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Editorial

Quality improvement and initiatives in neonatal intensive care

Avroy A. Fanaroff*

Eliza Henry Barnes Professor of Neonatology, Rainbow Babies and Children's Hospital, Professor of Pediatrics, Case Western Reserve University School of Medicine, Cleveland, OH, USA

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1. Introduction and background

According to the Department of Health and Human resources in the USA, "Quality Improvement (QI) is not simply an end goal but a continuous process that employs rapid cycles of improvement. The key elements are structure, process and outcome, which is the impact of the care on health status. The Institute of Medicine has six specific aims for improvement. These are safety, effectiveness, patient centered, timely, efficient and equitable. Key elements for the success of quality initiatives are an enthusiastic staff who undergo rigorous education and training and develop a culture of communication and teamwork. Rigorous documentation and feedback to the staff are also important. Flow charts documenting the process and the results are valuable too. The positive feedback when a daily updated chart indicates, for example, no documented infections for the past 88 days draws attention and focus to the task.

The neonatal intensive care unit networks which cover regions, states, entire countries and even multiple countries, are the ideal forums platform to implement continuous quality improvement initiatives and improve the outcomes for all neonates. Spearheaded by the Vermont Oxford Network Quality collaborative, quality improvement has gained traction and is an integral part of the standard of care in most tertiary neonatal units. Diverse quality endeavors range from antenatal care, antenatal steroids for preterm deliveries between 23 and 34 weeks gestation, intrapartum administration of antibiotics to Group B streptococcus positive women, intrapartum cord management, delivery room thermal protection to prevent moderate hypothermia, screening for critical congenital heart disease, promotion of human milk feeding, pain management, to algorithms for the management of neonatal jaundice and the very successful programs to prevent central line infections.

Quality improvement has become an integral component of neonatal care and is improving outcomes. Here follow some examples of quality improvement initiatives and their achievements.

2. Antenatal corticosteroids

Despite clear documentation that antenatal corticosteroids reduced mortality, the severity of respiratory distress syndrome and intra-ventricular hemorrhage, prior to 1995 only 20 percent of preterm deliveries received antenatal corticosteroids. In 1994, following a consensus conference, the National Institutes of Health recommended a full course of antenatal corticosteroids (ACS) to women who were at risk of delivery at 24–32 weeks of gestation [1–3]. In 2010, the Joint Commission on Accreditation of Healthcare Organization incorporated ACS administration rates as a perinatal core quality measure. Despite these guidelines only 80–85% of women delivering at these early gestations receive ACS. Opportunities for systems based improvement in ACS include continuing education, decreasing the time interval from patient evaluation to ACS administration and standardizing outpatient follow-up evaluation for patients who were discharged with symptoms of preterm labor [4].

3. Intrapartum antibiotics for prevention of group B streptococcal infection

Since the early 1970s, group B streptococci (GBS) have been the leading cause of early-onset neonatal sepsis in the United States and many countries worldwide. Pregnant women with GBS colonization are 25 times more likely to deliver an infant with early-onset GBS sepsis than women who are culture negative. Affected infants become colonized/infected during

* *E-mail address:* Avroy.Fanaroff@UHhospitals.org (A.A. Fanaroff).

labor and delivery and present with respiratory distress or other signs of sepsis in the first 24–48 h of life. In the absence of intrapartum prophylaxis, 2% of infants will develop early-onset GBS sepsis with a significant morbidity and mortality.

Initial recommendations for the prevention of early-onset GBS disease permitted either screening cultures or a risk based strategy. Universal screening by culturing all pregnant women at 35–37 weeks' gestation and treatment of culture-positive women were recommended in 2002. By 2008 this resulted in a dramatic decline in GBS sepsis from 1.7–2/1,000 live births to 0.28/1,000 live births. About 85% of women were being screened for colonization with GBS and more than 80% of colonized women received intrapartum prophylaxis.

The guidelines were updated in 2010 [5] with the recommendation that all pregnant women should undergo vaginal-rectal screening for GBS colonization at 35–37 weeks. In addition to women with GBS positive screening, in the current pregnancy intrapartum antibiotic prophylaxis (IAP) is recommended for women who delivered a previous infant with GBS disease, women with GBS bacteriuria and women with unknown GBS status who deliver at less than 37 weeks' gestation, have an intrapartum temperature of 100.4°F or greater, or have rupture of membranes for 18 hours or longer. remains the preferred agent with ampicillin an acceptable alternative.

