Implementing Potentially Better Practices to Improve Neonatal Outcomes After Reducing Postnatal Dexamethasone Use in Infants Born Between 501 and 1250 Grams

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ABSTRACT. *Objective.* **The purpose of this article is to describe how a neonatal intensive care unit (NICU) was able to reduce substantially the use of postnatal dexamethasone in infants born between 501 and 1250 g while at the same time implementing a group of potentially petter practices (PBPs) in an attempt to decrease the incidence and severity of chronic lung disease (CLD).**

Methods. **This study was both a retrospective chart review and an ongoing multicenter evidence-based investigation associated with the Vermont Oxford Network Neonatal Intensive Care Quality Improvement Collaborative (NIC/Q 2000). The NICU specifically made the reduction of CLD and dexamethasone use a priority and thus formulated a list of PBPs that could improve clinical outcomes across 3 time periods: era 1, standard NICU care that antedated the quality improvement project; era 2, gradual implementation of the PBPs; and era 3, full implementation of the PBPs. All infants who had a birth weight between 501 and 1250 g and were admitted to the NICU during the 3 study eras were included (era 1, n = 134; era 2, n = 73; era 3, n = 83). As part of the NIC/Q 2000 process, the NICU implemented 3 primary PBPs to improve clinical outcomes related to pulmonary disease: 1) gentle, low tidal volume resuscitation and ventilation, permissive hypercarbia, increased use of nasal continuous positive airway pressure; 2) decreased use of postnatal dexamethasone; and 3) vitamin A administration. The total dexamethasone use, the incidence of CLD, and the mortality rate were the primary outcomes of interest. Secondary outcomes included the severity of CLD, total ventilator and nasal continuous positive airway pressure days, grades 3 and 4 intracranial hemorrhage, periventricular leukomalacia, stages 3 and 4 retinopathy of prematurity, necrotizing enterocolitis, pneumothorax, length of stay, late-onset sepsis, and pneumonia.**

Results. **The percentage of infants who received dexamethasone during their NICU admission decreased from 49% in era 1 to 22% in era 3. Of those who received dexamethasone, the median number of days of exposure dropped from 23.0 in era 1 to 6.5 in era 3. The median total NICU exposure to dexamethasone in infants who received at least 1 dose declined from 3.5 mg/kg in era 1 to 0.9 mg/kg in era 3. The overall amount of dexamethasone administered per total patient population decreased 85% from era 1 to era 3. CLD was seen in 22% of infants in era 1 and 28% in era 3, a nonsignificant increase. The severity of CLD did not significantly change across the 3 eras, neither did the mortality rate. We observed a significant reduction in the use of mechanical ventilation as well as a decline in the incidence of late-onset sepsis and pneumonia, with no other significant change in morbidities or length of stay.**

Conclusions. **Postnatal dexamethasone use in premature infants born between 501 and 1250 g can be sharply curtailed without a significant worsening in a broad range of clinical outcomes. Although a modest, nonsignificant trend was observed toward a greater number of infants needing supplemental oxygen at 36 weeks' postmenstrual age, the severity of CLD did not increase, the mortality rate did not rise, length of stay did not increase, and other benefits such as decreased use of mechanical ventilation and fewer episodes of nosocomial infection were documented.** *Pediatrics* **2003;111:e534–e541. URL: http://www.pediatrics.org/cgi/content/full/111/4/e534;** ***chronic lung disease, dexamethasone, extremely low birth weight infants, nasal continuous positive airway pressure, permissive hypercarbia, Vermont Oxford Network, collaborative quality improvement, NIC/Q 2000.***

ABBREVIATIONS. NICU, neonatal intensive care unit; PBPs, potentially better practices; NCPAP, nasal continuous positive airway pressure; CLD, chronic lung disease NIC/Q 2000, Neonatal Intensive Care Quality Improvement Collaborative; ReLi, reduce lung injury; Pco_2, partial pressure of carbon dioxide.

KEY POINTS OF ARTICLE

- Dexamethasone use in premature infants 500 to 1250 g can be substantially curtailed without any significant worsening in clinical outcomes.
- Benefits from reducing dexamethasone use include significantly fewer nosocomial infections and a highly suggestive reduction in the incidence of periventricular leukomalacia.
- Reduction in the use of mechanical ventilation for lung disease in premature infants can be achieved by greater reliance on nasal continuous positive airway pressure (NCPAP) and permissive hypercarbia.
- Collaborative quality improvement among neonatal intensive care units (NICUs) allows for efficient sharing of outcome data, review of variant bedside clinical practices, and the rational implementation of potentially better practices (PBPs) to reduce neonatal morbidity.

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APPLYING LESSONS LEARNED TO PRACTICE

- There is virtually no indication to use dexamethasone for the treatment of lung disease in premature infants.
- NCPAP is a physical and cognitive skill that takes multidisciplinary effort and time to apply successfully.
- NICU staff should strive toward an understanding of how each provider in the nursery affects clinical outcomes; this is not immediately obvious or intuitive and can come only through careful practice review and repetitive communication.
- NICUs should self identify opportunities for improvement in clinical outcomes and collaborate with other NICUs to enrich and hasten true quality improvement.

