Improving Neonatal Intensive Care (NICU) Risk-Adjusted Outcomes (Survival without “major” morbidity in Very Low Birth Weight (VLBW) Infants in a Regional California NICU using Potentially Best Perinatal Practice (PBPP) bundle.

Executive Summary for HQI VANGUARD AWARD: NICU Performance Improvement: Improved Survival without Major Morbidities for the smallest babies (<1500g birth weight and <32 weeks gestation at birth)

One of every 8 US babies is born in California at >320 hospitals, half of whom have a NICU. Twenty-three of ~150 NICU’s provide the highest level of care for ~third of these infants and are “Regional” NICUs. 18/23 have inborns and outborns while 5/23 have only outborn babies. NICUs evaluate processes and outcomes benchmarked through the California Perinatal Quality Care Collaborative (CPQCC) based at Stanford University. Of ~500,000 annual live births in CA, <2% weigh <1500g and are Very Low Birth Weight (VLBW). The babies reported herein are limited to <32 weeks gestation at birth as these are the CPQCC “small babies” and benchmarked to their regional, state and national counterparts.

SCVVMC (Regional NICU) has the lowest rate of inborns admitted (7.4%), lowest antibiotic use of the Regional NICUs (~8 per 100 NICU patient days). In 2016, our NICU inborns had the highest (83%) survival without major morbidity (Nosocomial Infection, severe retinopathy/intraventricular hemorrhage/necrotizing enterocolitis or chronic lung disease) of any Regional Center, the lowest bowel perforation rate, lowest severe retinopathy rates, lowest discharge home on Oxygen (2014-2016) and a significantly lower length of stay. We believe our bundled multitude of potentially better perinatal practices is associated with excellence.

3. Background and Relevance of the problem being addressed and effort undertaken.

Of the annual 500,000 live births in CA, <2% weigh <1500g and are Very Low Birth Weight (VLBW). A third of these babies are cared for in 23 Regional NICUs, eighteen of whom have both Inborn and Outborn babies. Our NICU has an overwhelming (>85%) inborn population. This provides ample opportunity for our team to optimize perinatal outcomes from the moment of birth and during the NICU course. Our population while severely socio-economically disadvantaged and cared for in safety-net setting, enjoys the best prenatal care.

Our NICU embraced innovation and aggressively introduced several Potentially Better Perinatal Practices (PBPP) over the last decade and we seek to demonstrate that this bundle of care is associated with improved patient safety and quality as measured by Better Survival without ‘major’ morbidities. The major morbidities include nosocomial infection, severe periventricular/IntraVentricular Hemorrhage (IVH), severe Retinopathy of Prematurity (ROP), severe Necrotizing EnteroColitis (NEC) or Chronic Lung Disease (CLD).

CLD represents the preponderance of major morbidity and unfortunately defies a universally agreed definition\(^1\): this presents limitations in the interpretation of this composite outcome. Fortunately, when the redefinition occurs the networks (VON, CPQCC) will automatically re-present composite data for future years. This is the first year that SPC charts have been provided and thus compels us to present this work at this time.
Survival without major morbidity has shown gradual improvement in the majority of NICUs nationwide. California is a leader in quality improvement (QI) and safety and for the 140 NICUs in California, this metric has shown slow consistent improvement in the last decade from <60% (2005-07) to now >70% (2014-16). The 23 Regional NICUs take care of a third of these babies have shown a slower improvement from <50% (2005-07) to just >60% (2014-16). SCVMC, while a Regional center shows this metric in the ~75% (2015-2017) and 83% for inborn babies.

Survival has been improving in NICU’s across the nation and Figure 1 and 2 show the Statistical Process Control (SPC) trends for Neonatal and Infant mortality respectively in CA NICU’s. Also illustrated is the declining rate of both Neonatal and Infant mortality at SCVMC.