> The key changes in the 2010 guidelines include the following:
> - expanded recommendations on laboratory methods for the identification of GBS,
> - clarification of the colony-count threshold required for reporting GBS detected in the urine of pregnant women,
> - updated algorithms for GBS screening and intrapartum chemoprophylaxis for women with preterm labor or preterm premature rupture of membranes,
> - a change in the recommended dose of penicillin-G for chemoprophylaxis,
> - updated prophylaxis regimens for women with penicillin allergy, and
> - a revised algorithm for management of newborns with respect to risk for early-onset GBS disease.

This has resulted in a 25% decrease in EOS evaluations performed among well-appearing infants ≥36 weeks' gestation [6].

In summary, *although early-onset GBS disease has been significantly reduced, the rates of maternal GBS colonization (and therefore the risk for early-onset GBS disease in the absence of intrapartum antibiotic prophylaxis) remain unchanged since the 1970s.* Over the past 25 years, the case death rate has fallen from 25–50% to 4–6%. Some of the cases relate to lack of screening, others to preterm delivery prior to screening which is done at 35 weeks, and a residual number of cases to false negative screens. The goal is to reduce these cases and case fatalities even further. Until a GBS vaccine is developed universal screening and intrapartum antibiotics remain the gold standard.

It is worth noting the critical conclusions from Ohlsson and Shah in their Cochrane review:

> Intrapartum antibiotic prophylaxis appeared to reduce Early Onset GBS Disease (EOGBSD), but this result may well be a result of bias as we found a high risk of bias for one or more key domains in the study methodology and execution. There is lack of evidence from well designed and conducted trials to recommend IAP to reduce neonatal EOGBSD. Ideally the effectiveness of IAP to reduce neonatal GBS infections should be studied in adequately sized double-blind controlled trials. The opportunity to conduct such trials has likely been lost, as practice guidelines (albeit without good evidence) have been introduced in many jurisdictions.
>
> Ohlsson and Shah (2014) [7]

I concur that the opportunity to do such trials has been lost [8].

4. Optimal cord clamping

It has been suggested that immediate clamping of the cord was implemented in the USA to prevent severe hyperbilirubinemia. If that was indeed the case the practice has deprived millions of newborn babies of their rightful transfusion at birth. Fortunately that trend is finally being reversed as the perinatal community comes to its senses and examines the ever accumulating evidence demonstrating the benefits of delaying cord clamping by 30–60 seconds or more, or milking a long segment of an early clamped cord. The new practice has been endorsed by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP) and the World Health Organization (WHO) as well as other societies. In term infants, data strongly support the benefits of delayed cord clamping, especially in the developing world, where iron deficiency is so prevalent. A brief delay in clamping the umbilical cord after birth offers health benefits to the newborn, with no adverse effects to the mother or her infant.

In term infants, umbilical cord clamping between 30 and 180 s after birth results in higher concentrations of hemoglobin and hematocrit during the neonatal period, and increased serum ferritin levels and a lower incidence of iron-deficiency anemia at 4–6 months of age [9]. This translates too into higher I.Q. somewhere in the order of 5 points which on a population basis is tremendous. In preterm infants, delayed cord clamping for at least 30 s or cord milking increases the concentrations of hemoglobin and hematocrit, stabilizes blood pressure, increases urine output, and enhances cardiac function [10–12]. All this is associated with a diminished need for vasopressors and blood transfusions during the neonatal period. Neonates receiving umbilical cord milking required fewer days on oxygen therapy, and less frequent use of oxygen at 36 weeks' corrected postmenstrual age in addition to a decreased prevalence of intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC) and sepsis [13,14]. There may be an increased need for phototherapy but bilirubin levels are usually only marginally higher in the late clamped group.

In summary, both delayed cord clamping and umbilical cord milking are associated with lower rates of serious morbidity in low birth weight infants. Recommendations from the American College of Obstetricians and Gynecologists are for a 1-minute delay for preterm infants "when feasible". The optimal umbilical cord clamping practice among neonates requiring immediate resuscitation remains uncertain. More data are needed on the long term outcomes related to these practices.

5. Avoiding moderate hypothermia

Despite recommendations from the Neonatal Resuscitation program and the WHO to maintain the temperature in the delivery room (DR) at 25.1°C, this recommendation is largely ignored. In developed countries the priority has been the comfort of the mother and medical staff rather than the critically important thermal environment of the preterm infant. This practice is intellectually justified by the assumption that the newborn's thermal needs will be met by a radiant warmer or incubator together with the immediate use of warmer pads or plastic bags.

Preterm infants are susceptible to hypothermia shortly after birth. Laptook et al. found that 47% of 5277 very low birth weight (VLBW) infants had a body temperature <36°C on admission to the neonatal intensive care unit (NICU) [15]. Adjusted analyses showed that admission temperature was inversely related to mortality, with a 28% increase in