Chronic lung disease (CLD), as defined by the need for supplemental oxygen at 36 weeks' postmenstrual age, occurs in approximately 40% of infants who are born between 501 and 1250 g.[1] Despite greater use of antenatal corticosteroids, widespread surfactant therapy, and advances in mechanical ventilation, the incidence of CLD is not declining.[2]

Postnatal dexamethasone can improve pulmonary mechanics, hasten the time to extubation, and reduce the incidence of CLD.[3] However, the beneficial effects of postnatal corticosteroid therapy is accompanied by a number of morbidities, the most serious being an increased risk of cerebral palsy, periventricular leukomalacia, and neurodevelopmental delay.[4,5]

The Vermont Oxford Network, in an effort to make measurable improvements in neonatal intensive care, has initiated a collaborative quality improvement model that has recently been described.[6] Because of the encouraging results seen in the initial 10 NICU study, a larger group of NICUs initiated a 3-year effort. The Vermont Oxford Network Neonatal Intensive Care Quality Improvement Collaborative (NIC/Q 2000) specifically aimed at making reductions in several important neonatal morbidities including CLD.

Providence St Vincent Medical Center has participated in the NIC/Q 2000 CLD focus group, also known as Reduce Lung Injury (ReLi). The ReLi group recognized that CLD has a major influence on other morbidities. There is marked variation in the rates of CLD among Vermont Oxford Network NICUs, suggesting that practice variation may contribute to the disease. This report describes implementation of the ReLi PBPs and subsequent patient outcomes related to this quality improvement project.

METHODS

The ReLi group agreed on the following definition for CLD: the numerator for this calculation included all infants who were born between 501 and 1250 g, were admitted to the NICU, and required supplemental oxygen at 36 weeks' adjusted postmenstrual age whether they were in the hospital or at home. The denominator included all infants who were born between 501 and 1250 g and were admitted to the NICU, excluding delivery room deaths. The primary goal of the group was a reduction in the rate of CLD from a group average incidence of 40% to 25%.

TABLE 1. Providence St Vincent Medical Center PBPs to Reduce CLD and Dexamethasone Use

1. Gentle ventilation
   - A. Low tidal volume resuscitation and ventilation, keep tidal volume <5–6 mL/kg if conventional ventilator used, keep peak inspiratory pressures <20 cm H_2O.
   - B. Conventional or high-frequency ventilation to be used at the discretion of the physician.
   - C. Permissive hypercarbia–attempt to maintain blood Pco_2 between 50 and 75 mmHg while on mechanical ventilation.
   - D. Increase use of NCPAP to avoid mechanical ventilation and to hasten extubation.
2. Decrease use of postnatal dexamethasone
   - A. Avoid dexamethasone use in the first 10–14 d of life.
   - B. At 10–14 d of age, consider the use of dexamethasone only if the following criteria are met:
     - infant remains on mechanical ventilation and is not weaning.
     - fraction of inspired oxygen >70%, mean airway pressure >10 cm H_2O, peak inspiratory pressure >20–25 cm H_2O.
     - chest radiograph shows pulmonary interstitial emphysema and/or cystic changes.
     - patent ductus arteriosus and pneumonia ruled out.
   - C. Discuss the risks and benefits of dexamethasone with the parents, and obtain informed consent.
   - D. If dexamethasone is used, start at 0.2–0.3 mg/kg/d divided every 12 h for 48 h. If the course continues beyond 48 h, then halve the dose every 48 h and limit the entire exposure to <7–10 d.
   - E. Use a graphic dexamethasone exposure tracking tool at the bedside, daily dose in milligram/kilogram along with infant weight, length, head circumference and concurrent oxygen, NCPAP, and ventilator settings.
3. Supplemental vitamin A
   Any infant who is born between 501 and 1250 g and requires mechanical ventilation, NCPAP, and/or fraction of inspired oxygen >30% at 24 h of age receives vitamin A 5000 IU intramuscularly 3 times per week for 4 wk, for a total of 12 doses.

Participant ReLi NICUs reviewed an array of PBPs related to CLD and were encouraged to select site-specific changes that were dependent on each NICU's preexisting clinical practices and outcomes. Providence St Vincent Medical Center implemented 3 PBPs: 1) gentle, low tidal volume resuscitation and ventilation, permissive hypercarbia, increased use of NCPAP; 2) decreased use of dexamethasone; and 3) supplemental vitamin A (Table 1).

Typical of any medical practice guidelines developed with multidisciplinary input, the acceptance of PBPs by individual practitioners in the NICU was gradual and not without contention. For assisting physicians, nurse practitioners, nurses, and respiratory therapists with the adoption of PBPs, a number of actions were taken. A process of intensive education, internal and external database review, site visits at other NICUs, scrutiny of variant clinical practices, newsletters, informational posters, multidisciplinary open forums, and bedside teaching rounds were implemented. Frequent review of outcome data as compared with the other ReLi NICUs and the entire Vermont Oxford Network were done. This was discussed openly with NICU coworkers. Figure 1 summarizes the ReLi PBP implementation process.

