

ORIGINAL ARTICLE

Effects of delivery room quality improvement on premature infant outcomes

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OBJECTIVE: Delivery room management interventions have been successfully implemented via collaborative quality improvement (QI) projects. However, it is unknown whether these successes translate to reductions in neonatal morbidity and mortality.

STUDY DESIGN: This was a prospective pre–post intervention study of three nonrandomized hospital groups within the California Perinatal Quality Care Collaborative. A collaborative QI model (Collaborative QI) was compared with a single-site QI model (NICU QI) and a non-participant population when implementing evidence-based delivery room practices. The intervention period was between June 2011 and May 2012. Infants born with gestational age between 22 weeks 0 days and 29 weeks 6 days and birth weight ≤ 1500 g were included. Outcomes were mortality and select morbidities (bronchopulmonary dysplasia (BPD), intraventricular hemorrhage (IVH), retinopathy of prematurity (ROP) and necrotizing enterocolitis (NEC)). Outcomes were compared between the baseline (January 2010 to May 2011) and post-intervention period (June 2012 to May 2013) within each comparison group.

RESULTS: Ninety-five hospitals were included with 4222 infants in the baseline period and 4186 infants in the post-intervention period. The Collaborative QI group had significantly reduced odds of developing BPD post-intervention (odds ratio (OR) 0.8, 95% confidence interval (CI) 0.65 to 0.99) or composite BPD-death (OR 0.83, 95% CI 0.69 to 1.00). In both the Collaborative QI and non-participants there were also reductions in IVH, severe IVH, composite severe IVH-death, severe ROP and composite severe ROP-death.

CONCLUSION: Hospitals dedicated to improving delivery room practices can impact neonatal outcomes.

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INTRODUCTION

The initial resuscitation and stabilization of the premature infant is a critical window of time during which many complex tasks need to be performed. Management of these high-risk deliveries should be informed by the Neonatal Resuscitation Program guidelines and other recently published evidence.^{1–3}

The first step in stabilization is the provision of warmth. In particular, very low birth weight (VLBW, birth weight less than 1500 g) neonates are at increased risk of hypothermia due to larger evaporative losses and decreased heat production compared with term neonates.^{4–6} Hypothermia (defined as core temperature less than 36 °C) continues to affect over 40% of VLBW infants and is independently associated with increased mortality and morbidity.^{7–11} The Neonatal Research Network demonstrated that for every 1 °C decrease in admission temperature below normal the odds of mortality increased by 28%.¹² Hypothermia is also associated with increased rates of necrotizing enterocolitis (NEC) and intraventricular hemorrhage (IVH).^{7,13,14} Furthermore, a recent study by the Canadian Neonatal Network on infants less than 33 weeks gestational age demonstrated U-shaped relationships between admission temperature and adverse neonatal outcomes, such as death, NEC, severe retinopathy of prematurity (ROP), severe neurological injury and bronchopulmonary dysplasia (BPD), underscoring the significance of maintaining normothermia in the newborn premature infant.¹⁵

Similarly, respiratory management of the VLBW infant in the first hour of life may have significant impact on the infant's outcome. Large multicenter trials have supported the initial use of continuous positive airway pressure (CPAP) in the delivery room within the first 15 min after birth.^{16–19} Maintenance of the functional residual capacity of the lung reduces the need for intubation, exogenous surfactant, postnatal corticosteroids and ventilator days. Studies have also suggested a reduction in BPD and mortality.²⁰ Given the strong emerging evidence, the Committee on the Fetus and Newborn, along with the Neonatal Resuscitation Program, currently recommends the initial use of CPAP in the delivery room rather than intubation.^{1,21}

With recommendations from professional organizations, the adoption of new delivery room practices is often aided by quality improvement (QI) projects. This may be particularly pertinent for neonatal resuscitation, as guidelines have evolved over time to include multiple members of the health-care team, with the need for training in communication and other behavioral skills. QI initiatives, both stand-alone and collaborative projects, have successfully reduced the rates of hypothermia, intubations in the delivery room and increased the appropriate use of surfactant and antenatal steroids.^{5,22–24} While QI initiatives are successful at optimizing delivery room processes, it is unknown whether these changes translate to reductions in neonatal morbidity and mortality.

