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Editor's Note:

Survey Contest Results

Congratulations to all our winners! Here are the quotes that were selected. Your iPods are on the way!

"*eNeonatal Review* provides a balanced synthesis of information about important aspects of neonatal care. The content reflects the collaborative nature of NICU care, addressing the continuum of care practices. We have integrated the *eNeonatal Reviews* into our fellows required readings and encourage the faculty to use this as one of their CME vehicles for maintenance of certification."

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Roles of Neonatal Networks in Assuring Clinical Quality

In this Issue...

Quality improvement (QI) methods developed in industry have been adapted to health care, and hold the promise of reducing variation and improving outcomes for our patients. Collaborative networks of neonatal care providers have formed to share outcomes and practices with a common goal of improving them.

In this issue, we review several approaches to applying QI methods through collaborative networks in neonatology, and discuss how the mixed results represent a sense of optimism as well as opportunities for continued learning.

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[CE Info](#)
[Accreditation](#)
[Credit Designations](#)
[Intended Audience](#)
[Learning Objectives](#)
[Internet CME/CNE Policy](#)
[Faculty Disclosure](#)
[Disclaimer Statement](#)

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POST-TEST

THIS ISSUE

■ [IN THIS ISSUE](#)

■ [COMMENTARY](#) from our [Guest Authors](#)

■ [COLLABORATIVE QUALITY IMPROVEMENT IN NEONATOLOGY](#)

■ [IMPROVING VERY LOW BIRTH WEIGHT INFANT WEIGHT GAIN](#)

■ [COLLABORATIVE QUALITY IMPROVEMENT OF SURFACTANT THERAPY](#)

■ [BENCHMARKING AND QUALITY IMPROVEMENT TO REDUCE BRONCHOPULMONARY DYSPLASIA](#)

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Guest Faculty Disclosure

William H. Edwards, MD has disclosed no relevant financial relationships.

Gautham K. Suresh, MD has disclosed a financial relationship with the **Pediatrix™** Corporation.

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The authors have indicated that there will be no reference to unlabeled/unapproved uses of drugs or products in the presentation.

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LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- Describe to colleagues the approaches to using multicenter collaborations to improve outcomes in neonatal intensive care
- Discuss with colleagues how quality improvement projects have and have not led to better outcomes in very low birth weight neonates
- Identify evidence qualification problems in developing quality improvement benchmarks

COMMENTARY

Our relatively young specialty of neonatology has been characterized by remarkable discovery and innovation. Collaboration among neonatal units and health professionals has been essential to this rapid progress, evidenced by willing participation, both funded and voluntary, in randomized controlled trials of new therapies. The creation of neonatal networks has facilitated such collaboration. Seventeen years ago, Lucey described the organized study of surfactant replacement therapy—from development to clinical trials to implementation—as an example of “getting it right.”¹ Despite the significant advances made, few would argue that the quality of neonatal care is the best it can be. For example, after improvements related to widespread adoption of surfactant treatment in the 1990’s had been realized, outcomes for vulnerable, extremely premature, or very low birth weight (VLBW) neonates have continued to improve only slightly, if at all. During this time another approach to achieving better outcomes began to be applied in medicine. QI techniques, largely developed in industry, employ the concepts of standardization, measurement of processes as well as outcomes, and habits of structured introduction of changes. An appealing aspect from industry, QI is the idea of benchmarking—finding out who is getting the best results and learning from them. These concepts have found fertile ground in neonatology. The papers reviewed herein represent several different models of how networks and collaborative projects have tested applications of QI in neonatology. The mixed results represent both a sense of optimism and opportunities for continued learning.

The [Northern New England Cardiovascular Disease Study Group \(NNECDSG\)](#), a multidisciplinary regional voluntary consortium of cardiovascular programs in Maine, New Hampshire, and Vermont, is one of the first examples of a collaborative for QI in medicine. Using feedback of outcome data, training in QI techniques, and site visits to other medical centers, the consortium reported a 24% reduction in hospital mortality rates from coronary artery bypass graft (CABG) surgery.² The NNECDSG has also contributed over 75 articles to the peer-reviewed literature, leading to greater understanding of individual patient risk for mortality from CABG, as well as team and process variables linked to outcomes. The first Vermont Oxford Network QI collaborative project was modeled on the NNECDSG. In the reports of this project, the Horbar and Rogowski studies showed a modest reduction in the incidence of coagulase-negative staphylococcal sepsis (BW 501-1500 gm), a reduction in rates of oxygen supplementation or death at 36 weeks postmenstrual age (BW 501-1000 gm), and an intriguing reduction in the costs of care when collaborative centers were compared to contemporaneous controls.