Data and Measures

The primary outcomes of interest were the total dexamethasone exposure per infant, the incidence of CLD, and the mortality rate. Secondary outcomes included the severity of CLD, total ventilator and NCPAP days, the incidence of grades 3 and 4 intracranial hemorrhage, periventricular leukomalacia, stages 3 and 4 retinopathy of prematurity, necrotizing enterocolitis, pneumothorax, length of stay, late-onset sepsis (defined as blood culture–proven sepsis at >72 hours of age), and pneumonia (defined as 4 or more days of treatment with antibiotics in an infant with a positive endotracheal culture and radiographic and clinical symptoms consistent with pulmonary infection).

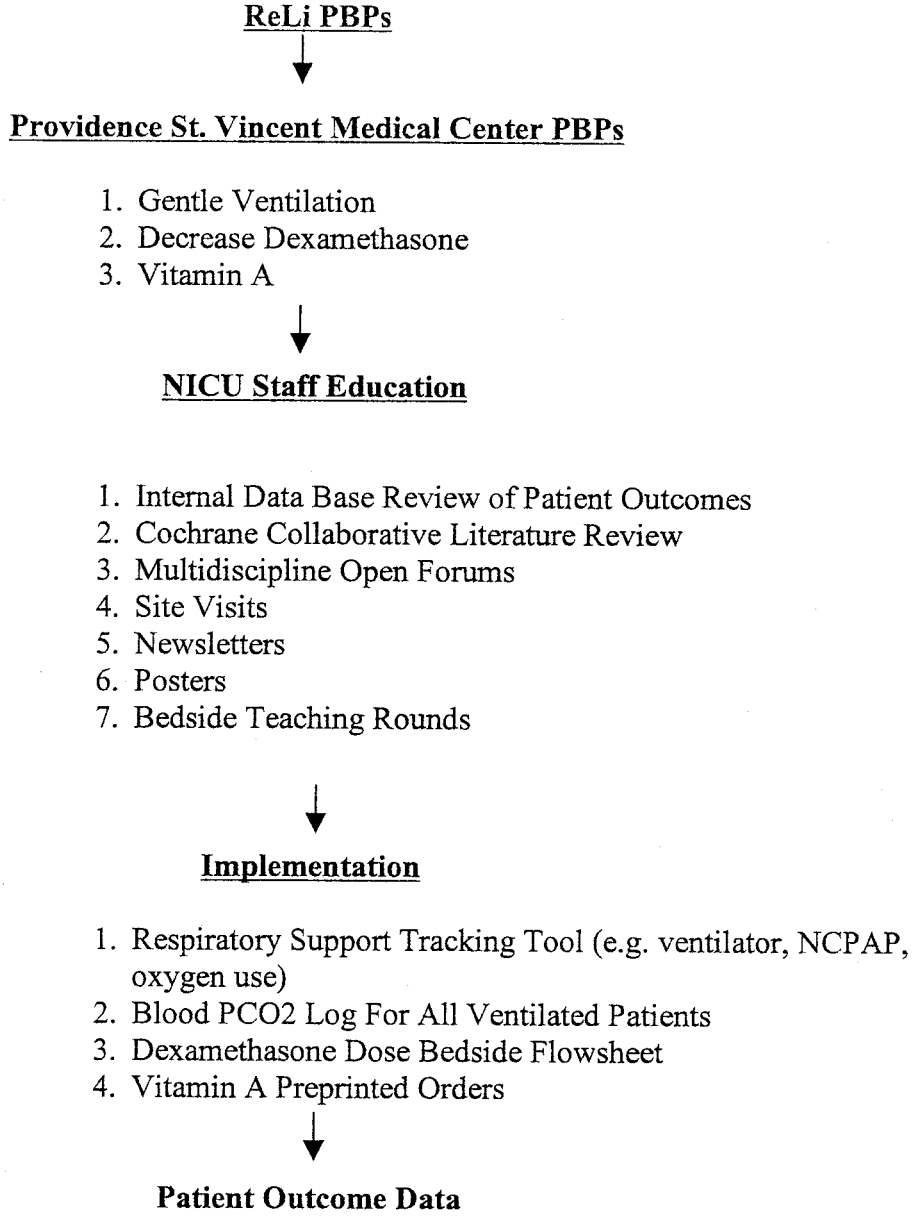

Fig 1. ReLi implementation process.

A severity scale was devised to examine whether the PBP implementation would affect the quality of CLD. On the day an infant reached 36 weeks' postmenstrual age, if he or she required supplemental oxygen to keep transcutaneous oxygen saturations 90% to 94%, the quantity of oxygen required was recorded (fraction of inspired oxygen and flow rate), whether there was an abnormal pulmonary examination (tachypnea, crackles, retractions), and/or whether diuretics were being used.

