A Multifaceted Approach to Improving Outcomes in the NICU: The Pediatrix 100 000 Babies Campaign

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Dr Ellsbury contributed to the conception and design of the study and leads our quality programs, wrote the first draft of the article, and wrote and edited the first to final draft with the help of his co-authors who offered suggestions for improvement; Dr Clark contributed to the conception and design of the study as well as the final approval of the version to be published, and provided extensive editorial input to the writing of the final article; Dr Ursprung contributed to the conception and design of the study as well as the final approval of the version to be published, is the associate director of our quality programs, and provided extensive editorial input to the writing of the final article; Mrs Dodd played a pivotal role in helping our medical directors access and review their quality reports and to set up quality improvement projects in their NICUs, and provided editorial input to the writing of the final article; Mr Handler is the lead developer who updates and improves our clinical data warehouse reporting system, which supports all of our quality improvement efforts, and provided editorial input to the writing of the final article; Dr Spitzer contributed to the conception and design of the study, analysis and interpretation of data, and critical revisions for important intellectual content; and all authors approved the final manuscript as submitted.

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Despite advances in neonatal medicine, infants requiring neonatal intensive care continue to incur substantial morbidity and mortality.1, 2 Unexplained variations in outcome between individual NICUs remain a dilemma for neonatal networks seeking to uniformly improve outcomes.3 Single-center and collaborative quality improvement (QI) initiatives have sought to decrease variation and improve outcomes, but results have been mixed.4-6

QI collaboratives commonly focus on a single clinical problem, rather than the most common group of problems that drive poor health outcomes.5, 7, 8 Such collaboratives often require expensive data collection and reporting systems that may not be readily available. These limitations create significant

BACKGROUND AND OBJECTIVE: Despite advances in neonatal medicine, infants requiring neonatal intensive care continue to experience substantial morbidity and mortality. The purpose of this initiative was to generate large-scale simultaneous improvements in multiple domains of care in a large neonatal network through a program called the “100,000 Babies Campaign.”

METHODS: Key drivers of neonatal morbidity and mortality were identified. A system for retrospective morbidity and mortality review was used to identify problem areas for project prioritization. NICU system analysis and staff surveys were used to facilitate reengineering of NICU systems in 5 key driver areas. Electronic health record–based automated data collection and reporting were used. A quality improvement infrastructure using the Kotter organizational change model was developed to support the program.

RESULTS: From 2007 to 2013, data on 422,877 infants, including a subset with birth weight of 501 to 1500 g (n = 58,555) were analyzed. Key driver processes (human milk feeding, medication use, ventilator days, admission temperature) all improved (P < .0001). Mortality, necrotizing enterocolitis, retinopathy of prematurity, bacteremia after 3 days of life, and catheter-associated infection decreased. Survival without significant morbidity (necrotizing enterocolitis, severe intraventricular hemorrhage, severe retinopathy of prematurity, oxygen use at 36 weeks’ gestation) improved.

CONCLUSIONS: Implementation of a multifaceted quality improvement program that incorporated organizational change theory and automated electronic health record–based data collection and reporting program resulted in major simultaneous improvements in key neonatal processes and outcomes.
barriers to large-scale improvement in neonatal care and outcomes. The objective of this initiative was to pragmatically reengineer the delivery of neonatal intensive care in a large neonatal network with the goal of simultaneous multidimensional improvements in process and outcome. We hypothesized that a structured approach to system evaluation and reengineering of neonatal intensive care in multiple key process areas would yield sustained improvement in neonatal morbidity and mortality.

**METHODS**

**Setting**

Pediatrics Medical Group (PDX) is a national group of clinicians that provides neonatal intensive care services for ~20% of the newborns in the United States who require intensive care. These clinicians practice in a diverse group of settings, from small community hospitals to large children’s hospitals, and reside in 34 states plus Puerto Rico.

**Ethics and Data Collection**

This analysis is a descriptive review of data from infants in the PDX network, composed of 330 NICUs that feed data into the PDX Clinical Data Warehouse (CDW). PDX clinicians used a proprietary software system (BabySteps; MEDNAX, Inc, Sunrise, FL). Infant data are added and modified by providers in BabySteps during their daily assessments. These data are used to generate the medical documentation (eg, admission, progress, and discharge notes), billing worksheets, and the CDW data set. To maximize validity, data for the CDW are extracted at the end of the infant’s NICU stay, so providers have multiple opportunities to review and verify the documentation. These data are deidentified, stored in a consolidated national data set, and are compliant with the Health Insurance Portability and Accountability Act of 1996 regulations. The Western Institutional Review Board approved the use of this deidentified data warehouse for this study.