Optimal and healthy development of the newborn biome is promoted by vaginal birth, early skin-to-skin (parent-baby), early oral colostrum, a commitment to exclusive human milk nutrition, maximizing breast feeding and eliminating unnecessary antibiotic exposure. For the last 376 consecutive small babies born at SCVMC maternal peripartum antibiotic use has declined from 57% (2009-2012, n=211) to 39% (2013-2016, n=165).

Unnecessary admissions to NICU must be minimized with strategies to promote mother infant bonding and strict criteria established to minimize unnecessary exposure to antibiotics. While it is impossible to prevent NICU admission in these smallest of babies, we demonstrate in Figure 3 that SCVMC has the lowest separation of Mom and baby by reason of NICU admission (7.4%) compared to all Regional NICU’s in California. Figure 4 shows a similar prudence with antibiotic use in the NICU, ours having the lowest (8 per 100 NICU days) antibiotic exposure compared to all Regional NICU’s in the state.

We have previously published our best center experience on receiving the Gage award for Elimination of Hypothermia on NICU Admission and implied in a subsequent study that our prolongation of duration of Delayed Cord Clamping (DCC) >1 minute is associated with multiple benefits to these smallest babies including less risk of NICU admission hypothermia, decreased respiratory interventions and risk of blood transfusion.

**Potential Best Perinatal Practices Bundle**
- ANS (improves survival), Decreased Maternal antibiotics (less risk of bowel perforation in baby)
- Standardized DR bundle inclusive of DCC to minimize probability of suboptimal admission temperature to NICU (risk factor for mortality and morbidity)
- Early CPAP (Continuous Positive Airway Pressure) at birth, minimize risk of intubation or mechanical ventilation - less risk of CLD.

Minimize maternal-infant admission separation rates, early skin-skin, shorten length of stay (promotes optimal baby biome, family centered approach, promotes family satisfaction, maternal oxytocin release, and enhances maternal milk supply.

Judicious NICU antibiotic use – decreases risk of Spontaneous Intestinal Perforation (SIP), and severe NEC.

Early colostrum, commitment to exclusive human milk nutrition in early NICU course and sustained mother’s milk at discharge were primarily done to increase family satisfaction of care given the long length of stay of these babies. The advantages to baby’s biome from more frequent contact with family members and baby’s immune system from transfer of cellular
elements in fresh human milk were also highly desirable (recent evidence is more compelling for decreased risk of severe ROP\(^7\) and possibly CLD\(^6,9\)).

Public Health Implication: A sustained rate of 83% survival without major morbidity for all small babies (SCVMC 2016 inborn outcome) compared to current 73% in California would mean 600 fewer babies per year would suffer severe morbidity or mortality. This, extrapolated nationwide, would benefit >5000 babies per year.

4. Description of effort, including scope, process, strategies and tactics, challenges and solutions.

SCVMC NICU joined CPQCC in 2005 and became a member of the national Vermont Oxford Network (VON) in 2008. All CPQCC NICUs are part of the 1000 VON NICUs (>830 in US) thus, national benchmarks are also monitored. VON data are not presented here to maintain the focus on California in the spirit of the Vanguard charter. In general, California (CPQCC) performance exceed national (VON) benchmarks for most processes and outcomes. SCVMC NICU consistently outperforms its regional peers (*Regional NICUs listed in Figure 3).

While there have been numerous changes in county government leadership, hospital leadership and NICU nursing leadership the institution has been extremely supportive of QI at all levels and this had made this journey possible, rewarding and fruitful. This institution hired 3 neonatologists in late 2005, a new division chief February 2006, a lactation coordinator March 2006, a High-Risk Infant Followup coordinator July 2006, and these investments permitted strategic opportunities for QI.

Sound QI requires understanding and fortifying structures and processes to optimize outcomes. The structure of our NICU with over 150 clinicians providing 24/7/365 support to 350 to >700 babies annually is managed primarily by nursing. Several other departments including obstetrics, anesthesia, respiratory therapy, radiology, laboratory, pharmacy, hospital administration, occupational and physical therapy have daily interactions and contributions integral to NICU performance. These are valued, cultivated, and certainly appreciated.