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In 2010, the California Perinatal Quality Care Collaborative (CPQCC) formed a Delivery Room QI Collaborative (Collaborative QI) using a design based on the Institute for Healthcare Improvement model.²⁵ The collaborative created a best practice bundle constructed from published evidence and guidelines for temperature and respiratory management.²³ The Collaborative QI group was compared with (1) neonatal intensive care units (NICUs) implementing the same best practices individually (NICU QI) and (2) non-participating NICUs. The latter group served as a comparison group for the secular trend. Patients in all three groups displayed significant reductions in hypothermia, delivery room intubations and delivery room surfactant use, along with increased use of CPAP as the initial ventilation strategy. For each outcome, the effect of the Collaborative QI approach was greater than that seen in the NICU QI and nonparticipant groups. In addition, there was no incremental improvement between the nonparticipant and NICU QI group, suggesting that a collaborative approach was superior for implementation of delivery room changes.

In the present study, we were interested in determining whether those improvements in process and intermediate measures would translate into reduction in mortality and select serious morbidities for those who participated in the Collaborative QI. We hypothesized that there would be incremental increases in the extent of improvement from non-participants to NICU QI to DR Collaborative QI centers in rates of mortality and morbidities.

METHODS

This was a prospective cohort study of the collaborative QI model compared with a single-site QI model (NICU QI) and a non-participant population when implementing an evidence-based practice bundle for delivery room management. This study used data from the CPQCC between June 2010 and May 2013. The CPQCC prospectively collects clinical data in 136 member hospitals on greater than 90% of VLBW infants receiving care in California by use of an expanded version of the Vermont Oxford Network Dataset. This study was approved by the Stanford University institutional review board. Parental consent was waived as all data collected and entered in the CPQCC database are de-identified.

Comparison groups

There were three separate comparison groups during this study as previously described.²³ In brief, the three groups were as follows:

Collaborative QI group—This group employed an evidence-based change package and corresponding metrics. Collaboration between hospitals included face-to-face learning sessions, monthly webcasts and teamwork training. The DR Collaborative QI group was actively guided by a multidisciplinary panel of experts in delivery room management.

NICU QI group—This group was provided with the same change package and metrics grid as the DR Collaborative QI group and was encouraged to implement all interventions. The NICU QI centers submitted reports to CPQCC monthly and had access to local QI experts but did not interact directly with other hospitals participating in similar projects.

Non-participant group—This group included CPQCC hospitals not in the two aforementioned groups. They had access to the CPQCC DR toolkit online, which is freely available to the public. They were not required to submit supplemental data to CPQCC during this time, but had routine collection of clinical data as members of CPQCC.

Hospitals were self-selected and characteristics during the baseline period differed with those in the DR collaborative group (20 hospitals) having a significantly higher median hospital volume of eligible patients, higher number of NICU beds and higher number of live births in the year 2010.²³

Population

Infants eligible for the study were born with birth weight ≤ 1500 g and gestational age from 22 weeks and 0 days to 29 weeks and 6 days. Infants who died in the delivery room or prior to 12 h of life were excluded.

Analyses were restricted to hospitals with at least 10 eligible infants born during each study period.

Outcomes

The outcomes of interest were mortality and known serious neonatal morbidities: BPD, IVH, ROP and NEC.

BPD was defined as any infant requiring oxygen at 36 weeks postmenstrual age, or if the infant was discharged home on oxygen between 34 and 36 weeks postmenstrual age, or if the infant was transferred to a non-CPQCC hospital on oxygen between 34 and 36 weeks postmenstrual age, as the database did not collect further data on the infant. This definition approximates the Vermont Oxford Network definition for BPD.²⁶ CPQCC does not currently collect any data on oxygen reduction tests and therefore it was not possible to use the physiologic definition of BPD.