The cluster-randomized trial of benchmarking in participating National Institute of Child Health and Human Development (NICHD) Neonatal Research Network centers (Walsh et al) failed to show significant improvement in rates of survival free of bronchopulmonary dysplasia (BPD) in infants of birth weights <1250 grams, in spite of evidence that intervention centers were able to change practices. The authors raise an important caution that the interventions chosen were supported by very weak existing evidence. The only three potentially better practices intended to be implemented in all study centers (higher PaCO₂ target; lower oxygen saturation goals; and high-saturation alarms set at 95%) were classified as having indeterminate or no supporting evidence. Reduced oxygen saturation targeting has



shown promise in reducing the incidence of retinopathy of prematurity (ROP) and BPD, but large scale multicenter randomized controlled trials which include longer-term neurodevelopmental outcomes are lacking.

On the other hand, the cluster-randomized trial by Horbar et al promoted implementation of a practice with strong evidence (surfactant use) but inconsistent clinical usage. That study showed success in changing practice, but failed to demonstrate the improved outcomes predicted by the existing evidence. The approach used in the study is similar to the Breakthrough Series Collaborative, popularized by the Boston-based Institute for Healthcare Improvement (IHI). The IHI conducts Learning Sessions for hospital or clinic teams on a focused topic area. Evidence-based practices are taught along with quality improvement methods. The IHI reports improved outcomes in many of the topics of the series, such as dramatically reducing hospitalizations for adult patients with congestive heart failure by 50%.³

Finally, the study by Bloom et al represents an innovative *Best Demonstrated Process* methodology used successfully by the Pediatrix® Medical Group. Following a process of isolating and sharing meaningful differences in care between centers in the top and bottom thirds for weight gain, they demonstrated an overall increase in average daily weight gain during the first 28 days after birth (BW 401-1500 gm).

Neonatal QI collaboratives are becoming quite popular. The California Perinatal Quality Care Collaborative (CPQCC), founded in 1997, has virtually all NICUs in California participating. New collaboratives are evolving in states and regions of the US and internationally. It is clear that we need to understand more about the interaction between processes of care or evidence-based practices and the contextual environment of individual centers. Rather than becoming discouraged by the mixed results reported in the articles summarized herein, we should realize that there are great opportunities, through collaboration, to develop new knowledge about how prevalent mental models affect adoption of new practices; how complex organizations work; how to analyze and change processes in a sustainable manner; how to rigorously measure processes and outcomes; and how to study and communicate results.

The science of healthcare quality improvement is in its infancy and must be nurtured. We are more likely to achieve and sustain better neonatal outcomes by taking advantage of the synergy between the science of clinical trials and the science of QI than by relying on either approach alone. Multi-institution collaboratives are ideal settings to create such synergy.

References

1. Lucey JF. [The Surfactant Era—Starting Off Right!](#) *Pediatrics* 1991;88(1):168.
2. O'Connor GT, Plume SK, et al. [A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. The Northern New England Cardiovascular Disease Study Group.](#) *JAMA* 1996;275(11):841-846.
3. [The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement.](#) IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2003. (Available at the [IHI website](#))

COLLABORATIVE QUALITY IMPROVEMENT IN NEONATOLOGY

Horbar JD, Rogowski J, Plsek PE, et al. **Collaborative quality improvement for neonatal intensive care. NIC/Q Project Investigators of the Vermont Oxford Network.** *Pediatrics*. 2001;107(1):14-22.

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Rogowski JA, Horbar JD, Plsek PE, et al. **Economic implications of neonatal intensive care unit collaborative quality improvement.** *Pediatrics*. 2001;107(1):23-29.

