Successful Implementation of a Neonatal Pain and Sedation Protocol at 2 NICUs

OBJECTIVE: To evaluate the implementation of a neonatal pain and sedation protocol at 2 ICUs.

METHODS: The intervention started with the evaluation of local practice, problems, and staff satisfaction. We then developed and implemented the Vienna Protocol for Neonatal Pain and Sedation. The protocol included well-defined strategies for both nonpharmacologic and pharmacologic interventions based on regular assessment of a translated version of the Neonatal Pain Agitation and Sedation Scale and titration of analgesic and sedative therapy according to aim scores. Health care staff was trained in the assessment by using a video-based tutorial and bedside teaching. In addition, we performed reevaluation, retraining, and random quality checks. Frequency and quality of assessments, pharmacologic therapy, duration of mechanical ventilation, and outcome were compared between baseline (12 months before implementation) and 12 months after implementation.

RESULTS: Cumulative median (interquartile range) opiate dose (baseline dose of 1.4 [0.5–5.9] mg/kg versus intervention group dose of 2.7 [0.4–57] mg/kg morphine equivalents; \( P = .002 \)), pharmacologic interventions per episode of continuous sedation/analgesia (4 [2–10] vs 6 [2–13]; \( P = .005 \)), and overall staff satisfaction (physicians: 31% vs 89%; \( P < .001 \); nurses: 17% vs. 55%; \( P < .001 \)) increased after implementation. Time on mechanical ventilation, length of stay at the ICU, and adverse outcomes were similar before and after implementation.

CONCLUSIONS: Implementation of a neonatal pain and sedation protocol at 2 ICUs resulted in an increase in opiate prescription, pharmacologic therapy, duration of mechanical ventilation, and outcome without affecting time on mechanical ventilation, length of intensive care stay, and adverse outcomes. Pediatrics 2013,132:e1–e8
Neonates in NICUs cannot verbalize pain or discomfort and therefore depend on health care takers to provide them with an adequate level of sedation and analgesia. International guidelines for adults\textsuperscript{1–4} and children\textsuperscript{5,6} recommend to titrate analgesics and sedative medication according to defined patient-specific end points. This goal is best accomplished by means of validated pain/agitation and sedation assessment using standardized scales. Outcome investigations provide strong evidence that the use of pain and sedation protocols resulted in a decrease in duration of mechanical ventilation\textsuperscript{4,7,8} and days of drug administration\textsuperscript{1,4} in adults and children. The American Academy of Pediatrics and the Canadian Pediatric Society policy statements on prevention and management of pain in neonates advocate routine pain assessment and the use of protocols for the management of pain and sedation in neonates.\textsuperscript{9} Until May 2010, neither an instrument to assess nor a protocol to treat pain, agitation, and sedation existed in our institution. The management of pain, agitation, and sedation had thus far been based on irregular and subjective evaluations of the patient’s condition in terms of pain and sedation and resulted in team dissatisfaction.

We hypothesized that implementing a protocol for the management of neonatal pain and sedation on the basis of a validated assessment instrument would improve frequency and quality of pain and sedation assessment. Our secondary aim was to show how this implementation affected analgesic and sedative medication according to defined patient-specific end points. This goal is best accomplished by means of validated pain/agitation and sedation assessment using standardized scales. Outcome investigations provide strong evidence that the use of pain and sedation protocols resulted in a decrease in duration of mechanical ventilation\textsuperscript{4,7,8} and days of drug administration\textsuperscript{1,4} in adults and children. The American Academy of Pediatrics and the Canadian Pediatric Society policy statements on prevention and management of pain in neonates advocate routine pain assessment and the use of protocols for the management of pain and sedation in neonates.\textsuperscript{9} Until May 2010, neither an instrument to assess nor a protocol to treat pain, agitation, and sedation existed in our institution. The management of pain, agitation, and sedation had thus far been based on irregular and subjective evaluations of the patient’s condition in terms of pain and sedation and resulted in team dissatisfaction.

We hypothesized that implementing a protocol for the management of neonatal pain and sedation on the basis of a validated assessment instrument would improve frequency and quality of pain and sedation assessment. Our secondary aim was to show how this implementation affected analgesic and sedative treatment, mechanical ventilation, short-term outcome, and staff satisfaction.