IVH was defined as any grade of IVH seen during cranial imaging on or before day 28 of life. Severe IVH was defined as grade 3 (intraventricular blood, ventricular dilation) or grade 4 (intraparenchymal hemorrhage).

ROP was defined as any stage of ROP from Stage 1 to 5 as defined by the International Committee for the Classification of Retinopathy of Prematurity.²⁷ Severe ROP was defined as stages 3, 4, 5 or requiring ROP surgery.

NEC was defined as infants who had (1) NEC diagnosed at surgery, or (2) NEC diagnosed at post-mortem examination, or (3) clinical and radiographic NEC defined using one or more clinical sign (biliary gastric aspirate or emesis, abdominal distension, occult or gross blood in stool with no apparent rectal fissure) and one or more radiographic sign (pneumotosis intestinalis, hepato-biliary gas or pneumoperitoneum).

Statistical analyses

Outcome variables were compared between two time periods: baseline (infants born June 2010 to May 2011) and post-intervention (June 2012 to May 2013) within each comparison group. The intervention period was from June 2011 to May 2012. Analysis for each of the morbidities was performed in two ways: morbidity alone and a combined morbidity–mortality. A combined morbidity–mortality comparison was used, as mortality is a competing risk outcome for the most critically ill infants.

Multivariable analyses were conducted at the patient level. Risk adjustment variables included NICU eligible patient volume, birth weight, gender, maternal age, race, multiple gestation, small for gestational age, congenital anomaly, receipt of antenatal steroids and mode of delivery. Birth weight and small for gestational age were used rather than gestational age alone as predictors as gestational age and birth weight were highly correlated. Hospital of care was accounted for as a random effect by using methods similar to those described previously.²³

RESULTS

Ninety-five CPQCC member hospitals (20 Collaborative QI, 31 NICU QI, 44 non-participant hospitals) were eligible. Thirty-seven hospitals were excluded (4 Collaborative QI, 4 NICU QI, 29 non-participant) for not meeting the minimum number of 10 eligible infant deliveries for each of the study periods. In the baseline period, there were 4222 infants included in the study (1624 Collaborative QI, 1009 NICU QI, 1589 non-participant hospitals). Baseline characteristics of infants in the study were described in more detail previously and did not differ between groups in terms of birth weight, gestational age, maternal age or mode of delivery.²³ There were a total of 4186 infants included in the post-intervention analysis (1541 Collaborative QI, 1145 NICU QI, 1500 non-participant hospitals). Unadjusted rates of morbidities and mortality during the baseline and post-intervention periods are demonstrated in Table 1. Results from the mixed effects logistic regression analysis accounting for risk adjustment for patient-level factors comparing baseline to post-intervention rates are shown in Figure 1.

BPD

The rate of BPD in the baseline period was 23.3% with the groups ranging from 22.7 to 23.7% and the post-intervention BPD rate was

Table 1. Unadjusted morbidity and mortality rates during the baseline and post-intervention periods by comparison group

Outcome	Comparison group	Baseline ^a (%)	Post-intervention ^b (%)
BPD	Collaborative QI	23.5	22.5
	NICU QI	23.7	25.3
	Non-participant	22.7	24.0
	Overall	23.3	23.8
BPD or death	Collaborative QI	28.0	26.5
	NICU QI	28.3	29.3
	Non-participant	27.4	27.2
	Overall	27.9	27.5
IVH	Collaborative QI	21.6	18.6
	NICU QI	21.6	22.0
	Non-participant	26.1	22.2
	Overall	23.2	20.8
Severe IVH	Collaborative QI	5.7	5.1
	NICU QI	5.0	6.4
	Non-participant	8.3	6.7
	Overall	6.5	6.0
Severe IVH or death	Collaborative QI	10.8	9.9
	NICU QI	10.1	11.7
	Non-participant	13.7	10.8
	Overall	11.8	10.7
ROP	Collaborative QI	28.3	27.9
	NICU QI	30.3	30.9
	Non-participant	33.1	31.3
	Overall	30.5	29.8
Severe ROP	Collaborative QI	6.6	4.9
	NICU QI	7.7	9.5
	Non-participant	10.4	6.8
	Overall	8.2	6.7
Severe ROP or death	Collaborative QI	12.4	10.8
	NICU QI	13.9	14.8
	Non-participant	16.1	11.6
	Overall	14.1	12.2
NEC	Collaborative QI	3.4	3.0
	NICU QI	4.1	2.8
	Non-participant	3.7	3.2
	Overall	3.7	3.0
NEC or death	Collaborative QI	10.2	9.1
	NICU QI	11.4	10.1
	Non-participant	11.5	9.1
	Overall	11.0	9.4
Death	Collaborative QI	7.8	6.9
	NICU QI	8.4	8.0
	Non-participant	9.0	6.7
	Overall	8.4	7.1