Numerous frontline providers (hospitalists, neonatal nurse practitioners, Stanford pediatric residents and senior medical students) are responsible for daily rounds and order entry. The attending neonatologists have teamed up with inter-disciplinary QI members focused on:

1. Data integrity and quality
2. Delivery room (DR) and respiratory care support
3. Lactation education and support
4. Newborn neuroprotection and improvement in feeding strategies
5. Prevention of nosocomial infection and continuous QI monitoring of morbidity and mortality
6. Optimal nutrition and growth
In addition the neonatologists serve on several county, state, national, professional organizations devoted to health, safety, quality, academia and public health. These domains help influence care on a daily basis at the bedside. In addition to the neonatologists, a growing cadre of pediatric hospitalists, NNP, and Stanford house staff maintain care continuity.

**Care processes are largely dominated by continuous and exemplary nursing.**

Integration of newer ideas such as DCC first implemented July 1, 2007, required extensive buy-in from the obstetric community and Labor and Delivery nursing staff. Standardized DR practice (Smart Start) was implemented under leadership of an interdisciplinary team: neonatologist, staff developer (RN) and Respiratory Therapist (RT). While Smart Start was original and innovative it included increasing periods of DCC, currently at >2 minutes. A variety of studied change management practices were employed to assist with implementation and maintenance of current protocols.

Aggressive expansion of lactation education and support was initiated by a lactation coordinator (early 2006) and taken to a second phase by adding a lactation medical director (mid 2008). This resulted in numerous RNs and MDs requiring extensive education and training in lactation support. Numerous PDSA cycles and feedback loops were in process to maintain implementation of effective processes e.g. DCC, eliminating admission hypothermia, minimizing suboptimal admission temperatures, early colostrum, and other aspects of PBPP bundle. Necessary fishbone and Pareto diagrams, failure mode and effects analysis, six sigma, DMAIC, weekly clinical rounds, periodic data evaluation, SPC charts and sharing were all part of maintaining healthy processes.

The smallest babies are least likely to have exclusive human milk nutrition (25-30%). There are multiple barriers to the mother successfully producing and maintaining milk supply through the time of discharge. Our most recent QI project seeks to secure mothers milk in the first hour of life. Given that 2/3rds of these mothers deliver by C-Section we have enlisted the support of our anesthesiologists in beginning manual expression of colostrum in the recovery room and sometimes sooner as surgery is being concluded.

The biggest challenge is sustaining gains in QI. Staff morale is frequently challenged with rapid cycle PDSA and the necessary frequent change. A focus on multiple layers of education, with much purposeful redundancy and reinforcement is requisite in managing change. Positive reinforcement is key and highlighting teams’ strengths when performance is good is necessary for successful transformation of culture.

5. **Results of the effort.**

In this section we will seek to illustrate the changes in processes and outcomes as a result of investments in our structure and implementation of our PBPP bundle. Figures 5 and 6 show process measures for 2 PBPPs: antenatal steroid (ANS) use and minimizing suboptimal admission temperature.

Figure 7 shows SCVMC 2016 inborn survival without major morbidity 83%. This in spite of the babies being 1 week average gestation less (27.4 SCVMC v 28.4 CPQCC and 28.5 regional) at
birth (Figure 8). Figure 9 shows SPC chart and patient volume in survival without major morbidity compared to benchmarks.

This outcome in 2013 and 2014 is seemingly suboptimal and attributable primarily to the current highly contested (and soon to be replaced) definition of CLD.