**METHODS**

**Setting**

The Medical University of Vienna is a tertiary perinatal center with \(~3000\ deliveries and admitting \(>180\) preterm infants weighing \(<1500\) g per year. The project started in May 2010 at two 10-bed NICUs with the establishment of a study protocol upon approval by the local ethics committee.

**Implementation Plan**

**Choice and Translation of a Pain, Agitation, and Sedation Assessment Tool**

A multidisciplinary team including neonatologists, NICU nurses, a psychologist, and a pharmacist extensively reviewed the published literature and agreed on the introduction of the Neonatal Pain, Agitation, and Sedation Scale (N-PASS). The N-PASS allows assessment of both sedation and pain for a wide range of patients from a gestational age of 23 weeks onward to older neonates.\textsuperscript{10,11} The 5 parameters of the N-PASS are crying/irritability, behavior/state, facial expression, extremities/tone, and vital signs. These criteria are graded 0, 1, or 2 for pain/agitation and 0, −1, or −2 for sedation. A score \(>3\) on the pain subscale indicates pain, whereas a score between −2 and −5 on the sedation subscale indicates light sedation and a score between −6 and −10 indicates deep sedation. We involved 2 professional certified translators to translate the original English version of the N-PASS into German and subsequently back into English. Upon discussions of the potential comprehensibility, clarity, and unambiguousness of different wordings, we reached a consensus on the final German version of the N-PASS.

**Development of the Vienna Protocol for Neonatal Pain and Sedation**

We discussed the best possible practice including published evidence\textsuperscript{1,5,10–20} and our own clinical experience to develop the Vienna Protocol for Neonatal Pain and Sedation (V-PNPS) (Fig 1). The V-PNPS is a detailed protocol for the management of pain, agitation, and sedation and includes frequency of assessments, drug type, dosage, and a flowchart indicating when to use which drug according to N-PASS values. Strategies for nonpharmacologic interventions such as swaddling, non-nutritive sucking,\textsuperscript{12} and sucrose\textsuperscript{16} for escalation and deescalation of continuous sedative and analgesic drugs were defined. We aimed for N-PASS values between 0 and 3 with regard to the pain subscale to avoid pain/agitation and for values between 0 and −5 with regard to the sedation subscale to avoid oversedation.

Regular N-PASS assessments were performed in patients receiving continuous analgesia or sedation; in those receiving mechanical ventilation or continuous positive airway pressure; in patients requiring \(>40\%\) oxygen; in cases of severe dyspnea, postoperative care, sepsis, indwelling pleural or abdominal drains, or large skin defects; and in patients receiving palliative care. The N-PASS was assessed 30 minutes after any procedure, escalation, or deescalation of continuous sedative or analgesic drug infusions but at least every 8 hours. In all cases, the physicians gave the orders to change medication according to the presented protocol, following the flowchart with regard to N-PASS values established by the bedside nurse.

**Staff Training and Education**

We introduced the V-PNPS on several occasions (eg, scheduled teaching sessions, ward rounds). Posters showing the V-PNPS flowchart were placed in every room of our NICUs and a laminated small version was placed at every bedside. We chose an interactive video-based tutorial for training purposes and created short movies of patients after parental consent had been obtained. The tutorial aimed to train N-PASS assessment in a stepwise approach. Nurses were trained to first
observe the patient in a calm, undisturbed state, then during a routine care procedure, and finally during consolation after the care procedure. Nurses were shown movie sequences demonstrating these 3 steps of assessment for each of the presented patients. The video sequences showed well-settled patients, patients in pain, as well as sedated patients.

**Evaluation of Baseline Level of Care**

We evaluated local problems and assessed staff satisfaction before the introduction of the V-PNPS. We administered anonymous questionnaires to the NICU nursing staff and physicians. The team was asked to rate by using a 4-item rating scale the following aspects of pain, agitation, and sedation management: (1) frequency of documentation, (2) incidence of severe pain/agitation, (3) time to intervention in case of severe pain/agitation, (4) effectiveness of sedative/pain therapy, (5) frequency of withdrawal symptoms, and (6) overall quality of pain and sedation management. There was also a free comments section (possible contributing factors that should be improved).