Abbreviations: BPD, bronchopulmonary dysplasia; IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; NICU, neonatal intensive care unit; QI, quality improvement; ROP, retinopathy of prematurity. ^aBaseline *n* of infants by comparison group: 1624 Collaborative QI, 1009 NICU QI and 1589 non-participants. ^bPost-intervention *n* of infants by comparison group: 1541 Collaborative QI, 1145 NICU QI and 1500 non-participants.

23.8% with the groups ranging from 22.5 to 25.3% (Table 1). Although crude rates were not significant among groups, only the Collaborative QI saw a reduction in BPD rates from baseline to post-intervention (Figure 1). Both the risk of BPD (odds ratio (OR) 0.80,

95% confidence interval (CI) 0.65 to 0.99, *P*-value 0.04) and the combined outcome of BPD-mortality (OR 0.83, 95% CI, 0.69 to 1.00, *P*-value 0.05) decreased for the Collaborative QI. The NICU QI and the non-participant group had a nonsignificant increase in BPD and composite BPD-death rates during this time period (Figure 1).

IVH

During the baseline period, unadjusted rates of IVH were 21.6 to 26.1% while severe IVH ranged from 5 to 8.3% (Table 1). Overall, there was a reduction in IVH, severe IVH and composite severe IVH-death in both the Collaborative QI group and the non-participant group. The NICU QI group saw a slight increase in these categories. In risk-adjusted analysis, the Collaborative QI (OR 0.80, 95% CI 0.66 to 0.97, *P*-value 0.02) and non-participant group (OR 0.81, 95% CI 0.67 to 0.98, *P*-value 0.03) had significantly reduced odds of overall IVH in the post-intervention period. However, there was not a decrease in severe IVH for any group. The combined outcome of severe IVH-death significantly decreased in the non-participant group (OR 0.77, 95% CI 0.61 to 0.98, *P*-value 0.03) but was not significant in either the Collaborative QI or the NICU QI group. Additionally, to examine the contribution of hypothermia to IVH rates, we did a multivariate analysis and found that infants with admission temperature < 36 °C had a significantly increased risk of developing IVH (OR 1.21, 95% CI 1.04 to 1.42, *P*-value 0.01). Infants with admission hypothermia did not have an increased risk of severe IVH alone (OR 1.14, 95% CI 0.90 to 1.44, *P*-value 0.27).

ROP

For both the Collaborative QI and the non-participant group, rates of ROP were decreased in all three categories of overall ROP, severe ROP and combined severe ROP-mortality (Table 1). The NICU QI group had an increase in ROP rates from baseline. In risk-adjusted analyses, the Collaborative QI and non-participant group had significantly reduced odds of developing severe ROP or composite severe ROP-death (Figure 1).

NEC

All groups saw a slight reduction in NEC rates when compared with baseline. In risk-adjusted analysis, the non-participant group had reduced odds of composite NEC-death (OR 0.78, 95% CI 0.61 to 1.00, *P*-value 0.054). Otherwise there were no significant differences between the baseline and post-intervention NEC or combined NEC-death rates (Figure 1).