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These 2 articles report on a project conducted within the Vermont Oxford Network with 10 self-selected NICUs. Each participating NICU created a multidisciplinary project team that, at a minimum, consisted of a neonatologist and a nurse, and could include members of other NICU-related disciplines as well. The goals selected were reduction of nosocomial infection (6 NICUs) and of chronic lung disease (4 NICUs). To attain these goals, teams developed "potentially better practices" based on review of the medical literature, detailed analyses of the processes of NICU care, site visits to other participating NICUs, and benchmarking visits to NICUs with superior outcomes in the Vermont Oxford Network. Each NICU could choose which of the potentially better practices to implement locally (i.e. uniform protocols were not followed across the project). The teams attended two project meetings a year for 2 years. These meetings included didactic sessions on QI, group exercises focused on specific improvement skills or tasks, presentations by the subgroups and individual hospital teams, and open discussion. A collegial atmosphere was fostered through social events at these meetings. Between meetings contact was maintained primarily through leader-facilitated conference calls. The project was conducted over a three-year period beginning in January 1995. The results were compared with those of 66 Network NICUs that did not participate in the project.

At the 6 NICUs in the infection subgroup, between 1994 to 1996 there was a decline in the rate of overall nosocomial infection (26.3% to 20.9% , $P = .007$) and in coagulase-negative staphylococcal infection (22.0% to 16.6% , $P = .007$), but not in infection with other bacterial pathogens. This percentage decrease was larger than that at the 66 comparison NICUs for coagulase-negative staphylococcal infections (-5.4% vs -0.8%; $P = .026$), and for overall nosocomial infections (-5.5% vs -1.6%; $P = .058$) – but not for infections with other bacterial pathogens (-0.9% vs -1.4%; $P = .96$).

Change in chronic lung disease over this period was analyzed for infants with a birth weight of 501 to 1000 grams and a gestation of 34 weeks or less. From 1994 to 1996, in the 4 project NICUs, the overall rate of death or supplemental oxygen need at 36 weeks postmenstrual age declined from 55.9% to 47.6% ($P = .039$), and the rate of supplemental oxygen administration at 36 weeks for infants alive at 36 weeks decreased from 43.5% to 31.5% ($P = .03$). This percentage change was larger than that at the 66 comparison NICUs for supplemental oxygen at 36 weeks (-12.1% vs -0.1%; $P = .045$), but not for death or supplemental oxygen at 36 weeks (-8.3% vs -1.2%; $P = .14$), or for death rates (+1.7% vs -2.1%; $P = .44$). There was heterogeneity among the project NICUs in their responses, with some showing a decrease and others showing an increase in the infection rates and respiratory outcomes targeted in the project.

Changes in treatment costs (with physician costs excluded) from 1994 to 1996 were analyzed in project NICUs in terms of 1996 dollars. Four of the 6 NICUs in the infection subgroup had cost decreases ranging from \$8,800 to \$18,500 per VLBW



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infant over the duration of the project, while 2 had no change in costs. The median treatment cost per VLBW infant in the entire group decreased from \$57,606 to \$46,674 ($P < .0001$ compared to control NICUs). The average VLBW infant cost savings per hospital was \$2.3 million.

The authors, while allowing for alternative explanations such as bias and differences in patient risk, inferred that structured multidisciplinary cross-institutional collaborative learning that leads to focused changes in local practice can improve clinical outcomes and reduce treatment costs.

IMPROVING VERY LOW BIRTH WEIGHT INFANT WEIGHT GAIN

Bloom BT, Mulligan J, Arnold C, et al. **Improving growth of very low birth weight infants in the first 28 days.** *Pediatrics*. 2003;112(1 Pt 1):8-14.

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This study from the Pediatrix® Medical Group, stimulated by the identification of significant unexplained variation in the weight gain of VLBW infants managed in different network units, attempted to improve the weight gain of such infants, using a method called *Best Demonstrated Processes*. The outcome targeted was the center's average daily weight gain in the first 28 days of life (calculated by subtracting birth weight from the weight on day 28 of life and dividing the difference by 28, and then averaging this number across all VLBW infants admitted to the center during the study period). Of 74 participating centers, 11 whose infants had high weight gains (top tercile) and 11 with low weight gains (bottom tercile) were identified using the ratio of actual weight gain to expected weight gain (the expected weight gain was derived from a linear regression model). The average (+/- SD) daily weight gain at the 11 high-weight gain sites and 11 low-weight gain centers was 12.7 (+/- 6) grams and 8.7 (+/-5) grams, respectively. An observation team of 7 volunteers visited selected centers and used an observation guide of over 170 processes and sub-processes developed from a literature review of neonatal nutrition. Each team member visited one low and one high-weight gain center (without knowing the performance record of the center he or she was visiting) and completed the guide using a combination of direct observation and discussions with care providers. The site visit observations were collectively reviewed in a two-day meeting. Processes with meaningful differences were defined as those that were noted in at least 6 of the 7 low-weight gain sites visited and in one or none of the 7 high-weight gain sites visited, or vice versa.