For the purpose of this, the outcome data and analysis was divided into 3 time periods at Providence St Vincent Medical Center:

1. Era 1 (pre-PBP: April 1, 1996, through December 31, 1998). This represents the time period from the opening of the level 3 NICU until the beginning of the PBP implementation. There were no major practice changes in regard to pulmonary disease or CLD during this era.
2. Era 2 (transition: January 1, 1999, through December 31, 1999). This represents the time period during which PBPs were gradually implemented and significant compliance with the PBPs was reached.
3. Era 3 (post-PBP: January 1, 2000, through December 31, 2000). This represents the time period of high compliance with the PBPs.

Statistical Analysis

All outcome measures were compared across the 3 study eras. Results have been reported as proportions (percentages) and averages. In most cases, the median, rather than the mean, was used to describe central tendency, because examination of skewness and kurtosis for the interval level variables showed that all but 2 had nonnormal distribution. The nonparametric Kruskal-Wallis H statistic was used to analyze skewed variables. Analysis of variance was used for the 2 normally distributed variables (gestational age, length of stay). The χ^2 test for linear trends was used to analyze changes in proportions over time. Statistical analyses were performed using SPSS (Release 10.1.4; SPSS, Inc, Chicago, IL) and Epi Info (Version 1.1; Centers for Disease Control and Prevention, Atlanta, GA).

RESULTS

Birth weight, gestational age, gender, inborn status, and racial distribution showed no statistically significant differences, and antenatal corticosteroid use was high throughout the 3 study periods (Table 2).

TABLE 2. Infant Demographic Data

	Era 1 4/1/96–12/31/98 (*n* [%])	Era 2 1/1/99–12/31/99 (*n* [%])	Era 3 1/1/00–12/31/00 (*n*[%])
Total number of infants	134	73	83
Birth weight			
501–1000 g	83 (62)	42 (58)	41 (49)
1001–1250 g	51 (38)	31 (42)	42 (51)
Median birth weight (range)	925 (510–1250)	900 (540–1250)	1005 (510–1250)
Mean gestational age (wk ± 1.0 SD)	27.6 ± 2.3	28.2 ± 2.8	28.4 ± 2.4
Gender			
Female	62 (46)	44 (60)	45 (54)
Male	72 (54)	29 (40)	38 (46)
Race			
White	89 (66)	53 (73)	63 (76)
Hispanic	14 (10)	7 (10)	12 (14)
Black	13 (10)	8 (11)	2 (2)
Asian	13 (10)	4 (5)	3 (4)
Other	5 (4)	1 (1)	3 (4)
Antenatal steroids	120 (90)	63 (86)	74 (89)

SD indicates standard deviation.
No significant differences were noted between eras.