Mortality

In all groups, there was a reduction in mortality rates over time. Overall, rates decreased from 8.4% in the baseline period to 7.1% in the post-intervention period. The Collaborative QI group saw a reduction from 7.8 to 6.9%; the NICU QI group saw a reduction from 8.4 to 8.0% and the non-participant group had the largest reduction from 9.0 to 6.7%. None of the three groups had a significant reduction in risk-adjusted mortality over time (Figure 1).

DISCUSSION

Participation in the Collaborative QI led to significant declines in morbidities, including BPD, severe ROP and IVH. The interventions in this project focused on thermal management, reducing aggressive respiratory management and improving communication. The collaborative QI model is a multicenter quality improvement model that creates a community of practice. Our comparison of two different QI models (Collaborative QI and NICU QI) with a non-participant group is a unique study design for implementation and dissemination research as it accounts for secular trends over time and the intent to perform QI. Overall, the

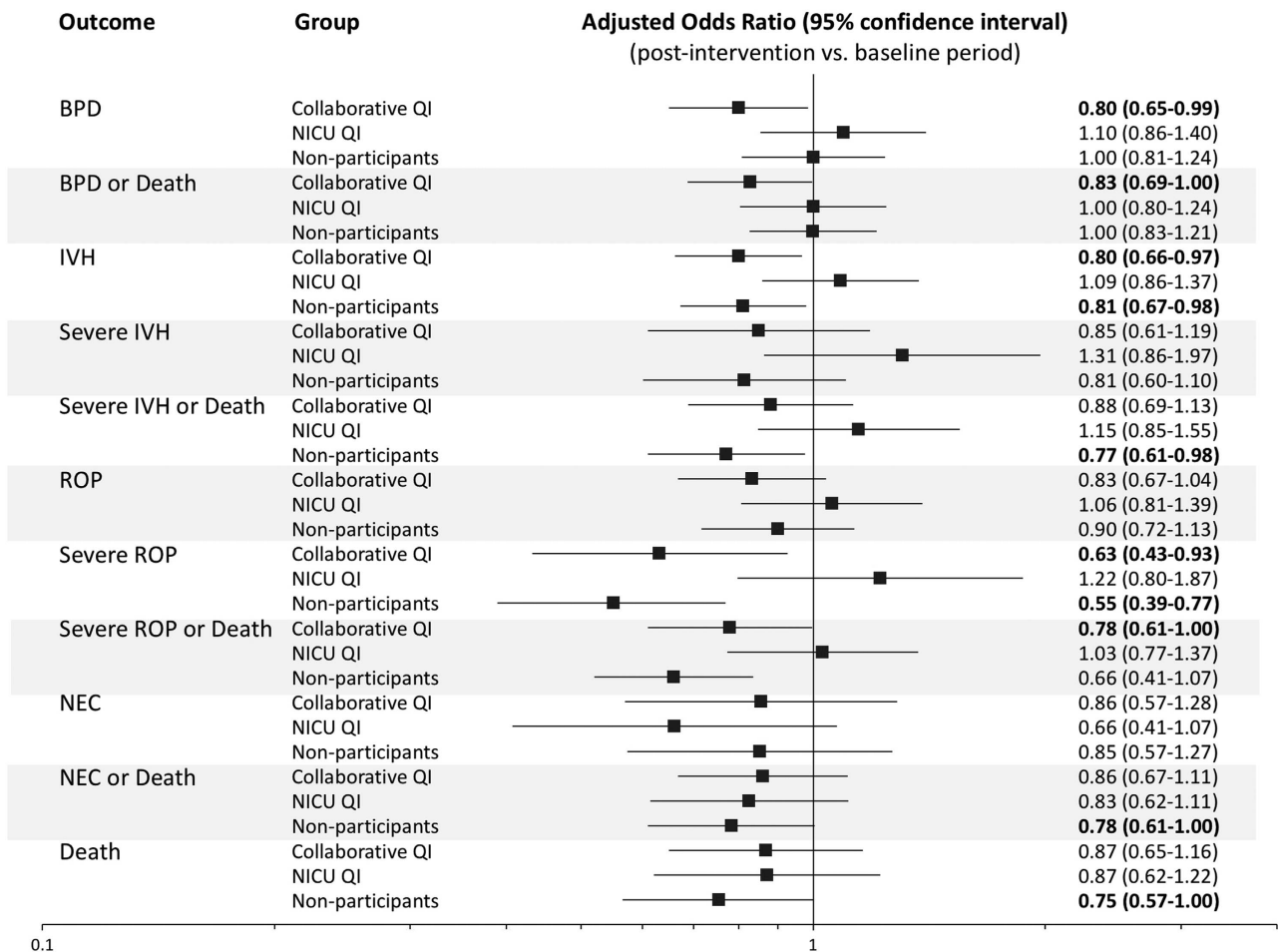


Figure 1. Morbidity and mortality outcomes from baseline to post-intervention. Adjusted odds ratio using multivariable analyses at the patient level comparing post-intervention to baseline period for each group is shown with 95% confidence intervals. Bolded odds ratio indicates those with significant P -value ≤ 0.05 . BPD, bronchopulmonary dysplasia; IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; ROP, retinopathy of prematurity.

improvements seen in the Collaborative QI and non-participant groups were more prominent than those seen in the cohort comprised of centers that pursued individual NICU QI projects.

The Collaborative QI group was the only group with overall reduced rates of BPD. There were reduced odds of BPD development compared with the other two groups (OR 0.80, 95% CI 0.65 to 0.99, P -value 0.04), as well as a reduction in combined BPD-death (OR 0.83, 95% CI 0.69 to 1.00, P -value 0.05). The initial study demonstrated that the Collaborative QI had the most significantly decreased rates of intubation in the delivery room, surfactant in the delivery room and increased rates of CPAP without intubation. The study looked at balancing measures and noted that despite increased CPAP use, pneumothorax rates were not affected. Other recent studies in implementation of comparable potentially better practices in the delivery room have shown similar results in single center NICU QI projects.