Thus we present discharge home on oxygen (figures 10 and 11) which demonstrate our exemplary low CLD. It should be noted that we also discharge home 3-5 median days earlier (figure 12). Figures 13, 14, and 15 demonstrate early CPAP, minimizing mechanical ventilation and limiting supplemental oxygen. All three strategies are protective to the extremely premature newborn lung. The temporal trend of our state and regional benchmarks lags SCMVC performance by 4-6 years (figures 13 and 14). These figures also illustrate 3 consecutive years (2014-16) we mechanically ventilate <50% of small babies compared to state, regional, and Bay Area centers (centers geographically proximate to us that maybe one of the 23 regional or other CPQCC NICUs).

Other major morbidities illustrated in figures:

16 = SPC Chart-reduction in major perinatal IVH in regional NICUs
17 = SPC Chart-reduction in NEC in all NICUs
18 = SCVMC is the only statistically significantly low bowel perforation rate in CA regional NICUs - 250 consecutive babies admitted over 5 years (SCVMC 0.3% v CPQCC and regional 2%)
19 = SPC Chart-reduction in nosocomial infections in our NICU and all other CPQCC, regional, and Bay Area NICUs

Finally, figure 20 illustrates sustained quality improvement (2014-16) in small babies receiving some mothers milk at discharge. Our 5 year cumulative average (2012-16) for 250 consecutive babies is also 80%.

6. Results and Outstanding achievement?

Our results integrate several Vanguard areas of focus: while we seem to report primarily on areas of safety and quality we do so because of benchmarked, risk adjusted, and SPC data from CPQCC. Patient experience is of utmost importance to us and led to the initiation of much of this bundle: it is to our immense gratification that well intentioned family centered initiatives have contributed so immensely to safety and quality.

In summary, we present temporal trends over 12 years with PBPPs introduced over a decade. Our innovative bundled PBPP has included decreased maternal/neonatal antibiotics, almost 100% ANS, standardized DR inclusive of a gradually prolonged DCC, early frequent skin-to-skin with family, early colostrum and sustained commitment to exclusive human milk nutrition. We believe that our PBPPs are associated with the excellence in processes and outcomes. We are confident our institutional structure for QI and culture of safety promotes excellent collaboration of several departments and teams in Nursing, Obstetrics, Pediatrics and Anesthesia.
7. Description of sustainability and scaling of the achievements.

We believe trends over time look very favorable for our smallest babies. Inter-center variation is not always based on patient characteristics or risk factors but often on practice variation. The benefit of networks like CPQCC and VON encourage collaboration and permit critical self-evaluation. Being outside the desirable distribution or in the lowest quintile of performance is hardly aspirational. This allows one to conclude that purposeful improvement would be sustained over time. The scalability of QI for small babies is being rapidly appreciated by leaders in QI science due to burgeoning networks. The knowledge, attitude, and practices of most clinical stakeholders and the inter-disciplinary QI collaboration exemplified at SCVMC leads us to conclude that dissemination is highly likely to be successful.

8. Key lessons learned and any advice to colleagues who might try to undertake a similar effort.

Embracing a culture of safety, keeping abreast of the latest evidence-based QI science and prioritizing patient safety and satisfaction are key to achieving sustained and meaningful gains in healthcare. Change is difficult and transformational change more so. Empowering each team member inclusive of key leadership and the C-suite is essential in achieving long-term success. While bundles work it is increasingly difficult to appreciate the most critical elements of a bundle in enhancing outcomes: Future QI work presents this study opportunity.

Bibliography

2Manani M. Elimination of Admission Hypothermia in Preterm VLBW Infants by Standardization of Delivery Room Management. Perm J 2013.