Sixteen meaningful differences were compiled. Examples of desirable practices based on these differences include: early focus on weight gain and nutrition, maintenance of growth charts and reference to them during patient rounds, requirements for specific gastrointestinal signs to stop enteral feeds, statements of explicit weight gain targets as a unit expectation, and incorporation of adequate weight gain in the decision to extubate from the ventilator. A summary of the meaningful differences was sent to each center's medical director, along with a report of that center's rank. Educational packets describing the meaningful differences were also sent to all neonatologists and nurse practitioners in the network, along with improvement targets. Data on average daily weight gain were compared between the pre-intervention period (January 1 – December 31, 1999) and the post-intervention period (January 1 - September 30, 2001) from centers that had at least 15 VLBW admissions per year.

Using this process, the study found the average (+/-SD) daily weight gain in the first 28 days increased from 10.4 (+/- 6) grams for neonates cared for in 1999 to 12.5 (+/- 6) for neonates cared for in 2001 ($p < .01$). These improvements occurred in all birth weight groups. Analysis by center revealed that of the 51 centers studied, the average daily weight gain improved in 39 (76%), was reduced in 8, and was unchanged in 4. Discharge weights and head circumferences were also significantly increased in the 2001 cohort. There was no difference between the 1999 and 2001



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cohorts in birth weight, gestation, exposure to antenatal steroids, or male gender. However, the 2001 cohort had a significantly lower usage of postnatal steroids (19% vs 29%, $P = <.01$) and an increased proportion of infants receiving respiratory support on day 28 (58% vs 55%, $P <.03$), primarily due to an increased use of continuous positive airway pressure support. No differences in incidence of necrotizing enterocolitis, ROP, severe intraventricular hemorrhage, or mortality were noted.

Competing explanations for the results noted were regression to the mean, reduced use of postnatal steroids, and a temporal trend in weight gain. The authors cautiously inferred that their method resulted in the improvements noted.

COLLABORATIVE QUALITY IMPROVEMENT OF SURFACTANT THERAPY

Horbar JD, Carpenter JH, Buzas J, et al. **Collaborative quality improvement to promote evidence based surfactant for preterm infants: a cluster randomised trial.** *BMJ*. 2004;329(7473):1004.

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This cluster-randomized trial was conducted in the Vermont Oxford Network in order to close an observed gap between evidence from randomized trials (which showed that, in preterm infants, prophylactic surfactant administration decreased mortality and pneumothorax rates and that early surfactant administration is superior to administration after 2 hours of life) and observed practice in Network centers (where these treatments were used infrequently). Fifty-seven hospitals were randomly assigned to the intervention group and an equal number to the control group. The multifaceted intervention consisted of: 1) provision of audit and feedback, comprised of site specific data and peer comparisons on surfactant administration practices and delivery room practices in infants 23-29 weeks gestation; 2) participation of teams from intervention hospitals in a workshop that exposed them to the evidence on surfactant therapy, to methods of quality improvement including four key “habits” (change, evidence-based practice, systems thinking, and collaborative learning), facilitated site team exercises, and multi-institutional group exercises; and 3) ongoing support and collaboration through periodic telephone conference calls and an email discussion list that continued through the one-year duration of the project. Control hospitals received only routine Network reports (which included surfactant-related data). Primary outcome measures were surfactant treatment in the delivery room, first surfactant treatment more than two hours after birth (among those receiving surfactant), time after birth when first surfactant dose was administered, mortality before hospital discharge, and pneumothorax. Analyses were adjusted for infant covariates, hospital covariates, and for clustering of hospitals. Results were compared using adjusted odds ratios (AOR) with 95% confidence intervals (CI).