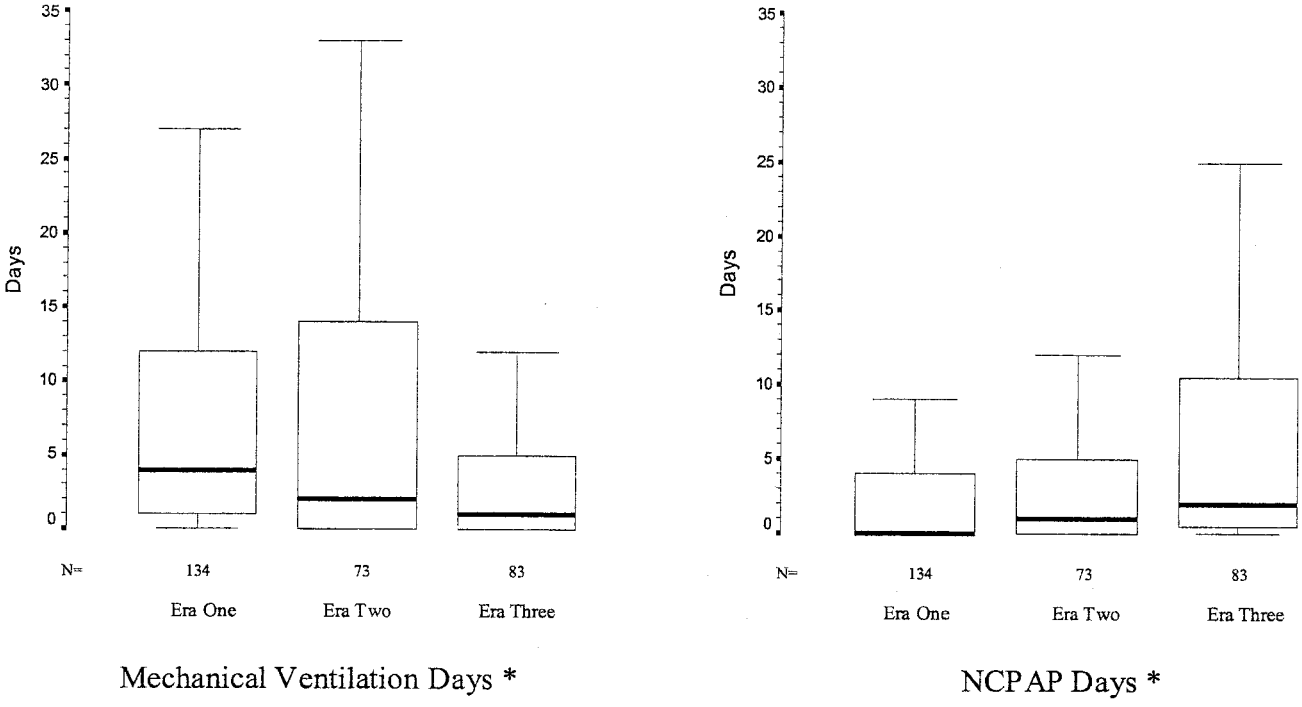

Fig 2. Mechanical ventilation and NCPAP days across 3 study eras. * $P < .001$ comparing all 3 eras.

The percentage of infants who were mechanically ventilated for at least 1 day decreased significantly from 85% in era 1 to 61% in era 3 ($P < .001$). The median number of days of mechanical ventilation decreased significantly from 4.0 days (range: 0–46) in era 1 to 1.0 day (range 0–41) in era 3 ($P < .001$; Fig 2). The median number of days of NCPAP increased significantly from 0 days (range: 0–33) in era 1 to 2.0 days (range: 0–55) in era 3 ($P < .001$; Fig 2).

If an infant was mechanically ventilated at any time during the first week of life, the partial pressure of carbon dioxide (Pco_2) from all blood gases was tracked as an objective marker of gentle ventilation and permissive hypercarbia. Figure 3 shows that the mean daily Pco_2 values increased significantly from era 1 to era 3.

The percentage of infants who received any dose of dexamethasone for pulmonary disease decreased significantly from 49% in era 1 to 22% in era 3 ($P < .001$; Fig 4). The median number of days of dexamethasone use in infants who received the drug decreased significantly from 23.0 days (range: 1–78) in era 1 to 6.5 days (range: 2–28) in era 4 ($P < .001$; Fig 4). The exact amount of dexamethasone used in each infant during the entire NICU hospitalization was calculated in total milligrams per kilogram of body weight. For infants who received at least 1 dose, dexamethasone exposure decreased significantly from a median of 3.5 mg/kg (range: 0.25–16.55) in era 1 to 0.9 mg/kg (range: 0.35–8.13) in era 3 ($P < .001$; Fig 4). Calculating the total dexamethasone dose in infants who received the drug and normal-

