0.03 ^{a,b,c}
Incidence of ICU delirium/coma, N (%) and Odds Ratio	76 (69)	86 (49)	0.46 (0.23-0.89)	0.02 ^{a,b}
Length of stay (LOS)				
ICU - survivors, mean days (SD) and Mean Difference	5.4 (9.5)	4.3 (6.8)	-1.12 (-2.33-0.08)	0.60 ^{a,d}
ICU - died in MICU, mean days (SD) and Mean Difference	6.3 (5.2)	7.5 (6.4)	1.21 (-2.04-4.46)	0.39 ^{a,d}
Hospital - survivors, mean days(SD) and Mean Difference	15.0 (14.6)	13.4 (17.0)	-1.60 (-5.15-1.94)	0.74 ^{a,d}
Hospital - died in hospital, mean days (SD) and Mean Difference	10.1 (9.1)	15.1 (26.9)	4.99 (-1.12-11.09)	0.12 ^{a,d}
Mortality				
ICU mortality, no. (%) and Odds Ratio	18 (16)	24 (14)	1.14 (0.53-2.45)	0.74 ^{a,e}
Hospital mortality, no. (%) and Odds Ratio	28 (25)	34 (19)	0.87 (0.45-1.66)	0.67 ^{a,e}

Abbreviations: QI: Quality Improvement; CI: Confidence Interval; MICU: Medical ICU; SD: Standard Deviation

^a Adjusted for age, gender, ICU admission diagnosis, mechanical ventilation status, and both bolus and infusion status for benzodiazepine and narcotic medications.

^b P value calculated using multivariable logistic regression with generalized estimating equations (GEE) to account for within-patient clustering of repeated daily measures of delirium/coma status.

^c Post-hoc analysis using the original multivariable regression model (described in footnote ^a) plus adjustment for all medications promoted and discouraged by the pharmacologic sleep aid guideline (e.g., haloperidol and atypical antipsychotics) used in the QI stage demonstrated similar results (odds ratio [95% CI] = 1.58 [1.00-2.49], $P = 0.048$) to the primary results presented in Table 4.

^d P value calculated using multivariable Poisson regression with standard errors corrected for overdispersion (based on scaled deviance).

^e P value calculated using multivariable logistic regression.

Table 5
Post-ICU sleep questionnaire and neurocognitive testing results^a

Measure	Baseline N = 34	Sleep QI N = 38	Adjusted Difference in Score for QI vs. Baseline (95% CI)	P Value
Sleep in the ICU Questionnaire ^b				
Sleep quality in ICU	6 (3-7)	5 (2-7)	-0.6 (-1.9, 0.8)	0.47
Daytime sleepiness in ICU	5 (4-7)	6 (5-9)	0.7 (-0.6, 2.0)	0.41
Level of disruption:				
Noise	4 (2-9)	7 (3-10)	1.4 (-0.4, 3.2)	0.19
Light	5 (4-9)	8 (5-10)	1.2 (-0.4, 2.9)	0.19
Nurse visits to room	4 (2-7)	5 (2-9)	1.1 (-0.5, 2.7)	0.11
Testing (X-rays, EKG, etc.)	5 (2-8)	9 (2-10)	1.3 (-0.6, 3.2)	0.15
Vital signs	5 (3-8)	8 (3-10)	1.4 (-0.2, 3.1)	0.08
Blood draws	4 (3-8)	6 (3-10)	1.2 (-0.6, 3.0)	0.25
Medication administration	5 (3-9)	9 (6-10)	2.2 (0.6, 3.8)	0.009
Neurocognitive testing score				
Digit Span - Total Score ^c	12 (10-14)	13 (10-14)	0.4 (-1.2, 2.0)	0.60
Trail Making Part A ^d	52 (38-94)	44 (36-70)	-10.6 (-27.2, 5.9)	0.50
Trail Making Part B ^d	180 (99-180)	146 (69-180)	-26.9 (-65.6, 11.8)	0.19

Abbreviations: ICU - Intensive Care Unit; QI - Quality Improvement; SOFA - Sequential Organ Failure Assessment

^aAll values are median (interquartile range) unless stated otherwise. Neurocognitive testing data presented as raw scores.

^bThe following questions were rated on a 1 to 10 scale. Higher scores indicated better quality of sleep on the "Sleep quality in ICU" question, and a higher level of alertness for the "Daytime sleepiness in ICU" question. The "Level of disruption" ratings assessed nighttime sleep disruptions, with higher scores indicating less disruptiveness. Adjusted differences were calculated using multivariable linear regression with adjustment for SOFA score and self-reported home sleep quality rating.

^cSum of Digit Span Forward and Backward scores (with higher score indicating better performance). Adjusted difference calculated using multivariable linear regression with adjustment for race, ICU admission diagnosis category and SOFA score, and current/prior heavy alcohol or drug use.

^dPresented as time to completion in seconds, with a maximum allowed time of 180 seconds (with lower score indicating better performance). Adjusted differences were calculated using multivariable linear regression with adjustment for gender, education (cubic polynomial), ICU admission SOFA score (cubic polynomial), self-reported home sleep quality rating (categorical), and current/prior heavy alcohol or drug use.