The intervention and control groups were largely similar in hospital and infant characteristics. Delivery room surfactant treatment was significantly higher in the intervention than in the control group (54.7% of infants vs 18.2%, AOR 5.38, 95% CI 2.84 to 10.20). The proportion of infants receiving surfactant after 2 hours of life was significantly lower in the intervention group than the control group (9.4% vs 24.9%, AOR 0.35, 95% CI 0.24 – 0.53). These improved outcomes were noticed in inborn as well as outborn infants. During this one-year study period, each calendar quarter, the intervention hospitals were able to document a progressive decline in median time to first surfactant administration and in the inter-hospital variability of this time. However, no differences were noted in infant mortality between intervention and control groups (17.8% in intervention group vs 18.2% in control AOR 1.01 95% CI 0.79 to 1.30) or in pneumothorax (6.6% intervention vs 7.4% control AOR 0.89, 95% CI 0.67 to 1.18).

Potential explanations for the lack of observed effect on mortality and pneumothorax are insufficient power, and the fact that the study was not designed to test the

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efficacy of prophylactic or early surfactant treatment (infants were not randomly assigned to these treatment options; rather, hospitals were assigned to interventions designed to change practice). The authors concluded that their multifaceted collaborative improvement intervention changed practice and made it more evidence-based by improving the timing of surfactant administration.

BENCHMARKING AND QUALITY IMPROVEMENT TO REDUCE BRONCHOPULMONARY DYSPLASIA

Walsh M, Lupton A, Kazzi SN, et al. National Institute of Child Health and Human Development Neonatal Research Network. **A cluster-randomized trial of benchmarking and multimodal quality improvement to improve rates of survival free of bronchopulmonary dysplasia for infants with birth weights of less than 1250 grams.** *Pediatrics*. 2007;119(5):876-890.

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This cluster-randomized study was conducted in the NICHD Neonatal Research Network, with 17 centers participating, to test whether benchmarking and multimodal QI techniques could improve rates of survival without BPD in neonates with a birth weight of <1250 grams. Seven centers each were randomly assigned to intervention and control groups, while the three that had the highest rates of survival free of BPD served as the benchmark centers. In the intervention group, a multidisciplinary team was formed in each center and trained in quality improvement methods. The teams used a combination of site visits to benchmark centers, comparison of individual center practices with those of benchmark sites, review of the literature on care practices relevant to BPD, and review of the data on actual care practices at intervention and benchmark centers, to develop a set of 27 potentially better practices in the domains of delivery room care, ventilation, fluid, and nutrition practices. Each center implemented between 5 and 13 (median of 7) of these potentially better practices and tracked such implementation with statistical process control charts. The control centers were masked to the work at the intervention centers, were prohibited from participating in other quality improvement efforts related to BPD, and had their performance data masked – however, they were provided with routine annual network summary data. Changes in the rates of survival free of BPD were compared between the first and third years in the two arms of the study, using standard definitions. The mixed model methods analyses accounted for the intra-class correlation within each center resulting from the cluster randomization.

There were some differences in the characteristics of the centers and the infants in the two arms of the trial. A majority of intervention group centers implemented their selected potentially better practices fairly successfully. However, in year 3 of the study the intervention and control centers had similar rates of survival without BPD (intervention 62.2% vs control 62.8%, $P=.40$) and of BPD (intervention 26.1% vs 27.2%, $P=.13$). The primary outcome (survival free of BPD) improved in one center in each group, was unchanged in 6 intervention and 5 control centers. In the intervention group, in infants less than 26 weeks gestation, there was a higher incidence of severe intraventricular hemorrhage than in the control group (45.6% vs 28.6%, $P=.04$).

The authors, postulated explanations for their results include ineffectiveness of quality improvement training, occurrence of important differences between intervention and control centers in spite of randomization, a type II error, and finally, the ineffectiveness of adopting care practices from high-performing centers when those practices are supported only by weak evidence. They questioned whether the factors that lead to superior results in some centers can truly be identified and transferred to other centers.

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- Describe to colleagues the approaches to using multicenter collaborations to improve outcomes in neonatal intensive care
- Discuss with colleagues how quality improvement projects have and have not led to better outcomes in very low birth weight neonates
- Identify evidence qualification problems in developing quality improvement benchmarks

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- **Mary Terhaar, DNSc, RN** has indicated no financial relationship with commercial supporters.
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