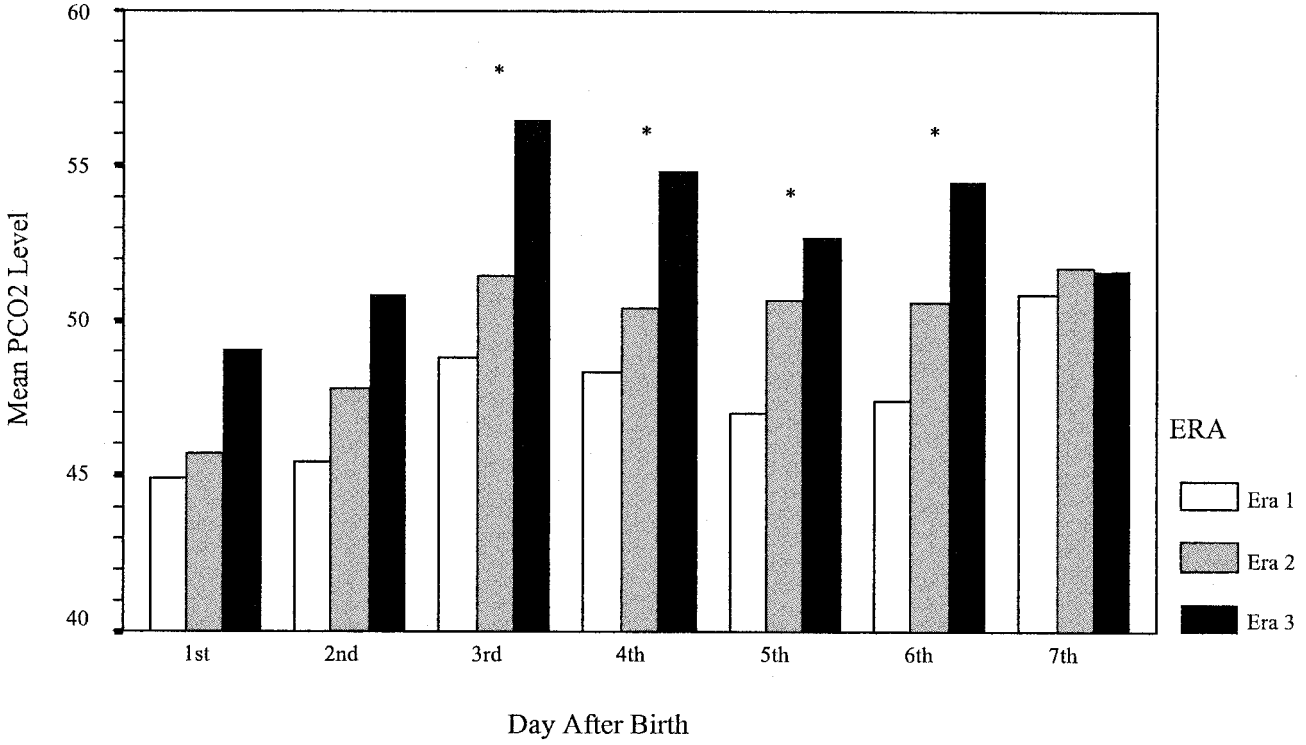

Fig 3. Mean daily Pco_2 levels. * $P < .007$ after a Bonferroni adjustment (era 1 compared with era 3).

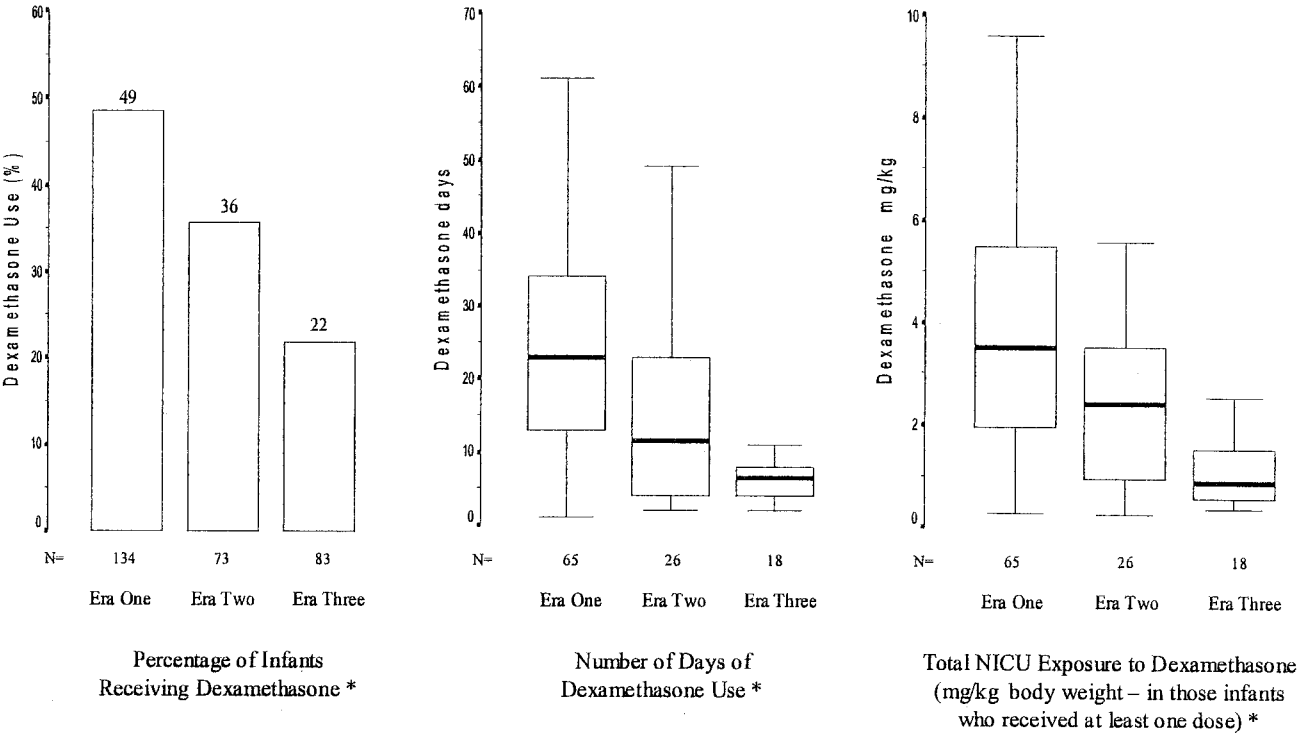

Fig 4. Dexamethasone use across 3 study eras. * $P < .001$ comparing all 3 eras.

izing this to the total number of infants per era documented an 85% reduction in dexamethasone use from era 1 to era 3.

The vitamin A PBP was fully implemented during the third month of era 3. From that time onward, 44 (96%) of the 46 eligible infants received supplemental vitamin A as described in Table 1. Supplemental vitamin A, ie, not including the vitamin A already in milk or hyperalimentation fluid, was not given to any infant who was born in era 1 or era 2. Only 1 infant was noted to have an elevated serum vitamin A level (104 μg/dL; normal range: 20–100), and no untoward side effects were observed in this or any infant.