**Model Development**

From 2007 to 2009, the authors defined key driver processes based on literature review and use of nominal group technique methods. Emphasis was placed on identifying clinical processes that were modifiable and had substantial impact on the primary drivers of poor health outcomes (Fig 1). John Kotter’s 8-step model for leading organizational change was used for the design and implementation of our campaign (Fig 2). The term “100 000 Babies Campaign” was used because of its similarity to the Institute for Healthcare Improvement’s “100 000 Lives Campaign,” which successfully targeted key problem areas in care with the goal of saving 100 000 lives. We sought to reengineer the care of 100 000 infants with the hope that the simultaneous targeting of key driver processes would translate into improved outcomes.

**Intervention**

**Engagement of Practices**

Various aspects of the 100 000 Babies Campaign were introduced informally from 2007 to 2009, with formal launch of the program in 2009. The program built on our previous QI successes in improving growth and reducing retinopathy of prematurity (ROP). Participation was not mandated, but was strongly encouraged. A key theme of the intervention was a flexible and adaptable approach to improving care within the context of the individual NICU’s microsystem. A variety of approaches to problems were provided, with the expectation that each NICU would adapt the interventions to their specific environment. Reliance on automated

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**FIGURE 1**

Driver diagram of the 100 000 Babies Campaign identifying the aims, outcomes, key drivers, and process changes targeted in the program. CPAP, continuous positive airway pressure; IV, intravenous.
central data collection via the electronic health record (EHR) rather than extensive local data collection was emphasized to remove barriers to participation in the program and to ensure the most reliable and reproducible outcome information.

### Outcome Review
NICUs were asked to review their outcomes for several years to assess their performance in the driver areas and in clinical outcomes. The CDW was used for NICU self-assessment and for comparison with PDX network benchmarks.

### System Analysis
NICUs were provided with a system analysis worksheet to guide analysis of their system’s ability to support the targeted project goals.

### Staff Survey
NICUs were provided with a survey to assess the attitudes, knowledge base, and biases of their clinical staff. Comparison of responses from physicians, nurse practitioners, and NICU nurses was emphasized to detect variation in knowledge gaps and attitudes within a NICU. These knowledge gaps and variations were used to inform their specific educational needs and project strategies.

### Project Prioritization
After review of surveys, outcomes, and system analysis, the NICU team used a project prioritization matrix to determine specific target areas for ongoing improvement efforts. Multidisciplinary project teams were then designated, with preference for multiple small teams rather than 1 large team that did all projects.

### Implementation
A project management tool (QualitySteps™ MEDNAX, Sunrise, FL) was used to facilitate tracking of each project, to help coordinate the QI team efforts, and to enable documentation that allow participants to obtain American Board of Pediatrics Part 4 Maintenance of Certification (MOC) credit. It contained project progress notes, educational materials, and templates.

### QI Culture
To facilitate a culture of improvement and to provide peer support, PDX provided “Quality Summit” conferences 3 times per year. The curriculum covered project selection, Pareto charts, root cause analysis, multidisciplinary team building, change concepts, plan-do-study-act cycles, basic data analysis, and use of run charts. Workshops included small group exercises that provided opportunity to apply QI methods to specific clinical problems and emphasized shared problem solving with clinicians from diverse backgrounds. QI project presentations were a major feature of the program, and were used to show multiple approaches to clinical problems and to create a setting that highlighted the work of high-performing NICUs. To remove barriers to participation and to emphasize the organization’s commitment to improving patient care, funding for travel and meeting costs was provided by PDX with the expectation that participants would take the acquired skills back to their practices and apply them within their own NICU’s QI infrastructure.

### CDW
The CDW was used as the primary mechanism for project data reporting at the local level. Data from the BabySteps EHR system were automatically extracted and transformed into near real-time clinical quality reports of multiple processes and outcomes. Data reports included network level comparisons to NICUs of similar volume. These reports did not require any specific data collection or extraction.
Definitions

Demographic Data

Estimated gestational age (EGA) was defined as the best estimate of the neonatologist of EGA, based on obstetric history, prenatal ultrasound, and postnatal physical examinations.