^{24,28,29} Therefore, these results are in line with current research and recommendations from the Committee of Fetus and Newborn and the Neonatal Resuscitation Program and support the notion that early CPAP use may be associated with decreased rates of BPD and mortality.

The reductions in IVH and severe ROP observed in the Collaborative QI were similar to those seen in the non-participant group. The reduced odds of developing IVH may have been associated with both prevention of hypothermia and decreased intubation. Our previous analysis showed greater

reductions in hypothermia in the Collaborative QI and non-participant groups, while the NICU QI group did not see a reduction in hypothermia between the post-intervention and baseline period (OR (95% CI): Collaborative QI 0.37 (0.31 to 0.43), non-participant 0.67 (0.57 to 0.79), NICU QI 0.86 (0.71 to 1.04)).²³ CPQCC previously demonstrated higher odds of IVH with both severe and moderate hypothermia⁶ similar to other published studies.^{13,30-32} Further analysis in this study supported this hypothesis by demonstrating significantly increased risk for IVH with moderate hypothermia defined as $< 36^\circ\text{C}$ (OR 1.21, 95% CI 1.04 to 1.42, P -value 0.01). The temporal association between IVH and hypothermia in the VLBW infant remains unclear. Theoretically, hypothermia may be a result of a perinatal insult, such as difficult or prolonged delivery or resuscitation. Conversely, hypothermia may affect the hemodynamic status and cerebral blood flow that contribute to the development of IVH itself. It is important to note that while many studies have associated hypothermia with increased mortality, we did not observe any changes in mortality rates in our study.

General reductions were noted in ROP, severe ROP and combined severe ROP-death in the Collaborative QI and the non-participant group. There were significantly reduced odds of developing severe ROP in the Collaborative QI and the non-participant group. This was likely related to ongoing changes in overall trends of oxygen management. Ubiquitous emphasis on

less aggressive respiratory intervention at birth may also translate to decreased oxygen exposure, and thus decreased ROP.