The incidence of CLD trended upward, 22% in era 1, 25% in era 2, and 28.0% in era 3, but the increase was not statistically significant ($P = .31$; Table 3). The

TABLE 3. CLD Incidence and Severity Across 3 Eras

	Era 1 (*n* [%])	Era 2 (*n* [%])	Era 3 (*n* [%])	*P*
Overall n	134	73	83	
CLD	29 (22)	18 (25)	23 (28)	.307
Median supplemental oxygen days (range)	34 (0–107)	20 (0–101)	27 (0–107)	.725
At 36 wk (*n*)	26	14	21	
Median FIO_2 (range)	90 (30–100)	100 (50–100)	100 (25–100)	.014*
Median flow rate (mL/min; range)	25 (25–100)	37.5 (25–150)	40 (25–175)	.553
Abnormal examination (respiratory rate >60, crackles, and/or retractions)	7 (26)	6 (38)	4 (18)	.327
Diuretics	9 (33)	5 (33)	5 (23)	.143

FIO_2 indicates fraction of inspired oxygen.
* Era 2 > Era 1; $P < .01$.

median total days of supplemental oxygen that an infant needed to keep transcutaneous oxygen saturations 90% to 94% trended downward across the 3 eras, but the decrease was not statistically significant (Table 3). The severity of CLD as measured at 36 weeks' postmenstrual age by the amount of nasal cannula supplemental oxygen required, presence of an abnormal pulmonary examination, and/or the need for diuretics did not change (Table 3).

The incidence of pneumonia decreased significantly from 23% in era 1 to 10% in era 3 ($P < .05$; Fig 5), and the occurrence of late-onset sepsis showed a similar decline from 11% in era 1 to 4% in era 3 ($P < .05$; Fig 5). The incidence of periventricular leukomalacia and necrotizing enterocolitis both trended downward, but the decreases did not reach statistical significance ($P = .05$, $P = .17$). There were no statistically significant changes during the study period in the incidence of grade 3 or 4 intracranial hemorrhage, stage 3 or 4 retinopathy of prematurity, pneumothorax, or the mortality rate (Fig 5). The average length of stay in the NICU trended downward, with a mean of 59 ± 2.5 days in era 1 and 53 ± 2.9 days in era 3, but the decrease was not statistically significant ($P = .10$).

DISCUSSION

Participant NICUs in the NIC/Q 2000 ReLi group recognized that CLD is perhaps the fundamental disorder of prematurity because it directly relates to most other morbidities, such as growth failure and neurodevelopmental delay.[7,8] Dexamethasone has been used to prevent CLD, but recent reviews have highlighted the many hazards of this therapy.[3–5] Although dexamethasone improves pulmonary mechanics, hastens the time to extubation, and can reduce the incidence of CLD, it has also been clearly linked to hyperglycemia, hypertension, gastrointestinal bleeding and perforation, increased infection, and subnormal growth. The appeal of postnatal dexamethasone as a rational therapy has waned con-