Process Measures

For each medication reported in all tables, we defined exposure to that specific medication as any report at any time during the NICU stay. Early ampicillin was defined as exposure to ampicillin on the day of birth (day 0) or day 1 or 2 after birth. Ampicillin duration of >3 days with negative cultures was the proportion of infants in whom the blood culture was negative who were treated with ampicillin for >3 days’ duration.

Daily data on nutrition were captured by using a nutritional support pick list. Any report of human milk (donor or maternal) during the hospital stay was considered exposure to human milk. Human milk at discharge was any report of human milk in the day of discharge feedings.

The care provider is required to report the degree of oxygen support and the type of support each day. We counted the total number of days each patient was on a ventilator and calculated the median days of ventilatory support for each year. Hypothermia was defined as a NICU admission temperature of >36°C.

Outcome Measures

In infants who had head imaging reported, we calculated the proportion of infants who had a grade 3 or 4 intraventricular hemorrhage (IVH). The highest degree of severity was based on the following: grade 3, ventricles are enlarged by the accumulated blood; and grade 4, bleeding extends into the brain tissue around the ventricles. In infants with a report of an eye examination, we calculated the proportion with severe (stage 3, 4, or 5) ROP. The highest degree of severity was used based on the following: stage 3, severely abnormal blood vessel growth; stage 4, partially detached retina; stage 5 completely detached retina.

The guidance definition for necrotizing enterocolitis (NEC) is that infants with NEC should have ≥1 of the following clinical signs: bilious gastric aspirate or emesis, abdominal distention, or blood in stool without evidence of a rectal fissure; and had ≥1 of the following radiographic findings: pneumatosis intestinalis, hepatobiliary gas, or pneumatosis. NEC-medical is treatment with antibiotics, bowel rest, and supportive care and NEC-surgical is when surgery is also required. Chronic lung disease (CLD) was defined as being on more than room air at 36 weeks postmenstrual age (PMA). The rates of NEC and CLD were based on the denominator of all infants (survived to discharge or died). We defined late-onset sepsis as any positive blood culture reported after 3 days of age. Infants were considered to have survived with no morbidity if they were discharged from the hospital with no report of severe IVH (grade 3 or 4), severe ROP (stages 3, 4, or 5), NEC (medical or surgical), or CLD. Weight gain (g/day) over the hospital stay was calculated (discharge minus birth weight divided by the age at discharge for survivors).

Data Analysis

Infants were categorized by year of discharge for the descriptive tables. The P values reported in the tables are based on trend analyses over the entire time period and are not simple comparisons of 2007 with 2013. For discrete categorical variables, we used Cochran-Armitage trend tests to determine if there were significant changes over time.

Continuous variables (EGA, birth weight, maternal age, ventilator days, age at discharge) were evaluated by using a 1-way analysis of variance (ANOVA) and linear regression to determine if there were significant changes over time. If the P value was <.01, we compared each year to 2007 (control) by using Dunnett’s method in JMP. Nonparametric data were assessed with Kruskal-Wallis ANOVA. Statistical analyses were performed by using JMP 11 (SAS Institute, Cary, NC).

For catheter-associated bloodstream infection calculations, an algorithm that is similar to the 2012 Centers for Disease Control and Prevention definition for central line–associated bloodstream infection (CLABSI) was developed and applied to the entire data set for consistent description of CLABSI over the study period. This algorithm did not include provider-driven interpretation of the algorithm, but was based on objective data components, such as culture results, timing, and presence of a central line relative to time of positive cultures. This model likely overestimates the CLABSI rate to a small degree, as other primary causes of infection may not have been identified and could be misattributed as a CLABSI.

A statistical process control chart analysis was done by using standard rules to detect special cause variation. The mean (center line) and upper and lower control limits were calculated and displayed as ±3 SD of the mean by using QI Macros for Excel (KnowWare International, Inc, Denver, CO).

RESULTS

Between January 1, 2007, and December 31, 2013, we provided care to 574 158 infants admitted for neonatal intensive care; 490 539 (85%) were inborn and 422 877 (74%) were cared for at a single hospital. Tables 1 and 2 report on
the subset of this population that had
birth weights between 501 and 1500
g (n = 58,555, 14%). A data table
on the entire population is in the
Supplemental Information.