**Intervention Phase**

**Analysis Plan**

The primary end point was frequency of pain and sedation assessments. Secondary end points included duration and amount of analgesic and sedative drug therapy, time on mechanical ventilation, time to discharge from the NICU, morbidity, and mortality. To analyze effects on therapy and short-term outcome, we compared patients treated during the 12-month intervention phase with a retrospective control group treated during a 12-month
baseline phase before the implementation of the V-PNPS.

Interobserver Agreement
Reassessment and retraining of the staff was performed throughout the entire intervention phase. Trained members of the study team randomly evaluated patients independently of the care-giving nurse to ensure quality of assessments. Patients were assigned for simultaneous assessment by using simple randomization. Twelve months after implementation of the V-PNPS, we established a new set of short training movies.

Evaluation of Staff Interaction, Communication, and Satisfaction
With the use of anonymous questionnaires, nurses and physicians were asked to estimate the incidence of pain and agitation in neonatal patients and to score the success rate of the administered pain relief as well as the interaction and communication between physicians and nurses.

Documentation of N-PASS Assessments
The N-PASS tool was integrated into our electronic patient data management system as part of the “vital sign” category.

Statistical Analysis
We used χ² tests to compare categorical variables between the study groups and the Wilcoxon-Mann-Whitney 2-sample rank-sum test to compare continuous variables. We used a linear regression model for the comparison of the mean number of N-PASS assessments per patient and day over time. Linear regression models with segmented relationships between week of intervention and number of N-PASS assessments were calculated. A segmented relationship was defined by the slope parameters and the break points where the linear relationship changed. An ordinal logistic regression model including an interaction term was calculated to determine the effect of implementation of the V-PNPS and the influence of staff profession on each question of the questionnaire by using SPSS 19.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY). Analysis was performed by using R 2.12 (R Foundation for Statistical Computing, Institute for Statistics and Mathematics, Vienna, Austria). P values <.05 were considered statistically significant.

RESULTS
Impact of the Implementation on Therapy and Outcome
Control and intervention groups were similar (Table 1). At baseline, 59% of all patients received continuous opiate infusions for a median (interquartile range [IQR]) duration of 5.1 (1.6–17.5) days at a median (IQR) cumulative dose of 1.4 (0.5–5.9) mg/kg morphine equivalents. After intervention, the median (IQR) cumulative dose significantly increased to 2.7 (0.4–57) mg/kg morphine equivalents (P = .002). After intervention, the percentage of patients receiving continuous opiate infusions was comparable (55%: P = .2) as was the median (IQR) duration of treatment (4.9 [1.0–14.1] days; P = .3). In the intervention group, significantly more pharmacologic interventions (escalation and deescalation) were performed per episode of continuous sedation/analgesia compared with baseline (4 [2–10] vs 6 [2–13]; P = .005). At baseline, 32 (7%) patients received oral morphine for a median (IQR) time of 4.5 (2.0–7.0) days. After intervention, significantly more patients received oral morphine (53 [11%]; P = .02) but for a similar time period (5.0 [3.0–12.5] days; P = .2). Before and after intervention, the number of patients receiving benzodiazepines and muscle relaxants was the same, as was the duration of continuous treatment and cumulative doses. The number of patients receiving bolus injections of paracetamol and oral chloral hydrate was similar before and after the intervention, as was the number of doses (Table 2).

At baseline, patients spent a median (IQR) of 2.2 (0.6–6.8) days on mechanical ventilation and 9.0 (3.0–32.2) days...
in the NICU. After intervention, both time on mechanical ventilation (2.6 [0.8–6.9] days; \(P = .4\)) and length of NICU stay (10.1 [3.3–30.3] days; \(P = .2\)) remained unchanged (Table 2). The main adverse outcomes, including intraventricular hemorrhage, retinopathy of prematurity, necrotizing enterocolitis, persistent ductus arteriosus, and mortality, were similar in both groups (Table 2).