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on behalf of the NICU, leadership and associated teams at SCVMC
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**Figure 1**
Neonatal Death
Infants 401 to 1500 grams or 22 to 31 Completed Weeks Gestation born between 01/01/2005 and 06/13/2017. This chart is final for years 2016 and earlier. The chart is preliminary for 2017 as the data collection is on-going. Santa Clara Valley Medical Center (SCVMC)

**Figure 2**
Infant Death
Infants 401 to 1500 grams or 22 to 31 Completed Weeks Gestation born between 01/01/2005 and 06/13/2017. This chart is final for years 2016 and earlier. The chart is preliminary for 2017 as the data collection is on-going. Santa Clara Valley Medical Center (SCVMC)

**Figure 3**
2016 Inborn Admission Percentage

- 140 CPQCC NICUs
- SCVMC NICU
- 23 Regional NICUs*

*Regional NICUs: Kaiser Oakland, LA, Roseville, UCSD, UCSF, UCI, UCD, UCLA, LPCH, Miller, Cedars-Sinai, Loma Linda, Alta-Bates, Good Sam, LA, Harbor UCLA, Sutter-Sacto, CPMC Childrens Hospitals (5 with outborns only): CHLA, Rady CHSD, CHOC, CH Madera, CH Oakland

**Figure 4**
2016 Antibiotic Usage

- 140 CPQCC NICUs
- SCVMC NICU
- 23 Regional NICUs

Antibiotic Usage per 100 NICU Patient Days
Figure 5
Use of ANS in infants 24/0 to 31/6 weeks gestation excluding infants with documented reason for not giving steroids, 2012-16
Infants 401 to 1500g or 22 to 31 weeks of Gestation

- CPQCC Network 2013-15: 94.9%
- Regional NICUs 2013-15: 93%
- SCVMC 2012-16: 98%

SCVMC 2016: 100%

Figure 6
Suboptimal Thermal Management (Body temperature at NICU admission <36.4degC), 2012 to 2016, Infants 401 to 1500g or 22 to 31 weeks of Gestation

- CPQCC Network 2013-15: 26.5%
- Regional NICUs 2013-15: 27.6%
- SCVMC 2012-16: 10%

VMC N=248 consecutive babies over 5 years compared to all 23 Regional centers

SCVMC 2016: 9.2%

Figure 7
Survival without Severe ROP or ROP Surgery, NEC, Severe IVH, NI or CLD, 2016, Inborn Infants 401 to 1500g or 22 to 31 weeks of Gestation

- CPQCC Network 2013-15: 70.8%
- Regional NICUs 2013-15: 68.8%
- SCVMC 2013-15: 66.9%

SCVMC 2016: 82.8%

Figure 8
Gestational Age
Infants 401 to 1500 grams or 22 to 31 Completed Weeks Gestation born between 01/01/2005 and 06/20/2017
This chart is final for years 2016 and earlier. The chart is preliminary for 2017 as the data collection is on-going.
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Figure 9
Survival without Severe ROP or ROP Surgery, NEC, Severe IVH, NI or CLD
Infants 401 to 1500 grams or 22 to 31 Completed Weeks Gestation born between 01/01/2005 and 06/13/2017
This chart is final for years 2016 and earlier. The chart is preliminary for 2017 as the data collection is on-going.
Santa Clara Valley Medical Center (SCVMC)

Figure 10
Discharged Home on Oxygen, 2014-16
Infants 401 to 1500g or 22 to 31 weeks of Gestation
- CPQCC Network 2013-15: 8.3%  
- Regional NICUS 2013-15: 9.8%  
- SCVMC 2013-15: 2.4%
N=135 VMC babies over 3 consecutive years compared to their contemporaneous cohorts at all 23 regional centers
- SCVMC 2014-16: 2.2%

Figure 11
Discharged Home on Oxygen
Infants born between 01/01/2005 and 06/13/2017
This chart is final for years 2016 and earlier. The chart is preliminary for 2017 as the data collection is on-going.
Santa Clara Valley Medical Center (SCVMC)

Figure 12
Median NICU Days at Home Discharge from Reporting Center, 2012-16, Infants 401 to 1500g or 22 to 31 weeks of Gestation
- CPQCC Network 2013-15: 51  
- Regional NICUS 2013-15: 53.4  
- SCVMC 2013-15: 48
SCVMC 2012-16: 48.3
N=244

CPQCC NRICUs in Ascending Order by Median