Results for Infants 501 to 1500 g

Demographics

There was no change over time in
median gestational age (29 weeks),
birth weight (1.1 kg), proportion
of males (14%), or delivery
by cesarean (7.6%). There was a
slight increase in median maternal
age from 27 to 28 years old (P <
0.01). Antenatal corticosteroid use
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from 2007 baseline of 78.8% to
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Outcome Measures

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| Table 1 Results for Process Measures for Infants With Birth Weight of 501–1500 g |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| 2007                          | 2008                          | 2009                          | 2010                          | 2011                          | 2012                          | 2013                          | P                              |
| Any human milk, n (%)a        | 6217 (77.3)                   | 6648 (78.3)                   | 6910 (82.3)                   | 7184 (85.2)                   | 7239 (85.9)                   | 7326 (86.9)                   | 7351 (87.9)                   | <.0001                         |
| Any human milk at discharge in survivors, n (%)  
| Desmethyl hydromorphone, n (%)a | 645 (8)                       | 644 (7.8)                     | 612 (7.3)                     | 571 (6.8)                     | 576 (6.8)                     | 568 (6.7)                     | 562 (6.7)                     | .0035                          |
| H2 blockers, n (%)a           | 1386 (17.2)                   | 1296 (15.2)                   | 1199 (14.3)                   | 932 (11.1)                    | 885 (10.5)                    | 894 (8.2)                     | 589 (7)                       | <.0001                         |
| Metoclopramide, n (%)a        | 1600 (20.6)                   | 1415 (16.7)                   | 1097 (13.1)                   | 411 (4.9)                     | 181 (2.1)                     | 142 (1.7)                     | 90 (1.1)                      | <.0001                         |
| Cefotaxime, n (%)a            | 1152 (14.3)                   | 940 (11.1)                    | 769 (9.2)                     | 692 (8.2)                     | 679 (8.1)                     | 677 (8)                       | 599 (7.2)                     | <.0001                         |
| Patients receiving early (on day 0, 1, 2) ampicillin, n (%)a | 6432 (80)                     | 6745 (79.7)                   | 6603 (78.7)                   | 6702 (79.5)                   | 6404 (76)                     | 6581 (75.4)                   | 6197 (71.4)                   | <.0001                         |

Early ampicillin duration of >3 d with negative cultures, n (%)a

| 2007                          | 2138/6076 (35.2)              | 2226/6598 (34.8)              | 2110/6272 (33.6)              | 2096/6531 (32.8)              | 1986/6111 (32.2)              | 1832/6065 (30.2)              | 1671/5983 (28.4)              | <.0001                         |
| Early ampicillin duration of >3 d with negative cultures, n (%)  
| Patients ventilated in first 3 d after birth, n (%)a | 4831 (60.1)                   | 4875 (57.6)                   | 4677 (55.7)                   | 4625 (54.9)                   | 4400 (52.2)                   | 4280 (50.7)                   | 3899 (46.6)                   | <.0001                         |
| Ventilator days in ventilated patients, median (10–90th)b  
| Hypothermia (admit temperature <36°C), n (%)a | 1889 (23.2)                   | 1762 (20.8)                   | 1619 (19.3)                   | 1446 (17.2)                   | 1180 (14)                     | 1070 (12.7)                   | 968 (11.8)                    | <.0001                         |

H2 blockers (ranitidine, cimetidine, n = 98,555, 14%). A data table on the entire population is in the Supplemental Information.

- Discrete categorical variables were evaluated by using a Cochran-Armitage trend test to determine if there were significant changes over time.
- Continuous variables were evaluated by using a 1-way ANOVA and linear regression to determine if there were significant changes over time.
Age at discharge of survivors was increased. Results for All Infants, All Weights

Human milk use increased, and use of targeted medications decreased (Supplemental Table 4). Early use of ampicillin decreased. Treatment with ampicillin for more than 3 days in infants with negative blood cultures decreased. Fewer infants were treated with mechanical ventilation. Admission hypothermia, late onset sepsis, mortality, and NEC decreased.

Statistical process control chart analysis (Fig 3) showed a continued decrease in CLABSI rate from a baseline of 6 CLABSI/1000 line days to 2.6 CLABSI/1000 line days. The continued improvement triggered special cause variation and recalculation of control limits 2 additional times, indicating continued improvement throughout the study period.31

DISCUSSION

In this large network of NICUs, the implementation of the 100,000 Babies Campaign was associated with simultaneous improvement in the key driver processes and outcomes. Late onset sepsis, catheter-associated infections, ROP, NEC, and mortality decreased. Survival without morbidity increased. Growth, severe IVH, and oxygen use at 36 weeks PMA were stable or slightly improved.