**Frequency, Distribution, and Time Expenditure of N-PASS Assessments**

A total of 20 740 N-PASS assessments in 376 (81% of all treated NICU) patients on 5304 patient days were performed during the intervention phase. On average, 36.5 scores per patient and 2.9 scores per patient-day were documented. Figure 2 shows the frequency of N-PASS assessments per eligible patient throughout the 12-month intervention phase. A total of 1843 (8.9%) N-PASS assessments were revealed to be in the goal range for sedated patients, 13 609 (65.6%) were in the comfort range for nonsedated patients, 3731 (18.0%) were in the range indicating moderate pain/agitation, 416 (2.0%) were in the range indicating severe pain, and 1141 (5.5%) were in the range indicating deep sedation (Fig 1). Nurses spent a mean (SD) of 4.9 (1.9) minutes to assess and 0.3 (0.1) minutes to document the N-PASS. In a random sample of 20 patients, the time expenditure for N-PASS assessments was measured. Patients from both NICUs were selected by using simple randomization. The mean time expenditure remained constant throughout the intervention phase.

**Assessment Quality**

The study team agreed on “goal” N-PASS values for 6 patients presented in short movies (3 patients before the intervention phase [patients A, B, C], 3 patients after the intervention phase [patients D, E, F]). For each patient, goal values for both the pain and the sedation subscale of the N-PASS were defined. Fifty-three nurses were tested before the intervention and 55 were tested after the intervention (2 additional nurses participated in the second session). We considered performance of N-PASS assessment as “very good” when the N-PASS assessment for both the pain and the sedation subscale differed only in 1 point or was identical with goal values. In the first (second) training session 76% (98%) of nurses performed “very good” with respect to the pain subscale and 95% (87%) with respect to the sedation subscale. The median (IQR) deviation in N-PASS assessments from goal scores did not differ significantly between training sessions (0 [0–1]; \(P = .4\)). During the intervention phase, trained members of the study team regularly evaluated patients independently of the regular evaluation by the care-giving nurse to ensure the quality of assessments. Ninety percent of the simultaneous assessments both of the N-PASS sedation and pain subscale yielded a very good assessment quality (in a subset of 30 patients).

**Evaluation of Staff Comfort and Satisfaction**

Thirteen (52%) physicians and 46 (84%) nurses answered the questionnaire at baseline and 19 (76%) physicians and 42 (76%) nurses after implementation.