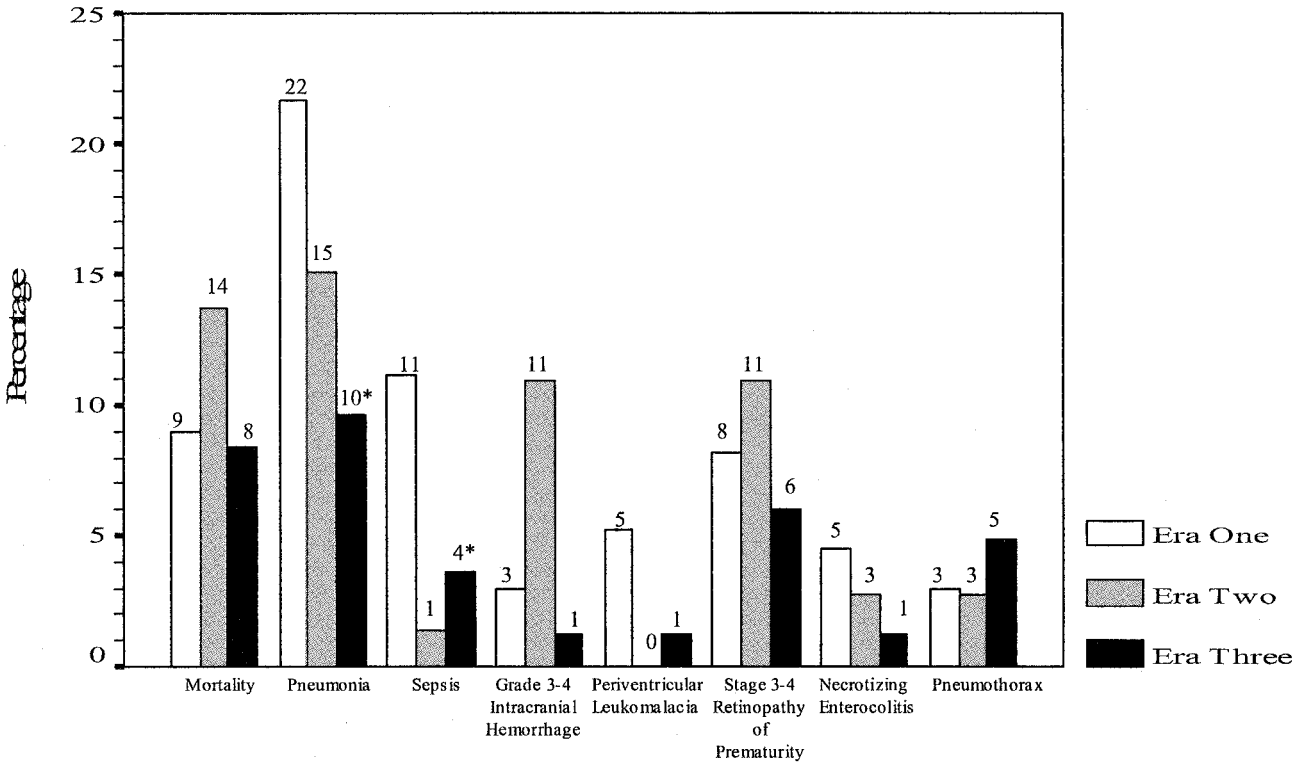

Fig 5. Clinical outcomes across the 3 study eras. * $P < .05$ comparing all 3 eras.

siderably with the recent publication of several reports detailing neurologic impairments associated with this drug, including a higher risk of cerebral palsy, periventricular leukomalacia, and neurodevelopmental delay.[4,5,9–13]

The primary goal of the ReLi group was the reduction of CLD by the implementation of PBPs developed from evidence-based study of published investigations, internal and external database review, and collaborative comparison of practice styles among participant NICUs. This was the essential paradox of the selected practice changes: PBP 1 (gentle ventilation) and PBP 3 (vitamin A) are guidelines that one could reasonably expect to reduce CLD, whereas PBP 2 (decrease use of dexamethasone) might actually increase CLD.[14,15] Achieving consensus and reasonably uniform clinical practice in a NICU is a daunting task that was made far easier by the organization, energy, and legitimacy that the NIC/Q 2000 collaborative process conferred on PBP implementation. Dexamethasone use has been ingrained into neonatology practice for many years. The collaborative quality improvement process seems to have contributed to an 85% reduction in the use of this therapy.

Also documented was a significant change in the approach to respiratory care, moving from a traditional reliance on mechanical ventilation to a style best described as gentle ventilation. The findings showed less reliance on mechanical ventilation, more utilization of NCPAP, and increasing clinician comfort with permissive hypercarbia. Hyperventilation and hypocapnia have been linked to adverse pulmonary and neurologic sequelae. However, the team recognized that the degree of permissive hypercarbia most appropriate for premature infants has not been established.[16]

The increased use of NCPAP resulted from an intensive and sustained evidence-based literature review, site visitation, staff education, and bedside trial and error. The application of NCPAP is both a physical and a cognitive skill, one whose mastery is a function of experience and perseverance and not simply enthusiasm and basic instruction. It is apparent that a large, multicenter, randomized trial is urgently needed to clarify the role of early NCPAP in the treatment of respiratory distress syndrome. NCPAP has not been rigorously shown in randomized, controlled trials to reduce CLD.[17]

Vitamin A administration has been shown to reduce the incidence of CLD.[18,19] The relatively modest number of patients studied in era 3 does not allow any particular inference regarding the efficacy of vitamin A as a preventive therapy for CLD.

The incidence of CLD did rise modestly through this interventional study, but the increase was not statistically significant. It was reasoned that any pulmonary advantages accrued from the application of gentle ventilation, NCPAP, and vitamin A were perhaps offset by the significant reduction in dexamethasone use, a drug that has been shown to reduce CLD.[14,15] A severity scale that expands the clinical utility of the traditional definition of CLD was described. Despite a significant reduction in dexamethasone use, the overall severity of CLD and the total supplemental oxygen days have not increased during era 3. There was also less reliance on mechanical ventilation.

Significantly fewer episodes of pneumonia and late-onset sepsis were documented in era 3. Important trends downward in the incidence of periventricular leukomalacia and necrotizing enterocolitis were also seen. All of these are clinical improvements plausibly related to decreased dexamethasone use.

CONCLUSIONS

Participation in the Vermont Oxford Network NIC/Q 2000 collaborative process has enabled the NICU to apply several evidence-based PBPs to clinical practice regimen specifically aimed at the reduction of CLD. Close collaboration with other participating NICUs has allowed for critical examination of multiple bedside practice styles, center-specific outcomes, large amounts of published investigations, and an expanded knowledge of the process of institutional change and quality improvement in medical care. It is highly doubtful that implementation of such rational quality improvement changes in such a relatively short period of time would have worked in isolation.

The principal finding of the interventional study is of considerable clinical utility: dexamethasone use can be sharply curtailed in infants born between 501 and 1250 g without significant negative consequences. In fact, a decreased nosocomial infection rate and less need for mechanical ventilation were seen. The intention is to continue the ReLi group collaboration with additional clinical outcome reports related to era 4 (2001). Preliminary data from the NICU through 2001 show an even more substantial decline in the use of dexamethasone, a CLD rate that is declining, and no untoward effects on other morbidities.

ACKNOWLEDGMENTS

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