The non-participant group had overall improved outcomes in morbidity and composite morbidity–mortality measures as compared with the NICU QI group. During the baseline period, the non-participant group had significantly lower rates of CPAP in the delivery room, lower rates of infants receiving CPAP without intubation in the delivery room and higher rates of hypothermia compared with the NICU QI group. In addition, the non-participant group had greater rates of morbidity and mortality at baseline compared with the other groups (Table 1). These baseline differences may have allowed the non-participant group to have greater room for improvement and thus account for improved outcomes over time compared with the NICU QI group.

In addition, the non-participant group performed as well as the Collaborative QI Group when comparing post-intervention to baseline rates. Although we have labelled this group as ‘non-participants,’ we did not gather data on potential QI projects that those units were performing during this time period nor do we know if they participated in any QI projects. These findings are a limitation of utilizing the CPQCC database as it does not have access to specific changes of delivery room management within each hospital of the non-participant group. Since the non-participant group had poorer rates of IVH and ROP at baseline, their improvement may represent regression toward the mean over time. Given that the non-participant group represents the contemporary comparison group, these results are encouraging as they likely signify performance improvement across many NICUs over time.

A major strength of this study is its unique design comparing three different hospital groups in a large population-based cohort. This allowed for a comparison group among those hospitals participating in the multicenter collaborative QI, single center NICU QI and those not actively enrolled in a QI project. The Collaborative QI group had improved outcomes compared with the NICU QI group in BPD, combined BPD–mortality, IVH, severe ROP and combined severe ROP–death. The immediate delivery room outcomes, as well as the morbidity outcomes, suggest that a multicenter collaborative QI project may have significant advantages over a single center QI project. CPQCC has demonstrated successes with multicenter collaborative QI in other areas, such as those promoting antenatal corticosteroid use and breast milk feeding.^{33,34} In addition, the Vermont Oxford Network experience also suggests a collaborative process results in significant adoption of potentially better practices, accelerated implementation and improved outcomes.^{35,36} A previous Neonatal Research Network study also demonstrated improved immediate outcomes using collaborative QI process; however, it did not show any improvement in rates of BPD.³⁷ Our study was unique in comparison as the CPQCC and its extensive population-based cohort allowed for a case-mix of varying levels of care, hospital systems and patient volume. Given the large sample size, we had sufficient power to calculate significant risk-adjusted differences over time despite relatively small crude incremental reductions in morbidity rates.

A limitation of our study was the inability to account for variation in practices such as radiographic readings (which could affect IVH and NEC rates) and prescriptive oxygen practices (affecting BPD and ROP rates). Other limitations include an inability to track if other QI projects were ongoing at non-participant hospitals, and the hospital groups were self-selected, possibly implying varying levels of motivation for change and resources available at each hospital. Other decisions beyond the delivery room—in the day to day management of the VLBW infant—such as ventilation strategies, diuretic use, postnatal corticosteroids, etc., could potentially impact the measured outcomes. Thus, while delivery room management is a significant step in initial stabilization of the infant, the overall morbidity and mortality outcomes are likely a complex interplay

between genetics, stabilization and management of the infant. Further research is needed to study the associations between each immediate delivery room outcome with neonatal morbidities and mortality, including long-term neurodevelopmental outcome, and the overall impact that delivery room QI may have regardless of whether the QI is performed as a single or multicenter project.

CONCLUSION

The Collaborative QI group had significantly reduced odds of BPD development following the implementation of the evidence-based delivery room practices. Our results provide further evidence to support the use of CPAP in the delivery room. We hypothesize that gentler ventilation practices in the delivery room while maintaining functional residual capacity with CPAP may result in decreased lung injury and reduced need for mechanical ventilation. In addition, IVH was reduced in the same groups that experienced a significant reduction in hypothermia. Hospitals dedicated to improving delivery room practices can impact neonatal outcomes.

CONFLICT OF INTEREST

All authors declare no conflict of interest.

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DISCLAIMER

The sponsor had no role in relation to study design, data collection, analysis and interpretation, or manuscript preparation and review.

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