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**TABLE 2** Comparison of Neonatal Intensive Care Therapy and Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group (n = 465)</th>
<th>Control Group (n = 484)</th>
<th>(P)</th>
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</thead>
<tbody>
<tr>
<td>Sedation and analgesia</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patients treated, n (%) sedation/analgesia</td>
<td>402 (87)</td>
<td>439 (91)</td>
<td>.2</td>
</tr>
<tr>
<td>Pharmacologic interventions per sedation/analgesia episode, median (IQR) Opiate use</td>
<td>6 (2–13)</td>
<td>4 (2–10)</td>
<td>&lt;.05</td>
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<tr>
<td>Patients treated, n (%)</td>
<td>255 (55)</td>
<td>285 (59)</td>
<td>.2</td>
</tr>
<tr>
<td>Time, median (IQR), d</td>
<td>4.9 (1.0–14.1)</td>
<td>5.1 (1.8–17.5)</td>
<td>.3</td>
</tr>
<tr>
<td>Total dose, median (IQR), mg/kg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.7 (0.4–57)</td>
<td>1.4 (0.5–5.9)</td>
<td>&lt;.05</td>
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<tr>
<td>Benzodiazepine Use</td>
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<tr>
<td>Patients treated, n (%)</td>
<td>76 (16)</td>
<td>85 (18)</td>
<td>.5</td>
</tr>
<tr>
<td>Time, median (IQR), d</td>
<td>4.0 (1.3–9.8)</td>
<td>5.7 (1.8–20.5)</td>
<td>.1</td>
</tr>
<tr>
<td>Total dose, median (IQR), mg/kg&lt;sup&gt;b&lt;/sup&gt;</td>
<td>5.2 (1.6–18.5)</td>
<td>6.6 (2.0–15.5)</td>
<td>.7</td>
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<tr>
<td>Muscle relaxant use</td>
<td></td>
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<tr>
<td>Patients treated, n (%)</td>
<td>54 (12)</td>
<td>66 (14)</td>
<td>.3</td>
</tr>
<tr>
<td>Time, median (IQR), d</td>
<td>2.6 (0.5–4.7)</td>
<td>2.9 (1.3–6.7)</td>
<td>.4</td>
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<tr>
<td>Total vecuronium dose, median (IQR), mg/kg</td>
<td>3.4 (1.1–10.6)</td>
<td>3.4 (1.5–7)</td>
<td>.5</td>
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<tr>
<td>Oral morphine</td>
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<tr>
<td>Patients treated, n (%)</td>
<td>53 (11)</td>
<td>32 (7)</td>
<td>&lt;.05</td>
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<tr>
<td>Time, median (IQR), d</td>
<td>5.0 (3.0–12.5)</td>
<td>4.5 (2.0–7.0)</td>
<td>.2</td>
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<tr>
<td>Mechanical ventilation</td>
<td></td>
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<tr>
<td>Patients treated, n (%)</td>
<td>158 (34)</td>
<td>175 (36)</td>
<td>.4</td>
</tr>
<tr>
<td>Time, median (IQR), d</td>
<td>2.6 (0.8–6.9)</td>
<td>2.2 (0.6–6.8)</td>
<td>.4</td>
</tr>
<tr>
<td>Time to discharge from NICU, median (IQR), d</td>
<td>10.1 (5.3–30.3)</td>
<td>9.0 (3.0–32.2)</td>
<td>.2</td>
</tr>
<tr>
<td>Outcome, n (%)</td>
<td>IVH grade II</td>
<td>19 (4)</td>
<td>25 (5)</td>
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<tr>
<td>ROP grade III</td>
<td>26 (6)</td>
<td>25 (5)</td>
<td>.8</td>
</tr>
<tr>
<td>Oxygen at 28 d of life</td>
<td>22 (5)</td>
<td>13 (3)</td>
<td>.1</td>
</tr>
<tr>
<td>NEC</td>
<td>7 (2)</td>
<td>16 (3)</td>
<td>.1</td>
</tr>
<tr>
<td>PDA</td>
<td>118 (25)</td>
<td>135 (28)</td>
<td>.3</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>38 (8)</td>
<td>38 (8)</td>
<td>.9</td>
</tr>
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</table>

<sup>P</sup> values were calculated by Mann-Whitney U test for continuous variables and by Pearson's \(\chi^2\) test for categorical variables. IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; PDA, persistent ductus arteriosus; ROP, retinopathy of prematurity.

<sup>a</sup> Expressed in morphine equivalents.

<sup>b</sup> Expressed in midazolam equivalents.
The most frequently mentioned contributing factors for nurse dissatisfaction with pain and sedation management at baseline were as follows: no assessment tool available (36%), treatment not effective (26%), no protocol available (28%), and medical intervention initiated too late (10%). Staff members were considered as being satisfied when they judged management as good or very good (separate analysis for physicians and nurses). Overall staff satisfaction of both physicians and nurses improved significantly from baseline to intervention (31% vs 89%; \( P < .001 \); and 17% vs. 55%; \( P < .001 \)). In addition, we found significant improvement before and after implementation with regard to the following aspects: frequency of documentation of pain and sedation (\( P < .001 \)), time to intervention in case of severe pain/agitation (\( P = .004 \)), and evaluation of pain/agitation relief (\( P < .001 \)) (\( P \) values indicate significance for both professions together and were corrected for multiplicity).

**DISCUSSION**

We report a successful implementation of a protocol for the management of pain and sedation in a neonatal environment. Our quality-improvement project involved 55 nurses and 25 physicians from 2 NICUs that included a broad diversity of neonatal care settings (eg, critically ill patients with chronic diseases up to 6 months of age versus specialized care for extremely premature neonates). Starting with the idea to change local attitudes and to standardize strategies of patient care, the entire team of nurses and physicians discussed deliberately and critically every step of the implementation process. The implementation process included consistent teaching and evaluation, ongoing reassessments, and repeated questionnaires.