Our findings are similar to previous analyses of NICU networks. Stoll et al32 showed an increase in antenatal corticosteroid use and decreased use of intubation and surfactant in similar subgroups of premature infants from 2003 to 2007. Horbar et al2 showed a decrease in morbidity and mortality in infants weighing 501 to 1500 g in the Vermont Oxford Network from 2000 to 2009. It is possible our findings are similar to previous analyses of NICI networks. Stoll et al showed an increase in antenatal corticosteroid use and decreased use of intubation and surfactant in similar subgroups of premature infants from 2003 to 2007. Horbar et al showed a decrease in morbidity and mortality in infants weighing 501 to 1500 g in the Vermont Oxford Network from 2000 to 2009.

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improvements mirror improvements seen in non-Pediatrix NICUs; however, we targeted and showed sustained improvement in multiple key process measures.

Our findings are consistent with NICU QI collaboratives that report improvement when a systemwide application of evidence-based practices is enacted and supported over time. The 100 000 Babies Campaign was unique in that it was successfully conducted within a large neonatal network with automated data collection, and improved multiple processes and outcomes simultaneously, rather than targeting a single process or morbidity.

The structure of our campaign has limitations. No contemporaneous control group was used. We acknowledge that statistical associations are not equivalent to establishing causality. The pragmatic approach to our patient population limited the ability to directly collect some data, such as central line maintenance bundle compliance. The details of project selection, prioritization, modification, and implementation were left to the discretion of the individual practices and may have been suboptimal. Some clinical results could have been affected by inconsistent electronic documentation. To combat this deficiency, educational sessions were provided to standardize documentation and BabySteps was enhanced to include reminders and forced functions to enhance accurate documentation.

Multiple factors contributed to the success of our campaign. Use of Kotter’s model for leading change was an important determinant of successfully changing behavior in a diverse neonatal network. An important step to creating transformative change is to “create urgency.” We produced this environment through the provision of a CDW that enabled clinicians to objectively see and compare their outcomes against other NICUs. Large, collaborative quality conferences were used to highlight these differences and create peer groups. Clinical practices that demonstrated the “quality chasm” in neonatology were emphasized, to show evidence-based practices that were not being fully implemented. Attendance at the Quality Summit (Table 3) demonstrates increasing participation in the meetings and use of the CDW during the study period. The American Board of Pediatrics’ requirement to complete QI projects for MOC created additional urgency. From March 2011 to December 2013, American Board of Pediatrics MOC credit for QI work was given for 414 projects.

We speculate that our campaign will have downstream positive effects on general health outcomes. The improvements in human milk utilization and antibiotic stewardship have important ramifications for public health and disease prevention. Unneeded drug exposure increases the risk of adverse drug events, opportunities for error, and consumes additional nursing and pharmacy resources. Compared
with baseline utilization in 2007, ~1,000,000 fewer doses of ampicillin, metoclopramide, and H2 blockers were given than expected. We estimate a cumulative cost savings of $58,000,000 associated with the reduction in catheter-associated bloodstream infection. Based on changes in mortality, we estimate that over the course of our campaign there were 1,885 fewer deaths than expected.

**CONCLUSIONS**

Implementation of the 100,000 Babies Campaign resulted in major improvements in key processes and outcomes. The structured reengineering of NICU care, with a supportive infrastructure to affect large scale organizational change was successfully used in a large and diverse neonatal network. We speculate that use of organizational change theory, targeting of key drivers of adverse health outcomes, automated data collection, and reporting by using a specialty-specific EHR system could be widely used in health care to enable large scale improvements in patient health and improve the value of clinical care.

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**ABBREVIATIONS**

ANOVA: analysis of variance  
CDW: Clinical Data Warehouse  
CLABSI: central line–associated bloodstream infection  
CLD: chronic lung disease  
EGA: estimated lung age  
EHR: electronic health record  
IVH: intraventricular hemorrhage  
MOC: maintenance of certification  
NEC: necrotizing enterocolitis  
PDX: Pediatrix Medical Group  
PMA: postmenstrual age  
QI: quality improvement  
ROP: retinopathy of prematurity

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