**Impact on Therapy and Outcome**

The implementation of a protocol to manage neonatal pain and sedation resulted in a more aggressive pain control using higher doses of opiates and a significant increase in pharmacologic interventions, without impacting morbidity or mortality. Patients spent the same time on mechanical ventilation and the same time in the NICU, with the same survival rate, when compared with the baseline. In contrast to previous studies in children and adults,\(^1,4\) which revealed a reduction in analgesic drug use, our protocol resulted in a more liberal prescription of continuous opiate infusions. In addition, the number of patients treated with oral morphine also increased significantly (Table 2). This effect might be due to the enhanced team awareness for neonatal pain and agitation but could also reflect a higher incidence of drug withdrawal in the...
intervention group. However, the duration of continuous analgesic therapy as well as the duration of oral morphine therapy was the same in both groups. Regular pain and sedation assessment resulted in a marked increase in the number of pharmacologic interventions when a patient received continuous analgesic/sedative therapy. This observation reflects the increased effort of the treating team to titrate medication until a patient reached the desired N-PASS (Fig 1). Outcome variables, including intraventricular hemorrhage, retinopathy of prematurity, necrotizing enterocolitis, and persistent ductus arteriosus, were unaffected by the implementation of the V-PNPS. We therefore conclude that managing pain and sedation according to a defined protocol is safe and effective in neonatal patients.

Quality of Teaching
We trained medical staff in the assessment of neonatal pain and sedation by using an interactive video tutorial in addition to individual bedside teaching. We achieved good interobserver agreement regarding both the pain and sedation subscale of the N-PASS. Video-based teaching can be an effective way when training large teams. Including the N-PASS into our electronic patient data management system in the “vital sign” category, in combination with regular training sessions, may have facilitated the process of considering pain as a “vital sign”.

Nurse Compliance
We observed a steep increase in nurse compliance during the first 2 months after implementation of the V-PNPS and a sustained increase throughout the entire study period reflected by an increasing number of N-PASS assessments per eligible patient (Fig 2). Interestingly, nurses assessed the N-PASS more frequently during night shifts. The assessment of pain and sedation is time consuming. Our nurses spent ~15 minutes per patient and per shift assessing pain and sedation. Night shifts might be less busy than day shifts, when most elective admissions, patient transfers, and routine interventions take place, allowing more time to perform regular assessments. We think that the positive attitude of the staff, in combination with an adequate leadership support, as well as an overall spirit of teamwork and collaboration greatly contributed to the high level of compliance and the sustained success of this quality-improvement project.

Limitations
Evaluation of pain and sedation by independent observers is desirable and relatively simple to obtain in adult patients. Neonates represent a unique group of patients with a very specific behavior. Behavior assessment of neonates requires extensive clinical experience and cannot be taught to students who could then have served as independent observers. When planning our study we did not reach team consensus on the idea of training a fraction of the nursing staff only. The main concerns were that pain assessment without direct clinical consequences and for the sole purpose of generating data before implementing a new protocol might be ethically problematic. There was agreement that the V-PNPS would need to be implemented in a timely manner to ensure that high levels of pain were treated as soon as possible. Therefore, we are not able to present data on incidences of pain or agitation before the study started. Another limitation is the fact that we compared our results with a retrospective control group. The data were collected in a single university hospital only. However, the fact that we included all nurses and physicians of 2 NICUs caring for very different patients strengthens this study.

CONCLUSIONS
We report a successful way of developing and implementing a protocol for the management of neonatal pain and sedation at 2 NICUs. The implementation resulted in more liberal opiate use and an increase in pharmacologic interventions without affecting short-term outcome. Quality of pain and sedation assessment, staff compliance, and staff satisfaction improved significantly. In our study setting, managing pain and sedation according to a defined protocol appears to be safe and effective in neonatal patients. Our multilayer approach, which includes medical staff education using interactive video-based tutorials, bedside teaching, questionnaires, regular assessments with defined responses, reassessments, and feedback, could be adopted whenever new protocols need to be accepted and implemented by a large team.

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